



July 17, 2017

The Honorable Sonny Perdue
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Ave., SW
Washington, DC 20250

Re: Responses to Proposed Rule Questions Under Consideration (Pub.L.114-216)
<https://www.ams.usda.gov/rules-regulations/gmo-questions>

Dear Secretary Perdue,

On July 29, 2016, Congress passed the National Bioengineered Food Disclosure Standard (Pub. L. 114-216). This law amends the Agricultural Marketing Act of 1946 to require the Secretary of Agriculture to establish a mandatory, national disclosure standard for genetically engineered foods. Under the law, food manufacturers will be required to disclose genetically engineered foods using either on-package text, a United States Department of Agriculture (USDA)-regulated symbol, an electronic or digital link or a 1-800 phone number, pursuant to the rules. The law gave the USDA 2 years to implement its provisions; and on June 28, 2017, the Agricultural Marketing Service (AMS) posted 30 questions to solicit feedback from interested stakeholders, which the AMS will use in forming the rules.

The Non-GMO Project appreciates the opportunity to provide feedback to AMS on the 30 questions under consideration for implementation of the National Bioengineered Food Disclosure Standard (“disclosure standard”) and we look forward to further commenting on any proposed rules during the rulemaking process.

The Non-GMO Project currently offers North America’s most rigorous and recognized program for GMO avoidance. Our mission is to preserve and build sources of non-GMO products, educate consumers, and provide verified non-GMO choices. As a non-profit organization that currently verifies more than 43,000 products representing thousands of companies and more than \$25 billion in annual sales, we have a deep understanding of both brand and consumer expectations regarding GMO transparency. In the 10 years since our incorporation, we have seen firsthand the importance of GMO transparency to consumers. During this time, we have built trust with consumers through our stringent, third-party standard and our Product Verification Program. Our Non-GMO Project Verified on-pack label has helped connect millions of consumers with the thousands of brands and their supply chain partners who are committed to a non-GMO food supply.

The Non-GMO Project was founded on a deeply held belief that everyone has a right to know what is in their food and that everyone should have access to non-GMO choices. Our process and testing-based program supports this by ensuring that all Non-GMO Project Verified products are compliant with our Standard and that they are clearly



labeled so that consumers can make informed decisions if they choose to avoid GMOs. It is because of this that we have fundamental concerns regarding the National Bioengineered Food Disclosure Standard and are hoping that our comments outlined below will help move the standard toward providing greater meaningfulness and consistency for the industry and true transparency for all consumers.

The success of the Non-GMO Project's Verification program as evidenced by the predominance of our consumer-facing on-pack Butterfly label proves that our Program fully and adequately meets consumer demand for non-GMO labeling. This assertion is backed by the over 3,500 brands engaged in the Non-GMO Project Verification program and the rapid growth in Non-GMO Project Verified product sales over the past 5 years – from \$2 billion in 2011 to \$25 billion in 2016. We therefore believe that the private sector, through these public and transparent processes, has established a widely accepted standard for non-GMO certification. It is critical then that AMS establish the disclosure standard rules that do not disrupt the significant economic investment made by these brands in Non-GMO Project Verification nor create confusion or erode consumer confidence in third-party verified, non-GMO claims.

We were encouraged to see that the disclosure standard includes a provision that recognizes that USDA Certified Organic products qualify for “not bioengineered” or “non-GMO” claims in the marketplace. Given the rigorous, process and testing-based standard requirements for Non-GMO Project Verification, we expect that the final rule will include the same recognition for products that have achieved Non-GMO Project Verification. Thus, it would mean that Non-GMO Project Verified products would also qualify for “not bioengineered” or “non-GMO” claims and that Non-GMO Project Verified products would not require bioengineered disclosure under these rules. This will ensure consistency within the industry and is critical to the thousands of farmers, food processors, and brands that have invested in Non-GMO Project Verification, as well as the millions of consumers who look for the Non-GMO Project's label in making their everyday shopping decisions.

