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Comments of Consumers Union to the
United States Department of Agriculture Agricultural Marketing Service on
Proposed Rule GMO Questions Under Consideration

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Background

On July 29, 2016, Congress passed P.L. 114-216, the National Bioengineered Food Disclosure Standard, which requires disclosure if a food product contains bioengineered (genetically engineered) materials. P.L. 114-216 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.

In preparation for proposing a formal rule on how P.L. 114-216 will be implemented , the USDA posted a series of 30 questions to get input on a range of implementation issues from various stakeholders. Below are our answers to some of these questions.

Many of these issues are important to consumers, the vast majority of whom, in many polls, by Consumer Reports[1] and others[2] have said they supported on-package labeling of genetically

[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#.

engineered food. It is thus important that the disclosures USDA requires should be 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 policy and mobilization arm of Consumer Reports,[3] welcomes the opportunity to comment on the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Proposed Rule GMO Questions Under Consideration, associated with implementation of P.L. 114-216, the National Bioengineered Food Disclosure Standard. Key points in our comments include:

- The Agricultural Marketing Service (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." 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).
- Products of bioengineering, or modern biotechnology, as defined by the Food and Drug Administration (FDA), Codex Alimentarius, the National Organic Standards Board (NOSB) and others, including gene-edited products, should not be considered "modifications found in nature" under Section 291(1)(B) of the law, and should be subject to the law's disclosure requirements because the genetic sequences that create bioengineered foods are made in a laboratory and are unique.
- 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, because the fact that genetic material cannot be detected using current methods does not mean it is not there. It was also the clear intent of Congress to cover highly refined products.
- 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 many other countries. Using this globally accepted threshold will facilitate international trade.
- AMS should not exclude dietary supplements from the disclosure requirements under P.L. 114-216 since dietary supplements are generally considered foods by the FDA, are widely consumed and may be bioengineered.

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[3] Consumers Union is the policy and mobilization arm of Consumer Reports, an independent, nonprofit organization that works side by side with consumers to create a fairer, safer, and healthier world. As the world's largest independent product-testing organization, Consumer Reports uses its more than 50 labs, auto test center, and survey research center to rate thousands of products and services annually. Founded in 1936, Consumer Reports has over 7 million subscribers to its magazine, website, and other publications.

Comments on 30 Questions

1. ***What terms should AMS consider interchangeable with 'bioengineering'? (Sec. 291(1))***

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." The first three are terms that FDA recognizes as interchangeable. In addition USDA/FSIS proposed allowing the latter two in its guidance on non-GMO labeling.

FDA, in two Guidances for Industry[4], has stated that its preferred term, "bioengineering" (which is the same term used in PL 114-216) 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.[5]

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' *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

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[4] 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/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm.059098.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.

[5] FDA. 2015a. *Op cit.*

not allowed use of the terms "genetically modified organism" or "GMO" in making negative claims. 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 these terms. As Katie Cleary, Campbell's senior manager of consumer and consumer 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."[6] 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."

We further note that the marketplace is already using "non-GMO" labels. The Non-GMO Project Verified label, found on more than 43,000 products with annual sales of over $19 billion uses the term "Non-GMO."[7] NSF International, an international standard development organization, has a Non-GMO True North program which uses the term "Non-GMO/GE."[8] The company SunOpta, which sells non-GE soy, uses the term "non-GMO." The company's soybeans are subject to 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.[9]

In sum, in light of existing FDA and FSIS policies, and marketplace developments, we urge USDA/AMS to consider the terms "modern biotechnology," genetic engineering," "GE," "genetic modification," "genetically modified organism," and "GMO" as all interchangeable with "bioengineering."

2. ***Which breeding techniques should AMS consider conventional breeding? (Sec. 291(1)(B))***

Conventional breeding consists of various techniques, defined by NOSB, 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 are also techniques of modern biotechnology and are not techniques of conventional breeding.

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 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

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[6] 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-consumersprefer-clear-gmo-labeling-526281.htm.

[7] Non-GMO Project. 2017. Product Verification. At: www.nongmoproject.org/productverification.

[8] 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/.

[9] *Id.*

basis for considering which breeding techniques should be considered as "conventional breeding":

> **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.[10]

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).[11]

The NOSB definition of "modern biotechnology" is the same as the FDA's definition. It 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.[12] Documents and 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.[13] 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 US and facilitate international trade.

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[10] 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.
[11] *Id.*
[12] 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.
[13] Convention on Biological Diversity (CBD). 2000. Text of the Cartagena Protocol on Biosafety. At: www.bch.cbd.int/protocol/text.

Gene editing techniques should not be considered conventional breeding

FDA recently 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."[14] 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, and the FDA's proposed revision of GFI #187, it is clear that these definitions include the newer technologies of biotechnology, 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). 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 PL-114-216.

