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**Comments of Consumers Union to the
United States Department of Agriculture Agricultural Marketing Service on
Proposed Rule on National Bioengineered Food Disclosure Standard
Docket No. AMS-TM-17-0050**

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Introduction

On July 29, 2016, Congress passed P.L. 114-216, the National Bioengineered Food Disclosure Standard (NBFDS), which requires disclosure if a food product contains bioengineered (genetically engineered) materials. NBFDS stated that the disclosure could take three different forms: digital disclosure (e.g., via QR codes, URLs, 800 numbers), words/text of the package, or symbol on the package. The law gave USDA two years to implement its provisions, and left many questions to be resolved.

Such questions include: how to define bioengineered (including whether new technologies such as CRISPR or RNAi, and sugars, oils and highly refined materials are included), what level (or threshold) of bioengineered materials trigger disclosure, and what specific text or symbols would be used for on-package labeling.

Many of these issues are important to consumers, the vast majority of whom, in many polls, by Consumer Reports¹ and others² have said they supported on-package labeling of genetically engineered food. It is thus important that the disclosures USDA requires should be as

¹ Consumer Reports National Research Center. 2016. Consumer Support for Standardization and Labeling of Genetically Engineered Food: 2014 Nationally-Representative Phone Survey, Survey Research Report. At: www.consumersunion.org/wp-content/uploads/2014/06/2014_GMO_survey_report.pdf.

² Center for Food Safety. 2015. U.S. Polls on GE Food Labeling. At: www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling#.

accessible as possible to consumers, consistent with other labels they see in the marketplace such as “organic” and “non-GMO,” and otherwise not misleading.

Summary

Consumers Union, the advocacy division of Consumer Reports,³ welcomes the opportunity to comment on the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) proposed rule to implement the National Bioengineered Food Disclosure Standard. Key points in our comments include:

- AMS should require disclosure for food that contains highly refined ingredients from bioengineered crops such as soy and corn regardless of whether the bioengineered DNA material can be detected using current methodology, because the fact that genetic material cannot be detected using current methods does not mean it is not there. Furthermore, consumers are not just interested in whether foods contain altered DNA, but also in the origin of and production system involved in bioengineered crops. The question of whether GMO disclosures would include highly refined and processed oils and sugars, such as high fructose corn syrup, was a major issue in the debate over the NBFDS, and a number of Senators expressed strong concern that these foods should be covered. Therefore, USDA should adopt Position 2 as described in section II.C. of the proposed rule.
- AMS should not consider products of bioengineering, or modern biotechnology, including gene-edited products, as defined by the Food and Drug Administration (FDA), Codex Alimentarius, the National Organic Standards Board (NOSB) and others, to be either products of conventional breeding, or “modifications found in nature” under 7 U.S.C. 1639(1)(B). They should be subject to the law’s disclosure requirements because the genetic sequences that create bioengineered foods, including gene-edited products, are man-made in a laboratory and are unique. Most of them are also patented. We support AMS’s proposal to consider whether a modification has intellectual property protection (i.e., is patented) under 35 U.S.C. 101 as one factor in making a determination about whether a specific modification could be found in nature or is man-made and covered by the disclosure law.
- AMS should set the threshold for the amount of genetically engineered material in a food or food ingredient, above which the ingredient would be considered to be bioengineered and therefore required to be disclosed, at 0.9% of each ingredient in a food, since this is the threshold used in the European Union and other countries. Using this globally accepted threshold will facilitate international trade.

³ Consumer Reports is an independent, nonprofit member organization that works side by side with consumers for truth, transparency, and fairness in the marketplace. Founded in 1936, Consumer Reports has the largest nonprofit educational and consumer product testing center in the world, and uses its dozens of labs, auto test center, and survey research center to rate thousands of products and services annually. CR’s premier magazine Consumer Reports has more than 3.6 million subscribers, and the award-winning CR.org has 2.9 million paying members and more than 15 million unique visitors monthly, on average.

- USDA should not require use of the term bioengineered and the abbreviation BE for disclosure as this is not a term in use today in the marketplace and is almost completely unfamiliar to consumers. Terms now in use in the marketplace should be utilized for disclosure. The Agricultural Marketing Service (AMS) should recognize a limited number of terms—namely “genetic engineering,” “GE,” “genetic modification,” “genetically modified organism,” and “GMO”—to be interchangeable with “bioengineering,” and allow those terms to be used in a disclosure statement on the product. The first three are terms recognized by the Food and Drug Administration (FDA), and the latter two by the Food Safety and Inspection Service (FSIS). These alternative terms should be the ones used for the disclosure statement on the food package, where such information could be placed both on the principal display panel as well as in the ingredient list. Bioengineered status can easily be indicated by an asterisk symbol (*) after each ingredient in the ingredient list that is bioengineered along with, at the end of the ingredient list, a note that * = “genetically engineered” or “genetically modified.”
- AMS should allow use of a symbol denoting GE content. However, the symbol should be easily understood by consumers and should be aesthetically neutral, like other AMS symbols. All three proposed alternatives appear to be promotional in nature, designed to create a positive image for bioengineered foods, rather than conveying information in a neutral manner. We urge AMS to simply use a circle with the letters “GE”, “GM” or “GMO” inside that circle since those are terms that consumers readily understand, and the circle would be neutral.
- Digital or electronic disclosure would inhibit and in some cases could entirely prevent those without a smartphone or wireless broadband access--who are disproportionately lower-income, older and rural Americans-- from learning if their food is bioengineered. If companies choose to use digital or electronic disclosure, USDA must also require disclosure via use of text or a symbol on the package.

Applicability: What is to be disclosed?

Definition of “bioengineering” should include highly processed/refined products.

We urge AMS to adopt “Position 2” in section II.C. of the proposed rule. AMS should require disclosure for food that contains highly refined ingredients from bioengineered crops such as soy and corn regardless of whether the bioengineered genetic material can be detected using current methodology. The fact that genetic material cannot be detected using current methods does not mean it is not there, and scientific methods may well advance to where it can be detected in the future. Perhaps even more important, consumers regard a food from a genetically engineered plant or animal to be genetically engineered, regardless of whether altered DNA is detectable, or even present. Members of the Senate expressed concern in the debate over the NBFDS as to whether highly processed ingredients would be covered. We predict that consumers will have little faith in this disclosure system if it excludes refined sugar, refined oil, and high fructose corn syrup that they know comes from genetically engineered plants.

