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Sent: Thursday, August 24, 2017 1:48 PM
To: AMS - GMO Labeling
Subject: Comments on proposed GMO labeling rules

Thank you for taking on this important task. As divisive as this topic has become, I can only imagine the range of responses you will get ranging from rational to histrionic, and claims ranging from clear fact to wild fiction. I have attempted to address those questions from your list as I am able. Others I have left marked as no response. I will lead with a few general remarks, followed by those answering the specific questions.

I have worked in Federal government science and engineering for 15 years, but am writing this response only in my civilian capacity, making no use of Federal resources. My comments and opinions here are my own, and I represent no other person, group or organization with this response.

First, I would say that I am disappointed that Congress found it necessary to mandate labeling of Genetically Modified ingredients. A labeling requirement is an infringement upon free commercial speech, and should only be imposed when there is pressing need to convey information regarding safety, nutrition, or health, or to prevent violation of other laws, such as fraud or truth in advertising. There has been no such demonstrated need for the topic at hand. There has been no demonstrated risk in any of those categories related to a product being genetically modified or engineered. The call for labeling has been driven largely by a series of highly effective marketing campaigns following the creation of the Organic marketing label, and consumers have been misled to associate any form of genetic engineering, modification, etc, as dangerous or unhealthy without cause. This requirement is a first amendment infringing "want" without a "need" or even a benefit, and it will simply be used as a marketing tool to demonize advances in biotechnology.

As a result of the marketing to date, a large portion of the public has been misled to equate "GMO" with a "Mr. Yuck" type label. Understandably, companies became hesitant to place that designation on their products. Bearing the "Scarlet letter" does them little benefit, while providing no real information to the consumer.

In fact, and this is an important point to keep in mind when formulating your rules, companies have admitted through their social media portals to changing their products to be "GMO free" specifically to avoid the negative stigma associated with the label.

This bears repeating: opponents to GM products successfully used false, negative, misleading marketing to induce other companies to reformulate their products to avoid the very labels for which you are considering rules. It is unfortunate that they were successful in lobbying for a legal mandate to enforce continuation of this highly successful marketing effort. Be sure it will be continued after enforcement begins next year. Companies will be stigmatized through false claims for using the labels you are proposing. In fact, opponents railed against this very labeling bill because parts might weaken the negative strength of their marketing efforts. They want a simple mark they can't paint a negative picture about, nevermind thoughts of accuracy or honesty.

With that as the current state of affairs, and being forced to mandate a label under threat of legal penalty, it is crucial that rules be created that are consistent and technically accurate. Word choice and definition must be clear. If accurate definitions make certain industries uncomfortable, that's simply unfortunate but necessary. Arbitrary exceptions cannot be made, such as Vermont granted to some of its chief exports. If an exception is granted or denied for some line of reasoning, that same line of reasoning must be applied to all products.

I would be happy to provide follow-up comment on anything stated herein.

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

I was quite pleased that the bill at least used the more technically meaningful term "bioengineered" rather than the ambiguous and technically incorrect term "genetically modified". GMO is a marketing term. Despite initially intended to refer only to transgenesis, the technical meaning involves any process where deliberate trait selection occurred through a genetic breeding or alteration process. In it's broadest sense this covers everything from selective breeding to single gene manipulation. A slightly narrower sense may limit it to where deliberate, but not necessarily controlled, gene changes were made. Mutagenesis techniques should most definitely be included under any definition including 'modification' as equivalent. Many organic companies would be quite upset by this, as they consider mutagenic varieties to be not genetically modified despite there being zero self consistency to this determination.

Alternatively, engineering implies controlled, planned, and deliberate modification with particular intent. Hence, this would cover modern genetic modification techniques like transgenesis, CRISPR, etc. It would not apply to selective breeding. Unclear is whether it should apply to mutagenesis, since that is a planned modification even though the results are far less controlled.

So, any form of "engineering" should be an acceptable equivalent to bioengineering. "genetically engineered", "genetic engineering". While "genetically enhanced" may be appropriate for some products, it would be difficult to define a process to justify the second word. With the goal of technical accuracy, the words should probably be limited to those using engineer or engineering. Historical use of GMO or genetically modified is simply unfortunate, it is too broad of a term to be usefully applied. It should not be considered equivalent.

