

August 25, 2017  
Mr. Bruce Summers  
Acting Administrator Agricultural Marketing Service  
United States Department of Agriculture  
1400 Independence Avenue, SW  
Room 3069 South Building Washington, DC 20250

*Submitted Electronically via [GMOLabeling@ams.usda.gov](mailto:GMOLabeling@ams.usda.gov)*

**Re: AMS Questions on National Bioengineered Food Disclosure Law**

Dear Mr. Summers,

The American Frozen Food Institute (AFFI) appreciates the opportunity to comment on the U.S. Department of Agriculture (USDA) Agriculture Marketing Service's (AMS's) questions on the specifics of the National Bioengineered Food Disclosure Standard.

From manufacturers to distributors to suppliers to packagers, AFFI is proud to represent publicly traded and family-owned companies who help produce frozen foods and beverages for today's food service and retail marketplace and serve as economic pillars within their communities throughout the U.S. In fact, the frozen food industry contributes approximately \$56 billion to U.S. GDP and accounts for 670,000 U.S. jobs.

In addition to our members' strong role in economic growth, AFFI members share a commitment to transparently communicating information about the food production process to consumers and contributing to a safe and affordable food supply.

**General Comments**

We appreciate that AMS has solicited stakeholder input as it engages in rulemaking to implement this important standard. AFFI believes the new uniform national disclosure standard will provide consistent and more cost-effective labeling of foods than would a state-by-state approach. As AMS develops the regulation, we ask the agency to be mindful of Congress's intent that the disclosure standard be a marketing standard and not one based on health, safety, or nutrition. We also want to underscore the importance of crafting regulations that are feasible for companies of all sizes, including providing an adequate period for compliance.

Please see our specific answers below to selected questions posed by AMS.

**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))**

AFFI members support mandatory disclosure for food that is or contains highly refined ingredients such as oils or sugars derived from bioengineered crops. Excluding these foods would result in the majority of products made with bioengineered ingredients being exempt from the disclosure standard. However, we caution AMS against using the term “highly refined products” to describe a finished product containing ingredients such as oils or sugars. AFFI advises using the more accurate term “refined ingredients” to describe single ingredients such as oils and sugars.

**Question 5. Although the Law states that the definition of bioengineering shall not affect any other definition, program, rule, or regulation of the Federal government, could there be potential areas of confusion between the definition of bioengineering as used in the Law and others similar terms used by the Federal government? If so, what are the potential remedies that could be added to this regulation to alleviate any confusion between this definition and others by the Federal government? (Sec. 292(b))**

The statute requires USDA to consider establishing consistency between the National Organic Program (NOP) requirements and the new bioengineered food disclosure. The statute also specifies that foods certified under the NOP Consistent may be represented as not bioengineered or “non-GMO.” Bioengineering is an excluded method under the NOP, so, consistent with these two statutory provisions, organic foods should be exempt from the disclosure standard. Additionally, any ingredients that are authorized for use in organic foods under the National List of Allowed Substances should not result in the need for a disclosure regarding bioengineering. Any future regulations implementing the bioengineered food disclosure standard should not impact the USDA Organic rules.

**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))**

AFFI recommends that AMS rely on the ingredient declaration on packaged food labels to determine the predominance of ingredients by weight. Both FDA and FSIS regulations generally require ingredients to be listed in descending order of predominance by weight.

**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 statutory language via regulation to make clear that a food is not subject to the disclosure requirements solely because it is derived or contains an ingredient derived from an animal that consumed a bioengineered substance such as feed.

