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August 25, 2017

Mr. Bruce Summers
Acting Administrator
Agricultural Marketing Service
United States Department of Agriculture
1400 Independence Avenue, SW
Room 3069 South Building
Washington, DC 20250

Submitted via GMOLabeling@ams.usda.gov

Re: Stakeholder Input on Questions Regarding the Establishment of a National Bioengineered Food Disclosure Standard.

Dear Mr. Summers:

On behalf of the U.S. Canola Association (USCA), I write to submit comments on USDA-APHIS's request for stakeholder input on questions regarding the establishment of a national bioengineered food disclosure standard. The USCA is a non-profit commodity organization whose mission is to increase domestic canola production to meet a growing demand for healthy oil. Since USCA's establishment in 1989, the Association has facilitated the growth of domestic canola acreage from zero to over 2 million acres in 2017.

USCA supports the consumer's desire to know what is in their food. Canola producers are proud of the sustainable methods and technology U.S. producers use to deliver a safe and affordable product to the consumer. The improvements in farming practices in recent years coupled with biotechnology is enabling us to grow more food in a sustainable environmentally sound manner through reduced inputs like water, fertilizer, and pesticides. Today, approximately 90 percent of the canola planted in the U.S. uses this technology allowing us to continue towards our quest of feeding 9.7 billion people by 2050, while putting less strain on our natural resources.

The USCA is focused on ensuring that any mandated disclosures not disparage biotechnology, impose undue regulatory burdens, or create market discrimination when there are no material differences between conventional foods and foods derived from biotechnology. USCA and other commodity and food supply organizations worked through the Coalition for Safe, Affordable Food

to engage with Congress during the drafting of the National Bioengineered Food Disclosure Standard and strongly support it because it strikes the correct balance between transparency, accuracy, and fairness by defining bioengineering with respect to a food as one that “contains genetic material” and directs the Secretary to “determine the amounts of a bioengineered substance that may be present in a food” for the food to be considered a “bioengineered food.”

Although the law is unambiguous that a bioengineered food must contain genetic material, there are others that, for different reasons, believe that if a food is derived from bioengineering it should be subject to the disclosure standard even if it can be shown that there is no genetic material in the food. AMS’s question regarding “highly refined products” has further heightened the debate. The USCA is proud to be a participant in the Coalition for Safe, Affordable Food and align ourselves with 26 of the 30 questions we have answered collectively as a coalition. The USCA would like to provide further recommendations on the critically important issues raised in Questions 1, 4, 8, and 12:

- The USCA urges AMS not to consider any other terms interchangeable with “bioengineering” because alternative terms will lead to confusion and misinterpretation of the scope of the Disclosure Standard. (Question 1)
- Consistent with the plain language of the law, the USCA urges AMS to, as Congress intended, determine that refined foods that can substantiate the absence of genetic material in the food below the established threshold, are not subject to the disclosure standard.¹ This does not preclude, as the legislative history discusses, the voluntary disclosure of information beyond that required by regulation. (Question 4)
- USCA urges AMS to establish a 5% threshold for triggering the Disclosure Standard. A 5% threshold is supportive of bioengineering, has the least impact on the domestic and international value chain, is the most compatible with our North American trading partners, Mexico and Canada, and, importantly is consistent with the National Organic Standard which allows organic product to retain the organic label with up to 5% non-organic content. (Question 8)
- Where those manufacturers subject to the Disclosure Standard opt to use text to disclose that a food is bioengineered, USCA urges AMS to limit the statement to “Contains Bioengineered Ingredients” or “May Contain Bioengineered Ingredients” if, and only if, the food meets the definition of a bioengineered food – one that contains genetic material above the threshold established by the Secretary. (Question 12)

¹ Report of the Committee on Agriculture, Nutrition, and Forestry on S. 2609, December 9, 2016 at 3, (hereinafter “Legislative History”) (“Congress intends the Secretary to provide exemptions and other determinations under which a food is not considered bioengineered.”).

Finally, USCA urges AMS to be mindful of Congress’s intent that the Secretary “minimize the impacts on all aspects of the domestic ... value chain,”² as well as President Trump’s Executive Orders stating, “It is the policy of the United States to alleviate unnecessary regulatory burdens placed on the American people.”³ As shown in our comments, arbitrarily subjecting refined products that do not contain genetic material to the disclosure standard creates significant burdens on the food supply chain that will result in less competition and higher consumer prices. It will further harm U.S. producers whose livelihoods depend upon the cultivation of bioengineered crops used in the production of refined products. This is directly contrary to “the national interest to ensure that regulatory burdens do not unnecessarily encumber agricultural production, harm rural communities, constrain economic growth, hamper job creation, or increase the cost of food for Americans and our customers around the world.”⁴

The USCA believes that these recommendations will help the Secretary of Agriculture follow the directives expressed by the Congress and President Trump.

Thank you for this opportunity to comment and for your review and consideration of these comments.

Respectfully yours,

A handwritten signature in blue ink, appearing to read "Rob Rynning", is placed over a light gray rectangular background.

Rob Rynning
President, U.S. Canola Association

The U.S. Canola Association’s comments on Questions 1, 4, 8, 12.

²Report of the Committee on Agriculture, Nutrition, and Forestry on S. 2609, December 9, 2016 at 4, (hereinafter “Legislative History”)(“Congress intends the Secretary to provide exemptions and other determinations under which a food is not considered bioengineered.”).

