



July 3, 2018

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

**Re: Docket ID: AMS-TM-17-0050, Proposed Rule, National Bioengineered Food Disclosure Standard**

To Whom It May Concern:

The New York Farm Bureau (NYFB), New York State's largest general farm organization, appreciates the opportunity to comment on the USDA Agricultural Marketing Service's (AMS) proposed rule to implement the National Bioengineered Food Disclosure Standard (NBFDS). Our farmers produce healthy fruits, vegetables, grains, dairy and meats that are produced in accordance with the highest standards for quality, food safety and environmental protection. To remain internationally competitive and lead the world in achieving the productivity and efficiency gains required to meet the food, fiber, and fuel demands and environmental challenges of the 21st century, New York agriculture must stay on the cutting edge of technology.

With the use of bioengineered seeds, NYFB's farm families produce safe food and raise healthier and more productive crops while providing a broad array of environmental benefits to help meet long-term sustainability objectives. We understand and support the consumers' desire to know what is in their food. However, our concerns have always been that any mandated disclosures not disparage biotechnology, impose undue regulatory burdens or create market discrimination when there are no material differences between conventional foods (those not produced with biotechnology) and foods derived from biotechnology. Farm Bureau worked with Congress in drafting the NBFDS and supported it because it strikes the correct balance between transparency, accuracy, and fairness. It prevents a state-by-state patchwork of food labelling requirements that would have driven up food costs and led to confusion among consumers.

We applaud AMS for addressing stakeholders' competing views on the scope of the NBFDS by setting forth several options for the final rule. Our overriding concern, however, is that some of the options being considered, if adopted, have the potential to harm U.S. agriculture and stifle American farming innovation by presuming or implying that refined ingredients like sugars and oils, derived from a bioengineered (BE) crop, contain generic material when sound science shows they do not. It's also important that dairy products, which are produced from dairy animals that consume feeds containing BE crops, are not labelled as a BE food. 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 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.” (S.R. No 114-403 (2016) at 2.

## 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 from 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;”<sup>1</sup>
- (3) AMS minimize the impacts on all aspects of the domestic and international value chain;<sup>2</sup> and
- (4) AMS provide “exemptions and other determinations under which a food is not considered a bioengineered food.”<sup>3</sup>

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

- **Definition of “Bioengineering” and “Bioengineered Food.”** We support AMS’s statement in the proposed rule that the “amended Act defines ‘bioengineering’ with respect to a food, as referring to a food ‘(A) that contains genetic material that has been modified through in vitro recombinant 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.’ 7 U.S.C. 1639(1). In accordance with its statutory mandate and for purposes of consistency, AMS proposes to directly incorporate this statutory definition into the definition of ‘bioengineered food’ without further interpretation of what ‘bioengineering’ means.”
- **AMS should not include highly refined ingredients in the definition of a BE Food** (Position 1).<sup>4</sup> Position 1 is supported by numerous scientific studies demonstrating the absence of genetic material from refined ingredients and AMS’s own economic analysis showing that exempting refined sugars and oils from the definition of a BE Food would

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<sup>1</sup> Senate Report at 8.

<sup>2</sup> Id.

<sup>3</sup> Id

<sup>4</sup> 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 multiingredient 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 recommend USDA to use the term “refined ingredients” when referring to single food components such as sugars and oils.

not reduce the number of foods subject to disclosure and would be far less costly than requiring product testing to prove the absence of genetic material.

- **If AMS is inclined to include refined products in the definition of a BE Food under Position 1, AMS must adopt the undetectable rDNA factor and condition.** Including refined products in the definition of a bioengineered food without providing a mechanism to exclude products that do not contain modified genetic material is contrary to Congress's express intent that the NBFDS apply only to foods that contain modified genetic material. It also treats refined ingredients derived from BE crops differently from foods derived from their non-bioengineered counterparts when they are molecularly identical. Disparate treatment of identical products has significant economic impacts on consumers, growers and the entire supply chain.
- **AMS's proposed list of BE Foods confuses BE Foods with 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 that has been modified."** 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 BE crops, which AMS proposes to serve as the "linchpin" for determining whether a regulated entity needs to disclose a BE Food, contradicts Congress's intent that a BE Food contain modified genetic material and renders Position 1 and the undetectable DNA factor and condition superfluous. Rather, AMS should adopt a BE ingredient list. Exhibit 2 of the Regulatory Impact Analysis (RIA), modified to reflect ingredients that are outside of the definition of BE under NBFDS (e.g., refined products, 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 modified 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 that are outside of the definition of BE Food under the NBFDS, (e.g., sugars, oils, or excluded ingredients like enzymes). Adopting a BE ingredient list is the preferred method for regulated entities to make disclosure decisions because most food manufacturers, especially small food manufacturers, do not know what crops many ingredients are derived from. The RIA itself supports this approach.
  - **It is especially important that AMS not require dairy products, when derived from animals that consumed BE feeds, to be labelled as a BE product.**
  - **Not only does this create confusion for consumers, it also implies that BE qualities can be transmitted through the animal and into the milk, which the science simply does not support.**
- **If AMS is inclined to address voluntary claims for foods that are not within the definition of a BE Food, AMS should not endorse specific 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 envisioned in 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 because consumers would presume that "sourced or derived from" means the food is BE. 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 without creating a secondary claim or disclosure that could mislead consumers into believing the food is BE when it is not.

