

Input to the National Bioengineered Food Disclosure Standard

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

The term “bioengineering” is sometimes used as a synonym for “genetic engineering”. Unfortunately neither of these terms are precise and so are subject to interpretation, much like the term “natural”. According to the Oxford dictionary, genetic engineering (GE) can be defined as “the deliberate modification of the characteristics of an organism by manipulating its genetic material” (https://en.oxforddictionaries.com/definition/genetic_engineering), but this definition could cover many breeding methods used in conventional breeding such as polyploidy. The USDA definition of GE is “Manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques...”, which is a little more precise although “the methods of modern biology” is also somewhat open ended. Does it, for example, include products producing using TILLING in which restriction endonucleases (i.e. a method of modern biotechnology) are used to introduce mutations? These definitions differ from those used by the FDA in its recent draft guidance for industry 187 “Intentionally Altered Genomic DNA in Animals” which suggested new animal drug regulatory oversight over all animals with “intentionally altered genomic DNA”, irrespective of the novelty of the alteration, the presence or absence of rDNA, or the phenotype of the animal. It is unclear if the intent of the “National Bioengineered Food Disclosure Standard” is to target products carrying transgenic DNA from non-sexually compatible species, the presence of any rDNA in the product, or the use of the methods of modern biology in the development of the variety or line irrespective of the attributes or presence of rDNA or protein in the food product.

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 in vitro methods such as artificial insemination, cloning, ovum pick up and similar methods. All types of mutagenesis, including targeted mutagenesis with gene editing, should be considered conventional breeding as this variation is the basis of all traditional breeding programs. It would, of course, be less confusing if the FDA and USDA were consistent in their interpretation of whether targeted mutagenesis with gene editing is subject to regulatory oversight.

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 the use of any existing genes as being “modifications found in nature”. I doubt that this was the intent of the authors, but “found in nature” should at least include all gene sequences found within 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 its scope, 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))

There are two schools of thought on this. One group of countries (e.g. Australia and New Zealand) does not require labeling if there is no rDNA or recombinant protein present in the product, whereas the European Union requires mandatory food labelling if GM has been present anywhere in the production process, meaning that it requires labeling irrespective of whether GM material is present in the final food. There are considerable costs associated with supply chain segregation of identical products (e.g. sugar and oil) based on the breeding method used to produce the plant from which these highly refined products were derived. Additionally, given they are compositionally equivalent, there is no way to test for cheaters, as product identity is based entirely upon supply chain traceability.

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))

There is currently no consistency among the different governmental agencies that regulate bioengineering either nationally or internationally. Ideally there would be a universal, agreed-upon definition but coming to consensus on this may well be akin to agreeing on the definition of “natural” – different stakeholders will have different opinions. I fear there is no easy remedy to this problem as it was imported with the ill-defined term “Bioengineered Food” in the title of the bill. Part of the problem is defining a process that has to be labeled when the process results in many different types of products and people having different opinions as to the need for labeling of these different products. It is easier to come to consensus when there is a clear health concern, such as a product labeled “contains peanuts” to raise awareness for those with allergies, rather than the use of a particular breeding method to affect a genetic alteration in the development of specific plant and animal varieties and lines.

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))

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 the product. Current food labeling regulations require ingredients to be listed in order of predominance, so I guess it would involve determining if ingredient number 1 (or number 2 if number 1 was broth, stock, water, or similar solution) was from a bioengineered variety.

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))

I would use the language “Milk, meat and eggs from animals fed bioengineered feed are not subject to labeling under the National Bioengineered Food Disclosure Standard as they are indistinguishable from those from animals fed conventional feed.” My recent review paper summarizes the relevant literature on this: **Van Eenennaam, A.L. and A.E. Young. 2017. Detection of dietary DNA and protein in meat, milk and eggs. Journal of Animal Science. 95(7):3247-3269.**

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 would argue that if there is no way to test for bioengineered substance present in a food then it should not be subject to the labeling law. There is no way to enforce this law if there is no way to validate/enforce compliance. There are dramatically different cost implications of stringent purity standards. The following excerpt on the costs of alternative purity standards and tolerances is taken from **Van Eenennaam, A.L., B.M. Chassy, N. Kalaitzandonakes, and T.P. Redick. 2014. The Potential Impacts of Mandatory Labeling for Genetically Engineered Food in the United States. Issue Paper 54. Council for Agricultural Science and Technology (CAST). Ames, Iowa.**

“The incremental costs associated with the production and distribution of non-GE foods are not fixed and are heavily dependent on the GE purity standards and tolerances used (Giannakas et al. 2011). Purity thresholds and tolerances are used to recognize that perfect avoidance (or zero tolerance) of GE material is difficult to achieve in practice. Agricultural land, transport, storage, and processing facilities are broadly shared in the food sector, and perfect segregation of any agricultural product is typically not possible. Tolerances set for the presence of GE material are determined with best industry practices in mind and permit small unintended GE amounts that can be present in non-GE or organic foods.