Part of the definition of “bioengineering” found in 7 U.S.C. 1639 states that it refers to a food “that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (DNA) techniques.” Some may say that this specific language means that highly refined products derived from bioengineered plants—such as highly refined oils, refined sugars, etc.— may not contain detectable levels of genetic material, and so would not meet the definition of “bioengineering.” Indeed, during floor addresses and at a press conference on July 6, 2016, multiple Senators expressed concern that this part of the definition of “bioengineering” might exclude numerous widely used products, such as soybean, corn or canola oil; high fructose corn syrup; and refined sugar, all made from genetically engineered plants.⁴ Senator Jeff Merkley, during a floor address on July 6, 2016, expressed a concern that the phrase “contains genetic material that has been modified” was one that “transforms a GMO ingredient to a non-GMO ingredient” explaining that “when you make high-fructose corn syrup, when you make sugar from sugar beets, when you make soybean oil from soybeans, that information is stripped out.”⁵

Senator Debbie Stabenow, a co-author of the bill along with Senator Pat Roberts, countered this concern, stating, during a July 6, 2016, floor address, that their “bill provides authority to the USDA to label refined sugars and other processed products.”⁶ On July 12, Senator Stabenow also 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.”⁷ In addition, in a letter to Senator Stabenow, USDA’s own General Counsel Jeffrey M. Prieto wrote that USDA has the authority to include ingredients derived from “novel gene editing techniques such as CRISPR” and products which contain “highly refined oils, sugars or high fructose corn syrup that have been produced or developed from genetic modification techniques.”⁸

In addition, even though a food or food ingredient may not contain detectable levels of genetic material from a “bioengineered” source using present technology, that does not mean that the ingredient does not contain any genetic material at all; it only means that it is not detectable using present readily available scientific methods. The U.S. Court of Appeals for the Sixth Circuit, in a case involving labeling of dairy products from animals not treated with the genetically engineered drug rbGH/rbST, reversed a lower court decision on the grounds that there could be a difference in the milk, even if the difference may not be detectable using present methodology. As the Sixth Circuit ruled:

“The district court held that the composition claims were inherently misleading because ‘they imply a compositional difference between those products that are produced with rb[ST] and those that are not,’ in contravention of the FDA’s finding that there is no measurable compositional difference between the two. . . . **In addition, and more salient to the regulation of composition claims like “rbST free,” the failure to discover rbST in conventional milk is not necessarily because the artificial hormone is absent in such**

⁴ https://www.youtube.com/watch?v=K_VTOqu7kVI

⁵ <https://www.c-span.org/video/?c4611539/sen-merkley-gmo-labeling-bill>.

⁶ <https://www.congress.gov/crec/2016/07/06/CREC-2016-07-06.pdf>.

⁷ 162 Cong. Rec. S4994. At: <https://www.congress.gov/crec/2016/07/12/CREC-2016-07-12-pt1-PgS4994.pdf>.

⁸ *Id.*

milk, but rather because scientists have been unable to perfect a test to detect it”⁹ bold added.

Similarly, although many food processing techniques, such as milling, heating, fermentation, and refining may degrade genetic material to such an extent that it cannot be detected using current scientific techniques, that does not mean that there is no genetic material present; it just means it is undetectable using currently available techniques.

However, as science advances, detection techniques improve and previously undetectable substance may become detectable. We see this in regard to soybean oil. A paper published in 1998 in *European Food Research & Technology* stated that “no genetic material can be recovered after the first processing steps of soybean oil, i.e., when crude soybean oils is simply centrifuged” such that “with respect to the presence of DNA, soybean oil from GMO soybeans is identical to traditional oil and does not need to be labelled as a GMO product in Switzerland.”¹⁰ More than ten years later, detection methodology had advanced enough such that a team of Portuguese scientists published a paper that “proved that it is possible to detect and quantify genetically modified organisms in the fully refined soybean oil.”¹¹ The following year a team of Chinese scientists published a paper showing 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, cornstarch and corn jam.¹²

A paper published in 2014 by a team of American scientists was able to detect DNA in various fractions generated during the industrial refining of sugar cane. While the amount of detected DNA declined throughout the processing steps, they still “detected minute quantities of sugar cane DNA in raw sugar.”¹³ Although they did not detect DNA in retail-purchased refined cane sugar, that does not mean that DNA was not there; it simply means that it cannot be detected using currently available methodology.

In terms of high fructose corn syrup (HFCS), in October, 2014 the Corn Refiners Association stated, in response to the question “Does High Fructose Corn Syrup contain GMOs?,” that “the genetically modified DNA or protein is degraded during the process that breaks corn down into HFCS, which makes the genetically modified DNA or protein undetectable.”¹⁴ Again, although the bioengineered DNA may be degraded to such an extent that

⁹ Pp. 9, 10 in *IDFA v Boggs* 622 F.3d 628 6th Circuit. At: <http://www.opn.ca6.uscourts.gov/opinions.pdf/10a0322p-06.pdf>.

¹⁰ Pauli U, Liniger M and A Zimmerman. 1998. Detection of DNA in soybean oil. *European Food Research & Toxicology* 207(4): 264-267. At: <https://link.springer.com/article/10.1007%2Fs002170050330>.

¹¹ Pg. 301 in Costa J, Mafra I, Amaral JS and MBPP Oliveria. 2010. Monitoring genetically modified soybean along the industrial soybean oil extraction and refining processes by polymerase chain reaction techniques. *Food Research International* 43(1): 301-306. At: <http://www.sciencedirect.com/science/article/pii/S0963996909003202>

¹² Jinxia A, Qingzhang L, Xuejun G, Yanbo Y, Lu L and Z Minghui. 2011. A multiplex nested PCR assay for the simultaneous detection of genetically modified soybean, maize and rice in highly processed products. *Food Control* 22(10): 1617-1623. At: <http://www.sciencedirect.com/science/article/pii/S0956713511001010>.

¹³ Pg. 1 in Cullis CA, Contento AL and M Schell. 2014. DNA and protein analysis throughout the industrial refining process of sugar cane. *International Journal of Agricultural and Food Research*, 3(2): 1-15. At: <https://www.sciencetarget.com/Journal/index.php/IJAFR/article/view/437/118>

¹⁴ <https://gmoanswers.com/ask/does-high-fructose-corn-syrup-contain-gmos>.

it is undetectable, it does not mean that the DNA is not present, simply that it cannot be detected using currently available methodology.

In sum, given that the co-authors of NBFDS and a legal opinion from USDA stated that it could require labeling of highly processed ingredients; that a legal opinion from the Sixth Circuit stated that just because present methodology cannot detect a substance does not mean that it does not exist in a food; and that detection methodologies have improved over time such that bioengineered genetic material has been found in highly processed products in which it had not previously been detectable, we urge AMS to require disclosure for food that contains highly refined ingredients derived from bioengineered crops.

