



Mr. Sonny Perdue, Secretary of Agriculture

U.S. Department of Agriculture

1400 Independence Ave., S.W.

Washington, DC 20250

From: The Northeast Organic Farming Association of New York (NOFA-NY)

The National Bioengineered Food Disclosure Standard – Response to the 30 Questions on GMO labeling from USDA

Founded in 1983, the Northeast organic Farming Association - New York (NOFA-NY) is the premier statewide organization growing a strong organic and sustainable farming movement in NYS. NOFA-NY is the largest organic certifier in NYS, certifying nearly 1000 farms and businesses (we will reach 1000 in the next couple of months). We have been growing at ~ 20% per year for the past 3 years. NOFA-NY has two divisions – the certification program and the educational section that provides education and technical assistance to farmers and gardeners and connects consumers with organic farm products. We appreciate this opportunity to comment on the labeling of genetically modified foods.

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

“Non-GMO” or other similar phrases are already familiar to most consumers. “Produced without GMO ingredients,” or “made without the use of GMOs” would be appropriate shorthand for “not produced using genetic engineering (or bioengineering).”

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.

The regulation should require on-package labeling that provides specific, unambiguous information but not “may be produced with genetic engineering” since that does not really inform the purchaser about the particular product in question.

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

In distinguishing what crops are grown without using genetic modification, AMS should utilize the definition recommended by the National Organic Standards Board. “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.”

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

3. Which modifications should AMS consider to be found in nature? (Sec. 291(1)(B))

Genetically engineered organisms should not include organisms resulting from techniques such as conjugation, transduction and hybridization which occur in nature.

Pub L. 114-216, (Sec. 291 (1)(B))states that a component of the term bioengineering refers to a food that “could not otherwise be obtained through conventional breeding or found in nature.” Product developers may make all kinds of claims to make connections between a product developed under highly controlled conditions and plants that are found in nature but have developed their particular characteristics over millennia. While specific traits may be found in nature, if the development of these traits occurs under highly controlled conditions using modern biotechnology, that food or ingredient is a product of biotechnology—not nature—and should be labeled as such.

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))

AMS should require disclosure for all foods developed through the process of biotechnology and ensure that all foods produced through genetic engineering are labeled; including those with ingredients derived from genetically engineered sources, such as highly refined sugars and oils and processed corn and soy ingredients. This should be the case even if the GE ingredients are present only at undetectable levels in the final product: they are still GE foods.

During the development of the law. Senator Debbie Stabenow issued a colloquy stating that the bill would "...give USDA broad authority to determine...which foods will be subject to this bill's mandatory disclosure standard, including highly refined products derived from GMO crops..." and specifically "this bill does not prohibit the labeling of highly refined products derived from GMO crops including soybean oil made from GMO soybeans, high fructose corn syrup made from GMO corn, and sugar made from GMO sugar beets." 4

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 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, the AMS should harmonize the definition of terms for genetic engineering to the 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 the U.N. Codex Alimentarius, a collection of standards, guidelines and codes of practice from around the world that have been adopted by the Codex Alimentarius Commission, a central part of the Joint Food and Agriculture Organization and the World Health Organization of the United Nations.

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, and the organic industry has grown alongside these requirements from its \$3 billion in annual sales in 2001 to \$43 billion today. 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.

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 FFDCA. How will AMS determine the predominance of ingredients? (Sec. 292(c))

Regardless of predominance, which is an arbitrary measure, all bioengineered ingredients should be labeled as such. The language and intent of law and the colloquy indicate that this measure is to apply to more products than any previously proposed labeling measure for the products of biotechnology. The determination process should be based on the procedure used to develop the food product.

7. How should AMS craft language in the regulations acknowledging that animals consuming bioengineered feed are exempt from the disclosure requirements as bioengineered solely because they fed on bioengineered feed? (Sec. 293(b)(2)(A))

Labeling should list the ingredients made with biotechnology. If the animals themselves are not the products of bioengineering, then they are not bioengineered. Many of our members would prefer labeling that includes the feed that animals have received and would avoid buying meat from livestock that has been fed bioengineered feed.

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 are unanimous in wanting the labeling of bioengineered foods to be applicable to foods that contain 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. 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.

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

AMS should utilize a single category 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; and the reality that even shoppers able to meet these two tests do not use QR codes. Shoppers are often on tight timelines, perhaps 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.

