United States Beet Sugar Industry

July 3, 2018

United States Department of Agriculture
Agricultural Marketing Service
Docket Clerk
1400 Independence Avenue, SW
Room 4543 - South
Washington, DC 20250

Submitted via www.regulations.gov

RE Proposed Rule – National Bioengineered Food Disclosure Standard – Doc. No. AMS-TM-17-0050 (83 Fed. Reg. 19860 (May 4, 2018))

Dear Sir/Madam:

The attached comments are submitted 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 comment on the USDA Agricultural Marketing Service's ("AMS") proposed rule to implement the National Bioengineered Food Disclosure Standard, Pub. L. 114-216, (the "NBFDS" or "Act"). We applaud AMS for attempting to address stakeholders' competing views on the scope of the NBFDS by setting forth a number of options for the final rule. Our overriding concern, however, is that some of the options being considered, if adopted, have the potential to harm the U.S. Beet Sugar Industry and stifle American farming innovation by presuming that foods like beet sugar contain genetic material[1] when sound science shows they do not. Above all else, AMS must ensure that the NBFDS is a marketing standard, not a health, safety, or nutritional standard. Congress expressly recognized that "the

[1] We support AMS's proposed definition of "bioengineered substance" that incorporates the statutory definition of ''bioengineering,'' which means ''matter 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." Throughout this comment we refer to the statutory term "genetic material" to mean "bioengineered substance" as AMS proposes to define that term.

comprehensive federal review process has determined that foods produced using bioengineering are safe and not materially different in any way from those made using other methods."[2]

As members of the Coalition for Safe Affordable Food we support many of the Coalition's comments and recommendations on the NBFDS. However, we are not aligned with the Coalition on several issues of critical importance to the U.S. Beet Sugar Industry, most importantly on the Coalition's position that AMS should not exclude refined ingredients under Position 1 and instead adopt Position 2 with the undetectable DNA factor and condition. Creating any presumption, even unintentionally, that beet sugar produced from transgenic sugarbeets is different and less desirable than its conventional counterparts or cane sugar is not supported by science, is contrary to the intent of the NBFDS, imposes a costly and discriminatory burden on the industry, and has harmful economic impacts throughout the supply chain. It also creates consumer confusion and increases consumer prices for identical products. As we explain in detail herein, for these reasons we urge AMS to exclude highly refined ingredients, and in particular refined sugar, from the scope of the NBFDS.

We also strongly disagree with the Coalition's recommendation to create a voluntary labeling program that would allow on-package labeling for non-BE Food products, such as beet sugar, with text such as "derived from" or "sourced from" a bioengineered crop. As we discuss in section V herein, any such "derived from" text was expressly rejected by Congress and is misleading to the consumer because it fails to fully explain that while a product may be derived from a bioengineered crop the food itself is not bioengineered.

Finally, we disagree with the Coalition's proposal that AMS adopt a dual threshold comprised of a 0.9% threshold for intentional presence, as measured in the finished food product, and a 5% threshold for unintentional presence, as measured by a particular ingredient. Rather, we urge AMS to adopt Alternative 1-C, allowing the intentional use of BE ingredients up to 5% of the weight of the finished product 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.

Respectively submitted,

American Sugarbeet Growers Association

U.S. Beet Sugar Association

Amalgamated Sugar Company

American Crystal Sugar Company

Big Horn Basin Beet Growers Association

Big Horn County Sugar Beet Growers Association

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[2] S. Rep. No 114-403 (2016 ("Senate Report") at 2.

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
Red River Valley Sugarbeet Growers Association
Sidney Sugars, Inc.
Spreckels Sugar Company
Southern Minnesota Sugar Cooperative
Southern Montana Sugarbeet Growers Association
Western Sugar Cooperative
Wyoming Sugar Company, LLC
Beet Sugar Development Foundation
American Society of Sugar Beet Technologists
Sugar Industry Biotech Council

United States Beet Sugar Industry

Comments on National Bioengineered Food Disclosure Standard Proposed Rule

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EXECUTIVE SUMMARY

In enacting the NBFDS, Congress expressly defined a bioengineered food ("BE Food") as one that "contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature" and provided guiding principles for its implementation, which include that:

(1) the NBFDS not treat bioengineered food differently than its non-bioengineered counterpart,

(2) AMS "take every effort to minimize the impacts [of the NBFDS] on growers, handlers, processors, manufacturers, distributors, retailers and consumers,"[3]

(3) AMS minimize the impacts on all aspects of the domestic and international value chain,[4] and

(4) AMS provide "exemptions and other determinations under which a food is not considered a bioengineered food."[5]

Adhering to these principles, we discuss in detail below the following points and recommendations:

- **AMS should not include refined ingredients in the definition of a BE Food (Position 1).**[6] Position 1 is supported by numerous scientific studies demonstrating the absence of genetic material from sugar and AMS's own economic analysis showing that excluding refined sugars and oils from the definition of a BE Food would not reduce the number of

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[3] Senate Report at 8.

[4] *Id.*

[5] *Id.*

[6] AMS continues to refer to processed sugars and oils as "highly refined ingredients." However, 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." *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). For these reasons, we urge USDA to use the term "refined ingredients" when referring to single food components such as sugar.

foods subject to disclosure and would be far less costly than requiring product testing to prove the absence of genetic material.

- **If AMS is not inclined to exclude refined ingredients as a group from the definition of a BE Food under Position 1, AMS should at a minimum exclude refined sugar from the definition**. AMS has before it seven published peer-reviewed studies demonstrating the lack of genetic material in refined sugar, as well as testing results from each of the 22 U.S. and one Canadian beet sugar processing factories showing there is no transgenic DNA or protein in the refined sugar extracted from transgenic sugarbeets. This body of science is conclusive and is more than sufficient for AMS to exclude refined sugar from the definition of a BE Food under Position 1. Australia, New Zealand, Japan, Malaysia, South Korea, and Brazil have all relied on this well-established body of science to conclude that refined sugar does not contain genetic material and therefore is not subject to their mandatory BE labeling laws.

- **If AMS is inclined to include refined ingredients in the definition of a BE Food under Position 2, AMS must adopt the undetectable DNA factor and condition.** Including highly refined ingredients, and particularly beet sugar, in the definition of a BE Food without providing a mechanism to exclude products that do not contain genetic material is contrary to Congress's express intent that the NBFDS apply only to foods that contain genetic material. It also treats a food like beet sugar differently than its non-bioengineered counterpart when they are molecularly identical. Disparate treatment of identical products is discriminatory, misleading, and has significant economic impacts on consumers, growers and the entire supply chain.

- **AMS's proposed list of BE Foods confuses BE Foods and crops and creates a presumption that foods "derived from" certain crops are BE Foods contrary to Congress's intent that a bioengineered food "contain genetic material."** We understand and support AMS's objective to create an easily referenced list to facilitate compliance with the NBFDS. However, creating lists of highly adopted and not highly adopted BE Foods by reference to bioengineered crops, which is intended to serve as the "linchpin" for determining whether a regulated entity needs to disclose a BE Food, is not only contrary to Congress's intent that a BE Food contain genetic material, it renders Position 1 and the undetectable DNA factor and condition superfluous. Rather, AMS should adopt a BE ingredient list. Exhibit 2 of the RIA, modified to reflect ingredients excluded from the scope of the NBFDS, i.e., refined ingredients, enzymes, is an easy to understand list that would facilitate compliance with the NBFDS without creating false presumptions or contravening the intent of the NBFDS that a BE Food is one that contains genetic material. Alternatively, AMS could use Table 5 from the RIA which lists the top 50 ingredients that would likely trigger disclosure, provided it eliminates from the list those products excluded from the definition of a BE Food, e.g., sugars, oils, enzymes. This is a far better way for regulated entities to make disclosure decisions because most food manufacturers, and especially small food manufacturers, do not know what crops many ingredients are derived from. The RIA itself supports this approach.

- **If AMS maintains its lists of highly adopted and not highly adopted crops, AMS should remove sugarbeet from the list.** The sugarbeet is not a food within the meaning of the NBFDS; it is grown only for the purpose of producing refined sugar, which under any reading of the NBFDS cannot be considered a BE Food for human consumption. The sugarbeet is the only transgenic crop that produces a single food for human consumption that is conclusively shown, in multiple independent studies, to not contain genetic material. Thus, including the sugarbeet on the list of highly adopted BE Foods creates a false and misleading presumption that refined sugar is a BE Food subject to the mandatory disclosure requirements. Creating a false presumption is contrary to the express will of Congress, is discriminatory and misleading, and has harmful effects to consumers, the industry and throughout the supply chain.

- **If AMS is inclined to address voluntary claims for foods that are not within the definition of a BE Food, AMS should not endorse on-package claims that ingredients are "derived from" or "sourced from" BE crops.** We support food manufacturers' desire to be transparent and disclose additional information concerning ingredients that are not BE Foods under the NBFDS. If AMS is inclined to create any safe harbors, which is not the intent of the law or within the scope of the proposed rule, or provide guidance for such claims, endorsing on-package claims that ingredients are "derived from" or "sourced from" BE crops would create confusion as consumers would presume that sourced or derived from means the food is bioengineered. Not only would this be misleading to consumers, it would defeat Congress's objective to achieve national uniformity in the labeling of BE Foods. Rather, if sourced or derived from claims are made, they should be provided through other means, such as an electronic or digital link, that allows complete and truthful information to be provided.

