July 5, 2017

The Honorable Sonny Perdue
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

RE: Proposed Rule Questions Under Consideration for GMO Disclosure and Labeling
https://www.ams.usda.gov/rules-regulations/gmo-questions

Dear Secretary Perdue,

The Organic Trade Association (OTA) thanks the United States Department of Agriculture (USDA) for requesting stakeholder input to inform the implementation of the National Bioengineered Food Disclosure Standard (Pub. L. 114-216) by the mandated July 2018 deadline. We appreciate the posted 30 questions and look forward to commenting on any proposed rule during the rulemaking process.

The Organic Trade Association is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The National Bioengineered Food Disclosure Law (Pub. L. 114-216) not only requires disclosure of genetically modified ingredients, but also includes important provisions that are critical for organic farmers and food makers—and for the millions of consumers who choose organic every day—because they recognize, unequivocally, that USDA certified organic products qualify for non-GMO claims in the marketplace. Those provisions safeguard USDA certified organic as the gold standard for transparency and non-GMO status.

Consistent with the statute and the related USDA Policy Memos released since the labeling law was signed, the Organic Trade Association requests a final rule that will put into action the following key organic provisions:

- USDA shall consider organic certification sufficient to make a claim regarding the absence of bioengineering in the food, such as “not bioengineered,” “non-GMO,” or another similar claim;
- The final rule should clearly state that products exempt from mandatory disclosure as bioengineered foods, such as milk from cows fed genetically modified feed, do not qualify for an absence claim solely because the food is not required to bear a disclosure. Non-GMO and other similar label claims must be substantiated by a third-party verification program such as USDA organic certification;
- No proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations; and

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- No certified organic products will require disclosure as bioengineered.

We also strongly urge USDA to:

- Recognize "non-GMO" or other similar phrases as acceptable shorthand term for "not produced using genetic engineering/bioengineering"
- Use its authority and broadly interpret the definition of "bioengineering" and include highly refined products such as oils or sugars derived from bioengineered crops, and
- Establish a clear mechanism for public comment on any future determinations regarding whether genetic modification techniques will require labeling.

In support of these organic provisions and other related areas, we have provided more detailed answers to the following questions USDA is requesting feedback on:

USDA Question: 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))

OTA Response: *The final rule should clearly state that products exempt from disclosure, such as milk or other dairy or livestock products from animals fed bioengineered feed, do not qualify for a "non-GMO" label claim.*

Organic certification is sufficient to make a claim regarding the absence of bioengineering in the food. However, products that do not require mandatory disclosure as bioengineered foods, such as milk from cows fed genetically modified feed, do not qualify for absence claims solely because the food is not required to bear a disclosure.

Section 294 (c) of Pub. L. 114-216 states:

> A food may not be considered to be 'not bioengineered', 'non-GMO', or any other similar claim describing the absence of bioengineering in the food solely because the food is not required to bear a disclosure that the food is bioengineered under this subtitle.

OTA strongly supports this provision and the final regulations should clearly apply this condition to products derived from animals that have consumed bioengineered feed.

Consistent with law, the final rule must state that products exempt from mandatory disclosure as bioengineered foods, such as milk from cows fed genetically modified feed, do not qualify for a non-GMO claim. Non-GMO or other similar negative label claims may only be used when substantiated and approved through third-party verification. For example, as instructed by Pub. L. 114-216, USDA shall consider organic certification sufficient to make a claim regarding the absence of bioengineering in the food, such as "not-bioengineered," "non-GMO," or another similar claim. Another example includes the USDA Food Safety and Inspection Service (FSIS) approval process for companies that seek to make labeling claims concerning the fact that bioengineered ingredients were not used in a meat, poultry or egg product. As a policy matter and in response to Pub. L. 114-216, FSIS will only approve "negative claims"

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for meat, poultry and egg products that do not contain bioengineered ingredients or that are derived from livestock that do not consume bioengineered feed and that contain the terms "genetically modified organism" or "GMO".

