

July 3, 2018

U.S. Department of Agriculture
Agricultural Marketing Service
1400 Independence Ave. SW
Washington, DC 20250
Submitted via regulations.gov
Cc: befooddisclosure@ams.usda.gov

Re: Docket No. AMS-TM-17-0050, Implementation of the National Bioengineered Food Disclosure Standard (Pub. L. 114-216)

Dear Secretary Perdue,

On behalf of Just Label It, a national coalition of more than 800 organizations, including the healthcare community, farmers, consumers' advocates, environmentalists and organic and natural food companies who have been working for the labeling of genetically engineered foods since 2011, we appreciate the opportunity to offer these comments on the U.S. Department of Agriculture, Agricultural Marketing Service's proposed rule on the National Bioengineered Food Disclosure Standard (NBFDS).

Nine out of ten Americans consistently report they want the right to know if their food is produced with genetic engineering.¹ Sixty-four other countries already require that this information be provided to consumers.² Congress has recognized "that consumers are interested in increased access to information about their food."³ On July 29, 2016, recognizing the consumer's right to know about genetically engineered (GE) foods or foods made with genetically modified organisms (GMO), Congress passed the National Bioengineered Food Disclosure Standard (Pub. L. 114-216) to require USDA to establish a mandatory, national disclosure standard for GMO foods.

Pub. L. 114-216 follows a trend towards greater transparency in consumer products. The last thirty years have seen the proliferation of new laws requiring greater transparency with regards to everything from credit scores, prescription eyeglasses and contact information, to online data sharing, advertising, debt collection and incandescent lightbulbs.⁴ Consumer surveys have found that 98 percent of respondents believe it's important for them to consider the ingredients in the

¹ See Just Label It! Right to Know Center, <http://www.justlabelit.org/right-to-know-center/polls-surveys/> (last visited July 2, 2018)

² See Center for Food Safety, International Labeling Laws, <https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws> (last visited July 2, 2018).

³ S. Rep. No. 114-403, at 7, <https://www.congress.gov/114/crpt/srpt403/CRPT-114srpt403.pdf>.

⁴ See, e.g., Energy Policy Act of 1992, 15 U.S.C. §§ 2821-2824; The Children's Online Privacy Protection Act of 1998, 15 U.S.C. §§ 6501-6506; Crimes Against Charitable Americans Act of 2001, 15 U.S.C. §§ 6102, 6106; Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 (CAN-SPAM Act), 15 U.S.C. §§ 7701-7713; Fairness to Contact Lens Consumers Act of 2004, 15 U.S.C. §§ 7601-7610; Energy Policy Act of 2005, 42 U.S.C. §§ 6294, 7545, 16471; Credit Card Accountability Responsibility and Disclosure Act of 2009 (Credit CARD Act), 15 U.S.C. §§ 1601-1667f; The Fair Debt Collection Practices Act of 2010, 15 U.S.C. §§ 1692-1692p.

food products they buy,⁵ 94 percent of consumers are more likely to be loyal to brands that offer transparency,⁶ and 73 percent of consumers will pay more for products when the brand is transparent.⁷

Consumer interest in greater transparency has also shaped market behavior. In January 2016, seven months before the passage of Pub. L. 114-216, Campbell Soup Company became the first major food company to voluntarily disclose the presence of genetically engineered ingredients in its products.⁸ Mars, Kellogg's, General Mills, and ConAgra followed suit not long after. This change was driven by consumer demand and the multiple state GMO disclosure laws passed in response to that demand. Campbell Soup Company noted the following in its responses to USDA's 30 questions: "We strive to be open and honest about what's in our food, and we believe transparency builds trust. Viewing GMOs through this transparency lens has caused us to think differently and changed our perspective on GMO labeling."⁹

Transparency will also be foundational to winning and maintaining consumer trust in the NBFDS. JLI believes it is critical that AMS create a meaningful disclosure standard for GMO foods that meets both Congressional intent and consumer expectations for transparency. To that end, we comment that:

- The disclosure standard should cover all foods produced with genetic engineering, including highly refined sugars and oils.
- The disclosure standard must encompass new GMO technologies like CRISPR and RNAi.
- The disclosure standard should be consistent with other federal and international standards to harmonize trade and avoid conflicts.
- The disclosure standard should adopt a 0.9 percent threshold for inadvertent or technically unavailable GE substances to be consistent with the majority of countries with GMO disclosure laws.
- The disclosure standard should use terms that consumers understand, like genetic engineering, genetically modified, or GMO.
- The disclosure standard should avoid "may be" or "may contain" statements.
- The disclosure standard should use a neutral symbol that clearly communicates the presence of a genetically engineered ingredient.
- The disclosure standard must have strong rules governing electronic or digital disclosures, which must be inclusive of all Americans – including consumers without smartphones, rural residents, and the elderly.
- The disclosure should be consistent with other federal agencies and existing standards overseen by the Department of Agriculture, like the National Organic Program.

⁵ Label Insight, *2017 Label Insight Shopper Trends Survey 2* (2017), <https://www.labelinsight.com/shopper-trends> (results based on survey of 2000 consumers).

⁶ Label Insight, *Driving Long-Term Trust and Loyalty Through Transparency: 2016 Label Insight Transparency ROI Study 3* (2016), https://www.labelinsight.com/hubfs/2016_Transparency_ROI_Study_Label_Insight.pdf.

⁷ *Id.*

⁸ Subrat Patnaik & Siddharth Cavale, *Campbell Soup Becomes First Major Company to Start GMO Labeling*, Reuters (Jan. 8, 2016, 12:55 am), <https://www.reuters.com/article/us-campbell-soup-gmo-idUSKBN0UM0H420160108?feedType=RSS&feedName=healthNews>.

⁹ Campbell Soup Company, *Comments re: National Bioengineered Food Disclosure Standard-USDA AMS Proposed Rule Questions Under Consideration*, p. 1 (Aug. 25, 2017).

- The disclosure standard should define small and very small companies consistent with other areas of FDA law.
- The disclosure standard should be implemented quickly.

Applicability

I. Scope of “bioengineered”

- a. The disclosure standard must cover highly refined foods and foods bioengineered with new GE technologies*

The proposed National Bioengineered Food Disclosure Standard (NBFDS) directly incorporates the definition of bioengineered from Pub. L. 114-216, defining “bioengineered” as food that “(A) 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.”

In the proposed NBFDS, AMS states that while it will not further interpret what “bioengineering” means, it welcomes public comment on what could be considered to constitute “bioengineering.” AMS is particularly interested in whether highly refined ingredients made from BE crops like sucrose, dextrose, corn starch, high fructose corn syrup, and corn, canola, and soybean oils would fall under the statutory definition of bioengineering.

The preamble to the proposed NBFDS lays out two conflicting positions. The first position is that these highly refined ingredients “do not contain” genetic material because these ingredients have undergone processes to remove the genetic material or the material cannot be detected using common methods. The second position contends that *all* foods produced from bioengineering fall within the scope of the definition of “bioengineering,” including highly refined foods. JLI believes strongly that AMS must clarify the proposed rule to adopt the second position and include *all* foods produced with genetic engineering.

As many respondents to USDA’s 30 questions commented, just because genetic material cannot be readily detected using current methodologies, does not mean that the genetic material is not present. Furthermore, as AMS acknowledges in the preamble to the rule, some studies have found genetic content in tests of highly refined sugars and oils.¹⁰ As Consumers Union pointed out in responses to USDA’s 30 questions, technology has advanced significantly over the last twenty years.¹¹ In 2010, a group of Portuguese scientists concluded that it was possible to detect and quantify genetically modified organisms in refined soybean oil.¹² A year later, in 2011, a

¹⁰ See Preamble to Proposed Rule, p. 14 (citing Christopher Cullis et al., *DNA and Protein Analysis Throughout the Industrial Refining Process of Sugar Cane*, 3 Int’l J. of Agricultural & Food Research 1(2014), <https://www.sciencetarget.com/Journal/index.php/IJAFR/article/view/437>).

