United States Beet Sugar Industry

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:

This submission is made on behalf of the United States Beet Sugar Industry representing all of the 10,000 progressive family farmers of sugarbeets in 11 states, who own all nine farmer cooperatives (22 factories), the cooperatives employees, seed producers and the scientists that are engaged in the production and processing of sugarbeets. We produce 56% of the sugar grown in the U.S. We raise sugarbeets on 1.2 million acres, provide 100,000 jobs and generate $10.6 billion for the U.S. economy. We proudly provide the highest quality of sugar for both the safety of our food supply and the food security of our nation. The sugarbeet is one of the best suited plants for use in biotechnology and we have produced 100% bioengineered plants since 2015.

We appreciate the opportunity to share our views and perspectives in response to the USDA Agricultural Marketing Service's ("AMS") request to address outstanding issues or clarifications AMS is considering in preparing a proposed rule to implement the National Bioengineered Food Disclosure Standard, Pub. L. 114-216, (the "Act" or "Disclosure Standard"). Because the Disclosure Standard was not enacted to address the safety, health, or nutrition of bioengineered crops or ingredients, the beet sugar industry's principal concern is that AMS not in any way cause the market to discriminate against biotechnology. For over 25 years activists, and to some extent farmers using competing production methods, have attacked and maligned biotechnology directly or indirectly in order to grow market share and drive biotechnology out of the food production system. For these reasons, we focus our comments largely on the scope of the Disclosure Standard and its focus on foods containing or not containing bioengineered genetic material. As explained in detail below, sugar produced from sugarbeets bioengineered to be resistant to the herbicide glyphosate is molecularly identical to sugar produced from conventional sugarbeets and from conventional and organic sugarcane. AMS therefore should not alter the definition of a bioengineered food under the Act or establish a threshold that would negatively differentiate beet sugar from all other sugar when there is no legal or scientific basis

to do so. Rather, AMS should, as Congress intended, determine that refined food products that can substantiate the absence of genetic material in the food, are not considered bioengineered under the Act.[1]

The American farmer is an innovator and is committed to growing healthy food for an expanding hungry world in a safe and sustainable manner. America is a global leader in biotechnology and the world will look to AMS as it fashions the regulations to ensure that the technology has a strong foundation for the future, while it informs consumers of its safety and presence in the food supply. It is a time to lead on the science and not acquiesce to unfounded fears.

We appreciate your thoughtful consideration of our submission and stand ready, along with counsel, to answer further questions or supplement additional details should you request them.

Respectively submitted,

American Sugarbeet Growers Association

U.S. Beet Sugar Association

Big Horn Basin Beet Growers Association

Big Horn County Sugar Beet Growers Association

California Beet Growers Association, Ltd.

Colorado Sugarbeet Growers Association

Elwyhee Beet Growers Association

Idaho Sugar Beet Growers Association

Michigan Sugar Company

Minn-Dak Farmers Cooperative

Montana-Dakota Beet Growers Association

Nebco Beet Growers Association

Nebraska Sugar Beet Growers Association

Nyssa-Nampa Sugarbeet Growers Association

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[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.").

Red River Valley Sugarbeet Growers Association

Southern Minnesota Sugar Cooperative

Southern Montana Sugarbeet Growers Association

Wyoming Sugar Company, LLC

Beet Sugar Development Foundation

American Society of Sugar Beet Technologists

Sugar Industry Biotech Council

The U.S. Beet Sugar Industry provides comments on Questions 1, 4, 8, 9, 10, 12, 23, and 30.

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.*

AMS should not use terms other than "bioengineering" because alternative terms will lead to confusion and misinterpretation of the scope of the disclosure standard, which would be directly contrary to Congress's intent to bring clarity and uniformity to the marketplace. Congress gave the term "bioengineering" a precise meaning from which the regulations should not deviate.

We recognize that food manufacturers whose products are not subject to the Disclosure Standard may nevertheless voluntarily disclose information about ingredients in the food. In the interest of uniformity, we urge AMS to provide guidance to manufacturers on appropriate terminology to use and make clear that any voluntary terminology used is not interchangeable with the statutory and regulatory definition of "bioengineering." For example, the terms "genetic engineering" or "Genetically Modified Organism" or "GMO" are inconsistent with Act. Congress intentionally used the term "genetic engineering," rather than "bioengineering" in the preemption provision (Section 295) to broadly preempt state, tribal, and local requirements regarding genetically engineered foods "regardless of whether the technology used to develop the food or seed falls within the definition of bioengineering."[2] Thus, Congress clearly viewed genetic engineering and bioengineering as different – not interchangeable – terms. The terms "Genetically Modified Organism" or "GMO" incorrectly imply that the food contains an "organism," when most foods do not contain organisms. The term "modification" also encompasses a broader range of technologies than in vitro recombinant deoxyribonucleic (DNA) techniques to which the Disclosure Standard is limited. In addition, terms non-genetically modified organisms or Non-GMO have been and are currently being used on food packaging to suggest to consumers that Non-GMO foods are healthier or safer than bioengineered foods, directly contradicting science and FDA's determination that approved bioengineered foods carry no more risk than conventional or organic food. Here, Congress was clear that the Disclosure Standard must not disparage biotechnology and thus the terms "Genetically Modified Organism" or "GMO" should never be confused with the term "bioengineering."

[2] Legislative History at 6.

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 ingredients" to refer to food products such as sugar. Rather, the more appropriate term is simply "refined ingredients." Highly processed or 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, is obtained by extraction or purification using physical or chemical processes, it is typically referred to as "refined."[3] For these reasons, we urge USDA to use the term "refined ingredients" when referring to single food components such as sugar.

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

The Disclosure Standard is ***unambiguous;*** Congress required disclosure only for foods that ***contain bioengineered genetic material*s**. Congress thoughtfully, deliberately and intentionally did not extend the scope of the Act to include crops derived from bioengineered plants. 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 to the definition if it contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and this same

[3] *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).

> modification could not be otherwise obtained through conventional plant breeding or found in nature."[4]

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

Some groups may argue that Congress defined "bioengineering" in § 291(1) of the Act and gave the Secretary discretion in § 293(a) to define a bioengineered food. They say this reading of the Act is consistent with floor statements made by Members during debate and with a memo from USDA's General Counsel, which some incorrectly describe as a legal opinion. We believe that these groups are reading Member statements and the memo out of context. Nevertheless, they 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 a refined food product that does not contain "detectable" amounts of bioengineered genetic material may nevertheless contain bioengineered genetic material and therefore is subject to the Disclosure Standard

Assuming that a refined food product that does not contain "detectable" amounts of genetic material may nevertheless contain genetic material and therefore should be subject to the Disclosure Standard is not scientifically supportable, inconsistent with the Act, at odds with international precedents, and is false and misleading. Also, in the case of sugarbeets, it contravenes scientific evidence that glyphosate tolerance can be achieved through conventional breeding techniques.

1. ***Assuming that a refined food product like beet sugar that does not contain "detectable" amounts of genetic material may nevertheless contain genetic material and therefore should be subject to the Disclosure standard is not scientifically supportable***

Sugar is the case in point: At the molecular level all refined sugar is the same regardless of the plant's genetic makeup (beet or cane) or the production method (Bioengineered, Conventional or Organic) in which the crop was produced. All the genetic material is removed during processing.

[4] Legislative History at 3.

a. Peer-reviewed scientific studies establish that all genetic material is removed during sugar processing[5]

In 1998, seven years before glyphosate resistant sugarbeets were deregulated in the U.S. and 10 years before their major cultivation in the U.S., German scientists with the Institute of Industrial Genetics at the University of Stuttgart published a study on the fate of DNA and protein during the standard purification steps of the sugar extraction process from both conventional sugarbeets and sugarbeets genetically engineered with the coat protein CP21 to confer resistance to a certain virus.[6] Sugarbeet plant DNA was present in the raw juice from conventional sugarbeets, but was rapidly degraded and removed in the clarification process. In fact, the researchers estimated that the clarification process had the potential to reduce the amount of sugarbeet DNA by a factor of ten to the fourteen (a hundred trillion), which exceeds the total amount of DNA present in sugarbeets. The coat protein CP21 was similarly found in the raw juice from the transgenic sugarbeets, but it too was removed in the clarification process. It was not found in the pulp, thin juice, thick juice, or sugar produced from the transgenic sugarbeets. The researchers therefore concluded that sugar produced from conventional and transgenic sugarbeets is indistinguishable.

Japanese researchers conducted a similar study that also found that sugarbeet plant DNA is degraded and removed in the early stages of the sugar extraction process and is therefore not present in the finished sugar.[7]

b. Industry studies further confirm that beet sugar contains no genetic material

Initially, as part of the deregulation protocol in the USDA/EPA/FDA Coordinated Framework for Regulation of Biotechnology, sugar from transgenic sugarbeets extracted in a laboratory was submitted to the FDA by the technology provider, showing that no transgenic protein or DNA was present.[8] Data submitted in support

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[5] Sugar is extracted from the root of the beet in a multistep process. Sugarbeets are first washed and sliced into thin strips and then placed into a diffuser tank where raw beet sugar juice is extracted with hot water. The raw juice is then "clarified" using excess calcium hydroxide and lime water called milk of lime and carbonation, where carbon dioxide is bubbled through the mixture to form calcium carbonate. Non-sugar particles including genetic material attach themselves to the calcium carbonate and settle to the bottom of the clarifying tanks. The juice is then filtered, resulting in a golden light brown clarified thin juice. At this point, there is no genetic material in the sugar. The thin juice is then boiled and concentrated through the removal of water to form a thicker juice and eventually sugar crystals. The resulting mix of sugar crystals and molasses-rich syrup is then sent to centrifuges for separation. The molasses syrup is spun off and the white sugar crystals are removed.

[6] Klein, J., Altenbuchner, J., and Mattes, R., Nucleic acid and protein elimination during the sugar manufacturing process of conventional and transgenic sugarbeets. *J. of Biotechnology*, 60: 145-153 (1998). *See* Attachment 1.

[7] Oguchi, T., et al., Investigation of residual DNAs in Sugar from Sugar beet (*Beta vulgaruis L.*), *J. Food Hyg. Soc. Japan*, 50: 41-46 (2009), *available at* https://www.jstage.jst.go.jp/article/shokueishi/50/1/50_1_41/_pdf.

[8] *See* FDA Biotechnology Notification of Food No. 90.

of the consultation also demonstrated that the concentrations of the CP4-EPSPS protein in the roots of the sugarbeet are very low (mean of 161 μg/g).[9] The very low level of the CP4-EPSPS protein in the roots, as well as the transgenic DNA in the sugarbeet tissue, are removed in the sugar extraction process.

Prior to commercial planting and sale of refined sugar into the commercial market, owners of the beet sugar farmer-owned cooperatives sought to reassure food manufacturers and individual customers that beet sugar produced from bioengineered sugarbeets was no different than conventional beet, cane, or organic refined sugar. Thus, in 2006 the Beet Sugar Development Foundation coordinated two studies to confirm the absence of transgenic DNA and the CP4-EPSPS protein in sugar produced from transgenic sugarbeets.

In the first study an independent, internationally respected analytics firm collected samples from each stage of the refining process (three samples each at the start, middle, and end of raw sugarbeet slicing to the finished sugar) at one processing facility. Using methods validated by the European Commission Joint Research Center,[10] the study demonstrated that while transgenic DNA and the CP4-EPSPS protein was detected in the raw sugarbeet and the raw juice, it was not detected at any other subsequent point in the refining process. Thus, consistent with the German study, the study confirmed that the transgenic DNA and CP4-EPSPS protein are removed early in the process at the clarification stage during the transformation from raw juice to thin juice.

