Input to the National Bioengineered Food Disclosure Standard

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

I am not personally in favor of singling out particular crop improvement techniques for labeling, as all plant breeding methods result in changes in the DNA of the organism. Whether it is done in vitro or by sexual crosses is immaterial to the qualities of the resulting product. I would not be opposed to other terms that might be used, bioengineering is as good as any. More latitude in the descriptions allowed by food companies to describe their products specifically, the better. The fallacy of the entire law is that there is some specific process that consumers need to be informed about across all applications. The more that those who have to comply with this law can say to explain what they have done to improve the crop, the better.

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

Conventional breeding should include all types of sexual crosses, including wide crosses enabled by embryo rescue and similar methods, bridge species, etc. All types of mutagenesis, including targeted mutagenesis with gene editing, should be considered to be with in conventional breeding. Protoplast fusion is now an old technology with many legacy varieties in the market in which it was utilized, so it should be considered conventional. It would, of course, be least confusing if the AMS and the BRS were consistent in their definitions, as the BRS is currently considering changes to its definition along the lines I have described.

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

I would argue for the broadest interpretation of this. All genes currently in any organism are obviously found in nature. This would seem to enable use of any existing genes found in nature. I doubt that this was the intent of the authors, but this should at least include all gene sequences found within the sexually compatible species that can be accessed through conventional breeding. If gene editing were used to match sequences found in such a related species

in a crop variety, a strict reading of the law would suggest that it would not be considered to be under the scope of the law, since the resulting gene is found in nature and could have been introduced using conventional 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))

Again, this reflects the non-scientific basis of the law. At the level of the individual molecules, starch or oil from an engineered variety is the same as from a non-engineered one, unless the target of the modification was to change the structure of that compound. In pure starch or sugar or oil, there is essentially no DNA or genetic material, so it would not be captured by the law as it no longer contains any modified genetic material.

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 mentioned above, if there is not consistency among the different governmental agencies that regulate bioengineering, there will be confusion if not chaos in the market place. In addition to the need to be consistent with the Biotechnology Regulatory Service definitions, the FDA and EPA will need to have the same definitions. The National Organic Program may well have its own definitions that do not agree with BRS. I expect that there will be rampant confusion, which was just as much the goal of the promoters of this labeling law as was actually informing consumers. If there is chaos in the marketplace, it is a strong deterrent to further expansion of biotechnology in agriculture, which was the primary goal of supporters of this law. I cannot think of remedies if the definitions of the different agencies differ widely. The best way to avoid such problems would be for all agencies to adopt the most limited definitions possible, giving the broadest interpretation to what may considered to be “conventional breeding”. Any specific restrictions imposed now will soon be out of date and called into question as further scientific developments progress.

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))

Good luck, AMS in trying to evaluate predominance to determine how the Law will apply to multi-ingredient food products. Since the meat or poultry product itself is not considered to be subject to labeling if the animal only ate such food (Sec. 293b2A), this would seem to apply to other ingredients. In that case, I guess it would just be the order of ingredients on the label and its source. Do we then have to ask what fraction of that ingredient (e.g., corn starch) may have come from engineered varieties and what fraction may have been conventional?

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

Yes, please do not require disclosure as a bioengineered food solely because their nutrition came from food with bioengineered ingredients. Help yourself by exemption as much as possible within the scope of the law. It is an endless hall of mirrors to try to trace everything that everything ate on its way to being food. Particularly as there is no valid evidence of any safety risk from either the engineering process or any of its commercial products to date.

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))

I am sure you are aware that no matter what you do here, you will be imposing a massive bookkeeping burden on the agricultural and food industry. In addition to keeping biotech and non-biotech products separate, a food manufacturer would further have to know what fractions of each might be present in all of the ingredients used. A large fraction of the vitamins added to foods are produced using biotechnology. Will they be considered to require labeling? If by weight, they will be a trivial amount in any food, so would not be required to be labelled. But they would prevent a food from being labeled “GMO-free”, even if it was not considered to be subject to this law. Make the threshold as high as you possibly can. The EU uses 0.9%, just so it can say it is less than 1%, but there is no scientific or other justification for selecting a threshold. Better to follow Japan, which for approved products has a threshold

of 5%. If you adopt the latter, you largely avoid all kinds of problems related to “adventitious presence” or very low, but possibly detectable, levels of presence. You can at least then be fairly confident that a significant component of the food was in fact engineered if it is considered to be subject to the law.

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

Does this mean that after you have decided that a food is subject to labeling, there would be different categories of that, or that some of these categories are subject to the law and others are not? I assume the former. Even then, this shows the absurdity of this law. I do not envy the AMS for having to try to make sense out of it, as this question and its context illustrate. If this were the Middle Ages, the question would be “How many angels can dance on the head of a pin?” For you, “How many categories of harmless foods can we devise in response to an inanely crafted law?” My condolences. All I can suggest on this is to make the whole thing as limited to the most clear-cut cases and as simple as possible.

