

Docket No. AMS-TM-17-0050

**BEFORE
THE AGRICULTURAL MARKETING SERVICE
OF THE UNITED STATES DEPARTMENT OF AGRICULTURE**

**COMMENTS OF THE
AMERICAN HERBAL PRODUCTS ASSOCIATION**

ON THE

**PROPOSED RULE FOR A
NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD**

July 3, 2018

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Prefatory remarks

On May 4, 2018 the Agricultural Marketing Service (AMS or the Agency) of the U.S. Department of Agriculture (USDA) published a Federal Register notice (the May 4 Notice¹) in which the Agency issued and requested comments on a proposed rule to establish a mandatory national bioengineered (BE) food disclosure standard (the Proposed Rule or the Proposed NBFDS Rule). The Proposed Rule was issued to address the requirements of Public Law 114-216 which upon its passage in July 2016 amended the Agricultural Marketing Act of 1946 (the Act or the amended Act) to, among other things, require the Secretary of Agriculture (the Secretary) to establish a mandatory NBFDS. The May 4 Notice reports that the Secretary delegated authority for establishing and administering the NBFDS to AMS.

The May 4 Notice states the Proposed Rule “would require food manufacturers and other entities that label foods for retail sale to disclose information about BE food and BE food ingredient content [and] ... is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods.” The May 4 Notice proposes to codify the NBFDS rule when finalized at Title 7 of the Code of Federal Regulations in new Part 66 (7 CFR Part 66).

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters and distributors of herbs and herbal products.

AHPA’s members are engaged in the commerce of herbs and herbal products in the United States and in other countries that have regulations regarding labeling of foods that contain ingredients that are, or are derived from, agricultural crops that are produced with bioengineering techniques and which are more commonly known as genetically modified organisms (GMOs).² AHPA also includes in its membership

¹ 83 FR 19860.

² The term “genetically modified organism” (or “GMO”) is used in these comments to describe a crop produced through techniques used in agriculture that alter the molecular or cell biology of an organism by means that are not possible under natural conditions or processes, as well as articles, including food ingredients, derived from such crops, irrespective of whether any “modified” genetic material present in the crop is still present in the article or food ingredient. As explained in detail in these comments, these are the common or usual terms used to describe such crops and articles, whereas the term “bioengineered” has little or no common use in these contexts.

companies that grow herbal crops and market herbal products that are certified as organic under USDA’s National Organic Program (NOP) and that are therefore subject to controls regarding the introduction of GMO crops and ingredients derived from such crops (GMO ingredients). Various AHPA members also market herbal products that are labeled as free of GMO crops and GMO ingredients.

This subject matter has been of interest to AHPA’s members for many years and AHPA has maintained a guidance policy for its members since 2003 (most recently updated in 2015) regarding the use of GMO agricultural inputs in herbal products such as dietary supplements and teas. Among other things, this policy has for 15 years encouraged voluntary label disclosure of the use of any herbal ingredients that have been knowingly and intentionally cultivated with GMO technologies, or extracts and natural flavors derived from such ingredients, in a manner that assures that consumers are informed that the ingredient (or more precisely, its source crop) was cultivated with GMO technology.

These comments are therefore submitted on behalf of AHPA’s members. The present comments follow comments submitted by AHPA on July 17, 2017 to provide stakeholder input to some of the 30 questions posed by AMS (the 30 Questions) in a bulletin issued on June 28, 2017³ related to implementing a NBFDS rule to address the July 2016 amendments to the Act.

In several sections of the present comments AHPA provides specific suggestions for revisions to the Proposed Rule. In so doing, standardized formatting is utilized in each such instance whereby AHPA identifies proposed added language in bold underline text (as **bold underline**) and proposed deleted language in strikethrough text (as ~~strikethrough~~ text).

Note that AHPA has not offered comments or proposed specific revisions to all elements in the Proposed Rule; absence of comments or a specific proposed revision to any element or section of the Proposed Rule should not be taken to mean that AHPA agrees with such element or section, unless such agreement is specifically stated.

³ Issued as “National Bioengineered Food Disclosure Updates” (<https://www.ams.usda.gov/rules-regulations/gmo-questions>; accessed June 27, 2018).

Overview and summary of points

AHPA reads the Proposed Rule as abandoning and contravening both the purposes for which the U.S. Congress passed Public Law 114-216 and the expressed needs and demands of American consumers that led to Congressional consideration of this law. AHPA therefore requests that AMS consider significant revisions prior to issuing a Final Rule to implement the NBFDS, as requested and delineated in the comments below. Particular attention should be given to replacing and revising the definition of “bioengineered food” with definitions for “genetically modified organism” and “genetically modified food,” which definitions should include all relevant genetic modification techniques; require use on affected food labels of the common or usual terms used to describe such techniques, i.e., “genetically modified organism” and “GMO”; extend the NBFDS labeling requirement to include refined products and ingredients that are derived from GMO crops; set a threshold for requiring NBFDS labeling that allows a labeling exemption for inadvertent or technically unavoidable GMO content only at the level allowed in most other countries, including the EU; and revise the design of the symbol options to avoid any emotive quality or any implication that GMO content in a food is a benefit or provides additional value.