³ See Executive Order 13777 “Enforcing the Regulatory Reform Agenda”

<https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda>

⁴ See Executive Order 13790, “Promoting Agriculture and Rural Prosperity in America”

<https://www.federalregister.gov/documents/2017/04/28/2017-08818/promoting-agriculture-and-rural-prosperity-in-america>;

QUESTION 1

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

***Context:** The disclosure standard would be a mechanism to inform consumers about their food. AMS is considering the advantages and disadvantages of allowing the use of other terms to provide for disclosure.*

No terms other than “bioengineering” should be considered interchangeable with “bioengineering” for the purposes of the Act. Use of a single term for purposes of the mandatory disclosure standard would be simplest for consumers.

The Legislative History of the Act makes clear that the purpose of the legislation is to “establish a mandatory uniform national disclosure standard for human food that is or may be bioengineered.” We therefore discourage use of any other words or terms within the context of this AMS mandatory marketing program.

Use of a single term for purposes of mandatory disclosure does not preclude the use of a different term in additional voluntary statements about foods. Additional descriptive terms used in voluntary statements, therefore, should not be considered interchangeable with the term “bioengineering” under section 291. For example, to the extent that AMS permits the term “genetically engineered” or “genetic engineering” to be used in additional voluntary statements that are truthful and not misleading, the agency should clarify that these terms are not considered interchangeable with “bioengineering” under section 291 and that the ability to use this term in the voluntary disclosure text has no impact on the meaning of “genetic engineering” as that term is used in section 295 of the Law.”

QUESTION 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))

Context: Many processed foods may contain ingredients derived from bioengineered crops, such as highly refined oils or sugars that contain undetectable levels of bioengineered genetic material such that they are indistinguishable from their non-engineered counterparts. AMS is considering whether to require disclosure for foods containing those derived ingredients that may be undetectable as bioengineered.

USDA is incorrectly using the term “highly refined products” to refer to food products such as sugar and oils. Rather, the more appropriate term is simply “refined ingredients.” The terms “highly processed” or “highly refined” ingredients typically refer to multi-ingredient mixtures processed to the extent that they are no longer recognizable as their original plant/animal source, e.g., candy, tomato sauce, ice cream, etc. In contrast, when a single isolated food component, such as sugar or oil, is obtained by extraction or purification using physical or chemical processes, it is typically referred to as “refined.”⁵ For these reasons, we urge USDA to use the term “refined ingredients” when referring to single food components such as sugar and oils.

Requiring disclosure for foods containing undetectable levels of genetic material would contravene Congressional intent and would exceed AMS’s authority

The National Bioengineered Disclosure Standard, Pub. L. 114-216, (the “Disclosure Standard” or Act”) is ***unambiguous***; Congress required disclosure only for foods that ***contain bioengineered genetic materials***. Congress thoughtfully, deliberately and intentionally did not extend the scope of the Act to include ingredients derived from bioengineered plants that after the refining process do not contain bioengineered genetic materials. Congress further directed the Secretary to “determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for that food to be a bioengineered food.” § 293(b)(2)(B). Thus, any food that does not contain the level of genetic material the Secretary determines to be appropriate for being considered a bioengineered food, cannot be considered a bioengineered food. The Act’s legislative history reinforces the plain language of the statute:

“The Secretary of Agriculture is directed to establish a mandatory uniform national disclosure standard for human food that is or may be bioengineered. For this purpose, *the definition of bioengineering is set in statute and establishes the scope of the disclosure standard*. Congress intends an item of food to be subject

⁵ See e.g., Poti, J.M., et al., Is the degree of food processing and convenience linked with the quality of food purchased by US households?, 101 *Am. J. Clin. Nutr.* 1251-1262 (June 2015). See also, Monteiro, CA, et al., A new classification of foods based on the extent and purpose of their processing, 11 *Cad Saude Publica*, 2039049 (Nov. 2010) (describing three categories of processed foods: (1) minimally processed foods (physical processes applied to single basic foods such as cleaning, chilling, etc.); (2) processed foods (extraction of one specific component of a single basic food, such as oils and fats, sugar, high fructose corn syrup, and milk and soy proteins); and (3) ultra-processed foods (processing of several foodstuffs, including ingredients from group 2 and unprocessed or minimally processed basic foods from group 1).

to the definition if it contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and this same modification could not be otherwise obtained through conventional plant breeding or found in nature.”⁶

Refined food products that do not contain genetic material *do not* meet the statutory definition of a bioengineered food.

We have heard the argument that Congress defined “bioengineering” in § 291(1) of the Act and gave the Secretary discretion in § 293(a) to define a bioengineered food, which is based largely on floor statements made by Members during debate and with a memo from USDA’s General Counsel, which has been incorrectly described as a legal opinion. We believe that those advancing this argument are reading Member statements and the memo out of context. Nevertheless, Member statements and an agency memo cannot supplant the plain language of the Act. As the Supreme Court has repeatedly made clear the “plain language” of a statute is the “primary guide” to Congress’ preferred policy.” *Sandoz, Inc. v. Amgen, Inc.*, 137 S. Ct. 1664, 1678 (2017) (quoting *McFarland v. Scott*, 512 U.S. 849, 865 (1994)). Here, the plain language makes clear that “bioengineering . . . with respect to a food, refers to a food . . . that contains genetic material.” § 291(1). It further directs the Secretary to set the threshold above which a food is considered a bioengineered food. § 293(a)(2)(B). There is no provision in the Act where Congress gave the Secretary the discretion to rewrite the definition of a bioengineered food from a food that itself contains genetic material to any food derived from bioengineering, a definition Congress expressly rejected. We urge AMS to reject all attempts to broaden the definition of a bioengineered food.