¹¹ Consumers Union, *Comments of Consumers Union to the United States Department of Agriculture Agricultural Marketing Services on Proposed Rule GMO Questions Under Consideration*, p. 11 (Jul 17, 2017).

¹² Joana Costa et al., *Monitoring Genetically Modified Soybean Along the Industrial Soybean Oil Extraction and Refining Processes by Polymerase Chain Reaction Techniques*, 43 Food Research International 301-306 (2010), <https://www.sciencedirect.com/science/article/pii/S0963996909003202>.

team of Chinese scientists showed that they could detect bioengineered DNA in a number of highly processed foods, including soy lecithin, soy protein powder, chocolate beverage, infant rice cereal, corn protein powder, corn starch and corn jam.¹³ As such, highly refined ingredients may still “contain” modified genetic material.

Including highly refined ingredients would also align with consumer expectations. Consumers care about where their food comes from and how it was produced, not whether the final product contains genetic material. A reasonable consumer would expect all foods derived from genetic engineering to be covered by the NBFDS. Furthermore, excluding highly refined ingredients like sugars and oils from the scope of the “bioengineering” definition could exempt a significant portion of the market from disclosure. A recent analysis of the 105,000 food products in the Environmental Working Group’s Food Scores database¹⁴ found that more than 67,000 products likely contain a GMO ingredient. Of those products, EWG identified the number of food products that only contain a GMO sugar or oil, and no other GMO ingredient that would trigger disclosure. EWG found that at least 10,000 foods, or one in six, only contain a GMO sugar or oil, meaning they would be excluded from the NBFDS if such ingredients were exempted.¹⁵ Exempting these foods from the NBFDS would mislead consumers into thinking that those foods are not produced with genetic engineering.

An unduly narrow interpretation of “bioengineering” could also exclude emerging genetic engineering technologies and limit future disclosures. For example, in April 2016, the USDA approved a white button mushroom that was edited with a controversial gene-editing tool called CRISPR/Cas9 to reduce browning.¹⁶ The mushroom was modified, not by adding new DNA to the mushroom, but rather by making small deletions of a specific gene.¹⁷ Gene editing is also being used to develop soybeans that have less trans fat when converted into soybean oil.¹⁸ A recent article in the MIT Technology Review, aptly titled “These are Not Your Father’s GMOs,” points to the proliferation of these gene editing techniques to create “designer plants” that do not contain foreign DNA.¹⁹ Reasonable consumers would expect that the NBFDS cover foods produced not only with current GE technology, but also any emerging or future technologies. Because this is a rapidly changing area of science, the NBFDS must be construed broadly enough to capture technological advances.

¹³ Ao Jinxia et al., *A Multiplex Nested PCR Assay for the Simultaneous Detection of Genetically Modified Soybean, Maize, and Rice in Highly Processed Products*, 22 *Food Control* 1617-1623 (2011), <https://www.sciencedirect.com/science/article/pii/S0956713511001010>.

¹⁴ Environmental Working Group, *Food Scores*, <http://www.ewg.org/foodscores#.Wzt8BRJKhTY> (last visited July 3, 2018).

¹⁵ Colin O’Neil & Sean Perrone-Gray, *EWG Analysis: Loophole Could Exempt Over 10,000 GMO Foods From Disclosure Law*, *EWG Ag Mag* (June 29, 2018), <https://www.ewg.org/agmag/2018/06/ewg-analysis-loophole-could-exempt-10000-gmo-foods-disclosure-law#.WzaZrxJKhTY>.

¹⁶ Letter from Animal and Plant Health Inspection Service to Dr. Yinong Yang, re: Request for confirmation that transgene-free, CRISPR-edited mushroom is not a regulated article (April 13, 2016), https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/15-321-01_air_response_signed.pdf

¹⁷ *Id.*

¹⁸ Antonio Regalado, *There Are Not Your Father’s GMOs*, *MIT Technology Review* (Dec. 19, 2017), <https://www.technologyreview.com/s/609230/these-are-not-your-fathers-gmos/>

¹⁹ *Id.*

Including highly refined ingredients within the definition of “bioengineering” was also supported by major industry stakeholders like the American Beverage Association, the American Frozen Food Institute, Campbell Soup Company, Danone Wave, the Grocery Manufacturers Association, the National Confectioners Association, the National Family Farm Coalition, and Unilever in responses to USDA’s 30 questions.

b. Congress intended that USDA interpret “bioengineering” broadly

Including highly refined ingredients in the scope of the “bioengineering” definition is also consistent with congressional intent. In a colloquy on July 12, 2016, Ranking Member of the Senate Agriculture Committee Senator Debbie Stabenow (D-Mich.) reiterated the broad authority of the USDA to include a wide range of ingredients, including highly refined and gene-edited ingredients, under this definition. She stated, “This bill gives USDA broad authority to determine . . . which foods will be subject to this bill’s mandatory disclosure standard, including highly refined products derived from GMO crops and products developed using gene editing techniques.”²⁰ More specifically, she clarified that “this bill does not prohibit the labeling of highly refined products derived from GMO crops including soybean oil made from GMO soybeans, high fructose corn syrup made from GMO corn, and sugar made from GMO sugar beets.”²¹

In crafting the definition of “bioengineering” in Pub. L. 114-216, Congress also provided USDA the authority to apply the definition broadly to include genetic engineering technologies other than rDNA, like CRISPR, gene editing or RNA interference (RNAi). In her colloquy, Senator Stabenow stated that “the bill gives USDA broad authority to periodically amend its labeling regulations to ensure that there are no new scientific biotechnology methods that may escape any overly prescriptive statutory definition of biotechnology.”²² In addition to a broad interpretation of what’s covered by “bioengineering,” USDA should establish a clear mechanism under the NBFDS that requires the inclusion of new genetic engineering techniques, as they are developed, to ensure that companies and consumers understand the full scope of the disclosure standard.

Former USDA General Counsel Jeffrey M. Prieto reaffirmed in 2016 that it is well within USDA’s legal authority to broadly interpret the definition of bioengineering to include foods derived from various forms of GE technology. In a letter to Ranking Member Stabenow on July 1, 2016, Prieto wrote:

Section 291(1) of the Senate bill provides authority to include food in the national disclosure program, including products of certain gene editing techniques. This would include novel gene editing techniques such as CRISPR when they are used to produce plants or seeds with traits that could not be created with conventional breeding techniques. In addition, the definition provides authority to include RNAi techniques that have been used on products such as the non-browning apple and potato.²³

²⁰ See 162 Cong. Rec. S4994 (daily ed. July 12, 2016).

²¹ *Id.*

²² *Id.*

²³ *Id.*

Congress also intended the NBFDS to cover more products than the disclosure law passed in Vermont. In numerous press releases, postings on social media and public statements, Ranking Member Stabenow stated that Pub. L. 114-216 would require 25,000 more products be subject to a mandatory disclosure requirement as compared to Vermont Act 120 and other state disclosure requirements. In a July 7, 2016, statement made on the Senate floor, Ranking Member Stabenow said:

[I]n Vermont and at the State level, meat, eggs, cheese, and dairy are exempt—totally exempt. So someone called it the Vermont meat loophole. So we said: You know what. That is not acceptable. So we added 25,000 more food products under this law that we would be voting on tonight. On this bill, 25,000 more food products will be labeled for people to know whether they are getting GMO ingredients.²⁴

Not including highly refined sugars and oils in the GMO disclosure requirement would betray the clear intent of Congress that the NBFDS require 25,000 more products to carry a GMO disclosure than was allowed by states like Connecticut, Maine and Vermont. In fact, a recent analysis by EWG found that more than 10,000 products could be excluded from the NBFDS if highly refined ingredients are excluded.²⁵

c. Defining “bioengineering” broadly will help harmonize trade and minimize trade conflicts

Adopting position 2 and including highly refined ingredients and new GMO technologies in the definition of “biotechnology” would be consistent with labeling requirements promulgated by our major trading partners and relevant international law. This would help to harmonize trade and reduce potential trade conflicts. It would also help facilitate mutual recognition agreements.