- AMS should adopt a 5 percent 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 percent 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 percent of non-organically produced agricultural ingredients. A lower threshold, such as 0.9 percent, would be more aligned with the Non-GMO Project and European standards which denigrate biotechnology, stifle innovation and reduce choice for both farmers and consumers.

## **OVERARCHING PHILOSOPHY TO BE APPLIED TO THE RULE**

NYFB agrees that the focus of the final rule should be to establish a workable marketing standard, the NBFDS, for disclosure of BE information. NYFB supports preserving the ability of food companies to voluntarily disclose information above and beyond what is required by the federal standard where that information is consistent with applicable federal law. NYFB also agrees that the NBFDS should be a uniform national standard sufficient to ensure that federal preemption is maintained in accordance with AMS's statutory mandate.

### **Definitions**

*Refined Ingredients.* Because use of the term “highly refined” in describing food ingredients and products is an inaccurate and poorly framed term in conjunction with the NBFDS, NYFB recommends AMS instead use the more accurate term “refined,” when describing ingredients and products.

*Bioengineering.* The statutory definition of the term “bioengineering” refers to a food “(A) 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.”<sup>5</sup> The following recommendations are intended to clarify the use of certain key terms in the definition of “bioengineering.”

*Conventional Breeding.* NYFB supports inclusion of a definition to clarify “conventional breeding” in the final rule. Plant and animal breeding encompasses an evolving set of scientific disciplines and enabling methods that produce more effective breeding outcomes. Any discussion of breeding techniques that attempts to define or delimit “conventional breeding” should recognize this ongoing progression of breeding methods. What is considered “new” today may be deemed conventional or traditional in the future but does not result in fundamentally different breeding outcomes. This is consistent with the Act's bipartisan Senate Report that directed the NBFDS to “be technology neutral and reflect technological changes over time.”<sup>6</sup> However, we recognize that there is value in providing clarification around the terms used in the statutory definition of “bioengineering”.

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<sup>5</sup> 7 U.S.C. 1639(1).

<sup>6</sup> 7 S. Rep. No. 114-403 (2016) (“Senate Report”), at 4.

AMS will need to clarify what is meant by a modification that “could not otherwise be obtained through conventional breeding.” We recommend that AMS provide a definition for those modifications that could be obtained through conventional breeding together with a non-exhaustive set of examples of resulting modifications that describe an organism’s potential genetic variability within its inherently diverse gene pool. AMS should avoid a static listing of current breeding techniques because any such list would ignore the constantly evolving science and hinder development of future enabling technologies that make the improvement of our food supply more efficient to accomplish. We also propose that AMS provide further guidance through explanatory text in the preamble to the final rule. Our suggested definition and explanatory text follow.

#### Suggested Definition:

*“Modifications that could be obtained through conventional breeding” refers to a wide range of modifications obtained through methods that use an organism’s potential genetic variability within its gene pool, such as, but not limited to, induced mutagenesis, somaclonal variation, induced haploidy, marker assisted breeding, and other methods that enable movement of existing genetic material between related organisms, such as, but not limited to, breeding crosses within the species, wide and bridging crosses, cell fusion, and embryo rescue.*

#### Suggested Explanatory Text:

*The goals of breeders have always been to create new variations of plant or animal characteristics, to provide solutions for diseases and pests, to increase tolerance to environmental stress, to improve quality and yields, and to meet consumer expectations. Breeding depends upon genetic variability within and across related species as a basis for developing new plant and animal varieties with improved traits. Breeders use this genetic variability to create new varieties through the movement of genetic material between different varieties within species, between closely related species, or closely related genera. They utilize a range of breeding methods in the process, such as wide crosses, bridging crosses, and embryo rescue. In vitro generated nucleic acids can be used to recreate or “mimic” many molecular changes or genetic variations that occur naturally or via conventional breeding. Plants and animals bred using these methods do not contain a transgenic insertion and, therefore, would not meet the definition of “bioengineered” and should be exempt from mandatory disclosure.*

Regarding microbes, the concepts of “breeding techniques” and “conventional breeding” have limited applicability, especially with respect to methods for genetically modifying microbes that are food, that produce molecular substances added to food, or that carry out biological processes used in food production and processing. Over many decades, a wide array of methodologies, all derived from or based upon natural microbial methods of genetic modification, have been used to change the prokaryotic and eukaryotic microbes used in the manufacture of food and food ingredients. These methodologies are viewed as “conventional” because of their long history of safe use in many common foods. Over time, these methods have been altered and improved, and these improvements will continue as more is learned about microbial molecular genetics. Each of these methods should be considered “conventional breeding” under the Act and products resulting from these techniques would not be subject to mandatory disclosure.

*Found in Nature.* NYFB recommends that AMS include a definition in the final rule and provide further guidance through explanatory text in the preamble to the final rule. Our suggested definition and explanatory text follow.

