

August 15, 2017

U.S. Department of Agriculture

Agricultural Marketing Service

1400 Independence Ave., S.W.

Washington, DC 20250

Via GMOLabeling@ams.usda.gov

RE: Comments to USDA in re: the National Bioengineered Food Disclosure Standard

The Information Technology and Innovation Foundation (ITIF) is a nonpartisan think tank whose mission is to formulate and promote public policies to advance technological innovation and productivity internationally, in Washington, and in the states, and around the world. Recognizing the vital role of technology in ensuring prosperity, ITIF focuses on innovation, productivity, and digital economy issues, with policies impacting biotechnology and biological sciences as a core concern.

The Agricultural Marketing Service (AMS) has solicited public comments as to how AMS should implement the National Bioengineered Food Disclosure Act.¹ The Information Technology and Information Foundation (ITIF) provides comments below to the questions posed by AMS.

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.

ITIF COMMENT: The purpose of the National Bioengineered Food Disclosure Act (Roberts-Stabenow) is public disclosure to satisfy the interests of certain consumers. The intent is to inform consumers when foods they purchase have been derived from plants or animals that have been improved by a specified set of advanced breeding techniques grouped under the term “bioengineered.” This shares at least some overlap with

¹ U.S. Department of Agriculture, “USDA Seeks Input in Developing a Proposed Bioengineered Food Disclosure Rule,” news release, June 28, 2017, <https://www.ams.usda.gov/content/usda-seeks-input-developing-proposed-bioengineered-food-disclosure-rule>; USDA, “Proposed Rule Questions Under Consideration,” accessed August 14, 2017, <https://www.ams.usda.gov/rules-regulations/gmo-questions>.

the terms “genetically engineered (GE)” or “genetically modified (GM)” which the legislative record clearly treated as a larger and nonequivalent category, and which AMS therefore cannot construe as synonymous. It is robustly demonstrated through experience corroborating the scientific literature, and widely acknowledged that all these terms are imprecise, and that none of them signal any potential hazards, nor any risk that may result from exposure, and have no bearing on the safety, quality, or nutritional value of such foods.²

There are additional processes that can be used to similar ends, including a number discovered and developed within recent years, which again the legislative history shows were deliberately not covered by the law. Terms like gene edited, and similar, were not intended to fall within the scope of mandated disclosure.

The lack of any legitimate science, data, or experience in support of the arbitrary category this law singles out for consumer notification ensnares USDA in an inescapable conflict with its overall mandate to serve, enable and support agriculture for the benefit of society. The only logical way to minimize the negative consequence of this Congressional diktat is to restrict the applicable scope of the notification/labeling requirement under this law as narrowly as possible.

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.

ITIF COMMENT: The notion underlying this question, that there is a definable category of “genetically modified” or “bioengineered” innovations that could not be found in nature or produced through “conventional” breeding is not supported by data or experience.³ What was cutting edge 30y ago (e.g., *Agrobacterium* mediated transformation) is today conventional, and the term “conventional” is unavoidably ill defined and constantly evolving. Any approach adopted by AMS is certain to be rendered obsolete in short order by the rapid pace of technological progress and understanding.

This question seeks guidance on how to accomplish something that cannot be done on the basis of science, data, or any appeal to what we find in the natural world, and whatever political compromise USDA comes up

² Giovanni Tagliabue, “The Meaningless Pseudo-Category of ‘GMOs’,” EMBO Reports, November 12, 2015, <http://dx.doi.org/10.15252/embr.201541385>; G. Tagliabue, “European Incoherence on GMO Cultivation Versus Importation,” Nature Biotechnology 34, 694–695 (2016), <http://dx.doi.org/10.1038/nbt.3588>.

³ Giovanni Tagliabue, “The Nonsensical GMO Pseudo-category and a Precautionary Rabbit Hole,” Nature Biotechnology 33, 907–908, (2015), <http://dx.doi.org/10.1038/nbt.3333>.

with will be vulnerable to legal challenge. The question posed here is the equivalent of demanding that we stipulate that the value of “Pi” is 3.0, for the sake of “convenience”, rather than 3.14 as the physical laws of the universe dictate.