Including highly refined oils and sugars would conform to the standards and guidelines²⁶ adopted by Codex Alimentarius, or “Food Code,” which are recognized by the World Trade Organization as the authoritative standard for purposes of settling international trade disputes, and therefore should be a guidepost for AMS. At its 39th session, held in 2011, the Codex Committee on Food Labeling adopted labeling standards for genetically modified foods and specifically stated in draft language that:

Different approaches regarding labeling of foods derived from modern biotechnology are used. Any approach implemented by Codex members should be consistent with already adopted Codex provisions. This document is not

²⁴ 162 Cong. Rec. S4906 (daily ed. July 7, 2016).

²⁵ O’Neil & Perrone-Gray, *supra* note 15.

²⁶ See Food and Agriculture Organization of the United Nations, Codex Alimentarius, <http://www.fao.org/fao-who-codexalimentarius/about-codex/en/>

intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.²⁷

Thus, to the extent possible, USDA should strive to interpret its definition of “biotechnology” consistent with the Codex Alimentarius. The following definition comes from the Principles for Risk Analysis of Foods Derived from Modern Biotechnology adopted by the Codex Alimentarius Commission in 2003.²⁸

Modern biotechnology:

- (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or
- (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection.

The Codex definition of modern biotechnology has also been adopted by the Food and Drug Administration²⁹ and the National Organic Standards Board.³⁰ The Codex Alimentarius also uses the following definitions:

Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Techniques of genetic engineering/modification include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.³¹

The Codex definitions for “modern bioengineering,” “genetically engineered/modified organisms,” and “techniques of genetic engineering” all are defined broadly and include things

²⁷ World Health Organization, Food and Agriculture Organization, Codex Alimentarius, Report of the Thirty Ninth Session of the Codex Committee on Food Labelling, U.N. Doc. Rep. 11/FL (2011), http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-39%252FREP11_FLe.pdf.

²⁸ Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003)* (2003), www.fao.org/input/download/standards/10007/CXG_044e.pdf

²⁹ Food & Drug Administration, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (2015), <https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm>.

³⁰ National Organic Standards Board, Materials/GMO Subcommittee Proposal, Additional Excluded Methods to be listed in the National Organic Program Excluded Methods Guidance Document (Aug. 22, 2017), <https://www.ams.usda.gov/sites/default/files/media/MSExcludedMethodsNOPFall2017.pdf>.

³¹ World Health Organization, Food and Agriculture Organization of the United Nations, Codex Alimentarius, *Organically Produced Foods, Section 2: Description and Definitions*, <http://www.fao.org/docrep/005/y2772e/y2772e04.htm>.

like direct injection, hybridization, and even gene deletion and doubling. Note that the Codex definition also says that the genetic engineering techniques “include, but are not limited to” the methods listed in its definition. This leaves room for interpretation and also new developing technologies. Thus, broadly interpreting “bioengineering” to cover highly refined ingredients and new technologies would be consistent with the Codex.

The U.S. is also a party to the Agreement on Technical Barriers to Trade (TBT), which requires Members to ensure that technical regulations are not adopted or applied with a view to or with the effect of creating unnecessary obstacles to trade, and regulations shall not be more trade restrictive than necessary to fulfill a “legitimate objective.” Such “legitimate objectives” include national security, *the prevention of deceptive practices*, protection of human health or safety, and the protection of the environment.³² As previously discussed, exempting highly refined ingredients from the NBFDS would betray consumer expectations. It could also exclude a significant portion of genetically engineered foods from disclosure, leading to potential consumer deception.

AMS states in the preamble to the rule its intention to establish recognition agreements with foreign governments that have established labeling requirements for BE food. These agreements would consider “whether the proposed partner nation’s BE labeling requirement is mandatory, what threshold requirement is imposed, and *what food products are subject to BE labeling*.” Most countries that require the disclosure of GMO foods, including some of our major trading partners, require that highly refined sugars and oils, as well as products of modern forms of biotechnology (including gene silencing or deletion via RNAi and CRISPR), be disclosed.³³ Based on our review of USDA Foreign Agricultural Service documents, at least 38 of the 64 countries identified as having mandatory labeling policies require that GMO oils and sugars be labeled, even if the transgenic material may not be detectable.³⁴ This includes the member countries of the European Union, as well as Russia, the United Kingdom, China, South Korea, and Brazil. These countries also have established broad policies with regard to the type of genetic engineering techniques used in the production of the specific GE product or ingredient. Interpreting “biotechnology” consistent with the majority of countries that require BE labeling would ease the process of creating and facilitating mutual recognition agreements, streamlining trade.

³² WTO Agreement on Technical Barriers to Trade, Article 2 Paragraph 2.2, Apr. 15, 1994, 1868 UNTS 120 (1994) [hereinafter TBT] (emphasis added).

³³ To assess the labeling policies of various countries, EWG reviewed materials prepared by Center for Food Safety (*see supra* note 2) relevant international governmental reports and regulations, and reports from USDA’s Global Agriculture Information Network, where applicable. For example, according to the European Union’s Law on the Application of EU Regulation 1829/2003 on GMO Food and Feed and Regulation 1830/2003 on Traceability and Labeling of Food and Feed Derived from GMOs that Amends EU Directive 2001/18/EC, food and feed containing agricultural biotechnology ingredients must meet the labeling requirements irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product. *See, e.g.*, Council Regulation 1829/03 of Sept. 22, 2003, On Genetically Modified Food and Feed, ¶ 21, 2003 O.J. (L 268) 3 (EC), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF>.

³⁴ *Id.*

d. Failure to require disclosure of food produced with modern forms of biotechnology could create conflict with other federal definitions

Other definitions of biotechnology promulgated by the federal government have included newer forms of genetic engineering. The definition of “biotechnology product” put forward in a 2015 memorandum issued by the Executive Office of the President includes all of the newer technologies used in biotechnology, such as those of gene editing or gene silencing.³⁵ The FDA uses the Codex definition of modern biotechnology, which is inclusive of new technologies.³⁶ In reference to the different methods of genetic engineering, USDA’s existing definition of excluded methods also includes gene editing and gene silencing.³⁷ The recent recommendation by USDA’s National Organic Standards Board clarifies that such forms of genetic engineering are prohibited under the organic standard.³⁸ USDA Animal and Plant Health Inspection Service also recently considered updating its regulations on genetically engineered organisms, “in response to advances in genetic engineering.”³⁹

e. Any definition of “conventional breeding” should be defined narrowly

AMS seeks comment on whether USDA should include a definition of “conventional breeding.” If AMS chooses to define “conventional breeding,” the definition should be construed narrowly. An overly broad definition could exclude a significant portion of the market. As the FDA pointed out in its technical assistance on Pub. L. 114-216, “[i]t may be difficult to demonstrate that a particular modification could not be obtained through conventional breeding (or even that it could not occur in nature).”⁴⁰ For example, although some kinds of gene editing could be achieved through conventional breeding, genetic engineering allows those modifications to take place significantly faster.⁴¹ However, a reasonable consumer would expect AMS to take into consideration the necessary time and conditions that would be needed for a gene modification to take place through “conventional breeding.”

As such, gene editing and gene silencing and other GE techniques should not be considered “conventional breeding.” JLI encourages AMS to follow the approach taken by FDA on genetically engineered animals. Proposed Guidance for Industry issued in 2016 covers animals whose “genomes have been intentionally altered using modern molecular technologies, which may include random or target DNA sequence changes including nucleotide insertions,

³⁵ Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture Regarding Modernizing the Regulatory System for Biotechnology Products, Executive Office of the President, July 2, 2015 (July 2015 EOP Memorandum) (online at: https://www.epa.gov/sites/production/files/2016-12/documents/modernizing_the_reg_system_for_biotech_products_memo_final.pdf).

