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Organic trade association

July 3rd, 2018

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

RE: Comments on Notice of Proposed Rulemaking, "National Bioengineered Food Disclosure Standard," Docket N. AMS-TM-17-0050, 83 *Fed. Reg*. 19860 (May 4, 2018)

Dear Secretary Perdue,

This comment addresses the U.S. Department of Agriculture (USDA) proposed rule titled "National Bioengineered Food Disclosure Standard (NBFDS)" as published in the May 4, 2018, *Federal Register*. The Notice proposes to add a Part 66 to Title 7 of the Code of Federal Regulations, to implement subtitles E (consisting of sections 291 through 294) and F [consisting of sections 295 and 296 of the Agricultural Marketing Act of 1946 (AMA), as amended by Public Law 114-216 (July 29, 2016)].

The Organic Trade Association (OTA) 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.

One of the hallmarks of being certified by USDA's National Organic Program (NOP) is that certified products may **not** be produced using excluded methods[1] [7 CFR 205.105(e)]. This prohibition on the use of excluded methods extends to all NOP certified label categories ("100% Organic," "Organic," and "Made with Organic") and all ingredients contained within each category. Because of this, OTA has actively and successfully advocated for the right of organic food producers and processors to label their products and product ingredients as "not genetically modified" (or similar phrases), to reinforce the consumer understanding that to be certified organic means – among other things – to be "non-GMO[2]." OTA also believes that consumers have the right and desire to know more about their food in general. To that end, we strongly support mandatory labeling of all genetically modified (GM) foods.

[1] *Excluded methods.* 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] Non-GMO, as defined by USDA's National Organic Standards Board, is term used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations. 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.

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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 as defined in the organic regulations and as expected by consumers who choose to purchase organic products.

Consistent with Law (Pub. L. 114-216), the Organic Trade Association requests a final rule that will put into action the following key provisions:

- No USDA-NOP certified products will require disclosure as 'bioengineered';
- USDA shall consider organic certification sufficient to make a claim regarding the absence of bioengineering in the food, such as "not bioengineered," "not genetically engineered," "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, may not by default automatically qualify for a "negative" or "absence" claim solely because the food is not required to bear a disclosure;
- The definition of the term 'bioengineering' shall not affect the definition of "excluded methods" or any other definition under USDA's National Organic Program; and
- The requirements set under the bioengineered food disclosure will not require that any modifications be made to the USDA organic regulations.

We also urge USDA to:

- Use its authority and broadly interpret the definition of "bioengineering" to include highly refined products such as oils or sugars derived from bioengineered crops;
- Recognize and allow common terms and shorthand that industry and consumers understand, such as "genetic engineering," "genetically modified," "not GE," and "non-GMO;"
- Adopt symbol disclosure options that 1) utilize acronyms that consumers are familiar with such as "GE" or "GMO," and 2) are consistent with the non-bias stylistic tone of other AMS logos;
- Adopt a threshold for inadvertent or technically unavoidable bioengineered DNA that is consistent with the level adopted by other major trading partners (no more than 0.9% of the specific ingredient).

We offer the following more detailed comments:

I. <u>No products certified under the National Organic Program will require disclosure as 'bioengineered.'</u>

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The Proposed Rule under Section 66.5 (Exemptions) states, "This part shall not apply to food and entities' described in this section and includes "Food certified organic under the National Organic Program." OTA strongly supports the intent behind this exemption because it ensures consistency with USDA's organic regulations (7 CFR 205) and the requirement that USDA-NOP certified products must be produced and handled without the use of excluded methods. However, a technical correction is needed to satisfy the terms of the statute and accurately exempt all food certified under the National Organic Program.

As stated earlier, the prohibition on the use of excluded methods extends to all NOP certified label categories ("100% Organic," "Organic," and "Made with Organic") and all ingredients (organic and non-organic) contained within each label category. We assume USDA intended to exempt all product categories certified under NOP. However, the inclusion of the phrase "…certified organic…" is problematic because it could imply that the exemption does not extend to products certified in the "made with organic (specified ingredients or food group(s))" labeling category. Therefore, we request that the language in the final rule be revised to read as follows (change indicated by red font with strikethrough):

§ 66.5 Exemptions
This part shall not apply to the food and entities described in this section.
(e) Food certified ~~organic~~ under the National Organic Program.

With this technical correction, OTA strongly supports the exemption of **"Food certified under the National Organic Program"** from the disclosure requirements of the NBFDS. The correction creates consistency with both the language and the meaning of section 2(c) in Pub. L. 114-216, and it will help protect against conflicts or inconsistencies with the NOP regulations.