Suggested Definition:

*“Found in nature” refers to the kinds of genetic modifications which can occur in nature within the genome of an organism, without human intervention.*

Suggested Explanatory Text:

*Examples of such genetic modifications found in nature include, but are not limited to, deletions, insertions, substitutions, duplications, and translocations of genetic sequences within the organism’s own genome. Changes can vary from single nucleotides to whole genes or larger segments of genetic material. Such modifications can occur through a variety of natural processes, including, but not limited to: crossing over in meiosis and sexual reproduction; microbial conjugation, transformation and transduction; transposon activity; horizontal gene transfer; and spontaneous gene mutations in somatic and germline cells.*

*In vitro* recombinant DNA techniques can also be used to “mimic” the end points of various types of changes to genes that occur in nature, independent of human intervention including, but not limited to, crossing over in meiosis and sexual reproduction; microbial conjugation, transformation and transduction; transposon activity; horizontal gene transfer; and spontaneous gene mutations in somatic and germline cells. These are the types of techniques that would result in modifications that could “otherwise be found in nature” and the resulting food products would not be considered BE and would not be subject to disclosure under the NBFDS. When *in vitro* recombinant DNA techniques are used to create combinations of genetic elements that could not “otherwise be found in nature,” food products containing these constructs would be considered BE and subject to mandatory disclosure under the NBFDS, unless otherwise excluded.

NYFB strongly recommends that AMS not use an approach that would rely on intellectual property protections as a method in determining whether a modification could not otherwise be found in nature. As a threshold matter, whether a BE trait is patentable (i.e., is a natural product but not a product of nature) is a completely separate question from whether the trait could be found in nature. That said, even if the tests were analogous, there is much uncertainty in the state of patent law and biotechnology such that guidance from the U.S. Patent and Trademark Office on the issue would be of little help.

*“Bioengineering” and “Bioengineered Food.”* NYFB supports incorporation of the statutory definition of “bioengineering” into the final rule, as suggested by AMS in the proposed rule and, further, in accordance with USDA’s statutory mandate and for purposes of consistency, NYFB agrees with the proposal by AMS to directly incorporate the statutory definition of “bioengineering” into the definition of “bioengineered food” without further interpretation.

### **AMS SHOULD ADOPT POSITION 1 AS THE DEFINITION OF A ‘BE’ FOOD.**

The Preamble to the proposed rule discusses two competing views on whether refined foods 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 farmers, consumers, food manufacturers, supply chain distribution and transportation systems, does not decrease the number of foods subject to the NBFDS, and is the better interpretation of the statutory definition of a BE Food.

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

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 which 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.<sup>7</sup> This study is particularly important because it not only failed to detect DNA and protein beyond the early raw juice stage of the 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.<sup>8</sup> Indeed, the Oguchi study was the basis upon which Japan exempted beet sugar from its mandatory GMO labeling requirements.<sup>9</sup> With respect to sugar produced from sugar cane, AMS correctly cites to Joyce, et al. (2013) and Taylor et al. (2009) demonstrating the absence of genetic material in refined cane sugar.<sup>10</sup> In addition, Pauli et al. (2000), did not find DNA in either raw or refined cane sugar.<sup>11</sup>

The science is further confirmed by a study published in March 2018.<sup>12</sup> 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

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<sup>7</sup> 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).

<sup>8</sup> Oguchi, T., et al., Investigation of residual DNAs in Sugar from Sugar beet (*Beta vulgaris* 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](https://www.jstage.jst.go.jp/article/shokueishi/50/1/50_1_41/_pdf).

<sup>9</sup> 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](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Tokyo_Japan_7-13-2015.pdf).

<sup>10</sup> Joyce, P.A., Dinh, S-Q., Burns, E.M., and O'Shea, M.G. (2013), "Sugar from genetically modified sugar cane 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 crystallised sugar from genetically engineered sugar cane does not contain transgene DNA", *Proc. Aust. Soc. Sugar Cane Technol.*, Vol. 21, pp. 502.

<sup>11</sup> Pauli et al (2000) Extraction and Amplification of DNA from 55 Foodstuffs. *Mitt. Lebensm. Hyg.* 91: 491-501.

<sup>12</sup> Cheavegatti-Gianotto, A., et al. "Lack of Detection of Bt Sugarcane CRY1Ab and NptII DNA and Proteins in Sugarcane Processing Products Including Raw Sugar (2018), *Frontiers in Bioengineering and Biotechnology*, Vo. 6, Art. 24 (2018).

agreement with the results of other studies that 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.<sup>13</sup> Brazil, as the largest producer of cane sugar, relied on the Cheavegatti-Gianotto study to determine that sugar produced from genetically modified sugar cane 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.”<sup>14</sup>

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)<sup>15</sup> as one study commenters claim shows that minute quantities of sugar cane DNA were detected in raw sugar (not for human consumption) after industrial milling prior to refining. Commenters do not understand the sugar refining process and misinterpret the scientific findings. 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 sugar cane DNA in refined sugar.”).<sup>16</sup> 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<sup>17</sup>.

