July 17, 2017

The Honorable Sonny Perdue
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Ave., S.E.
Washington, DC 20250

Re: Proposed Rule Questions Under Consideration for GMO Disclosure and Labeling

Dear Secretary Purdue,

The Coalition for Supplement Sustainability is deeply thankful to the United States Department of Agriculture for the opportunity to inform the implementation of the National Bioengineered Disclosure Act.

The Coalition for Supplement Sustainability is a member-driven trade association of the dietary supplement industry established to maintain sustainable, independently verifiable and transparent standards across the entire supplement supply chain. Our members collaborate to review proposed third-party verification standards across all aspects of the supply chain with the common goal of creating a common consensus rooted in application of internal best practices, validated testing and reliable scientific evidence. We seek ways to keep things simple for our supply chain and our customers and we seek points of commonality across member issues and opportunities.

As a Coalition, we have been focused on GMO absence claims and the associated standards for the last several years. This subject matter, collating industry feedback and solutions and engaging the relevant existing third party standard holders on GMO related claims has been our central focus as a group.

Please accept our detailed answers to the following questions on which you are seeking feedback.

On behalf of our members, thank you for the opportunity to comment.

Respectfully submitted,

Bethany Davis
President, Coalition for Supplement Sustainability

Proposed Rule Questions Under Consideration

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.

Coalition for Supplement Sustainability Comment:
Genetic modification; genetic engineering; transgenic; synthetic biology; gene technology; recombinant DNA technology; modern biotechnology; gene editing; GMO. Likewise, non-GMO should be acceptable shorthand to confer a status of "not produced using genetic engineering/bioengineering".

2. Which breeding techniques should AMS consider as 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.

Coalition for Supplement Sustainability Comment:
All traditional breeding techniques which permit the movement of genetic material between different varieties within species, closely related species, or closely related genera. Including, sexual and asexual reproduction, hybridization and wide crosses. *

*Hansen, Michael K., 2000. Genetic Engineering is not an extension of conventional plant breeding.

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.

Coalition for Supplement Sustainability Comment:
All products of conventional breeding emphasizing characteristics which are not new for the species, having been present for millennia within the genetic potential of the species. *

Mutagenesis of an organism occurring spontaneously in nature, resulting in mutation.

Though not found in nature, the grafting of plant tissues each derived through conventional breeding, is an acceptable modification proposed to be exempt from mandatory disclosure.

*Hansen, Michael K., 2000. Genetic Engineering is not an extension of conventional plant breeding.

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.

Coalition for Supplement Sustainability Comment:

These foods should be subject to disclosure if derived from bioengineered crops, regardless of whether bioengineering is detectable or not. This aligns with international GMO labelling legislation as well as consumer and food industry accepted non-GMO schemes.

Fermentation organisms derived through genetic modification, though often removed in the final product (or killed during the product manufacturing process), should be subject to disclosure. Food and dietary supplement industries use many characterizing ingredients derived through fermentation.

The vast majority of GMO/bioengineered ingredients grown in the US are ultimately used as feed or are produced into highly refined ingredients. Exempting animals fed GMO/bioengineered crops and highly refined GMO/bioengineered ingredients would render this law largely meaningless and would exempt the vast majority of products found in commerce, and therefore not attain its goals of disclosure. CSS strongly opposes an overly narrow definition.

Furthermore, any dairy or livestock products derived from animals fed bioengineered feed should not automatically qualify for an absence claim, just because they will not be required to disclose.

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))

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.

Coalition for Supplement Sustainability Comment:

Without harmonization in language and definition of the term bioengineering, confusion will continue. As an interim solution pending harmonization, language can be added to this section that, in all matters related to labeling of foods per this regulation, the definition and language contained herein apply.

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))

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

Coalition for Supplement Sustainability Comment:

If the AMS is looking to the product label, then listing of ingredients is generally in order of predominance.

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.

Coalition for Supplement Sustainability Comment:

The current language of referencing "animal" does need to be further explained. An approach could be taken to define "animal" as any living organism which is not the product of bioengineering.

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.

Coalition for Supplement Sustainability Comment:
The food industry is a global business with a global supply chain. Adopting a globally unified method for bioengineering disclosure is necessary to assure supply chain compliance with the Law.

The EU labeling requirement does not apply to foods containing GMOs in a proportion equal to or less than 0.9 percent of the food ingredients considered individually, provided their presence is adventitious or technically unavoidable. All food products containing or consisting of GMOs, produced from GMOs or containing ingredients produced from GMOs must be labeled even if they no longer contain detectable traces of GMOs. *

Like-wise, consumer-accepted non-GMO schemes in the US incorporate a 0.9% threshold as the maximum GMOs allowed for a non-GMO claim. There is wide-spread food-industry participation in these schemes, indicating an ability to manufacture in compliance with the 0.9% action threshold.