In the second study, multiple samples of sugar produced from transgenic and conventional sugarbeets and sugarcane from around the world were analyzed for the presence of plant (plastid) DNA. More specifically, the study sampled organic sugar from Europe, South America and the U.S.; turbinado/muscovado sugar from Africa, Mauritius, and the U.S.; white beet sugar from Canada, Europe, and the U.S. (including sugar produced from transgenic sugarbeets); and white cane sugar from Africa, Australia, Canada, the Caribbean, Europe, Japan, and the U.S.[11] No plant DNA was detected in any of the samples, thus again confirming the German findings that the clarification process effectively removes *all* plant DNA (by a factor of 10^{14}).

In 2014, the Beet Sugar Development Foundation conducted a third study of all U.S. beet sugar factories. Sixty-nine samples of refined sugar were collected from all North American beet sugar factories (three random samples from each of the 22 U.S. factories and the one and only Canadian factory) by the same independent analytic

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[9] Only the roots of the sugarbeet are used in the production of sugar.

[10] Mazzara M., Foti N., Savini C., Van Den Eede G.; "***Event-Specific Method for the Quantitation of Sugarbeet Line H7-1 Using Real-Time PCR - Validation Report and Protocol,***" Online Publication (2006); http://gmo-crl.jrc.ec.europa.eu/gmomethods/entry?db=gmometh&id=qt-eve-bv-001&rq=id%3aQT-eve-BV*.

[11] Forty-four samples of sugar were analyzed, as well as four samples of laboratory pure (analytical grade) sucrose.

firm to test for any presence of transgenic DNA and the CP4-EPSPS protein. A polymerase chain reaction (PCR) test specific for the detection of trace amounts of DNA from the transgenic sugarbeet was used. **All 69 samples of commercial sugar tested negative for transgenic sugarbeet DNA**. All samples were further analyzed for the presence of the particular novel protein, CP4-EPSPS, which confers Roundup® tolerance to the H7-1 Roundup Ready® sugarbeet plant. A commercially available protein test kit for CP4-EPSPS (Romer, Union, MO #7000014) was used for this analysis**. None of the sixty-nine samples showed any detectable CP4-EPSPS protein.** This comprehensive study reaffirmed the 2006 study and the scientific literature that shows that there is no transgenic DNA or protein in the sugar extracted from transgenic sugarbeets.[12]

In sum, the science demonstrates that the sugar extraction process removes all plant DNA regardless of whether the plant is conventional, organic, or transgenic. It would be erroneous for AMS to assume otherwise.

2. Assuming that a refined food product that does not contain "detectable" amounts of genetic material may nevertheless contain genetic material and therefore should be subject to the Disclosure Standard is inconsistent with the Act

Assuming 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 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 the case of refined sugar, the science unequivocally demonstrates that the sugar refining process reduces the amount of sugarbeet DNA by a factor of ten to the fourteen (a hundred trillion), which exceeds the total amount of DNA present in sugarbeets. Thus, refined sugar does not contain any plant DNA or proteins, transgenic or otherwise. Should AMS assume that beet sugar contains genetic material for purpose of the Disclosure Standard it would be rewriting the statutory definition of a bioengineered food and arbitrarily mandating disclosure.

[12] Since highly specific, state-of-the-art tests do not detect any transgenic DNA or protein, both the sugar and molasses extracted from glyphosate tolerant sugarbeets are approved in all major foreign markets (Canada, Mexico, EU, Russia, Japan, China, South Korea, Singapore, Philippines, Australia, New Zealand and Colombia). The plant tissue, or pulp, from glyphosate resistant sugarbeets is highly desirable for use as cattle feed sold in the U.S. and is readily accepted in Europe and Japan.

3. Assuming that refined sugar produced from bioengineered sugarbeets contains genetic material is not consistent with international precedents

Japan, China, Australia, New Zealand, Thailand, Indonesia, Malaysia, and S. Korea have strict labeling regimes, but because sugar extracted from a bioengineered sugarbeet does not contain transgenic DNA or protein, there is no requirement to label it. Indeed, as noted above, the Japanese government conducted a study that found that plant DNA is not present in the final sugar product and therefore does not include sugar produced from bioengineered sugarbeets in Japan's mandatory GMO labeling requirements.[13] Similarly, sugar produced from bioengineered sugarbeets is not included in Australia/New Zealand's mandatory GMO labeling laws because of the absence of DNA and protein in the sugar.[14] China excludes from its labeling requirements "various" highly refined products, including sugar produced from bioengineered sugarbeets.[15]

In Thailand, the Ministry of Public Health lists 22 food products which are subject to labeling requirements when the contents exceed the five percent tolerance threshold. Sugar is not included on the list.[16] 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 GE material cannot be identified (to include but not limited to oils, fats, sucrose, and starch) do not require any non-GMO statements.[17] In Malaysia refined foods, defined as those

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[13] In Japan, processed foods that contain detectable amounts of transgenic DNA or proteins must be labeled to indicate that genetically modified ingredients are used. Japan does not require sugar from GE sugarbeets s to be labeled because it does not contain transgenic DNA or proteins. USDA FAS "Japan, Agricultural Biotechnology Annual, Japan's regulatory system for GE crops continues to improve", https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Tokyo_Japan_7-13-2015.pdf;

[14] Under Australia New Zealand Food Standards Code - Standard 1.5.2 - Food Produced Using Gene Technology, genetically modified food or ingredients must be labeled if novel DNA and/or protein are present in the final food and also where the food has altered characteristics. In its assessment of transgenic sugarbeets, the government found that there was "no novel protein . . . present in the refined sugars, derived from sugarbeet line H7-1" and that "[i]t is unlikely that novel DNA would be present either." Thus, sugar produced from transgenic sugarbeets is not subject to the mandatory labeling requirements. *See* Food Standards Australia New Zealand Final Assessment Report Application A525 Food Derived from Herbicide-Tolerant Sugarbeet H7-1 (25 May 2005) pages 5-6 *available at* http://www.fao.org/fileadmin/user_upload/gmfp/docs/A525%20GM%20Sugar%20beet%20FAR.pdf.

[15] *See* USDA FAS, "China-Agricultural Biotechnology Annual, China Moves Towards Commercialization of Its Own Biotechnology Crops, https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Beijing_China%20-%20Peoples%20Republic%20of_12-16-2016.pdf .

[16] *See* USDA GAIN Report No. TH6136, Thailand Biosafety Act, available at https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Bangkok_Thailand_11-16-2016.pdf.

[17] *See* USDA GAIN Report No. 1526, Indonesian National Biosafety Commission for Genetically Engineered Products, available at

where processing has removed all novel DNA and protein, are not included in the labeling requirements (refined oil, sugar, corn syrup, honey and dextrin).[18] Finally, South Korea recently expanded their labeling law but does not include refined products such as cooking oil, sugar, soy sauce, etc.[19] No supporting documentation is required for the listed products.

4. Requiring disclosure for beet sugar when it does 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 beet sugar to be disclosed as a "bioengineered" food would be false and misleading because as shown above, it does not meet the definition of a bioengineered food under the Act regardless of what threshold AMS may establish. ***Importantly, mandating that beet sugar is subject to the Disclosure Standard would represent to consumers that the beet sugar is somehow different, less safe, and less desirable than conventional beet sugar or organic or conventional cane sugar when it is molecularly identical.*** *See e.g., Center for Food Safety v. Vilsack*, 636 F.3d 1166, 1170 (9th Cir. 2012) *(*"The sugar produced from Roundup Ready sugarbeets is identical to sugar processed from conventional sugarbeets, and has been approved for food safety in the United States and the European Union."). As discussed above, analysis of transgenic and conventional sugarbeets and sugarcane from around the world found no plant DNA in any samples, confirming that the sugar clarification process effectively removes *all* plant DNA (by a factor of 10^{14}).

AMS should not pursue this approach because as shown above, it runs counter to the scientific evidence and contravenes Congress's intent that "USDA's implementing regulations treat the safety of a bioengineered food the same as its non-bioengineered counterpart."[20] *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.).

In addition, labeling beet sugar as a bioengineered food, when it does not meet the statutory definition of a bioengineered food, *misbrands* beet sugar within the meaning of the Food, Drug and Cosmetic Act. However, Congress prohibited the Disclosure Standard from affecting any

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https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Jakarta_Indonesia_7-14-2015.pdf.

[18] *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_Kuala%20Lumpur_Malaysia_9-2-2016.pdf.

[19] *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.

[20] Legislative History at 4.

other federal definition, program, rule, or regulation.[21] AMS must remember the Disclosure Standard is a marketing standard, which requires disclosure when the bioengineered genetic content of a food exceeds an established threshold, and is specifically 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.

5. Requiring beet sugar to be labeled as a bioengineered food also contravenes the Act's limitation that a bioengineered food is one for which the modification could not otherwise be achieved through conventional breeding and is found in nature

AMS should not arbitrarily mandate that beet sugar is subject to the Disclosure Standard because it can be shown that the event used to confer glyphosate resistance in the sugarbeet (H7-1 conferring glyphosate tolerance; Roundup Ready™), *can also be obtained through conventional breeding methods* and is *found throughout nature*. Glyphosate tolerant sugarbeets were developed using bioengineering not based on the fact that it was the only breeding method able to create glyphosate tolerance, but rather based on the speed and accuracy with which the trait could be introduced.

All plants and microbes naturally contain a gene encoding for 5-enolpyruvylshikimate 3-phosphate synthase (a.k.a. EPSP synthase), a shikimate pathway enzyme producing aromatic amino acids in the plant essential to life. The native, or endogenous, form of this gene creates an enzyme that glyphosate binds to which inhibits functionality, killing the plant.[22] Commercially available glyphosate tolerant crops were created using bioengineering to introduce a slightly modified version of the native gene derived from *Agrobacterium tumefaciens* strain CP4.[23] The only difference between the native and transgenic version of the gene is a slight mutation which changes the 100th amino acid in the protein sequence from a Glycine to an Alanine that no longer allows glyphosate to bind to or inhibit the enzymatic pathway, conferring plant survival.[24]

Since only a mutation to the existing gene is necessary, the conventional breeding method known as mutagenesis could also have been used to create this trait in the sugarbeet. In fact, physical and chemical mutagenesis has been used to create the trait in corn.[25] It should be noted, initial attempts at mutagenesis were difficult, lengthy and often unstable. However, by 2006, Konzak

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[21]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, . . .").

[22] *See* Funke , T., *et al*., Molecular basis for the herbicide resistance of Roundup Ready crops, 103 *PNAS* 35 (August 29, 2006), 13010-13015.

[23] *See* Padgette, S.R., *et al*., Development, identification, and characterization of a glyphosate-tolerant soybean line, 35 *Crop Sci*. 5 (1995), 1451-1461.

[24] *See* Funke , T., *et al*., *supra* n. 22.

[25] *See* ZHAO, J., *et al.* Selection of Glyphosate-resistant Maize Mutants by Mutagenesis, 4 Journal of Henan Agricultural Sciences (2011).

and Rice filed a patent (US20070136837 A1) outlining mutagenesis protocols that produce glyphosate tolerant plants without the use of bioengineering. They demonstrated the effectiveness of the approach by creating glyphosate tolerant wheat through mutagenesis technology. Glyphosate tolerance can also be created by selection for increased expression of the EPSP synthase using conventional breeding techniques as demonstrated for carrot, alfalfa, tobacco and soybean.[26] Both of these modes of action would be equally as efficacious in sugarbeet and therefore the trait used in bioengineered sugarbeets could have been created through conventional breeding methods, although mutagenesis would take longer than bioengineering.