Regarding refined ingredients as a class, Japan, Australia, New Zealand, Thailand, Indonesia, Malaysia, and South Korea have strict labeling regimes, but do not require the labeling of refined ingredients from BE crops because they do not contain transgenic DNA or protein. Indeed, Japan’s labeling laws do not apply to corn oil, corn starch, dextrin, starch syrup, hydrolyzed protein derived from BE corn; soy sauce, soybean sprout, margarine, hydrolyzed protein derived from BE soy; canola oil derived from BE canola; or sugar derived from BE sugarbeets because they “do not contain traces of DNA.”<sup>18</sup> Similarly, refined foods such as sugars and oils produced from BE crops are not included in Australia or New Zealand’s mandatory GMO labeling laws because of the absence of DNA and protein in the refined product and “because the composition and characteristics of these foods are exactly the same as the non-GM food.”<sup>19</sup>

Indonesia’s food registration procedures require labeling for food containing genetically modified potatoes, soybeans, corn and their derivative products. However, product derivatives, which have undergone further refining processes to the point where the genetic material cannot be identified (to include but not limited to oils, fats, sucrose, and starch), do not require any GMO statements.<sup>20</sup> In Malaysia refined foods, defined as those where processing has removed all novel DNA and protein, are not included in the labeling requirements (refined oil, sugar, corn

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<sup>13</sup> Klein et al., 1998; Oguchi et al., 2009; Joyce et al., 2013.

<sup>14</sup> Cheavegatti-Gianotto et al., 2018.

<sup>15</sup> 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>.

<sup>16</sup> Cullis, et al. at 14.

<sup>17</sup> Klein et al., 1998; Oguchi et al., 2009; Joyce et al., 2013.

<sup>18</sup> See Gain Report, Japan

[https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual\\_Tokyo\\_Japan\\_7-13-2015.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Tokyo_Japan_7-13-2015.pdf); See USDA GAIN Report No.

<sup>19</sup> 20 See USDA GAIN Report, Australia New Zealand:

[https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual\\_Canberra\\_Australia\\_11-27-2017.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Canberra_Australia_11-27-2017.pdf)

<sup>20</sup> See USDA GAIN Report No. 1526, Indonesian National Biosafety Commission for Genetically Engineered Products, available at



syrup, honey and dextrin).<sup>21</sup> Finally, South Korea recently expanded their labeling law but still does not include several refined products.<sup>22</sup>

**2. *There is No Rational Basis to Include Refined Ingredients in the Definition of a BE Food While Excluding 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 BE. 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 BE substrate, such as a BE 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. Each of these proposed and requested exclusions are food products and ingredients that are likely to contain genetic material. While we do not object to these food products and ingredients being excluded from the definition of a BE Food, we are frustrated that there is a willingness to exclude certain foods and ingredients that contain some level of genetic material, albeit small, but an unwillingness to clarify that refined ingredients do not meet the definition of a BE Food when scientific evidence unequivocally demonstrates that refined ingredients 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.

**A. *Including Refined Products 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 Agriculture Value Chain.***

In its RIA, AMS analyzed three scenarios for the scope of the NBFDS: (Scope 1) all foods and dietary supplements that have been produced through BE (including highly refined oils, sugars, and high fructose corn syrup); (Scope 2) exclusion of sugars and oils; and (Scope 3) exclusion of foods where the genetic material cannot be detected. 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 applies the proposed factor and condition undetectable DNA.

The RIA demonstrates that Position 1/Scope 2 (excluding refined products) 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 products were presumed to be a BE Food. We show below that creating any presumption that refined ingredients are a BE Food results in product deselection and price differentials.

When these costs are considered, Position 1/Scope 2 (excluding refined products) is the lowest cost option. With respect to Scope 3 (the undetectable DNA factor and condition), the RIA

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[https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual\\_Jakarta\\_Indonesia\\_7-14-2015.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Jakarta_Indonesia_7-14-2015.pdf)

<sup>21</sup> See USDA GAIN Report, Indonesia:

[https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual\\_Jakarta\\_Indonesia\\_11-20-2017.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Jakarta_Indonesia_11-20-2017.pdf)

<sup>22</sup> See USDA GAIN Report No. KS1716, Korea's New Biotech Labeling Requirements, available at

[https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Update%20to%20Korea's%20New%20Biotech%20Labeling%20Requirements\\_Seoul\\_Korea%20-%20Republic%20of\\_6-23-2017.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Update%20to%20Korea's%20New%20Biotech%20Labeling%20Requirements_Seoul_Korea%20-%20Republic%20of_6-23-2017.pdf)

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. Clarifying that Refined Products do not meet the Definition of a BE Food Does Not Decrease the Number of Products Subject to the NBFDS.**

One of the principal arguments that has been raised in opposition to clarifying that refined products do not meet the definition of a BE Food is that it would significantly decrease the number of foods subject to the NBFDS. Some have even suggested there could be 80 percent fewer products labeled as a BE 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.<sup>23</sup> The RIA found that not including sugars and oils did not result in any noticeable difference in the number of labeled products subject to the NBFDS.<sup>24</sup> The RIA further found that dietary supplements are even less sensitive to the exclusion of refined oils and sugars, with only 0.5 percent 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 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 percent of labels being 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).

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 Ingredients are BE Foods 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.”<sup>25</sup> Moreover, the NBFDS “is not intended to increase the costs of food manufacturing or changes in distribution or handling.”<sup>26</sup> Congress’s intent that the NBFDS not disrupt domestic and international supply chains is reinforced by E.O. 13777, which established

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<sup>23</sup> 24 RIA at 51.

<sup>24</sup> Id. (finding that under Scope 1, 66 percent of labels would be subject to the NBFDS and under Scope 2, 64 percent of food labels would potentially be subject to the NBFDS).

<sup>25</sup> Senate Report at 4, 8.