Virtually every combination of genetic material one can imagine replicates or echoes genotypes that can be found in nature as a consequence of wholly natural processes. Advances in genomics and the ongoing explosion in gene sequencing and genomic analysis have shown that the notion of mechanisms of gene exchange used by scientists in the laboratory but which are not found in nature is a null set. There are new discoveries of previously unknown mechanisms of gene exchange in evolution almost every week, and everything genetic engineers do in the laboratory is done with enzymes and compounds discovered and found widely in nature. These are used by scientists to reproduce or emulate mechanisms of gene exchange which have been discovered to be ubiquitous in the real world. The conceit that “genetic engineering” or “bioengineering” somehow leads to different results that could not be found in the real world is abundantly contradicted by the data.⁴

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.

ITIF COMMENT: Forty years ago it might have been reasonable to posit the notions underlying this question as posed. What we have since learned through advances in gene and genome sequencing and genomic analysis makes this impossible today.

As explained above, there is virtually nothing that meets or could meet the criteria stipulated in this question. Everything genetic engineers do in the laboratory is done with enzymes and compounds discovered in nature. They use them to perform the functions they perform in nature, to deliver results analogous if not identical to

⁴ See, for example: Fay-Wei Li, et al., “Horizontal Transfer of an Adaptive Chimeric Photoreceptor From Bryophytes to Ferns,” *Proceedings of the National Academy of Sciences* vol. 111 (18), 6672–6677, <http://dx.doi.org/10.1073/pnas.1319929111>; L. Gasmi, et al., “Recurrent Domestication by Lepidoptera of Genes from Their Parasites Mediated by Bracoviruses,” *PLOS Genetics*, September 17, 2015, <https://doi.org/10.1371/journal.pgen.1005470>; Science Newline Biology, “Koala Study Reveals Clues About Origins of the Human Genome,” November 6, 2014, <http://www.sciencenewline.com/news/2014110622000026.html>; Ed Yong, “How An Antibiotic Gene Jumped All Over The Tree of Life,” *Not Exactly Rocket Science*, October 24, 2014, <http://phenomena.nationalgeographic.com/2014/10/24/how-an-antibiotic-gene-jumped-all-over-the-tree-of-life/>.

what we find everywhere we have looked in nature. It is not possible to draw a distinction between “natural” and “not found in nature” in the way this question asks us to presume.

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.

ITIF COMMENT: What is a “highly refined product?” Some refined products (e.g., sugar, purified oils) do not contain residual DNA sequences. There are no analytical methods that would allow such products to be identified as coming from “GM” plants or animals vs. others. For AMS were to apply a notification requirement to such products would be a grave mistake. It would be impossible to enforce without costly and intrusive supply chain record keeping and auditing. This would impose significant costs while delivering little or no benefit; they would certainly consume resources that could actually be otherwise used to improve food safety if allocated to other efforts. Such a disclosure requirement would also provide perverse incentives that would be an enticement to misrepresentation or fraud at multiple stages in the food value chain as unscrupulous parties (especially importers) would scramble to avoid a classification with a long history of abuse by parties seeking to mislead consumers. The experience with honey imports from China is illuminating and should be consulted.⁵

Other refined products may contain residual DNA fragments of sufficient length to allow them to be identified as coming from plants or animals improved through biotechnology. A disclosure requirement for such material could be defended on the basis of transparency, though the issue of threshold levels could be important (see below).

It is important to recall here that this notification requirement is part and parcel to a marketing exercise. It has nothing to do with nutrition, quality, or food safety, else it would be tasked to FDA or USDA’s Food Safety and Inspection Service, rather than the Agricultural Marketing Service. If not implemented with great care, it runs the grave risk of further confusing consumers into believing that “GM” is an ingredient, which it

⁵ This also is relevant: A. L. Van Eenennaam and A. E. Young, “Detection of Dietary DNA, Protein, and Glyphosate in Meat, Milk, and Eggs,” *Journal of Animal Science* 95(7)3247-3269, June 1, 2017, <https://www.animalsciencepublications.org/publications/jas/articles/95/7/3247>.

is not, rather than a breeding method for genetic improvement squarely in the mainstream of more than ten thousand years of human history. If AMS is not careful in implementing this notification requirement it will only exacerbate the confusion and misunderstanding the authors of the law intended to ameliorate.