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

Context:

See response to question 9.

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

Yes, please do exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered.

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))

If a food is required to disclose, the categories of “Produced with Bioengineering,” “Partially Produced with Bioengineering,” or “May be Produced with Bioengineering” seem to cover the space. Again, the more flexibility food producers are given, the less you will need to be splitting hairs over and over and over.

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:

I think that the use of a symbol or logo would itself be sufficient in many cases. There is not room on a label to give all of the potential information anyway, so why not just have the label and a link to a website with more information? The GMO Project's GMO-free logo doesn't have to provide anything else with it, and it seems to be widely recognized for the prejudice-invoking tactic that it is. Similarly, I think that a clearly identifiable logo is critical for AMS to develop. As you say, it should not be disparaging and should be neutral about implications. I suggest doing a lot of brainstorming followed by focus groups to find a symbol that is recognizable but not inherently negative. I do not know what that is, but maybe just a symbolic double helix is enough, given that the law is all about what DNA is in the food (Sec. 291(1)A).

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))

Again, keep it simple. Let the manufacturer give as much or as little information as they want, so long as they meet the requirement of the law to disclose that some in vitro recombinant DNA techniques were used. It is not your job to anticipate how companies might choose to inform their customers. Stick to the minimum that you have to do to meet the requirements of the law. Remember, the term GMO gives no information about what the modification was done for, whether it was for herbicide tolerance or for vitamin A that could save a child's life. Similarly, basing this law on a method rather than a product is inherently misleading, so just meet the requirement with a logo on the label and let the food companies decide from there. If consumers demand more information, they will give it.

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))

I find it interesting that AMS recognizes that disclosure technologies may quickly surpass regulations, yet will have to deal with equally rapidly changing scientific advances in bioengineering. Again, just keep it simple and have a

link go to the company. As foods change, the links will change to keep up. Remember, companies are also advertising on the web, so they know how to find them. It is not the AMS's job to make implementation of this law more complex or comprehensive than it needs to be. Also, we are dealing with food. In general the shelf life of an individual food package is much shorter than that of a given electronic technology. This problem will take care of itself.

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))

See previous comments

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:

Focus on the logo as a symbol meeting the intent of the law. Virtually all packages are large enough to have a logo on them. Maintain a common site where a consumer could put in their product name and it would give them the company information site. It would be a simple registry that food companies would need to send their information link to, and that would be it.

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:

See comment on question 17.

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

Further evidence that this law is not about food safety or consumer choice, but rather about marketing. Why else have a special exemption for small manufacturers? Anyway, number of employees or total sales is generally the way this is done.

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))

I think people generally recognize a phone number and would know what to do with it even without the “Call for more food information” part if it was associated with a logo.

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, be as broad and liberal in providing exemptions as you can. As these questions illustrate, this is going to be a regulatory nightmare already, so exclude as much as you can from being subject to the disclosure requirement. People particularly concerned with biotech in their sandwich will go to an organic deli.

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))

See response to question 21.

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))

Put the least that you can on the package or label itself, and invent your effort into advertising and general knowledge that when you see the logo indicating bioengineered, call (if there is a phone number) or scan (if there is a symbol) or go to the link. People are quite programmed for what these things mean, so it is not necessary to have an instruction book on every single package.

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))

See above.

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

Don’t even go there. You cannot assure that everyone will be able to access the information any more than you can be sure that some customers are not illiterate. It is not your job to assure that it is effortless to get this information. You have to require that the package is labeled (use a logo) and that the information can be accessed reasonably easily. We have Proposition 65 warning labels everywhere in California, and you have to go to a website to get the actual information. The state does not try to assure that you have a device, can operate it, can read what it shows you, etc. Stay out of this completely.

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

My only comment is that this should be just the fact that the label is marked and that there is a site to go for more information. It is up to the company what they want to put on that site. The record should just be that in fact they have established and have a live site or phone number or something where the information can be accessed.

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))

I suggest letting it be driven by consumer input. Have a site where people can complain if they can’t find information on a labeled product. This would trigger AMS to check whether the product/company is registered and have the required information available. There are plenty of watchdog groups that will initially be sure to try all of the links out. Do not consider it your duty to do random checks on products, etc. As a taxpayer, I consider that to be a complete and total waste of money. Let it be demand driven.

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

No idea.

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

Have a website where such actions are posted and let it go at that.

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

Should they not be the same as for domestic products? When we try to sell biotech products in other countries, we have to meet their import, regulatory and labeling conditions. Why would it be different for imports here?