<sup>26</sup> Id. at 7.

a federal policy to alleviate unnecessary regulatory burdens. Creating any presumption that refined ingredients are BE Foods when they not contain modified 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 refined ingredients that do not contain modified genetic material are BE Foods under Position 2 when they are identical to all other refined ingredients from conventional crops.

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.

NYFB recommends AMS adopt Position 1 and exclude refined ingredients from the definition of BE Foods to avoid market discrimination that results in higher consumer prices and harmful impacts to the agriculture value chain.

- (b) Presuming Refined Ingredients are BE Foods harms the American farmer.

Disruption in the supply chain and disparagement of the technology harms the American farmer because demand for BE crops will decline, even though they improve crop yields and are more environmentally sustainable than conventional crops.<sup>27</sup> Indeed, when the Vermont law was enacted many farmers faced uncertainty regarding the future viability of their BE crops which have enabled farmers to adopt production practices that have significantly offset rising costs. These include increases in diesel prices,<sup>28</sup> land costs,<sup>29</sup> water costs,<sup>30</sup> industrial energy supplies,<sup>31</sup> seed, fertilizers and pesticides.<sup>32</sup>

If AMS creates any presumption that refined ingredients are BE Foods, the costs stretching back to the farm will be far greater than the RIA estimates. Farmers would have to begin producing non-BE crops. All the cost savings BE crops provide would be lost, and the cost to begin producing non-BE crops would be much higher. In other words, they would be cost prohibitive.

This could cause farmers to seek other crop alternatives, which could lead to major disruptions in domestic commodity supplies.

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<sup>27</sup> "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>.

<sup>28</sup> 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](https://www.eia.gov/dnav/pet/hist/LeafHandler.ashx?n=PET&s=EMD_EPD2D_PTE_NUS_DPG&f=M).

<sup>29</sup> 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>.

<sup>30</sup> OECD, "Agricultural Water Pricing: United States," (2010) available at <https://www.oecd.org/unitedstates/45016437.pdf>.

<sup>31</sup> 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](https://www.eia.gov/electricity/monthly/epm_table_grapher.php?t=epmt_5_3).

<sup>32</sup> 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>.

Congress instructed AMS to make “every effort . . . to ensure that farmers access to seed technology and not limit the options available to agricultural production” and directed USDA “to take every effort to minimize the impacts on growers.”<sup>33</sup> Adopting Position 2 creates a presumption that refined ingredients derived from BE crops are BE Foods which is difficult to overcome in the market even if AMS also adopts the undetectable DNA factor and condition. AMS’s proposed list of BE Foods exasperates the presumption and harms the industry. The risks to the American farmer are too significant for AMS to ignore science and adopt Position 2.

Impacting the American farmer contradicts E.O. 13790, which established an Interagency Task Force on Agriculture and Rural Prosperity (Task Force) to “identify legislative, regulatory, and policy changes to promote in rural America agriculture, economic development, job growth, infrastructure improvements, technological innovation, energy security, and quality of life.”<sup>34</sup> 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 an incredible opportunity for American farmers and rural communities to thrive at the forefront of innovation.<sup>35</sup>

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.<sup>36</sup> Indeed, in making clear that the NBFDS is a marketing standard, not a health, safety or nutritional standard, Congress 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.”<sup>37</sup> If there were any safety concerns, FDA, not USDA, would act under its authority.

## **B. Position 1 is the Better Interpretation of the Statutory Definition of a BE 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.<sup>38</sup> If the statute is ““silent or ambiguous with respect to the specific issue,” the agency’s interpretation is

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<sup>33</sup> Senate Report at 7.

<sup>34</sup> 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>.

<sup>35</sup> 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>.

<sup>36</sup> 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.

<sup>37</sup> Senate Report at 4.

<sup>38</sup> *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 224 (D.C. Cir. 2001).

given deference if it is reasonable.<sup>39</sup> Here, Congress unambiguously defined a BE Food as a “food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.”<sup>40</sup> Congress thoughtfully, deliberately and intentionally did not extend the scope of the Act to include ingredients derived from bioengineered crops.

The legislative history reinforces the plain language of the statute and makes clear that the definition of a BE 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.”<sup>41</sup>

Refined foods that do not contain genetic material do not meet the statutory definition of a BE Food. As demonstrated by the science discussed above, refined ingredients do not contain genetic material and therefore cannot be a BE Food within the scope of the NBFDS.

Some groups argue that Congress defined “bioengineering” in § 291(1) of the Act and gave the Secretary discretion in § 293(a) to define a BE Food. They say this reading of the Act is consistent with floor statements made by Members of Congress during debate and with a memo from USDA’s General Counsel, which some incorrectly describe as a legal opinion. These groups are reading the 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 USDA Secretary the discretion to rewrite the definition of a BE Food from a food that itself contains genetic material to any food derived from BE, a definition Congress expressly rejected. Position 2 modifies the statutory definition of a BE Food by creating a presumption that refined products are BE Foods because they are derived from BE crops. 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 USDA 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.<sup>42</sup> Here, the plain language makes clear that “*bioengineering . . . with respect to a food, refers to a food . . . that contains genetic material.*”<sup>43</sup>

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

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<sup>39</sup> Citizens Coal Council v. Norton, 330 F.3d 478, 481 (D.C. Cir. 2003) (quoting Chevron, 467 U.S. at 843).

<sup>40</sup> 7 U.S.C. § 1639(1)(A).