AHPA notes that Public Law 114-216 was the outcome of legislation introduced in the U.S. Senate as S. 764 in the 114th Congress. In describing his reasoning for introducing this legislation, Senator Pat Roberts (R-KS) noted that the bill would provide “a reasonable solution to consumer demand for more [food] information.”⁴ Senator Heidi Heitkamp (D-ND) added her understanding that the bill would act “for the first time to give national access to every consumer in this country and a way to find out what the ingredients are in their food, particularly whether their food has been processed or manufactured with genetically modified ingredients.”⁵

Also relevant to evaluating whether the Proposed Rule will actually deliver information about GMO ingredients in foods is a review of the well-publicized consumer interest in this topic that preceded this Congressional action. According to one consumer survey conducted in 2014, fully 92 percent of Americans expressed an

⁴ Congressional Record – Senate, S4781, July 6, 2016.

⁵ Congressional Record – Senate, S4854, July 7, 2016.

opinion that genetically engineered foods “should be labeled accordingly.”⁶ These results are similar to a poll conducted a year earlier that found that 93 percent of respondents believed then that foods containing “genetically modified or engineered” ingredients “should be identified.”⁷ A more recent study, conducted after the Proposed Rule was issued by AMS in 2018, concluded that 41 percent of Americans “consider the genetic modification of foods when buying them” though also found that 47 percent “avoid at least somewhat genetically modified foods.” This study also reported, “Consumers want food packaging labels to inform them” (no quantification was provided for this statement); and that 53 percent believe that even “highly refined foods which may or may not contain trace amounts of genetic material should be labeled” to disclose this, while only 17 percent believe this information is not needed.⁸

Thus it is certain that a significant portion of the population, numbering into the tens of millions, share this interest and in fact have been insisting on gaining this information through legal mechanisms for several years. This interest led to over 1 million signatures gathered early in 2012 in support of a citizen petition submitted by the Center for Food Safety to the Food and Drug Administration seeking mandatory labeling of GMO foods.⁹ In addition, ballot initiatives were considered by voters in several states from 2012 to 2014 to attempt similar mandates on a state-by-state basis, which were qualified by gathering as many as 350,000 signatures in the State

⁶ Consumer Reports® National Research Center. April 2014. Consumer Support for Standardization and Labeling of Genetically Engineered Food, 2014 Nationally-Representative Phone Survey. The survey was described as “a nationally-representative phone survey to assess the opinion of 1,004 adult U.S. consumers,” and was reported to have a margin of error is +/- 3 percentage points at a 95% confidence level.

⁷ Kopicki A, July 27, 2013. Strong Support for Labeling Modified Foods. *New York Times*. This survey was conducted as a national telephone poll from January 24-27, 2013 with 1,052 adults and was reported to have margin of sampling error of plus or minus three percentage points.

⁸ International Food Information Council Foundation. June 2018. IFIC Foundation Survey: Research with Consumers To Test Perceptions and Reactions To Various Stimuli and Visuals Related to Bioengineered Foods. This survey was conducted May 18-027, 2018 with a sample size of 1,002 U.S. respondents aged 18 to 80 with sole or shared responsibility for household’s grocery shopping; no margin of error was disclosed.

⁹ <http://www.justlabelit.org/one-million-strong-record-breaking-comments-delivered-to-fda-to-label-ge-foods-3/>. Accessed July 2, 2018.

of Washington¹⁰ and 970,000 signatures in California.¹¹ Although these and other state initiatives ultimately failed to pass, most by very small margins, they generated millions of votes in support. These ballot measures all indicate a significant interest in gaining more information about GMO food through mandatory labeling.

In AHPA's view the Proposed Rule as issued by AMS will completely fail to deliver on the Congressional visions expressed by Senators Roberts and Heitkamp or the desires expressed by citizens across the country over most of the last decade. In fact, without significant revisions to the NBFDS it is very unlikely that American consumers will be satisfied with the level of information about genetic modification provided for the foods they find in the marketplace, nor will they actually have a reasonably accessible way to find out whether their food has been processed or manufactured with genetically modified ingredients. Against this unsatisfactory rule, millions of consumers will continue to agitate for the labeling laws and regulations to be adjusted to provide the complete transparency they demand.

AHPA comments as presented here therefore request numerous significant revisions to the Proposed Rule, and also offer suggestions for additional amendments that are more technical in nature. If AHPA's recommendations are accepted and adopted in the Final Rule, the NBFDS will provide meaningful transparency in food labeling as related to GMO ingredients. AHPA's key suggestions as presented here are:

- The required terms for disclosure of GMO ingredients in food must be those that are common or usual in the American vernacular, that is, "genetically modified organism" or "GMO."
- The term "genetically modified foods" ("bioengineered foods" in the current draft) should be broadly defined to include all relevant GMO techniques.
- The NBFDS should apply to processed and refined food ingredients that are derived from GMO crops.

¹⁰ <https://www.reuters.com/article/us-usa-food-washington/genetically-modified-food-labeling-measure-to-qualify-for-washington-state-ballot-idUSBRE90402G20130105>. Accessed July 2, 2018.

¹¹ [https://ballotpedia.org/California_Proposition_37,_Mandatory_Labeling_of_Genetically_Engineered_Food_\(2012\)](https://ballotpedia.org/California_Proposition_37,_Mandatory_Labeling_of_Genetically_Engineered_Food_(2012)). Accessed July 2, 2018.

