



August 25, 2017

Mr. Bruce Summers
Acting Administrator
Agricultural Marketing Service
United States Department of Agriculture
1400 Independence Avenue, SW
Room 3069 South Building
Washington, DC 20250

Submitted via GMOLabeling@ams.usda.gov

RE: Proposed Rule Questions Under Consideration (Posted June 26, 2017)

Dear Mr. Summers:

The Biotechnology Innovation Organization (BIO) thanks the United States Department of Agriculture (USDA) Agricultural Marketing Service (USDA-AMS or the Agency) for seeking input into the implementation of the National Bioengineered Food Disclosure Standard. BIO is pleased to submit responses to questions 1-5 and 7-12, for which BIO members have unique expertise. In addition, BIO is a member of the Coalition for Safe Affordable Food (CFSAF), a broad-based coalition spanning the food supply chain – from seed producers, to growers, to food manufacturers and retailers – dedicated to increasing the public's understanding about the science and safety of genetically engineered organisms. In addition to these responses, BIO directs USDA-AMS to the CFSAF's responses submitted August 25, 2017, to which BIO is a signatory.

BIO is the world's largest bioscience innovation trade association representing nearly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO represents the majority of agricultural biotechnology product developers in North America.

In the past few years, a number of states passed laws requiring or conditionally requiring on-package labeling of certain bioengineered food, setting up the potential for a patchwork of differing and conflicting national, state, and local requirements. Because this patchwork legislation could threaten the free movement of food throughout the United States and worsen stigmatization of technology, Congress passed and the President signed The National Bioengineered Food Disclosure Law (the Law), which broadly preempts state and local laws while establishing a mandatory bioengineered food disclosure program with uniform national standards.

It is notable that responsibility for establishing and implementing the disclosure program rests with USDA, under the Agricultural Marketing Act, and not the United States Food

and Drug Administration (FDA). This is because the disclosure program is designed solely for marketing purposes. The law creating the program has not changed the FDA's separate and distinct authority to require accurate labeling on all food, including bioengineered food, with respect to safety, nutrition, or material differences related to composition or certain properties of the food. That legal authority remains intact.

BIO supports the labeling laws and regulations as currently administered by the FDA and the principles underlying the USDA-AMS program that establishes a uniform national bioengineered food disclosure standard, including the scope of food subject to the standard and the various options available to food manufacturers for complying with the standard.

BIO and its members were actively engaged with the entire food value chain – some 1,100 organizations from across the United States – in support of the federal legislation establishing a national standard and preventing inconsistent and misleading state laws from causing confusion and commercial disruption. We are happy that we can engage with USDA-AMS, food companies, farmers, food retailers and other stakeholders to help establish the regulations necessary to implement the law, including offering BIO's point of view on a number of the questions published by USDA-AMS on its website.

It is important to note that in addition to supporting the new mandatory marketing program for bioengineered food, BIO has always supported the right of food companies to voluntarily label their products, including foods that are not bioengineered, for marketing purposes, as long as the labels are truthful, not misleading, and consistent with the future national mandatory disclosure standard. We embrace transparency and will continue to support robust voluntary disclosure even outside the defined scope of the USDA-AMS program.

BIO members are actively engaged in efforts to promote transparency and these efforts will continue and become even more critical through the implementation of the USDA-AMS program. In 2013, the Council for Biotechnology Information (CBI) launched "GMO Answers," an innovative project that embraces consumer curiosity about how our food is grown, including the use of biotechnology in food and agricultural production. GMO Answers is committed to an open, transparent conversation with consumers. The program makes information about technology easy for the public to access and evaluate. It enables consumers to make their own informed decisions with facts in hand. GMO Answers also has established a strong online and social media presence. BIO and CBI continue to engage with food manufacturers and retailers to help them answer consumer questions about the use of science in agricultural and food production and will continue to do so as this law is implemented.

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

Response: Use of terms other than "bioengineering" or "bioengineered" for purposes of the USDA-AMS mandatory disclosure standard would be contrary to the intent of the National Bioengineered Food Disclosure Standard Law (the Law). Additionally, use of a

single term for purposes of the mandatory disclosure standard would be simplest for consumer understanding.