AMS should not assume that refined products produced from bioengineered crops that do not contain detectable levels of genetic material nevertheless contain genetic material

We are further concerned that the way in which Question 4 is framed, AMS appears to assume that even if a refined food product does not contain “detectable” amounts of bioengineered genetic material, it may nevertheless contain bioengineered genetic material and therefore should be subject to the Disclosure Standard. To take this approach would render superfluous Congress’s direction that the Secretary “determine the *amounts* of a bioengineered substance” that may be present in food to be considered a bioengineered food because AMS is not specifying a threshold. Rather, AMS would be incorrectly assuming that any food derived from bioengineering must contain bioengineered genetic material even if the material cannot be detected through validated scientific methods.

In addition, such an approach would be inconsistent with international precedence. Japan, China, Australia, New Zealand, Thailand, Indonesia, Malaysia, and S. Korea have strict labeling regimes, but do not require the labeling of several products refined from bioengineered crops because they do not contain transgenic DNA or protein. Indeed, Japan’s labeling laws do not apply to corn oil, corn starch, dextrin, starch syrup, hydrolyzed protein derived from

⁶ Legislative History at 3.

bioengineered corn; soy sauce, soybean sprout, margarine, hydrolyzed protein derived from bioengineered soy; canola oil derived from bioengineered canola; or sugar derived from bioengineered sugarbeets because they “do not contain traces of DNA.”⁷ Similarly, refined foods such as sugars and oils produced from bioengineered crops are not included in Australia or New Zealand’s mandatory GMO labeling laws because of the absence of DNA and protein in the refined product and “because the composition and characteristics of these foods are exactly the same as the non-GM food.”⁸

Indonesia’s food registration procedures require labeling for food containing genetically modified potatoes, soybeans, corn, and their derivative products. However, product derivatives which have undergone further refining processes to the point where the genetic material cannot be identified (to include but not limited to oils, fats, sucrose, and starch) do not require any GMO statements.⁹ In Malaysia refined foods, defined as those where processing has removed all novel DNA and protein, are not included in the labeling requirements (refined oil, sugar, corn syrup, honey and dextrin).¹⁰ Finally, South Korea recently expanded their labeling law but still does not include several refined products.¹¹

Requiring disclosure for refined foods that do not contain genetic material is false and misleading, not supported by the evidence before the Agency, and will only lead to consumer confusion

Requiring all refined products produced from bioengineered crops to be labeled as a “bioengineered” food would be false and misleading. *Importantly, it represents to consumers that the refined products produced from bioengineered crops are somehow different, less safe,*

⁷ See Gain Report, Japan
https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Tokyo_Japan_7-13-2015.pdf;

⁸ Genetically modified (GM) food labeling, Food Standards-Australia and New Zealand,
<http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx>

⁹ See USDA GAIN Report No. 1526, Indonesian National Biosafety Commission for Genetically Engineered Products, available at
https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Jakarta_Indonesia_7-14-2015.pdf.

¹⁰ See USDA GAIN Report No. MY6005, Malaysia Biosafety Law, the National Biosafety Board, available at
https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_KualaLumpur_Malaysia_9-2-2016.pdf.

¹¹ See USDA GAIN Report No. KS1716, Korea’s New Biotech Labeling Requirements, available at
https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Update%20to%20Korea's%20New%20Biotech%20Labeling%20Requirements_Seoul_Korea%20-%20Republic%20of_6-23-2017.pdf.

*and less desirable than refined products produced from non-bioengineered crops even though “the composition and characteristics of these foods is exactly the same as the non-GM food.”*¹²

AMS should not pursue this approach because: (1) if it runs counter to the scientific evidence, (2) it contravenes Congress’s intent that “USDA’s implementing regulations treat the safety of a bioengineered food the same as its non-bioengineered counterpart,” and (3) *misbrands* the food within the meaning of the Food, Drug and Cosmetic Act, when the Act prohibits the disclosure standard from affecting any other federal definition, program, rule, or regulation.¹³ *See Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (an agency’s decision is arbitrary or capricious if it runs counter to the evidence before the agency, relies on factors which Congress did not intend, and/or is not otherwise the product of reasoned decision making.). AMS must remember the Disclosure Standard is a marketing standard, not a health, safety, or nutrition standard, which the general public is unlikely to understand. Therefore, AMS must be extremely cautious to avoid any mandated disclosures that imply differences between foods when none exist.

Requiring refined products produced from bioengineered crops to be labeled as a bioengineered food when they do not contain genetic material imposes unnecessary regulatory burdens resulting in less competition and higher consumer prices and harms the American farmer.

The legislative history of the Act makes clear that “the Secretary, when determining the amounts of a bioengineered substance that may be present in food, or the threshold requirement, shall *minimize the impacts on all aspects of the domestic and international value chain.*”¹⁴ Moreover, the Act “is not intended to increase the costs of food manufacturing or changes in distribution or handling.” Congress’s intent that the Disclosure Standard not disrupt domestic and international supply chains is reinforced by E.O. 13777, which established a federal policy to alleviate unnecessary regulatory burdens. The Department of Agriculture recently requested public comment on how its Task Force, required by E.O. 13777, can reduce the regulatory burdens of existing regulations, particularly regulations that are unnecessary, impose costs that exceed benefits, or eliminate jobs. 82 Fed. Reg. 32649 (July 17, 2017). The same principles apply to new regulations.