In addition, AMS must consider that glyphosate tolerance is found in nature. It was originally thought that glyphosate resistance would be unlikely to naturally evolve in plant populations. However reports began emerging in the late 1990s that resistance was the result of a gene mutation within EPSP synthase, a similar mode of action as glyphosate tolerant sugarbeet made through bioengineering. As more tolerance in native populations was observed, there was further confirmation that EPSP synthase was naturally mutated, reducing binding efficiency of glyphosate as well as translocation of the herbicide, both conferring resistance.[27] These and the overexpression of EPSP synthase have all now been described in nature, as well as created through conventional breeding. In fact, some plants were confirmed to be naturally resistant to glyphosate even without selective pressure.[28] Today, this natural evolution of glyphosate tolerance, especially in the presence of selective pressure from the herbicide is widely recognized throughout the published literature. Fortunately for the farmers relying on this technology at the commercial scale, effective management strategies to control resistance development in their weed species exist. Sugarbeet farmers were aware of the weed resistance issues before glyphosate tolerant sugarbeets were deregulated in 2005 and proactively took steps to use different herbicides in the fields before and after their sugarbeet crop to avoid herbicide resistance.

6. ***Requiring beet sugar to be labeled as a bioengineered food when it does 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*."[29] Moreover, the Act "is not intended to increase the costs of food manufacturing or changes in distribution or

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[26] *See e.g.,* Yu-Yau, Jo., *et al.,* Glyphosate selected amplification of the 5-enolpyruvylshikimate-3-phosphate synthase gene in cultured carrot cells, 232 *Molecular and General Genetics MGG 3* (April 1992) 377-382.

[27] *See* Powles, S. and Preston, C., Evolved Glyphosate Resistance in Plants: Biochemical and Genetic Basis of Resistance, 20 *Weed Tech.* 2 (2006) 282-289.

[28] *See* Chiou-IngYuan, *et al*., Triple mechanisms of glyphosate-resistance in a naturally occurring glyphosate-resistant plant *Dicliptera chine,* 163 *Plant Sci.* 3 (2002) 543-54.

[29]Legislative History at 3.

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 beet sugar to be labeled as bioengineered foods when it does not contain genetic material exacerbates the impacts on the domestic and international value chain:

a. It discriminates against beet sugar by implying to consumers that it is different or less desirable than conventional beet sugar and organic and conventional cane sugar when it is molecularly identical to these other refined sugars. This leads to price differentiation, with premiums imposed for the "more desirable" products and aggressive marketing to gain market share. Already the Non-GMO Project label on some cane sugar brands and cane sugar-containing products is being used to suggest to consumers that cane sugar and products containing it are more desirable than beet sugar.

b. 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 through higher prices. This was clearly evidenced in 2015-2016 as food manufacturers began to constrict their supply chains in order to comply with the Vermont law.

c. Large nationwide retailers will source sugar from multiple suppliers of beet and cane that are then packaged into the retailer's house-branded packages. If disclosure requirements are different for beet and cane, then house brands would need different labels and present implied differences to consumers where none exist, resulting in higher consumer prices.

d. Through a process known in the industry as "swapping", beet and cane sugar is often sold by a particular sugar refiner but delivered to customers from competitors who are geographically closer to the competitor's customers market. This efficient system that reduces transportation costs and congestion on rails and roads, and lowers costs to consumers, would be lost.

Finally, disruption in the supply chain and disparagement of the technology harms the American sugarbeet farmer because demand for genetically engineered sugarbeets will decline, even though they improve crop yields and are more environmentally sustainable than conventional crops.[30] Indeed, when the Vermont law was enacted many farmers faced uncertainty regarding

[30] *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.

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."[31] 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."[32] 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 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, instilling fear in the general public when the global scientific community has repeatedly attested to its safety.[33] 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."[34]

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[31] Legislative History at 7.

[32] 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;

[33] *See 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.

[34] Legislative History at 4.

7. Mandating disclosure would threaten other foreign beet and cane producers that may adopt bioengineered technology in the future to improve environmental impact and sustainability.[35]

The U.S. is the third largest sugar importer in the world. The U.S. provides access to 41 countries to supply approximately 30% of our sugar market. Any effort to differentiate between beet and cane sugar would cause foreign beet and cane producers to avoid technology that would be better for the environment and increase their efficiency and productivity. This undermines global sustainability objectives.

The United States already imports sugar derived from BE sugarbeets (Alberta) and actual BE sugarbeets from Ontario, Canada for processing in Michigan. Brazil's government recently approved the world's first commercial bioengineered sugarcane modified to express Bt (Bacillus thuringiensis), which confers resistance to an insect referred to as the cane borer. Brazil is by far the largest sugarcane producer and exporter in the world and is the third largest supplier of raw sugar to the U.S. Current expectations are that sugar derived from the new variety will reach commercial export markets in 2020. As the world leader in sugarcane production, other cane producing countries look to Brazil for technical advances. For example, Australia and Indonesia are currently developing BE sugarcane varieties with drought resistance, herbicide tolerance, plant development, increased sugar content, and yield.[36] These advances will provide many environmental benefits and increase long term sustainability. Misguided labeling schemes for refined ingredients, such as sugar, should not inhibit such advances.

If sugar derived from a BE plant were required to be labeled it would also be problematic for our trade with Canada. Brazil is the largest raw sugar supplier to Canada. (7-year Olympic average is 78% of all raw imports). Canadian companies manufacture sugar-containing products for export to the United States. If the sugar derived from bioengineered crops were required to be disclosed then raw sugar imported from Brazil would have to be segregated from other raw sugars derived from non-bioengineered cane in the Canadian refineries. Also, Canada annually exports around 550,000 short tons of sugar in sugar-containing products to the United States duty free. If sugar derived from bioengineered crops would be required to be labeled, this would place unnecessary burdens on our trading partners and discourage the adoption of bioengineered crops that are more productive and environmentally sustainable.

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[35] *See* U.S. Beet Sugar Industry Submission to the National Academy of Sciences, September 9, 2015, http://www.sugarindustrybiotechcouncil.org/wp-content/uploads/2015/11/U-S-Beet-Sugar-Industry-Submission-to-NAS3.pdf. *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.

[36] https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Canberra_Australia_8-7-2015.pdf USDA Gain Report on Australia; https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Jakarta_Indonesia_7-14-2015.pdf USDA Gain Report on Indonesia

8. There is no legal or scientific basis for AMS to treat beet sugar differently than fermentation products that are derived from bioengineering

According to the Legislative History, "Congress intends the Secretary to provide exemptions and other determinations under which a food product is not considered bioengineered. Congress recognizes that states that had passed labeling mandates provided exemptions for a range of food products including … those that may include enzymes, additives, and processing aides."[37] 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. There is wide consensus 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. Even the EU, with its strict labeling regime exempts "processing aides (like food enzymes produced from GE microorganisms)."[38] This position 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 beet sugar. As shown above, the science substantiates that beet sugar does not contain genetic material of any kind. There is no rational basis under the Act to exempt one category of foods produced using a bioengineered organism but require disclosure for beet sugar that does not contain any genetic material.[39] Fairness dictates that all foods should be subject to the same criteria. In both cases the definition of bioengineering in the Act makes it clear that the law does not apply to products that do not contain genetic material above any threshold established by the Secretary.

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[37] Legislative History at 3.

[38] USDA Gain Report on the EU at 29, https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf

[39] 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 which allows up to 5% of non-organically produced agricultural ingredients.*** Like the USDA, we have conducted extensive research on bioengineering disclosure methods worldwide and provide the following observations.[40]

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.[41] Accordingly, thresholds are simply a tool to

[40] *See* Attachment 2 ("Bioengineered Disclosure Thresholds").

[41] *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

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.[42] 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."[43] 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 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.

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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;

[42] The European Union's moratorium on approving new genetically modified food illustrates the point. In 2003, the U.S., Canada, and Argentina challenged the moratorium as unfair protectionist measures prohibited by the General Agreement on Tariffs and Trade (GATT). The Panel concluded that "the European Communities applied a general de facto moratorium on approvals of biotech products between June 1999 and 29 August 2003." *See* European Communities – Measures Affecting the Approval and Marketing of Biotech Products. WTO Document WT/DS291R (29 September 2006).

[43] Legislative History at 4.

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 [44], Russia, etc.) following Approach 3 have thresholds that range from 4% to 0.0% and outright bans. For example, Nigeria has a 4% threshold;[45] 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;[46] 21 countries representing 43% of the world population have a 0.0% threshold;[47] and Kenya, Morocco, Benin, Sri Lanka, and Serbia have outright bans. [48] 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 severely restricted 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. It is the lowest cost, lowest liability approach that results in consumer savings. It also has the least impact on the domestic and international value chain and is less of a burden

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[44] "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 . The pending acquisition of Syngenta by ChemChina may facilitate a greater acceptance of biotechnology.

[45] 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.

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

[47] 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.

[48] "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.

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.[49] "The use of genetic engineering, or genetically modified organisms (GMOs), is prohibited in organic products."[50] 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."[51] 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. 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 AMS to keep Congress's intent in mind that "[n]othing in the [disclosure] requirement can be used to denigrate biotechnology."[52] 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 inhibit or reject U.S. exports because of their overly restrictive biotechnology standards, based principally on fear (the precautionary principle), not science.[53]

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[49] USDA Labeling Organic Products, https://www.ams.usda.gov/sites/default/files/media/Labeling%20Organic%20Products.pdf.

[50] https://www.ams.usda.gov/publications/content/can-gmos-be-used-organic-products

[51] https://www.ams.usda.gov/publications/content/can-gmos-be-used-organic-products

[52]Legislative History at 2.

[53] 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 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

This has 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 from U.S. competition.

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**."[54] 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.[55] 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 farmers that embrace 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 only threshold that will allow the United States to remain a world leader in the production of bioengineered crops and minimizes impacts on the value chain, minimizes the regulatory burden on farmers, is a 5% threshold. 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.[56]

Biotechnology Annual, December 6, 2016. https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf.

[54] *Id.*

[55] Non-GMO Project, https://www.nongmoproject.org/about/mission/.

[56] Legislative History at 2.

QUESTION 9

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

Context: *AMS is considering if it should develop various categories for disclosure and if it should differentiate between those products that a) are bioengineered, b) contain ingredients that are bioengineered, or c) contain ingredients derived from bioengineered crops or animals. Additionally, AMS is considering the creation of a set of disclosures for a category of bioengineered foods for those products that, due to changes in sourcing, include bioengineered ingredients for part of the year, and non-bioengineered ingredients for other parts of the year. AMS is considering the advantages and disadvantages, based on cost, clarity, and other factors, of using a single disclosure category or multiple disclosure categories.*

The law creates two categories for disclosures: bioengineered foods and foods that may be bioengineered. We urge AMS to adhere to the statutorily prescribed categories.

Under no circumstances should AMS create a category of disclosure for foods that "contain ingredients derived from bioengineered crops or animals," As set forth in our comments on Question 4, such a disclosure category would be contrary to the plain language and intent of the Act and would exceed AMS's authority. The determining factor for whether the Act applies to a food is not the breeding method by which a food was derived but the "presence of 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" above an amount determined by the Secretary.

It is unrealistic for a company to change labels every time it changes ingredients between bioengineered and conventional commodities. For a category of bioengineered foods for those products that, due to changes in sourcing, include bioengineered ingredients for part of the year, and non-bioengineered ingredients for other parts of the year, a single label noting "may contain bioengineered ingredients" can account for different sourcing throughout the year of bioengineered and non-bioengineered crops.