II. <u>USDA shall consider organic certification sufficient to make a claim regarding the absence of bioengineering in the food, such as "not genetically modified," "non-GMO," or another similar claim.</u>

While the proposed rule explicitly exempts food certified under the National Organic Program, it does not affirmatively clarify that organic certification is sufficient to make a negative claim such as "not genetically engineered" or "non-GMO."

Section 2 (c) of Pub. L. 114-216 (Organically Produced Food) states:
In the case of a food certified under the National Organic Program established under the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.), the certification shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as "not bioengineered," "non-GMO," or another similar claim.

OTA contends that Section 2 (c) of Pub. L. 114-216 will not be satisfied unless the final rule clearly articulates, "certification shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as "not bioengineered," "non-GMO," or another similar claim." **See Section III below.**

III. <u>The final rule must clearly convey that products that are not required to bear a disclosure, such as milk or other dairy or livestock products from animals fed genetically modified feed, do not by default automatically qualify for an absence label claim.</u>

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The USDA organic label certifies that a product has been made through a ***process*** in which all organic production standards (such as soil fertility requirements, pest management practices, contamination prevention measures and livestock production practices and inputs) have been followed. This means that excluded methods are prohibited at all stages of the process and extend to inputs including livestock feed that must be certified organic. More explicitly, the term "non-GMO" when applied to certified organic milk, meat and eggs means that the animals have not been fed genetically modified feed because the organic regulations require the use of certified organic (non-GMO) feed. 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.

As mentioned above, organic certification is an example of a third-party verification system that may be used to substantiate a "non-GMO" claim on food product based on the requirements of the organic regulations. Consistent with Pub. L. 114-216, products that do not require genetic engineering disclosure through this program must not by *default* automatically qualify for a "non-GMO" claim.

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 in the statute. However, the proposed rule is silent on any requirements or guidelines related to the use of absence claims despite a provision that clearly explains, "In the case of a food certified under the National Organic Program established under the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.), the certification shall be considered 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 disclosure standard should include language that conveys the full meaning of the Pub. L. 114-216, and it should provide clarification for when an "absence" claim may be used. To do otherwise may lead to the use of absence claims that are misleading and inaccurate as well as inconsistent with other AMS regulation and policy. For example, to allow an absence claim on products from animals fed genetically modified feed would be inconsistent with the USDA organic regulations and it would be inconsistent with the USDA Food Safety and Inspection Service (FSIS) policy on approving non-GMO claims on meat, poultry and egg products. As a policy matter, and in response to Pub. L. 114-216, FSIS will only approve "negative claims"[3] for meat, poultry and egg products that do not contain bioengineered ingredients or that are derived from livestock that do not consume bioengineered feed. Negative claims are approved only if a third-party certifying organization is identified and the label or labeling discloses a website where consumers can obtain additional information regarding the claim and the certification process.

[3] **Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products - https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/claims-guidance/procedures-nongenetically-engineered-statement/**

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To satisfy the requirements of Pub. L. 114-216, prevent conflict with other AMS regulation and policy and prevent confusion in the marketplace, the final rule should state that a food that is not required to bear a disclosure as a bioengineered food may not automatically be considered to be 'not bioengineered.' Consistent with the statute, the final rule should also clarify that absence claims, such as "non-GMO," may be made on USDA-NOP certified organic products. OTA suggests the following language be added to the final rule (suggested revision in red font and underlined):

§ 66.116 Voluntary disclosure

(e) *Absence claims.* 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 part.

(1) Organic certification is sufficient documentation to support an absence claim such as "not bioengineered," "non-GMO" or another similar claim.

IV. The final bioengineered disclosure rule should address Section 292(b) and Section 293 (f)(2)) of Pub. L. 114-216 to ensure consistency between organic certification and bioengineering disclosure programs and prevent any potential conflict or confusion.

The USDA organic regulations have been in place since 2002. Over the past 16 years, USDA's NOP has developed an extensive body of federal regulations relating to its prohibition on the use of genetic engineering. 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. As AMS moves forward and implements Pub. L. 114-216, it is critical that the language addressing consistency with certain laws found in section 293(f)(2), as well as the language in Section 292(b) addressing the applicability of the definition of the term 'bioengineering,' are 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.

Section 292(b) of Pub. L. 114-216 states:

APPLICATION OF DEFINITION—The definition of the term 'bioengineering' under section 291 shall not affect any other definition, program, rule, or regulation of the Federal Government.

