Thank you for the opportunity to comment. I've tried to make constructive suggestions (in blue font) but fundamentally what USDA has been asked to do here is kind of absurd and risks many unintended consequences.

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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.

I'm sorry that you have been given this task of labeling based on process instead of product. It's not logical, but perhaps a solution would be to label based on whether the "process" involves known genetic changes or unknown genetic changes. In that framework many more modern methods would be "interchangeable with bioengineering" because they involve known genetic changes such as "transgenic," "cisgenic" and various kinds of genome editing. The way that these various terms could be qualified as "bioengineering" is that the developer of the trait/line can document what DNA changes were involved and how that fits into the plant genome. Some "marker assisted breeding" efforts could fit that bioengineered standard.

If the crop was developed through radiation or chemical mutagenesis or was a "sport" found in the field, it should be in a different, but still labeled category called "uncharacterized genetic change" or something like that unless the developer of the variety can give sequence data to characterize the DNA change. Any crop that was subjected to chromosome doubling would need the same scrutiny.

Bottom line – "bioengineered" should be reserved for known DNA changes.

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.

I'm not sure there is a meaningful way to do this. For instance the late blight resistance in the recently approved Innate® Potatoes is a potato gene in a potato which in theory could occur via conventional breeding. The reality is that is would be virtually impossible to make that beneficial change without carrying along some undesired genes from the wild potato.

Again, any sort of mutation or minor sequence change could occur by the natural mechanisms of genetic change that breeders tap.

I don't think there is any bright line for what qualifies as "conventional breeding" from a method point of view. Is chromosome doubling "conventional?" Is a "wide cross" or a "doubled haploid" or a selection based on gene sequencing "conventional?" Is back-crossing a line until it "breeds true" conventional? Is "chromosome doubling" conventional? Is chemical or radiation mutagenesis "conventional?"

Lots of these methods are simply historically common and by this time transgenesis is also historically common.

"Conventional breeding" isn't a meaningful term. There is no "bright line" between methods in this regard that means anything from a safety record or other point of view. Attempting to draw such a line is beneath the scientific dignity of the USDA

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.

As a science-based agency you must certainly know that "could be found in nature" is a bit of an absurd standard when it comes to genetics. Almost by definition the plants that feed us are genetic variants that would never have been successful in nature. Agriculture

as a human enterprise has been an anti-nature exercise for 10,000 or so years.

There are quite a few genes shared by humans and fungi that are not only similar by sequence but which function the same in both organisms. There are huge overlaps in the DNA sequences of all organisms and certainly among plant species. The standard "could be found in nature" is completely open ended. How hard has anyone looked?

So, if there are potatoes in the Andes resistant to Late Blight isn't that a "could be found in nature" thing that could end up in a commercially relevant potato cultivar? In theory someone could "conventionally" cross Cabernet Sauvignon with some wild grape species and eventually back cross to Cabernet with just some downy mildew or powdery mildew resistance. That would probably take several decades and maybe never get to the DNA content of Cabernet + this trait. So if some winery had the courage to grow a Cabernet with a cisgenic gene from a wild NA grape, is that something that "could be found 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))

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.

Sadly, this is currently the most important, but most absurd question for the USDA. If there was the slightest bit of legitimate evidence for harm from "GMO" crops the question of whether there was any DNA or protein associated with the traits would matter and whether that came through processing would be a "thing." It isn't.

Any burden on the farmer or food manufacturer should only rest on someone wanting to make a claim that something isn't "GMO." Otherwise you impose a huge and unnecessary cost of identity preservation on everyone and ultimately charge the consumer for that.

There is no scientifically sound reason to have labeling for these ingredients.

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.

If the USDA wants to be science-based on this question, they might be treading difficult ground. I can't imagine any easy solution to this.

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.

The USDA should never be involved in aiding the marketing of foods based on basic distrust of the system they are charged to protect.

With zero evidence of harm, why would the USDA or FDA want to highlight "GMO" feed? Did you see the "Trillion Meal Study?" Unless USDA wants to drive feed sourcing off-shore more than they already have with Organic, this would be something that USDA should avoid

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.

The public would be much better served by increasing your agency's monitoring of real issues like aflatoxin in feed which is not only bad for the animals but which can be passed on to consumers

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.

This question assumes that there is some actual problem with something that is bioengineered. In the absence of evidence, why are we even talking about this? Even so, at least set a generous threshold for "adventitious presence" or you will end up costing everyone money for not good reason

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

Yes, basically there should be two categories. Crops/foods for which we know what genetic changes we have made and those for which we do not.

Most foods/crops would fall into the "don't exactly know what we did genetically" camp. If the agency wants to submit to the "process" demand, then virtually all food needs to be labeled as having some level of uncertainty about what genetic changes it involves. Politically, only certain methods have been challenged, but that was not a science-driven choice. Indeed, because transgenic crops were voluntarily submitted to the "coordinated framework" review system, they should be highlighted as more likely to be safe as opposed to changes that did not ever trigger any sort of review.

