

**Written Testimony to the Record  
United States Department of Agriculture,  
Agricultural Marketing Services**

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**National Bioengineered Food Disclosure Standard  
Proposed Rule Questions Under Consideration**

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The Agricultural Marketing Services (AMS) has been charged to develop a national mandatory system of rules to ensure open and transparent labeling of GMO foods. On July 29, 2016, Congress passed the National GMO Bill 764. This bill requires disclosure if food products contain bioengineered (GMO or GE) materials. The bill stated included three different options of disclosure: digital disclosure such as QR codes, URLs, and 800 numbers, words/text of the package, or symbol on the package. Congress gave the USDA two years to implement the law.

In response to this mandate, the Hippocrates Health Institute (HHI) and the POP Campaign (POP) are submitting this document on behalf of its constituents and clients. More than 50 years ago, the Hippocrates Health Institute was founded by Ann Wigmore, a humanitarian and health visionary. She advanced a simple concept first voiced by the father of modern medicine – Hippocrates - who nearly 2,500 years ago taught: "Let food be thy medicine and medicine be thy food."

As someone who from personal and professional experience has seen the difference eating a healthy plant based diet can make in health and vitality, I am very concerned that the United States continues falling behind in health status, in part because of lifestyle decisions, in particular around food choices. A study recently published by the Commonwealth Fund reiterated what has been previously reported, that the United States spends more than any other high-income country on health care, 2-3 times the GDP (over \$9,000 per person) but has poorer health outcomes and shorter life expectancy than our international counterparts. <sup>(1)</sup> The study also found that 68 percent of American seniors are living with two or more chronic health conditions. <sup>(2)</sup>

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(1) <http://www.ensser.org/increasing-public-information/no-scientific-consensus-on-gmo-safety/>

(2) <http://www.commonwealthfund.org/publications/issue-briefs/2015/oct/us-health-care-from-a-global-perspective>

The health, vitality and freedom for all of us to make informed food choices is at the root promoting improved health status in our country as a majority of chronic health conditions are related to diet and lifestyle. The regulations regarding any disclosure on food standards must be clear, comprehensive, and transparent to support the citizenry of this wonderful country. Especially, these must be in complete support of the consumer's best interest and at the core of safe families and children for our future health. This is an obligation on the part of parents for their families and an equal obligation on the Department of Agriculture and Congress to support transparency in labeling.

We still presume and stand by past comments made to the Senate where it was stated that the research on the safety of GMOs still is far from settled and that hundreds of scientists from around the world agree that there is a risk to consumers. Therefore, it is our primary position that clear transparent labels are absolutely necessary and that every provider of food in this country provide consumers truth and clarity on the quality of that food and what is in it – the driving principle of the POP Campaign being “Quality Food is a Human Right.” Certainly Genetically Engineered foods and ingredients do not fit into this equation. As it is recommended below that small businesses and institutions also comply, adequate governmental support is needed and would be required and provided to cover all certification costs. Please see the responses below to the 30 questions proposed.

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

**Context:** *The disclosure standard would be a mechanism to inform consumers about their food. AMS is considering the advantages and disadvantages of allowing the use of other terms to provide for disclosure.*

The market continues to be very creative in its ability to scoot around any definition that is placed on a label. Honest refinements of definitions are constantly challenged and often get stalled in the court system to refine points of law and regulations. We continue to seek clarity and simplicity in labeling to prevent such quagmires and advocate transparency at all levels.

We propose a radical yet simple approach for true labeling. As a rule, it is recommended that any “terms” used now and in the future that are different from the purest definitions of food used 50 years ago that described crops and food, be the guidepost. This “50 year” marker would ensure transparency and a simple and clear policy directive.

In essence, any term would be labeled that is different from describing food of that era before the chemistry revolution took hold and exploded with such mantras DuPont used: “Better Living Through Chemistry”, which changed in 1999 to “The Miracles of Science”. Within this context, any reference or

technology within “modern biotechnology” or “genetic modification” or “bioengineering” or CRISPR/Cas9 et cetera would be subject to clear labeling.

Any current or future refined definitions would state that Bioengineering is interchangeable with any in vitro or mediated gene or clustering of genes in any bacteria or DNA fragments that might be within the scope of any modification including the CRISPR/Cas9 mediated system. This includes any edited gene out of a plant or living species or any insertion of synthetic fragments or gene of any other type. Any new name or current name under which and where any future scientific advances purport to improve plant and/or growing strategies exist, would be included in the transparent labeling process. Any targeted modification editing or in-frame deletions or insertions to a species that are presumed to affect pathways of the bio-species would have to be considered “bioengineered” and therefore labeled.

Also included are any “next generation” biosynthetic or bio-compatible expressions or “advancements” that will emerge that we today are not aware of which in some way mediate the current “organic” strains of the plants and animals we have now. Such a policy would include cloning of any type orchestrated through mediated recombining of genes. There also should be included any strategies that seek to alter the DNA of any food source through the manipulation of its gene reorganization or reconstruction.

