



August 25, 2017

SNAC International
1600 Wilson Blvd, Suite 650
Arlington, VA 22209

Via Email (GMOLabeling@ams.usda.gov)

Re: AMS Questions on National Bioengineered Food Disclosure Standard

To Whom It May Concern:

SNAC International is writing to comment on the questions posed by the U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) regarding the National Bioengineered Food Disclosure Standard.

SNAC International (formerly the Snack Food Association) is the international trade association of the snack food industry representing snack manufacturers and suppliers. Founded in 1937, SNAC International represents over 400 companies worldwide including but not limited to, manufacturers of potato chips, tortilla chips, cereal snacks, pretzels, popcorn, kettle corn, cheese snacks, snack crackers, meat snacks, pork rinds, snack nuts, party mix, corn snacks, pellet snacks, fruit snacks, snack bars, granola, snack cakes, cookies, and various other snacks.

SNAC International and its member companies strongly supported and advocated for the establishment of a national standard for the disclosure of bioengineered foods. We appreciate the opportunity to provide comments to AMS as the agency works to develop a proposed rule to implement the disclosure standard.

In the following comments, we respond to AMS's questions related to the scope of the standard (questions 1, 4, 6, 7, 8, and 10), how the disclosure should be made (question 9, 12-20, 22-25), recordkeeping (question 26), and imported foods (question 30).

Scope of Disclosure Standard – Questions 1, 4, 6, 7, 8, and 10
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Question 1. What terms should AMS consider interchangeable with 'bioengineering'? (Sec. 291(1))

AMS should clarify that no terms other than "bioengineering" are considered interchangeable with "bioengineering" for the purposes of section 291(1) of the Law, as that term was specifically defined by Congress whereas other terms were not. AMS should also clarify that the term "genetic engineering," as used in section 295 of the Law, is broader than the term "bioengineering." This request is consistent with Congressional intent and would help to clarify the scope of the preemption provision in section 295.¹

¹ S. Rep. No. 114-403, Report of the Committee on Agriculture, Nutrition, and Forestry, *S. 2609, Related to Roberts Senate Amendment #4935 to S. 764, A National Bioengineering Labeling Disclosure Standard*, at 6 (2016) ("Congress selected the term "genetically engineered" food or seed, rather than "bioengineering," because it is the intent for the provision to broadly preempt state, tribal, and local requirements regarding genetically engineered foods or seed regardless of whether the technology used to develop the food or seed falls within the definition of bioengineering").

Question 4: Will AMS require disclosure for food that contains highly refined products, such as oils or sugars derived from bioengineered crops? (Sec. 291(1)(A))

SNAC supports disclosure for ingredients derived from bioengineered crops, such as sugar derived from bioengineered sugar beets or oils derived from bioengineered corn or canola, regardless of whether the finished ingredient or food contains rDNA. Such an interpretation is consistent with USDA's legal authority under sections 293(b)(2)(B) and (2)(C) of the Law, which provide AMS the authority to define those foods that are "considered a bioengineered food" based on the agency's consideration of "other factors and conditions" and on the "amounts of a bioengineered substance that may be present in a food." Ingredients that are derived directly from bioengineered crops should be disclosed as bioengineered foods because a significant component of the ingredient is from a bioengineered source. For example, for corn oil, consumers would expect that because corn planted in the U.S. is overwhelmingly bioengineered, they will be informed of that source when it is used. The fact that it is processed in a way that results in no rDNA being present in the ingredient should not change whether the ingredient is considered bioengineered. We believe a disclosure requirement that includes such ingredients on the label derived from bioengineered crops will result in a transparent standard that is consistent with consumer expectations on which foods should be disclosed.