- **AMS should adopt a 5% threshold that allows for the intentional use of small quantities of BE ingredients.** The threshold AMS establishes impacts how biotechnology is viewed by consumers and global trading partners. A 5% threshold 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% (low level presence) of non-organically produced agricultural ingredients.

I. AMS SHOULD ADOPT POSITION 1 AS THE DEFINITION OF A BIOENGINEERED FOOD

The Preamble to the proposed rule discusses two competing views on whether refined foods, such as refined sugar, should be included within the scope of the NBFDS and invites comment on three specific issues: (1) additional studies that address the presence of genetic material in refined foods, (2) the cost of implementation, including whether the scope of foods subject to the NBFDS would lower costs to affected entities, and (3) which position is the better interpretation of the statutory definition. We address each of these issues below to demonstrate that AMS should adopt Position 1 because it is grounded in science, does not impose unnecessary and unreasonable economic burdens on consumers, food manufacturers, supply chain distribution and transportation systems, or the beet sugar industry, does not decrease the number of foods subject to the NBFDS, and is the better interpretation of the statutory definition of a bioengineered food.

A. The Science is Conclusive: Refined Sugar Produced from Transgenic Sugarbeets Does Not Contain Genetic Material and Therefore Should Be Excluded from the Definition of a BE Food

Refined sugar is defined by FDA as sucrose obtained by crystallization from sugarcane or sugarbeet juice that has been extracted by pressing or diffusion, then clarified and evaporated, which is of a purity suitable for its intended use.[7] In the United States, cane and beet sugar is refined to a purity of 99.9%, thus removing all impurities, including genetic material.[8] For this reason alone, creating any presumption that refined sugar is a BE Food is erroneous. Moreover, the numerous studies discussed below confirm that refined sugar does not contain genetic material.

1. *The Peer-Reviewed Scientific Literature Establishes the Lack of Genetic Material in Refined Sugar*

AMS correctly cites to a number of studies that demonstrate the absence of genetic material in refined sugar. These include a study conducted by German scientists that examined 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. (Klein, J., *et al*. 1998).[9] This study is particularly important because it not only failed to detect DNA and protein beyond the early raw juice stage of the

[7] 21 C.F.R. § 184.1584.

[8] The remaining 0.1% is made up of carbohydrates such as glucose, fructose and raffinose, as well as organic and inorganic salts of sodium, potassium, calcium and magnesium.

[9] 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).

refining process, it estimated that the beet sugar clarification process had the potential to reduce the amount of sugarbeet DNA by a factor of ten to the fourteen (a hundred trillion or 0.00000000000001), which exceeds the total amount of DNA present in sugarbeets. AMS also cites to Oguchi, *et al*. (2009) that also found that sugarbeet plant DNA is degraded and removed early in the sugar extraction process and is therefore not present in the finished sugar.[10] The Oguchi study was the basis upon which Japan exempted beet sugar from its mandatory GMO labeling requirements.[11]

With respect to sugar produced from sugarcane, AMS correctly cites to Joyce, *et al*. (2013) and Taylor *et al*. (2009) demonstrating the absence of genetic material in refined cane sugar.[12] In addition, Pauli *et al*. (2000), did not find DNA in either raw or refined cane sugar.[13]

The science is further confirmed by a study published in March 2018. (Cheavegatti-Gianotto, *et al*. 2018).[14] Specifically, Brazilian researchers examined whether sugar produced from sugarcane genetically modified to express the Cry1Ab protein to control the sugarcane borer (*Diatraea saccharalis*) contained transgenic material. The study found that clarified juice, molasses, and raw sugar showed no detectable levels of Cry1Ab protein. Similarly, no heterologous DNA was detected in clarified juice and downstream products including raw sugar. As the researchers conclude, the results are in agreement with the results of other studies that

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[10] 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.

[11] 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 transgenic sugarbeets s to be labeled because the refined sugar 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.

[12] Joyce, P.A., Dinh, S-Q., Burns, E.M., and O'Shea, M.G. (2013), "Sugar from genetically modified sugarcane tracking transgenes, transgene products and compositional analysis," Proc. Int. Soc. Sugar Cane Technol." Vol. 28, pp 1-9; Joyce, P.A., Sedl, J.M. and Smith, G.R. (1999), "Laboratory crystallized sugar from genetically engineered sugarcane does not contain transgene DNA", Proc. Aust. Soc. Sugar Cane Technol., Vol. 21, pp. 502.

[13] Pauli *et al* (2000) Extraction and Amplification of DNA from 55 Foodstuffs. Mitt. Lebensm. Hyg. 91: 491-501.

[14] Cheavegatti-Gianotto, A., *et al*. "Lack of Detection of Bt Surgarcane CRY1Ab and Nptll DNA and Proteins in Sugarcane Processing Products Including Raw Sugar (2018), Frontiers in Bioengineering and Biotechnology, Vo. 6, Art. 24 (2018).

investigated the degradation of specific DNA fragments inserted into genetically modified sugarcane (NptII) and glyphosate-resistant sugarbeet (CP4 EPSPS) that reported the complete elimination of the inserted DNA during processing to refined sugar (Klein *et al*., 1998; Oguchi *et al*., 2009; Joyce *et al*., 2013). Brazil, as the largest producer of cane sugar, relied on the Cheavegatti-Gianotto study to determine that sugar produced from genetically modified sugarcane is a "chemically defined pure substance" that does not fall within the scope of Brazil's Biosafety Law and therefore "is not a genetically modified organism or a derivative thereof." The determination is attached as Attachment 1.

Importantly, the Brazilian study refutes any suggestion that the science is inconclusive about whether refined sugar contains genetic material. In the proposed rule, AMS cites Cullis *et al*. (2014)[15] as one study commenters claim shows that minute quantities of sugarcane DNA were detected in raw sugar (not for human consumption) after industrial milling prior to refining.[16] Commenters do not understand the sugar refining process and misinterpret the scientific findings.

Understanding the steps in the sugar refining process is critical to correctly interpreting the studies. The schematic in Figure 1 illustrates the steps in both the beet and cane refining processes and identifies the points in the process where studies have tested for genetic material. While there is some variability among the studies as to precisely when the DNA and protein are no longer detectable, largely based on the DNA extraction methods used, primer selection, and polymerase chain reaction ("PCR") conditions and fragment length, all studies demonstrate that the genetic material is removed early in the refining processes for both beet and cane sugar.

First, with respect to the Cullis study, as the schematic shows, raw sugar is not refined cane sugar. Raw sugar is produced at a sugar mill as the feedstock to the cane refining process. Raw sugar is not sold for human consumption in the United States. As FDA explains, raw sugar is "the intermediate food product as it leaves the sugar factory mill for further refinement in sugar refineries before use as food. In general, raw sugar is unsuitable for human food use because it contains extraneous impurities which are removed in the refining process."[17] At the refinery,

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[15] Cullis, C., Contento, A., Schell, M., DNA and Protein Analysis throughout the Industrial Refining Process of Sugar Cane. International Journal of Agricultural and Food Research, North America, 3, jul. 2014. Available at: https://www.sciencetarget.com/Journal/index.php/IJAFR/article/view/437.

[16] AMS also cites to one study that purports to have found genetic material in all stages of crude soybean oil processing. We defer to the oil processors to address the merits of the study, but we observe that detection was only possible by using primer combination RRS-3J1 and RRS-3J3 to amplify the NOS terminator, which fall outside the coding region for EPSPS (the glyphosate tolerance gene).

[17] FDA's Compliance Policy Guide (CPG), CPG 515.400 (revised March 1995).