Crucial to this labeling requirement, also, is the growing process. Of special concern, for example, is a process wherein the beginning is a fermentation base starter wherein a new growth begins with one type of a modified organism, and then, it is modified or mitigated by a second generation of a plant or animal species not modified, usually growing on top of it or using it as a starter. A clear label is still a must. An example is where current algae is GE modified and grown as a base (like soil or a mold) which serves in essence as a host to another organism or seed of a plant or animal. In essence, the line of this life cycle is not complementary to the purity of the plant or animal species. Therefore, clearly it is recommended that any foods involved in such a process be subject to GMO labeling. Again, a 1950s marker would draw lines clearly.

Recombining of any fragments or sequencing of DNA of a plant or animal in any gradient form to ensure enhanced strength, gene resistance, or complementary compatibility with any environmental factor still would be considered a form of re-sequencing and under a blueprint of another species than what nature intended. Therefore, it would require labeling. The backbone of this label is the exposure of truth and the trust of the consumer.

Although we are a plant-based community, all of these comments apply to animal or species bioengineering when used at any level for human consumption. This would pertain to next generation species, such as GE salmon, that have evolved and/or interbreed with “natural” salmon.

Lastly, any new or interchangeable terms to describe new recombinant of food gene creation or recombinant generation advancements through engineered or manufacturing principles are to be clearly labeled GMO. Beyond conventional breeding, this would include use of artificial tissues or organs where animal genes have been modified or used to replace an original gene or used in food production and the use of 3-D printing of genes or seeds or any replication of the natural process of a food product. Included would be any bioengineered “bio-sack” or “protective” shield to encapsulate an animal organ or meat section while in the animal to make it “super enhanced” or more compatible with our human digestion or consumption. It is key to note that animals fed with any such products would also be subject to the GMO labeling process.

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

**Context:** *AMS is considering what would be defined as modifications that could otherwise be obtained through conventional breeding because these modifications would be exempt from mandatory disclosure.*

It is acknowledged that there is a modern day chess game of definitions that are played out by various boards and protocols around the globe. The slicing and dicing of definitions explode into a salad mix of classification refinement driven by industry needs and consumer demand. There are conflicting regulations to ensure trade, the Cartagena Protocol, Codex Alimentarius, FDA, USDA, NOSB, NOP, etc.

Therefore, to simplify this for consumers, again, it is safest to revert back to a “date in time” where techniques used in farming and crop growth occurred prior to the 1950s in the United States and worldwide. There is no major “roll-over” definition here triggered by pesticides that were used at that time and no “loop hole” for wiggle room around labeling.

Notwithstanding any “mutagenesis” or “buzz word” description (3) pertaining to gene alteration through nature where selective breeding techniques were intentionally and naturally used or a particular “loci” in nature happened, this time period had limited evidence of mutations and purposeful manipulation of crops. Although there clearly may have been experiments, it appears that it wasn’t until the 1960’s where “experiments showed that there were growth expressions although no colony formations, subsequently, although DNA synthesis transfers occurred, the continuation was not significant with often cell divisions ceasing and pronounced fulmination observed....there was very little and basic progress made at that time, which, although was useful did not translate into any significant gains and impact on the food supply.

3. Mutagenic DNA repair in *Escherichia coli* -  
<https://link.springer.com/article/10.1007%2FBF00277304?LI=true> )

Using this measure precludes the politics and refining of definitions that have emerged since. Applying this 1950's point in time bypasses using "harmonization" arguments and precedes setting plant breeding and gene altering protocols. Labeling becomes clear and not subject to the influence of industry and biotech at the expense of consumer free choice and health.

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

**Context:** *AMS is considering what would be defined as modifications that could otherwise be found in nature because these modifications would be exempt from mandatory disclosure.*

There is an excellent and complex response to this question, most clearly presented in the Consumers Union statement below, which we agree with.

In reference to the above standard, "found in nature" can be defined and interpreted in so many ways, in particular considering any "scientific method" and subsequent dialectic. Therefore, again, a simpler focus might be considered as a defining marker – for example, a date in time of 11/16/1950. Any technological advances pertaining to food development beyond this date shall be considered "not" found in nature. Policy must maintain a sensible base where changes with the times are woven clearly into it but not surreptitiously replaced.

Noting the comments in #2 above, any food source with gene manipulation or sequencing involving any genetic reconstruction, silencing or rehabilitation not found in nature in 1950 would be labeled. This includes genetic construction such as GE salmon, gene silencing in CRISPR, such as apples, mushrooms and potatoes and gene resequencing as found in gene editing, TALENs mega nucleases, zinc finger nuclease manipulations, RNAi pesticides, etc.