QUESTION 10

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

Context: *AMS must develop a process to help stakeholders determine whether a food is subject to bioengineered disclosure. AMS anticipates the process would include considering factors such as these: whether a food contains a substance that has been modified using recombinant in vitro DNA techniques (Sec. 291(1)(A)), and for which the modification could not be obtained through conventional breeding or found in nature (Sec. 291(1)(B); Question 2 and 3), , and whether a food requires disclosure based on the predominance of ingredients (Sec. 292(c), Question 6), among others. The outcomes of these determination requests might be publicly posted on a Web site. The process to implement Sec. 293(b)(2)(C) is not intended to be an investigation or enforcement process (see Questions 26-29); instead, the implementation would likely be framed for manufacturers or developers of bioengineered food or ingredients who have a question on whether their food is subject to disclosure. AMS is considering the factors to be considered, the way to inform the public about the outcome of the requests, and ideas regarding the process to be used to make the determination.*

We agree that it would be helpful for AMS to establish a process for manufacturers or developers of bioengineered food or ingredients to seek clarification on factors that should be considered in determining whether a food meets the definition of a bioengineered food. However, as stated throughout this comment, any determinations made in response must adhere to the statutory definition of a bioengineered food, one that "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" above an amount determined by the Secretary. Section 293(b)(2)(C) is not a broad grant of authority that allows AMS to rewrite the definition of a bioengineered food. Thus, whatever factors AMS considers, they cannot modify the definition of a bioengineered food as one that contains bioengineered genetic material.

We also recommend that AMS, as part of the § 293(b)(2)(C) process, allow manufacturers to seek a confirmation that a food is not bioengineered within the meaning of the Act. Such a mechanism would be consistent with APHIS's current "Am I regulated" letter of inquiry process that allows biotechnology developers to inquire as to whether a genetically engineered organism is regulated under the Plant Protection Act. AMS could, as APHIS does, make these determinations public which would further help clarify those foods that are not subject to the Disclosure Standard. It would also be consistent with Congress's intent that "the Secretary . . . provide exemptions *and other determinations* under which a food is not considered bioengineered,"[57] as well as with other countries (Japan, China, Australia, New Zealand,

[57] Legislative History at 3.

Thailand, Malaysia, S. Korea, and Indonesia), that specifically recognize that certain foods, such as sugar are not bioengineered.[58]

[58] Japan exempts sugar from GE sugarbeets from their GE labeling requirements. USDA FAS "Japan, Agricultural Biotechnology Annual, Japan's regulatory system for GE crops continues to improve", https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Tokyo_Japan_7-13-2015.pdf; in China, sugar derived from GE sugarbeets and various other refined foods, e.g., cottonseed oil, are not subject to mandatory labeling, "China-Agricultural Biotechnology Annual, China Moves Towards Commercialization of Its Own Biotechnology Crops, https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Beijing_China%20-%20Peoples%20Republic%20of_12-16-2016.pdf; Australia exempts sugar derived from GE sugarbeets and other foods that do not contain any novel DNA or protein from its labeling laws, Food Standards, Australia New Zealand, http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx.

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 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 manufacturer 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. (*See* Question 9 at 21).

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."[59] Giving the on-package disclosure more prominence than allergy warnings would potentially denigrate biotechnology.

[59] Legislative History at 3.

QUESTION 23

Is there other equivalent on-package language that AMS should consider to accompany an electronic or digital disclosure besides "Scan here for more food information"? (Sec. 293(d)(1)(A)

Under no circumstances should the text accompanying an electronic or digital disclosure reflect that a food may or may not be bioengineered. Congress purposely directed that text accompanying the electronic or digital disclosure be limited to "scan here for more food information" or equivalent language "that only reflects technological changes." § 293 (d). Congress was rightfully concerned that any text relating to bioengineering would equate to *de facto* on package labeling which Congress expressly rejected.

To address the concern that the word "scan" may not be relevant as technology changes in the future we suggest that equivalent language could be "Access more food/ingredient information here." This would alert the consumer that some further action was required to obtain more information about the food.

QUESTION 30

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

Context: *AMS considering how the disclosure requirements should be applied to imported products*

Imported products should be required to follow the same disclosure requirements as products manufactured in the United States. The U.S. should allow stickers or stamps to be used for any required disclosures before import and customs clearance to assure compliance and eliminate the risk of liability to U.S. entities throughout the distribution chain. The U.S. should apply any requirements in a nondiscriminatory way that is consistent with U.S. obligations under World Trade Organization and other international trade and investment agreements.

As outlined in the response to Question 4, the United States already imports sugar derived from BE sugarbeets (Alberta) and actual BE sugarbeets from Ontario, Canada for processing in Michigan. Brazil's government recently approved the world's first commercial bioengineered sugarcane that contains the gene Bt (Bacillus thuringiensis) that is resistant to an insect referred to as the cane borer. Brazil is by far the largest sugarcane producer and exporter in the world and is the third largest supplier of raw sugar to the U.S. Current expectations are that sugar derived from the new variety will reach commercial export markets in 2020. As the world leader in sugarcane production, other cane producing countries look to Brazil for technical advances. For example, Australia and Indonesia are currently developing BE sugarcane varieties with drought resistance, herbicide tolerance, plant development, increased sugar content, and yield.[60] These advances will provide many environmental benefits and increase long term sustainability. Misguided labeling schemes for purified ingredients, such as sugar, should not inhibit such advances.

If sugar derived from BE sugarbeets were required to be labeled it would also be problematic for our trade with Canada. Brazil is the largest raw sugar supplier to Canada. (7-year Olympic average is 78% of all raw imports). Canadian companies manufacture sugar-containing products for export to the United States. If the sugar derived from bioengineered crops were required to be disclosed then raw sugar imported from Brazil would have to be segregated from other raw sugars derived from non-bioengineered cane in the Canadian refineries. Also, Canada annually exports around 550,000 short tons of sugar in sugar-containing products to the United States duty free. If sugar derived from bioengineered crops would be required to be labeled, this would place unnecessary burdens on our trading partners and discourage the adoption of bioengineered crops that are more productive and environmentally sustainable.

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[60] https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Canberra_Australia_8-7-2015.pdf USDA Gain Report on Australia; https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Jakarta_Indonesia_7-14-2015.pdf USDA Gain Report on Indonesia

ATTACHMENT 1

ELSEVIER

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Nucleic acid and protein elimination during the sugar manufacturing process of conventional and transgenic sugar beets

Joachim Klein, Josef Altenbuchner, Ralf Mattes *

Institute of Industrial Genetics, University of Stuttgart, Allmandring 31, D-70569 Stuttgart, Germany

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Abstract

The fate of cellular DNA during the standard purification steps of the sugar manufacturing process from conventional and transgenic sugar beets was determined. Indigenous nucleases of sugar beet cells were found to be active during the first extraction step (raw juice production) which was carried out at 70°C. This and the consecutive steps of the manufacturing process were validated in terms of DNA degradation by competitive PCR of added external DNA. Each step of the process proved to be very efficient in the removal of nucleic acids. Taken together, the purification steps have the potential to reduce the amount of DNA by a factor of $> 10^{14}$, exceeding by far the total amount of DNA present in sugar beets. Furthermore, the gene products of the transgenes neomycin phosphotransferase and BNYVV (rhizomania virus) coat protein CP21 were shown to be removed during the purification steps, so that they could not be detected in the resulting white sugar. Thus, sugar obtained from conventional and transgenic beets is indistinguishable or substantially equivalent with respect to purity.

Keywords: *Beta vulgaris*; Transgenic sugar beets; Sugar purification; Competitive PCR; Rhizomania

1. Introduction

The development of transgenic varieties of various plants, and also sugar beets, had become feasible by application of selectable marker gene introduction with the Ti-plasmid derived vectors due to the pioneering work of Bevan et al. (1983) and Herrera-Estrella et al. (1983). For the generation of transgenic sugar beets (*Beta vulgaris*), an improved method using stomatal guard cells has recently been reported (Hall et al., 1996). Since then, numerous transgenic lines have been constructed and their usefulness demonstrated in outdoor plantations.

* Corresponding author. Tel.: +49 711 6856971; fax: +49 711 6856973.

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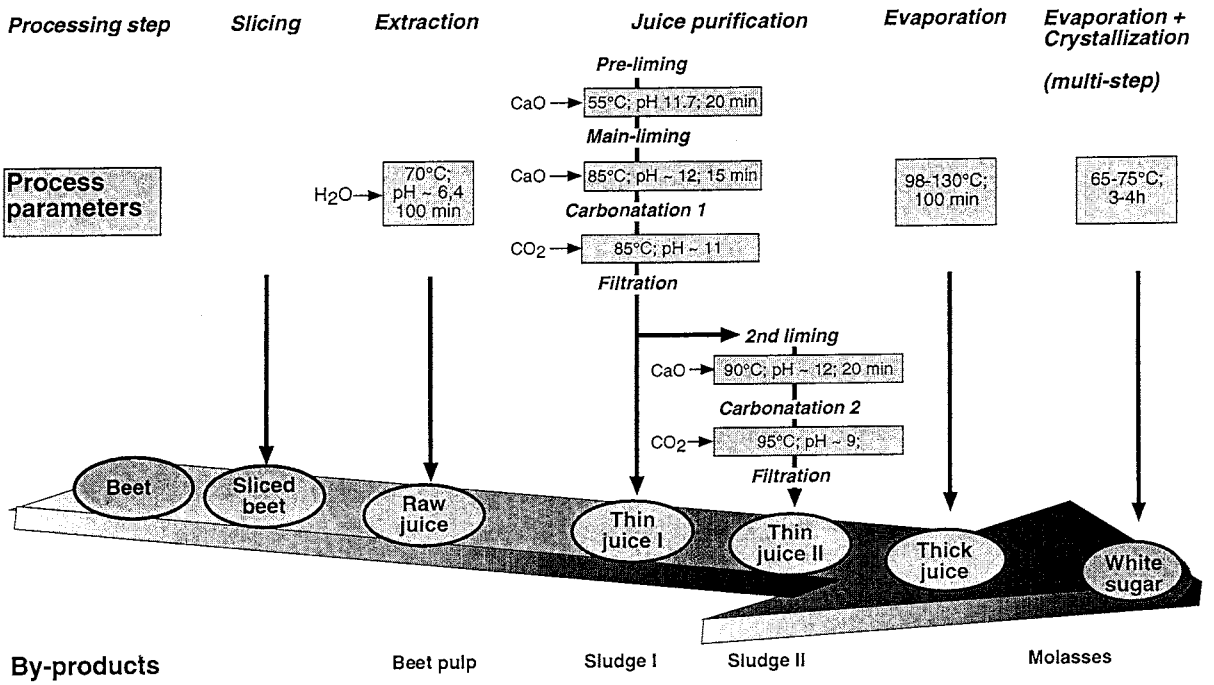

Fig. 1. Principal steps of sugar production from sugar beets.

One major goal in generating transgenic varieties is the establishment of resistance against plant viruses. The first report on this made use of the introduction and expression of virus coat protein genes in plant cells (Abel et al., 1986). The major virus related disease of sugar beets is rhizomania caused by the beet necrotic yellow vein virus (BNYVV). The genetic map of the multipartite genome of this virus has been reviewed (Richards and Tamada, 1992). The introduction of a gene cassette coding for the *cp*21 gene product (coat protein, CP21) of BNYVV under the control of the cauliflower mosaic virus promoter into cells of *B. vulgaris* resulted in plants resistant to BNYVV infection (Kallerhoff et al., 1990; Ehlers et al., 1991). The addition of this gene cassette to the genome of *B. vulgaris* was supported by coupling the CP21 construct to a neomycin resistance gene (*aphA*) allowing selection by G418 treatment of cultivars during the early stages of their cultivation.

The first successful outdoor plantations of transgenic virus resistant sugar beet cell lines raised the question about the fate of genetic material and proteins during the sugar manufacturing process.

Sugar is recovered from beet by a multistep extraction and purification procedure (Fig. 1). This includes slicing of washed beets (to 'cossettes') followed by extraction with water at elevated temperature (70°C) for about 100 min. The raw juice obtained is clarified by two consecutive steps comprising CaO addition (liming) and subsequent carbonatation. The material precipitated thereby (sludge) is removed by filtration to yield a so-called thin juice. It is concentrated by evaporation first to thick juice and then further to a crystal magma from which high purity sugar is recovered by centrifugation. The evaporation of thin juice to thick juice is carried out in a multi-effect evaporator working at a temperature range of 98–130°C.