The statute clearly states that the definition of "bioengineering" shall not affect any other definition, program, rule, or regulation of the federal government. However, this language, as well as anything to its effect, is not included in the proposed rule.

In July 2017, USDA requested feedback from the public on the following 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 other 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

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by the Federal government? (Sec. 292(b))

Both the USDA organic regulations and the National Bioengineered Food Disclosure Standard include terms and definitions related to products of genetic engineering ('Bioengineering' and 'Excluded Methods'). Therefore, there is a high degree of potential confusion. The clear and simple remedy is to include the clarifying language from the Law in the final disclosure standard under section § 66.3 (Disclosure Requirement and Applicability). We have provided a suggested revision on Page 7 of our comments.

Related is the need to ensure consistency, in general, between the National Bioengineered Food Disclosure Standard and USDA's National Organic Program.

Section 293 (f) 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."

To be clear, this section of the Law serves as the basis for preventing conflict between the requirements of the AMS National Organic Program and the AMS National Bioengineered Food Disclosure Standard. Again, however, this provision of the statute was not fully addressed in the proposed rule. Contrary to the intent of Section 293(f)(2) of Pub. L. 114-216, there is concern that this provision could lead to a revision of the organic regulations in order to bring consistency with the NBFDS. However, as clarified through USDA's 9/19/2016 Policy Memorandum on "Consistency with the AMS National Organic Program," this is not the intent and it 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.

It appears that USDA has overlooked the importance of both Section 293(f)(2) and Section 292(b) of Pub. L. 114-216, both of which protect against conflicts or inconsistencies with OFPA or NOP regulations.

To satisfy Pub. L. 114-216, OTA requests the following revisions be made to the final disclosure standard (suggested revision in red font and underlined):

Subpart C – Other Factors and Conditions for Bioengineered Food

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§ 66.3 Disclosure requirement and applicability.

(a) *General*. A label for a bioengineered food must bear a disclosure indicating that the food is a bioengineered food or contains a bioengineered food ingredient consistent with this part.

(b) *Application to food*. This part applies only to a food subject to:

(1) The labeling requirements under the Federal Food, Drug, and Cosmetic Act ("FDCA"); or

(2) The labeling requirements under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act only if:

(i) The most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA; or

(ii) The most predominant ingredient of the food is broth, stock, water, or a similar solution and the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA.

(c) *Application of Definition*. The definition of the term 'bioengineering' under this part shall not affect any other definition, program, rule, or regulation of the Federal Government.

(d) *Consistency with the National Organic Program.* The requirements under this part shall not affect the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.) and any regulations implementing that Act.

The NOP definition of 'excluded methods' and the prohibition thereof is 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 $50 billion today. To be consistent with the statute and avoid any potential confusion, disruption, conflict or economic hardship within the organic industry, as well to provide clarity to AMS and stakeholders, the final bioengineered disclosure rule should explicitly address the application of the term 'bioengineering' as described in Section 292(b), and consistency with USDA's NOP as described in Section 293 (f)(2)) of Pub. L. 114-216.

V. OTA urges USDA to allow terms the public understands such as "genetic modification (GM)" and "genetic engineering (GE)," as well as shorthand terms such as "non-GMO" or other similar phrases

USDA has proposed that all GM disclosures exclusively be made using the terms "bioengineered food" or "bioengineered food ingredients." OTA strongly disagrees and urges USDA to allow the terms "genetic engineering," "genetic modification," "GMO," "GE" and "GM" for purposes of the disclosure standard and requirement because of their contemporaneous use in state and federal policy, as well as in international standards and guidelines developed by Codex Alimentarius. The term "bioengineering" is a new term that consumers are not familiar with, especially in the context of food. It is most often related to the medical field, which *Webster's Dictionary* defines as being "biological or medical application of engineering principles (as the theory of control systems in models of the nervous system) or engineering equipment (as in the construction of artificial organs)."[4]

Contrary to the term "bioengineering," organic consumers are highly familiar with the term "genetically modified" and "genetic engineering" as well as with the acronyms "GMO," "GM" and "GE."