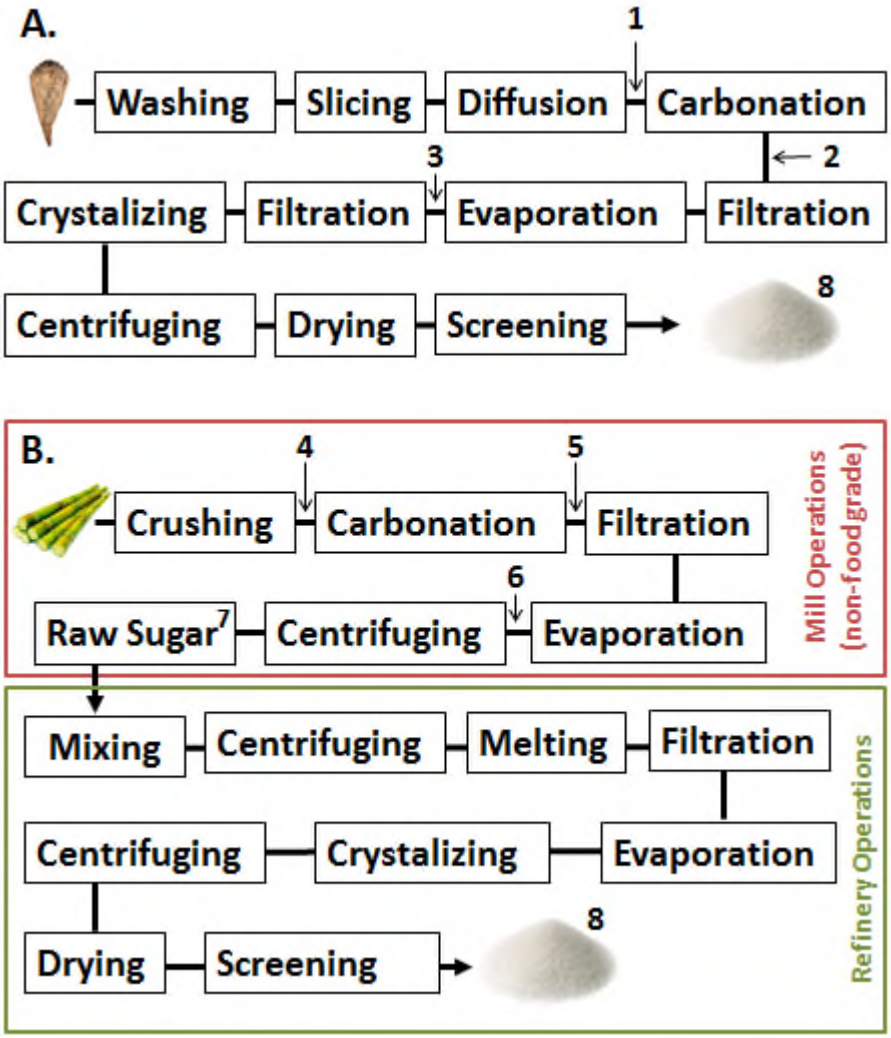
raw sugar undergoes a number of refining steps, including cooking, filtering, evaporation, crystallization, centrifuging, and drying to produce refined cane sugar.

Second, Cullis did not detect fully coding regions of DNA or functional proteins in raw sugar, but rather highly degraded fragments. For example, the PCR amplification of target sequences in raw sugar was only successful using 1 of 4 primer combinations with the shortest amplification length (less than 300 basepairs), suggesting the larger coding region was fragmented and therefore unable to be amplified. Further, regarding protein presence the authors explain "[raw sugar] showed little or no evidence of bands or high molecular mass material suggesting proteins in these fractions are fragmented" as well as the fact that a "…majority of staining material accumulated in a low molecular mass smear…further supports the conclusion that proteins in these later fractions may be significantly degraded."

Finally, and most importantly, as the Cullis study itself demonstrates, even if there is genetic material in the raw sugar, the refining process eliminates it altogether ("PCR failed to detect any sugarcane DNA in refined sugar.").[18] As Cullis concluded, the study's failure to detect DNA in the refined sugar is consistent with previous studies on the detection of DNA through the refining process (Joyce *et al*. (2013), Klein, *et al*. (1998), Oguchi, *et al*. (2009).

[18] Cullis, *et al*. at 14.

Figure 1 Schematic of Beet and Cane Refining Processing Identifying Points Where Samples Have Been Taken to Test for Genetic Material



Beet processing **(A)** occurs all in one food-grade facility. Cane processing **(B)** occurs in two separate facilities: the mill (red box) and the refinery (green box). None of the products produced by the cane mill are considered or handled as food grade products.

Samples at various points in the refining processes have been analyzed to evaluate the presence of absence of DNA/proteins. Those samples for sugarbeet (**A**) include: Raw Juice (**1**), Thin Juice (**2**), Thick Juice (**3**) and Refined Sugar (**8**). Samples for sugarcane (**B**) include: Raw Juice (**4**), Clarified Juice (**5**), Syrup (**6**) and Refined Sugar (**8**). None of the studies have found genetic material in Refined Sugar (**8**).

2. *Extensive Studies Conducted by the Beet Sugar Industry Establish the Lack of Genetic Material in Refined Beet Sugar*

AMS should also acknowledge three studies conducted by the beet sugar industry that similarly show the absence of DNA and protein in refined beet sugar. While these studies have not been published in the scientific literature, they were conducted using methodologies validated according to Codex Alimentarius guidelines by an ISO/ICE 17025 accredited laboratory. In the first study conducted in 2008 samples were collected from eight different points in the refining process [three samples each at the beginning (sliced beet, pressed pulp, dried pulp), middle (raw, thin, and thick juice, and end (refined sugar and molasses)] at one processing facility. The study demonstrated that while transgenic DNA and the CP4-EPSPS protein[19] was detected in the raw sugarbeet and the raw juice (Point 1 on Figure 1), it was not detected at any other subsequent point in the refining process. Thus, consistent with Klein *et al*. (1998), 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. The study is provided in Attachment 2.

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.[20] No plant DNA was detected in any of the samples, thus again confirming the Klein *et al*. (1998) findings that the clarification process effectively removes *all* plant DNA (by a factor of 10^{14}). *See* Attachment 2.

In 2014, the Beet Sugar Development Foundation conducted a third study of all U.S. and Canadian 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 firm to test for any presence of transgenic DNA and the CP4-EPSPS protein. *All 69 samples of commercial sugar tested negative for transgenic sugarbeet DNA, as well as the CP4-EPSPS protein.* The results are provided in Attachment 3. This comprehensive study reaffirmed the 2008 study and is consistent with the scientific literature that shows that there is no transgenic DNA or protein in the sugar extracted from transgenic sugarbeets.

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[19] The CP4-EPSPS protein confers Roundup® tolerance to the H7-1 Roundup Ready® sugarbeet plant.

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

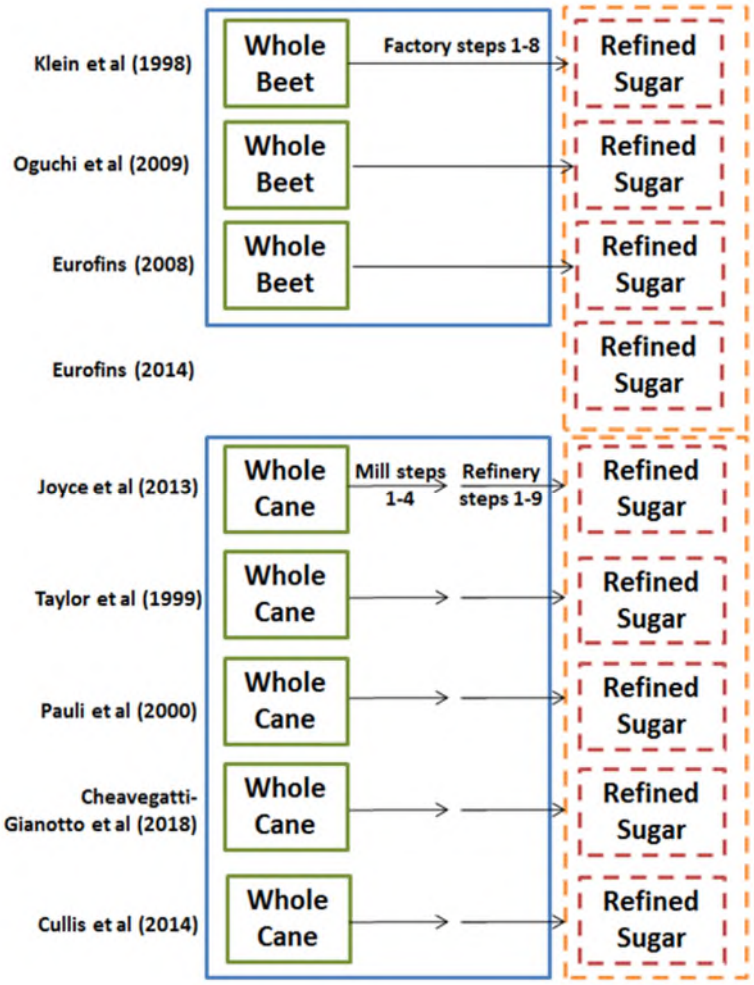
3. *Summary of the Science Supporting Excluding Refined Sugar from the Definition of a Bioengineered Food*

To negate any doubt or misunderstanding of the science, Figure 2 provides a visual summary of the studies examining DNA and protein degradation during the sugar refining process. Because the studies use various terms to refer to similar stages of the refining process, the stages are aligned vertically to provide consistency across studies.

Figure 2 shows that all studies conclude that refined sugar, which is 99.9 percent sucrose, does not contain DNA or protein. These findings are not only scientifically sound, they make logical sense. Any product that is refined to a purity of 99.9% under continuous high heat and in the presence of native nucleases will not contain extraneous impurities or genetic material. Indeed, Klein *et al*. (1998) and other researchers explain that these two factors are responsible for eliminating genetic material from refined ingredients. Even if it is assumed that the remaining 0.1% is genetic material, which it is not, refined sugar would not fall within the definition of a BE Food under AMS's strictest threshold (0.9%).