The objective of this study was to analyse intermediate and end products of the standard sugar recovery process for DNA using the ADP-glucose pyrophosphorylase gene (AGPase, *agp*, Smith-

White and Preiss, 1992) as a general marker for sugar beet DNA, and the genes for the BNYVV coat protein (*cp*21) and neomycin phosphotransferase (*aphA*) and their respective gene products as specific markers for transgenic beet DNA and proteins. Furthermore, the potential of each principle processing step to remove DNA was validated with added pUC18 DNA (Yanisch-Perron et al., 1985). The methods applied comprised agarose gel electrophoresis, hybridisation methods, competitive PCR and immunological as well as enzymatic methods.

2. Materials and methods

2.1. Bacterial strains, media and growth conditions

Cloning experiments and plasmid preparations were carried out in *E. coli* JM109. Strains with plasmids were grown in 2 × YT liquid medium or on 2 × YT agar plates (Sambrook et al., 1989) supplemented with 100 μg ml^{-1} ampicillin at 37°C.

2.2. DNA preparation, DNA manipulation and cell transformation

Plasmid preparations from *E. coli* were performed by the method of Kieser (1984). Large scale plasmid preparation was done by using the Qiagen plasmid giga kit (Qiagen, Hilden, Germany). To isolate genomic DNA, frozen beets or frozen cossettes (3 g) were chopped up in liquid nitrogen and homogenised for 2 min in 1 vol Kirby mix (1% triisopropylnaphthalenesulfonic acid, Na salt, 6% 4-aminosalicylic acid and 6% phenol in 50 mM Tris–HCl, pH 8.3; Sambrook et al. (1989)) and 2 vol phenol/chloroform. After centrifugation, the supernatant was reextracted with 1 vol phenol/chloroform and the DNA precipitated with ethanol. Finally, the DNA was resuspended in TE buffer (Sambrook et al., 1989) and dialysed in the same buffer. Raw juice (1 ml), thin juices (1 ml), samples of sludge I and II (1 g resuspended in 1 ml TE buffer), thick juice (1 ml) and white sugar (3 g diluted in 3 ml water) were treated with 0.5 ml phenol/chloroform and centrifuged at 6000 × *g* for 15 min. The supernatant was dialysed in a buffer containing PEG 6000 (5 mM Tris–HCl, pH 8.8, 0.5 mM EDTA, 5 mM NaCl, 3.5% PEG 6000) and hereby 10-fold concentrated. Finally, the DNA was purified via the Qiaquick-spin PCR purification kit of Qiagen. All other DNA manipulations were carried out as described elsewhere (Sambrook et al., 1989).

2.3. Quantitative PCR

The competitive PCR was carried out as already described (Gilliland et al., 1990; Ferre, 1992). In a total volume of 40 μl DNA, 10 mM Tris–HCl (pH 9.0), 50 mM KCl, 1.5 mM $MgCl_2$, 0.2 mM of each of the four deoxynucleotide triphosphates (Pharmacia, Uppsala, Sweden), 0.5 μM of each forward and reverse primer and 2.5 U *Taq* DNA polymerase (Pharmacia) were added. The first step was for 1 min at 94°C, followed by 30 cycles of denaturation for 30 s at 92°C, annealing for 1 min (S672/S673: 59°C, S674/S675: 59°C, S700/S701: 53°C, S708/S709: 50°C) and extension for 2 min at 72°C (thermal cycler PTC-200, MJ Research, Watertown, USA). The PCR fragments were separated by electrophoresis through 1% agarose gels, visualised by UV light after ethidium bromide staining, documented and quantified. A videocamera and the software package of Cybertech (Cybertech DS1, Cybertech, Berlin, Germany) was used to determine the equivalence concentration where standard and target DNA concentration were identical. The competitor DNA was added at concentrations ranging from 5 ag to 500 fg. This corresponded to about 1.5 and 150 000 molecules.

2.4. Primer, target and competitor DNA

The plasmids, primers and fragment sizes obtained by PCR are listed in Table 1. The plasmids pJKS224, pJKS230 and pJKS219 were generated by amplification of fragments of *agp*, *cp*21 and *aphA* from transgenic beet DNA and inserted between the *Pvu*II sites of pUC18. The plasmids with the competitor DNA were generated by deleting a *Pvu*II fragment from pUC18

Table 1
Target and competitor DNAs

Primer sequence	T_{anneal} (°C)	Target DNA		Competitor DNA	
		Plasmid/gene	Fragment size (bp)	Plasmid	Fragment size (bp)
S672: ATACGCAAACCGCCTCTCC S673: ATACCGCATCAGGCGCCAT	59	pUC18	434	pADI2.2	800
S700: TGGCAGAAGCACATTGA-CAC S701: TTGGGAGGCTGTTGTG-TAAG	53	*agp* (pJKS224)	776	pJKS227	600
S708: CCAGGGACTTCAGCAGGTG S709: CAGGAACCGCAGGAGTGGA	50	*cp*21 (pJKS230)	177	pJKS232	350
S674: CTCTGATGCCGCCGTGTTC S675: GCCCATTCGCCGCCAAGCT	59	*aphA* (pJKS219)	618	pJKS222	800

The used primers and the sizes of the PCR fragments after quantitative PCR are listed. The plasmids which contain the target PCR fragments are shown in brackets.

(pADI2.2), a *Eco*RV/*Nsi*I fragment from pJKS224 (pJKS227), a *Nsi*I/*Sca*I fragment from pJKS230 (pJKS232) and a *Pst*I/*Sph*I fragment from pJKS219 (pJKS222) and replacing them with *Hae*II fragments from bacteriophage λ. It was verified that the constructed internal standard (competitor) DNAs had comparable efficiencies of amplification as the appropriate pUC18-based target DNAs using the method described by Scadden et al. (1992). The 5 pg target and competitor DNA were independently analysed.

2.5. Hybridisation of DNA

Total genomic DNA was isolated and digested with restriction endonucleases. After electrophoresis, the DNA was transferred onto a nylon membrane (Immobilon P, Millipore, Eschborn, Germany) and hybridised with the cloned PCR fragments of the target DNA, labelled by using a non-radioactive DNA labelling and detection kit (Boehringer, Mannheim, Germany). Hybridisation was carried out at 68°C in hybridisation buffer as described by the manufacturer.

2.6. Immunological methods

Neomycin phosphotransferase and CP21 protein were detected by sandwich ELISAs using a biotin–streptavidin amplification system (5'Prime 3'Prime Inc., Boulder, USA). Absorbance values at 405 nm were read in a microplate reader (model 3550, Bio-Rad, Munich, Germany).

3. Results and discussion

3.1. DNA disappears from cossettes during extraction

The plant material used (about 25–30 kg of beets) was collected from different field trials and subjected to standard processing in a pilot plant and analysed. Conventional beets free of BNYVV (A) and conventional BNYVV-infected beets (B) served as controls. Beets of transgenic varieties (C) from BNYVV free areas were compared with the controls.

Genomic DNA from fresh sugar beet cossettes could be prepared by standard DNA extraction

methods based on phenol extraction and ethanol precipitation (Section 2). However, DNA could not be detected in ethidium bromide (EtBr) stained agarose gels when this method was applied to post-extraction beet cossettes (pulp) or raw juice either. Southern blot analysis of these gels using a labelled cDNA of ADP-glucose pyrophosphorylase as a reference for genomic sequences of *B. vulgaris* cells and fragments from *aphA* or *cp*21 genes in case of transgenic beets again gave negative results (data not shown). Obviously, DNA disappeared during the process of juice extraction at 70°C for unknown reasons.

3.2. Nucleases from beet extracts degrade DNA in raw juice

When purified nucleic acid from fresh sugar beet cossettes was added to raw juice at 70°C, a quick degradation of DNA was observed by EtBr-stained agarose gel electrophoresis (Fig. 2A). This pointed towards the presence of DNA degrading activities, e.g. nucleases in the raw juice.

To corroborate this point, 250 μg ml^{-1} pUC18 DNA were added to fresh raw juice samples and incubated for the periods indicated in Fig. 2B. The amount of pUC18 DNA added by far exceeded the calculated amount of $\sim$10 μg ml^{-1} whole cellular DNA, assuming total lysis of all beet cells. Under these conditions, the added pUC18 DNA was shown to be degraded within minutes.

The rate of this DNA degradation could be shown to be temperature dependent (Fig. 2C) having low efficacy at 4°C, a slow degradation at 37°C but a high degradation activity at 70°C. Protein denaturation measures such as heating of raw juice at 95°C for 10 min or phenol extraction of raw juice resulted in the protection of added beet genomic DNA or pUC18 DNA from degradation (data not shown).

3.3. Degradation of the agp, aphA and cp21 DNA during the sugar recovery process steps as analysed by PCR

The *B. vulgaris* genomic DNA content both in raw juice and pulp (sugar beet cossettes after

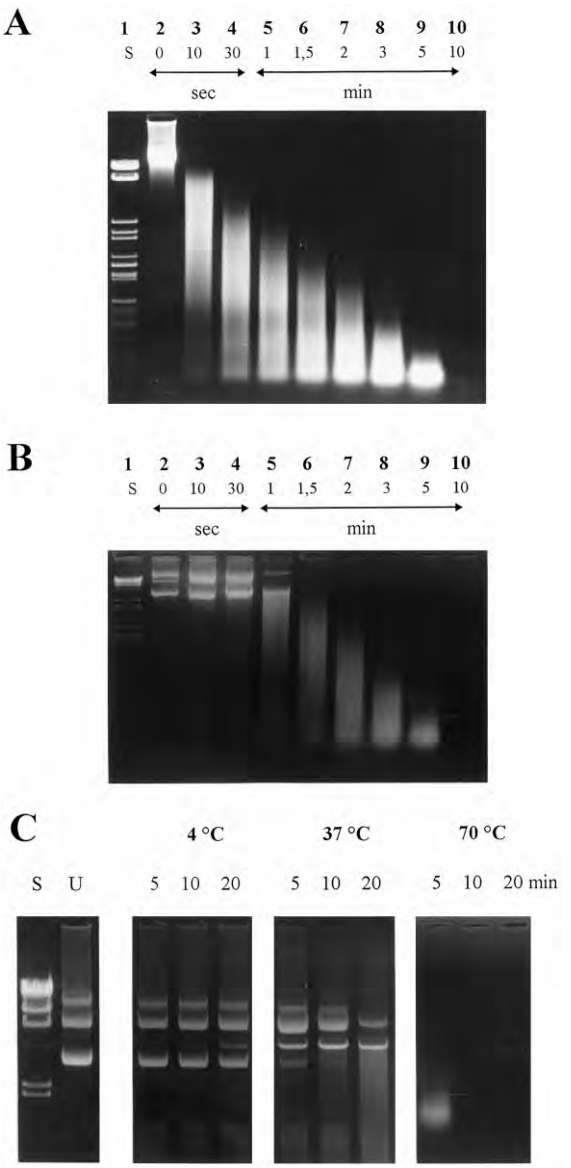

Fig. 2. Degradation of sugar beet chromosomal DNA (A), pUC18 DNA (B) and pUC18 DNA under various temperatures (C) in sugar beet raw juice. Chromosomal (A) or pUC18 DNA (B, C) were added to 500 μl raw juice from conventional beets free of BNYVV at a final concentration of 250 μg ml^{-1} at 70°C (A, B) or at 4, 37 and 70°C (C). Samples (20 μl), which were immediately extracted in the same volume of phenol/chloroform solution, were taken at the indicated times. Of the samples, 10 μl were separated by agarose gel electrophoresis; λ DNA cut with *Bgl*I (S) and uncut pUC18 DNA (U) were used as markers.