Provided there is no interest in such a radically simple approach as stated above, there is an excellent and complex response to this question, most clearly presented in the Consumers Union statement below.

"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.” 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))**

**Context:** *Many processed foods may contain ingredients derived from bioengineered crops, such as highly refined oils or sugars that contain undetectable levels of bioengineered genetic material such that they are indistinguishable from their non-engineered counterparts. AMS is considering whether to require disclosure for foods containing those derived ingredients that may be undetectable as bioengineered.*

Absolute clear labeling and disclosure is a must with a caveat of clarification that disclosure applies across the board in full transparency, including all aspects of bioengineering. Clear labeling is necessary for unrefined, low refined, medium refined and highly refined products that go through any process or modern combining of products. The ingredients are the drivers and any present for future manufacturing and/or future process of combining gene, plants, sugars, oils, et cetera through chemistry, bioengineering, or creative growing processes. Scientific knowledge exists to determine whether or not any inert chemicals, salts, or any other ingredient surfaces that is detrimental to human beings, especially our babies. (See Article entitled “Genetically Engineered Food Linked to Iodine Deficiency and Congenital Birth Defects: <http://hippocratesinst.org/wp-content/uploads/2015/08/33-4.pdf> )

**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))***

**Context:** AMS recognizes that other Federal agencies have different terms to describe organisms created through recombinant DNA techniques. AMS is considering areas of potential overlap or confusion over terms, as well as potential language to add to this regulation to ensure the term bioengineering does not affect any other definition, program, rule, or regulation.

Policy can lead, simply “instruct” or become part of a background. We are at the point where a definition of bioengineering should become the marker for other rules and technically take the lead pertaining to all regulations and laws pertaining to food groups.

Too many times we see that policy definitions are compromised domestically for other agendas where laws were made for other purposes. As we know Congress passes an average of 758 bills each year – with approximately 7,600 every ten years. As part of the business of legislating, contradictions emerge often.

Therefore, it is suggested that the USDA take the lead and lay down a definition to which other pieces of legislation must incorporate. Otherwise, there exists too much bioengineering industry wiggle room with no checks and balances for organic. Further, the clarity should be driven by a “Domestic” provision where all GMOs used on American soil or within its territories clearly be labeled. This bill could become the driver for future and past legislation with the definition of GMO and the standard bearer for future concerns.

Bioengineering advancements are exploding and future definitions and provisions are coming “down the pike” and must accommodate these existing food rules. Subsequently, if the above bold recommendation is accepted using a 1950s marker, a “bioengineering” definition can stand on its own in this case but will have absolutely no impact.

The intention and Spirit of the law is to be clear with the American citizenry. These are moms and dads consumers on both sides of the aisle who want the freedom to purchase quality food with clear labels for their children. If there is a need to go back to the US Senate for clarification and debate, an opportunistic window exists in the 2010 the Food Modernization Act passed wherein a provision exists where a reporting was due back to the Senate. To date, it appears that this has never happened. This may be one avenue of reporting to refine any definitions legislatively.

***6. Meat, poultry, and egg products are only subject to a bioengineered disclosure of the most predominant ingredient, or the***

***second most predominant ingredient ....(B) 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))***

**Context:** AMS is considering how to evaluate predominance to determine how the Law will apply to multi-ingredient food products.

Technical note: The regulations above continue with another subsection noting the second-most predominant ingredient as stated:

*“...the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act.”*

As a general rule of thumb, all animal products must be labeled GMO unless their animal food source markers are clearly labeled otherwise. This appears to be a complex issue to monitor and legislate with such an effective mandate. The selection of the “two most predominant ingredients” appears too risky and easy to orchestrate an end run on. Much more clear instructions are needed.

For example, a farmer may get a corn, barley, oats and molasses mix for chickens. Obviously, the ingredients that may be questionable as GMO are the corn and molasses. Yet, as the legislation reads, a farmer could choose barley and oats as the reportable items under this provision. The outlet where the items were bought may or may not have clear labels because so often this “pickup point” is a cooperative. When the many farmers bring in their crops, these often are mixed together without sorting out GMO and organic, unless there is a clear market advantage to do so. This does not always exist in “farm country”.

These practices seem nearly impossible to regulate and monitor as the clarity that is needed appears to be a daily meal recording of what is fed animals or poultry and how much when. This would be too much of an added burden on farmers with costs being rolled over to consumers. Therefore, the recommendation is to label any and all ingredients used in feeding crops and the “organic standard” fall in line accordingly.

***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))***

**Context:** AMS is considering regulatory language similar to the wording in the Law and if the Agency should provide clarity that food derived from any animal, including invertebrates such as crickets or bee products, would not require disclosure as a bioengineered food solely because their nutrition came from food with bioengineered ingredients.