Finally, consumers themselves are not concerned about whether a product contains altered DNA per se, but whether a food comes from a genetically engineered plant or animal. Various “non-GMO” labels in the marketplace, as well as the organic label, insist that the product be from non-GMO seed. The presence or absence of altered DNA is not the determining factor in the definition of non-GMO for these labels. This is true even if the product is highly refined such as soy or canola oil, sugar or high-fructose corn syrup. We therefore urge AMS to adopt Position 2 as described in section II.C. of the proposed rule.

AMS should define conventional breeding using the NOSB definition

Conventional breeding consists of various techniques that do not include techniques of modern biotechnology, as defined by the National Organic Standard Board (NOSB), FDA, Codex and the Cartagena Protocol. We urge AMS to adopt NOSB’s approach. Based on these definitions, gene editing techniques, and RNAi are also techniques of modern biotechnology and are not techniques of conventional breeding.

Part of the definition of “bioengineering” found in 7 U.S.C. 1639 states that it refers to a food for which “the modification could not otherwise be obtained by conventional breeding,” but does not give a definition for “conventional breeding.” In addition, the law urges harmonization of these disclosure standards with those of the organic standards, which are overseen by another AMS program, the National Organic Program. Consumers Union urges AMS to define “conventional breeding” and to use the definition for “classical/traditional plant breeding” agreed to at the November 2016 National Organic Standards Board (NOSB) meeting by a vote of 14-0, as a basis for considering which breeding techniques should be considered as “conventional breeding.” The NOSB definition states:

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.¹⁵

Utilizing the definition of classical/traditional breeding already agreed to by NOSB, any “techniques of modern biotechnology” would not be considered to be part of “conventional” (i.e., classical/traditional) plant breeding. We note that the November 2016 NOSB meeting also adopted a definition of “modern biotechnology”:

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. (From Codex Alimentarius).¹⁶

The NOSB definition of “modern biotechnology” is the same as the FDA’s definition of “bioengineering.” FDA, in two Guidances for Industry,¹⁷ has stated that its preferred term, “bioengineering” is interchangeable with the terms “recombinant DNA technology,” “modern biotechnology” and “genetic engineering.” FDA states:

In this guidance, we use the terms “bioengineering,” “bioengineered,” and “genetic engineering” to describe the use of modern biotechnology. Modern biotechnology means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection (Ref. 1). The term “modern biotechnology” may alternatively be described as “recombinant DNA (rDNA) technology,” “genetic engineering,” or “bioengineering.” These terms are often used interchangeably by industry, federal agencies, international bodies, and other interested stakeholders and are used in this guidance to refer to foods derived from new plant varieties developed using modern biotechnology.¹⁸

The NOSB definition is the same as the definition in the Principles for Risk Analysis of Foods Derived From Modern Biotechnology adopted by the Codex Alimentarius Commission in 2003.¹⁹ This document was agreed to by the United States government. Documents and

¹⁵ National Organic Standards Board (NOSB). 2016. Excluded Methods Terminology Recommendation. Adopted November 18, 2016. At: <https://www.ams.usda.gov/sites/default/files/media/MSExcludedMethods.pdf>.

¹⁶ *Id.*

¹⁷ Food and Drug Administration (FDA). 2015a. Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants. At: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm> ; and FDA. 2015b. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon. At: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm>.

¹⁸ FDA. 2015a. *Op cit.*

¹⁹ Food and Agriculture Organization of the United Nations (FAO), Codex Alimentarius Commission (CAC). 2003. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) At: www.fao.org/input/download/standards/10007/CXG_044e.pdf.

standards developed by Codex are referenced by the World Trade Organization in trade disputes involving food, and constitute a globally accepted standard. In addition, the term “modern biotechnology” defined by Codex Alimentarius is also used in the Cartagena Biosafety Protocol under the Convention on Biological Diversity, another globally accepted standard.²⁰ USDA should use the definition of “modern biotechnology” adopted by the NOSB, FDA, Codex Alimentarius, and the Cartagena Protocol because it will minimize consumer and regulatory confusion in the U.S. and facilitate international trade.

Newer techniques of biotechnology (e.g., gene editing, gene silencing, etc.) should not be considered to be conventional breeding

FDA has clearly indicated that it regards gene-edited animals as products of modern biotechnology, and not products of conventional breeding. FDA stated that it is revising Guidance for Industry (GFI) #187, *Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs*, to make clear that developers of animals produced using emerging technologies (e.g., genome editing) would fall under this guidance document. We strongly agree with FDA’s new proposed language in the GFI #187 stating that it “addresses animals whose genomes have been intentionally altered using modern molecular technologies, which may include random or target DNA sequence changes including nucleotide insertions, substitutions, or deletions, or other technologies that introduce specific changes to the genome of the animal.”²¹ This language is broad enough that it would include present emerging technologies (e.g., genome editing), as well as future technologies designed to alter the genome of animals or other organisms.

A July 2, 2015 memorandum, “Modernizing the Regulatory System for Biotechnology Product,” from the director of the White House Office of Science and Technology Policy (OSTP) to the heads of the FDA, EPA and USDA, states that “‘biotechnology products’ refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes.”²² This language is broad enough that it would include present emerging technologies (e.g., genome editing), as well as future technologies designed to alter the genome of animals or other organisms.

If we consider the definition of “modern biotechnology” as agreed upon by NOSB, FDA, Codex Alimentarius and the Cartagena Protocol of the Convention on Biological Diversity, the FDA’s proposed revision of GFI #187, and the OSTP memo on modernizing the regulatory system for biotechnology products, it is clear that all these definitions include the newer technologies of biotechnology, such as those of gene editing (including sequence-specific

²⁰ Convention on Biological Diversity (CBD). 2000. Text of the Cartagena Protocol on Biosafety. At: <https://bch.cbd.int/protocol/text/>.

²¹ P. 3 in FDA, 2017. Draft Guidance for Industry #187 Regulation of Intentionally Altered Genomic DNA in Animals, online at: www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf.

²² Holdren JP, Shelanski H, Vetter D and C Goldfuss. 2015. MEMORANDUM FOR HEADS OF FOOD AND DRUG ADMINISTRATION, ENVIRONMENTAL PROTECTION AGENCY, AND DEPARTMENT OF AGRICULTURE: Modernizing the Regulatory System for Biotechnology Products. Executive Office of the President. At: https://www.epa.gov/sites/production/files/2016-12/documents/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

nucleases, meganucleases, zinc finger nuclease, CRISPR-Cas system, TALENs, and oligonucleotide directed mutagenesis) or gene silencing (including RNAi, RNAi pesticides, and RNA-dependent DNA methylation). Under these established definitions, any organisms developed using “modern biotechnology” or “modern molecular technologies” would not be considered as “conventional breeding” and should not be exempt from the mandatory disclosure requirement of NBFDS.

