

# GMO Labeling Response

Amber King

██████ ██████ ████  
Shoreline, WA ██████  
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To AMS

USDA

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## 1. What terms should AMS consider interchangeable with ‘bioengineering’? (Sec. 291(1))

GMO, GE, Genetically modified organism, Genetically modified, genetically altered, bioengineering, CRISPR, gene editing, advanced bioengineering, gene drive, RNAi and DNA or genetically enhanced.

In addition, we agree with the Consumers Union who has stated the following:

**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<sup>1</sup>, 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,

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<sup>1</sup> 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/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 Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon.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>.

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.<sup>2</sup>

**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 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.”<sup>3</sup> 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.”<sup>4</sup> NSF International, an international standard development organization, has a Non-GMO True North program which uses the term “Non-GMO/GE.”<sup>5</sup> 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.<sup>6</sup>

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.”

**1. 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**

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<sup>2</sup> FDA. 2015a. *Op cit*.

<sup>3</sup> 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](http://www.agra-net.com/agra/food-chemical-news/food-safety/packaging/campbell-soup-finds-consumersprefer-clear-gmo-labeling-526281.htm).

<sup>4</sup> Non-GMO Project. 2017. Product Verification. At: [www.nongmoproject.org/productverification](http://www.nongmoproject.org/productverification).

<sup>5</sup> 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/>.

<sup>6</sup> *Id.*

**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 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.<sup>7</sup>

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).<sup>8</sup>

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.<sup>9</sup> 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.<sup>10</sup> USDA should use the definition of “modern biotechnology” adopted by the NOSB, FDA, Codex

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<sup>7</sup> 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>.

<sup>8</sup> *Id.*

<sup>9</sup> 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](http://www.fao.org/input/download/standards/10007/CXG_044e.pdf).

<sup>10</sup> Convention on Biological Diversity (CBD). 2000. Text of the Cartagena Protocol on Biosafety. At: [www.bch.cbd.int/protocol/text](http://www.bch.cbd.int/protocol/text).

Alimentarius, and the Cartagena Protocol because it will minimize consumer and regulatory confusion in the US and facilitate international trade.

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

Conventional breeding consists of seeds which have not been genetically altered in any way other than selective breeding or hybrid methods.

We agree with the Consumers Union statement on conventional breeding:

### **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."<sup>11</sup> 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 only modifications that are found in nature are those that are only found in nature, untouched by humankind. Any modifications performed in a lab are not "found in nature."

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<sup>11</sup> 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](http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf).

We agree with the Consumers Union statement below:

**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).**

**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 be 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 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.”<sup>12</sup> These codon optimized

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<sup>12</sup> 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).

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 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 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))**

Yes. AMS must disclose all foods derived from GMOs. Parents who have children that are allergic to GMO soy or corn for example must be allowed to know that an oil or sugar in a product is GMO soy or corn just as a parent of a child allergic to peanuts must know if a food is cooked in peanut oil, regardless of it being highly processed, in order to protect their child.

#### **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 other 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))**

ALL GMOs should be banned from our food supply. Any current GMOs in the market must be labeled. Any future GMOs must be barred from entering the food supply. The health issues in America are skyrocketing. We can no longer afford the health care costs connected to GMO and related chemicals to appease chemical corporations.

**6. Meat, poultry, and egg products are only subject to a bioengineered disclosure if the most predominant ingredient, or the second most predominant ingredient if the first is broth, stock, water, or similar solution, is subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act. How will AMS determine the predominance of ingredients? (Sec. 292(c))**

All GMOs should be labeled, including any animals fed GMO feed at any time in their raising, including nursing from a mother who ate GMOs.

**7. How should AMS craft language in the regulations acknowledging that the Law prohibits animal products from being considered bioengineered solely because the animal consumed feed products from, containing, or consisting of a bioengineered substance? (Sec. 293(b)(2)(A))**

Yes, the Agency should provide clarity that food derived from any animal, including invertebrates such as crickets or bee products, will require disclosure as a bioengineered food solely because their nutrition came from food with bioengineered ingredients.

**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))**

Any detectable presence above 0 of bioengineered food should be clearly labeled. Although it is not the topic of this inquiry we would like to add, pesticides, herbicides and fungicides should also be clearly labeled, in writing, on the package as they are more than a “process” they are a “additive” as well..

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

The label should be required for any product which contains GMO ingredients or GMO ingredients derived from bioengineered crops or from animals who consumed GMOs for any part of the year or their life, at any time.

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

The AMS must consider that GMOs have been shown to alter DNA, cause unpredictable mutations, produce toxins called Putrascine and Cadaverine, cause the growth of tumors, reduce the development of young, decrease fertility and cause sterility of future generations. The AMS must consider that current GMOs, which make up the majority of our crops, either are a registered pesticide or are engineered to withstand an herbicide or pesticide. The toxins do not dry, wash, or cook off. We consume them and pregnant mothers who are not warned pass these foreign proteins and chemicals on to their fetuses, which are extremely vulnerable.