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

What is considered conventional breeding for plants? Has this itself been defined. Obviously it should include any type breeding that occurs without human intervention. However, even this is broad. I do not believe grafting occurs naturally. Mutagenesis is human directed, but obviously mutation occurs in nature. Maybe the difference is the sharp degree of mutations in mutagenic breeding. Similarly, transgenesis has occurred in nature (eg, the sweet potato). Gene suppression can occur in nature. These gene modifications then pass through breeding.

So, what is defined as "conventional breeding"? I would suggest anything that can be done "in the field" without chemical, electrical, or radiological aid would be considered conventional breeding. This would exclude any forms of mutagenesis and modern genetic engineering. In any case, a definition must be consistently applied.

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

See answer for #2. This is problematic, because example if most all genetic modification techniques can point to at least one example in nature. However, some "conventional" techniques like grafting cannot.

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))

This is important. "GMO opponents" would say yes. This is because to them the label is not about ingredients. It's sometimes about pesticides used, even if none gets into the food. It's about some arbitrary, ideological definition of food purity, and the invention of unsafe food definitions.

But this ruling is about ingredients and contents, is it not? Is it about process? Is it about association? A gm trait for pesticide resistance doesn't mean that pesticide was used. If it was used it doesn't mean it's in the product.

Similarly, DNA does not imprint itself on other, nongenetic parts of the food. Refined sugar is indistinguishable between sources. Refined oils are indistinguishable between sources.

If the law is about labeling "made with " or "made from" bioengineered crops, then yes, I guess they should bear that label. If it is "includes" or "contains" bioengineered material, then no it shouldn't.

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))

As a first example, it appears mutagenesis should be considered a bioengineered method to be logically consistent in definition. This could conflict with current Organic regulations that preclude such "unnatural" breeding methods. Even though mutation does occur naturally, it does not occur in nature to any degree even close to what is done in mutagenesis. This conflict needs to be addressed, and it should not simply be dismissed to avoid upsetting organic proponents. Consistency is key.

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))

No comment

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))

This will be a huge contention. GM opponents consider gm grain fed animals to be non-organic, or even gm themselves. Ridiculous monikers such as "Monsanto milk" have been hurled at Starbucks for using non-organic milk. This goes with the misinformation campaign about gm crops being unhealthy, and thus gm fed animals being unhealthy as a consequence. The notion is ridiculous but persistent in public opinion thanks to a few misleading and misinterpreted studies.

There is no reason to call livestock bioengineered unless it carries some deliberate genetic modification in its own DNA. Any other definition is illogical and inconsistent. Again, however, it must match the "includes" or "made from" distinctions.

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))

For truth in advertising, it should be any measurable amount using test methods appropriate to such measurement. If it was arbitrarily set at 95%, then the manufacturer could deliberately seek to achieve 4.99% bioengineered content and avoid the label. But 5.01% would require a label. This is not logical.

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

multiple labels would alleviate some of the concerns in previous sections. However one must then wonder about depth of the chain for such determinations of "made from". What about a cow fed bioengineered grain? What about the calf of a cow fed bioengineered grain? What about the milk of the first cow? What about a calf fed milk from a non-parent cow that was fed bioengineered grain? What if there was sugar from a bioengineered sugar beet in formula-fed to the cow, even if the sugar has no discernible genetic material, and the cow was raised on organic grain?

I see no meaningful distinction between options A and B. The option C is the really concerning one. careful definition with logical and self-consistent meaning will be very difficult to achieve and justify in this case. It will almost certainly never justify the food purist ideologues. Because "made from" could never tell you anything useful about what you are about to eat, I would suggest that unless the item being labeled contains modified DNA it should not warrant a label.

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

There are several genetic engineering traits that have been recreated using non engineering methods. One example of this is the nonbrowning Arctic Apple, whose nonbrowning trait has been reproduced with selective breeding. And while glyphosate resistance was achieved through genetic engineering, similar pesticide resistance such as those found in Clearfield crops were made through selective breeding. Does the exact trait need to be exactly mimicked? how much difference in DNA is required before they aren't considered the same trait? or how similar can the traits be before we consider them available through none engineered means? again, whatever definition is decided here needs to be consistent across all products that will be labeled.