³⁶ See Food & Drug Administration, *supra* note 29.

³⁷ 7 CFR § 205.105

³⁸ Formal recommendation from National Organic Standards Board to the National Organic Program, Excluded Methods Terminology to be Listed in the National Organic Program Excluded Methods Guidance Document (Nov. 2, 2017), <https://www.ams.usda.gov/sites/default/files/media/MSExcludedMethodsFinalRec.pdf>.

³⁹ Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms, 82 Fed. Reg. 7008 (Jan. 19, 2017) (to be codified at 7 C.F.R. pt. 340), https://www.aphis.usda.gov/brs/fedregister/BRS_20170119.pdf.

⁴⁰ FDA Technical Assistance on Senate Agriculture Committee draft legislation to establish a national disclosure standard for bioengineered foods (EDW16734) (June 27, 2016).

⁴¹ See Regalado, *supra* note 18.

substitutions or deletions, or other technologies that introduce specific changes to the genome of the animal.”⁴² This definition makes clear that animals with any altered DNA would fall under the guidance and would not be considered conventionally-bred animals. Likewise, any DNA sequence changes in food through gene editing, including “insertions, substitution or deletions” should not be considered “conventional breeding” and should be subject to the NBFDS.

The law also requires harmonization with organic standards. Thus, if AMS chooses to define “conventional breeding,” the most appropriate definition would be the definition for classical/traditional plant breeding agreed to by the NSOB:

Classical/traditional plant breeding—Classical (also known as traditional) plant breeding relies on phenotypic selection, field-based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.⁴³

f. None of the modifications produced through genetic engineering should be considered “found in nature”

AMS also seeks comment on whether it should define the term “found in nature.” If AMS decides to define the term “found in nature,” it should do so in a way that ensures the NBFDS rule covers all foods produced with or derived from genetic engineering, including those using new techniques of modern biotechnology.

An unduly broad definition of “found in nature” would exempt nearly all GE foods from the NBFDS. Virtually all GE foods have some trait that is “found in nature.” For example, crops like corn and sugar beets are modified to be herbicide-resistant, but herbicide resistance can also develop naturally.⁴⁴ The EPSPS gene, which makes crops resistant to glyphosate, is found in

⁴² U.S. Food & Drug Administration, *Draft Guidance for Industry #187: Regulation of Intentionally Altered Genomic DNA in Animals* p. 3 (Jan 19, 2017), <https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf>

⁴³ Formal recommendation from National Organic Standards Board to the National Organic Program, *Excluded Methods Terminology to be Listed in the National Organic Program Excluded Methods Guidance Document* (Nov. 2, 2017), <https://www.ams.usda.gov/sites/default/files/media/MSExcludedMethodsFinalRec.pdf>.

⁴⁴ Timothy S. Prather, Joseph M. Ditomaso, & Jodie S. Holt, *Herbicide Resistance: Definition and Management Strategies*, Publication 8012, University of California (2000), <http://anrcatalog.ucanr.edu/pdf/8012.pdf> (“In a plant, resistance may occur naturally due to selection or it may be induced through techniques such as genetic engineering”).

nature.⁴⁵ “*Bacillus thuringiensis*” is a bacteria that naturally produces a crystal protein that is toxic to pests.⁴⁶ Bt crops like corn have been genetically engineered to produce this same toxin to ward off pests.⁴⁷ Foods produced with these genetic modifications make up a substantial part of the GMO marketplace. Exempting these products from disclosure would clearly be contrary to consumer expectations and Congressional intent.

A broad definition of “found in nature” would also go against the plain meaning of the term “nature.” Merriam-Webster defines the term “nature” as “the physical world and everything in it (such as plants, animals, mountains, oceans, stars, etc.) that is not made by people.”⁴⁸ None of the modifications produced through genetic engineering could be “found in nature,” under this definition. Because these modifications cannot be “found in nature,” foods produced with these modifications would fall within the scope of the NBFDS.

One simple way to define “found in nature” and ensure that all GE foods are covered by the NBFDS, as intended by Congress, would be to take the approach suggested by Consumers Union in its response to USDA’s 30 questions. Consumers Union recommended interpreting “modification found in nature” to mean the *exact genetic construct* (e.g., the same nucleotide base sequence for the full construct) that has been inserted into the organism.⁴⁹ As Consumers Union explained in its response to USDA’s 30 questions, the natural traits or genes inserted into plants during genetic engineering usually have to be “codon optimized” first.⁵⁰ This means that the nucleotide base sequence in a gene is slightly altered before being inserted into the plant. Because that *exact* sequence is not a modification which can be “found in nature,” any food derived from genetic engineering would be covered by the NBFDS. Additionally, any excluded method under the National Organic Program should not be considered to be methods “found in nature.”

Finally, AMS also seeks comment on whether to consider intellectual property law as one potential method for determining whether a genetic modification is found in nature. The U.S. Patent and Trade Office has issued guidance for patent examiners that products of nature are not patentable subject matter. As such, AMS suggests that patented genetic modifications would not be considered “found in nature” for the purposes of the NBFDS. This approach may be used as one method to inform AMS’s decision-making on covered foods. However, as AMS recognizes, there are GE technologies and foods that have not sought intellectual property protection. The absence of a patent should not be a factor in determining if a modification can be found in nature.

II. List of commercially available GMO products

⁴⁵ Loredano Pollegioni, Ernst Schonbrunn, & Daniel Siehl, *Molecular basis of glyphosate resistance: Different approaches through protein engineering*, HHS Author Manuscript (June 28, 2011), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3145815/>.

⁴⁶ Matthew Niederhuber, *Insecticidal Plants: The Tech and Safety of GM Bt Crops*, Harvard University Graduate School of Arts and Sciences (August 10, 2015), <http://sitn.hms.harvard.edu/flash/2015/insecticidal-plants/>.

⁴⁷ *Id.*

⁴⁸ “Nature.” Merriam-Webster.com, <https://www.merriam-webster.com/dictionary/nature> (last visited July 2, 2018).

⁴⁹ See Consumers Union, *supra* note 11, at 7-8.

⁵⁰ *Id.* at 8.

AMS is proposing to create two lists of commercially available GE foods to inform food companies about which foods should be required to carry a disclosure and how. Only foods or products on the lists would be subject to disclosure under the law. The GE foods on these proposed lists are included in FDA's list of Biotechnology Consultations on Food from GE Plant Varieties,⁵¹ produced anywhere in the world, and commercially available for retail sale in the U.S.

The two lists USDA has created are:

- Highly Adopted Commercially Available BE – This includes crops like canola, field corn, cotton, soybeans, and sugar beets, where there is an adoption rate of 85 percent or greater. Foods on this list would be presumed to be GE, unless the producer can demonstrate otherwise, and would carry affirmative disclosures.
- Not Highly Adopted Commercially Available BE Foods – This includes non-browning apples, sweet corn, papayas, potatoes, and summer squashes. Only certain cultivars on this list would be presumed to be GE, unless the producer can demonstrate otherwise, and would be allowed to carry “may contain” disclosures.

JLI supports the creation of a presumption of disclosure for foods on the highly adopted commercially available list and for certain cultivars on the not highly adopted commercially available BE foods list. However, commercially available foods on the not highly adopted list should also be required to have an affirmative disclosure, rather than a “may contain” or “may be” disclosure. Raw foods like papayas and summer squash, and particularly GE raw foods with distinct traits like the non-browning apple should not be allowed to carry a “may be” disclosure just because these foods are not yet highly adopted BE foods. The proposed rule is already narrowly limited to select cultivars of these groups that use GE technology. These crops are relatively easy to segregate from their non-GE counterparts and should be labeled accordingly. AMS should also consider maintaining just one list of commercially available GE crops and cultivars of crops, all of which would be presumed to be BE and required to carry a disclosure. Foods, like the AquAdvantage Salmon, that have gone through FDA premarket consultation, but are not yet commercially available, should be subject to the NBFDS as soon as they become commercially available.

