

U.S. Department of Agriculture Agricultural Marketing Service 1400 Independence Avenue SW Washington, DC 20250

Submitted via GMOlabeling@ams.usda.gov.

Re: National Bioengineered Food Disclosure Standard; Comments from National Organic Coalition on Proposed Rule Questions Under Consideration

July 17, 2017

The National Organic Coalition (NOC) submits the following comments in response to the 30 questions posted by the Agricultural Marketing Service regarding the National Bioengineered Food Disclosure Standard.

The National Organic Coalition (NOC) is a national alliance of organizations working to provide a "Washington voice" for farmers, ranchers, environmentalists, consumers, and industry members involved in organic agriculture. NOC seeks to advance organic food and agriculture and ensure a united voice for organic integrity, which means strong, enforceable, and continuously improved standards to maximize the multiple health, environmental, and economic benefits that only organic agriculture affords. The coalition works to assure that policies are fair, equitable, and encourage diversity of participation and access.

NOC appreciates the opportunity to give input in advance of the proposed rule. We believe it is critical to consider input from a full range of stakeholders in crafting the proposed rule. In the interest of transparency and since this request for comments is not an advanced notice of proposed rulemaking, which establishes a docket to receive and post comments at Regulations.gov, we respectfully request that AMS post all the comments it receives on the AMS website.

Summary of NOC Comments

The standards for disclosing bioengineerd food, as determined by the USDA, should be accessible to consumers, consistent with other labels they see in the marketplace such as "organic" and "non-GMO," and otherwise not misleading. NOC believes that:

- The definition of "bioengineering" must be consistent with international standards and include all forms of genetic engineering, including newer forms like CRISPR and RNA interference (RNAi). We urge AMS to follow FDA's lead and consider that the term "bioengineering" is a synonym for "modern biotechnology." The term "modern biotechnology" is accepted by FDA and the National Organic Standards Board, and has a common, globally accepted standard definition, as noted both by the Codex Alimentarius Commission and the Convention on Biological Diversity.
- Each GE ingredient must be identified, including highly refined GE sugars and oils and processed corn and soy ingredients. Even if they are so highly processed that the GE ingredients are present only at undetectable levels in the final product, they are still GE foods.
- GE ingredients must be identified on product labels, or product shelves in the case of raw foods. All products required to label ingredients should include identification of GE ingredients on the label. We urge USDA to reject the option of allowing electronic or digital disclosure for bioengineered food, for a number of reasons, including lack of access to smartphones among a broad swath of the population and increased burdens on the consumer.
- There must be no delays in making the regulations effective. Manufacturers have already had years' worth of notice and preparation to provide this information, at the state and federal level. Indeed, many major food companies have been labeling for some time.
- To maintain consumer confidence in the organic label, which garners nearly \$50 billion in sales annually, it is critical that the USDA ensure that the rules for bioengineered food disclosure are consistent with the AMS Policy Memorandum from September 19, 2016 entitled "AMS Bioengineered Foods Disclosure Program – Consistency with the AMS National Organic Program": no proposed rules for bioengineered food disclosure will require modifications to the USDA organic regulations.

NOC has provided further information on these points and others below in response to the questions posed by the USDA.

NOC supports the detailed comments submitted by NOC member organizations including Beyond Pesticides, Center for Food Safety, Consumer Reports, OEFFA, and NOFA-NY.

NOC Comments on 30 Questions

1. What terms should AMS consider interchangeable with 'bioengineering'? (Sec. 291(1))

The Agricultural Marketing Service (AMS) should recognize a limited number of alternative terms—namely "modern biotechnology," "genetic engineering," "GE," "genetic modification," "genetically modified organism," and "GMO"—to be interchangeable with "bioengineering." The first three are terms recognized by the Food and Drug Administration (FDA), and the latter two by the Food Safety and Inspection Service (FSIS).

NOC supports the more detailed comments provided by Consumer Reports on this topic.

Which breeding techniques should AMS consider conventional breeding? (Sec. 291(1)(B))

Conventional breeding consists of various techniques that do not include techniques of modern biotechnology, as defined by the National Organic Standard Board (NOSB), FDA, Codex and the Cartagena Protocol. We urge AMS to adopt NOSB's approach. Based on these definitions, gene editing techniques are also techniques of modern biotechnology and are not techniques of conventional breeding.

NOC member organizations Consumer Reports and OEFFA have provided more detailed comments on this topic and we support the points addressed in those comments.

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

We urge AMS to require disclosure for all foods that contain any level of highly refined GMO products, including oils and sugars derived from bioengineered crops, even at undetectable levels. The entire reason for disclosure standards are to inform consumers about the origin of ingredients in their food products, so ignoring this and failing to label products as such would hide the information the law was meant to provide. Overly narrow interpretations, creating loopholes to exempt some GE foods from labeling requirements, would be contrary to Congress's intent and to USDA's own statements in the legislative process.

