



To: Mr. Sonny Perdue, Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

From: The Ohio Ecological Food and Farm Association

Regarding: GMO Disclosure and Labeling-Proposed Rule Questions under Consideration

The Ohio Ecological Food and Farm Association (OEFFA) appreciates the USDA's commitment to an open, transparent process for the development and implementation of the National Bioengineered Food Disclosure Standard Law. We hope that the USDA will heed comments from all sectors of the stakeholder community as the rules are finalized. Food manufacturers are already moving forward with various types of labeling absent USDA guidance. It is critically important that the final labeling option's work not just for food manufactures but also for the general public.

While there may be an ideological divide related to how much government involvement in the economy is appropriate, there is greater agreement that a major function of government is to correct for failures of the free market. One such failure is an asymmetry of information and the imbalance of power in transactions created when one party in the marketplace has more or better information than the other. If the final rule includes labeling options that are not clear and transparent the food industry will possess more information than the public resulting in such a market failure. It is an appropriate role for the agency to ensure this does not happen.

In implementing the law as written by Congress, the USDA must take great pains to ensure that the information provided does not obfuscate or in any other way prevent consumers from having full knowledge about the characteristics of the food they purchase. To do so would go against the intent of the law as stated by the legislature, and against the will of the public.

Please accept OEFFA's comments that follow as you formulate the proposed rule for the National Bioengineered Food Disclosure Law.

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

The use of terms should be basic and consistent with public understanding. Options 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 applied to 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.¹

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

AMS should utilize the following definition recommended by the National Organic Standards Board.²

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.

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

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.” This language will likely lead to product developers going through intellectual gymnastics 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.

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. FDA’s technical comments from June 27th, 2016 indicate that wording in Sec. 291 (1)(A) results in a “...*narrow scope of coverage*...” and that the phrasing used in this section of the law would exempt many foods produced by bioengineering from disclosure.³

1. U.N World Health Organization, Food and Agriculture Organization, Codex Alimentarius: The Guidelines for the Production, Processing, Marketing and Labelling of Organically produced foods 7 (2001) <ftp://ftp.fao.org/005/Y2772E/Y2772e.pdf>

2. National Organic Standards Board | November 2016| Proposals & Discussion Documents, pp.78

3. See FDA technical assistance on Senate Agriculture Committee draft legislation to establish a national disclosure standard for bioengineered foods (EDW 16734) (June 27, 2016)

This is contrary to assurances from legislators during 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 the 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 Clearly the intent of this legislation is that all foods created through biotechnology, independent of the amount of genetic material remaining, should fall under the mandatory disclosure requirement.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))

OEFFA appreciates the development of the Policy Memorandum on “Consistency between Bioengineered Disclosure and the National Organic Program” issued by USDA AMS September of last year but we are less concerned with “consistency” than with ensuring that current and future rulemaking does not cause confusion or have negative implications for the work of the NOP in maintaining the integrity of the standards with regard to excluded methods. It is important that the scope of the policy memorandum applies to “...any current and future implementing regulations and guidance for mandatory disclosure of bioengineered food or food derived from bioengineering...” and that “No proposed rules for bioengineered food disclosure will require that modifications be made to the USDA organic regulations.”⁶

In order to alleviate potential confusion, the AMS should harmonize the definition of terms for genetic engineering to the NOP standards of excluded methods and to the international standards codified in Codex Alimentarius.

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 most the 64 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.

4. See 162 Cong. Rec. S4994 (daily ed. July 12, 2016)

5. Ibid

6. See <https://www.ams.usda.gov/sites/default/files/media/PolicyMemoGMODisclosureNOPConsistency.pdf>

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

OEFFA strongly suggests that the USDA utilize a single category and the most straightforward one: 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 those able to meet these two tests do not use QR codes. Consumers 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.

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; therefore rule that should be a guiding principle.

Further, predominance of ingredients is an arbitrary measure. 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.

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.

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.” Manufacturers can trace the

source of product formulation and labeling accordingly. 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 is truly informative for consumers. Allowing manufacturers flexibility to choose from multiple phrases would add to consumer confusion and may be misleading.

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))

OEFFA believes the 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.

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))

While OEFFA is not supportive of digital disclosure, if the USDA uses this method, the agency should ensure that the bioengineered food disclosure is the first thing that consumers see on the product information after scanning a digital disclosure. It should also be both prominent and consistent across product types and should not include any marketing or promotional materials.

USDA will need to ensure that this can be implemented nationally with equal access, ease of use and understanding. Consumer privacy should be protected in using this form of disclosure. 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.

This and any methods used should be a presence disclosure and provide ingredient level information along with prominently displayed text and toll-free phone number consistent with the statute. Access to in-store scanners in sufficient number based on store size should be made available so that shoppers without access to smart phones and those in areas with limited internet capacity have equal access.

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))

As indicated previously in our comments, OEFFA strongly advises against this method but if AMS allows for digital disclosure the agency should specify in the regulations the type of digital disclosure method to be used and the accompanying parameters for the use of that disclosure method. While there are different forms of electronic disclosure and additional methods may evolve, the use of each method should go hand in hand with parameters for each specific type of disclosure. If the type of disclosure specific becomes obsolete, the USDA

should issue a new proposed rule for review and comment to reflect newer technologies and methods of implementation.

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.

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))

Providing the public with the information they want in a format they use 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. According to research from the Hartman Group, consumers expect a company to openly share its practices with the public. They most want to hear about:

- what is in the products they buy;
- where and how products are manufactured; and
- what a company does to assure the welfare of its workers as well as the animals used in its products.⁷

We agree with the assertion that the same information associated with the text disclosure should also be required for the electronic or digital disclosures. AMS should consult with the FDA with regard to the size of text to ensure information is prominently and consistently displayed.

What should the requirements for imports into the United States of products covered by the Law/regulation be? (Sec.294 (a))

The USDA 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.⁸

7. See "Sustainability 2015: Transparency, the Hartman Group: <http://store.hartman-group.com/content/sustainability-2015-overview.pdf>

8. See World Health Organization, Food and Agricultural Organization, Codex Alimentarius, Report of the Thirty Ninth Session of the Codex Committee on Food Labelling, U.N. Doc. Rep. 11/FL (2011)