3. Which modifications should AMS consider to be found in nature? (Sec. 291(1)(B))

The purpose of PL 114-216 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 Section 291(1)(B).

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[14] 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.

A broad view of "modifications found in nature" is contrary to Congressional intent

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 the 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, to define "modifications … found in nature" in a broad fashion would be misleading and would clearly contrary to the intent of Congress since it would mean that the overwhelming majority of GE crops on the market 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 P.L. 114-216.

"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" (aka "modern biotechnology") would fall under the disclosure requirements—consistent with the intent of the law.

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 tumafasciens*, 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."[15] These codon optimized genes are not found in nature, so plants developed using such CRISPR/Cas9 systems would not be eligible to be exempted from the labeling requirements of P.L. 114-216.

In cases where the genetic material comes from the same type of organism, although the genes do not have to be condon-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 should therefore be subject to the law's disclosure requirement.

4. ***Will AMS require disclosure for food that contains highly refined products, such as oils or sugars derived from bioengineered crops? (Sec. 291(1)(A))***

We urge AMS to 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

[15] 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.

be detected using current methods does not mean it is not there. It was the intent of Congress to cover highly refined products.

Part of the definition of "bioengineering" found in Section 291(1)(A) of P.L. 114-216 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 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. Senator Jeff Merkley, during a floor address on July 6, 2016 stated 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."[16]

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."[17] 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."[18] 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."[19]

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,

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[16] https://www.c-span.org/video/?c4611539/sen-merkley-gmo-labeling-bill.
[17] https://www.congress.gov/crec/2016/07/06/CREC-2016-07-06.pdf.
[18] 162 Cong. Rec. S4994. At: https://www.congress.gov/crec/2016/07/12/CREC-2016-07-12-pt1-PgS4994.pdf.
[19] *Id.*

> "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 milk, but rather because scientists have been unable to perfect a *test* to detect it.** "[20]

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."[21] 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."[22] The following year a team of Chinese scientist 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, corn starch and corn jam.[23]

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."[24] Again, although the bioengineered DNA may be degraded to such an extent that it is undetectable, it does not

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[20] 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.

[21] 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.

[22] 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

[23] 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.

[24] https://gmoanswers.com/ask/does-high-fructose-corn-syrup-contain-gmos.

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

In sum, given that the coauthors of P.L. 114-216 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.

5. ***Although the Law states that the definition of bioengineering shall not affect any other definition, program, rule, or regulation of the Federal government, could there be potential areas of confusion between the definition of bioengineering as used in the Law and others [sic] similar terms used by the Federal government? If so, what are the potential remedies that could be added to this regulation to alleviate any confusion between this definition and others by the Federal government? (Sec. 292(b))***

While there is a potential area of confusion between the definition of "bioengineering" in P.L. 114-216 and the terms "bioengineering," "modern biotechnology" "genetic engineering," as used by FDA, AMS could avoid much of this confusion by adopting the FDA definition, which is also the one adopted by NOSB, and we strongly urge AMS to do so.

We note that FDA uses the term "bioengineering," but states that that term along with the terms "bioengineered," "genetic engineering," and "recombinant DNA (rDNA) technology" are used "to describe the use of modern biotechnology," which FDA goes on to define as "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."[25] We also note that the NOSB uses the same definition as FDA for "modern biotechnology." The same definition is also the global standard, used in the Principles for Risk Analysis of Foods Derived From Modern Biotechnology adopted by the Codex Alimentarius Commission in 2003,[26] and in the Cartagena Biosafety Protocol under the Convention on Biological Diversity.[27]

In elaborating on what specifically is meant by the definition in Section 291 of the law, we urge AMS to follow FDA's lead and consider that the term "bioengineering" is a synonym for "modern biotechnology." The term "modern biotechnology" is both accepted by FDA and the

[25] FDA. 2015a. *Op cit.*
[26] FAO/CAC. 2003. *Op cit*.
[27] CBD. 2000. *Op cit*.

NOSB, and has a common, globally accepted standard definition, as noted both by the Codex Alimentarius Commission and the Convention on Biological Diversity. We urge AMS to use this definition of "modern biotechnology," so as not to create confusion among regulatory schemes, among food producers, or among consumers, and for food exporters and importers. Adopting any other definition could lead to massive consumer confusion, with the same words meaning different things on different products, and could become an obstacle to international trade.

Questions 6 and 7: We do not have specific comments at this time.

8. ***What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered? (Sec. 293(b)(2)(B))***

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.