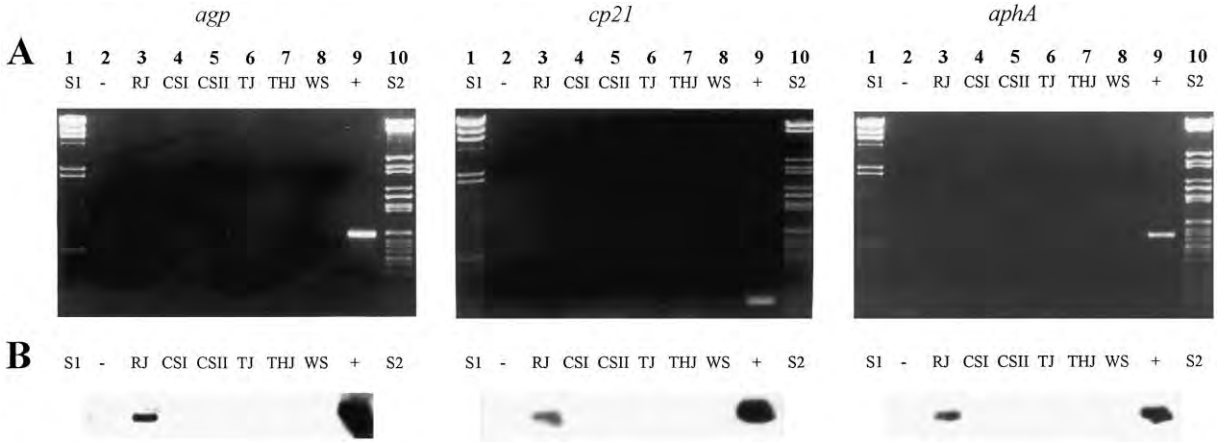

Fig. 3. Analysis of the *agp*, *cp*21 and *aphA* genes in raw juice (RJ), carbonatation sludge I (CSI), carbonatation sludge II (CSII), thin juice (TJII), thick juice (THJ) and white sugar (WS) from transgenic beets. The DNA was prepared as described in Section 2. DNA solutions (5 μl) were subjected to PCR using the primer set S700/S701 for the *agp* gene, S708/S709 for the *cp*21 gene and S674/S675 for the *aphA* gene; 100 pg of the appropriate plasmids containing the different target DNAs (pJKS224: *agp*, pJKS230: *cp*21 and pJKS219: *aphA*) were added as positive PCR controls (lane 9, +), the negative control was without DNA (lane 2, −). PCR reactions (10 μl) were separated via agarose gel electrophoresis (A), the DNA transferred to a nylon membrane and hybridised to DIG-labelled target DNA (B).

extraction of raw juice) was below detection limit of conventional methods such as Southern blot analysis. Therefore, the more sensitive PCR analysis was applied to these materials as well as to samples from the latter process steps.

Direct PCR analysis of raw juice samples with added pUC18 DNA gave only barely detectable signals, pointing towards factors in raw juice preventing efficient PCR amplification. Therefore, raw juice samples and those from subsequent processing steps were purified by phenol extraction followed by dialysis and DNA affinity chromatography. pUC18 DNA added to such purified samples could then be amplified as efficiently as the control with buffer (data not shown).

In samples from all processing steps, from raw juice to white sugar, from conventional as well as transgenic beets, DNA could not be detected using PCR with primers for *agp*, *aphA* and *cp*21 DNA (Section 2) followed by agarose gel electrophoresis and EtBr-staining (Fig. 3A). The more sensitive Southern blot hybridisation with digoxigenin-labelled DNA of the target DNAs gave clearly recognisable signals in PCR samples from raw juice only, but in none of the consecutive products. Chromosomal *agp* DNA was detected in raw juice from conventional and transgenic beets whereas the specific transgenic markers were found in raw juice from the respective beets only (Fig. 3B).

Quantification of DNA was performed by competitive PCR analysis according to Piatak et al. (1993). This comprises the comparison of the amounts of PCR products resulting from the co-amplification of a target sequence and an added internal standard of known concentration and recognisable by the same primer pair. Competitive plasmids for *cp*21, *aphA* and *agp* sequences as well as for pUC18 DNA were constructed (Section 2). The internal standard (competitor) DNAs were determined to have comparable amplification efficiencies as the appropriate pUC18-based target DNAs using the method described by Scadden et al. (1992).

The DNA content in raw juice being too low for proper quantification, it had to be concentrated 10-fold by DNA-affinity chromatography. Thereby, for each of the three gene fragments analysed equivalence concentrations of 2×10^4 molecules per 1 ml raw juice could be determined. This corresponds to about 5–10 fg of the constructed plasmids.

Assuming a triploid genome (3 pg DNA per cell), a cell content of 10^6 cells in 1 g beet material (microscopically determined) and as 1 kg of sugar beets results in about 1.15 l of raw juice, this would mean a 100-fold reduction of the gene fragments (copy number basis). However, as the methodology is based on copy number comparison and the competitor DNA used is much smaller than chromosomes, the actual fragmentation of chromosomal DNA is to be expected to be much higher. The quantification of *agp* is shown as an example in Fig. 4.

3.4. DNA reduction potential of various sugar recovery process steps using added pUC18 DNA

The low number of DNA fragments detected in raw juice prompted us to validate all steps of the sugar recovery process for their potential to degrade or remove DNA.

For the first carbonatation step pUC18 DNA was added at a high dosage of 250 μg ml^{-1} to heat inactivated raw juice and liming and carbonatation was performed according to standard procedure. After filtration, samples of juice (so-called thin juice I) and sludge (sludge I) were retained and the main portion of juice subjected to a second liming and carbonatation treatment resulting in thin juice II and sludge II. The samples of thin juice I and II were dialysed and the DNA concentrated by affinity chromatography. Competitive PCR showed a 10^3-fold reduction of pUC18 DNA in the first and a 10^5-fold reduction in the second carbonatation step. Samples of sludge I and II were extracted, each with the same volume of water, dialysed and concentrated by affinity chromatography. They were shown by PCR to be free of DNA.

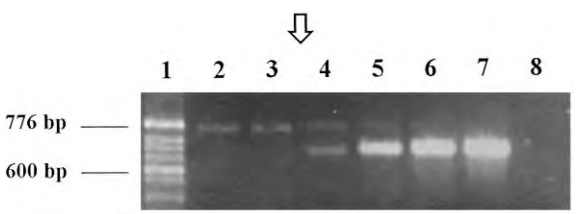

Fig. 4. Quantitative PCR of the *agp* DNA in raw juice: 15 μl of the 10 times concentrated and purified raw juice in the presence of 750 ag (lane 2), 5 fg (lane 3), 10 fg (lane 4), 30 fg (lane 5), 50 fg (lane 6) and 500 fg (lane 7) of competitor DNA pJKS227, respectively 220, 1470, 2940, 8800, 14 700 and 147 000 copies of pJKS227 were subjected to PCR. A negative control (lane 8) did not contain any DNA; 10 μl of the PCR reactions were separated via agarose gel electrophoresis and analysed as described in Section 2; λ DNA cut with *Bgl*I was used as molecular weight marker. The arrow indicates the equivalence concentration.

The results were verified by adding 0.250 μg ml^{-1} pUC18 DNA to heat inactivated raw juice. The competitive PCR confirmed a 10^3-fold reduction of pUC18 DNA in the first carbonatation step and showed this factor independent from the actual amount of DNA present. After the second carbonatation step no DNA was found, i.e. the DNA concentration was reduced by a factor of at least 10^5 in the second carbonatation. Again, there was no DNA to be detected in the sludge samples. In summary, during juice purification residual DNA fragments from raw juice will be reduced at least 10^8-fold.

The next step in the sugar recovery process is the multistep evaporation of thin juice II at a temperature range of 98–130°C and a residence time of $\sim$30 min to produce a thick juice. To simulate this step in the laboratory, a thin juice II sample with 250 μg ml^{-1} pUC18 DNA added was autoclaved at 121°C for 30 min. Thereby, a 10^3-fold reduction of pUC18 DNA concentration was shown by competitive PCR.

The last purification step in the sugar recovery process is crystallisation by evaporation of thick juice at a temperature of about 70°C followed by separation and washing of crystals in a sieve-basket centrifuge. This process step was carried out in the laboratory after adding 250 μg ml^{-1} pUC18 DNA to thick juice and evaporating to crystallisation. It was, however, not possible to wash the crystals in the laboratory centrifuge. Nevertheless, only about one-tenth of the DNA added could be found again.

The DNA degrading potential of nucleases in the raw juice was tested by adding pUC18 DNA (0.025 and 2.5 μg ml^{-1}) at 70°C. Samples taken at different times up to 120 min were analysed by competitive PCR. As shown in Fig. 5, pUC18 DNA was rapidly degraded within 15 min, reducing the copy numbers of intact target sequence by

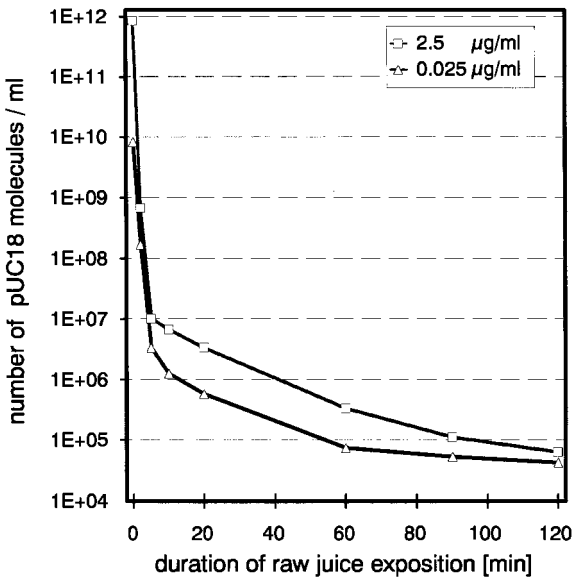

Fig. 5. Decrease of pUC18 DNA molecules in sugar beet raw juice. pUC18 DNA was added to 500 μl raw juice from conventional beets free of BNYVV at final concentrations of 0.025 (△) and 2.5 μg ml^{-1} (□); 20 μl samples were taken at the indicated times, immediately extracted with 20 μl phenol/chloroform and purified via a Qiagen column (Qiagen, Hilden, Germany). The amount of pUC18 molecules per μl raw juice was quantified via competitive PCR using the standard DNA pADI2.2.

a factor of about 10^5 (in the 2.5 μg ml^{-1} sample) followed by a slowing down of the degradation rate. This was found to be not due to inactivation of nucleases during the incubation period as a preincubation of raw juice for 120 min at 70°C led to similar degradation kinetics (not shown). It is assumed that the nuclease activity decreases at low DNA concentrations and increasing DNA fragmentation.

The factor of overall efficacy of DNA elimination under standard process conditions can be calculated to about 10^{14}. These activities include nucleolytic degradation in raw juice, irreversible adsorption on sludge, precipitation, denaturation and presumably hydrolysis due to alkaline pH and high temperature in the carbonatation steps, hydrolysis at the very high temperature during the evaporation step and exclusion of DNA from sugar crystals in the last step. The non-enzymatic steps should be independent of DNA concentrations and therefore capable of completely removing the low amounts of DNA left in the raw juice.

The reduction of biologically active DNA should even be greater as the DNA was considerably reduced in size in the raw juice and, later on, denatured to single-stranded DNA. This is because only small parts of the genes or pUC18 DNA were amplified and the actual size of the fragments may have even been smaller than the PCR fragments due to the extension of overlapping small fragments by *Taq* polymerase.