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

**No the AMS should not** exclude certain food types such as medical food and dietary supplements, and others from requiring disclosure as bioengineered. An food which humans or animals consumed should be clearly labeled, with full disclosure. Anything else is dishonest, irresponsible, and dangerous to the health of the American public and the future of our country.

**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))**

Regarding the fact that some food manufacturers use language compliant with the Consumer Protection Rule 121 from the State of Vermont to identify their food products as bioengineered (“Produced with Genetic Engineering,” “Partially Produced with Genetic Engineering,” or “May be Produced with Genetic Engineering”). These disclosures are not sufficient for protecting the American public from the health risks of GMOs and related toxins.

We request:

**Warning: This product contains genetically modified organisms which have been shown to produce toxins and stimulate tumor growth in animals. Many GMOs are engineered to withstand pesticides which do not dry, wash, or cook off. Therefore, this product may contain carcinogenic, neurotoxic, antibiotic, and endocrine disrupting chemicals which cause liver disease.**

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

There should not be a symbol to use in place of a label for GMOs. A symbol simply hides the health and environmental risks of GMOs.

**14. If a manufacturer chooses to use an electronic or digital link to disclose a bioengineered food, what requirements should AMS implement for an electronic or digital link disclosure? (Sec. 293(b)(2)(D))**

An electronic or digital link to disclose GMOs is elitist, inconvenient, and is of the intention to hide the fact that GMOs are present. Many people, especially the elderly, low income citizens, and minors do not have a Smartphone. It is a social injustice issue to ignore the disadvantage they will have if they do not have the ability to determine if a food is GMO or not because they can not afford a Smartphone. If the AMS has any intention of requiring companies to be honest, provide information which supports healthy decisions and hold companies to account for the contents of their products, you will not allow an electronic or digital link on the package. Only a clearly written warning label hold manufacturers to account for their products, is honest and helpful to consumers.

**15. Should AMS specify in the regulations the type of electronic or digital disclosure manufacturers, e.g. QR code, can use to disclose bioengineered food? What steps**

**should AMS take if an electronic or digital disclosure method becomes obsolete? (Sec. 293(b)(2)(D))**

The most appropriate electronic or digital disclosure technologies to use are: NONE. Clear, simple, writing on the package, short of banning GMOs, is the only way to responsibly protect the American people and give them the opportunity to prevent long term, tragic, and expensive health care issues which are currently devastating America.

**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))**

If labeling on the package is not possible, any vendor selling GMOs must be require to display the warning with a clear and legible sign above or below the food item.

**17. The Law offers special provisions for disclosure on very small or small packages. How should AMS define very small or small packages? (Sec. 293(b)(2)(E))**

Any food or product manufacturers must make room for full disclosure, honest and clear written labeling no matter how small the packaging, If this is challenging for them, they should add a tag or make the packaging larger.

**18. What are the reasonable disclosure options AMS should provide for food contained in very small or small packages? (Sec. 293 (b)(2)(E))**

See above.

**19. How should AMS define small food manufacturers? (Sec. 293(b)(2)(F))**

The CA EPA defines a small company as any company of 10 or more people who expose humans to glyphosate must disclose a warning. However our federal government should have more stringent standards and decree that any company of any size, 1 or more, which serves food must disclose if they serve GMOs and related toxins. No matter what size a company is, it is in the best interest of the consumer to be informed about what they eat. And any company of any size should be accountable for the ingredients in their products.

**20. For disclosures by small food manufacturers, what is the appropriate language indicating that a phone number provides access to additional information? (Sec. 293(b)(2)(F)(ii)(I))**

We are completely opposed to a website, telephone number, QR Code or symbol on the package to be the *only disclosure* about whether a product contains GMOs or not. When a consumer has a toddler running around the store, a baby in the shopping cart and a hungry spouse at home or sporting event to get to, they do not have time to call a company and ask if the product is GMO or not. Not is it safe for them to handle that distraction and the children they are responsible for. Having to call a company, be put on hold, and ask questions adds undue stress and inconvenience to a consumer simply to hide the fact that a product is GMO or not. If GMOs are safe, why not just simply label them? Because they are not safe. So there should be

a warning label, simply, clearly, on the package just like cigarettes. Cigarettes are clearly labeled with a warning. GMO food should have at least the same, if not banned. The difference between smoking and food is that smoking is a choice, eating is not. That is all the more reason why we should know what is in our food and be able to choose.

**21. The Law excludes restaurants and similar retail food establishments from disclosure requirements. How should AMS define similar retail food establishment to exclude these establishments from the requirements of the regulation? (Sec. 293(b)(2)(G)(i))**

Establishments that sell food ready for human consumption, such as institutional food service, delicatessens, or catering businesses and restaurant-type food should all be required to clearly label that the food they serve is GMO or not. A warning on a menu, at the entrance of a food serving establishment or signs on the display case of any food offerings must be required to fully disclose the presence of GMOs in the food.

