The following are answers to selected questions from Michael Schechtman:

1. The key characteristics of allowed terms are that they must be accurate, informative, and must not impugn the safety of either products that will require disclosure or those that will not require such disclosure. AMS might consider proposing a performance standard to allow functional descriptions within so that, for example, a product might be described as "produced by introducing a spinach defense protein gene into cultivated orange by modern breeding techniques." If this approach is not deemed appropriate for label disclosures, it might be considered for text disclosure under question 12 (Sec. 293(b)(2)(D)).
2. "Conventional breeding" must be recognized as a moving target that has expanded with new advances. What was conventional 100 years ago is not the same as what was conventional 50 years ago and is not the same as what is conventional today. Nor will it be the same as what will be considered "conventional" in another 50 years. One hundred years ago, "conventional breeding" would not have included chemical or X-ray mutagenesis, but both are contained within today's accepted range of conventional technology. In a sense, "conventional" has the hidden implication of "familiar," and what is familiar is in a constant state of evolution. No definition for "conventional" should be promulgated without: providing a rationale for inclusion of one technique and exclusion of another; specifying that the definition will be adjusted regularly; and suggesting a mechanism by which such updates might occur. In my view, at present, conventional breeding should include all genetic manipulations that do not involve exchange of nucleic acids between non-sexually-compatible species, with a wide view of what "sexual compatibility" means (including bridging crosses, for example). Conventional breeding would also include any mechanisms that result in deletions or single base-pair changes, regardless of how they are introduced. Introductions of synthetic DNA sequences larger than perhaps 20 bases and not corresponding to any sequence found in a sexually compatible species would not constitute conventional breeding.
3. "Modifications found in nature" should refer to modifications that could possibly have occurred via random natural processes within the collective gene pool of sexually compatible species. This would include any modifications that could have arisen from insertions, deletions, rearrangements, translocations within and among members of that gene pool. Whether or not a particular molecular event has actually occurred in nature and has been detected to date is irrelevant. The observation or detection of a specific event is a function of the ability to screen for and detect such events, the effort undertaken to find them, random natural processes, and accidents of geography--the potential for two sexually compatible strains to coexist at the same place, not whether the event is of a type that could occur in nature.
4. For processed foods that contain highly refined products that are indistinguishable from their non-engineered counterparts, in which there has been no modification of the intended highly refined product, and in which there is no detectable level of bioengineered component, to impose a disclosure requirement would invite fraud and deceptive practices in the marketplace absent the concurrent implementation of an onerous and rigid traceability system for all the ingredients of food products, whether derived through genetic engineering or not. The desire of some consumers for meaningful information about the products they are purchasing should not extend to purified food components that are entirely indistinguishable from their conventional counterparts.
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7. AMS' proposed approach is appropriate. Suggested language: "No food derived from an animal product shall be subjected to mandatory disclosure solely because the animal consumed feed products from, containing, or consisting of a bioengineered substance." The definition of "animal product", for the purposes of the regulation, should be included in a Definitions section to reflect all relevant potential product sources, as suggested in the question.
8. It is a very difficult proposition to identify an appropriate content threshold for what is to be considered bioengineered and hence subject to disclosure. On the one hand, even engaging in such a discussion invites the U.S. to embark on a "race to zero" as has been observed in other countries, which would lend credence to fears that foods bearing such disclosures are in some way unsafe, thereby distorting the marketplace, and also impose huge costs and risks at very low thresholds. Bearing in mind that the Act did not intend to imply any lack of safety for products carrying a disclosure, imposing a very low threshold would seem unjustified. At the opposite extreme, independent of the practical impacts of establishing a threshold, setting no threshold at all would seem inconsistent with the intent of the law.

   Any threshold that is set will of course be fraught with the challenges inherent in testing, sampling, and quantitation, especially in processed food matrices. From the perspective of convenience for the largest segment of producers, adopting a threshold high enough that it could be enforced or monitored with only occasional spot checks of products would be desirable. This will be most easily accomplished by accounting for the starting materials in each major ingredient and obliging the food manufacturer to maintain a paper trail documenting their use. On the other hand, the non-GMO and organic markets in the United States have largely conformed with a 0.9% threshold for labeling, which has been adopted in the EU and a number of other countries. While this approach serves adequately for products that derive additional premiums based on customers' willingness to spend more to purchase non-GMO products, it does not account for the extra costs imposed on the rest of the market for documentation of their ingredients, etc., or for reformulation of those products that they do not wish to bear a disclosure. Studies and reports (e.g., Carter, C.A., & Gruère, G.P. (2003). Mandatory labeling of genetically modified foods: Does it really provide consumer choice?. *AgBioForum*, *6*(1&2), 68-70. Available on the World Wide Web: http://www.agbioforum.org.; USDA Advisory Committee on Biotechnology and 21st Century Agriculture (2005) Global Traceability and Labeling Requirements for Agricultural Biotechnology-Derived Products: Impacts and Implications for the United States) have demonstrated the negative impacts of the EU labelling requirements on the availability of GMO-containing products on the consumer markets there. Therefore, a numerical threshold for disclosure in the U.S. would need to impose a lesser burden than that imposed by 0.9%. Non-GMO food manufacturers who wish to export to GE-sensitive markets may wish to provide extra screening for products going overseas. However, whatever threshold is enacted in regulations should become the standard within the U.S. for all food products sold within the U.S. and its territories. Private labels adhering to alternative thresholds should be disallowed.

Disclosure should also be limited to ingredients that form a major component of a food. As a hypothetical example, a cheese pizza which is 0.1% oregano should not require disclosure for bioengineered oregano, even if that ingredient is 100% bioengineered.

9. It would make sense to have two different but related disclosures, one for products that are whole and themselves bioengineered and one for those complex foods that either contain bioengineered ingredients or contain ingredients derived from bioengineered crops or animals, providing that those ingredients meet the disclosure requirements discussed in the answer to Question 4, above. It would seem to be needlessly confusing to distinguish between two classes of disclosed ingredients. As for allowing seasonal disclosures, I don't see anything intrinsically problematic for entities that wish to take on the added expense of doing so, but having such a cyclical disclosure change might engender additional scrutiny or paperwork. Allowing a separate year-round "may contain" label for those products only would be confusing to the public.
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11. Dietary supplements are currently woefully under-regulated. They should not be immune to disclosure requirements.
12. AMS should set up an initial list of allowed disclosure language options which would be posted on its website. It should allow interested parties to submit other potential choices, and then decide which others, if any, might be allowable, based on the criteria of being informative, truthful, and not misleading, and post a revised list on its website.
26. Recordkeeping should not apply solely to manufacturers that sell products for which disclosure is required. For manufacturers producing a food product for which there are available ingredients of the same type which would require disclosure, but the manufacturer has sourced alternative versions that do not require disclosure, recordkeeping requirements should also be applied.