There is clear disagreement on this provision because the stance is that ALL ingredients given to animals must be part of the equation when consumed. If crickets and bees are about to become genetically altered, as any other insect or animal that is used in animal production, there certainly is a need to clearly label the product. A huge concern that might emerge, for instance, is where GMO salmon is ground up and used for feedstock for other animals, fish, etc. Then these are shipped off to be processed for the consumer.

### **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))**

**Context:** *The Law authorizes the Secretary to determine the amount of a bioengineered substance present in food in order for the food to be disclosed as a bioengineered food. The amounts of a bioengineered substance that may be present in food in order for the food to be a bioengineered food might be determined in a variety of ways: if a bioengineered substance is near the top of the list of ingredients, by determining the percentage of bioengineered ingredients in a food product, or by listing any ingredient that was produced through bioengineering, among others. AMS is considering how to determine the amount of bioengineered food or ingredient needed for a product to require a bioengineered disclosure, as well as the advantages and disadvantages of various methods.*

The time is now to establish in our food a 100% GMO and bioengineered free label option where the label of 100% means truly 100%. Under such a label, any and all GMO ingredients and markers of bioengineering would be subject to complete disclosure. Following the standard thresholds as found today in the European Union and the “non GMO” labeling project would no longer apply.

The current “organic” and “100% organic” labels currently have non-organic (and GMO) thresholds of 5% and 0.9% respectively. A new gold standard would be in order with a 0.0 threshold where products, manufacturers, institutes and farmers clearly offer 100% pure GMO free food products. As growing advancements and sourcing options keep pace with technology, companies that truly purport healthy products for consumers easily would move their products in a direction of high transparency. This is what consumers want, with no “smoke screens and hidden allowances”.

Advantages would simply be to the consumers with the burden of transparency on the shoulders of industry.

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

**Context:** *AMS is considering if it should develop various categories for disclosure and if it should differentiate between those products that a) are bioengineered, b) contain ingredients that are bioengineered, or c) contain ingredients derived from bioengineered crops or animals. Additionally, AMS is considering the creation of a set of disclosures for a category of bioengineered foods for those products that, due to changes in*

*sourcing, include bioengineered ingredients for part of the year, and non-bioengineered ingredients for other parts of the year. AMS is considering the advantages and disadvantages, based on cost, clarity, and other factors, of using a single disclosure category or multiple disclosure categories.*

Underneath these questions is a new approach to policymaking where the policy is formed to accommodate technological innovations in favor of business. A multiple category approach is clearly an advantage to allow industry the flexibility to promote its “different types” of advancements with as little constraint as possible. Subsequently, “high tech policy framing” captures the advancements of technological innovation at the expense of clear disclosure for consumers.

If AMS or the USDA considers that there is a need to remain in step with technological advances, then a “different type” of category may be needed but not at the expense of full disclosure of GMO.

For example, such a policy would take into account the rapid development of CRISPR technology where the technological advances may be “very close to” the existing product but is missing certain genes. We do not know what will happen to organic potato crops down the road, for example, if generations of varying potatoes become cross tubers on purpose.

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

**Context:** *AMS must develop a process to help stakeholders determine whether a food is subject to bioengineered disclosure. AMS anticipates the process would include considering factors such as: whether a food contains a substance that has been modified using recombinant in vitro DNA techniques (Sec. 291(1)(A)), whether the modification could not be obtained through conventional breeding or found in nature (Sec. 291(1)(B); [Question 2 and 3](#)), , and whether a food requires disclosure based on the predominance of ingredients (Sec. 292(c); [Question 6](#)), among others. The outcomes of these determination requests might be publically posted on a Web site. The process to implement Sec. 293(b)(2)(C) is not intended to be an investigation or enforcement process (see [Questions 26-29](#)); instead, the implementation would likely be framed for manufacturers or developers of bioengineered food or ingredients who have a question on whether their food is subject to disclosure. AMS is considering the factors to be considered, the way to inform the public about the outcome of the requests, and ideas regarding the process to be used to make the determination.*

It appears that the intention of this section is going in the right direction to clarify for industry certain factors that may require labeling.

One very important major consideration that is not paid attention to is “inert” combinations of GMO or bioengineered foods where intake may trigger inert genes or hidden deficiencies to occur that may result in detrimental combinations of chemistry. Such a deficiency may be linked to serious detrimental health issues. For example, it is purported in an Article published a few years ago where

toxic halogens called salts were hidden in GMO foods that causes birth defects. See Article entitled “Genetically Engineered Food Linked to Iodine Deficiency and Congenital Birth Defects: ,<http://hippocratesinst.org/wp-content/uploads/2015/08/33-4.pdf>

Such hidden actors in our foods and chemistry are not natural and should be considered a byproduct of the GMO/bioengineering process and therefore clearly labeled. Such a major policy consideration is a policy stance of precaution to avoid any damage, changes, or mutations of genes of current generations or the following generations. An 1950s marker again may be the safest. Such a cautionary approach is of particular interest to Moms and Dads with little children.