Question 6: Meat, poultry, and egg products are only subject to a bioengineered disclosure if the most predominant ingredient, or the second most predominant ingredient if the first is broth, stock, water, or similar solution, is subject to the labeling requirements under FFDC. How will AMS determine the predominance of ingredients? (Sec. 292(c))

Under FDA and USDA ingredient labeling regulations, the ingredients must be listed in descending order of predominance by weight. Therefore, AMS should determine the predominance of ingredients by consulting the ingredient statement on the food label. USDA-regulated snack products such as beef jerky or pork rinds list meat or poultry as the first ingredient in the ingredient statement, indicating it is the most predominant ingredient. These products are exempt from the disclosure requirement.

Question 7: How should AMS craft language in the regulations acknowledging that animals consuming bioengineered feed are exempt from the disclosure requirements as bioengineered solely because they fed on bioengineered feed? (Sec. 293(b)(2)(A))

AMS should adopt the language in the statute, which prohibits a food derived from an animal to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance.

Question 8: What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered? (Sec. 293(b)(2)(B))

SNAC recommends that AMS accommodate the presence of low levels of bioengineered substances due to adventitious or unintentional presence in the food supply and set a threshold of no more than 5 percent as the amount of a bioengineered substance that may be present in a food due to adventitious presence before it requires disclosure as a bioengineered food. This would be consistent with the USDA organic regulations, which in fact set no upper limit on the amount of adventitious presence of bioengineered substances, provided the organic operation can demonstrate compliance with the regulations. A food with > 5% of a bioengineered substance would indicate more than inadvertent

presence. For example, we understand that while the U.S. grain standards permit wheat to contain up to 10% commingled grains such as soy, most wheat contains less than 5% soy due to inadvertent presence. AMS should define the term "bioengineered substance" in this context as referring to the ingredient or food that meets the definition of bioengineered food, and not the level of bioengineered genetic DNA found in the food.

With respect to intentionally added ingredients, AMS should establish a low threshold level of permitted bioengineered substances that do not result in the food requiring disclosure. The appropriate level for such a threshold will depend on which ingredients are exempted from the definition of bioengineered food based on AMS's consideration of other factors or conditions. We are requesting a number of exemptions in our response to question 10 below.

Question 10: What other factors or conditions should AMS consider under which a food is considered a bioengineered food? (Sec. 293(b)(2)(C))

A food should not be considered a bioengineered food solely because it contains or is:

1. Food derived from animals, insects, or microorganisms which grow or feed on a bioengineered substrate, such as a bioengineered crop or other substance or ingredients directly derived from such a crop or substance. Examples of such foods include milk, eggs, honey, alcohol, amino acids, enzymes, citric acid, and vinegar.
2. Incidental additives, including processing aids and secondary direct food additives, that may be from a bioengineered source material. Examples include carriers (such as those used for flavor components) and substances that have a functional role in ingredients but no function in the final product. By their very definition, incidental additives are present at insignificant levels in the finished food and have no technical or functional effect in that food. (21 C.F.R. § 101.100(a)(3)(i) and (ii); 173.) For that reason, FDA regulations do not require the declaration of processing aids or incidental additives in the ingredient statement on food labels. Therefore, their use in processing is not material to whether the finished food is bioengineered. Indeed, the EU recognizes that processing aids are outside of the scope of the GMO disclosure regulation.²
3. Food produced with microbially-derived products, including fermentation products, should not be subject to the mandatory disclosure standard solely because they are produced using a bioengineered microorganism. Such products used in food include vitamins, amino acids, and enzymes.
4. Food derived from animals treated with bioengineered animal drugs and pharmaceuticals.
5. An ingredient currently authorized for use in certified organic foods, including those on the National List of Allowed Substances. Providing such an exception will establish consistency with the National Organic Program, as AMS is required to consider doing under the law.
6. Food derived by the chemical transformation of materials directly obtained from a bioengineered crop (examples include caramel flavoring and color, polydextrose, vitamin C, and sugar alcohols).

² Regulation (EC) No 1829/2003 (clause (16)),
<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF>.