AMS therefore has before it seven peer-reviewed published studies demonstrating the lack of genetic material in refined sugar, as well as testing results from each of the 22 U.S. and one Canadian beet sugar processing factories showing there is no *transgenic* DNA or protein in the sugar extracted from transgenic sugarbeets. This body of science is more than sufficient for AMS to exclude refined sugar from the definition of a bioengineered food under Position 1. Australia, New Zealand, Japan, Malaysia, South Korea, and Brazil have relied on one or more of these studies to conclude the refined sugar does not contain genetic material and therefore is not subject to their mandatory BE labeling laws.

Figure 2 Visual Summary of Science Demonstrating Lack of Genetic Material in Refined Sugar



4. *There is No Rational Basis to Include Refined Sugar in the Definition of a BE Food and Exclude Other Food Products and Ingredients that May Contain Genetic Material*

AMS proposes to exclude from the definition of a BE Food incidental additives such as enzymes, which are bioengineered. The Coalition for Safe Affordable Food is also requesting that (1) incidental additives, processing aids, secondary direct additives; (2) food derived from insects or microorganisms that grow or feed on a bioengineered substrate, such as a bioengineered crop or other substance; (3) enzymes; (4) ingredients derived via fermentation regardless of whether the microorganisms used in the fermentation are derived using rDNA technology, and (5) food products with medicinal or supplementary applications be excluded from the definition of a BE Food, and (6) unpackaged BE Foods, e.g., bulk foods and fresh produce. Each of these proposed and requested exclusions are food products and ingredients that are likely, or in the case of bulk foods and fresh produce are certain, to contain genetic material. While we do not object to these food products and ingredients being excluded from the definition of a BE Food under the NBFDS, we are concerned that there is a willingness to exclude certain foods and ingredients that contain some level of genetic material, albeit small, but an unwillingness to exclude refined sugar from the definition of a BE Food when scientific evidence unequivocally demonstrates that refined sugar contains no genetic material at all. Such disparate treatment is not rationally related to the purpose of the NBFDS. Nor is it scientifically or legally justified.

We therefore request and urge that at a minimum AMS adopt Position 1 with respect to refined sugars in the event that AMS is not inclined to exclude refined ingredients as a group from the definition of a BE Food under Position 1.

Creating a presumption that sugar produced from transgenic sugarbeets is different and less desirable than its conventional counterparts is not truthful, is misleading to consumers, contrary to the purpose of the NBFDS, and has harmful economic impacts throughout the supply chain.

We therefore urge that section 66.1 of the regulations expressly exclude refined sugar as follows:[1]

Bioengineered food means—

(1) Subject to the factors, conditions, and limitations in paragraph (2) **and exclusions in paragraph** (3) of this definition, a food 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.

(2) A food that meets the following factors and conditions is not a bioengineered food.

(i) An incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3) or any successor regulation.

(ii) [Reserved].

(3) Refined sugar produced from bioengineered sugarbeets or sugarcane is not a bioengineered food.

B. Including Refined Ingredients in the Definition of a BE Food Imposes Unnecessary and Unreasonable Economic Burdens on Consumers, Food Manufacturers, Supply Chain Distribution and Transportation Systems, and the U.S. Beet Sugar Industry

In its Regulatory Impact Analysis ("RIA"), AMS analyzed three scenarios for the scope of the NBFDS: (Scope 1) all foods and dietary supplements that have been produced through bioengineering (including refined oils and sugars); (Scope 2) all foods and dietary supplements excluding sugars and oils; and (Scope 3) foods where the genetic material cannot be detected are excluded. As we understand it, Scope 2 equates to Position 1 described in the Preamble, Scope 1 equates to Position 2 without the adoption of the undetectable DNA factor and condition, and Scope 3 equates to Position 2 with the proposed undetectable DNA factor and condition.

The RIA demonstrates that Position 1/Scope 2 (excluding refined ingredients) does not result in fewer food products being subject to the NBFDS, nor does it impose unreasonable costs. However, the RIA's conclusion that the costs of Position 2/Scope 1 are the same as Position 1/Scope 2 does not consider all costs "stretching back to the farm" that would be incurred if refined ingredients like beet sugar were presumed to be a BE Food.

We show below that creating any presumption that beet sugar is a BE Food results in product deselection and price differentials. Our concerns about product deselection and price differentials are validated by a recent survey conducted by the International Food Information Council Foundation (IFIC),[21] which shows that "[a] majority of respondents (53%) say they are less likely to consume food if they know it contains BE ingredients."[22] Furthermore, consumers' willingness to pay for identical products with no-BE disclosure versus products with a BE disclosure decreased prices by up to 15%.[23] When the costs related to product deselection and price differentials are considered, Position 1/Scope 2 (excluding refined ingredients) is the lowest cost option. With respect to Scope 3 (the undetectable DNA factor and condition), the RIA confirms that it results in far fewer products being subject to the NBFDS and imposes far higher testing costs on the industry. For this reason alone, AMS should adopt Position 1 over Position 2 with the undetectable DNA factor and condition.

1. *Excluding Refined Ingredients from the Definition of a Bioengineered Food Does Not Decrease the Number of Products Subject to the NBFDS*

One of the principal arguments raised in opposition to excluding refined ingredients from the definition of a BE Food is that it would significantly decrease the number of foods subject to the

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[21] IFIC Foundation Survey (2018) available at https://www.foodinsight.org/sites/default/files/GMO-foods-survey-results-FINAL.pdf. IFIC surveyed 1002 respondents between May 18-27, 2018 regarding the proposed NBFDS;

[22] *Id*. at 11.

[23] *Id*. at 26 showing the price consumers were willing to pay for a product with no disclosure and an identical product with a BE disclosure was $2.96 and $2.51, respectively.

NBFDS. Some have even suggested there could 80 percent fewer products labelled as a bioengineered food. The RIA squarely refutes these claims.

As the RIA explains, the concept of nesting recognizes that most foods subject to the NBFDS are multi-ingredient foods, any one of which could potentially trigger disclosure under the NBFDS. The RIA therefore evaluated the number of food labels potentially subject to the NBFDS with and without refined sugars and oils included.[24] The RIA found that excluding refined sugars and oils did not result in any noticeable difference in the number of labelled products subject to the NBFDS.[25] The RIA further found that dietary supplements are even less sensitive to the exclusion of refined oils and sugars, finding that only 0.5% of products required to be labeled under Scope 1 would be excluded under Scope 2. In other words, refined sugars and oils are not the ingredients that drive disclosure.

In stark contrast, the RIA demonstrates that adopting the undetectable DNA factor and condition, which would apply to many more foods than just refined foods, results in only 45% of labels being be subject to the NBFDS. Indeed, Exhibit 2 of the RIA demonstrates that only 28 ingredients would be exempt under Position 1/Scope 2, while 98 ingredients would be exempt under Scope 3 (undetectable DNA).

Accordingly, excluding refined sugars and oils under Position 1 has no meaningful effect on the number of food labels subject to the NBFDS and therefore should not be a determining factor in AMS choosing Position 2 over Position 1. Adopting the undetectable DNA factor significantly reduces the number of food labels subject to the NBFDS and, as discussed below, imposes unnecessary costs.

2. *The RIA Does Not Address the Market and Agricultural Impacts that Flow from Presuming Refined Sugar is a BE Food Under Position 2/Scope 1*

The legislative history of the NBFDS 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*," as well as "minimize the impacts on growers, handlers, processors, manufacturers, distributors, retailers, and consumers.[26] Moreover, the NBFDS "is not intended to increase the costs of food manufacturing or changes in distribution or handling." Congress's intent that the NBFDS not disrupt domestic and international supply chains is reinforced by E.O. 13777, which established a federal policy to alleviate unnecessary regulatory burdens. Creating any presumption that beet

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[24] RIA at 51.

[25] *Id.* (finding that under Scope 1, 66% of labels would be subject to the NBFDS and under Scope 2, 64% of food labels would potentially be subject to the NBFDS).

[26] Senate Report at 4, 8.

sugar is a BE Food when it does not contain genetic material exacerbates impacts on growers, handlers, processors and the domestic and international value chain.

(a) The RIA fails to consider price impacts of presuming beet sugar is a BE Food under Position 2 when it is identical to all other refined sugar products

The RIA requests comment on the potential market reaction to the NBFDS and in particular, solicits evidence of market reaction to products presumed to be BE Foods. The impact of the Vermont law on beet and cane sugar prices illustrates the harmful impacts that will flow to the beet sugar industry if AMS adopts Position 2.

Historically, the wholesale price per pound of beet sugar and cane sugar has remained steady either with no price differential at all or a one cent or less differential. This is because the market has correctly viewed beet and cane sugar as interchangeable commodities, with prices driven largely by supply and demand. However, as the Vermont law was nearing implementation, the price differential between beet sugar and cane sugar grew substantially because the law required any foods derived from bioengineered crop to be labeled, which caused the market to view beet sugar less favorably.