Requiring refined food products produced from bioengineered crops to be labeled as bioengineered foods when they do not contain genetic material exacerbates the impacts on the domestic and international value chain. First, it discriminates against refined products derived from biotechnology by implying to consumers that they are different or less desirable than their

¹² Genetically modified (GM) food labeling, Food Standards-Australia and New Zealand, <http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx>

¹³ Under the Food, Drug and Cosmetic Act a food is misbranded if “its labeling is false or misleading in any particular.” 21 U.S.C. § 343(a). *See also* Legislative History at 6 (“Congress does not intend the legislation to impact the authorities or obligations under the Federal Food, Drug, and Cosmetic Act, . . .”).

¹⁴ Legislative History at 3.

conventional counterparts, when they may in fact be identical. This leads to price differentiation, with premiums imposed for the “more desirable” conventional products and aggressive marketing to gain market share. Second, any time identical products are differentiated in the market it causes food manufacturers and retailers to restrict their supply chain thereby reducing competition and driving up costs which are eventually passed onto consumers. This was clearly evidenced in 2015-2016 as food manufacturers began to constrict their supply chains in order to comply with the Vermont law. Third, for retailers that source refined products from multiple suppliers, often interchangeably, requiring refined products derived from biotechnology to be disclosed would require different labels for identical products leading to increased costs and further disruption in the supply chain.

Finally, disruption in the supply chain and disparagement of the technology harms the American farmer because demand for genetically engineered crops will decline, even though they improve crop yields and are more environmentally sustainable than conventional crops.¹⁵ Indeed, when the Vermont law was enacted many farmers faced uncertainty regarding the future viability of their bioengineered crops. AMS should be mindful that in enacting the Disclosure Standard Congress made “every effort . . . to ensure that farmers access to seed technology and not limit the options available to agricultural production” and directed USDA “to take every effort to minimize the impacts on growers.”¹⁶ Impacting the American farmer is also directly contrary to E.O. 13790, which established an interagency Task Force to “identify legislative, regulatory, and policy changes to promote in rural America agriculture, economic development, job growth, infrastructure improvements, technological innovation, energy security, and quality of life.”¹⁷ This includes advancing “the adoption of innovations and technology for agricultural production and long-term, sustainable rural development.” Biotechnology is at the forefront of agricultural innovation enabling farmers to produce more food on fewer acres using less energy and fewer pesticide applications. Any mandate that refined foods that do not contain genetic material be subject to the Disclosure Standard undermines the advancement of technology for agricultural production in direct contravention of E.O. 13790.

As the world leader in bioengineered crop production, the United States should send a strong message to all nations that bioengineered seeds have significant economic and environmental benefits; the U.S. should not create a Disclosure Standard that discriminates against the

¹⁵ See also “Crop biotechnology has contributed to significantly reducing the release of greenhouse gas emissions from agricultural practices. This results from less fuel use and additional soil carbon storage from reduced tillage with GM crops. In 2012, this was equivalent to removing 27 billion kg of carbon dioxide from the atmosphere or equal to removing 11.9 million cars from the road for one year.” GM crops: global socio-economic and environmental impacts 1996-2012. PG Economics Ltd, UK, <http://www.pgeconomics.co.uk/page/36/-gm-crop-use-continues-to-benefit-the-environment-and-farmers>.

¹⁶ Legislative History at 7.

¹⁷ See Executive Order 13790, “Promoting Agriculture and Rural Prosperity in America” <https://www.federalregister.gov/documents/2017/04/28/2017-08818/promoting-agriculture-and-rural-prosperity-in-america>;

technology. Requiring disclosure of refined food products not containing genetic material would only perpetuate the misinformation activists have used for decades to distort the truth about biotechnology and instill fear in the general public when the global scientific community has repeatedly attested to its safety.¹⁸ Indeed, in making clear that the Disclosure Standard is a marketing standard, not a health, safety, or nutritional standard, Congress expressly recognized that “the comprehensive federal regulatory review process has determined that foods produced using bioengineering are safe and not materially different in any way from those made using other methods.”¹⁹

There is no legal or scientific basis for AMS to treat refined food products differently than fermentation products that are derived from bioengineering

As members of the Coalition for Safe and Affordable Food, we strongly endorse the Coalition’s response to Question 11 identifying categories of foods that AMS should exempt from the Disclosure Standard. Each recommended exemption category can be legally and scientifically justified. In addition, USCA recommends that fermentation products, e.g., enzymes, processing aids, should not be subject to the Disclosure Standard solely because they are produced using a bioengineered microorganism. This recommendation is legally justified because a food product produced with enzymes or processing aids would not meet the definition of a bioengineered food under the Act (one that contains genetic material above the established threshold) and is scientifically substantiated using validated scientific methods.

The same legal and scientific justification applies to many refined products. Refined food products that can substantiate the absence of genetic material in the food below the established threshold should similarly not be subject to the Disclosure Standard. There is no rational basis under the Act to exempt one category of foods because of the absence of genetic material but require disclosure for another category of food when those foods also do not contain genetic material.²⁰

To be clear, we are not recommending that AMS categorically exempt refined food products from the Disclosure Standard. Rather, we are urging AMS not to categorically mandate that refined food products are subject to the Disclosure Standard. This will allow those refined food products that can substantiate the absence of genetic material below the established threshold to be treated fairly under the Act.