[4] https://www.merriam-webster.com/dictionary/bioengineering

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Over the past 17 years, USDA's NOP has developed an extensive body of federal regulations relating to GMOs. 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. Furthermore, prior to passage of Pub. L. 114-216, three states – Connecticut, Maine and Vermont – passed mandatory disclosure laws for GE foods and Alaska established a mandatory disclosure law for GE salmon.[5] Each of these laws used the term "genetic engineering" to describe the technology and the terms "genetically engineered" or "genetically modified" for purposes of the disclosure requirement. In addition to state laws, federal policy has long used the terms "genetic modification" and "genetic engineering"[6] to describe this process, as do USDA's own regulations of plants produced using biotechnology.[7]

Since 1997, the organic industry has grown from $3 billion to $50 billion. This growth has been accompanied by the acceptance of the terms "genetic engineering," "genetic modification," and "non-GMO" on organic products. Additionally, the use of 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. If the final rule were to discourage or not allow the use of such terms, this would cause extensive disruption and economic hardship within the organic industry. Ultimately, the NBFDS will only succeed in fulfilling its purpose if consumers understand what the label says.

VI. OTA urges USDA to use its authority and broadly interpret the definition of 'bioengineering' to 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[8] 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.

[5] http://www.legis.state.ak.us/basis/get_bill_text.asp?hsid=SB0025Z&session=24

[6] *See* Office of Science and Technology Policy, Executive Office of the President, *Coordinated Framework for Regulation of Biotechnology*, 51 FR 23302 (1986) https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf

[7] 7 CFR § 340.1

[8] 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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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 this bill's mandatory disclosure standard, including highly refined products derived from GMO crops and products developed using gene editing techniques."[9] 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."[10]

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[11] 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.

VII. OTA supports a threshold for inadvertent or technically unavoidable bioengineered DNA that is consistent with the level adopted by other major trading partners (no more than 0.9% of the specific ingredient).

OTA understands the value of harmonizing our standards with those of our major trading partners. To be consistent with as many countries as possible, as well as with the standards set by the scientific committee of the European Commission,[12] USDA should choose a revised version of the second proposal (Alternative 1-B (for paragraph (c)), which states that food, in which an ingredient contains a GM substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9%) of the specific ingredient by weight, would not be subject to disclosure as a result of that one ingredient.

The other two thresholds proposed by USDA – five percent by weight of the specific ingredient, or five percent of the total weight of the food in its final form – would not be suitable options. These options would be inconsistent with most of our major trading partners and may exempt wide swaths of foods from disclosure. While a small handful of countries have established a threshold above 0.9 percent,

[9] *See* 162 Cong. Rec. S4994 (daily ed. July 12, 2016).
[10] *Id.*
[11] 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.
[12] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (2003). Available online at https://ec.europa.eu/food/plant/gmo/traceability_labelling_en

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using the 0.9 percent standard would set a regulatory floor that would ensure that American companies are in compliance with all standards internationally – those set at 0.9 percent and those above it.

A 5% threshold for a genetically engineered substance is not analogous with the 5% allowance for non-organic ingredients in "certified organic (95+%") product. The organic regulations were drafted to allow for the use of minor non-organic ingredients that are ***essential*** to the function of a processed organic product yet ***non-agricultural*** and therefore UNAVAILABLE in organic form (e.g. baking soda). Non-agricultural ingredients can never be organic because the NOP regulations apply to agricultural products only. The organic regulations also carve out a short list of non-organic **agricultural** ingredients that may be used ***only*** if they are commercially unavailable in organic form. The approval to use a non-organic ingredient is made on a case-by-case basis as approved in the Organic Systems Plan by an Accredited Certifying Agency. Either way, all non-organic ingredients are maintained on a closed list (the National List at 7 CFR 205.605 or 205.606), organic (agricultural) ingredients must be used if they are available and each substance is reviewed every five years by the National Organic Standards Board (NOSB) to ensure that they are safe for human health and the environment and there are no organic alternatives available. Furthermore, any non-organic ingredient or processing aid allowed in a NOP certified product must be verified as non-GMO. OTA refutes any argument that a 5% allowance for GE material should be made because the NOP regulations allow for the use of 5% non-organic ingredients. This is a faulty argument based on an illogical comparison.

Alternative 1-B is by far the strongest option, aligning most closely with the 0.9% threshold used by the majority of our major trading partners. However, the proposed language does have some technical errors that should be corrected to ensure correct interpretation. OTA requests the following revision be made to Alternative 1-B:

> *Alternative 1-B (for paragraph (c))*
> (c) Food in which any ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9 %) ~~by weight~~ of the specific ingredient.

The first correction is to ensure that the threshold applies to ALL (one or more) ingredients in the food. The second correction will align the threshold requirement with the measurement unit used when testing for presence of GM material. PCR tests do not provide a result by weight; rather, the result indicates the percent of GM contamination by units of DNA. It is not possible to reliably calculate GM contamination by weight, and thus the reference to weight should be struck from the rule.