AMS should define “found in nature” to exclude products of modern biotechnology

The purpose of NBFDS is to require disclosure of bioengineered foods, that is, foods created in the laboratory using techniques of modern biotechnology rather than through conventional breeding. While virtually all bioengineered foods do contain traits that are found in nature, the entire altered genetic sequence used to produce such foods is not found in nature. Therefore, products of modern biotechnology, as defined by NOSB, FDA, Codex Alimentarius, and Convention on Biological Diversity and others, including gene-edited products, should not be considered “modifications found in nature” under U.S.C. 1639(1)(B).

A very broad view of “modifications found in nature” would be contrary to the plain language of the law, since Congress clearly did not intend to exclude virtually all bioengineered foods from coverage under the NBFDS. AMS should therefore adopt a narrow definition of this term.

In trying to determine which “modifications” AMS should consider to be “found in nature,” AMS should not define these terms broadly. If the term “found in nature” is taken literally, that could mean that only synthetic traits that do not occur anywhere in nature would make a food “bioengineered.” Such a definition would exclude virtually all present GMO crops. At present, the overwhelming majority of the acreage in GE crops in the US (over 99%) contains the trait(s) for herbicide tolerance and/or pest resistance. The main herbicide tolerance trait is for tolerance to glyphosate (although some crops are engineered to be resistant to glufosinate, 2,4-D or dicamba), while the main insect resistant trait is to produce one or more delta-endotoxins, called Cry proteins, from the soil bacterium *Bacillus thuringiensis*, often referred to as Bt crops. Virtually all the glyphosate tolerant crops (e.g., corn, soy, canola, sugar beets, cotton, alfalfa) contain a glyphosate tolerance gene derived from *Agrobacterium* sp. strain CP4 which is found in nature. The bulk of the Bt crops use a Bt gene, e.g., such as Cry1Ab, Cry1Ac, Cry3Bb, Cry1F, etc. which is also found in nature. Thus, one could argue that virtually all the herbicide tolerant and insect resistant traits are “found in nature,” just not found in the plant species to which they have been inserted, and so could end up not being included in the disclosure requirements. In addition, virtually all the genetic material that has been inserted into GE plants as part of the genetic engineering process, such as the CaMv 35s promoter (from the cauliflower mosaic virus), the Ti plasmid (from *Agrobacterium tumefaciens*), as well as all the various antibiotic resistant marker genes, can be “found in nature,” just not in the plant species that have been engineered. Even the one GE animal approved by the FDA, the GE Atlantic salmon (aka AquAdvantage salmon [AAS]), would not be considered as “bioengineered,” using a broad definition of “modifications ... found in nature.” The AAS contains a growth hormone gene

from Chinook salmon, while the promoter gene came from the Ocean pout. Both these genes are "found in nature;" just not in Atlantic salmon.

So, if AMS were to define “modifications ... found in nature” in a broad fashion, it would render the plain language of the NBFDS essentially meaningless, since the Standard would cover almost none of GE crops on the market that would be considered to have “modifications ... found in nature,” and none of the products derived from them would be required to be disclosed.

In implementing this law, AMS should therefore define “modifications ... found in nature” in a narrow fashion. Organisms that are produced through human intervention in a laboratory via “bioengineering” (i.e., “modern biotechnology”) should not be considered to be “modifications ... found in nature,” and should not be exempt from being disclosed under NBFDS.

“Modification” should be the exact genetic construct; exact constructs are not found in nature

Rather than taking a broad approach, we urge AMS to interpret “modification” more narrowly to mean the exact genetic construct (e.g., the same nucleotide base sequence for the full construct) that has been inserted into the organism (plant, animal or microorganism). Defining “modification” in this specific fashion ensures that all products of organisms produced using “bioengineering” (i.e., “modern biotechnology”) would fall under the disclosure requirements.

We note that the vast majority of the traits/genes engineered into GE plants come from bacterial or viral sources (e.g., the glyphosate, glufosinate, 2,4-D and dicamba tolerance genes from various bacterial species, the CaMV 35S promoter from cauliflower mosaic virus, use of the Ti plasmid from *Agrobacterium tumefaciens*, the numerous antibiotic resistance genes from various bacteria) have to be “codon-optimized” so that they work in a plant genome. What this means is that rather than inserting the exact glyphosate tolerance gene as found in *Agrobacterium* sp. strain CP4 into a plant, one modifies the nucleotide base sequence of the gene from *Agrobacterium* sp. strain CP4 so that it will “work” more efficiently when put into a plant, e.g., the enzyme produced by the gene will be produced in enough quantity in the plant to have the desired effect (resistance to glyphosate). Usually, this entails changing roughly 20% of the nucleotide bases in a gene from a bacterial source to get it to be efficiently produced in a plant background. In a sense, a plant can tell when foreign genetic material—say from an invading bacteria or virus—comes in because it does not have the same characteristics at the nucleotide base level as plant genetic material. So, the fact that genes from bacteria or viral sources have to be changed at the nucleotide base level, even though the amino acid sequence of the gene product may be the same whether the gene is expressed in a bacteria or a plant, means that the “modification,” e.g., the exact genetic construct does not occur in nature.

The phenomenon of codon optimization also occurs with gene-editing techniques. The CRISPR/Cas9 system is considered to be the best system for gene editing. The CRISPR/Cas system is based on a prokaryotic immune system, whereby bacteria can detect and destroy “foreign” genetic elements. The CRISPR/Cas system has two basic elements—a molecular scissors (a protein that cuts genetic material, e.g., DNA, RNA), and guide element (a short piece of RNA) to tell the molecular scissors where to cut. The molecular scissors is the Cas (CRISPR

associated system) element, while the guide RNA (gRNA) is the CRISPR (clustered regularly interspaced short palindromic repeats) element. The Cas element and the gRNA combine to form a complex (aka Cas nuclease complex) which will then lead to DNA being cut at a specific location (as determined by the gRNA). When plants are transformed using CRISPR/Cas, the gene to produce the Cas element (usually Cas9) and the gene(s) to produce the gRNA(s) are inserted into a plant, often along with a marker gene, such as antibiotic resistance gene, to help in the detection of the plant cells that have been transformed (e.g., taken up the Cas9 gene and gRNA genes and expressed). In this example, both the Cas gene and the antibiotic resistance marker gene come from bacteria so those genes must be codon optimized. As a recent review noted, “To improve *Cas9* expression in plants, most modified *Cas9* genes for plant genome editing have also been optimized with plant-usage bias codons.”²³ These codon optimized genes are not found in nature, so plants developed using such CRISPR/Cas9 systems, whether or not those genetic elements have been inserted into the plant genome, would not be eligible to be exempted from the labeling requirements of NBFDS.

