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

   Since many consumers may not know or understand the term bioengineering, there should be allowable interchangeable terms for the disclosure standard. The terms used should be basic and consistent with public understanding and should include genetic engineering and genetic modification. These terms have broad applicability to varied forms of biotechnology applied to food products including genetic material that has been modified, according to Pub L. 114-216 through “in vitro recombinant deoxyribonucleic acid (DNA) techniques…” or through gene editing or other evolving biotechnical approaches.

   It is critical that the terms genetic engineering or genetic modification are applied to the full range of biotechnologies used in food production. The definitions that govern application of the labeling should be based on those widely used and recognized in the international community, by our trading partners, and the World Health Organization through Codex Alimentarius.

   **Genetically engineered/modified organisms:** Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

   **Techniques of genetic engineering/modification:** include but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.

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

   Conventional breeding consists of various techniques that do not include techniques of modern biotechnology, as defined by the National Organic Standard Board (NOSB), FDA, Codex and the Cartagena Protocol. Based on these definitions, gene editing techniques are also techniques...
of modern biotechnology and are not techniques of conventional breeding. We urge AMS to adopt the USDA National Organic Standards Board (NOSB) definition of classical/traditional breeding when considering conventional breeding techniques, as stated below.

**Classical/Traditional plant breeding**: Classical (also known as traditional) plant breeding relies on phenotypic selection, field based testing and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.

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))

We strongly urge AMS to require disclosure for all foods that contain any amount of highly refined GMO products, including oils and sugars derived from bioengineered crops, even at undetectable levels. The entire reason for disclosure standards is to inform consumers about the origin of ingredients in their food products, so ignoring this and failing to label products derived (even in part) from bioengineered crops would hide the information the law was meant to provide. Overly narrow interpretations that exempt some GE foods from labeling requirements would be contrary to Congressional intent and to USDA’s own statements during the legislative process of passing the National Bioengineered Food Disclosure Standard.

Senator Debbie Stabenow, a co-author of the bill along with Senator Pat Roberts, stated during a July 6, 2016 floor address, that the bill “provides authority to the USDA to label refined sugars and other processed products.” On July 12, Senator Stabenow also stated that “the bill gives USDA broad authority to periodically amend its labeling regulations to ensure that there are no new scientific biotechnology methods that may escape any overly prescriptive statutory definition of biotechnology.” In addition, in a letter to Senator Stabenow, USDA’s own General Counsel Jeffrey M. Prieto wrote that USDA has the authority to include ingredients derived from “novel gene editing techniques such as CRISPR” and products which contain “highly refined oils, sugars or high fructose corn syrup that have been produced or developed from genetic modification techniques.”

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

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3 Id.
areas of confusion between the definition of bioengineering as used in the Law and others 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))

In order to alleviate potential confusion, AMS should harmonize the definition of terms for genetic engineering to the National Organic Program (NOP) standards of excluded methods. The definition used for this new GE labeling standard should be consistent with and aligned with the NOP and with other U.S. national and international standards such as those developed by the WHO through Codex Alimentarius.

GMO food disclosure regulations must include language that explicitly protects the USDA organic regulations from any modifications as a result of the GMO food disclosure rule. USDA has provided clarification that the rules for bioengineered food disclosure will not require that modifications be made to the USDA organic regulations. The conditions expressed in USDA’s Policy Memorandum entitled “Consistency with the AMS National Organic Program” should also be clearly stated in the final GMO food disclosure regulations.

Section 299 (f)(2) of Pub. L. 114-216 states: “the Secretary shall consider establishing consistency between the national bioengineered food disclosure standard established under this section and the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.) and any rules or regulations implementing that Act.” There is concern that, contrary to the intent of the law, that this provision may actually lead to a revision to the organic regulations to bring consistency with the standards established under Pub. L. 114-216. As clarified through USDA’s Policy Memorandum on “Consistency with the AMS National Organic Program,” this is not the intent and should not be interpreted as such. The AMS policy was written to ensure that any new proposed regulations or specifications of Pub. L. 114-216 comply with its policy. Central to avoiding conflict and protecting the organic standards, the policy states:

When proposing standards for national bioengineered food disclosure program, AMS policy will be as follows:
- No certified organic products will require disclosure as bioengineered; and
- No proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations.

The definition and prohibition on excluded methods are well established in the regulations of the NOP. To maintain consumer confidence, it is critical that USDA ensure that the rules for mandatory GMO food disclosure adopt the language included in the AMS policy that no proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations.