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

**Context:** *AMS is considering if it could exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered.*

There appears to be a need for clarification in this section, as there appears to be a mixing of apples and carrots in this equation.

A key provision in the Bill’s regulations (C) states “...*other factors and considerations under which a food is considered a bioengineered food*”. This question and inclusion of “dietary supplements” really does not appear in the legislation. Any “tampering” with supplements is very tricky because doing so appears to be an attempt to open the door to issues in DSHEA, the Dietary Supplement Health and Education Act of 1994.

It has been long held that there are many distinctions between food and supplements where lines must not be merged. Below is the definition section of dietary supplements used in DSHEA:

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.”<sup>32</sup>

Within this DSHEA provision and definition, “food” is not to be compromised by any precedent setting provision from another act. It is independent and sacrosanct in these instructions, intention and recommendations.



As consumers greatly favor the protection they enjoy under DSHEA, then certainly a “regulatory instruction” from the FDA would be appropriate as long as there was no jeopardizing of the Act itself and no precedent set. If the USDA has the regulatory flexibility to allow or disallow any ingredient in DSHEA without jeopardizing the boundaries of the Act and its intent and spirit, then, certainly the narrow applications of GMO / bioengineered appropriately applies.

Clearly this is not a statement in favor of GMO derived supplements as any vitamins and dietary supplements derived from GE sources ought to be clearly labeled. The major concern is opening the door for industries’ footprint and manipulation of the consumer protection elements of DSHEA which have been a gold standard.

**12. 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))**

**Context:** *Currently, 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”). AMS is considering whether to allow manufacturers to continue using these disclosures under the new national bioengineered disclosure standard and if their language is appropriate. Further, AMS is considering what phrases could be used as a text disclosure for bioengineered food that consumers would find informative, truthful, and not misleading.*

*AMS is also considering whether there should be one standard text disclosure language, or whether manufacturers should be allowed flexibility to choose from more than one acceptable phrase and where the bioengineered food disclosure should be placed on food packages.*

This new labeling opportunity invites everyone involved to “get it right” and to be more transparent and clear, aiming to benefit consumers over industry. Therefore, it is recommended that there be one clear provision – either labels are “bioengineered” or possibly “GE” or “BE”.

In hindsight, the working of the Vermont GMO language was an attempt to refine words for purposes of forming coalitions and getting votes for passage, especially since it was one of the first States to orchestrate such a passage. As we know, the compromises that can occur within such a lengthy, precedent setting process can be significant and orchestrated as a voting strategy.

The preference here is 100% clarity. This would mean that, if a product were labeled “100% GMO free”, there would be NO doubt to a consumer that the ingredients would be 100% lacking of GMO ingredients. Any margin of error, as seen today, such as the 0.9 % margin under the “organic” seal ought to be eliminated for the 100% GMO label. The argument for the .9% was that industry

would be hamstrung by costs in formulating its products and that binders were required for the proper product mix, binders often being GMPO. If there is no significant change, a GE or BE label would have to be inserted as part of the .9% variance, as presented below where Moms Across America have made a good attempt with their warning label..

Warning label: 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))**

**Context:** AMS needs to ensure that the symbol designed for the bioengineered disclosure is not disparaging toward bioengineering. As with the text disclosure, AMS must develop criteria for placement of the symbol to ensure consumers can readily locate the symbol, the symbol is scalable for different sized packages, and the symbol is a meaningful representation of bioengineered foods. AMS is considering what the symbol should look like and guidance on its use.

The most important point in any labeling is to ensure that there is full disclosure of GMO and bio-engineered elements in food, and that consumers are clearly aware and notified. A symbol on a package is clearly a trade-off of full, clear disclosure and is not acceptable. Consumers must have full access to ingredients and a complete education process must be in place to ensure easy and truthful selections.

As a symbol obviously will come into the market place at some point, a simple stylized strand of DNA would do the trick, meaning that the DNA would appear on any package where any GMO related technologies exist. This would also apply to CRISPR and subsequent technologies where there may be an extraction of one or more genes. Here are a few examples of a type of label that would indicate to consumers a manipulation of food gene is in the ingredients.



**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))**



**Context:** *D) in accordance with subsection (d), require that the form of a food disclosure under this section be a text, symbol, or electronic or digital link, but excluding Internet website Uniform Resource Locators not embedded in the link, with the disclosure option to be selected by the food manufacturer;*

The proposed electronic route at the tradeoff of shelf full disclosure is “bigger than necessary” for this bill at this time. We are against implementing electronic approaches and disclosures in favor of “keeping the truth on the shelves”.