- The threshold for label disclosure must be set at 0.9 percent to be consistent with common international standards to support ready international trade in food products.
- The symbols suggested in the Proposed Rule should be replaced with symbols that are appropriately neutral in tone and incorporate the abbreviations consumers are familiar with, i.e., “GMO” (or perhaps “GE”).
- The exception for foods certified under the National Organic Program should be clarified to ensure that this statutory exception is accurately described in regulation.
- The proposed lists of “highly adopted” and “not highly adopted” genetically modified foods should be combined and expanded, and no presumption that a food is derived from a genetically modified crop can be based merely on U.S. adoption rates.

The commonly used terms “genetically modified” and “GMO” must be used in the Final Rule to clearly communicate to consumers

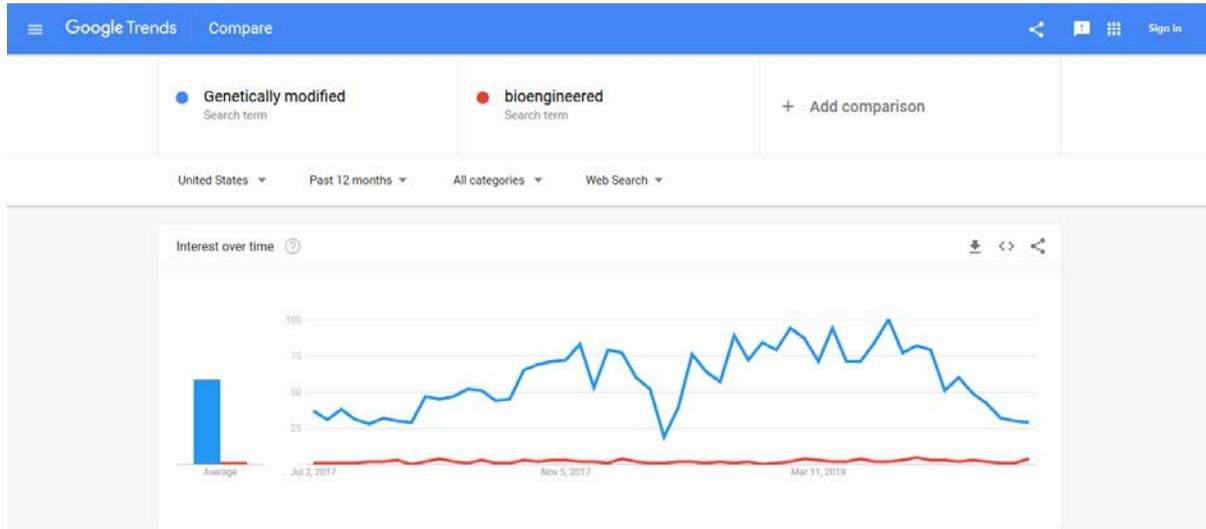
Public Law 114-216 provides a definition for “‘bioengineering’, and *any similar term*, as determined by the Secretary, with respect to a food” (emphasis added).¹² With regard to the Secretary’s authority as emphasized here to determine “any similar term” to “bioengineering,” AMS states in the May 4 Notice that it “is not proposing any similar terms” in the NBFDS.

AHPA strongly opposes this decision by AMS not to propose a similar term for “bioengineering.” On the contrary, AHPA requests that the eventual Final Rule use and define the terms “genetically modified organism,” “genetically modified food,” and “GMO” to describe organisms, crops and livestock produced through techniques used to modify the organisms by means that are not possible under natural conditions, as well as the foods and food ingredients derived from such organisms. AHPA further requests that “genetically modified organism,” “genetically modified food,” and/or “GMO” be the terms required on food labels to indicate foods or ingredients derived from GMO crops.¹³

¹² In the Proposed Rule AMS provides a definition for “bioengineered food”, which proposed definition is the subject of the next section of these AHPA comments.

¹³ AHPA believes the terms “genetic engineering” and “genetically engineered” (with their corresponding abbreviation “GE”) may also be recognized by consumers, although not as broadly as

These terms should be included in the Final Rule because they are the terms best known by the food industry, and more importantly, by consumers. Analysis with Google Trends¹⁴ for the United States in the last 12 months indicates that the term “genetically modified” is 15 to 50 times more commonly used than the term “bioengineered,”¹⁵ as shown below:



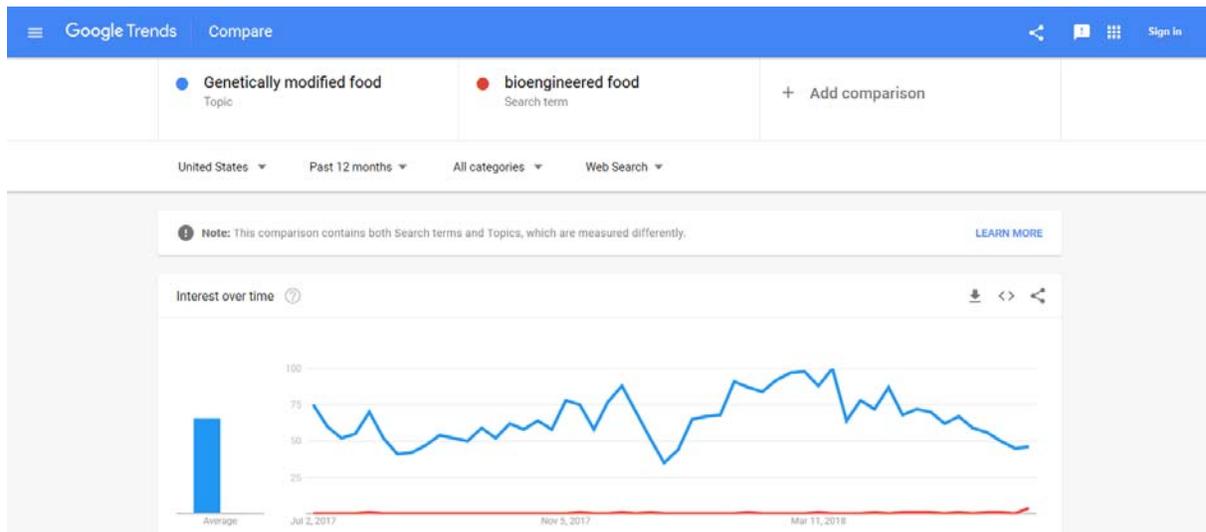
Similarly, Google Trends reports that the term “genetically modified food” has been between 50 to almost 100 times more commonly used in the U.S. than the term “bioengineered food” for almost all of the last year, during which there were zero searches for the term “engineered foods” for most of the time periods analyzed; the only variation from this trend came just in the last week, which may possibly be explained by attention to the present rulemaking.¹⁶ A graph of this comparison follows.