AMS is proposing that incidental additives exempt under 21 C.F.R. 101.100 not be required to be disclosed unless the incidental additive would require disclosure pursuant to other labeling requirements under the FDCA. JLI does not object to this approach. However, JLI does not agree with commenters who requested that the NBFDS exclude products where the modified genetic material ultimately cannot be detected. As JLI commented above with regards to highly refined sugars and oils, current technology may not always be able to detect genetically modified material. Excluding foods with “undetectable” genetic material could potentially exclude a large portion of GE foods on the market and would be contrary to both consumer expectations and Congressional intent.⁵²

⁵¹ U.S. Food & Drug Administration, Biotechnology Consultations on Food From GE Plant Varieties, <https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon>

⁵² See O'Neil & Perrone-Gray, *supra* note 15.

AMS also invites comment on the process to add products to the list. JLI agrees with AMS that the list of commercially available foods should be updated annually. We support the development of a process to help stakeholders determine whether a food is subject to disclosure. Such a process should include a rubric to help stakeholders, food manufacturers and the public understand how disclosure requirements are triggered, as well as a publicly available and searchable online database that includes the full list of determinations, with information provided as to the reason(s) for why a food product does or does not meet the disclosure requirement under the standard. JLI believes that AMS should establish a clear mechanism under the disclosure standard that requires the inclusion of new genetic engineering techniques, as they are developed, to ensure that companies and consumers understand the full scope of the disclosure standard. JLI believes that the 18-month grace period proposed under § 66.7(c) is unnecessarily long and should be shortened to a period of no longer than one year.

AMS should also establish a clear mechanism under the disclosure standard that requires the inclusion of new genetic engineering techniques, as they are developed, to ensure that companies and consumers understand the full scope of the disclosure standard.

III. Exemptions

- a. To avoid trade conflicts, the standard's de minimis threshold should be consistent with those of the majority of U.S. trading partners with a 0.9 percent threshold of the specific ingredient*

An important consideration for maintaining consistency with international standards and trading partners is the establishment of a consistent threshold – the amount of inadvertent or technically unavoidable GE content above which triggers the mandatory disclosure requirement. We urge AMS to adopt the most common international standard and current industry standard for mandatory disclosure, which is alternative 1-B, 0.9 percent by individual GE ingredient. Over half of the 64 countries that require GMO labeling have a GMO threshold level of at minimum 0.9 percent.⁵³ The European Commission standard has a lower, 0.5 percent threshold, which applies to unapproved GMO traits that have received a “favourable safety assessment” from an EC scientific committee.⁵⁴ This threshold is also consistent with the Non-GMO Project standard, the leading voluntary GE-free certification standard in the U.S.⁵⁵ This threshold was also endorsed by major industry stakeholders like Danone Wave, Procter & Gamble, the Specialty Food Association, and Unilever in response USDA’s 30 questions.

The other two thresholds proposed by USDA – five percent by weight of the specific ingredient, or five percent of the total weight of the food in its final form – would not be suitable options. These options would be inconsistent with most of our major trading partners and may exempt

⁵³ See *supra* note 33.

⁵⁴ See *Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (2003)*,

<https://www.food.gov.uk/sites/default/files/multimedia/pdfs/gmguidancent.pdf>.

⁵⁵ See *The Non-GMO Project, Non-GMO Project Standard* (Sept. 22, 2017), <https://www.nongmoproject.org/wp-content/uploads/2017/09/Non-GMO-Project-Standard-Version-14.2.pdf>.

wide swaths of foods from disclosure. While a small handful of countries have established a threshold above 0.9 percent, using the 0.9 percent standard would set a regulatory floor that would ensure that American companies are in compliance with all standards internationally – those set at 0.9 percent by weight of the specific ingredient and those above it. Establishing this floor would ease the process of negotiating and executing mutual recognition agreements, facilitating international trade.

However, as we have noted earlier, the ability to detect the presence of GE content alone should not serve as the basis for the GMO disclosure. The use of genetic engineering methods to produce a desired trait should also serve as the basis for the disclosure when it is difficult to detect the GE material in the finished product. As we have noted, consumers are not merely interested in the presence of GMOs but are also interested in the processes by which GMO traits are produced.

b. Very small food manufacturers

Pub. L. 114-216 specifically exempts “very small” food manufacturers. The proposed rule suggests defining very small food manufacturers as food manufacturers with annual receipts of less than \$2.5 million. This would exempt 74 percent of food manufacturers and exclude 4 percent of products from the disclosure requirement. AMS also asked for comment on alternative cutoffs of \$5 million or \$500,000 in annual sales.

In exempting very small food manufacturers from having to comply with the disclosure requirements of Pub. L. 114-216, Congress intended to only exempt “cottage foods” and very small companies. While “very small food manufacturer” is not defined in the statute, FDA’s regulations for nutrition labeling exempt very small food manufacturers as defined as companies that sell directly to consumers, such as retailers, that average less than \$500,000 in gross annual sales.⁵⁶ Because the NBFDS and nutrition labeling are both labeling requirements, \$500,000 is a logical cutoff point. Additionally, by AMS’s calculations, this cutoff point would exclude 45 percent of food manufacturers, but only 1 percent of products.

The FDA has elsewhere defined “very small businesses” as those “averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).”⁵⁷ According to AMS’s own analysis in the proposed rule, defining small or very small food manufacturers at this threshold would cover 58 percent of firms, but only exclude 2 percent of products. While AMS did not propose \$1,000,000 as an alternative cut-off, it should take this number into consideration.

c. Organic food

The use of “excluded methods,” which includes the use of GMOs, is strictly prohibited in organic production and handling. Because of these longstanding rules, Pub. L. 114-216 expressly

⁵⁶ 21 CFR § 101.9(j)(1)

⁵⁷ 110 C.F.R. § 117.3 (definitions for FDA rule titled *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*).

acknowledges that organic certification is sufficient to make an absence claim such “non-GMO” or “not bioengineered.” While the proposed rule exempts organic food from making a GE disclosure, it does not address non-GMO claims for organic foods. AMS should incorporate this statutory provision into the rule. Section 294 of Pub. L. 114-216 also explicitly states that foods cannot make absence claims solely because they are not required to make a GE disclosure, but this is not addressed in the proposed rule. AMS should clarify in the rule that other products exempt from disclosure, like milk from cows fed GE feed, or food produced by very small manufacturers, are not by default able to make a non-GMO claim simply because the food is not required to carry a disclosure.

AMS should also modify the organic exemption from “(e) Food certified organic under the National Organic Program” to “(e) Food certified under the National Organic Program.” This minor technical change will ensure that all NOP certified label categories (e.g., “100% Organic,” “Organic,” and “Made with Organic”) and all ingredients contained within each category are covered.

As described in section 293(f)(2) of Pub. L. 114-216 and further clarified through USDA’s Policy Memorandum on “Consistency with the AMS National Organic Program,” the NBFDS must also ensure that any proposed rules for bioengineered food disclosure will not require any modifications be made to the USDA organic regulations, including any definition of “excluded methods.” JLI suggests adding this statutory language to the rule to more explicitly require consistency with the National Organic Program.

The Disclosure Standard

I. Text disclosures

- a. The GMO disclosure standard should use terms that consumers understand, like “GMO,” “genetically modified,” or “genetically engineered”*

USDA has proposed that all GMO disclosures exclusively be made using the terms “bioengineered food” or “bioengineered food ingredients.” USDA should consider the terms “genetic engineering,” “genetic modification,” and “GMO” as interchangeable with “bioengineering” for purposes of the NBFDS because of their contemporaneous use in state and federal policy, as well as in international standards and guidelines developed by Codex Alimentarius.

