National Bioengineered Food Disclosure Standard: Proposed Rule Questions Under Consideration
https://www.ams.usda.gov/rules-regulations/gmo-questions
Input to GMOlabeling@ams.usda.gov

Responses from:

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

Response

I prefer the term "bioengineered" to "GMO" (=genetically modified organism). While the public is accustomed to the term GMO, it is an imprecise and vague term with little scientific meaning. In fact, with the continuing emergence of a wide range of possible genetic changes through biotechnology (genome editing, targeted mutagenesis vs. gene insertion, synthetic biology, cisgenes vs. transgenes, etc.), the term "GMO" does more to confuse discussion than to inform it. Thus, I would exclude the term "GMO" from the standard.

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

Response

"Conventional breeding" is a vague term. However, there may be a somewhat common understanding of this term among informed people. There has been no significant public opposition to the many and diverse crop improvement techniques that do not involve human-directed DNA manipulation. Therefore, perhaps informed persons understand "conventional" breeding techniques to be all those that do not involve human-directed DNA manipulations. It is worth noting that, in my extensive outreach experience on genetically engineered (GE) crops, very few members of the general public are aware that "conventional" breeding techniques are almost always more disruptive to the genome, transcriptome, proteome, and metabolome of the plant than is genetic engineering (GE). This fact surprises and interests most people, which suggests to me that the perceived public distinction between "GMOs" and "conventional" crops is subject to revision in many members of the general public.

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

Response

Indels and nucleotide substitutions of many types are perfectly natural and sometimes even beneficial, as sources of genetic variation that fosters ecological adaptability or that serves to advance breeding goals. The same is true of chromosomal inversions, translocations, and copy-number variants. Genomic changes induced by human manipulation that are similar to any of these should not,* a priori*, be considered "unnatural." Most people may draw a line of discomfort with transference of genes from outside a crop's natural breeding pool (=transgenesis). There are, of course, challenges to the application of such a standard. Even breeding techniques widely considered to be "conventional," such as embryo rescue or bridging crosses, overcome breeding barriers and create "transgenes" in the absence of any human-directed DNA manipulation. Furthermore, transgenesis certainly has abundant analogies in Nature, as there are many published studies reporting natural horizontal gene transfer over geological time scales among organisms that are remarkably divergent evolutionarily. Even inverted repeats that trigger RNAi can be found in Nature. From an operational standpoint, one way to simplify such considerations for purposes of labeling is to consider any genetic transfer beyond the taxon of botanical family to be "unnatural." As noted above, horizontal gene transfer can take place across even greater evolutionary barriers than the botanical family, but such horizontal gene transfer events generally occur infrequently in Nature.

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))

Response

I personally have no need for such a label, as I perceive no scientific justification for labeling ingredients or foods derived from bioengineering if they are, for practical purposes, indistinguishable from their non-bioengineered counterparts. The justification for such labeling would be based on strictly on social—rather than scientific—considerations: to provide anxious consumers the option of avoiding products derived from bioengineered crops. Whether to require such labeling to address such social considerations depends on the wording and intent of the National Bioengineered Food Disclosure Standard.

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 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))

Response

I am not sufficiently familiar with the potential conflicts to formulate a thoughtful response.

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 FFDCA. How will AMS determine the predominance of ingredients? (Sec. 292(c))

Response

Evaluating predominance on a per-weight basis seems the most defensible to me.

7. How should AMS craft language in the regulations acknowledging that animals consuming bioengineered feed are exempt from the disclosure requirements as bioengineered solely because they fed on bioengineered feed? (Sec. 293(b)(2)(A))

Response

Since my expertise is in plant science, I abstain from responding to this question.

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.

Response

No matter what threshold is applied, I believe all required labels of bioengineered foods should clearly reflect the findings of the world's most prestigious scientific societies, which have concluded that bioengineered foods are as safe as non-bioengineered foods. (See, for example, Genetically Engineered Crops: Experiences and Prospects, Committee on Genetically Engineered Crops: Past Experience and Future Prospects (2016, http://www.nap.edu/catalog/23395/genetically-engineered-crops-experiences-and-prospects) and EASAC Policy Report No. 21, The Science Advisory Council of the National Science Academies of the EU Member States (2013). ISBN: 978-3-8047-3181-3 (http://www.easac.eu/home/reports-and-statements/detail-view/article/planting-the.html). **This is an essential point because GE foods are commonly and unjustifiably stigmatized. I believe such stigma does a disservice to present and future citizens by eroding consumer confidence in genetic innovations that may help meet important goals for our food system in ways that address the shared values of most Americans.**

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.

Response

These categories listed above seem reasonable to me.

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 these: whether a food contains a substance that has been modified using recombinant in vitro DNA techniques (Sec. 291(1)(A)), and for which 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.

Response

My impression is that the factors described above, in the "Context" section of this question, seem reasonable. I am supportive of labeling bioengineered food, not for scientific reasons, but to provide the public with transparency and consumer choice. I believe the factors listed above in the "Context" section seem reasonable on this basis. However, I do wish to stress again the importance of clearly and repeatedly communicating to the public that there is no intrinsic food-safety risk from human-directed DNA manipulation.

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

Response

Based on the well-established equivalence and safety of GE crops, there is no scientific basis, and therefore no reason, to label medical foods and dietary supplements differently from other foods. Therefore, any standards developed for general foods and food ingredients should serve these needs also.

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.

Response

I appreciate how the Law provides several options for fulfilling the labeling requirement, including pointing consumers to websites with the requisite information. I believe a similar level of flexibility in the specific language seems reasonable.

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))

Response

I have no specific suggestions, though I agree strongly with the AMS statement that "…the symbol designed for the bioengineered disclosure is not disparaging toward bioengineering."

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))

Response

I have no specific recommendation on this question, though whatever is employed, it should be generally accessible to people of all income levels. Perhaps this may require portable digital link

readers that retailers can make available to customers. However achieved, attention should be given to accessibility across income levels.

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))

Response
I don't see an advantage of specifying the particular technology to be used. Rather, it seems to me that the federal government should specify the standards and allow food manufacturers and retailers to meet the federal standards in ways that are suitable to their business.

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))

Response
I have no specific recommendations but it seems a topic that merits attention.

17. The Law offers special provisions for disclosure on small or very 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.

Response
I have no specific recommendations.

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?

Response

I am in favor of providing a reasonable range of options for food providers and manufacturers. The options listed above (18a and 18b in the "Context" section) are satisfactory, in my opinion. In fact, the option suggested in 18b—pointing consumers to text disclosure or a web site—seems suitable to me for all packaging sizes.

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

Response

I have no specific recommendations.

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))

Response

I have no specific recommendations.

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))

Response

I have no specific recommendations.

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))

Response

I have no specific 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))

Response

I have no specific recommendations.

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))

Response
I have no specific recommendations.

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))

Response
I have no specific recommendations.

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

Response
I have no specific recommendations.

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))

Response
I have no specific recommendations.

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

Response
I have no specific recommendations.

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

Response
I have no specific recommendations.

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

Response

There is no reason to exempt imported foods from these requirements. We certainly should not disadvantage our own food producers by requiring disclosure of them but not of importing competitors.