Key Messages

Overall, the Non-GMO Project requests that the final rules put into action have the following key provisions:

1. **AMS should include Non-GMO Project Verification as sufficient to make a product claim that bioengineered ingredients are absent.** As stated above, the disclosure standard includes provisions that grant USDA Certified Organic “shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as “not bioengineered.” “non-GMO,” or another similar claim (Pub. L. 114-216, Sec. 297). Given the rigor of the Non-GMO Project Standard and its requirement for ongoing testing, Non-GMO Project Verification should receive the same allowance for absence claims as granted to USDA Certified



- Organic. This would also ensure consistency with USDA Food Safety and Inspection Service (FSIS) acceptance of the “Non-GMO Project” logo as a form of non-GMO claim approved for use on meat, poultry, and egg products.¹
2. **AMS should ensure that Non-GMO Project Verified products will not be required to have a bioengineered ingredient disclosure.** Following from our request above (see #1), this is critical to avoid confusion among the millions of consumers who look to and trust the Non-GMO Project label for GMO avoidance in the marketplace, and to avoid a significant economic disruption for the thousands of farmers, food processors, and brands that have invested in Non-GMO Project Verification over the past 10 years.
 3. **The USDA’s definitions of bioengineering, genetic engineering, and GMO must be broad enough to include all current forms of gene editing and synthetic biology. This definition must be supported by a rigorous process for continuously assessing what is considered bioengineering as new genetic engineering technologies emerge.** The current definition of “bioengineering” and any similar term in Section 291 (1) A & B of Pub. L. 114-216 is much too limited in scope to be meaningful to consumers and is inconsistent with existing industry and policy definitions. Consumers will expect the mandatory GMO disclosure standard to apply to all foods produced with or derived from genetic engineering, including foods produced with new forms of genetic engineering.
 4. **AMS should make clear in the final rules that products that do not require bioengineering disclosure through this program must not by default be allowed to claim “not bioengineered,” “non-GMO,” or a similar claim.**

This is captured in the following provision:

Section 294 (c) of Pub. L. 114-216: A food may not be considered to be ‘not bioengineered,’ ‘non-GMO,’ or any other similar claim describing the absence of bioengineering in the food solely because the food is not required to bear a disclosure that the food is bioengineered under this subtitle.

Absence claims of “not bioengineered” or “non-GMO” must only be supported through stringent third-party verification such as that offered by the Non-GMO Project. This is critical to ensure transparency, clarity, and consistency for consumers.

¹ FSIS Notice 54-16 8/19/16 – Voluntary labeling statements that bioengineered or genetically modified ingredients or animal feed were not used in meat, poultry, or egg products.
<https://www.fsis.usda.gov/wps/wcm/connect/08fa27e2-d0cb-4352-b91d-c150f06ef1b4/54-16.pdf?MOD=AJPERES>



The Non-GMO Project also urges the USDA develop final rules that:

- **Exclude the option to use electronic disclosures, such as QR codes, and 1-800 numbers on packages as adequate disclosure channels.** These channels for disclosure do not provide sufficient transparency to allow consumers to make informed choices. On-package labeling has proven to be the most effective channel for delivering transparent, timely, and accurate product claims for consumers.
- **Ensure that highly refined food products (such as oils and sugars) derived from genetically engineered ingredients and animal products produced from animals that consume GMO feed require disclosures.** Just because a food or food ingredient may not contain detectable levels of genetic material from a “bioengineered” source does not mean that the food or ingredient does not contain any genetic material; it only means that it is not detectable using present-day, readily available scientific methods.

In our 10 years of working with consumers, we consistently hear feedback that they also want to know whether their food has been processed using any form of bioengineering, at any stage in the production process – from seed, to animal feed, through the processing of all ingredients in the final product. For these growing number of consumers GMO transparency through the entire production chain, as well as the final product, matters. Therefore, to provide meaningful transparency to consumers, the AMS must include highly refined foods and animal products produced from animals that consume GM feed in its disclosure requirements.

Responses to Proposed Rule Questions Under Consideration

In response to the AMS request for input on the 30 questions posted to their website, the Non-GMO Project has provided detailed responses to a number of these questions below.

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

With over 43,000 products already verified under the Non-GMO Project, we know that millions of consumers are already familiar with the term “non-GMO.” Consumers will expect the mandatory GMO disclosure standard to apply to all foods produced with or derived from genetic engineering, including foods produced with new forms of genetic engineering. The definition of “Bioengineering” as stated in the National Bioengineered Food Disclosure Standard, Section 291 (1) A & B, of Pub. L. 114-216 is too narrow to encompass newer-generation genetic engineering technologies, such as gene editing and synthetic biology. It is therefore much too limited in scope to be meaningful to

consumers and is inconsistent with existing international and other USDA definitions.