Prior to passage of Pub. L. 114-216, three states – Connecticut, Maine and Vermont – passed mandatory disclosure laws for GE foods, and Alaska established a mandatory disclosure law for GE salmon. Each of these laws used the term “genetic engineering” to describe the technology and the terms “genetically engineered” or “genetically modified” for purposes of the disclosure requirement. In addition to state laws, federal policy has long used the terms “genetic modification” and “genetic engineering”⁵⁸ to describe this process, as do USDA’s own

⁵⁸ See Office of Science and Technology Policy, Executive Office of the President, *Coordinated Framework for Regulation of Biotechnology*, 51 FR 23302 (1986) https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf

regulations of plants produced using biotechnology.⁵⁹ All communications on genetic engineering from the National Organic Program since 2000 refer to “GMOs.”⁶⁰ Several companies that have chosen to voluntarily disclose the presence of GE ingredients have used terms like “genetic engineering” or “partially produced with genetic engineering.”

A recent study of consumer shopping habits and attitudes in Vermont following the rollout of its mandatory labels using the disclosures “produced with genetically engineered,” “partially produced with genetic engineering,” and “may be produced with genetic engineering” found that sales of GE foods didn’t decrease following these disclosures.⁶¹ In fact, consumer attitudes towards genetically engineered foods actually improved.⁶² What’s more, allowing use of these terms would provide continuity and ease compliance for companies that created labels for use in Vermont or that chose to voluntarily disclose.

The term “bioengineering” is often associated with the medical field, rather than food. Webster’s Dictionary defines “bioengineering” as the “biological or medical application of engineering principles (as the theory of control systems in models of the nervous system) or engineering equipment (as in the construction of artificial organs).”⁶³ The common use “bioengineering” in the medical, rather than the food context, could be confusing for some consumers.

Many of our major trading partners use some variation of “genetically modified” or “genetically engineered” in their disclosure standards. China,⁶⁴ South Korea,⁶⁵ and Japan⁶⁶ use the term “GM,” and the European Union⁶⁷ and Australia⁶⁸ use “genetically modified.” Several major industry stakeholders including the Campbell Soup Company, Danone Wave, the Grocery Manufacturers Association, the Independent Bakers Association, the National Pork Producers Council, Procter & Gamble, and Unilever voiced support for using these terms in the disclosure standard in their responses to USDA’s 30 questions.

Polling shows that consumers are less familiar with the term “bioengineered” or the abbreviation “BE.” In a recent consumer survey, 60 percent of respondents said they knew “not too much” or “nothing at all” about “bioengineered food.”⁶⁹ Only 25 percent said they knew “some” and only

⁵⁹ 7 CFR § 340.1

⁶⁰ Organic Trade Association, *Comments RE: Proposed Rule Questions Under Consideration for GMO Disclosure and Labeling*, p. 5 (July 17, 2017).

⁶¹ Jane Kolodinsky & Jayson L. Lusk, *Mandatory Labels Can Improve Attitudes Toward Genetically Engineered Food*, 4 *Science Advances* 1 (June 27, 2018) <http://advances.sciencemag.org/content/4/6/eaq1413.full>.

⁶² *Id.*

⁶³ “Bioengineering.” Merriam-Webster.com, <https://www.merriam-webster.com/dictionary/bioengineering> (last visited July 2, 2018).

⁶⁴ Library of Congress, Restrictions on Genetically Modified Organisms: China, <https://www.loc.gov/law/help/restrictions-on-gmos/china.php> (last visited July 2, 2018).

⁶⁵ Library of Congress, Restrictions on Genetically Modified Organisms: South Korea, <https://www.loc.gov/law/help/restrictions-on-gmos/south-korea.php> (last visited July 2, 2018).

⁶⁶ Library of Congress, Restrictions on Genetically Modified Organisms: Japan, <https://www.loc.gov/law/help/restrictions-on-gmos/japan.php> (last visited July 2, 2018).

⁶⁷ European Commission, Genetically Modified Organisms, Traceability and Labelling, https://ec.europa.eu/food/plant/gmo/traceability_labelling_en (last visited July 2, 2018).

⁶⁸ Food Standards Australia & New Zealand, Genetically Modified Food Labelling (Sept. 2016), <http://www.foodstandards.gov.au/consumer/gmfood/labelling/Pages/default.aspx> (last visited July 2, 2018).

⁶⁹ Mellman Group, National Omnibus Online Survey (June 25, 2018).

six percent said they knew “a great deal” about bioengineered food.⁷⁰ By contrast, 35 percent of surveyed consumers said they knew “some” about “foods containing GMOs” and eleven percent said they knew “a great deal.”⁷¹ Fewer than half of the respondents reported knowing “not too much” or “nothing at all” about foods containing GMOs.⁷²

The Campbell Soup Company also conducted its own consumer surveys when developing its voluntary disclosure in 2016. When testing nine different potential labels, the Campbell Soup Company found that consumers found the terms “bioengineered” and “genetically engineered” confusing and had a clear preference for “GMO.”⁷³ In its responses to USDA’s 30 questions, Campbell argued that “Not including genetically modified and GMO as permitted synonyms to ‘bioengineered food’ would likely confuse some consumers.”⁷⁴ Whole Foods also reported in its response to USDA’s 30 questions that based on its experience with customers and suppliers, “genetically modified organism,” “GMO,” and “Non-GMO” are widely and well-understood by consumers.⁷⁵

Consumers are also already familiar with “Non-GMO” labels in the marketplace. The Non-GMO Project Verified label can be found on more than 50,000 products across 3,000 brands and represents annual sales of more than \$22.3 billion.⁷⁶ Because consumers are already accustomed to seeing the term “Non-GMO” in absence claims, consumers will likely expect to see the same language used in presence disclosures.

b. The GMO disclosure should be a presence disclosure and should not allow for “may contain” statements

AMS is specifically seeking comment on the uses of “may be” or “may contain” disclosures. USDA has proposed allowing use of the phrases “may be a bioengineered food” or “may contain bioengineered food ingredients” for food derived from crops appearing on USDA’s list of “Commercially Available BE Foods – Not Highly Adopted.” The clear majority of the 64 countries that require the mandatory disclosure of GMO foods do not allow the use of a “may contain” statement to meet their disclosure requirements.⁷⁷ Companies subject to the disclosure requirement will already have to keep records to indicate compliance with the disclosure requirement, meaning they will be required to know if their product contains, or likely contains, a GMO ingredient or is genetically engineered. As such, there is no need for a “may contain” or

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ J.R. Pegg, *Campbell Soup Finds Consumers Prefer Clear GMO Labeling*, IEG Policy (Sept. 8, 2016), <https://iegpolicy.agribusinessintelligence.informa.com/PL037029/Campbell-Soup-finds-consumers-prefer-clear-GMO-labeling>.

⁷⁴ See Campbell Soup Company, *supra* note 9, at 3.

⁷⁵ Whole Foods Market, *Comments re: Proposed Rule Questions Under Consideration for GMO Disclosure and Labeling*, p. 1 (Aug. 23, 2017).

⁷⁶ Non-GMO Project, Verification FAQs, <https://www.nongmoproject.org/product-verification/verification-faqs/> (last visited July 2, 2018).

⁷⁷ See *supra* note 33.

“may be” statement in the disclosure, and allowing these statements will likely confuse consumers.

II. Symbols

Any symbol disclosure must sufficiently meet consumer expectations and accurately convey to a consumer that the food product is genetically engineered, was produced with genetic engineering, or contains certain genetically engineered ingredients. Each of the three proposed symbols contains the letters “BE” for bioengineered or statements using the terms “bioengineered food.” As explained above in the section on text disclosures, consumers are unfamiliar with the term “bioengineered” and are unlikely to understand that “be” is an abbreviation for bioengineered. Consumers readily recognize the acronym “GMO” as synonymous with genetic engineering or bioengineering. JLI recommends that AMS incorporate the term GMO into the symbol design.