Consumers Union recommends a threshold of 0.9%, on a per ingredient basis, which 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.[28]

It is also the standard set by various certification programs for "non-GMO" labels. 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 40,000 products with annual sales of $20 billion.[29] 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.[30] 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.[31]

With these established thresholds as bench marks, we urge AMS to require disclosure under PL-114-216 for any ingredient in the ingredient list that exceeds 0.9% bioengineered. That standard is in widespread use in the European Union. 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.

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[28] Roseboro K. 2015. *Op cit.*
[29] Non-GMO Project. 2017. *Op cit.*
[30] Roseboro K. 2015. *Op cit.*
[31] *Id.*

Furthermore, disclosure should not be triggered only if the top ingredient in a product is bioengineered. If only the top ingredient triggered disclosure, it would be highly misleading to consumers since they would think that an unlabeled product did not contain any bioengineered ingredients.

In sum, AMS should require disclosure under P.L. 114-216 for any bioengineered ingredient in a food product that exceeds 0.9%. Such disclosure should 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."

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

AMS may want to develop various categories for disclosure—such as differentiating if a product a) is bioengineered, b) contains ingredients that are bioengineered, or c) contains ingredients derived from bioengineered crops, animals or microorganisms—as long as AMS also requires that disclosure should also occur on the ingredient list, for the reasons laid out in answer to Question 8.

As noted in the answer to Question 12, categories such as "bioengineered," "produced with bioengineering," and "partially produced with bioengineering," can be useful to consumers since they do indicate that a food product does contain bioengineered ingredients, as well as the rough indication of the amount of the food products that is derived from bioengineered sources. However, these terms do not indicate which ingredients have been bioengineered, information that consumers are interested in and that could help track any adverse health impact which may appear post-marketing. Disclosure should also thus occur on the ingredient list. One easy way to do this is to use an asterisk symbol (*) as noted in Question 8.

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

No comment at this time.

11. ***Could AMS consider whether a type of food is considered a bioengineered food under the determination process? (Sec. 293(b)(2)(C))***

AMS says they are considering if they "could exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered." AMS should not exclude dietary supplements from the disclosure requirements under P.L. 114-216 because dietary supplements, except for those that meet the definition of a drug,

generally are considered foods by the FDA, are very widely consumed and may be bioengineered.

The Dietary Supplement Health and Education Act (DSHEA) of 1994 (P.L. 103-417) defines a dietary supplement as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)" as a category of food and states: "Except for purposes of section 201(g) [which defines the term "drug"], a dietary supplement shall be deemed to be a food within the meaning of this Act."[32]

Use of dietary supplements is widespread among consumers. A study published in 2016 found that 52% of the population reported taking a dietary supplement within the last 30 days in 2011-2012, which is the same rate as found in 1999-2000.[33] By far the most common supplements taken are vitamins, whether taken individually or as part of a multivitamins/multiminerals. The same study found some 48% of the population reported taking a supplement containing vitamins in 2011-2012.[34]

Numerous vitamins, such as vitamin B2 (riboflavin), vitamin C (ascorbic acid), vitamin E (tocopherols) are produced using a GE microorganism and/or are derived from GE corn or soy.[35] In addition, standardization materials (i.e. excipients) used in supplements, such as citric acid, citrates and maltodextrin are derived from corn, which is overwhelmingly genetically engineered in the US.[36]

Given the facts that a majority of Americans consume dietary supplements, that dietary supplements generally are considered foods by the FDA unless the agency indicates otherwise, and that many dietary supplements are likely to be derived from GE sources, we urge AMS not to exempt dietary supplements from the disclosure requirement in P.L. 114-216.

12. ***If a manufacturer chooses to use text to disclose a bioengineered food, what text should AMS require for a text disclosure? (Sec. 293(b)(2)(D))***

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[32] https://ods.od.nih.gov/About/DSHEA_Wording.aspx.

[33] Kantor ED, Rehn CD, Du M, White E and EL Giovannucci. 2016. Trends in dietary supplement use among US adults from 1999-2012. *JAMA* 316(14): 1464-1474. At: http://preview.thenewsmarket.com/Previews/JOUR/DocumentAssets/451034.pdf.

[34] *Id.*

[35] Anonymous. 2008. Vitamins present GMO challenge for organic industry. *The Organic & Non-GMO Report*. At: http://www.non-gmoreport.com/articles/oct08/vitamins_gmo_challenges_for_organic_industry.php.

[36] Daniells S. 2013. Going non-GMO in dietary supplements: 'The supply community is not there with us yet', say manufacturers. *Nutra ingredients-usa.com* At: http://www.nutraingredients-usa.com/Markets/Going-non-GMO-in-dietary-supplements-The-supply-community-is-not-there-with-us-yet-say-manufacturers.