Question 9: Should AMS consider more than one disclosure category? (Sec. 293(b)(2)(D))

With respect to the number of disclosure categories, AMS should provide an option for the disclosure of products where the origin of the disclosed ingredient can periodically switch from a bioengineered crop to a non-bioengineered crop. This option is important to accommodate current and potential future applications of bioengineering. Current examples of situations where this type of disclosure would be appropriate include foods that are or contain:

- Sugar, which can be derived from cane (non-bioengineered) or beet (largely bioengineered); and
- Blends of oils, where FDA ingredient labeling regulations permit the use of the term “and/or” with a listing of the specific oils, some of which may be derived from bioengineered crops (e.g. corn oil) and others from non-bioengineered crops (e.g. sunflower oil). (21 C.F.R. § 101.4(b)(14).)

In such cases, if the sugar or oil(s) is the only potentially bioengineered food or ingredient in the product, AMS should provide an option where the disclosure language conveys that the product may be sourced from bioengineered crops. Use of this type of qualifying language should be voluntary and manufacturers should be permitted to use the standard disclosure statement instead of the qualified statement. The situations in which such an option may be used should be clearly and narrowly defined. In addition, the terminology used should be clear to consumers and consistent with the regular disclosure statement.

Question 12: If a manufacturer chooses to use text to disclose a bioengineered food, what text should AMS require for a text disclosure? (Sec. 293(b)(2)(D))

AMS should provide for an option that allows companies to disclose that a food may be sourced from bioengineered crops.

The required disclosure text should be concise. SNAC suggests that AMS adopt language such as “sourced from bioengineered crops” or “may be sourced from bioengineered crops,” where the name of the specific crop (e.g., “corn”) or bioengineered animal (e.g., “salmon”) may be substituted for the term “crop.” SNAC encourages AMS to conduct a consumer education campaign to explain the language to consumers.

AMS should also ensure that sufficient time is provided for compliance with the disclosure standard to accommodate label changes for those companies using the language required under the now-preempted Vermont labeling law (“produced with genetic engineering” or “partially produced with genetic engineering”).

As for placement, SNAC recommends the disclosure text be placed on the information panel of the label, as defined in FDA regulations at 21 C.F.R. § 101.2, or on the back or side panel (which may or may not be the information panel). It would be appropriate for AMS to require a minimum type size of 1/16th an inch (the same size as required by FDA for the ingredient statement).

Question 13: If a manufacturer chooses to use a symbol to disclose a bioengineered food, what symbol should AMS require for disclosure? (Sec. 293(b)(2)(D))

The symbol should not be disparaging and should contain an agreed upon acronym (such as “BE” for bioengineered). AMS should not prescribe placement requirements beyond general location (on the side or back panels of the label, for example) in order to maintain flexibility in label design for food and beverage manufacturers. This would be consistent with the USDA organic labeling rules, which are not overly prescriptive with respect to the prominence of the symbol. We note that FDA regulations require that no intervening material appear between the FDA-mandated labeling elements. (21 C.F.R. § 101.2(e).)

Question 14: If a manufacturer chooses to use an electronic or digital link to disclose a bioengineered food, what requirements should AMS implement for an electronic or digital link disclosure? (Sec. 293(b)(2)(D))

AMS should establish two definitions to implement the requirements for an electronic or digital link disclosure:

1. The electronic or digital “link” should be defined as a Uniform Resource Locator (URL); and
2. The URL requires a “carrier” which is a barcode or other technology that can embed the URL on a package.

SNAC supports the position of the Grocery Manufacturer’s Association (GMA) in response to question 14, which is consistent with the current SmartLabel program and in line with the Law.

Question 15: Should AMS specify in the regulations the type of electronic or digital disclosure manufacturers, e.g. QR code, can use to disclose bioengineered food? What steps should AMS take if an electronic or digital disclosure method becomes obsolete? (Sec. 293(b)(2)(D))

Emerging or obsolete technology is best managed by a set of guidelines or principles, such as defining the requirements for the digital link and the carrier, as discussed in our response to question 14. SNAC supports GMA’s position in response to question 15, which is consistent with the current SmartLabel program and in line with the Law.