**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))**

AFFI asks that AMS consider that the bioengineered food disclosure standard is a marketing standard, and not a health, safety, or nutrition standard, when selecting the amount of a bioengineered substance present in food that triggers mandatory disclosure. AFFI recommends that AMS establish a standard that is flexible enough to account for inadvertent presence of bioengineered substances from the agricultural supply. Consider that the U.S. grain standards allow up to 10 percent commingled grains in wheat, which could include bioengineered soy. As a practical matter, we understand most wheat contains less than 5 percent soy due to inadvertent presence.<sup>1</sup> Additionally, the USDA organic standards do not set an upper limit on inadvertent presence and the National Organic Program has recognized that certified organic foods may contain trace amounts of genetically modified substances without necessarily indicating a violation of the organic regulations.<sup>2</sup>

**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))**

AFFI believes that the terms to disclose that foods have been produced with bioengineering should be scientifically accurate, non-disparaging, and educational. The disclosure standard should not require manufacturers to convey that a product itself is bioengineered and instead should refer to the specific "ingredients" as being derived from bioengineered sources. We recommend that AMS conduct consumer research to gain insights into which terminology consumers understand and do not view as disparaging. In particular, while we recognize the statute uses the term "bioengineered," it does not require that term to be used in the disclosure text. AFFI is concerned that mandatory disclosure language using the term "engineered" – including "bioengineered" or "genetically engineered" – is inaccurate or could be viewed as disparaging. We therefore encourage AMS to consider consumer perception and understanding when proposing the specific

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<sup>1</sup> 7 C.F.R. § 810.2201.

<sup>2</sup> *Can GMOs Be Used in Organic Products?* May 2013, <https://www.ams.usda.gov/sites/default/files/media/Can%20GMOs%20be%20Used.pdf>; *Organic 101: Can GMOs Be Used in Organic Products*, May 17, 2013, <https://www.usda.gov/media/blog/2013/05/17/organic-101-can-gmos-be-used-organic-products>.

terminology to be used. We also ask the agency to consider the language “genetically modified,” as it may be more fitting for on-package labeling.

For example, the disclosure could read:

*“Contains ingredients derived from genetically modified crops”*

AMS should also recognize that it is appropriate to include additional clarifying information following the mandatory disclosure text, provided such voluntary information is neither false and misleading (for example, clarifying that the disclosure language refers to crops “commonly known as GMOs”).

The text and font that AMS selects should be non-disparaging and consistent with other on-package mandatory disclosures.

**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))**

Any symbol that AMS chooses for the purposes of disclosure should be non-disparaging.

**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 21. The Law excludes restaurants and similar retail food establishments from disclosure requirements. How should AMS define similar retail food establishment to exclude these establishments from the requirements of the regulation? (Sec. 293(b)(2)(G)(i))**

AFFI members’ products include not only packaged goods found in traditional retail store environments, but also include food and ingredients served in a variety of food service settings including schools, restaurants, and in-grocery eateries. To implement the statutory direction that foods served in restaurants and similar retail food establishments are to be exempt from the disclosure requirements, AFFI asks

that AMS limit the scope of the standard to only require disclosure for packaged foods subject to FDA's and FSIS's nutrition labeling regulations.

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

The recordkeeping requirements should reflect that the disclosure standard is a marketing and not a health or safety standard. AMS should also implement Congress's direction to establish recordkeeping requirements based on the types of records that are "customary or reasonable in the food industry" to establish compliance. For these reasons, it is unnecessary for AMS to require records that document a specific percentage of bioengineered content in the food. Instead, AMS should draft regulations that presume that when an ingredient is derived from a crop that is widely available in a bioengineered form, such as corn, canola, soy, and sugar beets grown in the U.S., the ingredient is bioengineered, unless the manufacturer has documentation rebutting that presumption. For example, if the manufacturer has records indicating the ingredient is certified organic, identity preserved and from a non-bioengineered crop, or the subject of another traceability program that provides assurance the ingredient is not derived from a bioengineered seed, it would not be subject to the disclosure.

AMS should not make clear that the recordkeeping provisions do not require recipe formulations or other proprietary information to demonstrate compliance with the regulation.

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We appreciate the opportunity to provide these comments. If we can assist the agency further with the National Disclosure for Bioengineered Food, please do not hesitate to contact us.

Respectfully submitted,



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