NOC supports the more detailed comments on this topic provided by NOC member organizations Beyond Pesticides, Center for Food Safety, Consumer Reports, OEFFA, and NOFA-NY.

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 [sic] 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))

While there is a potential area of confusion between the definition of "bioengineering" in P.L. 114-216 and the terms "bioengineering," "modern biotechnology" "genetic engineering," as used by FDA, AMS could avoid much of this confusion by adopting the FDA definition, and we strongly urge AMS to do so.

In elaborating on what specifically is meant by the definition in Section 291 of the law, we urge AMS to follow FDA's lead and consider that the term "bioengineering" is a synonym for "modern biotechnology." The term "modern biotechnology" is both accepted by FDA and the National Organic Standards Board, and has a common, globally accepted standard definition, as noted both by the Codex Alimentarius Commission and the Convention on Biological Diversity. We urge AMS to use this definition of "modern biotechnology," so as not to create confusion among regulatory schemes, among food producers, or among consumers, and for food exporters and importers. Adopting any other definition could lead to massive consumer confusion, with the same words meaning different things on different products, and could become an obstacle to international trade.

USDA has provided clarification that the rules for bioengineered food disclosure will not require that modifications be made to the USDA organic regulations. The conditions expressed in USDA's Policy Memorandum entitled "Consistency with the AMS National Organic Program" should also be clearly stated in the final GMO food disclosure regulations.

Section 299 (f)(2) of Pub. L. 114-216 states: "the Secretary shall consider establishing consistency between the national bioengineered food disclosure standard established under this section and the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.) and any rules or regulations implementing that Act." There is concern that, contrary to the intent of the law, that this provision may actually lead to a revision to the organic regulations to bring consistency with the standards established under Pub. L. 114-216.

As clarified through USDA's Policy Memorandum from September 19, 2016 entitled "AMS Bioengineered Foods Disclosure Program – Consistency with the AMS National Organic Program", this is not the intent and should not be interpreted as such. The AMS policy was written to ensure that any new proposed regulations or specifications of Pub. L. 114-216 comply with its policy. Central to avoiding conflict and protecting the organic standards, the policy states: When proposing standards for national bioengineered food disclosure program, AMS policy will be as follows:

• No certified organic products will require disclosure as bioengineered; and

• No proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations.

The definition and prohibition on excluded methods are well established in the regulations of the National Organic Program, and the organic industry has grown alongside these requirements to reach nearly \$50 billion in organic sales annually. To maintain consumer confidence in the organic label, it is critical that the USDA ensure that the rules for bioengineered food disclosure are consistent with the AMS Policy Memorandum from

September 19, 2016: no proposed rules for bioengineered food disclosure will require modifications to the USDA organic regulations.

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))

If a product contains one or more ingredient(s) produced through bioengineering, regardless of quantity, it should be considered bioengineered and require a label stating the presence of the genetically engineered ingredient. This clear standard would eliminate the need to set a level or percentage, which would likely lead to food manufacturers tweaking their product formulations to avoid having the bioengineered label.

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

AMS may want to develop various categories for disclosure—such as differentiating if a product a) is bioengineered, b) contains ingredients that are bioengineered, or c) contains ingredients derived from bioengineered crops, animals or microorganisms—as long as AMS also requires that disclosure should also occur on the ingredient list.

Categories such as "bioengineered," "produced with bioengineering," and "partially produced with bioengineering," can be useful to consumers since they do indicate that a food product does contain bioengineered ingredients, as well as the rough indication of the amount of the food products that is derived from bioengineered sources. However, these terms do not indicate which ingredients have been bioengineered, which is information that consumers would like to access. Disclosure should also thus occur on the ingredient list. One easy way to do this is to use an asterisk symbol (*) after each ingredient in the ingredient list that is bioengineered and then at the end of the ingredient list note that * = "genetically engineered" or "genetically modified."

11. Could AMS consider whether a type of food is considered a bioengineered food under the determination process? (Sec. 293(b)(2)(C))

AMS should not exclude specific food types. People with medical conditions, dietary restrictions, or those utilizing dietary supplements deserve the same right to know as the general public.

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))

NOC urges AMS to allow a limited range of flexibility in terms of the text disclosure language. The terms "genetically engineered" and "produced with genetic engineering" and "partially produced with genetic engineering," which were compliant with the Consumer Protection Rule 121 from the State of Vermont, and which some food manufacturers are presently using, should be allowed, but the phrase "may be produced with genetic engineering" should not be allowed. The first three phrases are informative, while the last one is not.