“GMO.” AHPA would support use of these terms for labeling under the final NBFDS. In any case, AHPA believes to avoid consumer confusion, only one term and one abbreviation should be permitted on retail labels.

¹⁴ This product is described as “an unbiased sample of Google search data.” Data can be requested for various time periods and geographical locations.

¹⁵ See <https://trends.google.com/trends/explore?geo=US&q=Genetically%20modified,bioengineered>; accessed June 27, 2018.

¹⁶ See <https://trends.google.com/trends/explore?geo=US&q=%2Fm%2F01fn1t,bioengineered%20food>; accessed June 27, 2018.



AHPA believes that although the information provided above from Google Trends is not by any means a complete record of the common uses of these terms, the fact remains that consumers have been exposed to the term “GMO” through the efforts of the Non-GMO Project and a wide range of food companies who use the description “non-GMO” in their labeling. The term “non-GMO” is also widely used by plant nurseries and garden centers to describe vegetable starts and seed stock offered for sale to the public. Furthermore, the terms “GMO” and “non-GMO” often occur on foods offered for sale in the U.S. if the finished food product was imported from a country that requires such labeling (e.g., at Asian grocery stores).

AHPA thus asserts that the term “genetically modified organism” and “GMO” have become the common or usual term for crops that are developed by the various techniques that are now utilized to develop such crops, and for the articles derived from those crops. It should be noted that the Food, Drug and Cosmetic Act establishes that a food “shall be deemed to be misbranded ... [unless] its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient...” [with additional specific details not relevant to the discussion here] (emphasis added).¹⁷ This statutory requirement has been implemented under the Food and Drug Administration’s food labeling regulations in numerous places,

¹⁷ 21 U.S.C. § 321(i).

including a rule that a food in packaged form must be identified by its “common or usual” name ... or, in the absence thereof, [an] appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food” (emphasis added).¹⁸ AHPA strongly believes that these consistent statutory and regulatory requirements that consumers be clearly informed about the identity of foods and food ingredients by using their “common or usual” names are directly relevant to the NBFDS regulation now under development as described in the Proposed Rule, such that “common or usual” terminology should be required to describe the agricultural techniques that are the subject of this rulemaking and the food ingredients derived from crops produced through these techniques – that is, “genetically modified,” “genetically modified organisms,” “GMOs,” etc.

AHPA also notes one of the 30 Questions posed by AMS in its June 2017 bulletin asked, “What terms should AMS consider interchangeable with ‘bioengineering’?” and provided as context that, “AMS is considering the advantages and disadvantages of allowing the use of other terms to provide for disclosure.” Although AMS made no reference in the May 4 Notice to any responses it received to this question, several such comments were submitted. Positions that agreed with AHPA’s view on this matter as expressed here were communicated by many individual respondents as well as by several organizations that have been advocates for labeling of GMO foods. On the other hand, several organizations that represent agricultural interests and food manufacturers expressed the view that only “bioengineering” or “bioengineered” should be allowed for disclosures under the NBFDS. Of significant interest, however, is that numerous food brands provided comments that also agreed that such terms as “genetically modified,” “genetically modified organisms” and “GMO” should be allowed. Such comments were submitted, for example, by Campbell Soup Company, DanoneWave, Proctor & Gamble and Sargento Foods; note that these examples are not an exhaustive list of such comments.

AHPA also notes that the term “GMOs” has been prominently used for almost two decades in communications issues by USDA with regard to administering the National Organic Program. AHPA cites here the Organic Trade Association’s comments to this Docket insofar as these comments report that NOP, in developing

¹⁸ 21 CFR § 101.3(a).

an extensive body of federal regulations relating to GMOs, has in all communications regarding genetic engineering since 2000 referred to “GMOs,” and that these communications have included USDA policy statements, instructions to certifiers and certified operations, and USDA fact sheets and educational materials for the public, all of which are available on the NOP website. Thus, the NOP as a U.S. federal regulatory program housed within AMS has for almost 20 years used the term “GMO” to describe the subject crops and food ingredients.

AHPA notes that the amended Act explicitly directs the Secretary to consider establishing consistency between the NBFDS and the Organic Foods Production Act and its implementing regulations.¹⁹ In light of the longstanding use by NOP of these more commonly used terms, AHPA believes that in order to comply with this provision of the Act AMS should include definitions for and require use of the term “genetically modified organism” and its common abbreviation “GMO,” rather than the novel term “bioengineered.”