<sup>41</sup> Senate Report at 3.

<sup>42</sup> Sandoz, Inc. v. Amgen, Inc., 137 S. Ct. 1664, 1678 (2017) (quoting McFarland v. Scott, 512 U.S. 849, 865 (1994)).

<sup>43</sup> § 291(1).

signals to the market that refined products produced from BE crops are somehow different or less desirable than refined ingredients produced from non-BE crops contrary to Congress's direction that the NBFDS not treat BE Food differently from its non-BE counterpart. As discussed in section I -B above, this leads to price differentials and harmful market impacts.<sup>44</sup> 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 BE ingredients but include in the definition refined ingredients that contain no genetic material whatsoever. Finally, adopting Position 2 and making refined products subject to the mandatory disclosure requirement compels commercial speech that is not truthful.<sup>45</sup>

**I. IF AMS IS INCLINED TO INCLUDE HIGHLY REFINED PRODUCTS IN THE DEFINITION OF A BE FOOD UNDER POSITION 2, AMS MUST ADOPT THE UNDETECTABLE DNA FACTOR AND CONDITION.**

If, despite the strong scientific evidence and international precedent that refined ingredients do not contain modified genetic material, AMS is inclined to adopt Position 2, then AMS must also adopt the undetectable rDNA factor and condition and make clear at the time the Final rule is published that refined ingredients do not meet the definition of BE Foods under the undetectable rDNA factor and condition. Including refined ingredients, in the definition of a BE Food without providing a mechanism to exclude them from the definition of a BE food is contrary to Congress's express intent that the NBFDS apply only to foods that contain modified genetic material. It also discriminates against refined foods like sugars and oils by treating them differently from their non-BE counterparts when the foods are molecularly identical, which leads to the harmful market impacts.

Including refined ingredients in the definition of a BE Food, but allowing their exclusion under the undetectable rDNA 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 ingredients. It sends misleading messages to consumers by creating a presumption that refined ingredients are BE Foods but are excluded from the mandatory disclosure requirements. It also places an onerous burden on the industry to overcome the presumption, educate consumers on the benefits of BE crops, and gain consumer acceptance of the technology. "A Fresh Look", which is supported by NYFB, brings farmers from across the country together to educate consumers about the benefits of GMO farming methods, including how BE crops allow farmers to produce food with less water, land, energy and pesticides.<sup>46</sup> 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 these efforts, not create misleading presumptions that undermine them.

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<sup>44</sup> 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).

<sup>45</sup> See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) (First Amendment protects commercial speech and protects advertisers from compelled speech).

<sup>46</sup> For more information about A Fresh Look, see <https://afreshlook.org/>.

Finally, AMS notes that it may consider compatibility of the undetectable rDNA factor and condition with U.S. trading partners. However, we believe that Position 1 (excluding refined products from the definition of a BE Food) is more compatible with U.S. trading partners than creating a presumption that refined ingredients are BE Foods but are excluded from mandatory disclosure under the undetectable rDNA factor and condition. We are not aware of any country that requires industry to demonstrate through testing that its food products do not contain genetic material. Rather, countries have relied on published studies to themselves conclude that certain refined products are outside the scope of their mandatory labeling laws. For example, Japan relied on Oguchi, et al. (2009) to exempt beet sugar from its mandatory GMO labeling requirements<sup>47</sup> and Brazil relied on Cheavegatti-Gianotto, et al. (2018)<sup>48</sup> to determine that bioengineered sugar cane 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.” We recommend AMS to do the same with respect to refined ingredients. There is simply no justification for creating a false presumption that refined ingredients are BE Foods but are not subject to mandatory labeling requirements when the agency has before it conclusive scientific evidence that refined ingredients are not BE Foods within the meaning of the NBFDS.

## **II. 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 MODIFIED 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 proposes 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 BE crops - not BE Foods. By creating a list of BE crops to serve as the “linchpin” for determining whether disclosure is required makes superfluous any exclusion AMS provides for refined products under Position 1 or under the undetectable DNA factor and condition. Regulated entities will rely on the crop list, not the exclusions under within the law to make disclosure decisions. Thus, by default, AMS is defining a BE Food as one derived from a BE crop in direct contravention of the NBFDS.

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

We support AMS’s intent to facilitate compliance with the NBFDS. However, we recommend the creation of 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 products, enzymes, is an easy to understand list that would facilitate compliance with the NBFDS without creating false presumptions or

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<sup>47</sup> 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](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Tokyo_Japan_7-13-2015.pdf).

<sup>48</sup> Cheavegatti-Gianotto, A., et al. “Lack of Detection of Bt Sugarcane CRY1Ab and NptII DNA and Proteins in Sugarcane Processing Products Including Raw Sugar (2018), *Frontiers in Bioengineering and Biotechnology*, Vol. 6, Art. 24 (2018).

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). Adopting a BE ingredient list is the preferred method 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.<sup>49</sup>

The attached document demonstrates a BE ingredient list is workable. The list is based on RIA Exhibit 2, not including refined ingredients or enzymes.