In cases where the genetic material comes from the same type of organism, although the genes do not have to be codon-optimized, the full genetic construct itself (i.e., the “modification”) would not be found in nature, even though separate parts of the construct may be. Take the AquAdvantage salmon (AAS), for example, where the genetic construct consists of a promoter (e.g., a genetic regulatory element) gene from the ocean pout attached to a growth hormone gene from Chinook salmon that is inserted into the genome of an Atlantic salmon. While both the promoter gene from ocean pout and the growth hormone gene from Chinook salmon do exist in nature with the same genetic sequence, the specific genetic construct (ocean pout promoter gene + Chinook salmon growth hormone gene) does not.

Gene silencing (including RNAi and RNA-dependent DNA methylation), which has been used to create a non-browning apple, usually involves inserting short genetic sequences into plants that result in the production of very short sequences of RNA (called microRNA [miRNA] and small interfering RNA [siRNA]) that shut down/prevent expression of specific genes that contain that same short genetic sequence. The very short sequences of RNA that are produced in the plants “bioengineered” to silence genes (such as the Arctic Apple which is engineered so that the gene [polyphenyl oxidase] that normally causes a cut apple to turn brown is turned off resulting in apples that don’t brown when cut) are not “found in nature.”

In sum, AMS should not regard gene sequences that are created in a laboratory through techniques of modern biotechnology to be “modifications...found in nature.” Both the older types of “bioengineering” along with the newer technologies such as those of gene editing (including sequence-specific nucleases, meganucleases, zinc finger nuclease, CRISPR-Cas system, TALENs, and oligonucleotide directed mutagenesis) or gene silencing (including RNAi, RNAi pesticides, and RNA-dependent DNA methylation) involve unique genetic constructs that are not found in nature. Products of these constructs used to produce an organism should therefore be subject to the law’s disclosure requirement.

²³ Ma X, Zhu Q, Chen Y and Y-G Liu. 2016. CRISPR/Cas9 platforms for genome editing in plants: Developments and applications. *Molecular Plant* 9: 961-974. At: [http://www.cell.com/molecular-plant/pdf/S1674-2052\(16\)30031-4.pdf](http://www.cell.com/molecular-plant/pdf/S1674-2052(16)30031-4.pdf).

We urge AMS to adopt the concept in the proposed rule that whether a modification is patented, i.e., has intellectual property protection under 35 U.S.C. 101, should be one method in making a determination about whether a specific modification could be found in nature. Bioengineered plants are widely (though not always) patented, which means that they have been found to be unique and not simply a product of nature. Bioengineered plants not found in nature are subject to disclosure under the law.

Lists of bioengineered foods that are highly adopted or not highly adopted

We agree with AMS that lists of commercially available bioengineered foods could make it easier for consumers and regulated entities to understand what potential products or ingredients may need to be disclosed under the NBFDS. AMS proposes to compile two lists, one for commercially available bioengineered foods that are highly adopted, the other for bioengineered foods that are not highly adopted. AMS states that only foods or products on one of these lists would be subject to disclosure.

For the highly adopted list, AMS proposes that foods on that list would be those that have an adoption rate of eighty five percent (85%) or more in the United States as determined by the Economic Research Service. Foods on this list would have to be labeled “bioengineered.” Any entity producing or selling a food on this list who did not disclose it as BE would need to maintain documentation that the food is not BE. We support dealing with high-adoption crops in this manner.

We do not support AMS’s proposal for addressing non-high adoption BE foods. There are too many examples of BE foods that would escape disclosure requirements altogether as a result of this proposal.

For the not highly adopted list, AMS proposes to include the following: non-browning apple cultivars, sweet corn, papaya, potato and summer squash. These may be disclosed with a “may contain” or “may be” BE statement.

This is not a complete list of genetically engineered or BE foods, however. We urge, at a minimum, that this list should include all foods for which there has been an FDA safety consultation, and which are therefore free to come on the market in the US.

We are concerned that this list categorically excludes bioengineered foods that are approved and available in other countries, which include rice cultivars, sugar cane cultivars, pink-fleshed pineapple cultivars, and fast-growing salmon. There are likely to be more of these in the future. Under this proposal they would escape any disclosure. To avoid this problem, any bioengineered food that is commercially available in any country should be on the not-highly adopted list, so that companies and consumers know that food products or ingredients from those foods may be present in foods sold in the U.S. Companies that are importing foods or food ingredients from those countries need to know that the product may be bioengineered.

This is particularly true for the GE salmon, which is approved for production in both Panama and Canada, although presently there is only production in Panama. Any salmon imported from Panama would be GE and so there should be disclosure, especially since the hold

on imports of salmon from Panama due to a provision championed by Sen. Lisa Murkowski in FY 2018 appropriations expires in October 2018. While this provision seems likely to also be included in appropriations for the following fiscal year, there is also the distinct possibility that this salmon product will go on the market at some point. For sources of information on GE plants available in other countries, there is the database from International Service for the Acquisition of Agri-biotech Applications (ISAAA).

Another concern is that the non-high adoption list foods could carry only a “may contain” label. This means that a piece of genetically engineered squash, apple or potato, 100% BE, could carry a “may contain” label, simply because it is not a high adoption crop. Any 100% BE food should always be required to be disclosed.

As noted above, all the foods that have gone through the FDA’s voluntary premarket consultation for genetically engineered plant varieties but have not been commercialized, or have gone through the FDA’s approval process for genetically engineered animals, should be required to carry a disclosure if they are sold in US commerce. This includes, for example, golden rice which is not expected to be grown in the US but could be shipped here for sale.

Another problem with these two lists is that they appear to apply only apply to crops. However, besides bioengineered crops, and BE animals, there are numerous bioengineered food ingredients, such as enzymes, yeast or foods/ingredients, and dietary supplements produced in controlled environments using bioengineering that are commercially available. All these foods and food ingredients that come from bioengineered organisms should be required to be disclosed. In terms of how to describe such foods, those that are produced using engineered microorganisms (yeast, bacteria, etc.) could be listed as the food ingredient, such as the soy leghemoglobin produced in yeast that is used as a key ingredient in the Impossible Burger, or the enzyme or yeast. Disclosure of such food ingredients should be reserved for any ingredient that would be listed on an ingredient list. Processing aids and micro-ingredients would not have to be disclosed, unless those ingredients collectively comprised more than 0.9% of the weight of the final food product.