AHPA further notes that inclusion in the Final NBFDS Rule of the terms “genetically modified,” “genetically modified organisms” and “GMOs” would be consistent with the terms used in the parallel regulation in the European Union (EU), by which foods packaged and labeled for end consumer purchase are required to be labeled with the words “genetically modified,” “produced from genetically modified (name of ingredient),” or similar terms if the foods “contain or consist of GMOs, or are produced from or contain ingredients produced from GMOs.”²⁰

AHPA does not believe terms that are largely unfamiliar to the consumer, such as “bioengineered,” should be allowed for labeling of genetically modified foods. Use of different terms by different companies will be confusing to consumers. AHPA recognizes that Congress used the term “bioengineered” in the text of Public Law 114-216, but Congress also provided the Secretary the option of using another term. AHPA believes “genetically modified organism” (and/or “genetically modified”) and “GMO” are commonly understood by consumers and are therefore greatly preferable terms for use in NBFDS disclosures.

¹⁹ 7 U.S.C. 1639b (f).

²⁰ Regulation (EC) No 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed at Article 12 (1).

AHPA therefore specifically recommends and requests inclusion of these terms in the Final Rule in a manner that assures that the terms are used for any declaration that is required under the final NBFDS as well as for any accurate declaration that a food does not contain any ingredients derived from genetically modified crops.

To implement AHPA’s recommendations in this section and the next two sections of these comments AHPA has provided specific suggestions for revisions to the Proposed Rule at the end of the second next section, titled, “The NBFDS should apply to processed food ingredients derived from GMO crops.”

The term “genetically modified foods” (or similar term) should be broadly defined to include all relevant GMO techniques

The Act as amended by Public Law 114-216 defines “‘bioengineering’, and any similar term, as determined by the Secretary, with respect to a food” to mean:

“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.”²¹

In the Proposed Rule, AMS thus defines “bioengineered food” to mean:

“(1) Subject to the factors, conditions, and limitations in paragraph (2) of this definition, 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 or found in nature.

“(2) A food that meets the following factors and conditions is not a bioengineered food.

“(i) An incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3) or any successor regulation.

“(ii) [Reserved].”²²

²¹ 7 U.S.C. § 1639 (1).

²² Proposed 7 CFR § 66.1.

In presenting this proposed definition for “bioengineered food” in the May 4 Notice, AMS acknowledges that it is proposing to directly incorporate the statutory definition of “bioengineering” in the amended Act into the definition of “bioengineered food” “without further interpretation of what ‘bioengineering’ means.” The Agency notes, however, that it welcomes public comment on what could be considered to constitute “bioengineering,” and AHPA offers the following suggestions and ideas relevant to this detail.

Of significant relevance, AHPA notes that there is already an existing USDA regulatory description of what constitutes methods used to “genetically modify organisms,” as established under the NOP within its definition of “excluded methods” of organic production,²³ as follows:

“A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.”

AHPA also notes that the National Organic Standards Board (NOSB), a Federal Advisory Board created by the Organic Foods Production Act, provided recommendations²⁴ to the NOP in November 2017 regarding additional terms and technologies that should be considered for inclusion under the “excluded methods” definition, in consideration of the continued development and advancement of DNA manipulation techniques. The NOSB recommendations highlight the fact that what can be considered to be genetically modified for agricultural products is not easily captured in a definition without the inclusion of significant descriptive details or examples significantly beyond what AMS has suggested in the Proposed Rule.

²³ 7 CFR § 205.2.

²⁴ NOSB Formal Recommendations: Excluded Methods Terminology to be listed in the National Organic Program Excluded Methods Guidance Document, November 2, 2017. <https://www.ams.usda.gov/sites/default/files/media/MSExcludedMethodsFinalRec.pdf>. Accessed June 29, 2018.

AHPA strongly recommends that AMS utilize the definition established in the definition of “excluded methods” under the NOP as the basis for the definition of “genetically modified” in the NBFDS (with some appropriate changes as described further below), and furthermore that AMS establish and maintain consistency in these definitions going forward.

Further to this recommendation, AHPA has previously noted in these comments that the amended Act explicitly directs the Secretary to consider establishing consistency between the NBFDS and the Organic Foods Production Act and its implementing regulations.²⁵ AHPA believes that in order to comply with this provision of the Act AMS should provide in the NBFDA broad definitions of the relevant terms in language that is consistent with the language used to describe or define these terms under the NOP.

To implement AHPA’s recommendations in this section, the immediately preceding section, and the immediately following section AHPA has provided specific suggestions for revisions to the Proposed Rule at the end of the next section, titled, “The NBFDS should apply to processed food ingredients derived from GMO crops.”

The NBFDS should apply to processed food ingredients derived from GMO crops

In the May 4 Notice AMS invites comments as to whether food products derived from a GMO food, but for which it can be demonstrated, e.g., by records of specific processing or by product analysis, that no detectable recombinant DNA is present in the food, should be required to provide a disclosure under the NBFDS. AMS also invites comments regarding two identified positions regarding the interpretation of whether highly refined foods and ingredients, such as certain oils and sugars, should be included in the definition of “bioengineered food” when they are derived from GMO crops.

AHPA believes that consumer expectations dictate that the presence of such foods or ingredients derived from GMO crops, which are prevalent in a great many processed foods available to U.S. consumers, should be disclosed under the NBFDS. Regardless of whether any residual recombinant DNA or altered proteins are present

²⁵ 7 U.S.C. 1639b (f).

in these highly processed ingredients, or in the foods in which they are used, consumers expect and deserve the opportunity to consider the presence of such ingredients in the foods they select for their families in order to make informed purchasing decisions.