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.

ITIF COMMENT: The terms “bioengineered” and “bioengineering” have decades of established history of use by FDA. The law may stipulate that, as used by AMS in the present context the term “bioengineering shall not affect any other definition, program, rule, or regulation of the Federal government” but the intractable reality is that if AMS uses the term in any way inconsistent with or different from the long-established FDA usage it will inevitably create exactly the sort of confusion the law specifically enjoins.

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.

ITIF COMMENT: The trigger stipulated here is whether or not the predominant ingredient is “bioengineered.” The present exercise is (unscientifically) driven by factually unsupported concerns over the presence or absence of specific DNA sequences introduced by methods alleged to be somehow, but in fact not at all, suspect or undesirable in the eyes of some. Any way AMS chooses to proceed here is predicated on a foundation of indefensible misunderstanding. So the challenge would be to try and find a way of rank-ordering the quantitative presence of ingredients that would have the result of minimizing the need to

“disclose.” Applying the measure of relative (wet or dry) weight of introduced exogenous DNA in the source/parental material (food/feed crops) vs. weight of other ingredients would accomplish this.

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.

ITIF COMMENT: A cow fed chocolate does not produce chocolate milk. The notion that an animal fed “bioengineered” feed becomes bioengineered is no more supported by science. This idea must be recognized for what it is—a tool used by opponents of modern breeding techniques to stigmatize them in hopes of fomenting a level of consumer concern sufficient to drive such products from the market. This is contrary to the intent of the law and the law should not be implemented in such a way as could be bent to serve such an objective.

If organisms could readily take up DNA from their food and incorporate it into their own genomes, then given the enormous selective advantages that would result animals would be green and photosynthetic. This is not the case; despite popular myth, organisms do not become what they eat. There is no basis for requiring notification under the law for products derived from animals that have eaten bioengineered ingredients.

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.

ITIF COMMENT: AMS here requests guidance for setting a threshold that is unavoidably arbitrary and capricious, and any standard they establish is certain to be disputed and vulnerable to legal challenge. It is not clear that there is a way to mitigate this vulnerability, though one approach might be to emulate other arbitrary and capricious standards set in the interests of practical implementability by some other governments. Japan and Australia have chosen a 5 percent threshold as a labeling threshold and had some (if incomplete) success in reducing consequent confusion and trade disruption.

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.

ITIF COMMENT: The answer to this question would perhaps be clearer if it were framed somewhat differently: “Congress has tasked us, for purely political reasons, lacking any basis in science, data, or experience, with drawing unsupportable distinctions between substantially equivalent foods and informing the consumer about this without misleading or alarming them unduly. Should we do this by establishing a single category for notification, or multiply the burden and potential for confusion by a factor of 2 or 3 by adopting additional, unsupportable criteria for notification?” More bluntly, “We have been mandated to deliver a train wreck. Should we create one, or two, or three?”

If AMS could conjure a scenario under which multiple categories of notification would reduce the potential for consumer confusion and decrease the burden of compliance on the food value chain then it might be worth considering. If not, not.

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.

ITIF COMMENT: See comment posted above for Question 9 inter alia.

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.

ITIF COMMENT: Anything AMS could do to exempt items or products from the requirements of this act will reduce the potential for consumers to be confused and misled. Any and all possible exclusions, therefore, would be highly desirable. But the question of whether or not a food is considered bioengineered is outside the competence of AMS, and properly resident at FDA.

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.

ITIF COMMENT: Language along the lines of “Produced with bioengineering” or “Partially produced through bioengineering” or “May be produced through bioengineering” should be sufficient to satisfy the mandate. But AMS should take care, here, not to inhibit unnecessarily the freedom companies or responsible individuals have to fulfill their obligations under the law. Performance criteria are far superior in this regard to design specifications.

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.

ITIF COMMENT: The overriding challenge here is to identify a symbol that would inform consumers without lending itself to confusion and abusive misinformation, which is intentionally and impermissibly widespread in this space. Perhaps a stylized double helix with a green seedling emergent would serve, but whatever symbol is developed would likely require extensive design consultation and multiple focus groups.