Finally, we are concerned that AMS proposes only to update the lists on a yearly basis. If used, the lists should be updated on a quarterly basis. Furthermore, if a food product or ingredient for a bioengineered source comes on the market between postings of the lists, the companies should still be required to label such ingredients and not wait for the lists to be updated. While the lists do serve a useful purpose for companies and consumers showing which foods and food ingredients may come from a bioengineered source, they should not be the sole criteria for determining whether a food or food ingredient requires disclosure.

Threshold of a bioengineered substance present in a food that should trigger disclosure

AMS should set the threshold for the amount of GE material in a food, above which the ingredient would be considered to be bioengineered and therefore required to be disclosed, at 0.9% of each ingredient in a food.

AMS proposes three different possible thresholds to determine the amount of a bioengineered substance that would be present in a food that would trigger disclosure: (1) five percent (5%) of the specific ingredient by weight, (2) nine-tenths of a percent (0.9%) of the specific ingredient by weight, and (3) 5% of the total weight of the product.

Consumers Union urges AMS to adopt the second option, of 0.9%, on a per ingredient basis, with a slight modification. The 0.9% threshold should be based on a per ingredient basis, not on the relative weight of the ingredient. We suggest this because the polymerase chain reaction (PCR) test used to detect DNA does not provide results based on weight of an ingredient; it provides results in terms of percent of the DNA in the ingredient that is bioengineered. As USDA's own Biotechnology Proficiency Program Annual Report, which provides reliable testing of modern biotechnology-derived grains and oilseeds, from October 2017 states, "Samples prepared at a particular %w/w fortification should in theory be concordant with consensus values as cited in the report. In many instances, however, the %w/w fortification value did not agree with analytical data generated by PCR when compared to commercially available reference standards using in-house validated methods."²⁴

The threshold of 0.9%, on a per ingredient basis, is currently a widely accepted standard. This is the threshold for labeling GE ingredients in the European Union, a primary US trading partner.

In addition, a number of "non-GMO" labels already use the threshold of 0.9%, on a per ingredient basis, above which the product cannot be labeled as non-GMO.²⁵ The Non-GMO Project uses a 0.9% threshold for ingredients, above which a product cannot bear its Non-GMO Project Verified label. This label is found on more than 43,000 products with annual sales of over \$19 billion.²⁶ NSF International, an international standards development organization, has a Non-GMO True North program that uses the 0.9% threshold for finished products, above which a product cannot use the NSF Non-GMO seal.²⁷ The company SunOpta, which sells non-GE soy, uses a threshold of 0.9%, above which its soybeans cannot be labeled as non-GMO. The company's soybeans use an in-house verification process and quality management system that is based on USDA's Process Verified Program (PVP) and utilizes the USDA Process Verified shield.²⁸

With these established thresholds as benchmarks, we urge AMS to require disclosure for any food that contains an ingredient in the ingredient list that exceeds a 0.9% bioengineered threshold. This is information that consumers want to know and would facilitate tracking of any health effects that might occur, such as a possible allergic response, after post-market exposure.

Incidental additives, e.g., those additives/ingredients that are present in a food at an insignificant level and do not have a technical or functional effect in the food, are exempt from

²⁴ Pg. 3 in Agricultural Marketing Service (AMS). 2017. Biotechnology Proficiency Program October 2017 Bi-Annual Report. USDA. At: <http://gipsa.usda.gov/fgis/proficiencyprogram.aspx>

²⁵ Roseboro, K. 2015. New non-GMO certification programs emerging. *Organic and Non-GMO Report*. At: <http://non-gmoreport.com/articles/new-non-gmo-certification-programs-emerging/>

²⁶ Non-GMO Project. 2018a. Product Verification. At: www.nongmoproject.org/productverification

²⁷ Roseboro K. 2015. *Op cit*.

²⁸ *Id.*

certain labeling requirements under the Federal Food, Drug, and Cosmetic Act (FDCA). We agree with the proposal that a trigger for disclosure should be reserved for any ingredient that would be listed on an ingredient list, so that processing aids and micro-ingredients would not have to be disclosed, unless those ingredients collectively comprised more than 0.9% of the weight of the final food product, as is the case in the EU.

In sum, AMS should require disclosure under BFDS for any food product that contains at least one bioengineered ingredient that exceeds 0.9% bioengineered. In addition, the disclosure should also occur on the ingredient list. One easy way to do this is to use an asterisk symbol (*) after each ingredient in the ingredient list that is bioengineered and then at the end of the ingredient list note that * = “genetically engineered” or “genetically modified.”

AMS should allow terms other than ‘bioengineering’ to appear on a food label

AMS proposes to prohibit terms other than “bioengineered” on bioengineered foods. AMS should recognize a limited number of alternative terms—namely “modern biotechnology,” “genetic engineering,” “GE,” “genetic modification,” “genetically modified organism,” and “GMO”—to be interchangeable with “bioengineering,” since the public does not recognize or understand the term “bioengineered,” but does recognize terms such as GMO. The first three are terms that FDA recognizes as interchangeable. USDA/FSIS proposed allowing the latter two in its guidance on non-GMO labeling. Presently, a number of companies in the US are presently labeling their products using terms such as “genetically engineered” or “partially produced with genetic engineering.”

Terminology Report prepared by the Non-GMO Project, a survey of average monthly Google searches from July 2017 to June 2018 found that the term GMO averaged more than 600,000 searches per month, while the terms “bioengineered food” and “BE food” didn’t even register. We strongly disagree with AMS proposal to only allow the terms “bioengineered food” or “bioengineered food ingredient” as text disclosure on a bioengineered food. AMS states that they are “not proposing any similar terms because we believe that the statutory term, ‘bioengineering,’ adequately describes food products of the technology that Congress intended to be within the scope of the NBFDS.” We strongly disagree since the public does not recognize or understand the term “bioengineered food” while they do recognize the term GMO and to a lesser extent GE. According to a²⁹ The paper also found that a “Google Trends report pulled on June 18, 2018 shows that ‘BE food’ literally doesn’t register as a term compared to ‘GMO food.’”³⁰ Thus, using the term “bioengineered” or its acronym “BE” would only serve to confuse consumers, and limiting disclosure to those terms will be doubly confusing.