AHPA notes that many consumers object to GMO crops not out of fear of consuming recombinant DNA or altered proteins, but due to concerns about the impacts of GMO crops on the environment, traditional farmers, animals, and genetic diversity. For example, a recent study by IFIC Foundation found that 67% of consumers have environmental concerns about GMO crops.²⁶ In addition, ballot measures to prohibit the cultivation of GMO crops were approved by significant margins (58 and 66% of voters) in two Oregon counties; these results were largely driven not by concerns about the health effects of the consumption of GMO crops, but rather by concerns about deleterious effects of GMO crops on farmers (e.g., crop loss and other economic harm due to windborne cross contamination by GMO pollen); GMO crops as a driver of increasing use of pesticides; etc.²⁷ These consumers' concerns will not be addressed if the absence of recombinant DNA or altered proteins allows GMO-derived ingredients to escape disclosure.

AMS appears to make its own argument for the inclusion of such ingredients within the “bioengineered [genetically modified] food” definition in its discussion of the maintenance of the list of “highly adopted” GMO foods:

“For example, since 92% of the field corn produced in the United States is bioengineered, foods made from or containing ingredients made from field corn are likely to contain BE corn. Those foods might include corn starch, cornmeal, corn syrup, grits, corn chips, corn tortillas, and corn cereal, among others, and would be subject to BE disclosure.”

²⁶ International Food Information Council Foundation. June 2018. IFIC Foundation Survey: Research with Consumers To Test Perceptions and Reactions To Various Stimuli and Visuals Related to Bioengineered Foods.

²⁷ [https://ballotpedia.org/Jackson_County_Genetically_Modified_Organism_Ban,_Measure_15-119_\(May_2014\)#Support](https://ballotpedia.org/Jackson_County_Genetically_Modified_Organism_Ban,_Measure_15-119_(May_2014)#Support) and [https://ballotpedia.org/Josephine_County_Genetically_Modified_Organism_Ban,_Measure_17-58_\(May_2014\)](https://ballotpedia.org/Josephine_County_Genetically_Modified_Organism_Ban,_Measure_17-58_(May_2014)), accessed 07/03/2018.

To not include such ingredients in the definition of “bioengineered [genetically modified] food” would be disingenuous, and would result in a definition that is so narrow as to render the NBFDS almost meaningless.

To implement AHPA’s recommendations in this section and the prior two sections of these comments AHPA suggests the following specific revisions to the Proposed Rule:

§ 66.1 Definitions

...

Genetically modified organism (or GMO) means an organism produced by a variety of methods used to influence growth and development by means that are not possible under natural conditions or processes do not occur by natural multiplication or natural recombination and are not considered compatible with organic production that use techniques designed to overcome natural physiologic or recombination barriers. Such methods include cell fusion, *protoplast fusion, liposome fusion, chemoporation, electroporation, microencapsulation and macroencapsulation, and recombinant DNA technology or the direct injection of nucleic acid sequences into cells or organelles (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes, *when these are achieved by recombinant DNA technology or direct injection). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.**²⁸

...

Bioengineered **Genetically modified** food means—

(1) Subject to the factors, conditions, and limitations in paragraph (2) of this definition, a food that ~~contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the~~

²⁸ This proposed definition is drawn primarily from the existing regulatory description of what constitutes methods used to “genetically modify organisms,” as established under the NOP within its definition of “excluded methods” of organic production at 7 CFR § 205.2; two phrases removed from that description are marked here in strikethrough font. Additional language included for greater clarity is taken directly from the rule that implemented Vermont’s former law for labeling foods produced with genetic engineering (VT Consumer Protection Rule 121, effective July 1, 2016) and the 2012 California ballot initiative on this subject (Proposition 37: California Right To Know Genetically Engineered Food Act); these phrases are italicized in this proposed definition. One additional phrase, presented in red font italics and double underlined, is original text for additional clarity.

~~modification could not otherwise be obtained through conventional breeding or found in nature~~ **consists of or contains an ingredient that is, or is derived from, a genetically modified organism.**

(2) A food that meets the following factors and conditions is not a bioengineered **genetically modified** food.

(i) An incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3) or any successor regulation.

(ii) [Reserved].

The threshold for disclosure must be consistent with international standards

The Act as amended by Public Law 114-216 provides that the regulation promulgated by the Secretary “shall determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food,”²⁹ and thus is directly related to whether a food must be labeled to comply with the NBFDS.

AMS reports in the May 4 Notice that respondents to AMS’ 30 Questions presented various concepts to consider regarding thresholds, including different threshold levels for determining exemptions to the disclosure requirement under the NBFDS. AMS therefore requests comments in the May 4 Notice on the following three options for thresholds of inadvertent or technically unavoidable GMO content that would be exempted from labeling under the NBFDS for as proposed at § 66.5(c):

- Alternative 1–A (for paragraph (c))
(c) Food in which 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.
- Alternative 1–B (for paragraph (c))
(c) Food in which an ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9%) by weight of the specific ingredient.

²⁹ 7 U.S.C. 1639b (b)(2)(B).

- Alternative 1–C (for paragraph (c))
(c) Food in which the ingredient or ingredients that contain a bioengineered substance account for no more than five percent (5%) of the total weight of the food in final form.