If a manufacturer chooses to use text to disclose a bioengineered food, we urge AMS to allow a limited range of flexibility in terms of the text disclosure language. The terms "genetically engineered" and "produced with genetic engineering" and "partially produced with genetic engineering," which were compliant with the Consumer Protection Rule 121 from the State of Vermont, and which some food manufacturers are presently using, should be allowed, but the phrase "may be produced with genetic engineering" should not be allowed. The first three phrases are informative, while the last one is not.

In Vermont's regulations, "genetically engineered" could be used on a product derived from a single source that was bioengineered, such as a filet from a GE salmon or an Artic Apple (which has been bioengineered not to turn brown when cut). "Produced with genetic engineering" could be used on a multi-ingredient product where 75% or more of the ingredients in the product (by weight) derived from bioengineered sources, while "partially produced with genetic engineering" could be used on a multi-ingredient product where less than 75%, but at least 0.9%, of the ingredients in the product (by weight) are derived from bioengineered sources. These three phrases on food products are useful—since they identify that the products contains bioengineered materials and the relative amount (e.g. 100%, more than75% but less than100%, and more than 0.9% but less than75%)—and should be allowed.

"May be produced with genetic engineering" could be misleading to consumers and could create confusion as to whether or not the food product contains bioengineered ingredients. Thus, this phrase should not be allowed.

In addition to any of these three phrases, which refer to the food product as a whole, any ingredient which is more than 0.9% from a bioengineered source should be identified as such on the ingredient list, for the reasons laid out in answer to Question 8.

13. ***If a manufacture chooses a symbol to disclose a bioengineered food, what symbol should AMS require for disclosure? (Sec. 293(b)(2)(D)***

In terms of the symbol that AMS should require for disclosure, we urge AMS to use a circle with the letters "GE", "GM" or "GMO" inside that circle.

Both FDA and USDA have said they would allow use of these symbols on labels. In addition, these three symbols are widely used for labeling of products that do not contain bioengineered ingredients, such as those from the Non-GMO Project Verified label, and the Non-GMO True North program from NSF International, so they would be seen in the market. These three symbols are not disparaging toward bioengineering.

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.

In addition to the symbol, we think that any ingredient which is more than 0.9% from a bioengineered source should be identified as such on the ingredient list, for the reasons laid out in answer to Q 8.

Questions 14, 15: We do not have specific comments at this time.

> **16.** ***What kind of text, symbol, or electronic or digital disclosure should AMS require for bioengineered food that is not purchased from a grocery store shelf, such as 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? (Sec. 293(b)(2)(D))***

Bioengineered food that is not purchased from a grocery store shelf should also have a text or symbol disclosure, as pointed out in answers to Questions 9, 12 and 13. If the food is sold in bulk, there could be a sign next to the display that contained 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 as laid out in Q 8.

Questions 17 to 23: We do not have specific comments at this time.

> **24.** ***How should AMS ensure that bioengineered food information is located in a consistent and conspicuous manner when consumers use an electronic or digital disclosure? (Sec. 293(d)(2))***

When consumers use an electronic or digital disclosure, AMS can ensure that the bioengineered food information is located in a consistent and conspicuous manner by requiring that the disclosure information (text and/or symbol) is located on the first landing page and is in a font/size that is large enough to be easily seen.

The disclosure information should be located on the landing page, seen by the consumer immediately after scanning the QR code or entering the website URL in a browser. In addition, for electronic or digital disclosure, we urge AMS to require that the disclosure information be made available for each of the ingredients in the food product that came from a bioengineered source and is at least 0.9% bioengineered. The text and/or symbol that should be required should be text and/or symbol as was discussed in Questions 12 and 13. In addition, the text/symbol

should be very conspicuous, either with a font size that is larger than the font size for other text on the page (with a minimum font size of 12 point) and/or is bolded.

Questions 25 to 28: We do not have specific comments at this time.

29. ***How should AMS make public the summary of any examination, audit, or similar activity? (Sec. 293(g)(3)(C))***

In the interest of transparency, we strongly urge AMS to make public the results and findings of any examination, audit, or similar by posting such information on the AMS website. We urge AMS to post the full results and findings of any examination, audit, etc. rather than just posting a summary. The publication of the full results, rather than a summary, will be useful for the interested public. If the full results of any inquiry, rather than just a summary, were published, perhaps that would result in companies being less likely to violate the provisions of this law.

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

AMS should treat imported products no differently than domestically produced products in terms of the disclosure requirements under PL-114-216. AMS can make such treatment easier if it adopts the Codex definition for products of modern biotechnology as its definition of "bioengineered" and if it adopts the threshold for labeling used in the European Union.

Thank you for your consideration of our comments.

Respectfully submitted,

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