Question 16: What kind of text, symbol, or electronic or digital disclosure should AMS require for bioengineered food that is not purchased from a grocery store shelf, such as food for sale in bulk (such as fresh produce in a bin or fresh seafood at a fish counter), in a vending machine, or online? (Sec. 293(b)(2)(D))

AMS should not require signage in, on, or near the vending machine that provides the disclosure, as there is no requirement in the law that the disclosure be provided outside of packages, and FDA’s implementation of the calorie labeling requirements for foods sold in vending machines has demonstrated the difficulty in providing signage in the vending machine context. For foods sold online, it would be appropriate, although not required by statute, for AMS to require the disclosure information on the label to be made available on the website through which the product is sold, either by providing the text of the disclosure or providing an image of the label.

Question 17: The Law offers special provisions for disclosure on small or very small packages. How should AMS define very small or small packages? (Sec. 293(b)(2)(E))

In defining the terms “small package” and “very small package,” AMS should consider FDA's definitions of the term “small package” and intermediate-sized packages in 21 C.F.R. § 101.9(j)(13).

Intermediate-sized packages refer to those packages eligible for the tabular Nutrition Facts Panel format and AMS should consider providing flexibility for the disclosure required for foods in such packages, consistent with the flexibility provided for nutrition labeling purposes.

Question 18: What are the reasonable disclosure options AMS should provide for food contained in very small or small packages? (Sec. 293 (b)(2)(E))

AMS should permit use of an address or phone number, abbreviated text disclosure, or website address (i.e., a URL address with no "carrier") that provides access to the disclosure for small and very small packages. When a phone number is used, it would be appropriate to use the same language discussed in our response to question 20.

Question 19: How should AMS define small food manufacturers? (Sec. 293(b)(2)(F))

The term “small food manufacturer” should be defined in the same way is defined under the FDA Food Safety Modernization Act (FSMA) final rules on preventive controls for human food, international adulteration of foods, and sanitary transportation of foods. All three of these rules define a small business as “a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.” 21 C.F.R. §§ 117.3; 121.2; 1.904. The term “full-time equivalent employee” is also defined at 21 C.F.R. § 117.3.

This standard is appropriate to use for the purposes of the bioengineered food disclosure standard because it reflects FDA’s recent consideration of which food manufacturers are considered small businesses. The standard is also based on the Small Business Administration’s (SBA’s) definition of small business.

Question 20: For disclosures by small food manufacturers, what is the appropriate language indicating that a phone number provides access to additional information? (Sec. 293(b)(2)(F)(ii)(I))

The statute provides flexibility as to the language used to indicate that a phone number provides access to additional information. In particular, section 293(b)(2)(F)(ii)(I) states that the phone number must be accompanied by “appropriate language to indicate that the phone number provides access to additional information.” Under this standard, appropriate language could include:

- “For more information, call ...”;
- “Call for more information”;
- “Call for more food information” (as provided for in section 293(d)(1)(B) of the Law, which mirrors the language used for electronic or digital disclosures; “Scan here for more food information”).

For use of a URL disclosure, AMS should permit the following options to indicate that the URL provides access to additional information:

- “For more information, see www.abcef.com”
- “For more food information, see www.abcef.com”
- “Use website for more information, www.abcef.com”

AMS should provide small food manufacturers with flexibility to use any of these language options when a phone number or website is used to make the disclosure.

Question 22: How should AMS define very small food manufacturers to exclude these manufacturers from the requirements of the regulation? (Sec. 293(b)(2)(G)(ii))

The term “very small food manufacturer” should be defined in the same way is defined under the FSMA final rule on preventive controls for human food, as adjusted for inflation. That rule defines very small business as “a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).” 21 C.F.R. § 117.3. This standard is appropriate to use for the purposes of the bioengineered food disclosure standard because it is based on FDA’s recent consideration of which food manufacturers are considered very small businesses, reflecting the current state of the industry.