The Vermont law was scheduled to become effective on July 1, 2016. Figure 3 demonstrates that prior to 2016, the price differential between beet and cane sugar was one cent or less. However, the price differential rose sharply beginning in March 2016 as manufacturers began making supply decisions based on the Vermont law mandating labeling and misleading disclosure text and negatively influencing consumer perceptions that beet sugar was a less desirable product. Indeed, it was well-publicized that one of the biggest sugar users, Hershey's, began reformulating its chocolate products to move from beet to cane sugar.[27] By February 2017, the price differential reached 7.5 cents per pound because of market substitution of cane sugar for beet sugar and concerns over whether cane supplies would be adequate to meet

[27] Hershey's response to consumer perceptions of GMOs demonstrates that manufacturers would substitute non-BE ingredients for BE ingredients where possible, either by using certified non-GE (including organic) forms of current ingredients, or reformulating products to use alternative ingredients that are not produced in GE forms. As in Europe, food processors and retailers are reluctant to offer for sale food with labels that may (a) frighten or otherwise dissuade some consumers, even though the label is not informative about food safety or the process used to produce it, and (b) provide a target for political action by groups opposed to BE Foods, whose stated intention is to take action if such foods are offered for sale. *See* Alston, Julian and Daniel Sumner, *Proposition 37 – California Food Labeling Initiative: Economic Implications for Farmers and the Food Industry if the Proposed Initiative Were* Adopted, Working Paper, September 3, 2012, http*://www.noprop37.com/wp-content/uploads/2014/09/Alston-Sumner-Prop-37-review.pdf.*

demand.[28] The price differential began decreasing in 2017 in response to the NBFDS and growing market confidence that beet sugar would not be considered a BE Food subject to labeling.

Today, the wholesale price differential between beet and cane sugar has returned to its historical levels of one cent or less per pound, with cane sugar priced at 37 cents per pound and beet sugar at 36 cents per pound.[29] However, if beet sugar is presumed to be a BE Food, even if only for a short period of time, the market reaction will be swift. 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. Already the Non-GMO Project label on some cane sugar brands and cane sugar-containing products is being used to suggest and mislead uninformed consumers that cane sugar and products containing it are different and more desirable than beet sugar.

Accordingly, we urge AMS to adopt Position 1 and, at a minimum, exclude refined sugar from the definition of a BE Food to avoid market discrimination that results in higher consumer prices and harmful impacts to the beet sugar industry.

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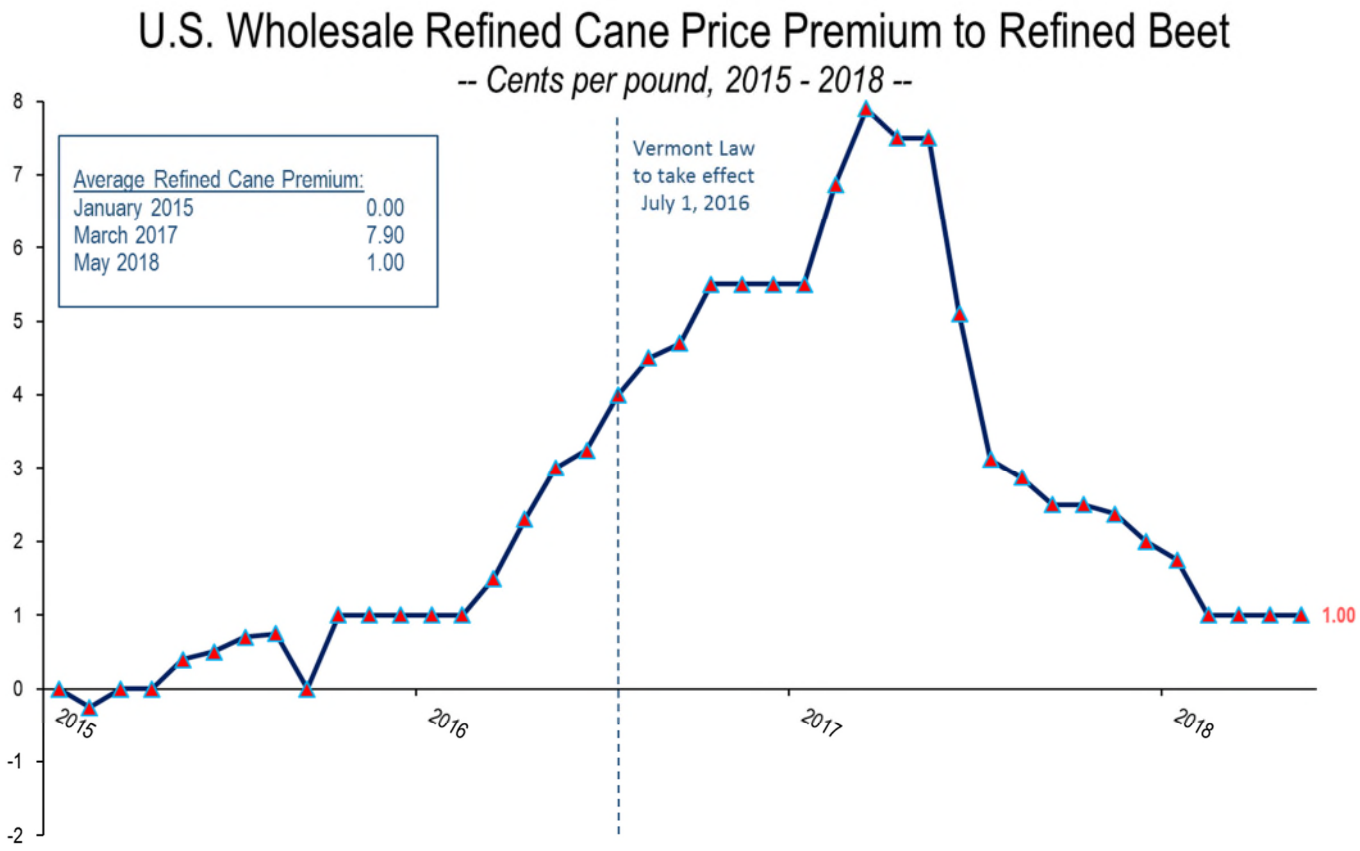
[28] *See also,* USDA, Economic Research Service, "Sugar and Sweeteners Outlook" (May 2016) at 5 (noting a "4.7 percent increase in cane sugar deliveries . . . [and a] 6.9 percent decrease in beet sugar deliveries").

[29] USDA, Economic Research Service, "Sugar and Sweeteners Outlook" (April 2018) at 8.

Figure 3 Price Differential Between Beet and Cane Sugar Due to the Vermont Law



Source: USDA. *Milling and Baking News*. Simple average of lower end of range of quotations for each month. Quotations are weekly. Wholesale refined beet sugar, Midwest markets; wholesale refined cane sugar, Northeast markets. Monthly average prices.

31-X2

(b) Presuming refined sugar is a be food results in supply chain distributions

The RIA addresses a number of impacts associated with manufacturer costs of replacing BE Food ingredients with non-BE Food ingredients to avoid labeling. While the RIA addresses segregation costs, it does not take into account many variables that drive up costs. For example, 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. In addition, private label sugar products for retailers often are supplied by both beet and cane suppliers providing sugar in the same retail package. To avoid different labeling requirements, products would need to be sourced from either the beet or the cane sector which would substantially reduce competition and drive-up costs to consumers. If sourced from both beet and can suppliers, bags of the same product would require different labels, which would also drive up costs. Not only does it disrupt the supply chain, it creates consumer confusion. We therefore believe that the RIA's estimate that segregation costs are 5% above BE market price is a low estimate.

(c) Presuming refined sugar is a be food harms the American farmer

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 the future viability of their bioengineered crops which have enabled farmers to adopt production

[30] "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.

practices that have significantly offset rising costs, including increases in diesel prices,[31] land costs,[32] water costs,[33] industrial energy supplies,[34] seed, fertilizers, and pesticides.[35]

If AMS creates any presumption that beet sugar is a BE Food, the costs stretching back to the farm will be far greater than the RIA estimates. Unlike other crops, there are no non-bioengineered sugarbeets grown for sugar production. Farmers would have to effectively start over to produce a non-bioengineered sugarbeet crop. Not only would all of the cost savings bioengineered sugarbeets provide be lost, the cost to start anew to produce a non-bioengineered sugarbeet would be 2-fold higher than they are today per ton of sugar produced. And, it would take years for farmers to obtain commercially available varieties, cultivars, and registered pesticides necessary to grow a crop. In other words, it would be cost and time prohibitive. This could cause farmers to seek other crop alternatives, which could lead to a major disruption in domestic sugar supplies. Beet sugar processing plants would not be able to run efficiently if there are not adequate supplies of sugarbeets.

Congress instructed AMS to make "every effort . . . to ensure that farmers have 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."[36] Adopting Position 2 creates a presumption that beet sugar is a BE Food which is very difficult to overcome in the market even if AMS also adopts the undetectable DNA factor and condition. As we discuss below, AMS's proposed list of BE Foods exasperates the presumption and harms the industry. The risks to the American farmer are far too great for AMS to ignore science and blindly adopt Position 2.