3.5. Proteins are removed during juice purification

The fate of the gene products of the transgenes was also looked at, e.g. neomycin phosphotransferase and BNYVV coat protein CP21. Applying ELISA methods for detection of neomycin phosphotransferase, 4×10^{-8} g ml^{-1} could be detected in raw juice from transgenic beets (C). Quantification of CP21 by the same technique showed that raw juice samples from BNYVV-infected conventional beets (B) contained 5×10^{-5} g ml^{-1} CP21, i.e. 10^3 times more than samples from BNYVV-free transgenic beets (C) which contained 3×10^{-8} g ml^{-1}. No AphA ($< 10^{-10}$ g ml^{-1}) or CP21 ($< 5 \times 10^{-9}$ g ml^{-1}) was found in pulp, thin juices, thick juice or white sugar from transgenic beets. This shows that proteins are efficiently removed during the juice purification steps.

In summary, extraction and purification steps of the standard sugar production process are very efficient in removal of nucleic acids and proteins irrespective of their origin. Consequently, the product, white sugar, is indistinguishable from its source: the transgenic beet varieties or conventionally bred controls.

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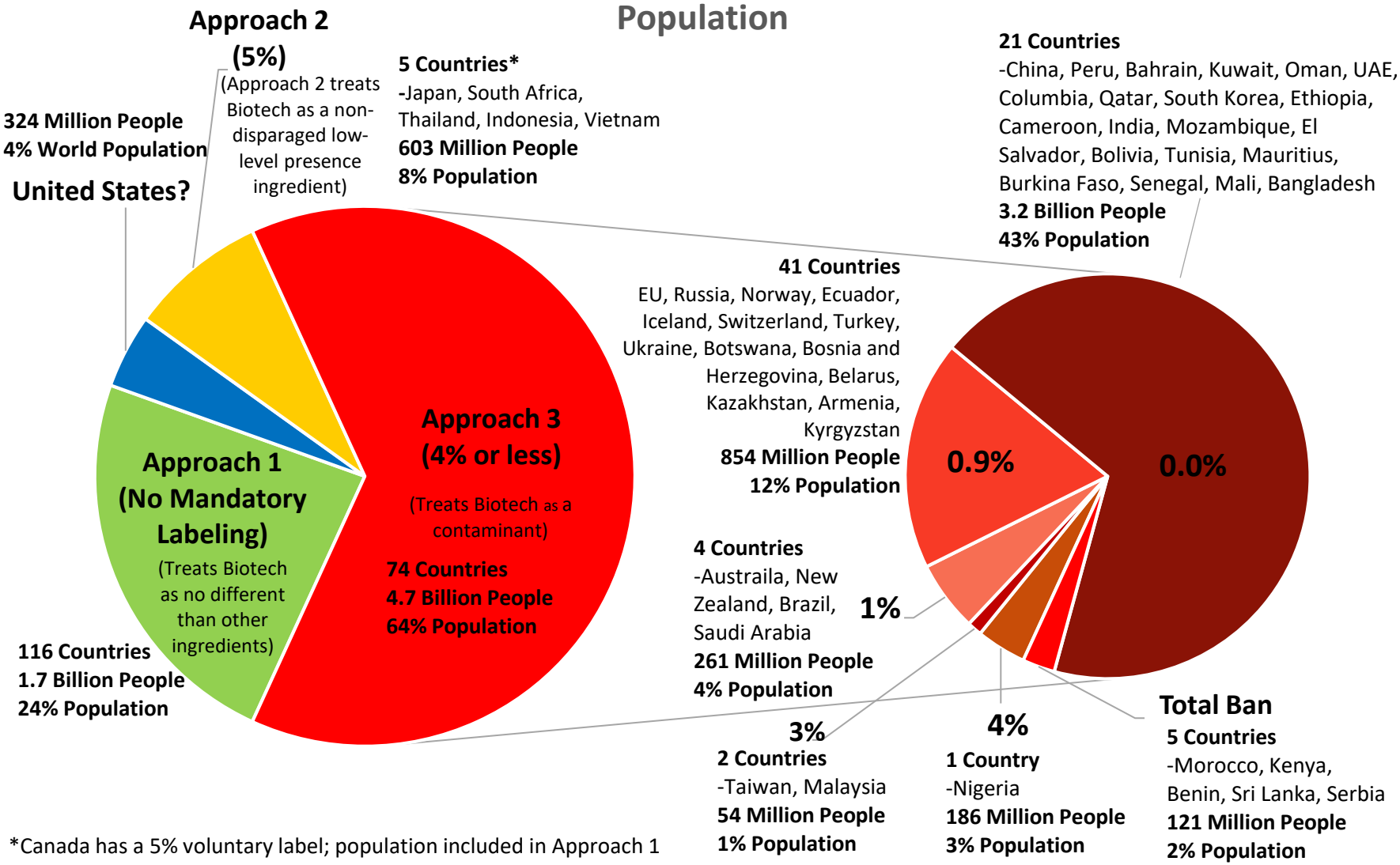
ATTACHMENT 2

Bioengineered Disclosure Thresholds by Approval, Countries, & World Population



*Canada has a 5% voluntary label; population included in Approach 1

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)

MAJOR LABELING APPROACHES*

***(Japan, Thailand, Indonesia, Malaysia, Australia, New Zealand, China, and South Korea do not require labeling of sugar and various other refined products)**

	Approach 1: **NO MANDATORY LABELING (116 Countries)**	**Approach 2:** **5% (5 Countries)**	**Approach 3:** **(4% - 3% - 1% - .9% - 0.0% - Bans)** **(74 Countries)**				
			4% **(1 Country)**	**3%** **(2 Countries)**	**1%** **(4 Countries)**	**.9%** **(41 Countries)**	**0.0%** **(21 Countries with 0.0%)** **(5 Countries with bans)**
ISSUES							
PRODUCTION, TRANSPORTATION, STORAGE COSTS (LOW, MEDIUM, HIGH)	Low	Medium/Low	Medium	Medium	High	High	High
IDENTITY PRESERVATION COSTS (LOW, MEDIUM, HIGH)	Low	Medium/Low	Medium	Medium	High	High	High
LIABILITY RISKS (LOW, MEDIUM, HIGH)	Low	Medium/Low	Medium	Medium	High	High	High
FOSTERS GE TECHNOLOGY (LOW, MEDIUM, HIGH)	High	Medium	Medium	Medium	Generally Low*	Low	Low
BIOTECH TREATED AS A "CONTAMINANT", NON-DISPARAGED "LOW-LEVEL PRESENCE" INGREDIENT, OR NO DIFFERENT THAN OTHER INGREDIENTS	Biotech treated as "normal" ingredient no different than others.	Non-Disparaged Low-Level Presence Ingredient	Mild Contaminant	Contaminant	Contaminant	Contaminant	Contaminant
Summary	**116 Countries (including our main trading partners, Canada and Mexico). Indicates support, trust, acceptance and fostering of biotechnology and biotech crop ingredients. Results in lower ingredients costs and consumer savings.**	**Japan, South Africa, Indonesia, Vietnam, and Thailand have 5% mandatory labeling thresholds. Canada and Hong Kong have 5% voluntary thresholds. The grain trade in Canada allows a 5% low level presence of biotech. This approach is the most supportive of biotech of the mandatory thresholds. The lowest cost approach and results in consumer savings. USDA Organic allows up to 5% non-organic ingredients. (Sugar and some other highly refined products are not required to be labeled in Japan, Thailand, and Indonesia)**	**Nigeria has mandatory labeling and draft legislation with a 4% threshold. The actual effects are unclear because the threshold is in draft form. In general, as biotech thresholds are less strict the associated costs go down.**	**Malaysia and Taiwan have a 3% threshold. This level generally results in lower prices for consumers and fosters the development of biotech. (Malaysia does not require labeling of highly refined products, including sugar).**	**Australia, New Zealand, Brazil, and Saudi Arabia have 1% thresholds. Australia and New Zealand (like the United States) don't require labeling if GE DNA is not present (highly refined foods such as sugars and oils). (Australia and New Zealand exempt sugar and other highly refined products from labeling)**	**The 28 EU Member States, Russia, Ecuador, Botswana, Bosnia and Herzegovina, Iceland, Norway, Switzerland, Turkey, Belarus, Kazakhstan, Armenia, Kyrgyzstan, and Ukraine have a .9% GE or GE-Derived Threshold. These countries generally shun GE crops and GE technology. This results in higher food costs to consumers. The thresholds are based on fear (precautionary principle) and not science. The current situation of the EU with very little cultivation of GE plants but high imports is not expected to change in the medium term. On July 3, 2016, Russia adopted FL 358-FZ, which prohibits the cultivation of genetically engineered (GE) plants. Regulations used as a non-tariff trade barrier to imports.**	**China is generally anti-biotech and as of December 30, 2016 had not approved any major food crops for cultivation or approved any GE food or feed crops developed by foreign biotechnology firms for domestic commercial production However, it is the world's largest importer of GE crops and one of the largest producers of GE cotton in the world. Government officials cite lack of public acceptance as an important factor behind the slow pace of biotechnology commercialization in China. Increases food costs. (Sugar and some other highly refined products are not required to be labeled in China and S. Korea)**