In Vermont's regulations, "genetically engineered" could be used on a product derived from a single source that was bioengineered, such as a filet from a GE salmon or an Arctic Apple (which has been bioengineered not to turn brown when cut). "Produced with genetic engineering" could be used on a multi-ingredient product where 75% or more of the ingredients in the product (by weight) derived from bioengineered sources, while "partially produced with genetic engineering" could be used on a multi-ingredient product where less than 75%, but at least 0.9%, of the ingredients in the product (by weight) are derived from bioengineered sources. These three phrases on food products are useful—since they identify that the products contains bioengineered materials and the relative amount (e.g. 100%, more than75% but less than100%, and more than 0.9% but less than75%)—and should be allowed.

"May be produced with genetic engineering" could be misleading to consumers and could create confusion as to whether or not the food product contains bioengineered ingredients. Thus, this phrase should not be allowed.

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

In terms of the symbol that AMS should require for disclosure, we urge AMS to use a circle with the letters "GE", "GM" or "GMO" inside that circle.

Both FDA and USDA have said they would allow use of these symbols on labels. In addition, these three symbols are widely used for labeling of products that do not contain bioengineered ingredients, such as those from the Non-GMO Project Verified label, and the Non-GMO True North program from NSF International, so they would be seen in the market. These three symbols are not disparaging toward bioengineering.

If used on a package, the symbol should be prominently displayed on the front of the package, preferably located next to the name of the product. The symbol should be of a similar font size to the name of the product (same font size or at least 75% of font size of product/brand name). The symbol should also be easily recognizable with a sharp contrast between the symbol and the background space.

In addition to the symbol, we think that any ingredient from a bioengineered source should be identified as such on the ingredient list.

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)

We urge USDA to reject the option of allowing electronic or digital disclosure for bioengineered food, for a number of reasons, including lack of access to smartphones among a broad swath of the population and increased burdens on the consumer.

Studies show that half of low-income people do not own smartphones. Almost half of rural people do not own smart phones. Two-thirds of the elderly do not own smartphones. In fact only 64 percent of Americans own a smart phone. Electronic disclosure is inherently discriminatory against all of these demographics.

In addition, electronic labeling disclosures place an undue burden on the consumer and greatly impede access to information. In many areas, access to the internet or cell phone access is non-existent or intermittent. Even for shoppers who have smartphones and are shopping in stores with internet or cell phone access, electronic or digital disclosures are burdensome and impractical. Shoppers are often on tight timelines, perhaps with children in tow, and may not have the time necessary to scan each food item they purchase and read information on a website. Shoppers already expect that they can read a label for critical product details so they can make an informed purchase and they should be able to do so for GE information as well.

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))

Bioengineered food that is not purchased from a grocery store shelf should also have a text or symbol disclosure. If the food is sold in bulk, there could be a sign next to the display that contained the words "genetically engineered" or a symbol such as GE, GM or GMO. If the product is sold in a vending machine, the label on the product in the vending machine (candy bar, bag of chips, soda, etc.) should bear the disclosure. For products sold online, the text or symbol should be prominently noted on the screen that shows the product as well as on the screen that is used to purchase the product. The disclosure should be prominently placed next to the item being purchased. In addition, any ingredient from a bioengineered source, should be identified.

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

AMS should not unreasonably exempt any manufacturers from the GE labeling requirements. Congress intended to only exempt "cottage foods" and very small companies from the

disclosure requirement.

The Food and Drug Administration defines "very small business" as businesses averaging less than \$1 million in sales and it provides special considerations and exemptions for small businesses in regulations for nutrition labeling, which it defines as averaging less than \$500,000 in gross annual sales.

For farms, small businesses are defined as farms with an average annual monetary value of produce sold during the previous 3-year period as no more than \$500,000. For farms that are very small businesses the limit is \$250,000.

AMS should follow the precedent set by these relevant definitions of small and very small businesses.

29. How should AMS make public the summary of any examination, audit, or similar activity? (Sec. 293(g)(3)(C))

In the interest of transparency, we strongly urge AMS to make public the results and findings of any examination, audit, or similar by posting such information on the AMS website. We urge AMS to post the full results and findings of any examination, audit, etc. rather than just posting a summary. The publication of the full results, rather than a summary, will be useful for the interested public. If the full results of any inquiry, rather than just a summary, were published, perhaps that would result in companies being less likely to violate the provisions of this law.

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

AMS should treat imported products no differently than domestically produced products in terms of the disclosure requirements under PL-114-216. AMS can make such treatment easier if it adopts the Codex definition for products of modern biotechnology as its definition of "bioengineered".

Thank you for your consideration of these comments.

On behalf of National Organic Coalition Members:

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National Organic Coalition

National Organic Coalition Members:

Beyond Pesticides Center for Food Safety Consumers Union Equal Exchange Food and Water Watch Maine Organic Farmers and Gardeners Association Midwest Organic and Sustainable Education Service National Co+op Grocers Northeast Organic Dairy Producers Alliance Northeast Organic Farming Association Ohio Ecological Food and Farm Association Organically Grown Company Organic Seed Alliance Rural Advancement Foundation International – USA