Question 23: Is there other equivalent on-package language that AMS should consider to accompany an electronic or digital disclosure besides “Scan here for more food information”? (Sec. 293(d)(1)(A))

SNAC is comfortable with the language of the Law which requires “‘Scan here for more food information’ or equivalent language that only reflects technological changes.” The language “Scan here for more information” (omitting the term food) would also be appropriate because it would allow the electronic disclosure to be used for multiple purposes (e.g., to provide disclosure related to sustainability, social responsibility, or others) with consistent language across multiple types of products (e.g., to provide disclosures for non-food items as required by state or other law). In terms of changes to this language to reflect changes to the technology, the changes should be the minimum needed to reflect the different technology (e.g., “Access more food information here”).

Question 24: How should AMS ensure that bioengineered food information is located in a consistent and conspicuous manner when consumers use an electronic or digital disclosure? (Sec. 293(d)(2))

The text disclosure and the information associated with the electronic or digital disclosure should be the same. Please see our response to question 12 for the precise language that should be used to provide disclosures accessed through a digital or electronic link.

Question 25: How should AMS ensure that an electronic or digital disclosure can be easily and effectively scanned or read by a device? (Sec. 293(d)(5))

The language in the statute is sufficient to ensure easy and effective scanning of the electronic or digital disclosure: “The electronic or digital link disclosure is of sufficient size to be easily and effectively scanned or read by a digital device.” This language sets forth a clear standard while providing appropriate flexibility to accommodate current and future technologies.

Recordkeeping – Question 26

Question 26: What types of records should AMS require to be maintained to establish compliance with the regulations? (Sec. 293(g)(2))

Types of Records Required: The recordkeeping requirements should be tailored to the definition of the term “bioengineered food,” because the definition of this term determines which foods are subject to the disclosure requirement and the types of records that would be appropriate to establish compliance with the Law. In general, for foods or ingredients derived from crops that are overwhelmingly produced using bioengineering in the country where they are grown, such as corn, canola, soy, and sugar beets grown in the U.S., AMS should apply a presumption that the ingredient is sourced from a bioengineered crop and is a bioengineered food, unless the manufacturer can obtain documentation showing that that is not the case, such as documentation showing the ingredient is certified organic or is identity preserved and not from a bioengineered crop. AMS should also establish recordkeeping provisions related to the threshold of a bioengineered substance established under section 293(b)(2)(B) of the Law and should make clear in the regulation that manufacturers are not required to disclose proprietary information such as recipes or formulations.

As required by the statutory language stating that the records that must be kept are limited to those that are “customary or reasonable in the food industry,” the recordkeeping provisions should not require manufacturers to keep additional records beyond those records customarily maintained. For example, to demonstrate that a food is not subject to the disclosure standard because meat or poultry is the first ingredient, a manufacturer could simply provide AMS with a copy of the label showing the USDA inspection legend and the ingredient statement listing the meat or poultry ingredient as the first ingredient. No additional records should be required to be kept.

Record Retention Period: It would be appropriate to require that records be kept no longer than two years after the product is introduced into interstate commerce regardless of shelf-life. While the product is in commerce each ingredient and finished product must be able to verify compliance. Documentation to support the non-BE status of an ingredient should be considered valid year over year unless suppliers, ingredients or formulas change.

Imported Foods – Question 30

Question 30: What should the requirements for imports into the United States of products covered by the Law/regulation be? (Sec. 294(a))

Imported products offered for sale in the United States should be subject to the same disclosure requirements as products manufactured in the United States and must comply with all requirements of the National Bioengineered Food Disclosure Standard.

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SNAC appreciates the opportunity to provide comments to AMS on the National Bioengineered Food Disclosure Standard. We would be pleased to provide any additional information as the agency develops the proposed rule.

Sincerely,

A handwritten signature in black ink that reads "Elizabeth Avery". The signature is written in a cursive style with a light grey rectangular background behind it.

Elizabeth Avery
President and CEO
SNAC International