One of the POP Campaign principals drafted and presented a digital communications bill for the California legislature years ago on telecommunications rights because of the notable economic discrimination that technology instilled in relationship to income disparity. Simply, economic discrimination triggered by technology was a real issue then and is a real issue now. If this “electronic or digital” portion actually goes through without any provision for clear labels, these accessibility issues may surface under the ADA, especially for seniors, and would than likely result in formal challenges.

Further, for busy Moms and Dads there is “No Time” during a quick shopping runs between work and school and dinner, etc, to access electronic in-depth information on products. This is a nice idea but unrealistic at this time,, especially because of the lack of infrastructure.

To implement this would be a completely new layer of product requirements that would set precedent for the future around ALL food products. The obvious next steps would be full and complete disclosure on ALL ingredients of every food product in the US. A new industry would be established with a possible “Seal of Good GE Keeping” with disclosure and transparency in every state and every industry.

However, if the compass is leaning to a “must implement”, then the following ought to be considered in the favor of consumers. The requirement would be that full disclosure be presented in a manner that is consumer friendly. Possibly a few schools around the country could be enrolled to edit the “ingredient context” and ensure that clarity that would be achieve full and complete understanding, even at their levels. Truth in labeling is absolutely crucial for consumers.

For example, on line, one example of a transparency sequence may be as follows:

**Intro:** short description of the reason this site exists – 2 sentences.

**Section 1:** A simple, clear, graph with descriptions of the product ingredients would be up front, visible and transparent.

**Section 2:** Statements of “why here” and concern about certain GMO products that are listed in this product with a little more back ground....both industry and consumer paragraphs on the same page next to each other.....somewhat like an election voter ballot explanation.

**Section 3:** More in depth statement from the manufacturer or/and product source about the ingredients in question as to the in depth studies presented, reports, etc. The same allowance would be given to groups protecting 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))**

**Context:** AMS recognizes that disclosure technologies may quickly surpass regulations. AMS is considering what terms will ensure the regulations keep pace with technological changes and how AMS can notify stakeholders about changes in technology as they occur. AMS is also considering what the most appropriate electronic or digital disclosure technologies are currently and how to deal with obsolete technologies.

The most favorable position for consumers is to “follow the package” disclosure. The responses above to question 15 are appropriate here.

**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))**

**Context:** In some situations, disclosures may not be easily located when such products are on display for sale. AMS is considering disclosure practices for these and other non-conventional purchasing or packaging scenarios.

Anything in a market place or store seems to have a place where prices are displayed. Any vendor of any product that does NOT contain GMOs will somehow find a way to disclose it because of the market advantage. Such an advertizing would be placed on the product, shelf, or anywhere the customer looks to drive the customer to buy that product. Even the smallest store owners or booths have the ability to display a sign that works..... no matter how small the store. Therefore, the recommendation is that there be NO wiggle room on this point, including on conventional packaging.

**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))**

**Context:** AMS is considering if it should mirror FDA’s treatment of very small and small packages for nutrition labeling.

a. In 21 CFR 101.9(j)(13)(i)(B), FDA defines small packages as those with less than 12 square inches in total surface area available to bear labeling.

b. *FDA also has allowances for packages that have less than 40 square inches of total surface are available to bear labeling.*

A symbol stating GMO ought to have no compromise because of size of the package. A 12 square inch space is plenty for wording or a label. A small entrepreneur or provider always seems to find a way if desired. Therefore, all products ought to be labeled and displayed, as this is the modern way. Where a small provider needs help, the USDA ought to provide free assistance.

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

**Context:** *AMS is considering the disclosure standards for very small or small packages. FDA regulates nutrition labeling on very small or small packages differently. For example:*

- a. *Could disclosure requirements for very small packages be met by providing an address or phone number where consumers could obtain the information?*
- b. *Could disclosure requirements for small packages be met by providing abbreviated text disclosure or a Web site address where consumers could obtain disclosure information?*

The labeling mandate should be maintained and required without compromise. The space that would have the address and phone number could be the same space whereby the content could be placed. Granted, there may be some hampering of esthetics in packaging; however, most products get around this by having part of the packaging paper overlapping, like some candy bars, where the information is on the outside and inside of the flap.

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

**Context:** *AMS is considering using regulatory language similar to that of other Federal government agencies that already define small businesses. For example:*

- a. *FSIS considers small businesses to be those with 500 or fewer employees and that produces 100,000 pounds or less of annual production of a single product, including single forms of meat such as sausage, bulk, patties, links, consumer product, etc., when determining exemptions from nutrition facts labeling (9 CFR 317.400 (a)(1)(ii)).*
- b. *FDA has several small business definitions with respect to food labeling rules, such as: i) retailers with total annual gross sales of \$500,000 or less, 21 CFR 101.9(j)(1) and (18); ii) food and dietary retailers with annual gross sales of foods or dietary supplement products of \$50,000 or less, 21 CFR 101.9(j)(1) and 101.36(h)(1); and iii) businesses that employ fewer than 100 full-time workers that produce a product that sells fewer than 100,000 units throughout the United States in a 12-month period, 21 CFR 101.9(j)(18) and 101.36(h)(2).*

*AMS is considering the advantages or disadvantages of these definitions of small food manufacturers for the bioengineered food disclosure regulations.*

Full transparency on all products for even small companies is the recommended compass. There should be no exceptions with small companies being required to be in compliance. Every company has the ability to place a price on their product and name it and say what it is. An added disclosure of GMOs for clarity in actuality is simple and not cost prohibitive. If there are cost issues, the USDA ought to assist the business.