AHPA strongly recommends adoption of Alternative 1-B. A review of existing international GMO disclosure regulations indicates that thresholds for adventitious or technically unavoidable GMO presence in food used in other international labeling and disclosure programs varies, but AHPA believes that using the 0.9% threshold would result in the widest compliance of U.S. goods against other international threshold standards for technically unavoidable GMO content, including those of major U.S. trading partners. For example, this is the criteria used by the European Union.³⁰ Selection of the 0.9% threshold represents a level that ensures the greatest acceptability of domestic products in the international market.

AHPA also recommends that the term “by weight” be stricken from the proposed wording and that, to be consistent with AHPA’s recommendations herein that common or usual terms be used throughout the regulation, an additional change be made as presented below:

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...

(c) Food in which an ingredient contains a bioengineered **genetically modified** substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9%) ~~by weight~~ of the specific ingredient.

This change is needed as tests for the presence of bioengineered content are not reported in percent by weight, but rather in the percent of GMO contamination by units of DNA.

³⁰ Regulation (EC) No 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed at Article 12 (2).

The symbols suggested in the Proposed Rule are not acceptable and should be revised

The amended Act provides for three separate forms for a GMO food disclosure, one of which is through use of a symbol.

In describing its proposal to codify the NBFDS in proposed 7 CFR § 66, AMS asserts at the beginning of the May 4th Notice, "...nothing in the disclosure requirements set out in this proposed rule conveys information about the health, safety, or environmental attributes of BE food compared to non-BE counterparts." In AHPA's view, however, each of the Agency's symbol disclosure options proposed in § 66.104 fail to fulfill this assertion.

AMS presents three alternatives for the proposed disclosure symbols: a green landscape with yellow sun and blue sky; a green disk with yellow and orange leaves (evoking the sun) and a smiley face using "be" for the eyes; and a circle with a smiley face using "be" for the eyes. The three symbol options are presented below in both color and black and white versions:



Each of these proposed symbols clearly convey a sense of comfort, friendliness, and reassurance. The symbols clearly imply that foods bearing them are safe, healthy, and environmentally friendly, since (it is to be assumed) if they were not the government would not allow the public to be misled with such disingenuous labeling.

Since no similar symbols are approved by any U.S. regulatory agency for non-GMO foods, the effect of the proposed symbols will therefore be to imply that GMO foods bearing the symbol are safer, healthier, and more environmentally friendly than their non-GMO counterparts that do not bear any such symbol.

With respect to safety, the proposed symbols contravene the explicit requirement of Section 293 (a)(3) of the Act, which requires that GMO foods be treated as no safer (nor less safe) than non-GMO foods. Congress clearly intended that AMS adopt a neutral position between the two types of foods. Therefore, it is wholly inappropriate

for AMS to propose symbols that, far from being neutral, imply GMO foods are safer than non-GMO foods.

AHPA therefore strongly recommends that the proposed disclosure symbols be scrapped and replaced with disclosure symbols that are appropriately neutral in tone and incorporate the abbreviations consumers are familiar with, i.e., “GMO” (or possibly “GE”).

The proposed lists of “highly adopted” and “not highly adopted” GMO crops are illogical and misleading

AMS proposes to maintain a list of “highly adopted” and “not highly adopted” GMO foods for which GMO disclosure may be required, based on GMO crops produced within the U.S., with the dividing line set at 85% of U.S. crop plantings (i.e., crops whose U.S. plantings are from GMO source material 85% or more of the time would be “highly adopted” while those that are 84% or less frequently from GMO source materials would be “not highly adopted”).³¹

AMS further proposes that for foods on the “highly adopted” list there would be a presumption that the food is GMO and that GMO disclosure is therefore required or permitted.

AHPA questions the utility of maintaining two separate such lists and believes they will be highly inaccurate and misleading, at least as currently proposed. AHPA also strongly objects to any presumption that a food is GMO and requires GMO disclosure based merely on the fact that U.S. plantings use GMO source material at a high rate.

To begin with, AHPA believes it is inaccurate and misleading to represent that if a crop’s U.S. plantings are from GMO source material “only” 84% of the time then farmers have “not highly adopted” use of GMOs for that crop. AHPA believes that something which occurs 84% of the time occurs at a “high” rate.³²

³¹ Proposed 7 CFR §§ 66.1 and 66.7.

³² Neither, however, does AHPA believe that any particular lower threshold would be more suitable to distinguish “highly adopted” from “not highly adopted,” since AHPA sees little value in maintaining two separate lists.

In addition, since a large percentage of the domestic food supply originates outside the U.S., in order for the “highly adopted” vs. “not highly adopted” distinction to be meaningful it would be necessary to consider the worldwide planting rates of the crop, not just U.S. planting rates. AHPA notes it may be difficult for AMS to obtain accurate and timely data on the rates of GMO plantings on a worldwide basis.

Even were such a worldwide information-gathering exercise possible, it would be highly inappropriate to use this data to establish a presumption that foods derived from crops with high worldwide GMO adoption rates require GMO disclosure, because GMO plantings in specific countries from which food is imported to the U.S. may be prohibited or occur at only low rates. For example, many foods consumed in the U.S. are manufactured in the People’s Republic of China, and planting of GMO corn is prohibited in the PRC – and even imports of GMO corn into the PRC for food processing are highly restricted. Therefore, it would be factually inaccurate to presume that corn, corn meal, corn starch, or other corn-based foods imported to the U.S. from the PRC are GMO foods requiring the GMO disclosure.