Pub. L. 114-216 prohibits USDA from implying that foods or ingredients made from bioengineering are safer or less safe than their non-GMO counterparts.⁷⁸ AMS, in the preamble to the proposed rule, claims that it has designed the symbols in a way that will not “disparage” bioengineered foods or make comment on “safety.” Although the symbols certainly do not “disparage” GE foods, they are far from neutral. The three proposed symbols are all bright, cheery, and green, which could mislead consumers into thinking that GE foods are somehow healthier, better, or more environmentally friendly than non-GE foods. These symbols could also convey to consumers that GMO foods are safer than non-GMO foods, which is expressly prohibited by the statute.

AMS’s descriptions of the symbols are equally misleading. AMS describes alternative 2-B as a green circle with the lower-case type “be” in white type with an “inverted arch” below the letters. However, the combination of the lower-case “be” letters and “inverted arch” clearly resembles a smiling face. The description also states that around the circumference of the circle there are 10 triangular leaves equally spread around the perimeter of the circle, which transition from yellow to orange. Nowhere does the description state that that the symbol resembles a sun, even though it clearly does. Alternative 2-C, which clearly resembles a winking face, is described as a circle with two lowercase “be” letters, “an inverted green arch,” and with a “bifurcating leaf” inside the middle of the lowercase “b.” These descriptions fail to capture how consumers are likely to actually perceive these symbols.

Research has shown that green colors and natural images like leaves help consumers identify products as being environmentally friendly.⁷⁹ According to color theory, green colors in advertising and branding communicate “health, freshness, or an ‘all-natural’ quality.”⁸⁰ Oranges

⁷⁸ Pub. L. 114-216 specifically states: “For the purpose of regulations promulgated and food disclosures made pursuant to paragraph (2), a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering.”

⁷⁹ Lindsay Richards, *Examining Green Advertising and Its Impact on Consumer Skepticism and Purchasing Patterns*, 4 *Elon Journal of Undergraduate Research in Communications* 78 (2013), <http://www.elon.edu/docs/e-web/academics/communications/research/vol4no2/07LindsayRichardsEJFall13.pdf>.

⁸⁰ Canva, Color Theory, <https://www.canva.com/learn/color-theory/> (last visited July 2, 2018).

and yellows like the ones used in alternative 2-B communicate “activity, energy, and optimism” and “happiness, cheerfulness, and the freshness of spring.”⁸¹ Children are also drawn to happy images like the winking face proposed in alternative 2-C. A recent study found that when preferred food options like whole grains, low fat, fruits, and vegetables contained a green smiley face emoticon, elementary school students selected those options twice as often.⁸²

The leaves and other environmental imagery in the proposed symbols are also similar to symbols used for organics in Europe and for vegan food. The U.S. Environmental Protection Agency also uses leaves in its “Safer Choice” symbol. Consumers who are familiar with those symbols could be misled into believing that GE foods are more environmentally friendly or are organic.

AMS should redesign the NBFDS to be more neutral. There are several governmental and non-government symbols that effectively convey information without making any value judgments. For example, the Kosher symbol and gluten-free symbols simply utilize circles, letters, and words in neutral font. The USDA organic symbol is also clear but neutral. AMS should consider consumer focus groups as a means of better understanding what symbols could be easily recognized by consumers. JLI agrees with AMS’s proposal to allow a black and white version of the symbol, just as USDA allows a black and white version of the organic label.



Finally, the rule must also stipulate that the symbol should be placed near other required disclosures and be prominently sized. AMS should develop criteria for placement such that the symbol is placed near other required disclosures, is prominently sized, and is formatted in a manner that is easily recognizable and seen by a consumer.

III. Electronic disclosures

a. USDA needs to establish strong rules governing the use of electronic disclosures

The use of electronic disclosures, like Quick Response (QR) codes, present a number of technological, regulatory, and access-related challenges. The USDA-commissioned study by Deloitte identified a number of obstacles to digital disclosures, including that:

- Consumers associate digital links with marketing information, rather than food

⁸¹ *Id.*

⁸² Robert M. Siegel et al., *A Two-Tiered School Cafeteria Intervention of Emoticons and Small Prizes Increased Healthful Food Selection by Over 300%*, 5 Int’l J. of Food & Nutritional Science 60 (2016), http://www.ijfans.com/ijfansadmin/upload/ijfans_5784ca415b87a.pdf.

information.

- Consumers may not have equipment to scan digital links and most retailers do not offer viable alternatives.
- There are a multitude of scanning apps, most of which are not intuitive to use.
- Consumers may not be able to connect to broadband or connect at a speed that is fast enough to load information.⁸³

The final rule must address the issues identified in the Deloitte study and include clear rules and performance standards for companies that decide to use the electronic or digital disclosure method to ensure that consumers can consistently scan products to access GMO disclosures.

The rules established by USDA governing the regulation of mandatory electronic disclosures will be the first of their kind in the U.S. and potentially in the world. The final rules will set the precedent for how other federal agencies regulate electronic disclosures on consumer products moving forward. But the proposed NBFDS left out many key details with regards to digital disclosures.

Therefore, it is critical that USDA ensure the following technical and performance challenges related to electronic or digital disclosures are addressed in the final rule:

- i.* Size – QR codes do not always scan properly in low-light conditions, and the ability to consistently scan a QR code can vary depending on the type and model of smartphone or scanner being used. Sec. 293 of the law directs the Secretary to require that the “electronic or digital link disclosure is of sufficient size to be easily and effectively scanned or read by a digital device.” Many industry experts recommend that QR codes be a minimum size of 1.25 square inches to be easily and effectively scanned.⁸⁴
- ii.* Color, contrast and “quiet zone” – QR codes perform best when they are designed as dark codes on light backgrounds, and when there is a high level of contrast between the code and the background. In addition, QR codes require a “quiet zone” to serve as a buffer around all four sides of the code itself.⁸⁵ This ensures that a scanner can register the code and read it without interference. USDA should ensure that QR code design is included in its performance standards.
- iii.* Packaging material and shape – The type of packaging material and its shape can negatively impact the performance of a QR code. QR codes perform optimally when used on smooth, opaque and flat surface like paperboard, as

⁸³ Deloitte, *Study of Electronic or Digital Link Disclosure: A Third-Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure* (July 2017), <https://www.ams.usda.gov/sites/default/files/media/USDADeloitteStudyofElectronicorDigitalDisclosure20170801.pdf>

⁸⁴ See, e.g., Associated Labels & Packaging, 2011 Business Trend: Scanning Everything, <http://associated-labels.com/what-we-do/special-services/2d-barcodes/> (recommending that use a minimum size of 1.25 x 1.25 inches, excluding the quiet zone).

⁸⁵ *Id.*

compared to irregular materials like foil wrappers and plastic bags. Packaging material and shape must also be included in the performance standards for QR codes.

- iv. Changes in technology* – As USDA recognized in its 30 questions, a QR code is not the only 2D code that companies could use to meet the electronic or digital disclosure requirements of the law. Other coding systems like SnapTag®, Data Matrix, MaxiCode and Aztec Code may be appropriate, however each may also present unique technological challenges or hurdles that could jeopardize a consumer’s ability to access a GMO disclosure.⁸⁶ In addition to 2D codes, manufacturers could conceivably use radio-frequency identification (RFID) data chips, or electronic or digital watermarks to meet the electronic or digital disclosure requirements if smartphones could reliably scan such data. USDA’s rules need to be responsive to changes in technology, so that products continue to consistently scan under all conditions and settings.

- b. USDA should prohibit the use of multiple QR codes on a package*

If a company opts to disclose the presence of GMOs with the electronic or digital disclosure option, it should not be able to put a second or third QR code on the package because that would be confusing to a consumer. It may not be clear which QR code is for GMO information, and consumers may be directed to marketing information before receiving GMO information, which is prohibited by the statute.