Finally, while the proposed rule requires entities subject to the rule to maintain records to demonstrate compliance, there is no detail in the proposal about the verification methods that may be used or what constitutes valid content in a testing record.

OTA REQUEST: To ensure meaningful testing (and therefore a meaningful rule), USDA will need to release guidance on acceptable testing methodology and reporting.

VIII. The GMO symbol must clearly, and in a neutral fashion, communicate that a product is genetically engineered or contains ingredients derived from genetic engineering.

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USDA has presented three symbol options that contain the abbreviation "BE" and a range of smiley faces to a bucolic representation of blue skies, bright sun and green land. Unlike the perception neutral USDA Organic seal, the proposed "BE" evokes sunshine and/or smiles, offers visual appeal and conveys a feeling of happiness and safety.

These symbols are highly misleading and could convey to consumers that GM foods are safer than non-GM foods, which is expressly prohibited by the statute.

Pub. L. 114-216 specifically states:

> "For the purpose of regulations promulgated and food disclosures made pursuant to paragraph (2), a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering."

Symbol disclosures must be unbiased and non-promotional. The proposed symbols, however, are the exact opposite. In fact, two of the three symbols incorporate smiling faces and one appears to be a winking face – far from the neutral approach that Congress intended.

OTA urges USDA to release a new set of symbol options for public feedback that are consistent with the non-bias stylistic tone of other AMS logos, such as USDA's Organic Seal, and utilize acronyms that consumers are familiar with such as "GE" or "GMO."

IX. OTA strongly objects to the notion that QR codes are an adequate disclosure of GE labeling.

OTA strongly views on-pack text disclosure as the most direct and transparent route to communicate with the consumer about the GM content of a product. While we prefer and strongly encourage food companies to disclose the presence of GM content 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.

CONCLUSION

OTA strongly supports mandatory labeling of all genetically modified foods. We urge USDA to finalize a food disclosure standard that will satisfy consumers' right to know if a food is genetically modified, and safeguard the meaning and requirements of the USDA organic regulations. To accomplish both and deliver a meaningful final rule, some key changes to the proposal are necessary. In summary, OTA's requested changes are as follows (changes indicated in red font):

- Consistent with Law (Pub. L. 114-216), revise Section **§ 66.5(e) (Exemptions)** to clarify that all certified food under NOP is exempt. The exemption should read as follows "Food certified ~~organic~~ under the National Organic Program"

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- Adopt Alternative 1-B (for paragraph (c)) under **§ 66.5 (Exemptions)** and revise the language to read:
  - *Alternative 1-B (for paragraph (c))*
    (c) Food in which any ingredient contains a bioengineered substance that is inadvertent or technically unavoidable, and accounts for no more than nine-tenths percent (0.9 %) ~~by weight~~ of the specific ingredient.

- Consistent with Law (Pub. L. 114-216), revise Section **§ 66.116 (Voluntary disclosure)** to include a section on absence claims:
  - **§ 66.116 Voluntary disclosure**

    (e) *Absence claims.* 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 part.

    (1) Organic certification is sufficient documentation to support an absence claim such as "not bioengineered," "non-GMO" or another similar claim.

- Consistent with Law (Pub. L. 114-216), revise **Section 66.3 (Disclosure requirement and applicability)** to address the application of the definition of the term 'bioengineering' and consistency with the National Organic Program:
  - **Subpart C – Other Factors and Conditions for Bioengineered Food**

    § 66.3 Disclosure requirement and applicability.

    (a)….

    (b)…

    (c) *Application of Definition*. The definition of the term 'bioengineering' under this part shall not affect any other definition, program, rule, or regulation of the Federal Government.

    (d) *Consistency with the National Organic Program.* The requirements under this part shall not affect the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.) and any regulations implementing that Act.

- **OTA also urges USDA to:**
  - Use its authority and broadly interpret the definition of "bioengineering" to include highly refined products such as oils or sugars derived from bioengineered crops;
  - Allow the use of common terms and shorthand that industry and consumers understand, such as "genetic engineering," "genetically modified," "not GE," and "non-GMO." The final rule must allow for disclosure using "genetic engineering" and associated shorthand.
  - Create a disclosure symbol that is consistent with the non-bias stylistic tone of other AMS logos and includes an acronym that consumers are familiar with such as "GE" or "GMO."

On behalf of our members across the supply chain and the country, OTA thanks USDA in advance for carefully considering our comments and accepting our requested changes.

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Respectfully submitted,

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