We recommend aligning the definition of “bioengineering” with existing national and international standards and guidelines. This includes those adopted by the *Codex Alimentarius*, which are recognized by the World Trade Organization as the authoritative standard for the purpose of settling international trade disputes. The following definition comes from the *Principles for Risk Analysis of Foods Derived from Modern Biotechnology* adopted by the *Codex Alimentarius* Commission in 2003.²

Modern biotechnology:

- (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or
- (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection.

In addition, the definition should be inclusive of newer technologies of “modern biotechnology,” “bioengineering,” “genetic engineering,” and “genetic modification,” as defined by the U.S. Food and Drug Administration (FDA) and adopted by the National Organic Standards Board (NOSB), to include those of gene editing (including sequence-specific nucleases, meganucleases, zinc finger nuclease, CRISPR, TALEN, and oligonucleotide directed mutagenesis (ODM) or gene silencing (including RNAi, RNAi pesticides, and RNA-dependent DNA methylation).

This list should not be considered exhaustive given the rapid evolution of these and other technologies. Therefore, the AMS must establish a rigorous, transparent process for continuously expanding and refining these definitions to include all relevant and related technologies (see Question 10 response below).

Based on this broader definition of “bioengineering,” AMS should recognize a limited number of interchangeable terms, including “modern biotechnology,” “genetic engineering,” “genetically modified organism,” and “GMO.” These are consistent with existing definitions: the FDA recognizes the first two as interchangeable, and the USDA/FSIS proposed allowing the latter two in its guidance on non-GMO labeling.³

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

² Food and Agriculture Organization of the United Nations, *Codex Alimentarius* Commission. 2003. *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (CAC/GL 44-2003). Available online at: www.fao.org/input/download/standards/10007/CXG_044e.pdf

³ USDA Food Safety and Inspection Service (FSIS), *Compliance Guide on Statements that Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in the Production of Meat, Poultry, or Egg Products*. Aug 19, 2016. Available online at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/claims-guidance/procedures-nongenetically-engineered-statement>



Conventional breeding consists of various techniques that do not include techniques of modern biotechnology as defined by the *Codex Alimentarius*⁴ and adopted by the Non-GMO Project and a wide range of other international stakeholders and certifiers. Based on these definitions, all forms of gene editing are also techniques of modern biotechnology and are therefore not techniques of conventional breeding.

The World Trade Organization references documents and standards developed by the *Codex Alimentarius* in trade disputes involving food and constitute a globally accepted standard. AMS should use this definition of “modern biotechnology”, and not consider any form of existing or new biotechnology techniques to be forms of “conventional breeding”, to minimize consumer and regulatory confusion in the U.S. and facilitate international trade.

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

Addressing which modifications AMS should consider to be “found in nature” is misleading as it focuses attention exclusively on the genotype and phenotype of the final organism. The Non-GMO Project considers a GMO to be an organism in which the genetic material has been changed through biotechnology⁵ in a way that does not occur naturally by multiplication and/or natural recombination. AMS should consider the sum of the process employed to create the modification and the final organism expressing the modification when determining whether the product requires disclosure. Therefore, products of modern biotechnology, inclusive of the definitions described in Nos. 1 and 2 above, should not be considered as “modifications found in nature,” even if the final product has no remaining detectable levels of genetic material from the bioengineered source.

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))

The Non-GMO Project believes that highly refined food products (such as oils and sugars) derived from genetically engineered ingredients should require disclosure. Just because a food or food ingredient may not contain detectable levels of genetic material from a “bioengineered” source does not mean that the food or ingredient does not contain any genetic material; it only means that it is not detectable using present-day, readily available scientific methods.

⁴ Food and Agriculture Organization of the United Nations, *Codex Alimentarius* Commission. 2003. *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (CAC/GL 44-2003). At: www.fao.org/input/download/standards/10007/CXG_044e.pdf

⁵ The Non-GMO Project’s definition of biotechnology is the application of: (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles; or (b) fusion of cells beyond the taxonomic family, that overcame natural physiological, reproductive, or recombination barriers and that are not techniques used in traditional breeding and selection. Source: *Convention on Biological Diversity* (CBD). 2000. Text of the Cartagena Protocol on Biosafety. At: www.bch.cbd.int/protocol/text.