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

OTA Response: *OTA urges the final rule to recognize "non-GMO" or other similar phrases as acceptable shorthand term for "not produced using genetic engineering/bioengineering."*

Over the past 15 years, USDA's National Organic Program (NOP) has developed an extensive body of federal regulations relating to GMOs. The NOP regulations prohibit the use of "excluded methods," including "Genetically Modified Organisms (GMOs)," during the production or handling of organic products [7 CFR 205.105(e)]. This prohibition on the use of GMOs extends to all NOP certified label categories ("100% Organic," "Organic," and "Made with Organic") and all ingredients contained within each category (organic and non-organic ingredients and processing aids). Compliance is verified through the robust and auditable NOP certification process that includes periodic testing for prohibited substances such as pesticides, heavy metals and GMOs.

Organic consumers are highly familiar with the acronyms "GMO" and "GM." All communications regarding genetic engineering from NOP since 2000 refer to "GMOs." This includes USDA policy statements, instructions to certifiers and certified operations, and USDA fact sheets/educational materials for the public, all of which are available on the NOP website. In fact, USDA's web page on this exact issue is entitled "GMO Disclosure & Labeling."

The term "non-GMO" has become established shorthand in communicating the regulations of NOP, among companies in the industry, and among consumers, as a *process* claim associated with NOP organic certification. For this reason, the final rule on GMO food disclosure should allow the term "non-GMO" and other similar phrases as suitable shorthand for "not produced using genetic engineering (or bioengineering)." Examples of similar phrases include "produced without GMO ingredients," "made without the use of GMOs" and "contains non-GMO ingredients only."

Since 1997, the organic industry has grown from $3 billion to over $40 billion. This growth has been accompanied by the acceptance of the term "non-GMO" on an organic product as shorthand for "not produced using bioengineering." If the final guidance were to discourage or not allow the use of "non-GMO," this would cause extensive disruption and economic hardship within the organic industry.

USDA Question: 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))

OTA Response: *GMO food disclosure regulations must include language that explicitly protects the USDA organic regulations from any modifications as a result of the GMO food disclosure rule.*

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OTA thanks USDA for clarifying in policy 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.

One of the hallmarks of being certified by USDA's National Organic Program (NOP) is that certified products must not be produced using "excluded methods[1]." The use of "excluded methods," also generally referred to as genetically modified organisms (GMOs), is a term that is explicitly defined and strictly prohibited in organic production and handling, and extends to all NOP certified label categories ("100% Organic," "Organic," and "Made with Organic") and all ingredients contained within each category (organic and non-organic ingredients and processing aids).

Over the past 15 years, USDA's NOP has developed an extensive body of federal regulations relating to GMOs. This includes USDA policy statements, instructions to certifiers and certified operations, and USDA fact sheets/educational materials for the public, all of which are available on the NOP website. Furthermore, the federal advisory board that advises the Secretary of Agriculture in setting organic standards (National Organic Standards Board) just completed three years of work through a transparent and public process and unanimously passed a recommendation[2] to NOP on "excluded methods terminology" further clarifying the methods that are prohibited under the organic regulations.

As AMS moves forward and implements Pub. L. 114-216, it is critical that the language addressing consistency with certain laws, found in section 299 (f)(2), is clearly interpreted and translated through rulemaking in such a way that will protect the definitions and practices that are currently established under the NOP organic regulations and any USDA NOP rulemaking or guidance in process.

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."

Contrary to the intent, there is concern 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 on "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.

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[1] A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

[2] NOSB Materials/GMO Subcommittee Proposal: Excluded Methods Terminology (August 30).

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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 NOP, and the organic industry has grown alongside these requirements from its $3 billion in annual sales in 2001 to $43 billion today. To avoid extensive disruption and economic hardship within the organic industry and maintain consumer confidence, it is critical that USDA ensure that the rules for mandatory GMO food disclosure adopt the language included in the AMS policy that no proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations.

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

OTA Response: *OTA urges USDA to use its authority and broadly interpret the definition of "bioengineering" and include highly refined products*

After the GMO labeling bill was introduced in June 2016, many were rightly concerned by the U.S. Food and Drug Administration's (FDA) comments[3] that it would read the bill narrowly to not cover highly processed products such highly refined oils or sugars, or emerging technologies such as gene editing. Since then, the Office of General Council at USDA has clarified its authority of the scope and applicability of the proposed legislation. USDA clarified that the proposed legislation:

- Provides authority to mandate labeling of food including all commercially grown GMO corn, soybeans, sugar, and canola crops used in food today;
- Provides authority to require labeling of food products that contain genetically modified material resulting from gene editing techniques;
- Provides authority to mandate labeling of food, including products that may contain highly refined oils, sugars, or high fructose corn syrup produced or developed from genetic modification techniques.

