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U.S. Department of Agriculture
Agricultural Marketing Service
1400 Independence Ave., S.W.
Washington, DC 20250
By email: GMOlabeling@ams.usda.gov

Re: Proposed Rule Questions Under Consideration for National Bioengineered Food Disclosure Standard.

These comments to the U.S. Department of Agriculture Agricultural Marketing Service (AMS) are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

We appreciate the opportunity to provide input on the questions posted by the U.S. Department of Agriculture (USDA) regarding the National Bioengineered Food Disclosure Standard. AMS will be drafting regulations to implement The National Bioengineered Food Disclosure Standard. Genetically engineered (GE) foods pose risks that are not considered by regulators. Consumers have a right to know whether the products they buy contain GE ingredients. This information should be on the product label.

In the interest of transparency –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 request that AMS post all the comments it receives on the AMS website. In response to the request for input, the following are important points to incorporate in the regulations, followed by responses to many of AMS's questions.

- The definition of "bioengineering" must include all forms of genetic engineering, including newer forms like CRISPR and RNA interference (RNAi). Definitions should be compatible with those recommended by the National Organic Standards Board.
- 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.
- There must be no delays in making 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.

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

In the disclosure law, the term "bioengineering" refers to a food that has been genetically modified in a way that could not be obtained through conventional breeding or found in nature.[1] Since many consumers may not know or understand the term bioengineering, there should be allowable interchangeable terms for the disclosure standard. These include the terms: genetically engineered, genetically modified organism, and GMO. We recommend that USDA allow and recognize these as interchangeable terms, since they have been used consistently by AMS in National Organic Program regulations and communications.

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

According to USDA, conventional farming is the "use of seeds that have been genetically altered using a variety of traditional breeding methods, excluding biotechnology, and are not certified as organic."[2] We suggest using the USDA National Organic Standards Board (NOSB) definition of classical/traditional breeding when considering conventional breeding techniques, as stated below.

> **Classical/Traditional plant breeding** – Classical (also known as traditional) plant breeding relies on phenotypic selection, field based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.

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))

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[1] Public Law 114-216. Available at https://www.congress.gov/114/plaws/publ216/PLAW-114publ216.pdf

[2] United States Department of Agriculture. "USDA Coexistence Fact Sheets: Conventional Farming." Available at https://www.usda.gov/sites/default/files/documents/coexistence-conventional-farming-factsheet.pdf.

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.

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 NOSB has made recommendations concerning excluded methods in USDA organic regulations. To avoid confusion between these definitions of terms and acronyms, we recommend adopting the definitions as laid out in the proposal by the NOSB Materials Subcommittee in fall 2016:[3]

> **Genetic engineering (GE)** – A set of techniques from modern biotechnology (such as altered and/or recombinant DNA and RNA) by which the genetic material of plants, animals, organisms, cells and other biological units are altered and recombined.
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> **Genetically Modified Organism (GMO)** – A plant, animal, or organism that is from genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources.
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> **Modern Biotechnology** – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection. (From Codex Alimentarius)
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> **Synthetic Biology** – A further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity)
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> **Non-GMO** – The term that is used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and

[3] National Organic Standards Board. August 2016. "Excluded Methods Terminology." Available at https://www.ams.usda.gov/sites/default/files/media/MSExcldMethTerminologyProposalNov2016.pdf.

corresponding NOP policy. The term "non-GMO" is consistent with process-based standards of the NOP where preventive practices and procedures are in place to prevent GMO contamination while recognizing the possibility of inadvertent presence. (Modified based on public comment from Spring 2016 NOSB.)

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.

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

The relevant factor to consider in determining whether a food is considered a bioengineered food is whether the food or its ingredients are bioengineered.

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

The relevant factor to consider in determining whether a food is considered a bioengineered food is whether the food or its ingredients are bioengineered. The type of food is irrelevant.

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))

The label text must provide clear, unambiguous information to the consumer. We suggest allowing the following text for disclosure: “produced with genetic engineering” and “genetically engineered.” The ingredient list should identify each genetically engineered ingredient.

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))

We urge USDA to reject the option of allowing electronic or digital disclosure for bioengineered food, for a number of reasons, including access to a smartphone and increased burden 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. Minorities are a disproportionate percentage of low-income and rural Americans. 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 that is currently required for all other forms of food labeling.

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))

We do not support the electronic or digital disclosure for these types of food sales, but either text or a symbol should be required that mirrors the way USDA organic products are labeled in bulk or bins. The rules for labeling organic retail products identify the wording allowed on both the front panel and the information panel of a product, which includes the USDA organic seal and organic text claims. If a symbol is used, it must be clear and unambiguous, such as “GMO” or “GE”.

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

Similar manner to the answer above, we support using rules that mirror organic requirements for labeling on produce. This would include a label or symbol on the shelf above or below the product.

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))

There does not seem to be a reason why small food manufacturers would be treated differently with these labeling standards, so we urge USDA to maintain consistency with the labeling precedent set by the Food and Drug Administration with regard to defining small and very small businesses. 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. For nutrition labeling, special considerations and exemptions apply to small businesses, which FDA defines as businesses averaging less than $500,000 in gross annual sales. Any product that is required to have an ingredient label must indicate which ingredients are genetically engineered.

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

AMS should require producers to document the source of the ingredients of their products on demand.

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

We urge USDA to require consistent, on-package text labeling as described in our answers above for all products sold in the United States, including imports. Just as USDA organic imports are required to comply with the organic standards and labeling requirements, any imported bioengineered food product or ingredient must be held to the same standards as laid out in this law.

We appreciate your soliciting public input into the draft regulations. Again, since this process has not involved an advanced notice of proposed rulemaking, which would have been posted to Regulations.gov along with comments, we request that AMS post comments it receives on the AMS website.

Thank you for your consideration of our recommendations.

Sincerely,

Carla Curle

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