In addition to these concerns, AHPA believes that any “list(s) of GMO crops that may require disclosure” must include not only U.S.-grown crops but all GMO food crops planted anywhere in the world, if the GMO crop makes its way into the U.S. food supply. Nothing in the law limits the scope of the disclosure requirement based on the food’s country of origin, and consumers are not less concerned about GMO foods simply because they originate outside the U.S.

AHPA therefore recommends that the lists be combined and expanded into one list of all GMO crops which may be present in the U.S. food supply. AHPA notes that, where relevant and practical, information about specific GMO cultivars can just as easily be included in a combined list as in separate lists. In addition, if information about U.S. planting rates is useful for some parties (e.g., food processors who use U.S.-grown crops) then the estimated “U.S. rate of adoption” could be stated in the combined list (e.g., for field corn this number would currently be 92%).

AHPA furthermore strongly recommends that no presumption of GMO disclosure be established based on the rates of U.S. GMO plantings, or even worldwide GMO plantings. Any presumption will invite spurious lawsuits by plaintiff’s attorneys challenging the failure to disclose the presence of GMO ingredients where none, in

fact, exists. Rather, the necessity of GMO disclosure must be based on a specific evaluation of the supply chain and source countries for the food in question.

Exemption for NOP certified products

Public Law 114-216 explicitly states that in the case of a food certified under the National Organic Program (NOP) “the certification shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as ‘not bioengineered’, ‘non-GMO’, or another similar claim.”

In discussing this provision of the amended Act the May 4 Notice observes, “Implicit in the statutory provision is that certified organic foods are not subject to BE disclosure.” The Proposed Rule at 7 CFR § 66.5(e) therefore clarifies that foods certified under the NOP are exempt from the disclosure requirements of the NBFDS. AHPA strongly supports this detail, but notes also that the Proposed Rule describes such foods as “certified organic under the National Organic Program” (emphasis added), rather than using the exact statutory language, “certified under the National Organic Program.”

The NOP defines several certified food categories, including “100% organic,” “organic,” and “made with organic (specified ingredients or food group(s))”. The NOP has previously clarified that there is no allowance for use of GMO ingredients in these categories, as follows:

“The use of GMOs is prohibited in all ingredients in ‘organic’ and ‘made with organic (specified ingredients or food groups(s)).’ There is no provision within the NOP regulations that allows the use of excluded methods (GMOs) in ingredients or processing aids under the ‘organic’ or ‘made with organic (specified ingredients or food group(s))’ label categories.”³³

AHPA is concerned that inclusion of the phrase “certified organic” rather than just the word “certified” in 7 CFR § 66.5(e) is potentially problematic if it comes to be interpreted that the exemption does not extend to foods certified under the NOP in the “made with organic” labeling category. Therefore, the word “organic” should be deleted from this text to avoid interpretations that could limit the application of the

³³ USDA AMS NOP Policy Memo 11-13. April 15, 2011. Subject: Genetically modified organisms. <https://www.ams.usda.gov/sites/default/files/media/OrganicGMOPolicy.pdf> (Accessed July 1, 2018).

exemption by potentially excluding “made with organic” foods certified under the NOP.

AHPA therefore requests that the Final Rule be amended to remove the word “organic” from this paragraph, as follows:

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...

(e) Food certified ~~organic~~ under the National Organic Program.

In addition, AHPA requests that AMS clarify whether the exemption for food certified under the NOP extends to food labeled as organic in compliance with other international organic product regulations and imported from countries with which the NOP has established either recognition or equivalency agreements. These types of agreement are currently in place with nine countries or regional trading partners, including Canada, Mexico, and the European Union.³⁴

Other comments related to disclosures under the NBFDS

AHPA provides here several additional suggestions related to the subpart B in the Proposed Rule, as follows:

- AHPA supports the flexibility AMS has provided in the proposed rule with respect to the location of GMO disclosures either on the information panel, the principal display panel, or if those panels provide insufficient space then elsewhere on the label.
- AHPA supports providing food manufacturers the option to state that a food “may be” GMO or “may contain” GMO ingredients where appropriate (e.g., where the manufacturer has reason to believe the food will be or may contain GMO-derived materials some of the time but not all of the time). The final rule should clearly state that such “may” statements are not allowed for foods where no uncertainty exists.

³⁴ USDA-AMS National Organic Program, International Trade Partners.
<https://www.ams.usda.gov/services/organic-certification/international-trade>. Accessed June 29, 2018.

- If AMS persists in maintaining separate lists of “highly adopted” and “not highly adopted” GMO foods, then foods on both lists should be provided similar “may be” or “may contain” options.³⁵
- AHPA strongly supports AMS’ efforts to ensure that manufacturers are not required to change labels from batch to batch depending on variability in the GMO status of the ingredients used.
- AHPA supports AMS’ position that, if a manufacturer wishes to provide additional information about GMO foods, such information cannot occur inside the landing page associated with a QR code.

AHPA greatly appreciates the opportunity to present comments on this rulemaking process. We welcome any questions that may arise from AHPA’s comments and look forward to prompt issuance of a Final Rule.

Respectfully submitted,



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³⁵ As discussed previously in these comments, the fact that a GMO crop is highly adopted in the U.S. does not mean the same is true in other countries. In addition, the complexities of international supply chains may introduce additional uncertainty with respect to the presence vs. absence of GMO materials.