**22. How should AMS define very small food manufacturers to exclude these manufacturers from the requirements of the regulation? (Sec. 293(b)(2)(G)(ii))**

No food manufacturers, despite the size of their manufacturing should be excluded from the requirements of the Law. If you serve GMO food, it must be labeled.

**23. Is there other equivalent on-package language that AMS should consider to accompany an electronic or digital disclosure besides “Scan here for more food information”? (Sec. 293(d)(1)(A))**

NO. The word ‘scan’ or electronic or digital disclosure must not be used in the present or in the future. The only reason why AMS would offer guidance to identify equivalent language as technology changes and what that equivalent language would be is to capitulate to the corporations and to hide the presence of GMOS. Ignoring that over 90% of consumer want to know what is in their food is a clear influence of corporate pressure, putting the profit of the corporations over the health, preference and safety of the consumer.

**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))**

AMS should require the placement of the following text, clearly written on the product in a font which is legible by the naked eye.

**Warning: This product contains genetically modified organisms which have been shown to produce toxins and stimulate tumor growth in animals. Many GMOs are engineered to withstand pesticides which do not dry, wash, or cook off. Therefore, this product may contain carcinogenic, neurotoxic, antibiotic, and endocrine disrupting chemicals which cause liver disease.**

**25. How should AMS ensure that an electronic or digital disclosure can be easily and effectively scanned or read by a device? (Sec. 293(d)(5))**

Electronic or digital link for GMO disclosure must not be used. The only reason why AMS would agree to this type of labeling is to appease the chemical/GMO companies who do not want the dangers of their products to be known so they can continue to profit from their products. It should be noted by the AMS that billions of dollars are made by the companies who make GMO seeds and pesticides when the consumers do not know GMOs and pesticides are present and they get sick. The same companies that make GMO seed and chemicals also have sister companies that sell the pharmaceuticals which treat the very same symptoms that the GMOs and related pesticides have been shown to cause. This profit circle excludes the health of the American people, it excludes the importance of lowering the burden of health care costs on the American people, and it excludes the democratic rights our nation was founded on for freedom, justice and liberty for all.

**26. What types of records should AMS require to be maintained to establish compliance with the regulations? (Sec. 293(g)(2))**

Recordkeeping requirements for persons subject to the Law should be kept to a minimum. Compliance should simply be added on to existing regulatory steps, such as showing proof of labeling when UPC codes are purchased.

**27. How should AMS obtain information related to potential non-compliance with these regulations? Is there information USDA should request prior to conducting an examination of non-compliance? (Sec. 293(g))**

A company should be informed that if they do not comply, a fine of \$2,500 per day per violation will be incurred if they are not compliant. Just as the CA EPA OEHHA enforcement of the Prop 65 laws, consumers, attorney generals and consumer groups should have the ability to report companies to the AMS not in compliance, without a lawyer, as long as they have proof, such as a photo and proof of date.

**28. What are the rules of practice for a hearing? (Sec. 293(g)(3)(B))**

Companies who are not in compliance of labeling should be fined and made to comply or they should be closed for business. Hearings are not necessary when proof of the violation is shown. Either a company has labeled and complied or they have not. Evidence is not debatable when a photo is submitted with UPC codes and lot numbers. If the evidence is refuted, a one time hearing with the presence of both parties able to present, and all costs paid for by the violator, should be held in the city of the person who reported the violation.

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

The AMS/USDA should make summaries of the examination, audit, or similar activity public on their website. Companies which have not been compliant should also be required to post that violation occurrence along with the date of correction.

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

All products imported should have full disclosure, the same as American standards unless their standards are higher and offer more information to the public. A sticker could be added to any product. The disclosure of GMOs and toxins should not be removed from any packaging, only added, regardless of the country of origin regardless of packaging, supply chain or other manufacturing of a original product.. In fact, the country of origin should be added to all foods. Many cases of mislabeled or intentionally fraudulently labeled cases of organic foods from Turkey have been reported. Therefore consumers should have the right to know if they are risking contamination of GMOs or pesticides by knowing the country of origin as well.

We call upon the AMS to do what is right, to protect the health of our country, our children, our parents and our pets with full clear labeling with a warning that GMOs and related toxins present a health risk to the American people.

Our health care costs are clearly going to bankrupt the US government in a few years, if not now, if we do not make drastic changes. If the American people are warned, with clear GMO labeling, and make better choices to reduce the toxic burden on our bodies, we can reduce health issues and health care costs and devastating impacts to society.

Your decision can literally be a part of driving America into bankruptcy or pulling us out of tragic health care crisis and cost and into a safer, healthier, more powerful and more prosperous future. Thank you for your dedicated attention to this matter. As a mother, a chef, an USDA early childhood educator, former large chain grocery store auditor and inspector now health professional I know how it is imperative that we have clear standards that are easily identifiable for all Americans not limited by socioeconomic status, race, creed, religion or sex. Our future as a nation depends how these rules are made and enforced.

Sincerely,

Amber King