The regulations should ensure that any GE foods and ingredients made with newer forms of genetic engineering, such as CRISPR and RNA interference (RNAi), are covered under the definition of bioengineering.
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))

Our members and supporters feel very strongly that labeling of bioengineered foods should be applicable to those foods containing any amount of bioengineered substance and those materials that were produced through the process of biotechnology even if the final product does not include any detectable material. We also understand that a zero tolerance standard may not be attainable and that adventitious presence is tolerated at a level of 0.9 percent by individual ingredient by the majority of other countries that require disclosure of bioengineered foods, the European Union and the Non-GMO project. To be clear, the standard should include products developed through the process of bioengineering that may have no detectable presence such as highly refined oils and sugar in addition to the application of the 0.9 threshold.

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

Categories such as “bioengineered,” “produced with bioengineering,” and “partially produced with bioengineering,” can be useful to consumers since they indicate that a food product does contain bioengineered ingredients, as well as a rough indication of the amount of the food product that is derived from bioengineering. However, these terms do not indicate which ingredients have been bioengineered, which is information that consumers want. Therefore, disclosure should also occur on the ingredient list. One easy way to do this is to use an asterisk symbol (*) after each ingredient in the ingredient list that is bioengineered and then at the end of the ingredient list note that * = “genetically engineered” or “genetically modified.”

In terms of options for labeling methods, AMS should utilize a single method that is clear, recognizable and straightforward: on-package text disclosure. This meets the test of clear, transparent disclosure the purchasing public seeks and will understand. Text disclosure avoids the problems associated with the use of QR codes including:

- lack of smart phone ownership by major segments of the public,
- non-existent or intermittent internet availability in many locations,
- the reality that even shoppers able to meet these two tests do not use QR codes, and
- the likelihood of any electronic disclosure method becoming obsolete (as USDA has acknowledged in these questions).

Shoppers are often on tight timelines, sometimes with children in tow, and may not have the time necessary to scan each food item they purchase and read information on a website. Shoppers already expect that they can read a label for critical product details so they can make an informed purchase and they should be able to do so for GE information as well. Text disclosure also avoids having to create an educational campaign to ensure the public understands the use of a symbol that they will not recognize. The disclosure should include a clear presence claim rather than an ambiguous “may contain” statement and list the ingredients produced with biotechnology.
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))

We support the use of language that clearly and unambiguously indicates whether a food product was produced using genetic engineering. Specific terms we would support include “bioengineered” (or “genetically engineered” or “genetically modified”), “produced with bioengineering” (or “produced with genetic engineering”), “partially produced with bioengineering” (or “partially produced with genetic engineering”), or “contains genetically engineered ingredients”.

A single form of text disclosure should be used so that it does not confuse shoppers. Allowing manufacturers flexibility to choose from multiple phrases would add to shopper confusion and may be misleading.

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))

AMS should require one form of disclosure: an on-package text statement. If the USDA chooses to utilize additional forms of disclosure, we do not believe a symbol should be included unless it is clear and straightforward such as a circle with the letters GE or GMO in the center. Anything else would require considerable resources to educate the public on the label and what it means. The industry is not likely to conduct a comprehensive marketing campaign on a new symbol and there are no resources appropriated with the Disclosure Law for that implementation.

USDA AMS should not facilitate use of a symbol for disclosure of bioengineered foods unless it is in the form presented above.

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))

We urge USDA to reject the option of allowing electronic or digital disclosure for bioengineered food, for the reasons stated in our answer to question 9 above.

Studies show that half of low-income people do not own smartphones. Almost half of rural people do not own smart phones. Two-thirds of the elderly do not own smartphones. In fact only 64 percent of Americans own a smart phone. Electronic disclosure is inherently discriminatory against all of these demographics.

In addition, electronic labeling disclosures place an undue burden on the consumer and greatly impede access to information. In many areas, access to the internet is non-existent or intermittent. Even for shoppers who have smartphones and are shopping in stores with internet access, electronic or digital disclosures are burdensome and impractical. Shoppers expect that they can read a label for critical product details so they can make an informed purchase and they should be able to do so for GE information as well.
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))

Bulk sales should require signage indicating the item is a product of biotechnology. Items for sale in a vending machine or online should require disclosure statements on the product or the electronic/video display of the product description online that is consistent with other parameters for disclosure of bioengineered foods in the final rule.

We appreciate the opportunity to provide these comments and look forward to commenting on proposed regulations when a draft is available.

Sincerely,

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NOFA-VT

Nicole Dehne, Certification Director
VOF