**B. If AMS is Inclined to Create a BE Food List that Includes Bioengineered Crops, AMS Must Also Create an Excluded Ingredient List When the Final Rule Is Published.**

Although its not the best approach for complying with the NBFDS, if AMS adheres to its proposal that the BE Food list reference BE crops, then 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 or not under the scope on the NBFDS either under Position 1 or the undetectable rDNA 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 ingredients do 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 ingredients. 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 producers of refined ingredients to overcome the false and misleading presumption that refined ingredients are BE Foods. We recommend that AMS create a BE Food list of ingredients, not crops.

**III. 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., 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 BE crop.

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<sup>49</sup> RIA at 29.



First, creating such a voluntary program exceeds AMS's statutory authority. The NBFDS grants the USDA Secretary authority to establish a mandatory BE disclosure standard and to establish requirements and procedures necessary to carry out the standard.<sup>50</sup> In enacting the NBFDS, Congress made clear that "the definition of bioengineering is set in statute and establishes the scope of the disclosure standard."<sup>51</sup> Thus, if a food is excluded from or does not meet the definition of a BE Food it is not within the scope of the NBFDS and within the USDA Secretary's authority to further regulate. Second, allowing such on-package text would effectively rewrite the statutory definition of a BE Food to a food that is derived from or sourced from a BE 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 BE, which is both false and misleading. This contradicts 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 BE 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.

#### **IV. AMS SHOULD ADOPT A 5 PERCENT 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 percent or 5 percent level in food (Alternatives 1-A and 1-B). The third threshold would allow regulated entities to use BE ingredients up to 5 percent of the total weight of the product (Alternative 1-C). While the threshold AMS adopts does not directly impact refined ingredients because they contain no modified genetic material, 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 recommend 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, including the USDA Organic Program which allows up to 5 percent of non-organically produced agricultural ingredients.

There is no scientific basis for any threshold because biotechnology does not raise health, safety or nutrition concerns.<sup>52</sup> Accordingly, thresholds are simply a tool to create a differentiation in the

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<sup>50</sup> NBFDS §293(a).

<sup>51</sup> Senate Report at 3.

<sup>52</sup> 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

market place to provide a marketing advantage to non-BE 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.<sup>53</sup> As a world leader, and a leader in biotechnology, AMS must provide sound rationale 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.”<sup>54</sup> Other countries are closely watching what the U.S. will do in these regulations and it will likely influence their internal discussions regarding acceptance and disclosure.

Of the thresholds that have been established world-wide, a 5 percent threshold is the most supportive of bioengineering.<sup>55</sup> 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 percent threshold is consistent with other U.S. regulatory programs. The USDA Organic Program allows up to 5 percent of non-organically produced agricultural ingredients which are not commercially available in organic form.<sup>56</sup> If an organic consumer product can retain the organic label with up to 5 percent non-organic content, then the NBFDS should be set at 5 percent as well. Indeed, federal courts have held that consumers hold products labeled organic to a higher standard than even products labeled natural.<sup>57</sup> Having the same 5 percent 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 percent low-level presence threshold, although there isn’t an international standard.

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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](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf).

<sup>53</sup> 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).

<sup>54</sup> Senate Report at 4.

<sup>55</sup> Japan, South Africa, Indonesia, Vietnam, and Thailand have all adopted a 5% threshold.

<sup>56</sup> USDA Labeling Organic Products,

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

<sup>57</sup>See e.g., *Pelayo v. Nestle USA Inc.*, 989 F. Supp. 2d 973, 979 (C.D. Cal. 2015).

To be clear and to avoid any misunderstanding, USDA says “[t]he use of genetic engineering, or genetically modified organisms (GMOs), is prohibited in organic products.”<sup>58</sup> 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.”<sup>59</sup>

In contrast, Alternatives 1-A and 1-B that allow only the inadvertent or unavoidable presence of genetic material treat BE ingredients as contaminants. For more than 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.<sup>60</sup> 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 percent per ingredient threshold above which a product cannot bear its Non-GMO Project verified label.<sup>61</sup> 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 to drive BE foods out of the market.<sup>62</sup> The Non-GMO Project describes GMOs as “contaminates” and “threats to the supply chain.”<sup>63</sup> To adopt the same threshold used by the Non-GMO Project is unsupportable and unacceptable to the American farmers and scientific community that embrace biotechnology. AMS should also carefully consider the potential consequences of a 0.9 percent percent “European-style” unintentional presence threshold (Alternative 1-B) could have on American agriculture.<sup>64</sup> In Europe, “consumers rarely

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<sup>58</sup> <https://www.ams.usda.gov/publications/content/can-gmos-be-used-organic-products>

<sup>59</sup> <https://www.ams.usda.gov/publications/content/can-gmos-be-used-organic-products>

<sup>60</sup> See also “In the EU, different types of civil society organizations have militated against agricultural biotechnology since it was first introduced in the 1990s. They are generally opposed to economic growth and globalization. They see more risks than opportunities in technical progress and campaign for a broad application of the precautionary principle. Some of them defend an ideal science that would focus solely on understanding phenomena, and not on developing useful and profitable applications; others reject or strongly criticize science and progress, in line with philosophers such as Hans Jonas and Bruno Latour. They are skeptical of new technologies, in general, and for biotechnology specifically they feel it is dangerous, of little public benefit, and developed by companies that seek private profit at the expense of the common good. As part of their political strategy, their actions include lobbying public authorities, acts of sabotage (destruction of research trials and cultivated fields), and communication campaigns to heighten public fears.” Page 37, USDA Foreign Agricultural Service, European Union 28, Agricultural Biotechnology Annual, December 6, 2016.