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

Arbitrary exceptions should be exceedingly rare. Any product requiring the standard nutrition label should be required to comply with the bioengineered label ruling. If supplements are considered a food product, they should include the label. Similarly there should not be exceptions given to food products simply because the genetic engineering has been done traditionally or for a long time. This for example was the excuse given to exclude cheese from the Vermont labeling law. it was an arbitrary exception meant to be protectionist for Vermont's exports. Such exceptions should not be allowed under federal law. If a food product contains or is derived from bioengineered material, it should follow the laws that every other food needs to follow regarding bioengineer material. Tradition or impact on a company's profits should obviously be no real consideration under this ruling.

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))

The disclosure on the package should be part of the nutritional label. it is where people are used to looking for food information, and it doesn't make sense to put it anywhere else. examples from Vermont labeling seem acceptable. Although they should certainly use the correct terms discussed in the questions above.

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))

No specific comment on appearance. I don't feel an actual symbol is completely necessary. however, it is possible that eventually the industry will overcome the negative stigma put upon the designation by competitors and it could be a desirable thing for companies to put on their packaging. I would recommend open submission to the industry and public for suggestions. this will obviously create quite the burden to separate useful from non useful submissions. due to previous misinformation fed stigma, the term GMO should be avoided. That well has been unfairly poisoned and there is likely no going back.

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))

Quite simply, a QR code or shortened URL should be provided next to the symbol discussed above or close to the text. If space does not permit both, maybe a standard symbol should be created that must accompany or surround such a code or link to make meaning more obvious. At the destination of the digital link, manufacturers should use whatever text would normally be appropriate for disclosure on their package as described in the previous questions. Manufacturers should then be free to provide whatever other information disclosure they want about their product.

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))

Rules should specify goals and functions, not specific technology items. Examples can be given such as QR codes or digital links or URLs, but they should not be limited to that. if things must be

specified, it should require the rules to dictate a process that must be followed to approve other digital linking options. If some future requirements is outside the scope of the rules set, then this would need to be carefully phrased to allow flexibility in the future.

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))

Labeling for food not sold in a grocery store should be labeled in the same way labeling is required for any other nutritional information. obviously online sales can provide that information so maybe an exception should be made there. also products in a vending machine are packaged, and should be labeled just like a packaged product on a store shelf. The nutritional information on a bag of chips is not available to the buyer at a vending machine so there is no special requirement created for bio-engineering disclosure either. since laws are already in place for nutritional labeling, it makes sense to follow those same policies.

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))

there seems to be no reason for an alternative definition. This would just be needless complication to the manufacturer and more unnecessary rulemaking here.

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

either A or B could be fine. And rules should follow the existing small-package ruling as much as possible.

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

Again, since this rule making should follow as much as possible existing food packaging label requirements, there is no need to create separate definitions. This labeling should follow existing labeling rules regarding small businesses.

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))

No comment.

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))

again, this ruling should just follow similar food nutritional and ingredient labeling requirements.

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))

Same comment as above.

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))

Any text should indicate if possible that they can follow the link to find information about the product being a bioengineered food. as mentioned above this might not be necessary if a unique symbol accompanying something like a QR code is provided. Any text should be appropriate to the link provided. Language should be crafted such that the manufacturer is free to use an appropriate verb or action that matches the digital link or object.

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))

as mentioned above any text that would be required for a non digital label should be required at the destination of a digital link label. the manufacturer should be able to include any other truthful information along with that disclosure but should not be required to do so. requiring additional information would be an extra burden placed on the digital link user that would not be placed on a printed label user. any rules related to size of text and other similar information at the location of the digital link should be minimal. such things shouldn't normally be specified on web pages, but there may be other guidelines that could be specified based on accessibility requirements of federal web pages, etc., that would be appropriate. Again, follow existing rules where possible.

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))

If the rules will not to specify a specific technology, then it also will be unable to specify details about the technology. perhaps if the approach is taken that certain technologies are defined based on current availability, and rules are implemented such that new technologies require a petition process, that process could also specify new details for ensuring effectiveness unique to that new technology.

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

Record keeping keeping similar to the Organic record-keeping requirements would make sense in this case. Specifics would have to be based on what is required to verify food content or ingredients.

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))

No comment.

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

No comment.

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

No comment

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

Imports should be required to comply with the labeling requirement. Again it should follow similar requirements to nutritional labeling requirements and/or organic labeling requirements for imported foods sold in the United States.