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.

ITIF COMMENT: This is an issue perhaps best addressed through performance criteria rather than a prescribed standard. Companies should have wide latitude to address their responsibilities under the law, as AMS will define those, but as they see fit. They should have the freedom to adapt the information they provide and the precise way they provide it in response to inputs from their consumers as well as evolution in communications technology, as long as the results are accurate, informative, and not misleading.

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.

ITIF COMMENT: AMS should apply performance criteria not design standards, and should leave companies bound by the performance criteria free to apply whatever design standards serve the purpose. This would render the issue of (inevitable) obsolescence of specific disclosure methods moot. In other words, AMS should allow, but not specify, QRL codes, bar codes, or any equivalent or technological successor that will deliver results that are accurate, informative, and not misleading.

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.

ITIF COMMENT: To ask this question is to presume the need for design specifications rather than recognize the superiority of performance criteria. See answers to Questions 15 and 16 above.

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.

ITIF COMMENT: See answers to Questions 15-17 above.

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?

ITIF COMMENT: See answers to Questions 15-17 above.

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.

ITIF COMMENT: As noted above, the number of employees or total sales volume (by value, weight, or other measure) above a stipulated threshold have been used in the past to suggest precisely where to draw the essentially arbitrary line between “large” and “small.” Since any threshold is necessarily at least somewhat arbitrary, so AMS should select a threshold that minimizes compliance burdens to the extent possible.

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.

ITIF COMMENT: Simply listing a phone number with no additional information is certain to be self-evident and sufficient in the vast majority of cases. Again, performance criteria are superior to design specifications.

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.

ITIF COMMENT: The purpose and intent of this law was and remains focused on retail food sales by grocery stores and the like, and not on the purchase of prepared foods in restaurants or eating establishments. To the extent that some patrons of restaurants and eating establishments have interest in this issue, they already have wide access to such that advertise as “organic” so as to make superfluous any further extension of the applicability of the law to eating establishments. There is clearly no need for AMS to wend its way further down this particular tangential rabbit hole.

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.

ITIF COMMENT: As noted above, the notification requirement, under the law, is entirely about marketing. It is not about health, food safety, or nutrition, although it does risk confusing consumers on those topics. AMS could reduce both the compliance burden and the potential for confusion by drawing exclusions as broadly as possible. Folks who have concerns about this issue will in any event choose to patronize producers and establishments that advertise themselves as serving “organic” foods. This is a problem already solved.

And as we have shown above, this disclosure requirement is so ill advised that anything that can be done to limit its scope and costs is worthwhile, including a small business exemption. But on the other hand, small business exemptions are unfair and distort markets, giving small businesses an unfair advantage in the marketplace. If a public need is so great or a purpose so important that compliance with a requirement must be compelled, then the principle of equal protection under the law should require application to be universal, and special interests groups of whatever class should not be exempt. Therefore, ITIF recommends no small business exemptions be allowed.

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.

ITIF COMMENT: No. Again, avoid design standards in favor of performance criteria to the maximum extent possible. 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? (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.

ITIF COMMENT: See answer to Questions 22 and 23 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 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.

ITIF COMMENT: See answer to Questions 22 and 23 above.

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.

ITIF COMMENT: Given that there are no health or safety issues involved here, all essential record keeping requirements would be embodied in and mooted by the presence on the label of disclosing language or symbol. No essential or useful public purpose is served by any additional record keeping requirements.

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.

ITIF COMMENT: AMS should establish a telephone number/website where consumers can report cases of non compliance that the agency can review. Absent any health or safety issues the creation of a large compliance and enforcement machine cannot be justified. A handful of interested taxpayers will do the auditing work on a voluntary basis.

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.

ITIF COMMENT: 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.

**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.

ITIF COMMENT: Post on a dedicated page on the AMS website.

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.

ITIF COMMENT: WTO SPS rules prohibit the US from treating imports differently than domestic production.

Thank you for providing the opportunity for ITIF to share these comments.

Sincerely,

L. Val Giddings, Ph.D.
Senior Fellow

Robert D. Atkinson
President and Founder, The Information Technology and Innovation Foundation