The US food industry exporting to Europe is already operating compliant to the 0.9% threshold.

Therefore, an EU-harmonized legislation for bioengineering disclosure appears to be supportable by US food industry and accepted by consumers.

Using alternative methods such as proposed above appear to add additional manufacturing quality system requirements, making implementation of the Law more complex and costly.

Harmonization with EU will not be synonymous with GMO labeling in all nations (e.g. Korea), but it is expected to comply with most.

*
http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/labeling-of-genetically-modified-products/

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.

Coalition for Supplement Sustainability Comment:
Having both text and symbol disclosure categories inform consumers easily and should be considered as viable options. Digital and electronic options put an undue burden on the consumer to investigate GMO status and should not be considered as viable.

Manufacturers have the knowledge of what goes into products. The most efficient method of disclosure is in the printing of labels, which informs all consumers equally and efficiently.

Digital or electronic disclosure methods require each consumer to individually investigate every product, informing one consumer at a time.

We support a single disclosure category. Tiered disclosure categories may further confuse consumers.

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 publicly 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.

Coalition for Supplement Sustainability Comment:
Current language appears to capture the ways known at present that would be defined as bioengineering, with the exception of ingredients that are produced via synthetic biology. Synthetic biology ingredients or ingredients derived from synthetic biology should be disclosed as these are ever-more present in the supply chain and new ingredients derived from synthetic biology are being released every month. As technology advances, the definition will undergo revision and modification. Language in the Law needs

to account for the possibility of updates coinciding with new knowledge and new techniques available world-wide.

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.

Coalition for Supplement Sustainability Comment:
We do not have an opinion on this matter.

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))

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.

Coalition for Supplement Sustainability Comment:
Having a single standard of disclosure text avoids confusion for the food industry and consumers.

Due to the global nature of food production, supply chain manufacturing crosses regional disclosure differences. The EU has already outlined an approach to disclosure which US exports are currently operating in compliance with. Therefore, harmonization with the EU method makes sense on an international scale though it should be noted that not all regions embrace the EU method.

The following examples of EU method disclosure are taken from http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/labeling-of-genetically-modified-products/.

– Where the food consists of more than one ingredient, the words "genetically modified" or "produced from genetically modified [name of ingredient]" must follow in brackets immediately after the ingredient

concerned. A compound ingredient with a GM component should be labeled "contains [name of ingredient] produced from genetically modified [name of organism]".
Example: a biscuit containing soy flour derived from GM-soy must be labeled "contains soy flour from genetically modified soy".
– Where the ingredient is designated by the name of a category (e.g. vegetable oil), the words "contains genetically modified [name of organism]" or "contains [name of ingredient] produced from genetically modified [name of organism]" must be used.
Example: for vegetable oils containing rapeseed oil produced from genetically modified rapeseed, the reference "contains rapeseed oil from genetically modified rapeseed" must appear in the list of ingredients.
The designations may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients or, where there is no list of ingredients, clearly on the labeling.
– Where there is no list of ingredients, the words "genetically modified" or "produced from genetically modified [name of ingredient]" must appear clearly in the labeling.

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.

Coalition for Supplement Sustainability Comment:
A simple symbol (USDA shield or circle) that just says "Bioengineered" which is distinguishable from other examples of disparaging symbols. Disclosures of this type are easily communicated on front-of-pack.

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: See Questions 23-25.

Coalition for Supplement Sustainability Comment:
We do not believe that electronic disclosures are an equitable means of communicating product information on bioengineering status. That being said, obvious placement of the link on package with reference to the use of bioengineering at a minimum is necessary to inform consumers. Without reference

to bioengineering in close proximity to the link, consumers would not know that they are able to find bioengineering disclosures via the link in question.

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.

Coalition for Supplement Sustainability Comment:

To minimize AMS involvement over time, include language that provides the parameters of what these technologies are required to do to uphold the method of disclosure. For example, this Law is addressing bioengineering only and new technologies will need to isolate info on bioengineering to be accessed through the link. As new technologies emerge, developers can complete a simple AMS online questionnaire which gives assurance of compliance and adds the new disclosure technology to a public database. Include language that recommends developers obtain approval from stakeholders for use on products (i.e., technological advancements also impact stakeholders such as requiring new scan devices). Allow sign up by stakeholders to receive notices of change to the database of approved technologies. This database can include a Q/A component and a means to contact the developers with further questions. Links to developer websites/information can also be permitted.

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.

Coalition for Supplement Sustainability Comment:

In these examples, informing consumers through electronic or digital disclosure seems unlikely. All food for sale in these categories has a labeling mechanism which can bear a seal or a text claim.

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.

Coalition for Supplement Sustainability Comment:

Continued uniformity in definition avoids confusion. Therefore, no additional recommendations are proposed.

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?