COUNTRIES WITHIN LABELING APPROACH CATEGORIES

	The United States Government recognizes 195 countries. **116** countries don't have mandatory labeling requirements. Afghanistan Albania* (A candidate for admission into the EU and if accepted would adopt EU standards) Algeria Andorra Angola (No labeling laws but limits GE products to food aid) Antigua and Barbuda Argentina Azerbaijan The Bahamas Barbados Belize Bhutan Brunei Burma Burundi Cabo Verde Cambodia Canada Central African Republic Chad Chile Comoros Congo (Brazzaville) Congo (Kinshasa) Costa Rica Côte d'Ivoire Cuba Djibouti Dominica Dominican Republic Egypt Equatorial Guinea Eritrea Fiji Gabon Gambia Georgia Ghana Grenada Guatemala Guinea Guinea-Bissau Guyana Haiti Holy See Honduras Iran	Indonesia "Food registration procedures require a Genetically Modified Organism (GMO) or non-GMO statement for food containing potatoes, soybeans, corn, and their derivative products. This sometimes confuses BPOM officials when approving entry permits for these types of food. For example, BPOM regulations require that product derivatives which have undergone further refining **processes to the point where the GE material cannot be identified (to include but not limited to oils, fats, sucrose, and starch**) do not require any non-GMO statements. Japan (Eight crops – vegetables -fruits (soy, corn, potato, canola, cotton seed, alfalfa, beet, and papaya) and thirty-three processed foods that include more than 5% of these eight foods in weight are subject to labeling. The 5% tolerance applies only to GM varieties that have been approved in Japan." Beet sugar from GE sugarbeets is exempt from labeling. Other citation South Africa The Consumer Protection Act of 2011 has a 5% threshold but is on hold. Thailand Labeling: As for processed food containing GE plant materials, the Ministry of Public Health lists 22 food products which are subject to labeling requirements when the contents exceed the five percent tolerance threshold. Sugar is not included on the list. Vietnam On November 23, 2015, the government issued detailed guidance for the labeling of pre-packed GE foods with at least one GE ingredient having a content of **five percent** or higher of the total ingredients forming the product. Canada-(Voluntary Threshold)	Nigeria "Work in progress draft regulation stipulates products with four percent GE content to be labelled GM."	Taiwan **Not on the official country list of the US Government.** Taiwan Has a three percent GE threshold and expanded requirements to highly processed products which are primarily made of GE raw materials, such as oils and starches, where transgenic fragments or proteins may not be detected. Malaysia. In April 2013, Food Safety and Quality Division of the Ministry of Health (MOH) published new "Guidelines on Labeling of Foods and Food Ingredients Obtained through Modern Biotechnology." As of December 2016, it was still not implemented. Key elements 1) If the GE content is not more than three percent, labeling is not required, "provided that this presence is adventitious or technically unavoidable." 2) For single ingredient foods, the words "genetically modified (name of the ingredient)" must appear in the main display panel. 3) For multi-ingredient foods, the words "produced from genetically modified (name	Brazil Consumers must be informed when more than 1% of a product marketed as food for human or animal consumption contains or is produced from GMOs. Law passed in 2005. Australia/New Zealand "Exemptions from GM labelling: GM foods that do not contain any novel DNA or novel protein, and do not have an altered characteristic, do not require GM labelling. The decision not to label these foods was made because the composition and characteristics of these foods is exactly the same as the non-GM food. **These foods are typically highly refined foods, such as sugars and oils, where processing has removed the DNA and protein from the food, including novel DNA and novel protein**."). Labelling is also not required when there is no more than 1% (per ingredient) of an approved GM food unintentionally present in a non-GM food. This means labelling is not required when a manufacturer genuinely orders non-GM ingredients but finds that up to 1% of an approved GM ingredient is accidentally mixed with the non-GM ingredient. GAIN Report Saudi Arabia If a product contains one or more GE plant ingredients with more than 1% GE content, the words (genetically modified) or (produced from genetically modified, name of the	EU (applies to all 28 member states)-**Not Cumulative** "genetically modified" or "produced from genetically modified [name of the organism]" must appear clearly next to the ingredient list. When GMOs are found in minute amounts in conventional food due to their adventitious or technically unavoidable presence during cultivation, harvest, or transport, the food is not subject to labeling provided that the amount present is less than 0.9%). Until the 1990's, the European Union (EU) was a leader in research and development of biotech plants. Under pressure from anti-biotech activists, EU and Member State (MS) authorities have developed a complex policy framework that has slowed down and limited research, development, and commercial production of biotech products. Due to repeated destruction of test plots by activists, programs are often limited to basic research inside laboratories and, in the past few years, several major private developers have moved their research operations to North America. Commercial cultivation of GE crops is minimal in the EU, as a result of strong regulatory constraints. The current situation of the EU with very little cultivation of GE plants but high imports is not expected to change in the medium term. Russia On July 3, 2016, Russia adopted FL 358-FZ, which prohibits the cultivation of genetically engineered (GE) plants and the breeding of genetically engineered animals in the territory of the Russian Federation. In addition, FL 358-FZ provides for stronger state monitoring and control of the processing and the importation of GE organisms and products derived from such organisms, and sets penalties for violations of this federal law. Products must be labeled if the presence of GE lines is over 0.9 percent. Journalists in Russia often report of consumer concerns with GE products. It is worth noting that labeling requirements increase the price of food containing GE ingredients. The price of examining products for the presence (or absence) of biotech components is high because the approved methods of testing are expensive. It is rare to find a "GMO" label in Russia. There currently is no ban on the registration of GE crops/lines/traits for imports for food and feed. However, Russia does not permit the importation of GE planting seeds. Therefore, U.S. exports of GE planting seeds to Russia are not allowed, and registration of GE lines in imports for processing into food and feed has become more and more difficult. Ecuador (contains or derived from) Botswana (No USDA citation available. Link to Botswana Investment & Trade Centre Information "You May Have to Show: Warnings, if they apply to your product: if the product contains GM ingredients, unless their presence is accidental and 0.9% or less " Bosnia and Herzegovina	China China's revised Food Safety Law, which entered into force on October 1, 2015, incorporates the existing regulations on biotechnology labeling into law (see GAIN Report CH15016). China's biotechnology labeling regulations, governed by MOA Decree 10 (see GAIN Report CH7053), require the labeling of approved agricultural biotech products, and prohibit the importation and sale of any unlabeled or mislabeled products. The 2015 Food Safety Law codifies into law existing biotechnology labeling regulations. The types of products subject to mandatory labeling include (list does not include sugar or cottonseed oil): 1. Soybean seeds, soybeans, soybean powder, soybean oil, and soybean meal 2. Corn seeds, corn, corn oil, and corn powder 3. Rapeseed for planting, rapeseeds, rapeseed oil, and rapeseed meal 4. Cottonseed 5. Tomato seed, fresh tomato, and tomato paste. **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."** S. Korea Recently expanded their law. Expansion of mandatory biotech labeling to all detectable products (i.e. detectable biotech proteins): Under the previous Act, biotech labeling was required for products that contain detectable biotech component as one or more of the top five ingredients. However, the new Act requires biotech labeling for products that contain any detectable biotech Soy, corn, cotton, canola, sugar beet, and alfalfa and food products containing these crops are subject to biotech labeling requirement. The same requirement applies to both domestic and imported products. even for a minor ingredient. **However, exempts highly refined products such as cooking oil, sugar, soy sauce, etc. No supporting document is required to get exempted from biotech labeling requirements for the listed products. (allows 3% unintentional presence for unprocessed foods).** Ethiopia "Foods made with GE ingredients must carry a label with the following statement: 'genetically modified food'." Cameroon India On June 5, 2012, the government stipulated "every package containing genetically modified food shall bear at the top of its principal display panel the word

	Iraq Israel Jamaica Jordan* (Listed by some sources as having GE labeling laws but the USDA states they have not yet been adopted) Kiribati North Korea Kosovo* (A candidate for admission into the EU and if accepted would adopt EU standards) Laos Lebanon Lesotho Liberia Libya Liechtenstein Macedonia* (A candidate for admission into the EU and if accepted would adopt EU standards) Madagascar Malawi Maldives Marshall Islands Mauritania Mexico Micronesia Moldova Monaco Mongolia Montenegro* (A candidate for admission into the EU and if accepted would adopt EU standards) Namibia Nauru Nepal Nicaragua Niger Pakistan Palau Panama Papua New Guinea Paraguay Philippines Rwanda Saint Kitts and Nevis Saint Lucia Saint Vincent and the Grenadines Samoa San Marino Sao Tome and Principe Seychelles	**USDA Organic May contain, up to 5%: a. nonorganically produced agricultural ingredients which are not commercially available in organic form**		of the ingredient)" should appear in list of ingredients and "contains genetically modified ingredient" must be stated on the main display panel. 4) Highly refined foods, **defined as those where processing has removed all novel DNA and protein, are exempt from labeling requirements (refined oil, sugar, corn syrup, honey and dextrin).** 5) Meat from animals fed with GE grains do NOT need to be labeled. 6) Only GE crops that have been approved by NBB can be used for foods and food ingredients.	ingredients) shall appear clearly and easily to read in parentheses immediately following the ingredient(s) concerned, with same font size and different color. ("no retail packed food products with positive biotech labeling have been imported into the Kingdom to date. In general, Saudi importers of retail-packed food products do not import foods with GE content over 1 percent that requires labeling. They are concerned that biotech labeling could jeopardize their product image and result in losing market shares, since Saudi consumers have limited knowledge about agricultural biotechnology.")	Iceland Norway-(.9% for approved products and .5% for products that have not undergone risk assessment) Switzerland Turkey Belarus Kazakhstan Armenia Kyrgyzstan Ukraine Non-GMO Project "Preserving and building the non-GMO supply chain is a critical step of transitioning toward a safe, healthy food supply for future generations." Mission statement is to also "change the way our food is grown and made."	"GM." Industry sources report that there has been no enforcement of the labeling requirement by DCA. As the government is still in the process of establishing labeling regulations for GM foods, the future status of the DCA GM labeling regulation remains uncertain. Mozambique "Compulsory labeling of GE products or food containing GE ingredients is necessary based on the Mozambique Biosafety Legislation." El Salvador "Labeling for food products that contain GEs is required under Article 128 of the Consumer Law; however, this rule is currently not being enforced." Peru Has moratorium on planting of biotech crops. The moratorium includes three exceptions: 1) laboratory research; 2) use in pharmaceuticals and veterinary products; and 3) use in food, animal feed and in food processing. Mandates the labeling of GE content products Zero tolerance. Peru has yet to establish a threshold level of detection, nor has it clarified scientific and technical considerations for standards settings. Bolivia (no USDA citation available so link to Commerce) Colombia The MHSP issued regulatory Resolution 4254 establishing the requirements for labeling of food derived from modern biotechnology in 2012. The resolution requires labeling information for product health and safety, such as potential allergenicity. Labeling must also address the functionality of the food, as well as the identification of significant differences in the essential characteristics of the food. In addition to Resolution 4254, the Colombian government drafted a Technical Annex to supplement the Resolution, but the Annex is still in internal discussion within the MHSP. There remains no indication when the Annex will be finalized and published/notified. Tunisia "Tunisia's Ministries of Trade and of Public Health published a joint order on September 3, 2008 (Art. 7) calling for mandatory labeling of all GE food ingredients and products. However, this law is not clear on what types of products are covered or the percentage of GE material that is allowed. There is also no clear understanding of which entity is responsible for enforcement." Mauritius Bahrain Kuwait Oman

	Sierra Leone Singapore Solomon Islands Somalia South Sudan Sudan Suriname Swaziland Syria Tajikistan Tanzania Timor-Leste Togo Tonga Trinidad and Tobago Turkmenistan Tuvalu Uganda Uruguay Uzbekistan Vanuatu Venezuela Yemen Zambia Zimbabwe						Burkina Faso "The biosafety law requires that any GE product intended for distribution or marketing on the national territory must be packaged and labelled in an indelible and non-modified manner in order to ensure the protection of ethical and cultural values and to avoid any risks for the environment as well as human and animal health. Also, all GE product developed on the national territory shall be packaged and labelled by the producer or the dispatcher with the indication "Produced on the basis of genetically modified organisms" or "Containing genetically modified organisms" in conformity with complementary standards defined by the competent national authority in cooperation with other departments concerned. The terms of labelling are established on the basis of a decree adopted by the Council of Ministers. Oman" Senegal "The law states that all GE products used for direct animal or human food or for transformation or introduction into the environment should be labeled 'contains GMOs'." Mali "The law has provisions covering the import, export, transit, contained use, and release or introduction into the market of any GE products, be it for pharmaceutical, food feed or other agricultural proposes. There is also provision in the law for mandatory labeling for all products made from GE." United Arab Emirates Qatar Bangladesh **USDA Organic- From Policy Memo April 15, 2011 "Compliance with the organic standards entails that operations have verifiable practices in place to avoid contact with GMOs. Since organic certification is process-based, presence of detectable GMO residues alone does not necessarily constitute a violation of the regulation. The inadvertent presence of genetically modified material does not affect the status of the certified operation and does not result in loss of organic status for the organic product."** **TOTAL BANS (5)** Morocco **has a total GMO Ban:** Morocco neither produces nor allows importation of agricultural products derived from biotechnology for human consumption. 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 tolerates biotech products for use in its animal feed sector, but bans genetically engineered (GE) products for human consumption. Kenya On December 1, 2016, Kenya's National Assembly Agriculture committee recommended that the import ban on GE products be upheld until a new legislation on food safety of GE foods for human consumption is developed. Kenya does not commercially produce GE crops or GE seeds. No plants are registered for cultivation, import and export in Kenya. Benin "Although the government of Benin has ratified the Cartagena Protocol in March 2005 and established a National Biosafety Committee, if Benin still enforces a moratorium prohibiting the production, sale and import of biotech crops and foods. Serbia "Serbia strictly prohibits all imports, production, and commercial growing of genetically engineered (GE) crops or products containing GE traits. Sri Lanka According to the Ministry of Healthcare and Nutrition's Food (Control of Import, Labelling, and Sale of Genetically Modified Foods) Regulation 2006, Sri Lanka prohibits the import, sale, storage, and distribution of any genetically engineered (GE) or GE-derived products for human consumption. This includes any food item containing GE materials, or any food product which contains GE-derived ingredients."