When GE tolerances are set to be very low, segregation methods must become more stringent. The incremental production, segregation, and certification costs of non-GE products increase disproportionately, however, when they are lowered, as the relative effectiveness of more stringent segregation methods diminishes with lower tolerances (Huygen, Veeman, and Lerohl 2004; Kalaitzandonakes, Maltsbarger, and Barnes 2001). Increasingly higher production and segregation costs are therefore applied to a progressively lower volume of non-GE products that can meet the stricter tolerances and purity standards. Production and segregation costs for non-GE corn, for instance, are estimated to increase by as much as 20% by lowering the tolerance for any unintended GE content from a maximum of 1% to 0.5% (Kalaitzandonakes, N. 2013. Personal communication based on a database at EMAC, University of Columbia, MO), and much more than that for tolerances below 0.5%.

A zero or near zero tolerance for GE content would be commercially challenging, if not impossible, to achieve at a large scale and would greatly complicate the procurement of food ingredients. The legal doctrine of commercial impossibility could be used to render contracts unenforceable, and such legal challenges could further increase the costs of non-GE products. These issues are recognized where mandatory GE labeling has been implemented in practice. While a number of countries have laws requiring GE food labeling, none has tried to enforce a

zero tolerance (the strictest is the EU at a maximum of 0.9%, whereas many Asian nations use 5%).

Zero tolerances would also increase uncertainty in the food supply chain. When food manufacturers and retailers choose to use non-GE ingredients in order to avoid GE labeling, they depend on testing and certification to guarantee the authenticity of such ingredients. Sampling, testing, and certification depend on statistical processes, however, and hence all are subject to some error, which increases at very low tolerances (Lamb and Booker, 2011)."

As the National Bioengineered Food Disclosure Standard is not related to food safety, the least costly approach would be to use the highest threshold possible. Perhaps it could be based on the Organic labeling standard "100 percent organic" which can only be used to label any product that contains 100 percent organic ingredients (excluding salt and water, which are considered natural). There is an additional problem of whether the "amount" is by weight, volume, % DNA, % protein or some other metric. It has been calculated that the intact DNA in crops is <0.02% on DM basis and only a small amount of that total DNA is rDNA. Beaver & Kemp (2000) calculated that for cows consuming a diet comprised of 40% silage & 20% grain from GE crop varieties, ~0.00042% of animal's total daily DNA intake would be rDNA (Beaver, D.E., Kemp, C.F. **Safety issues associated with the DNA in animal feed derived from genetically modified crops. A review of scientific and regulatory procedures. Nutrition Abstracts and Reviews. Series B: Livest. Feeds Feeding. 2000;70:175–182.**)

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

No that will only cost more and complicate things.

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

Indistinguishable products should not be subject to differential labeling requirements.

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

If there is no way to distinguish whether a product is a bioengineered food it should not be subject to mandatory differential labeling requirements.

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 due to some arbitrary detectable level of rDNA, 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))The label used in Brazil is a



small yellow triangle with a T in it representing transgenic – but this would not be appropriate for products that did not contain transgenic DNA. Again the symbol should represent what is distinguishable about the product – presumably some trace rDNA – but most food contains DNA so perhaps an r for recombinant in a triangle – assuming those foods carrying no rDNA are exempt from labeling – or “B” for bioengineered.



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))

If there is no way to distinguish whether a product is a bioengineered food it should not be subject to differential labeling requirements. If it has to be labeled then it should disclose that distinguishable difference and that is what the label should represent.

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))

AMS recognizes that disclosure technologies may quickly surpass regulations, yet this labeling law will have to deal with equally rapidly changing scientific advances in bioengineering which is going to make it increasingly difficult to determine what is bioengineered. Is a single intentional base pair change covered by this labeling law? It would seem advisable to not be too prescriptive, just keep it simple and have a link go to the company. As foods change, the links will change to keep up

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))

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))

See comment on question 17.

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

This is further evidence that this law is not about food safety or consumer choice, but rather about marketing. Why else would you need to have a special exemption for small manufacturers?

a. FSIS considers small businesses to be those with 500 or fewer employees that produces 100,000 pounds or less of annual production of a single product 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).

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. I would think a website would be an easier approach.

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))

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 logo on the package or label itself, and invest 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. The food

industry's "Smart Label" program has already disposed of most of these issues in a way that is fully consistent with the letter and intent of the law.

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?

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))

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. 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.

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))

Again non-compliance can only be verified if there is a way to distinguish whether a product is a bioengineered food – hence that should be the trigger for mandatory labeling – similar to the laws in Australia and NZ which do not require labeling if there is no rDNA or recombinant protein present in the product.

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

No party should be sanctioned without due process, which includes the right to confront an accuser, the right to counsel, the right to present a defense, and the right to appeal. Although I might question whether this is the best use of taxpayer money?

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)) They should be the same as for domestic products. WTO SPS rules prohibit the US from treating imports differently than domestic production.