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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 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.

Again, I'm sorry that AMS has been given this burden. I think it would be best to consider how the consumer would best be served. Would they learn anything meaningful about their safety from a purely "process-based" label or would they be better served by a regulatory approval of the soundness of whatever genetic process was used to achieve the food quality that is available to them? Since USDA has been tasked with a process-based scheme, it could at least recognize that a process involving a known change is intrinsically more desirable than a change with potentially unintended consequences that are not ever even evaluated (e.g. via radiation mutagenesis…)

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.

Please don't let your scientific role have anything to do with the woo market! You are better than that!

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.

The precedent of what was done for the state of Vermont should not be considered at all in your process. That was a violation of Constitutional barriers to interstate trade and would have ultimately been overturned in the courts. If your goal is something "informative, truthful, and not misleading" then the label should have something to do with whether or not the genetic change is something known or unknown. Perhaps the wording should be something to the effect that "a known and carefully approved genetic change has been made to this crop." The only problem with that is that such language is misleading in that it does not acknowledge that other genetic changes have been made that are not in any way characterized or approved.

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.

Sadly we live in a society that is spoiled enough by our wealth and access to food to buy items for what they are not. Since the FDA has already abdicated it's responsibility on this topic, food items are already being marketed as "non-GMO" etc. Unless the AMS symbol (whatever it is) replaces that unregulated marketing scheme, consumers will be completely mislead. If the USDA really wants to respond to a consumer interest in "knowing" things about their food, then they cannot tolerate a "non-GMO" label that is patently false (e.g. a Ruby Red Grapefruit labeled as non-GMO when it was the product of mutagenesis of bud wood). Any biotech label required in a market place that features an unregulated non-GMO claim will simply serve marketing schemes that have nothing to do with consumer benefits, farming sustainability etc. If

FDA won't step up to challenge this kind of labeling, at least maybe the USDA could do the job.

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.

The requirements should only be about whether the link gives scientifically accurate information. Ideally this modern communication mechanism can be a way to overcome the fear mongering and disinformation about this food topic. This is the 21st century and we should not be limited to cryptic labels that have been so ill-used to manipulate consumers over the last few decades.

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.

If the regulation is that the label disclosure be truthful, it does not matter what evolves in terms of technology around these labels.

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.

How about a sign that says, “this food might be produced using carefully regulated improvement methods.”

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.

This is an absurd discussion

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?

Why are we even talking about this? The size of the package has nothing to do with it

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.

Why are we even talking about this? The size of the food producer has nothing to do with it

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.

Why are we even talking about this? The size of the food producer has nothing to do with it

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.

Sorry, but this just speaks to the absurdity of this law. Americans now eat a huge amount of their food out of the home and this exemption could simply further encourage that trend as opposed to home cooking/eating that is more conducive to consumption of healthy foods like fruits and vegetables. This is yet another unintended consequence of an ill-advised law

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.

Why are we even talking about this? The size of the food producer has nothing to do with it

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.

Whatever the language is, the idea of getting consumers to real, contextual information could be a good thing.

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.

Look, unless you are also regulating all the other food labeling nonsense this will be a minor issue. As long as there are unregulated labels like "non-GMO" or "natural" this will be lost in the "noise".

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.

All you can do is encourage food companies to make a reasonable effort to stay up with changes. The details are clearly not part of the USDA focus

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.

Please don't make this some paperwork nightmare for farmers in particular. Since there is absolutely no evidence of harm related to biotechnology as it has been commercialized, it makes no sense to complicate life for anyone over the topic

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.

This is where USDA risk's an unwarranted increase in the cost of food. Particularly in the case of commodity crops, there are major efficiencies that rely on shared use harvesting equipment, grain handling and storage infrastructure etc. I think that unless you have someone trying to market something as non-GMO that isn't, there should be very loose allowances for "adventitious presence" etc.

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. Again, if we are talking about this it would only make sense in the case of intentional fraud. Growing, processing and even selling foods involving crops that go through the three agency approval system of the coordinated framework should never be in any way construed as something illegal or bad.

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.

What does USDA do today when it discovers violations of the USDA-organic rules? That is a case where a claim in being made and generally where a consumer is being asked to pay a price premium. My impression is that those are not very public interactions. Why would there be something more dramatic for a case of a fully approved, safe food with no claim?

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. Sorry USDA, but your track record in the regard is not at all good. The net effect of USDA organic requirements has been to drive many feed and food purchasers to source from outside of the US. Unless you are going to do something very different here that will be the same net effect. What I would suggest is that you do what Canada has done and start routinely testing both organic and non-GMO imports for real hazards (e.g. mycotoxins, heavy metals, legacy insecticides…).