Moreover, impacting the American farmer is directly contrary to E.O. 13790, which established an interagency Task Force to "identify legislative, regulatory, and policy changes to promote in

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[31] US Energy Information Administration, "US Retail Diesel Prices," available at https://www.eia.gov/dnav/pet/hist/LeafHandler.ashx?n=PET&s=EMD_EPD2D_PTE_NUS_DPG&f=M.

[32] The price of land has increased from a national average of $1,830/acre to $3080/acre. *See* USDA, National Agricultural Statistical Service, "Land Values, 2017 Summary," (Aug. 2017), available at https://www.usda.gov/nass/PUBS/TODAYRPT/land0817.pdf.

[33] OECD, "Agricultural Water Pricing: United States," (2010) available at https://www.oecd.org/unitedstates/45016437.pdf.

[34] US Energy Information Administration, "Electric Power Monthly," (March 2018) available at https://www.eia.gov/electricity/monthly/epm_table_grapher.php?t=epmt_5_3.

[35] Univ. of Illinois, "Growth Rates of Fertilizer, Pesticide, and Seed Costs over Time," (July 2016) available at http://farmdocdaily.illinois.edu/2016/07/growth-rates-of-fertilizer-pesticide-seed-costs.html.

[36] Senate Report at 7.

rural America agriculture, economic development, job growth, infrastructure improvements, technological innovation, energy security, and quality of life."[37] In its first report, the Task Force expressly identified technological innovation as one key indicator of rural prosperity. Specifically, with respect to biotechnology, the Task Force noted:

> Biotechnology is another area of U.S. leadership, being a sector that has driven innovation in fuels, chemicals, manufacturing, and agriculture. In 2016, biotech crops were grown on over 170 million acres in the United States, including over 92% of corn, soybean and cotton total acreage, according to the Department of Agriculture's National Agricultural Statistics Service. Globally, the biotechnology sector is a driver of the 'fourth industrial revolution,' and presents and an incredible opportunity for American farmers and rural communities to thrive at the forefront of innovation.[38]

Any mandate that refined foods that do not contain genetic material be subject to the NBFDS undermines the advancement of technology for agricultural production in direct contravention of E.O. 13790. It also perpetuates the misinformation that 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.[39] Indeed, in making clear that the NBFDS 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."[40] If there were any safety concerns, FDA, not USDA, would act under its authority.

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[37] 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.

[38] Report to the President of the United States from the Task Force on Agriculture and Rural Prosperity (Oct. 2017), available at https://www.usda.gov/sites/default/files/documents/rural-prosperity-report.pdf.

[39] *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.

[40] Senate Report at 4.

(d) Including refined sugar in the definition of a be food impacts foreign beet and cane producers that adopt bioengineered technology to improve environmental impact and sustainability and disrupts international trade.

The United States is the third largest sugar importer in the world, providing 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 bioengineered 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. In March 2018, Brazil also determined that the sugar produced from the bioengineered sugarcane is a "chemically defined pure substance" that does not fall within the scope of Brazil's Biosafety Law and therefore "is not a genetically modified organism or a derivative thereof." *See* Attachment 1. Brazil is by far the largest sugarcane producer and exporter in the world and is the third largest supplier of raw sugar to the United States. 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.[41] These advances will provide many environmental benefits and increase long term sustainability, which food manufacturers are demanding to ensure sustainability throughout their supply chains. Misguided labeling schemes for refined ingredients, such as sugar, would inhibit such advances and should not be adopted by AMS.

If refined sugar is not excluded from the definition of a BE Food, international trade with Canada would be impacted. 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 refined sugar is considered a BE Food, 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 refined sugar is considered a BE Food, it would place unnecessary burdens on our trading partners and discourage the adoption of bioengineered crops that are more productive and environmentally sustainable.

[41] 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

For these reasons we urge AMS to adopt Position 1 with respect to refined sugars in the event that AMS is not inclined to exclude refined ingredients as a group from the definition of a BE Food under Position 1.

C. Position 1 Implements the Plain Language of the Statutory Definition of a Bioengineered Food

Agency interpretations of statutes they implement are generally considered under the two-part inquiry articulated in *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). First, if Congress has "directly spoken" to the question at issue," the unambiguous intent of Congress controls. *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 224 (D.C. Cir. 2001). If the statute is "'silent or ambiguous with respect to the specific issue," the agency's interpretation is given deference if it is reasonable. *Citizens Coal Council v. Norton*, 330 F.3d 478, 481 (D.C. Cir. 2003) (*quoting Chevron*, 467 U.S. at 843). Here, Congress unambiguously defined a bioengineered food as a "food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques." 7 U.S.C.§1639(1)(A). Congress thoughtfully, deliberately and intentionally did not extend the scope of the Act to include ingredients derived from bioengineered crops that do not contain transgenetic material.

The legislative history reinforces the plain language of the statute and makes clear that the definition of a bioengineered food set forth in the statute establishes the scope of the disclosure standard:

> "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 modification could not be otherwise obtained through conventional plant breeding or found in nature."[42]

Accordingly, refined foods that do not contain genetic material ***do not*** meet the statutory definition of a bioengineered food. As demonstrated by the science discussed in section I-A, refined sugar indisputably does not contain genetic material and therefore cannot be a bioengineered food within the scope of the NBFDS.

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

[42] Senate Report at 3.

USDA's General Counsel, which some incorrectly describe as a legal opinion. These groups are reading Member statements and the memo out of context. Nevertheless, they cannot supplant the plain language of the NBFDS.

There is no provision in the NBFDS where Congress gave the Secretary the discretion to rewrite the definition of a BE Food from a food that itself contains genetic material to any food derived from bioengineering, a definition Congress expressly rejected. Position 2 modifies the statutory definition of a BE Food by creating a presumption that refined ingredients like sugar are BE Foods because they are derived from BE crops. As discussed further below, AMS's proposed lists of highly adopted and not highly adopted foods amplifies the presumption and further contravenes the statutory definition of a BE Food. The presumption also renders superfluous Congress's direction that the Secretary "determine the *amounts* of a bioengineered substance" that may be present in food to be considered a BE Food because it creates a zero threshold. 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).

Even if the definition of a BE Food were considered ambiguous, which it is not, adopting Position 2 would be an unreasonable interpretation of the NBFDS for four reasons. First, it signals to the market that sugar produced from bioengineered sugarbeets is somehow different or less desirable than sugar produced from sugarcane contrary to Congress's direction that the NBFDS not treat bioengineered food differently from its non-bioengineered counterpart. As discussed in section I -B above, this leads to price differentials and harmful market impacts. *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.). Second, it creates chaos in the domestic and international supply chain contrary to Congress's direction that AMS minimize the impacts on all aspects of the domestic and international value chain. Third, there is no reasonable rationale for exempting from the definition of a BE Food foods that contain genetic material, such as incidental additives, enzymes, yeasts, and other bioengineered ingredients but include in the definition refined sugar that contains no genetic material whatsoever. Finally, adopting Position 2 and making refined ingredients like sugar subject to the mandatory disclosure requirement compels commercial speech that is not truthful, *see Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) (First Amendment protects commercial speech and protects advertisers from compelled speech), which is also false and misleading under the Food, Drug and Cosmetic Act.

II. IF AMS INCLUDES REFINED INGREDIENTS IN THE DEFINITION OF A BE FOOD UNDER POSITION 2, AMS MUST ADOPT THE UNDETECTABLE DNA FACTOR AND CONDITION.

If, despite the unequivocal evidence that refined sugar does not contain genetic material, AMS is inclined to adopt Position 2, AMS must also adopt the undetectable DNA factor and condition and, as discussed in section IV-C below, make clear at the time the Final Rule is published that

refined sugar is excluded from the definition of a BE Food under the undetectable DNA factor and condition. Including refined beet sugar, in the definition of a bioengineered food without providing a mechanism to exclude it from the definition of a BE Food is contrary to Congress's express intent that the NBFDS apply only to foods that contain genetic material. It also discriminates against refined foods like beet sugar by treating it differently from its non-bioengineered counterpart when the foods are molecularly identical, which leads to the harmful market impacts discussed in section I-B above.

Including refined sugar in the definition of a BE Food, but allowing its exclusion under the undetectable DNA factor and condition is confusing and not necessary when the agency has before it multiple scientific studies demonstrating the absence of any genetic material in refined sugar. It sends misleading messages to consumers by creating a presumption that refined sugar is a BE Food but is excluded from the mandatory disclosure requirements. And, as the IFIC survey shows, it places an onerous burden on the industry to overcome the presumption, to educate consumers on the benefits of bioengineered crops, and to gain consumer acceptance of the technology. Indeed, the U.S. Beet Sugar Industry was a founder of "A Fresh Look" which brings farmers from across the country together to educate consumers about the benefits of GMO farming methods, including how bioengineered crops allow farmers to produce food with less water, land, energy and pesticides.[43] A Fresh Look strives to, among other things, promote food marketing practices that address science-based health and environmental benefits — not spread misinformation to justify inflating prices for some foods, while playing on consumer fears to stigmatize other, equally healthy options. AMS should support such efforts, not create misleading presumptions that undermine them.