²⁹ Non-GMO Project. 2018b. Report: Terminology proposed in USDA GMO labeling rule would confuse consumers. At: <https://www.nongmoproject.org/blog/report-terminology-proposed-in-usda-gmo-labeling-rule-would-confuse-and-mislead-consumers/>

³⁰ *Id.*

FDA, in two Guidances for Industry,³¹ has stated that its preferred term, “bioengineering,” which FDA has used since the early 1990s, is interchangeable with the terms “recombinant DNA technology,” “modern biotechnology” and “genetic engineering”:

In this guidance, we use the terms “bioengineering,” “bioengineered,” and “genetic engineering” to describe the use of modern biotechnology. Modern biotechnology means the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection (Ref. 1). The term “modern biotechnology” may alternatively be described as “recombinant DNA (rDNA) technology,” “genetic engineering,” or “bioengineering.” *These terms are often used interchangeably by industry, federal agencies, international bodies, and other interested stakeholders* and are used in this guidance to refer to foods derived from new plant varieties developed using modern biotechnology. *Italics added.*³²

We further urge AMS to authorize the use of the terms “genetically modified organism” or “GMO,” which the USDA Food Safety Inspection Service (FSIS) proposed allowing for negative labeling, in addition to terms such as “bioengineering,” “genetically engineered,” and “modern biotechnology.” We note that FSIS’s *Compliance Guide on Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in the Production of Meat, Poultry, or Egg Products*, published in late 2016, proposed allowing use of the terms “genetically modified organism” or “GMO,” in addition to terms such as “bioengineering,” “genetically engineered,” and “modern biotechnology.” Previously, FSIS had not allowed use of the terms “genetically modified organism” or “GMO” in making negative claims.

In addition, up until at least February 2018, the AMS webpage that presently is titled “BE Disclosure & Labeling,”³³ was titled “GMO Disclosure & Labeling,” and stated that for “Questions or Comments? Please mail us as GMOLabeling@ams.usda.gov.”³⁴ Clearly, AMS, until recently was comfortable with using the term GMO, and recognized that this was a term that was readily understood by consumers.

Among other studies, research done by Campbell Soup Company, discussed on an August 30, 2016, webinar by the Food and Drug Law Institute (FDLI), shows that consumers prefer the term GMO. As Katie Cleary, Campbell’s senior manager of consumer and consumer

³¹ Food and Drug Administration (FDA). 2015a. Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants. At: <https://www.fda.gov/RegulatoryInformation/Guidances/ucm059098.htm> ; and FDA. 2015b. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon. At: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm>.

³² FDA. 2015a. *Op cit.*

³³ <https://www.ams.usda.gov/rules-regulations/be>

³⁴ <https://web.archive.org/web/20180209001825/https://www.ams.usda.gov/rules-regulations/gmo>

insights stated, “Campbell has tested nine labels related to GE food ingredients in the past few months and found individuals viewed use of terms like ‘bioengineered or genetically engineered’ confusing ... The feedback has been very consistent in our research that the preferred language is GMO.”³⁵ We supported FSIS allowing use of the terms “genetically modified organism” and “GMO,” and urge AMS to also allow use of these terms as alternatives to “bioengineering.”

In addition, a number of companies, such as General Mills, Mars,³⁶ and Campbell Soup Company are already labeling products using language such as “genetically engineered” or “partially produced with genetic engineering.”³⁷ By requiring that companies only use the term “bioengineered,” AMS would cause companies that are presently labeling foods using terms such as “genetically engineered” or “partially produced with genetic engineering,” which people readily recognize and understand, to unnecessarily incur costs to change the present labels to use the new term “bioengineered.”

Furthermore, the terms “GM” and “GMO” are used by many of our trading partners that require labeling, such as all the countries in the European Union, Australia, and New Zealand. Not allowing terms such as GM and GMO could create difficulties for products from those countries being sold in the US.

In sum, in light of existing FDA and FSIS policies, past AMS policy, and marketplace developments, we urge USDA/AMS to allow the terms “genetic engineering,” “GE,” “genetically modified organism,” and “GMO” to be used as part of the text disclosure, since these are terms that are more familiar and understandable to the public than “bioengineered.” We support AMS’s proposal that the location of the text disclosure would be on the principal display panel but also urge that the disclosure also should appear on the ingredient list. One easy way to do this is to use an asterisk symbol (*) after each ingredient in the ingredient list that is bioengineered and then at the end of the ingredient list note that * = “genetically engineered” or “genetically modified.”

AMS must require that disclosure symbols be aesthetically neutral like other AMS symbols

While we agree that a symbol should be allowed, the symbol should be easily understood by consumers and should be aesthetically neutral, like other AMS symbols, rather than try present bioengineering in a positive light. Thus, use of the acronym BE (for bioengineered), which is an invented abbreviation that consumers do not appear to understand or recognize, should not be allowed. AMS should use a simple circle with the

³⁵ Pegg JR. 2016. Campbell Soup finds consumers prefer clear GMO labeling. *Food Chemical News* (Sept. 8, 2016) At: www.agra-net.com/agra/food-chemical-news/food-safety/packaging/campbell-soup-finds-consumers-prefer-clear-gmo-labeling-526281.htm.

³⁶ Kim S. 2016. Candy maker Mars adding GMO labeling to its products. March 22, 2016. At: <https://abcnews.go.com/Business/candy-maker-mars-adding-gmo-labeling-products/story?id=37839000>

³⁷ Moodie A. 2016. GMO food labels are coming to more US grocery shelves – are consumers ready? *The Guardian*, March 22, 2016. At: <https://www.theguardian.com/sustainable-business/2016/mar/24/gmo-food-labels-general-mills-kellog-mars>

letters “GE”, “GM” or “GMO” inside, since those are terms that consumers readily understand, and the circle would be seen as neutral.

While the NBFDS allows the use of symbols, we strongly disagree with the three alternatives proposed by AMS. First, the allowed acronym, “BE” is a newly invented term, not widely recognized by consumers, as noted in the Non-GMO Project Terminology Report.³⁸ The term is so new it does not even appear in the USDA’s own Agricultural Biotechnology Glossary.³⁹ The acronym should be “GMO” since this is the commonly-used term that consumers recognize and understand.

In addition, all three proposed symbols seem to be promotional of GE foods, rather than neutral (See Fig 1). The first proposed symbol has the acronym “BE” in a circle with the bottom portion of the circle containing what looks like two round hills. Above the hills on the left side of the circle is a stem arching over the hills and toward the center of the circle, ending in a four-pointed starburst with a sun and blue sky in the background. This symbol is not aesthetically neutral; rather it seems to suggest that “BE” is better on more environmentally friendly than non-BE products.

The second symbol looks like a smiley face that is winking, not a neutral image. The third symbol looks like a smiley face in the sun. Both symbols appear to be promotional. Contrast this with the AMS symbols for USDA Process Verified and USDA Organic, both of which are aesthetically neutral (Figure 2).