At times, a lengthy third party verification process may come into play although it may be expensive for smaller manufacturers. It is recommended that Federal and State subsidies be made available for transparent labeling and that a “piggy-backing” system be established to mitigate these costs. This unique added cost effective approach may include a product ingredient that has been determined GMO prior through a process of labeling by a third party company. A company may be able to “piggy-backed” on the certification of another company provided there are no changes.

***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))***

***Context:*** AMS is considering using language in Sec. 293(d)(1)(B) of the Law.

No. A phone number is a step away from on the shelf disclosure, as mentioned above, and most inconvenient for the busy families and consumers of today. We can't imagine that a busy consumer or a modern mom during a shopping rush hour shop would make a phone call to get clear labeling information.

There are ways smaller manufactures have figured it out; labeling is NOT rocket science and very doable, especially if someone really wants it done. For those who need a little help, possibly there could be an allocation for a template on line and some assistance for them, as mentioned in #19. If consumer access on a phone is in order, there certainly would have to be a “common approved” script with full technical disclosure and a conformity across the board....which is another head ache.

***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))***

***Context:*** AMS is considering how to treat establishments that sell food ready for human consumption, such as institutional food service, delicatessens, or catering businesses. In its regulations for Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (21 CFR 101.11), FDA defines restaurant or similar retail food establishment and restaurant-type food For FSIS, the Federal Meat Inspection Act (FMIA) provides for the mandatory inspection of commercial meat and meat products. The FMIA and implementing

*regulations do, however, provide exemptions from the continuous inspection provisions for retail operations and restaurants (9 CFR 303.1(d)(2)). NOP also defines retail food establishment in its regulations (7 CFR 205.2). AMS is using this information as it considers definitions for restaurants and similar retail establishments, with the understanding that these definitions will be used to determine what types of retail establishments are excluded from the requirements of the Law.*

The preference is that any person or entity that provides food to consumers, in particular families, children, and the elderly, must have GMO labeling disclosures, including restaurants and small providers

If the law is not strong mandating an allowance on this issue, there could be a provision where a consumer friendly restaurant would be acknowledged formally or placed on a list or receive some type of Federal insignia if it is willing to volunteer for GMO labeling. Because consumers want everything labeled GMO at every level, this could be an incentive for a restaurant. Any USDA guidelines might be set up through a special program and include incentives for participation.

***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))***

***Context:*** [See Question 19](#). AMS could use definitions similar to how other Federal agencies define very small businesses, and is considering definitions to distinguish small food manufacturers (Question 19) and very small food manufacturers, with understanding that very small food manufacturers would be excluded from the requirements of the Law.

ALL food manufacturers should be subject to GMO/GE labeling with no exception. Manufacturers need to be respected for the know-how that got them to this point in the production space. They know what is going on within the confines of their production or manufacturing or canning or bottling plants and operations. They also know exactly where and how to label.

Further, production with technology makes everything more efficient than ever, which is where the mystery is eliminated. Labeling is NOT a mystery...at least not for the mixers, machine operators, slicers and dicers on the floors where products are processed. The frontline workers usually know how things really work and pride themselves in finding answers and facing challenges. This is their profession. The truth may more be that the owners simply “don’t want labeling” because there is too much “disclosure” and “distraction” from profits and the bottom line. To strongly support consumers, “being real” under this circumstance would mean that the USDA would step in with assistance.

There is a strong need for transparency because no mom on the street or busy dad really believes that the American way really thrives with such a roadblock.

So, on behalf of every Mom and Dad and consumer, all products should 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))**

**Context:** The word ‘scan’ may or may not be relevant for each type of electronic or digital disclosure in the present or in the future. AMS is considering if it should issue guidance to identify equivalent language as technology changes and what that equivalent language would be.

Direct and transparent disclosure on any product is the most preferable and bottom line at this time. The word “mark” as in bio-markers which is more common in the industry is a word that might be used.

**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))**

**Context:** AMS is considering requiring the same information associated with the text disclosure as the requirement language for an electronic or digital disclosure ([See Question 12](#)). Further, AMS is trying to determine how various disclosure options affect the amount and type of information available to consumers. AMS is also determining if there should be requirements or guidance on what size text would ensure the information is conspicuous to ensure the food information is located in a consistent and conspicuous manner when electronic or digital disclosure is accessed.