Finally, AMS notes that it may consider compatibility of the undetectable DNA factor and condition with U.S. trading partners. However, we believe that Position 1 (excluding refined ingredients from the definition of a BE Food) is more compatible with U.S. trading partners than creating a presumption that a refined food like beet sugar is a BE Food but is excluded from mandatory disclosure under the undetectable DNA factor and condition. We are not aware of any country that requires industry to demonstrate through testing that refined ingredients do not contain genetic material prior to determining that the ingredients are not subject to the county's labeling laws. Rather, countries have relied on published studies to determine that refined ingredients are outside the scope of their mandatory labeling laws. As noted above, Japan relied on Oguchi, *et al*. (2009) to exempt beet sugar from its mandatory GMO labeling requirements[44]

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[43] For more information about A Fresh Look, *see* https://afreshlook.org/.

[44] 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 transgenic sugarbeets to be labeled because the refined sugar 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.

and Brazil relied on Cheavegatti-Gianotto, *et al*. (2018)[45] to determine that bioengineered sugarcane is a "chemically defined pure substance" that does not fall within the scope of Brazil's Biosafety Law and therefore "is not a genetically modified organism or a derivative thereof." *See* Attachment 1. We urge AMS to do the same with respect to refined sugar. There is simply no justification for creating a false presumption that refined sugar is a BE Food but is not subject to mandatory labeling requirements when the agency has before it conclusive scientific evidence that refined sugar is not a BE Food within the meaning of the NBFDS.

III. AMS SHOULD ESTABLISH A DEFINITION OF UNDETECTABLE DNA IF THE UNDETECTABLE DNA FACTOR AND CONDITION IS ADOPTED

AMS proposes that compliance with the undetectable DNA factor and condition be demonstrated by records showing that genetic material was not detected through testing performed by a laboratory accredited under ISO/ICE 17025:2017 standards, using methodology validated according to Codex Alimentarius guidelines. We support AMS's framework for standardized laboratory accreditation and rigorous analytical method validation for determining the presence of genetic material.

However, the proposed rule's undetectable standard may be construed as establishing "absolute zero" as the standard for disclosure of refined ingredients, which would impose substantial regulatory burden due to significant substantiation difficulty based on the inherent nature of test methods having established "analytical/detectable zero" criteria, not absolute zero. As previously stated, we urge AMS to adopt Position 1 and exclude refined ingredients from the definition of a BE Food based on well-established science, but if the undetectable DNA factor and condition is adopted, we support the Coalition's recommendation that the final rule establish a "de minimis" level of recombinant DNA (rDNA) at or below which ingredients qualify as refined ingredients not subject to mandatory disclosure. The "de minimis" level should be set at the generally recognized level of detection of 0.1% rDNA. Specifically, the final rule specify that ingredients qualify as refined ingredients not subject to mandatory disclosure if rDNA is at or below a "de minimis" level set at 0.1%, as measured by the relative proportion of rDNA compared to total DNA using a standard DNA control." Where 0.1% is below the level of rDNA detection for some ingredients, we recommend that such ingredients be excluded from the definition of a BE Food based on "the limit of detectability of modified rDNA as determined by results developed and practiced in accordance with the ISO/ICE 17025:2017 standard, using methodology validated according to Codex Alimentarius guidelines."

By establishing a "de minimis" level for refined ingredients, the rule would avoid the substantial regulatory burden associated with an on-going search to substantiate zero genetic material in various ingredients and the regulatory uncertainty that may accompany advances in scientific methods. Recognizing that no accurate method for testing of DNA exists when the overall

[45] Cheavegatti-Gianotto, A., *et al*. "Lack of Detection of Bt Surgarcane CRY1Ab and Nptll DNA and Proteins in Sugarcane Processing Products Including Raw Sugar (2018), Frontiers in Bioengineering and Biotechnology, Vo. 6, Art. 24 (2018).

content is below 0.1%, many European countries have adopted a "technical zero" of 0.1% rDNA. This burden-reducing strategy is particularly appropriate in this rulemaking where the statute expressly requires a threshold for disclosure and where disclosure is not a matter of public health and safety.

Should AMS believe a "de minimis" level not to be appropriate, AMS should allow and define undetectable rDNA to mean "the level below the limit of detectability of modified rDNA as determined by results developed and practiced in accordance with the ISO/ICE 17025:2017 standard, using methodology validated according to Codex Alimentarius guidelines." The final rule should clearly state that test methodology in accordance with the ISO/ICE 17025:2017 standard and accreditation (specific to rDNA/PCR testing) is required to validate or challenge presence of modified rDNA in an ingredient whether or not the level of its presence is at a uniform "de minimis" level or the limit of detection determined by each tested ingredient. We submit that failure to require use of an appropriate validated and accredited methodology to detect modified genetic material in an ingredient would add significantly to AMS's burden in administering the rule and could undermine the scientific integrity of rule administration.

We also encourage AMS to provide expectations regarding PCR (polymerase chain reaction) testing, as PCR has become the standard analytical tool used for the detection, identification, and quantification of specific DNA sequences, including rDNA. Specifically, we request that AMS establish minimal standards for selecting appropriate PCR primers for each and any rDNA event that would be subject to the definition of bioengineering.

IV. AMS'S PROPOSED LIST OF BE FOODS CONFUSES BE FOODS AND CROPS AND CREATES A PRESUMPTION THAT FOODS "DERIVED FROM" CERTAIN CROPS ARE BE FOODS CONTRARY TO CONGRESS'S INTENT THAT A BE FOOD "CONTAIN GENETIC MATERIAL"

AMS proposes to create two lists of "BE Foods," one for "highly adopted" BE Foods and the other for "not highly adopted" foods. AMS intends that these lists "would serve as the linchpin in determining whether a regulated entity would need to disclose a BE Food under the NBFDS." However, the "BE Food lists" are lists of bioengineered crops - not BE Foods. By creating a list of BE crops, which includes sugarbeet, to serve as the "linchpin" for determining whether disclosure is required makes superfluous any exclusion AMS provides for refined ingredients under Position 1 or under the undetectable DNA factor and condition. Regulated entities will rely on the crop list, not the exclusions under the law to make disclosure decisions. Thus by default, AMS is defining a BE Food as one derived from a bioengineered crop in direct contravention of the NBFDS.

A. AMS Should Create an Ingredient List to Facilitate Compliance with the NBFDS

We understand and support AMS's intent to facilitate compliance with the NBFDS. However, we believe the better way is to create a BE ingredient list, which the RIA has already created through an extensive analysis of food product labels. Exhibit 2 of the RIA, modified to reflect ingredients excluded from the scope of the NBFDS, *i.e.*, refined ingredients, enzymes, is an easy to understand list that would facilitate compliance with the NBFDS without creating false

presumptions or contravening the intent of the NBFDS that a BE Food is one that contains genetic material. Alternatively, AMS could use Table 5 from the RIA which lists the top 50 ingredients that would likely trigger disclosure, provided it eliminates from the list those products excluded from the definition of a BE Food, e.g., sugars, oils, enzymes. This is a far better way for regulated entities to make disclosure decisions because most food manufacturers, and especially small food manufacturers, do not know what crops many ingredients are derived from. The RIA itself supports this approach:

> If the USDA provided a definitive list of final ingredients by type of disclosure (may contain, does contain), manufacturers' analysis would consist of matching their list of ingredients to the list of required disclosures. That would move most, if not all, products into the low cost category. Therefore, all else held equal, the more clarity USDA provides on which ingredients should apply each label type, the higher the potential savings.[46]

To demonstrate that such a list is workable, we provide in Attachment 4 a BE ingredient list based on RIA Exhibit 2, that does not include refined ingredients or enzymes.

B. If AMS Maintains Its BE Food Lists by Reference to Highly Adopted and Not Highly Adopted Crops, AMS Should Remove Sugarbeet from the List.

If AMS insists on creating a list of BE Foods by reference to bioengineered crops, the sugarbeet should not be included on the list for two important reasons. First, the sugarbeet is the only crop that produces a single food for human consumption – refined beet sugar. As shown throughout this comment, refined beet sugar is pure sucrose, which does not contain any genetic material from the sugarbeet. Including the sugarbeet on the list creates the false and misleading presumption that refined beet sugar is a BE Food.

Second, the sugarbeet itself is not a food for human consumption. As part of its review of the transgenic sugarbeet, FDA described the food and feed uses of the sugarbeet and made clear that the sugarbeet is not a food for human consumption.[47] FDA also exempts sugarbeets from its produce rules under the Food Safety Modernization Act because they are not intended for human consumption.[48] Moreover, the Monsanto Technology/Stewardship Agreement, which grants growers a license to use the transgenic sugarbeet seed expressly prohibits growers from planting the sugarbeet seed for any use other than for processing for sugar, for energy production, or for animal feed. For these reasons, AMS's expressed intent that "only foods or products on either of those lists or made from foods on either of the lists would be subject to disclosure under the NBFDS" is arbitrary and not workable.

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[46] RIA at 29.

[47] FDA Biotech Consultation for H1-7 (#90).

