National Bioengineered Food Disclosure Standard
U.S. Department of Agriculture

Proposed Rule Questions under Consideration

Comments and Responses of the Specialty Food Association

July 17, 2017

The U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) has posted questions for stakeholder input regarding the establishment of a National Bioengineered Food Disclosure Standard (Standard) to implement the federal law that requires a mandatory National Bioengineered Food Disclosure Standard (Law). USDA will use the input received when drafting a proposed rule.

The Specialty Food Association (SFA or the Association) welcomes this opportunity to submit comments concerning the Standard in response to the Proposed Rule Questions under Consideration. The Questions were published by USDA at https://www.ams.usda.gov/rules-regulations/gmo-questions. These comments reflect the views of SFA members - small food businesses processing, importing, distributing and retailing specialty foods.

THE SPECIALTY FOOD ASSOCIATION

The Specialty Food Association (SFA) is a non-profit trade association, headquartered in New York City, that represents the interests of the specialty food industry and its 3,600 members situated throughout the United States. SFA owns the Summer and Winter Fancy Food Shows, publishes *Specialty Food Magazine* and annual State of the Specialty Food Industry reports, sponsors the sofi awards and presents many educational events.

Specialty foods exemplify quality, innovation and style in their category. According to the SFA Bylaws, their specialty nature derives from some or all of the following characteristics: their originality, authenticity, ethnic or cultural origin, specific processing, ingredients, limited supply, distinctive use, extraordinary packaging or specific channel of distribution or sale. Their differentiation in their categories creates a high perceived value and often a premium price. Specialty foods sales in 2016 were $127 billion and represent 15% of all foods sold at retail in the U.S., according to research from the Specialty Food Association and Mintel International.

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SUMMARY OF SFA's POSITIONS

Although several of USDA's Questions present issues of interest to SFA and its members, the following responses by SFA are limited to the definitions of small and very small businesses, small packages, and bioengineered foods; disclosure formats and exemptions; disclosures on imported foods; and retail establishments that are similar to restaurants. In most instances, SFA recommends that the Standard follow rules that apply to the foods regulated by the U.S. Food and Drug Administration (FDA). FDA regulates the majority of foods available in the U.S. and the Law defines food according to the definition of food in the Federal Food, Drug and Cosmetic Act.[1]

Several key considerations underpin SFA's positions. The Association understands that the goal of the Law is to create a uniform, national, pre-emptive disclosure standard. At the same time, the Law acknowledges the need to consider the interests of small and very small food businesses from SFA's perspective. A federal standard will be effective only if it is understandable and usable by four key constituencies: consumers, manufacturers, retailers and importers.

Consumers want to know what they are eating, by whom and how it is processed, often judging from labels, ingredient statements and other public information (including on-line information). The challenge is to provide any required or trending information without overwhelming consumers and while leaving space for a manufacturer's design and "romance copy" that also informs consumers.

Equally important, as the Law recognizes, the standard must be adaptable and flexible enough to be affordable to and manageable by *small and very small food manufacturers*.

The third key constituency for consideration is *retailers*. All retailers, but especially specialty retailers, succeed when they can educate their customers about the foods they offer. Currently, many consumers want access to clear and accessible information about a food's production process, including whether it is organically grown or bioengineered. Retailers, like individual consumers, want this information to be available to consumers.

A fourth constituency includes *foreign exporters and their U.S. importers, distributors and brokers*. U.S. trade commitments require non-discrimination between U.S. and foreign suppliers to the U.S. market. Of course, SFA understands that exporters from other countries must provide foods that conform to U.S. standards.

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[1]The Law refers to "food (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that is intended for human consumption." Later the Law refers to the labeling provisions of laws implemented by USDA, but with limitations: e.g., if the food would independently be subject to the labeling requirements under the FFDCA or (B)(i) the most predominant ingredient of the food is broth, stock, water, or a similar solution; and (ii) the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the FFDCA.

RESPONSES TO QUESTIONS

BIOENGINEERED

1. What terms should AMS consider interchangeable with 'bioengineering'?

   SFA recommends that "genetically modified" be interchangeable with bioengineering. The term "genetically modified" is used by consumers and in commerce, often with no specific technical definition in mind. Under the Standard, the term would have the same meaning as bioengineered under the Law.[2]

   In addition, USDA should consider organic certification sufficient to make a claim regarding the absence of bioengineering in the foods, such as "non-GMO" or another similar claim. Plus, no proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations.

2. What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered?

   SFA again recommends using a standard that is widely accepted currently as the level of bioengineered content above which a food will be subject to the Law. That should be 0.9 percent.

   In the European Union, biotechnology labelling requirements "do not apply to GM food/feed products in a proportion no higher than 0.9 percent of the food/feed ingredients considered individually and if this presence is adventitious or technically unavoidable."[3]

SMALL FOOD MANUFACTURERS

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

   Again, SFA recommends that the Standard define a small food manufacturer as the term is defined in the Food Safety Modernization Act or the Nutrition Labeling Act. Those two laws regulate most foods on the U.S. market. Under FSMA, a small business is one that employs fewer than 500 full-time workers. The Nutrition Labeling Act defines a small business as having fewer than 100 full-time employees.