Clear transparency on the package itself is the preference. A 12 point lettering is preferable in bold, especially so that Seniors and those who are sight challenged can easily read what is in the packages. Lettering should always be in black print as the easiest to read for everyone. Other colors and light colors camouflage easy and clear access.

Consistent with transparency principles, in any electronic implementation, all primary and secondary information ought to be presented on the landing page for clear consumer disclosure.

**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))**

**Context:** AMS is aware that electronic or digital disclosures need to be effective, that requirements will vary for each specific type of electronic or digital disclosure, and that the technology for electronic or digital disclosure may change faster than AMS will be able to update its regulations. AMS is determining how to address these issues given the variety of electronic or digital disclosures currently available in the marketplace,



*along with the specifications for these disclosures to be used effectively in a retail setting.*

Again, the preference is for consumers to receive all of the information on a product in full disclosure at point of purchase and sale of a food product. An electronic approach that trumps easy access for every consumer is more of a barrier than a free transparent access channel. Such an action does not give the consumer the edge but more favors companies.

Also, in any digital approach, issues of accessibility per the ADA, Americans Disability Act, come into play. In this case, a complete digital scanner that may meet all of these terms may be years in the future.

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

**Context:** *Each person or entity subject to the mandatory disclosure requirement would be required to maintain and make available to the Secretary records that establish compliance with the Law. Typically, record keeping requirements include those for the records required to be kept, the place of maintenance of such records, the record retention period, and what it means for AMS to have adequate access to and inspection of such records.*

*Under current FSIS regulations, records must be maintained at a place where business is conducted, except that if business is conducted at multiple places of business, then records may be maintained at a headquarters office. When the business is not in operation, records should be kept in accordance with good commercial practices. For FSIS, records are required to be maintained for a 2-year period. The maintenance time for FDA records vary from 6 months through up to 2 years.*

*AMS is considering what recordkeeping requirements for persons subject to the Law would be most appropriate.*

Simplification and less paperwork makes the most sense so that a “business can do business” which is a norm most consumers seek and support. However, the minimal requirements should reflect the commitment of any business to consumer transparency and to the labeling process. A two-year record maintenance record period may not be long enough to complete everything in the process because of dependency on third party clearances. Possibly a 4 year record-keeping measure would make more sense. A key variable is a reporting requirement if a product formula is changed after reporting periods.

**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))**

**Context:** *AMS is considering what tools could be used to identify potential non-compliance and enforce compliance with the regulations. AMS is considering the types of information needed to verify compliance with the Law and the most optimal way to obtain such information.*



Since there is such a huge move towards the integration of digital technology from the USDA, an easy access phone number for consumer reporting should be in order. Any compliance procedure must include consumer updates and information on a company's progress. A sufficient compliance rule obviously ought to be in place whereby a company is given "reasonable time" to comply with the rules. Reports that are binding ought to be submitted pertaining to progress of a violation with the appropriate enforcement actions forthcoming. If the companies are large and do not comply, significant fines should be included, such as \$2,000 a day. All proceeds would go to consumer education and access to ensure "on the pulse" updated information for quality food choices.

A consumer could proceed forward with a complaint without an attorney with correctable proof of compliance that may include photos as a simple verifiable remedy.

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

**Context:** AMS is considering the appropriate procedures for audits and other compliance actions, including opportunities for hearing. AMS is considering this aspect for the rules of practice and other options regarding a prospective hearing and internal adjudication process.

The most important issue in a hearing is to ensure that the hearing officers in truth clearly have the consumers' interests as a priority. Too often, this is sacrificed and/or cleverly cloaked. Also, it is key to eliminate the influence of industry in any hearing where the outcome is biased. Regular monitoring procedures ought to be kept at a minimum in respect for the overload of paper and requirements most businesses face; yet, without compromise of the consumer's best interest.

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

**Context:** AMS is considering if the results and findings of any examination, audit, or similar activity should be posted after the notice and opportunity for a hearing described under Sec. 293(g)(3)(B). AMS is also considering how it should make summaries of the examination, audit, or similar activity public.

Transparency is the preference at all levels. Audits, findings, minutes and recommendations, as well as violations and missed requirements of a company, ought to be made public in the same manner that public and non-profit entities and organizations are required. Since GMO and bioengineering are public issues, disclose and enforcement requirements ought to be made public at all levels.

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

**Context:** *AMS is considering how the disclosure requirements should be applied to imported products.*

Full disclosure of GMO on all products entering America is the ideal. Spot check monitoring of the production processes of International companies is a way to add another layer of warning and monitoring. There ought to be a strengthening of both the Cartagena Protocol monitoring and compliance as well as any Codex and trade requirements to meet the US full disclosure efforts.