In addition, to ensure meaningful and transparent disclosure for consumers, it is critical that AMS consider that many consumers want to know if biotechnology is used in the process of creating the product, not just whether there are detectable levels of GMOs in the final product. The Non-GMO Project Standard has responded to public feedback to provide assurances to consumers who want to know whether the product has been processed using any bioengineering at any stage in the production – from seed, to animal feed, through the processing of all ingredients in the final product. The entire production chain, as well as the final product, matters to them. Therefore, to provide meaningful transparency to consumers, AMS must include highly refined foods and animal products produced from animals that consume GMO feed in its disclosure requirements.

Questions 5 & 6: No comments at this time.

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))

The Non-GMO Project disagrees with the language in Section 293(b)(2)(A). Exemption from disclosure for products of animals fed bioengineered feed may mislead consumers into concluding that the animals were fed “non-GMO” feed. Through our work at the Non-GMO Project, we have seen a significant increase in consumer demand for animal-derived products from animals fed non-GMO feed and subsequently a significant industry investment in the non-GMO supply chain over the past 5 years. The Non-GMO Project therefore urges AMS to prevent potential confusion in the marketplace by requiring GMO disclosure on all animal-derived food products produced from animals fed genetically modified 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))

The Non-GMO Project Standard outlines the action thresholds for GMOs under our verification program.⁶ The Non-GMO Project Standard is a consensus-based document. It has been crafted with the insight and expertise of stakeholders reflecting a diverse range of perspectives throughout the supply chain. Beginning with a 60-day public comment period in October and November of 2007, ongoing public comment periods over the past 10 years have been established as an important mechanism for keeping the standard rigorous, current, transparent and collaborative.

As noted above (Question #4), our consumer engagement work has revealed an increasing number of consumers are not merely interested in the presence of GMOs in the final product they purchase but are also interested in knowing about the processes by which GMO traits are produced when making their purchasing decisions. Therefore,

⁶ Non-GMO Project Standard Version 14.1 At: https://www.nongmoproject.org/wp-content/uploads/2017/07/Non-GMO-Project-Standard-Version-14.1_5-18-17.pdf



AMS should not rely on the current technical ability to detect the presence of GMO content alone as the basis for the GMO disclosure. The process by which the product is produced should be considered so that genetic engineering methods to produce a desired trait should also serve as the basis for the disclosure.

Questions 9: No comments at this time.

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

Given the rapid evolution of bioengineering technologies we believe AMS should establish a clear mechanism under the disclosure standard that requires the inclusion of new genetic engineering techniques, as they are developed, to ensure that companies and consumers understand the full scope of the disclosure standard. Therefore, AMS must establish a rigorous and transparent process for continuously expanding and refining the definitions to include all relevant and related bioengineering technologies, and update the disclosure requirements to meet these new definitions.

Questions 11-13: No comments at this time.

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))

As a non-profit organization built around the belief that everyone has a right to know what is in their food and that everyone should have access to non-GMO choices, the Non-GMO Project strongly urges AMS to remove options for manufacturers to use electronic (and 1-800 phone numbers), as channels for disclosure under this standard.

The use of electronic disclosures, like Quick Response (QR) codes, for disclosure do not provide sufficient transparency to allow consumers to make informed choices. This is because electronic disclosures present many technological and access-related challenges that will prevent or limit many consumers from accessing GMO disclosures. Without intensive regulation and costly ongoing oversight, the use of electronic disclosures could lead to increased consumer confusion and ultimately fail to provide consumers with a meaningful GMO disclosure. With no additional steps or technology required, on-package labeling has proven to be the most effective channel for delivering transparent, timely and accurate product claims and disclosures for consumers.

Questions 15-30: No comments at this time.



On behalf of the thousands of brands, food manufacturers, food processors and farmers invested in Non-GMO Project product verification, and the millions of consumers who rely on the Non-GMO Project label for making their GMO avoidance purchasing decisions, we strongly urge AMS to exempt Non-GMO Project Verified products from disclosure requirements under the final rules of disclosure standard.

Thank you again for the opportunity to provide input on these rules and for your consideration of our comments.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jeffrey Bos".

Jeffrey Bos
Chief Operating and Financial Officer,
Non-GMO Project

cc: Megan Westgate
Executive Director
Non-GMO Project