[https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual\\_Paris\\_EU-28\\_12-6-2016.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Paris_EU-28_12-6-2016.pdf)

<sup>61</sup> Non-GMO Project, <https://www.nongmoproject.org/about/mission/>.

<sup>62</sup> 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/>

<sup>63</sup> 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/>

<sup>64</sup> According to the USDA’s own FAS GAIN report, “Until the 1990’s, the European Union (EU) was a leader in research and development of biotech plants. Under pressure from anti-biotech activists, EU and Member State (MS) authorities have developed a complex policy framework that has slowed down and limited research, development, and commercial production of biotech products.”

find GE labels on 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.”<sup>65</sup>

In conclusion, 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 BE crops, (2) minimize impacts on the value chain, (3) minimize regulatory burden on farmers, and (4) promote sustainability. Any lower threshold would treat BE ingredients as a contaminant and not be technology neutral and would “denigrate biotechnology” in contradiction of Congress.<sup>66</sup>

With the use of bioengineered seeds, our members produce safe foods, and raise healthier and more productive crops, while providing a broad array of environmental benefits to help meet long-term sustainability objectives. We understand and support the consumer’s desire to know what is in their food. However, our concerns have always been that any mandated disclosures must not disparage biotechnology, impose undue regulatory burdens, or create market discrimination when there are no material differences between conventional foods and foods derived from biotechnology.

NYFB thanks you for the opportunity to share these comments and appreciate your thoughtful consideration of this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "David Fisher". The signature is fluid and cursive, with a large initial "D" and "F".

David Fisher  
President, New York Farm Bureau

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<sup>65</sup> USDA, Foreign Agricultural Service, Global Agricultural Information Network, EU-28, Agricultural Biotechnology Annual, Report SP1743 (2017) at 36.

<sup>66</sup> Senate Report at 2.

## ATTACHMENT

List of Ingredients	Contains or May Contain
Natural Flavor	Corn
Citric acid	Corn
Spice	Corn
Lecithin (soy)	Soy
Riboflavin (Vitamin B2)	Yeast
Corn Syrup	Corn
Xanthan Gum	Corn
Natural and Artificial Flavor	Corn
Corn Starch	Corn
Mono and Diglycerides of Fatty Acids	Corn
Modified Starch (corn)	Corn
Vitamin C	Corn
Yeast	Yeast
Modified Food Starch	Corn, soy, potato
Vinegar	Corn
Flour	Corn
Artificial Flavor	Corn
Sodium Citrates	Corn
Yeast Extract	Yeast
Malt Flour (barley)	Corn
Flavor	Corn
Molasses	Corn
Soybeans	Soy
Brown Sugar	Corn
Distilled Vinegar	Corn
Sodium Carboxymethylcellulose	Corn
MSG	Corn
Corn Syrup Solids	Corn
Malic Acid	Corn
Rice Flour	Rice
Vanilla	Corn
Corn	Corn
Corn Flour	Corn
Soy Flour	Soy
Potatoes	Potato
Potato Starch	Potato
Sorbic Acid	Corn
Vanilla Extract	Corn
Glycerin or Glycerol	Corn
Sodium Oleyl Lactylate	Corn
Seasoning	Corn
Sodium Erythorbate	Corn
Polyoxyethylene Sorbitan Monostearate	Corn
Tocopherols Concentrated, mixed	Corn
Apple	Apple
Artificial Vanilla Flavor	Corn
Rice	Rice
Flour (bleached)	Corn
Baking Powder	Corn
Corn Meal	Corn

Polysorbate 80	Corn
Fructose	Corn
Hydrolysed Soy Protein	Soy
Soy Protein	Soy
Erythrosine	Corn
Diacetyltaric & Fatty Acid Esters of Glycerol	Corn
Soy Sauce	Soy
Soy Protein Isolate	Soy
Autolysed Yeast Extract	Corn, Yeast
Apply Juice Concentrate	Apple
Sorbitol	Corn
Canola	Canola
Cellulose Powder	Corn
Hydrolysed Corn Protein	Corn
Cider vinegar	Apple
Pineapple	Pineapple
Fumaric Acid	Corn
Flour (unbleached)	Corn
Patassium citrates	Corn
Cottonseed	Cotton
Breadcrumbs	Corn
White Vinegar	Corn
Mustard	Corn
Propylene Glycol Propan	Corn
Herbs and Spices	Corn
Acetic Acid	Corn
Propylene Glycol Mono- and Di-Esters or Propylene Glycol Esters of Fatty Acids	Corn
Barley Malt	Corn
Natural Vanilla	Corn
Sorbitan Monostearate	Corn
Rice Starch	Rice
Cheese (sour cream)	Corn
Alcohol	Corn
Torula Yeast	Corn, Yeast
Rice Syrup	Rice
Calcium Lactate	Corn
Sodium Lactate	Corn
Vitamin E	Corn
Rice (brown)	Rice
Potato Flower	Potato
Crust	Corn
Barley Malt Extract	Corn
Rice Flour (Brown)	Rice
Rice Crisps	Rice
Vegetables	Corn
Gum Base	Soy
Alpha-Tocopherol	Corn
Malt	Corn
Pineapple Juice Concentrate	Pineapple