[48] 21 C.F.R. § 112.2(a)(1).

C. If AMS Creates a BE Food List that Includes Bioengineered Crops, AMS Must Also Create an Excluded Ingredient List When the Final Rule Is Published

Although we do not believe it is the best approach to facilitating compliance with the NBFDS, if AMS adheres to its proposal that the BE Food list reference bioengineered crops, we support the Coalition for Safe Affordable Food's recommendation that AMS also create an Excluded Ingredients List that identifies those ingredients that are excluded from the scope on the NBFDS either under Position 1 or the undetectable DNA factor and condition. Providing an Excluded Ingredients List is the only way AMS can mitigate the false and misleading presumptions created by a crop list alone. However, because AMS has before it ample evidence that refined sugar does not meet the statutory definition of a BE Food, it is imperative that an initial Excluded Ingredients List be published with the Final Rule and that initial list include refined sugar. If there is any delay between the publication of the Final Rule and the creation of an Excluded Ingredient List, AMS will create confusion in the market and impose an onerous burden on the beet sugar industry to overcome the false and misleading presumption that refined beet sugar is a BE Food. Market and consumer reaction to the Final Rule will be swift and will likely overtake any efforts by the beet sugar industry to correct the erroneous presumption that refined beet sugar is a BE Food. For these reasons, we urge AMS to create a BE Food list of ingredients, not crops.

V. IF AMS IS INCLINED TO ADDRESS VOLUNTARY CLAIMS FOR FOODS THAT ARE NOT WITHIN THE DEFINITION OF A BE FOOD, AMS SHOULD NOT ENDORSE ON-PACKAGE CLAIMS THAT INGREDIENTS ARE "DERIVED FROM" OR "SOURCED FROM" BE CROPS.

We support voluntary labeling and believe that AMS has correctly provided a mechanism to allow regulated entities to voluntarily disclose information concerning BE Foods that are exempted from mandatory disclosure, e.g., very small food manufacturers. We also respect regulated entities' right to make other claims regarding BE Foods consistent with federal law. However, we do not support any voluntary labeling scheme linked to a BE crop list that would allow regulated entities to use on-package text or a symbol to indicate that a non-BE Food was "derived from" or "sourced from" a bioengineered crop.

First, creating such a voluntary program exceeds AMS's statutory authority. The NBFDS grants the Secretary authority to establish a mandatory bioengineered disclosure standard and to establish requirements and procedures necessary to carry out the standard.[49] In enacting the NBFDS, Congress made very clear that "the definition of bioengineering is set in statute and establishes the scope of the disclosure standard."[50] Thus, if a food is excluded from the definition of a bioengineered food it is not within the scope of the NBFDS and within the Secretary's authority to further regulate. Second, allowing such on-package text would

[49] NBFDS §293(a).

[50] Senate Report at 3.

effectively rewrite the statutory definition of a BE Food to a food that is "derived from" or "sourced from" a bioengineered crop, a definition Congress expressly rejected. Both the market and the consumer will assume that the derived from or sourced from text means the food is bioengineered, which is both false and misleading. Indeed, the IFIC survey validates that "[a] majority of respondents (53%) say they are less likely to consume food if they know [or assume] it contains BE ingredients."[51] Furthermore, consumers' willingness to pay for identical products with no-BE disclosure versus products with a BE disclosure decreased prices by up to 15%.[52] Thus, many consumers would avoid products with a "derived from" or "sourced from" label because they would erroneously assume that those products contain BE ingredients. As we have shown throughout this comment, such a false and misleading presumption is extremely harmful to the beet sugar industry.

This undeniably frustrates Congress's purpose that there be a uniform standard for disclosure. There is simply not enough room on a label to fully explain that while certain ingredients may have been derived from a bioengineered crop, the food itself is not a BE Food. Finally, even if AMS were inclined to allow non-BE Foods to have on-package derived from or sourced from text, it is not a logical outgrowth of this rulemaking and therefore would require a separate notice and comment proposal to comply with the Administrative Procedures Act.

We are not opposed to regulated entities providing additional information about the source of their ingredients, provided that the information is placed in context and is not misleading. We believe such information can be provided through the QR code/Smart Label, website, etc. which many food manufacturers are already providing. We see little need for AMS to regulate in this area.

VI. AMS SHOULD ADOPT A 5% THRESHOLD THAT ALLOWS THE INTENTIONAL USE OF SMALL QUANTITIES OF BE FOODS (ALTERNATIVE 1-C)

AMS requests comment on three proposed thresholds, two of which would allow the inadvertent or technically unavoidable presence of genetic material at either a 0.9% or 5% level in food (Alternatives 1-A and 1-B). The third threshold would allow regulated entities to use BE ingredients up to 5% of the total weight of the product (Alternative 1-C). While the threshold AMS adopts does not directly impact refined sugar, because beet sugar contains no genetic material at all, it does impact 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 urge AMS to adopt Alternative 1-C because it supports biotechnology, appropriately balances disclosure, market dynamics, and international trade, and is consistent with other U.S. regulatory programs,

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[51] IFIC at 11.

[52] IFIC at 26 showing the price consumers were willing to pay for a product with no disclosure and an identical product with a BE disclosure was $2.96 and $2.51, respectively.

including the USDA Organic Program which allows up to 5% of non-organically produced agricultural ingredients.

There is no scientific basis for any threshold because biotechnology does not raise health, safety or nutrition concerns.[53] Accordingly, thresholds are simply a tool to create a differentiation in the market place to provide a marketing advantage to non-bioengineered products. Thresholds are arbitrarily established mainly to drive consumers away from the technology and create non-tariff trade barriers to imported biotech commodities to protect domestic producers who do not have access to the technology.[54] As a world leader, and a leader in biotechnology, AMS must provide sound rational for its threshold 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 NBFDS to be technology neutral."[55] Other countries are closely

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

[54] 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).

[55] Senate Report at 4.

watching what the U.S. will do in these regulations and it will likely influence their internal discussions regarding acceptance and disclosure.

Of the thresholds that have been established world-wide, a 5% threshold is the most supportive of bioengineering[56]. 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 on our developing foreign suppliers. It is the most compatible with our North American trading partners, Mexico and Canada, neither of which require disclosure. 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.[57] If an organic consumer product can retain the organic label with up to 5% non-organic content, the NBFDS 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.

To be clear and to avoid any misunderstanding, "[t]he use of genetic engineering, or genetically modified organisms (GMOs), is prohibited in organic products."[58] 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."[59]

In contrast, Alternatives 1-A and 1-B that allow only the inadvertent or unavoidable presence of genetic material treat bioengineered ingredients as contaminants. 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.[60]

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[56] Japan, South Africa, Indonesia, Vietnam, and Thailand have all adopted a 5% threshold.

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

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

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

[60] 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

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.

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.[61] That is not Congress's intent. Congress made clear that the NBFDS cannot "denigrate biotechnology," which is precisely the Non-GMO Project's undeniable objective in order to drive bioengineered foods out of the market.[62] The Non-GMO Project describes GMOs as "contaminates" and "threats to the supply chain."[63] To adopt the same threshold used by the Non-GMO Project is unsupportable and unacceptable to the American farmers that embrace biotechnology. AMS should also carefully consider the potential consequences of a 0.9% percent "European-style" unintentional presence threshold (Alternative 1-B) could have on American agriculture.[64] In Europe, "consumers rarely find GE labels on

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

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

[62] See Non-GMO Project's webinar description that discusses one of the proposed threshold alternatives as "[a]llow[ing] an unreasonably high 5% threshold for GMO contamination in ingredients" : https://www.nongmoproject.org/blog/comment-on-the-national-bioengineered-food-disclosure-standard/

[63] See Non-GMO Project's webinar description and webinar that discusses one of the proposed threshold alternatives as "[a]llow[ing] an unreasonably high 5% threshold for GMO contamination in ingredients" : https://www.nongmoproject.org/blog/comment-on-the-national-bioengineered-food-disclosure-standard/

[64] According to the USDA's own FAS GAIN report, "Until the 1990s, 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

food, because many producers have changed the composition of their products to avoid losses in sales. Indeed, although products undergo a safety assessment and labels are simply there to inform consumers, they are often interpreted as warnings, and producers expect labeled products to fail in the market."[65] As shown above in section I-B, the Vermont law, which adopted the 0.9% threshold, caused food companies to reformulate products to avoid disclosure leading in significant price differentials between identical sugar products and impacts on the American farmer.

In sum, AMS 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." Alternative 1-C is the only threshold that will (1) allow the United States to remain a world leader in the production of bioengineered crops, (2) minimize impacts on the value chain, (3) minimize regulatory burden on farmers, and (4) promote sustainability. Any lower threshold would treat bioengineered ingredients as a contaminant and not be technology neutral and would "denigrate biotechnology" in contradiction of Congress.[66]

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that has slowed down and limited research, development, and commercial production of biotech products."[64]

[65] USDA, Foreign Agricultural Service, Global Agricultural Information Network, EU-28, Agricultural Biotechnology Annual, Report SP1743 (2017) at 36.

[66] Senate Report at 2.