Coalition for Supplement Sustainability Comment:

An important outcome of this Law is the obvious disclosure to consumer on the use of bioengineering. If the package size precludes full disclosure, then, minimally, packaging space can be found to display a small symbol or small text. Typically, space has not presented an obstacle in order to display information required by Law or for other product attributes.

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.

Coalition for Supplement Sustainability Comment:
Continued uniformity in definition avoids confusion. Therefore, no additional recommendations are proposed.

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.

Coalition for Supplement Sustainability Comment:
"Call for information on the use of bioengineering".

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.

Coalition for Supplement Sustainability Comment:
Continued uniformity in definition avoids confusion. Therefore, no additional recommendations are proposed.

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.

Coalition for Supplement Sustainability Comment:

Continued uniformity in definition avoids confusion. Therefore, I make no additional recommendations.

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.

Coalition for Supplement Sustainability Comment:

"Access more information on use of bioengineering here".

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.

Coalition for Supplement Sustainability Comment:

Having the link placed in the front of the product allows easy viewing on any of the mediums discussed in this section. Text size can simply be described as smaller than the defining characteristics but large enough for consumer viewing with the naked eye.

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.

Coalition for Supplement Sustainability Comment:
A process and pathway has been recommended in question 15, which, through stakeholder approval of new technologies for use in a retail setting, will keep access relevant. For example, cell phone access through developer apps and in-store technology available to consumers (it is expected that stakeholders will require developer investment to establish the means for access as a part of the approval process).

Overall all, the use and access of links as the means to inform consumers may not be cost effective to implement. A much simpler, efficient and cost-effective means can be found in symbols/text claims embedded in packaging.

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.

Coalition for Supplement Sustainability Comment:
The common thread here is that 2 years recordkeeping is embedded in current regulations. While a reasonable timeline, 2 years does not always span the shelf life of a product, especially a highly processed one. 3 - 5 years is suggested to be a more appropriate recordkeeping timeline without having to stage timelines by shelf life.

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.

Coalition for Supplement Sustainability Comment:

Companies should be able to provide the USDA with evidence of exemption status. If they cannot, then an environment of non-compliance exists.

Initial documentation to be considered to investigate potential non-compliance can include:

- Third party quality system certificates to demonstrate FSMA compliance or those which have been GFSI benchmarked or other type third party schemes determined to avoid bioengineering.
- Information on bioengineered risk crops which demonstrates the exempt status of the ingredient.
- Country of Origin of the GMO risk crop (COO sourcing where GM moratoriums exist could exempt disclosure)

AMS may require an initial risk assessment upfront rather than a reactionary process to a potential non-conformance. Perhaps a USDA PVP-type application could be used. Or, like USDA Organic, make use of third party certifying bodies to make the initial risk assessment.

AMS may filter potential risk by exempting from compliance products which are:

- Certified Non-GMO by third parties having public, robust standards.
- Manufactured within corporate non-GMO IP systems audited by third parties or audited through an in-house mechanism which assures compliance. IP systems to include GMO testing.
- Manufactured without ingredients which are at risk for bioengineering.
- Manufactured with ingredients which are at risk for bioengineering in the US but derived from crops grown in countries having GM moratoriums.

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.

Coalition for Supplement Sustainability Comment:

The standard can include the specific actions and timelines to cure any non-compliance, as well as a procedure for appealing the findings. The stages may require an onsite audit or a hearing but only as a

last resort and not necessarily on a first-time offense. Curing a non-compliance can involve continuous improvement and not necessarily be penal or made public, unless there is cause, such as repeated offenses.

A company can provide the USDA with an action plan to remedy over a reasonable timeline. This may include notice by the company to stakeholders that improper labeling is currently in use, providing the stakeholder with a different means of disclosure until new labels can be printed. The printing of new labels alone can be expensive and a detriment to repeat offenses.

In the event of an appeal of findings by the company, AMS will need an appeals committee to consider such requests and commit to a finding within a reasonable timeframe. Only after the appeal fails could a hearing be requested.

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.

Coalition for Supplement Sustainability Comment:
If the process of remedy ends in a hearing, onsite audit or more extreme actions on the part of the USDA, then public notice of the non-compliance and its cure should be made public. There is incentive in avoiding this step which will help motivate compliance to the Law.

The USDA already has processes in place to make public issues of food safety and product recall. A similar process can be followed to notify the public. Also, the USDA can maintain and make public a database containing the action and cure.

It is possible (even likely) consumers will want a refund from the company for products purchased which are not in compliance with the Law. Companies should be required to issue refunds and credits to consumers.

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.

Coalition for Supplement Sustainability Comment:

Imported products should be required to comply with the Law. Reciprocity can be established with regional laws governing disclosure, such as with EU regulation, if synergistic.

It is possible that organisms subject to bioengineering vary regionally. Language in the Law and trade agreements needs to establish equality within the definition of bioengineering.

END