¹⁸See e.g., National Academy of Sciences, The Royal Society of Medicine, WHO, OECD, the American Medical Association, Food and Agriculture Organization of the United States, American Diabetes Association, and the Society of Toxicology.

¹⁹ Legislative History at 4.

²⁰ To justify the disparate treatment of fermentation products and refined products some may argue that fermentation products such as microbes and processing aids are not themselves food but refined products such as sugar and oils are food. That distinction is legally and scientifically unsupportable.

QUESTION 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)).

Context: *The Law authorizes the Secretary to determine the amount of a bioengineered substance present in food for the food to be disclosed as a bioengineered food. The amounts of a bioengineered substance that may be present in food for the food to be a bioengineered food might be determined in a variety of ways: if a bioengineered substance is near the top of the list of ingredients, by determining the percentage of bioengineered ingredients in a food product, or by listing any ingredient that was produced through bioengineering, among others. AMS is considering how to determine the amount of bioengineered food or ingredient needed for a product to require a bioengineered disclosure, as well as the advantages and disadvantages of various methods.*

In determining the amount of a bioengineered substance (referred to in the Act as “genetic material”), AMS identifies as one option “listing any ingredient that was produced through bioengineering.” This option would be wholly inconsistent with the Act because the Congress did **NOT** intend and the Act does **NOT** apply to food or ingredients produced *through* bioengineering. Rather, the Act only applies to a “bioengineered food” which “contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.” Congress clearly recognized that there would be foods that are produced through bioengineering that would not be subject to the disclosure standard. Basing the trigger for disclosure on whether an ingredient was produced *through* bioengineering impermissibly rewrites the statutory definition of a bioengineered food and contravenes Congress’s intent.

Other methods AMS may use to set the disclosure threshold are critically important and have direct implications as to how the technology is viewed by consumers and global trading partners. Thus, given its impact on the current and future use of the technology, we are compelled to offer our views. ***We strongly urge AMS to set a 5% threshold because it supports biotechnology, appropriately balances disclosure, market dynamics, and international trade, and is consistent with other U.S. regulatory programs, including the USDA Organic Program that allows up to 5% of non-organically produced agricultural ingredients.*** To support our recommendation and put it into a global context, we have conducted extensive research on bioengineering disclosure methods worldwide. (See Attachment 1 (“Bioengineered Disclosure Thresholds”). We provide the following observations.

It should be clearly understood that there is no international standard for bioengineered thresholds. Nor is there any scientific basis for the threshold percentages because biotechnology

does not raise health, safety or nutrition concerns.²¹ Accordingly, thresholds are simply a tool to create a differentiation in the market place to provide a marketing advantage to non-bioengineered products. Thresholds are arbitrarily established mainly to drive consumers away from the technology and create non-tariff trade barriers to imported biotech commodities to protect domestic producers who do not have access to the technology.²² As a world leader, and a leader in biotechnology, the U.S. must set its threshold standard on multiple justifications and not acquiesce to standards set by other countries that attempt to oppose or stigmatize the technology. It is also important to keep in mind that “Congress intend[ed] for the standard to be technology neutral.”²³ Other countries are closely watching what the U.S. will do in these regulations and it will likely influence their internal discussions regarding acceptance and disclosure.

International thresholds for disclosure of bioengineered foods can be categorized into three groups:

Approach 1 is to treat bioengineered ingredients as no different than other ingredients and not have any mandatory labeling requirements. There are 116 countries (including neighboring trading partners, Canada and Mexico), representing 59% of the countries in the world and 24% of the world population, following this approach. This approach indicates support, trust, acceptance and fostering of bioengineering and bioengineered crop ingredients. This results in lower ingredient costs, greater savings to consumers, provides multiple environmental benefits, does not impact the domestic and international

²¹ See e.g., USDA Foreign Agricultural Service, European Union 28, Agricultural Biotechnology Annual, December 6, 2016 at 20, 37 (noting that “the EC continues to pursue inconsistent and unpredictable approaches regulating the technology. Due to the strong emotional and ideological stance taken by EU consumers and nongovernmental organizations (NGOs) on biotechnology, born in many ways out of the misleading information provided by anti-biotechnology groups, legislation adopted by the EC as well as the process surrounding the approval for cultivation and use of GE crop varieties has suffered,” and further noting that “different types of civil society organizations have militated against agricultural biotechnology since it was first introduced in the 1990s. They are generally opposed to economic growth and globalization. They see more risks than opportunities in technical progress and campaign for a broad application of the precautionary principle. Some of them defend an ideal science that would focus solely on understanding phenomena, and not on developing useful and profitable applications; others reject or strongly criticize science and progress, in line with philosophers such as Hans Jonas and Bruno Latour. They are skeptical of new technologies, in general, and for biotechnology specifically they feel it is dangerous, of little public benefit, and developed by companies that seek private profit at the expense of the common good. As part of their political strategy, their actions include lobbying public authorities, acts of sabotage . . . and communication campaigns to heighten public fears.”), available at https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf;

²² “In September 2014, the government released remarks by President Xi Jinping affirming official support for biotechnology research, but calling for a cautious approach to commercialization. He also said that foreign companies should not be allowed to “dominate the agricultural biotechnology product market.” Page 2, USDA Foreign Agricultural Service, China, Agricultural Biotechnology Annual, December 16, 2016, https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Beijing_China%20-%20Peoples%20Republic%20of_12-16-2016.pdf

²³ Legislative History at 4.

value chain, and is technology neutral. This should be the global standard. However, after two decades of activists maligning the technology and costly state-by-state labeling referendums, Congress responded by enacting the Disclosure Standard. Therefore, this approach is no longer available to the U.S.