Figure 1. Proposed NBFDS symbols

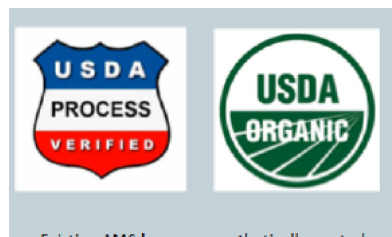


Figure 2. Existing AMS symbols

Clearly, the three proposed NBFDS symbols are not neutral, when compared to other existing AMS labels, and could mislead consumers into thinking these products are somehow better for the consumer or for the environment. Consequently, AMS should not use any of the three symbols. Rather, AMS should develop a neutral symbol. We urge AMS to use a circle with the letters “GE”, “GM” or “GMO” inside that circle since those are terms that consumers readily understand.

If used on a package, the symbol should be prominently displayed on the front of the package, preferably located next to the name of the product. The symbol should be of a similar font size to the name of the product (same font size or at least 75% of font size of product/brand name). The symbol should also be easily recognizable with a sharp contrast between the symbol and the background space.

³⁸ Non-GMO Project. 2018b. *Op cit.*

³⁹ USDA. 2018. Agricultural Biotechnology Glossary. At: <https://www.usda.gov/topics/biotechnology/biotechnology-glossary>

AMS will allow disclosure via digital or electronic means. However, digital or electronic disclosure is not accessible for almost a third of Americans. If companies choose to use digital or electronic disclosure, AMS must also require disclosure via on-package use of text or symbol

USDA proposes to allow companies to affix “QR codes,” which are encoded images on a package that must be scanned by a smartphone, to disclose whether a product was derived from genetic engineering. Because reading QR codes requires a smartphone and a reliable broadband connection, disclosure via QR codes puts what amounts to insurmountable obstacles in front of more than 57 million Americans who may want to know if a product is bioengineered but lack a smartphone. Consumers in many rural communities and low-income, minority, and elderly populations are known to disproportionately lack access to these technologies. According to 2018 research by Pew,⁴⁰ only 46% of people over 65 years old own a smartphone, compared to 94% of those aged 18-29 or 77% of the population overall. In addition, only 65% of people in rural areas own a smartphone, compared to 83% of urban and 78% of suburban. Finally, only 67% of those that make less than \$30,000 own a smartphone, compared to 93% of those that make more than \$75,000. In total, almost 58 million adult Americans do not have smartphones.⁴¹

USDA’s own 2017 commissioned study, which “identifies potential challenges associated with accessing a bioengineering disclosure through an electronic digital link,” found that “in direct observations of consumers who are interested in accessing the disclosure, researchers observed key technological challenges that prevented nearly all participants from obtaining the information through electronic or digital disclosure methods.”⁴² In addition, the study made clear that patrons of smaller retailers would be more disadvantaged, noting that “20 percent of retail stores do not currently have in-store wifi, including 63 percent of small retailers.”⁴³ Certain subpopulations would be disadvantaged as well, noting that “of those who are interested in accessing the bioengineering disclosure, low-income populations, rural residents, and consumers over the age of 60 are more likely to lack the tools and the broadband services needed to effectively access an electronic or digital link.”⁴⁴

In sum, if you cannot afford a smartphone, or live in a rural area with no broadband, or are not tech savvy, you will be excluded from GMO disclosure. Without a smartphone, you cannot read a QR code, and if you cannot read a QR code, there will be no way to determine if certain foods are bioengineered, under AMS’s current proposed rule.

The USDA’s own study clearly shows that many consumers, and especially certain subpopulations, would be disadvantaged by digital disclosure and not be able to access the

⁴⁰ Pew Research Center. 2018. Mobile Fact Sheet. February 5, 2018. At: <http://www.pewinternet.org/fact-sheet/mobile/>

⁴¹ *Id.*

⁴² Pg. 4 in Deloitte. 2017. Study of Electronic or Digital Link Disclosure: A Third Party Evaluation of Challenges Impacting Access to Bioengineered Food Disclosure. At: https://www.ams.usda.gov/sites/default/files/media/USDA_Deloitte_Study_of_Electronic_or_Digital_Disclosure_20170801.pdf

⁴³ *Id.*

⁴⁴ Pg. 61 in *Id.*

disclosure that Americans say they want in polls. On-package labeling must be required, as it is in dozens of other countries, including in the European Union. U.S. companies selling in Europe that use the QR code option in the United State could not use this option across the Atlantic. It is established policy in the EU that labels appear on packages.

We also oppose the Standard's proposed access to information option via on-package website URLs or text messaging, as unavailable to some and impractical for others. Many people are charged per texts sent and received, which would increase the burden on consumers to discover what they are eating. Looking up a URL takes time and requires a smartphone and a good internet connection. These proposed methods to implement the NBFDS put unnecessary barriers in the way of true transparency.

The proposed indirect forms of food labeling are unprecedented. In all other countries that require GE food labeling (64, around the world),⁴⁵ clear, on-package labeling is the norm. This distortion of labeling potentially could lead to trade disputes with countries that refused to recognize the technologically indirect information as equivalent to their own food labeling rules, and be contrary to Congress's mandate that the rules be consistent with U.S. international trade obligations; since the law states that it will "be applied in a manner consistent with United States obligations under international agreements."⁴⁶ We urge AMS to insist on clear, plain language or a neutral symbol front-of-package labels to maximize the benefits of required disclosures to all consumers.

AMS should require bioengineered food that is not purchased from a grocery store shelf, including food for sale in bulk (such as fresh produce in a bin or fresh seafood at a fish counter), in a vending machine, or online to have a text or symbol disclosure.

Bioengineered food that is not purchased from a grocery store shelf should be required to have a text or symbol disclosure. If the food is sold in bulk, there could be a sign next to the display that contains the words "genetically engineered" or a symbol such as GE, GM, or GMO. If the product is sold in a vending machine, the label on the product in the vending machine (candy bar, bag of chips, soda, etc.) should bear the disclosure. For products sold online, the text or symbol should be prominently noted on the screen that shows the product as well as on the screen that is used to purchase the product. The disclosure should be prominently placed next to the item being purchased. In addition any ingredient that appears on an ingredient list which is more than 0.9% from a bioengineered source, should be identified.

Thank you for your consideration of our comments.

Respectfully submitted,

⁴⁵ <https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws>

⁴⁶ 7 U.S.C § 1639(c)(a). At: <https://www.law.cornell.edu/uscode/text/7/1639c>

A handwritten signature in black ink that reads "Michael Hansen". The signature is written in a cursive style with a large, prominent 'M' and 'H'.

Michael Hansen, Ph.D.
Senior Scientist
Consumers Union