   The Association recognizes that USDA applies a different definition of small business when determining exemptions from its nutrition facts panel (9 CFR 317.400 (a)(1)(ii)) for meat, poultry and egg products. The agency uses a cap of fewer than 500 employees and 100,000 pounds or less of annual production of a single product, including single forms of meat such as sausage, bulk, patties, links, consumer product, as the composite definition.

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[2] According to the Law, "the term `bioengineering', and any similar *term*, as determined by the Secretary, with respect to a food, refers to 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." (emphasis added) 7 USC 1639 Note.

[3] European Commission, Traceability and labelling, https://ec.europa.eu/food/plant/gmo/traceability_labelling_en.

VERY SMALL FOOD MANUFACTURERS

4. How should AMS define very small food manufacturers to exclude them from the requirements of the regulation?

   The Law requires that the implementing regulation exclude very small food manufacturers. SFA recommends using the definitions of very small business applied by FDA in the Food Safety Modernization Act. The basic definition of a very small business is a business "averaging less than $1,000,000 (adjusted for inflation)" in sales of human food (including sales by any subsidiaries or affiliates).[4] These are the very small food manufacturers that should be exempted.

SMALL & VERY SMALL PACKAGES

5. The Law offers special provisions for disclosure on small or very small packages. How should AMS define very small or small packages? What are the reasonable disclosure options AMS should provide for food contained in very small or small packages?

   The Law requires that the Standard provide alternative reasonable disclosure options for food contained in small or very small packages. Under FDA's nutrition label regulations, a small package is a package with 40 or fewer square inches of available label space.[5] Several alternative label formats are possible for a small package, including deleting the footnote, abbreviations and smaller type size.

   The regulation also refers to a package with less than 12 square inches of available label space, which could be considered a very small package under the Standard.

   SFA recommends that a no-charge telephone number or digital link be among the options offered to replace biotechnology labeling on small packages. This possibility would be like the on-package disclosure options offered under the Law to small food manufacturers: a telephone number accompanied by appropriate language to indicate that the phone number provides access to additional information; or an internet website maintained by the small food manufacturer.

   The Association also recommends that very small packages and food in packages that are not for retail sale (such as individual chocolates offered to hotel guests and snacks offered by airlines) be exempt from the Standard.

[4] The $1 million includes the market value of human food that is manufactured, processed, packed, or held without sale (e.g. held for a fee), per year during the 3-year period preceding the current calendar year.

[5] 21 CFR 101.9(j)(13.

"SIMILAR RETAIL FOOD ESTABLISHMENT"

6. The Law excludes restaurants and similar retail food establishments from disclosure requirements. How should AMS define similar retail food establishments to exclude these establishments from the requirements of the regulation?

   The definition of similar retail food establishment should include retail food stores that sell prepared foods to customers to eat on the premises and for carry out. Both sales are retail sales. These stores are like restaurants and are increasingly important options for consumers interested in affordable and convenient away-from-home food. They should be within the exemption provided by the Law.

REQUIREMENTS FOR IMPORTED FOODS

7. What should the requirements for imports into the United States of products covered by the Law/regulation be?

   The requirements for domestic and imported food products should be the same. This is the position taken by FSMA and the position required by the international trade law commitments of the U.S. Rigid but similar disclosure rules as with domestic production should be required.

RECORDS

8. What types of records should AMS require to be maintained to establish compliance with the regulations?

   The records should be the documents that food manufacturers maintain in their good manufacturing practices. Product tracing is implied in the law, since food manufacturers will need to produce information about ingredients or processing that destroys the genetically modified material.

   A Seed source declaration record could easily be added to the typical COA that most ingredient suppliers utilize currently with the sale of their ingredients to another company.

IMPLEMENTATION DATE

9. SFA recommends that the implementation date for small food manufacturers be delayed for two (2) years and the implementation date for very small food manufacturers for three (3) years after the date for large food manufacturers.

   According to the Law, the authority to stage implementation exists in the case of small food manufacturers. For those companies the Secretary may decide an implementation date that is not earlier than 1 year after the implementation date for the regulations. The language does not preclude a staged implementation for very small food companies.

CONCLUSIONS

The mandatory label for bioengineered food will be one of the most significant recent regulatory developments for the food sector and consumers. The label should respond to the growing interest of consumers for transparency, especially their desire to know what they are eating - its content, method of production and processing. SFA believes that the best way for this interest to be recognized and yet be manageable for specialty food companies is to use the definitions of small and very small food manufacturers used by FDA, which regulates most of the U.S. food supply, including under the Nutrition Labeling Law and FSMA. We also urge USDA to address in the regulation the challenges for importers and retailers of complying with this Law.

SFA thanks USDA for the opportunity to contribute the concerns of its 3,600 members to the implementation of the National Bioengineered Food Disclosure Standard.

Sincerely,

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President, Specialty Food Association