USDA's interpretation clarifies that the definition of "bioengineering" in Pub. L. 114-216 does not need to solely require the presence of genetic material nor does it need to be solely limited to recombinant deoxyribonucleic acid (rDNA) techniques. In a colloquy on July 12, 2016, Ranking Member of the Senate Agriculture Committee Senator Debbie Stabenow (D-Mich.) reiterated the broad authority of USDA to include a wide range of ingredients, including highly refined and gene-edited ingredients. Senator Stabenow stated, "This bill gives USDA broad authority to determine . . . which foods will be subject to

[3] FDH/HHA Technical Assistance on Senate Agriculture Committee draft legislation to establish a national disclosure standard for bioengineered foods (EDW16734), June 27, 2016

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this bill's mandatory disclosure standard, including highly refined products derived from GMO crops and products developed using gene editing techniques."[4] More specifically, she clarified that "this bill does not prohibit the labeling of highly refined products derived from GMO crops including soybean oil made from GMO soybeans, high fructose corn syrup made from GMO corn, and sugar made from GMO sugar beets."[5]

OTA strongly agrees. In establishing the mandatory disclosure standard, OTA urges USDA to use the authority it has to implement the definition of "bioengineering" in Pub. L. 114-216 broadly enough to ensure that a wide range of products, which include ingredients derived from bioengineering, are subject to mandatory disclosure. We believe that a narrow interpretation of the definition would be contrary to the promise[6] of Pub. L. 114-216 and would not result in "25,000 more products" being subject to mandatory disclosure requirements compared to Vermont Act 120 and other state disclosure requirements. An overly narrow interpretation could potentially exclude a significant portion of the market from disclosure requirements, undermining both the legislative authority of Pub. L. 114-216 and reasonable consumer expectations.

USDA Question: 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))?

OTA Response: *OTA does not view QR codes as ideal or adequate disclosure.*

We view on-pack text disclosure as the most direct and transparent route to communicate with the consumer about the GMO content of a product. While we hope that food companies will disclose the presence of GMOs through on-package text or the USDA symbol—as consumers overwhelmingly want, we recognize that some companies may use the digital disclosure option. Therefore, USDA needs to have strong rules to make sure that digital disclosures made using QR codes consistently scan every time, work in all conditions, and are easily accessible for consumers who don't have smartphones.

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

OTA Response: *A mechanism is needed for public comment on advances in GE technology.*

USDA has the authority to apply the definition of bioengineering Pub. L. 114-216 broadly to include genetic engineering technologies other than rDNA. Limiting the definition only to foods with ingredients derived from rDNA would unduly exclude foods derived from newer technologies like CRISPR gene editing or RNA interference (RNAi). As mentioned earlier, both Senator Stabenow's colloquy and the USDA General Counsel Jeffrey Prieto's letter to Senator Stabenow support interpreting the definition of bioengineering broadly enough to encompass technologies other than rDNA.

[4] *See* 162 Cong. Rec. S4994 (daily ed. July 12, 2016).
[5] *Id.*
[6] In numerous press releases, postings on social media and public statements, Ranking Member Stabenow stated that Pub. L. 114-216 would require 25,000 more products would be subject to mandatory disclosure requirements compared to Vermont Act 120 and other state disclosure requirements.

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To accommodate the development of new genetic engineering techniques and advances in technology and ensure that companies and consumers understand the full scope of the disclosure, the Organic Trade Association also strongly urges USDA to establish a clear mechanism for public comment on any future determinations regarding whether genetic modification techniques will require labeling.

On behalf of our members across the supply chain and the country, OTA thanks USDA for the opportunity to comment, and for your commitment to protecting the integrity of the USDA organic seal.

Respectfully submitted,

Gwendolyn Wyard
Vice President, Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

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