- c. The GMO disclosure needs to be prominent and detailed if companies opt for the electronic or digital method*

Sec. 293 of the law clearly states:

the electronic or digital link will provide access to the bioengineering disclosure located, in a consistent and conspicuous manner, on the first product information page that appears for the product on a mobile device, Internet website, or other landing page, which shall exclude marketing and promotional information.

USDA should include in the NBFDS a requirement that the GMO disclosure be the first thing a consumer sees on the product information page after scanning an electronic or digital disclosure using their smartphone, tablet or any other type of electronic scanner. The disclosure should be prominent on the product information page and it should be consistent across all product types. The law expressly prohibits any marketing or promotional information, and any such information must also be omitted from any clearinghouse information pages. The product information page should be a mobile enabled or optimized landing page so that consumers using their smartphones to access GMO disclosures are able to view it in real time.

⁸⁶ See Tec-IT, Overview 2D Barcode Symbolologies, <http://www.tec-it.com/en/support/knowledge/barcode-overview/2d-barcodes/Default.aspx> (last visited July 2, 2018)

With regard to the specific GMO disclosure that appears on the product information page, we believe that AMS should establish in its proposed rule a requirement that GMO disclosures made on the product information page via the electronic or digital disclosure option be an affirmative presence or derived from claim, not a may contain claim, and provide ingredient-level information. The clear majority of the 64 countries that require the mandatory disclosure of GMO foods do not allow the use of a may contain statement to meet their disclosure requirements. The presence or derived from claim should denote the specific ingredients that were produced with biotechnology, just as required by many countries around the world, including all EU member countries, Australia and New Zealand.

d. Accompanying prompt and phone number should be prominently displayed

The law requires any digital disclosures to be accompanied by a toll-free phone number and a prompt. This information should be located in a conspicuous and consistent location and be appropriately-sized. When consumers call that number, they should get the same information about the product included in the digital disclosure, including ingredient-level information.

To satisfy the intent of the statute, AMS should use language that alerts the consumers that scanning the QR code or calling would provide GMO information, not merely more food information, such as “Scan for GMO Information” or “Call for GMO information.” A clear prompt is especially important given Deloitte’s finding that most consumers associate digital links with marketing information.⁸⁷

IV. Text message disclosure

The rule proposes a fourth option for disclosure – the text message option. This is a new option for disclosure, not specifically accounted for in the statute. The text message disclosure option cannot be considered a “comparable option” because it is not clear that this option, as written, would be in addition to the electronic or digital option. Additionally, even if someone has a cellphone, Deloitte’s study found that 20 million Americans – especially in rural areas – do not have reliable cellular service that would allow them to send or receive text messages.⁸⁸

The NBFDS must ensure that any comparable options be just as convenient as it is for someone to take out their phone and scan a product. For instance, USDA may want to consider requiring that retailers make Wi-Fi internet available to customers if reliable cellular service in their stores is a problem. Another way this condition could be met would be a requirement that retailers place scanners in grocery store aisles. A survey of 2D barcode image scanners on the website www.amazon.com found that scanners could be purchased for as little as \$39.99.⁸⁹

This would not be the first time that a government has required that retailers place scanners in

⁸⁷ See Deloitte, *supra* note 83.

⁸⁸ *Id.*

⁸⁹ Amazon, https://www.amazon.com/TEEMI-barcode-Handheld-Automatic-Computer/dp/B074KH88Z7/ref=sr_1_3?ie=UTF8&qid=1530327414&sr=8-3&keywords=2d+barcode+scanner (visited and price-checked on June 29, 2018).

stores. State and local governments have required in-store scanners to provide pricing information to consumers. The Massachusetts Grocery Pricing Law (G.L. c. 94, §§184B-184E) requires food stores and retailers with food departments to either individually place a price tag on all food and grocery items or provide electronic scanners in stores for consumer use to find a product's price.⁹⁰ Suffolk County, N.Y., has a similar law.⁹¹

USDA could tailor such a requirement to make an exception for any retailer that elects to make it a requirement that any product sold in their store subject to the NBFDS use either the text or symbol disclosure options.

V. Small food manufacturers

Section 293(b)(2)(F) requires that small food manufacturers receive additional implementation time and alternative disclosure options, including a telephone number or internet website. AMS has proposed defining small food manufacturers as manufacturers with less than \$10 million but more than \$2.5 million in annual receipts. By AMS's calculation this would cover 86 percent of food manufacturers and 8 percent of products. This threshold is too large and exempts too many products. Companies with \$10 million in annual receipts are large enough to meet the disclosure requirements under the NBFDS without an additional year of implementation time or the need for alternative disclosure options. A better threshold would be \$2.5 million in annual receipts, which would still accommodate 74 percent of food manufacturers, but only delay disclosure for 4 percent of products.

Additionally, the proposed prompts for the alternative telephone and web disclosures merely state "call for more food information" or "visit [URL of the website] for more food information." These prompts do not clearly convey to the consumer that this is how to obtain information about GMOs. The prompts should be amended to say "call for GMO food information" and "visit [URL of the website] for GMO food information" or something similar that clearly conveys to the consumer that this is how to get GMO information.

VI. Small and very small packages

Section 293(b)(2)(E) requires USDA to create alternative disclosure options for small and very small packages. These terms are well defined in FDA and USDA rules. In particular, FDA rules permit the creation an "acceptable alternative"⁹² for disclosure when the display panel is too small to accommodate the required disclosure.

The proposed NBFDS defines "small packages" as "food packages that have a total surface area of less than 40 square inches" and "very small packages" as "food packages that have a total surface area of less than 12 square inches." It shortens the prompts for digital, text message, and phone disclosures to "scan for info," "text for info," and "call for info." JLI recommends that AMS clarify in the prompts that consumers for scan, text, or call for "GE info." This only adds

⁹⁰ Mass. Gen. Laws ch. 94, § 184E (2014).

⁹¹ Suffolk County Local Law, 37-2008, ch. 542, § 1-19.

⁹² 21 C.F.R. § 101.2

two letters to the prompt, but will provide consumers with significantly more information. JLI also recommends the NBFDS encourage small and very small packages to use the symbol disclosure.

Record-Keeping, Enforcement, and Compliance

AMS seeks comment on various record-keeping provisions. In general, JLI supports the approach proposed by USDA whereby regulated entities that are making affirmative BE disclosures are not required to verify the BE status of foods and have minimal record-keeping requirements for the purposes of the NBFDS. Regulated entities that use commercially available BE crops or cultivars of crops that do not disclose, however, should be required to keep records verifying the non-BE status of those crops. The rule should make clear that certification under the National Organic Program is sufficient to meet any non-BE record-keeping requirements. JLI does not support the use of a “may contain” disclosure, but if AMS allows “may contain” statements, it should require that entities making “may contain” disclosures retain records demonstrating sourcing from both BE and non-BE suppliers.

Record-keeping timelines should coincide to the extent possible with the minimum expected shelf life of the covered food. Regulated entities that source from non-BE suppliers and therefore do not have to disclose, as well as entities making “may contain” statements, should be subject to periodic compliance audits.

The proposed rule suggests an effective 60 days after the date of the final rule’s publication with a compliance deadline of January 1, 2020, delayed to January 1, 2021 for small food manufacturers. AMS states that these dates are intended to align with the proposed rule to extend compliance dates for changes to the nutrition facts and supplemental facts label final rule. To the extent practicable, AMS should shorten these proposed compliance deadlines to more expeditiously provide consumers with GE information. Under no circumstances should the compliance deadlines be any later than the compliance dates for changes to the nutrition facts and supplemental facts panel.

Conclusion

JLI appreciates the opportunity to comment on the proposed NBFDS and hopes to continue to work with USDA to ensure that all Americans have access to information about food derived from genetically engineered ingredients.

Sincerely,

Gary Hirshberg
Chairman