Approach 2 is to treat bioengineered ingredients as a non-disparaged low-level presence ingredient. Some countries that follow this approach have a 5% threshold, including Japan, South Africa, Indonesia, Vietnam, and Thailand (collectively representing 8% of the world population). Canada has a voluntary 5% threshold.

Approach 3 is to treat bioengineered ingredients as contaminants. Countries (EU, China, Russia, etc.) following Approach 3 have thresholds that range from 4% to 0.0% and outright bans. For example, Nigeria has a 4% threshold;²⁴ Malaysia and Taiwan (not recognized as a country) have a 3% threshold; Brazil, Australia, New Zealand, Saudi Arabia have a 1% threshold; 41 countries have a 0.9% threshold;²⁵ 21 countries representing 43% of the world population have a 0.0% threshold;²⁶ and Kenya, Morocco, Benin, Sri Lanka, and Serbia have outright bans.²⁷ It is important to note that there is clear evidence that a low threshold in one country has a direct and dramatic negative impact on the acceptance of biotechnology by other countries. The EU's 0.9% threshold that has existed for some time has shunned the use of biotechnology within the EU and also with its trading partners who supply the EU with raw agricultural products and finished food products.

We urge AMS to adopt a 5% threshold (Approach 2) and demonstrate its leadership on biotechnology

Of the thresholds that have been established world-wide, a 5% threshold is the most supportive of bioengineering and recognizes that the Act establishes a marketing standard, not a food safety standard. It is the lowest cost, lowest liability approach that results in consumer savings. It also

²⁴ Nigeria enacted the Biosafety Act in 2015 that requires mandatory labeling of all products of agricultural biotechnology. Work in progress regulations have a 4% threshold.

²⁵ These include the 28 EU Member States, Russia, Ecuador, Iceland, Norway, Switzerland, Turkey, Ukraine, Botswana, Bosnia and Herzegovina, Belarus, Kazakhstan, Armenia, Kyrgyzstan).

²⁶ These include China, Peru, Columbia, Bahrain, Kuwait, Oman, Qatar, United Arab Emirates, South Korea, Ethiopia, Cameroon, India, Mozambique, El Salvador, Bolivia, Tunisia, Mauritius, Burkina Faso, Senegal, Mali, and Bangladesh.

²⁷ "Morocco's heavy reliance on the EU market as the principal destination for its agricultural exports has instilled a reluctance among policy makers and producers to accept biotechnology products." Morocco, Agricultural Biotechnology Annual, 2016, USDA Foreign Agricultural Service, Global Agricultural Information Network (GAIN Report Number MO1610), https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Rabat_Morocco_11-7-2016.pdf.

has the least impact on the domestic and international value chain and is less of a burden on our developing foreign suppliers. It is the most compatible with our North American trading partners, Mexico and Canada. Finally, it is the closest to technology neutral of the mandatory categories.

Importantly, a 5% threshold is consistent with other U.S. regulatory programs. The USDA Organic Program allows up to 5% of non-organically produced agricultural ingredients which are not commercially available in organic form.²⁸ “The use of genetic engineering, or genetically modified organisms (GMOs), is prohibited in organic products.”²⁹ However, “[t]here aren’t specific tolerance levels in the USDA organic regulations for GMOs. As such, National Organic Program policy states that trace amounts of GMOs don’t automatically mean the farm is in violation of the USDA organic regulations. In these cases, the certifying agent will investigate how the inadvertent presence occurred and recommend how it can be better prevented in the future.”³⁰ If an organic consumer product can retain the organic label with up to 5% non-organic content, the Disclosure Standard should be set at 5% as well. Indeed, federal courts have held that consumers hold products labeled organic to a higher standard than even products labeled natural. *See e.g., Pelayo v. Nestle USA Inc.*, 989 F. Supp. 2d 973, 979 (C.D. Cal. 2015). Having the same 5% threshold reduces consumer confusion and avoids any implication that biotechnology is less safe or less desirable and therefore must be treated more stringently than organic products. Congress clearly established the Act as a marketing tool, not a food safety standard. A 5% threshold is consistent with that intent. In addition, the grain trade has coalesced around a 5% low-level presence threshold, although there isn’t an international standard.

Establishing a threshold below 5% (Approach 3), as many groups will urge, denigrates biotechnology

We implore USDA to keep Congress’s intent in mind that “[n]othing in the [disclosure] requirement can be used to denigrate biotechnology.”³¹ Approach 3, is not supportive of bioengineering or bioengineered foods, crops or biotechnology. For over 20 years the U.S. has battled foreign countries that reject U.S. exports because of their overly restrictive biotechnology standards, based principally on fear (the precautionary principle), not science.³² This has

²⁸ USDA Labeling Organic Products, <https://www.ams.usda.gov/sites/default/files/media/Labeling%20Organic%20Products.pdf>.

²⁹ <https://www.ams.usda.gov/publications/content/can-gmos-be-used-organic-products>

³⁰ <https://www.ams.usda.gov/publications/content/can-gmos-be-used-organic-products>

³¹ Legislative History at 2.