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

AMS should consider the process used to create the food product. If that process encompasses alterations that fit within the broad definition of bioengineering/genetic engineering in Codex Alimentarius—being 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—those products should be labeled under the Disclosure Law. A focus on the presence of a substance and specifically on one modified using one technique is overly narrow and will result in many bioengineered foods not being disclosed. The letter by USDA General Counsel Jeffrey Prieto to Senator Debbie Stabenow dated July 1, 2016 lays out the broad applicability under this legislation to include products developed using many forms of biotechnology; that should be a guiding principle. The language and intent of law and the colloquy indicate that this measure is to apply to more products than any previously proposed labeling measure for the products of biotechnology. The determination process should be based on the procedure used to develop the food product.

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

AMS should not exclude specific food types. People with medical conditions, dietary restrictions, or those utilizing dietary supplements deserve the same right to know as the general public.

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))

The text should state the food is “produced with genetic engineering” or “partially produced with genetic engineering” but should not include “may be produced with genetic engineering.” Many of the manufacturers that will comply with the Disclosure Law are already meeting those requirements in other countries and can also do so in the U.S.

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 not consider a symbol, but require the words “produced with genetic engineering” or “partially produced with genetic engineering” on the food package.

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))

If a manufacturer chooses to put an electronic or digital link on the label, it should only be in addition to the on-package labeling with the words “produced with genetic engineering” or “partially produced with genetic engineering”. To prevent confusion, the use of multiple QR

codes should be prohibited. Prohibiting the use of multiple QR codes would align with FDA labeling guidance.

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))

No, AMS should not waste time and resources on this effort. Simply require on-package labeling.

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))

If food is sold in bulk or from a bin, vending machine or on-line, the vendor should be required to display the words “produced with genetic engineering” or “partially produced with genetic engineering” in the product display, through signage, or in the on-line description of the product.

17. The Law offers special provisions for disclosure on small or very small packages. How should AMS define very small or small packages? (Sec. 293(b)(2)(E))

There is space for the words “produced with genetic engineering” or “partially produced with genetic engineering” even on very small packages. AMS should consult with the FDA with regard to the size of text to ensure information is prominently and consistently displayed.

18. What are the reasonable disclosure options AMS should provide for food contained in very small or small packages? (Sec. 293 (b)(2)(E))

It is perfectly reasonable to require on-package labeling so that shoppers know what they are purchasing.

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

AMS should not unreasonably exempt any manufacturers from the GE labeling requirements. Congress intended to only exempt “cottage foods” and very small companies from the disclosure requirement.

The Food and Drug Administration defines “very small business” as businesses averaging less than \$1 million in sales and it provides special considerations and exemptions for small businesses in regulations for nutrition labeling, which it defines as averaging less than \$500,000 in gross annual sales.

For farms, small businesses are defined as farms with an average annual monetary value of produce sold during the previous 3-year period as no more than \$500,000. For farms that are very small businesses the limit is \$250,000.

AMS should follow the precedent set by these relevant definitions of small and very small businesses.

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))

Any manufacturer, large enough to put a label on a product can include the words “produced with genetic engineering” or “partially produced with genetic engineering.”

Providing the public with the information they want in a format they can read will further the goals of an honest and transparent food system. Food manufacturers that hide ingredients behind obscure symbols or through digital codes consumers do not use will not fare well in the marketplace.

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))

AMS should use the same definitions as FDA and the NOP.

22. How should AMS define very small food manufacturers to exclude these manufacturers from the requirements of the regulation? (Sec. 293(b)(2)(G)(ii))

See answer to question 19.

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))

This is not necessary if AMS simply requires on-package labeling.

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))

See answer to question 23.

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))

This is not necessary if AMS simply requires on-package labeling.

26. What types of records should AMS require to be maintained to establish compliance with the regulations? (Sec. 293(g)(2))

For the purposes of this regulation, AMS should be consistent with 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.

30. What should the requirements for imports into the United States of products covered

by the Law/regulation be? (Sec. 294(a))

The AMS should utilize definitions and guidelines consistent with Codex Alimentarius which are recognized by the World Trade Organization. These guidelines state that any approach implemented by member countries should be consistent with those already adopted under Codex.

Thank you for this opportunity to comment.

Respectfully,

Elizabeth Henderson
Member of the Board of NOFA-NY