³² See also “In the EU, different types of civil society organizations have militated against agricultural biotechnology since it was first introduced in the 1990s. They are generally opposed to economic growth and globalization. They see more risks than opportunities in technical progress and campaign for a broad application of the precautionary principle. Some of them defend an ideal science that would focus solely on understanding phenomena, and not on developing useful and profitable applications; others reject or strongly criticize science and progress, in line with philosophers such as Hans Jonas and Bruno Latour. They are skeptical of new technologies, in

resulted in higher food costs to foreign consumers and less sustainable food production. In many instances, these restrictive thresholds are used as a non-tariff trade barrier to imports to protect their domestic producers.

Adopting a threshold of less than 5% would complicate our trade with our major and neighboring trading partners, Canada and Mexico, neither of which require any disclosure. As the legislative history directs, "...the Secretary, when determining the amounts of a bioengineered substance that may be present in food, or the threshold requirement, **shall minimize the impacts on all aspects of the domestic and international value chain.**"³³ Any threshold of less than 5% maximizes impacts to all aspects of the domestic and international value chain.

Moreover, the Non-GMO Project, whose stated mission is to "to change the way our food is grown and made," has a 0.9% per ingredient threshold above which a product cannot bear its Non-GMO Project verified label.³⁴ That is not Congress's intent. Congress made clear that the Disclosure Standard cannot "denigrate biotechnology," which is precisely the Non-GMO Project's undeniable objective in order to drive bioengineered foods out of the market. To adopt the same threshold used by the Non-GMO Project is unsupportable and unacceptable to the American farmer that embraces advancements in agriculture like biotechnology.

In sum, USDA will determine whether the United States will continue to treat the presence of bioengineered substance in food as a "non-disparaged low-level presence ingredient" or a "contaminant." It is our belief that the 5% threshold is the only threshold that (1) allows the United States to remain a world leader in the production of bioengineered crops, (2) minimizes impacts on the value chain, (3) minimizes the regulatory burden on farmers, and (4) is consistent with other U.S. marketing standards. When a food product contains over 5% of ingredients that are bioengineered, this should be disclosed to consumers to inform their purchasing decisions. Any lower threshold would treat bioengineered ingredients as a contaminant and not be technology neutral and would "denigrate biotechnology" in contradiction of Congress.³⁵

general, and for biotechnology specifically they feel it is dangerous, of little public benefit, and developed by companies that seek private profit at the expense of the common good. As part of their political strategy, their actions include lobbying public authorities, acts of sabotage (destruction of research trials and cultivated fields), and communication campaigns to heighten public fears." Page 37, USDA Foreign Agricultural Service, European Union 28, Agricultural Biotechnology Annual, December 6, 2016. https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf.

³³ *Id.*

³⁴ Non-GMO Project, <https://www.nongmoproject.org/about/mission/>.

³⁵ Legislative History at 2.

QUESTION 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))

Context: Currently, some food manufacturers use language compliant with the Consumer Protection Rule 121 from the State of Vermont to identify their food products as bioengineered (“Produced with Genetic Engineering,” “Partially Produced with Genetic Engineering,” or “May be Produced with Genetic Engineering”). AMS is considering whether to allow manufacturers to continue using these disclosures under the new national bioengineered disclosure standard and if their language is appropriate. Further, AMS is considering what phrases could be used as a text disclosure for bioengineered food that consumers would find informative, truthful, and not misleading. AMS is also considering whether there should be one standard text disclosure language, or whether manufacturers should be allowed flexibility to choose from more than one acceptable phrase and where the bioengineered food disclosure should be placed on food packages.

We offer the following recommendations:

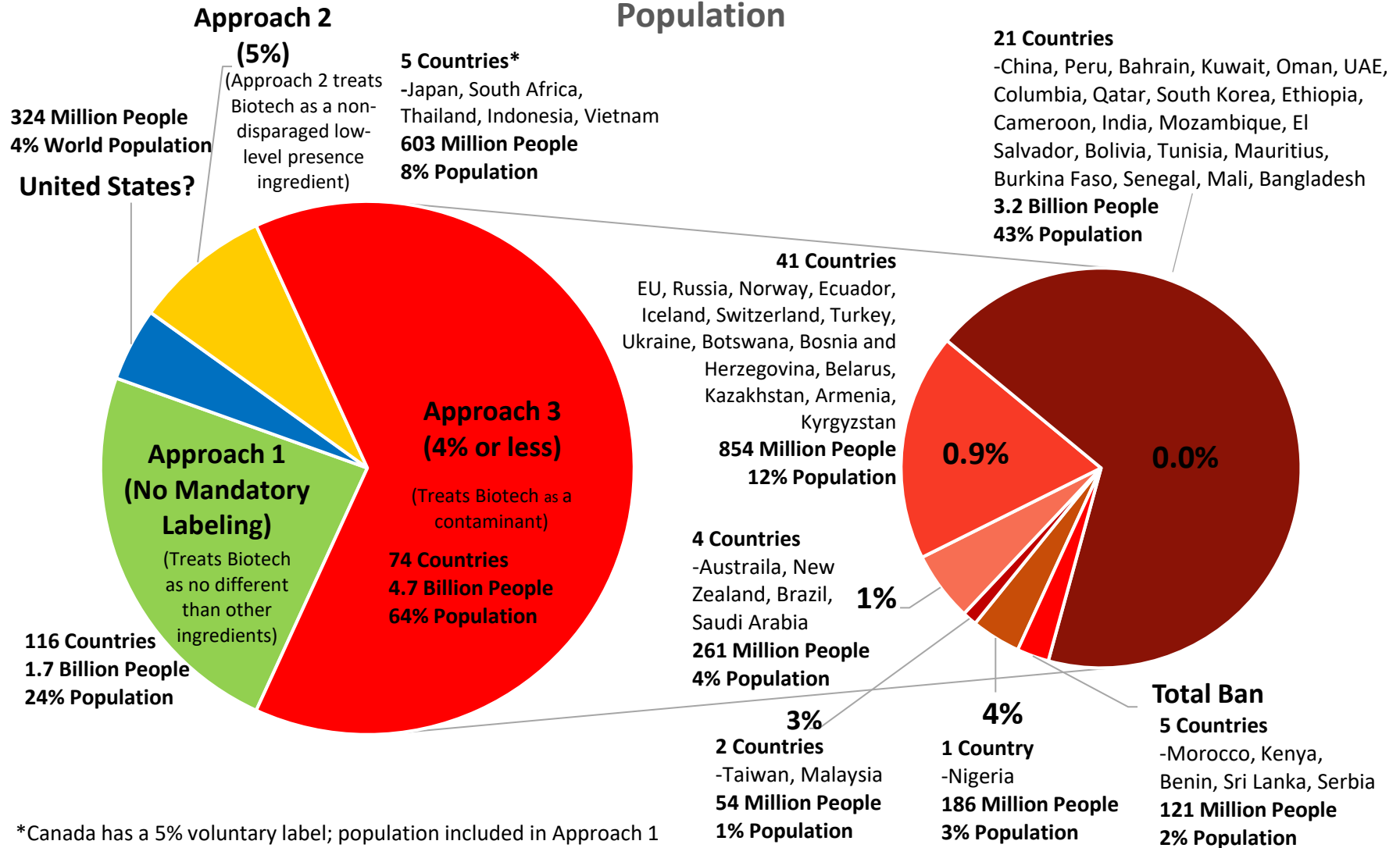
- 1) AMS should not allow manufacturers to continue using the disclosures established under the Vermont law that contradicts the Disclosure Standard enacted by Congress most importantly because the Vermont law disclosures conflict with the plain language and intent of the Act. The Vermont disclosures have highly restrictive thresholds and include food ingredients that are derived from but do not contain genetic material. While such disclosures may have been consistent with Vermont’s unfounded health, safety, and nutritional concerns, Congress expressly rejected Vermont’s approach and instead defined bioengineering with respect to a food as one that contains genetic material. Thus, adhering to Vermont’s prescribed disclosure language (“Produced with Genetic Engineering,” “Partially Produced with Genetic Engineering,” or “May be Produced with Genetic Engineering”) cannot be reconciled with the Act. Further, adhering to this language would be misleading because it would imply differences in certain food products when none exist. For the many reasons stated in response to question 4, any language that includes “produced from,” “derived from” or “sourced from” is unacceptable when the ingredient provided to the consumer is no different than an ingredient derived from a conventional or organically grown crop.
- 2) We also urge AMS not to allow the use of “May be Produced with Genetic Engineering”. First, the “may be” language is ambiguous and therefore creates a perception that the food manufacture is uncertain about a product’s ingredients. Second, “produced with” implies that the food is “derived from” or “sourced from” a bioengineered crop, contrary to the intent of the Act. Third, the term “genetic engineering” is broader than and therefore inconsistent with the Act’s definition of bioengineering. Similarly, “Partially

Produced with Bioengineering” is incorrect because it implies that the food is “derived from” or “sourced from” a bioengineered crop.

- 3) The terminology that we urge AMS to use is “*contains* bioengineered ingredients” or “*May contain* bioengineered ingredients.” These statements are informative, truthful, and not misleading. They also adhere to the Act’s definition of bioengineering and would not require manufacturers to change labels when they change sources between bioengineered and non-bioengineered ingredients.
- 4) We urge AMS to adopt one standard text disclosure language to fulfill the Act’s purpose to establish uniformity in disclosure. As AMS is well aware, there are many terms used to describe whether a food is or is not bioengineered, most of which are not accurate nor well understood by the general public. We believe uniformity is best accomplished and consumer understanding advanced by limiting on package text to “contains bioengineered ingredients” or “may contain bioengineered ingredients.”
- 5) Just as important as the text, is the font size and location on the package. For consumers who want to know what is in their food, the information is located on the Nutrition Facts Panel, the ingredient list and the allergy warnings, all under FDA’s authority. Any information about bioengineered ingredients or non-bioengineered ingredients should be located as close to the ingredient list as possible, but not in a font size larger or more prominent than the allergy warnings which is alerting consumers that the food contains an allergen that can be harmful or fatal to sensitive individuals. Non-GMO labeling efforts attempt to imply to consumers that a product is safer, healthier or more nutritious than other products derived from biotechnology, which is false and misleading. Therefore, all text information or symbol regarding bioengineered food should be located in close proximity to the ingredient list and allergy warning in a font size that does not exceed that information. The legislative history also provides guidance in this area, stating: “Congress intends USDA to establish any text or the symbol that could appear on packaging to solely satisfy the disclosure requirement and not be used as a tool to denigrate biotechnology.”³⁶ Giving the on-package disclosure more prominence than allergy warnings would potentially denigrate biotechnology.

³⁶ Legislative History at 3.

Bioengineered Disclosure Thresholds by Approval, Countries, & World Population



Sugar and other refined products do not require labeling in several countries that have mandatory labeling (Japan, Thailand, Indonesia, Malaysia, Australia, New Zealand, China, and South Korea)