Additional information: The bipartisan Senate Report (attached hereto) on the Law makes clear that the purpose of the Law is to “establish a mandatory uniform national disclosure standard for human food that is or may be bioengineered.” BIO, therefore, discourages use of any other words or terms within the context of this USDA-AMS mandatory marketing disclosure program. Use of a single term for purposes of mandatory disclosure, however, does not preclude the use of different descriptive terms in any additional voluntary statements about foods. But, USDA-AMS should make clear that any additional terms used in voluntary statements are not interchangeable with the term “bioengineering” under Section 291 of the Law. For example, to the extent that USDA-AMS permits the term “genetically engineered” or “genetic engineering” to be used in additional voluntary statements, the Agency should clarify that these terms are not interchangeable with “bioengineering” under Law Section 291. Furthermore, USDA-AMS should make clear that the ability to use “genetic engineering” in the voluntary disclosure context has no impact on the meaning of “genetic engineering” as that term is used in Section 295.

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

Draft Response: “Conventional breeding” should encompass breeding methods that use the organism’s gene pool and other methods that enable efficient movement of native genes from unadapted to elite organisms. This approach is consistent with Congress’s direction that the USDA-AMS mandatory marketing disclosure program “be technology neutral and reflect technological changes over time.” (Senate Report). The concept of “conventional breeding” does not apply to most microorganisms, however, but many other forms of genetic modification have been applied to microbes for decades. As is true of plants and animals, if the genetic modification could have been obtained by these well-established microbial genetic modification techniques, the resulting food product should not be subject to disclosure in the USDA-AMS mandatory marketing disclosure program.

Additional information: Plant and animal breeding encompasses an evolving set of scientific disciplines and enabling methods to ensure the availability of effective breeding outcomes on an ongoing basis. Any discussion of breeding techniques that would constitute “conventional breeding” should recognize this evolution. USDA-AMS should avoid a static listing of breeding techniques because any such list would ignore this evolution and hinder development of future enabling technologies that make the improvement of our food supply more efficient to accomplish.

Regarding microbes, the concepts of “breeding techniques” and “conventional breeding” have limited applicability, especially with respect to methods for genetically modifying microbes that are food, that produce molecular substances added to food, or that carry out biological processes used in food production and processing. Over many decades, a wide array of methodologies, derived from or based upon natural microbial methods of genetic modification, have been used to change the prokaryotic and eukaryotic microbes

used in the manufacture of food and food ingredients. We view these methodologies as “conventional” because of their long history of safe use in many common foods. Over time, these methods have been altered and improved, and this evolution will continue as more is learned about microbial molecular genetics. Each of these methods should be considered “conventional breeding” under the Law and products resulting from these techniques should not be subject mandatory disclosure.

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

Response: The relevant text in the definition found in Section 291(1) is “contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise ... be found in nature.” In vitro recombinant DNA techniques can be used to recreate or ‘mimic’ many molecular changes or genetic variation that occurs naturally or via conventional breeding; these food products would not meet the definition of “bioengineered” and should therefore be exempt from mandatory disclosure.

In vitro recombinant DNA techniques also allow scientists to use enzymes to assemble combinations of genetic elements into genetic constructs that are not found in nature. When in vitro recombinant DNA techniques are used to create combinations of genetic elements that would not be found in nature, food products containing these constructs should be subject to disclosure within the USDA-AMS mandatory marketing disclosure program.

Additional Information: In vitro recombinant DNA techniques can be used to recreate or ‘mimic’ many molecular changes or genetic variation that occurs naturally, independent of human intervention, including: gene deletions, duplications, additions; nucleotide deletions, duplications, additions, substitutions; transposon insertion, and horizontal gene transfer. Horizontal or lateral gene transfer is the acquisition of genetic material from another organism without being its offspring, although it frequently refers to transfer from organisms belonging to another species. It contrasts with vertical gene transfer, which is the acquisition of genetic material from an ancestor.

Additional forms of genetic modification that occur in nature include the genetic recombinations achieved by crossing over in meiosis and sexual reproduction; microbial conjugation, transformation and transduction; and spontaneous gene mutations in somatic and germline cells. Naturally occurring mutations include: (i) point mutations that delete, add, duplicate or substitute nucleotides and/or genes; (ii) chromosomal mutations such as duplication, deletions, translocations, inversions; and (iii) random insertions of transposons. Some, but not all, of these naturally occurring genetic modifications would be very difficult, or even impossible, to create with current in vitro recombinant DNA techniques, because those modifications can involve large amounts of genetic material.

In vitro recombinant DNA techniques rely on the use of laboratory methods and exogenous enzymes to assemble genetic constructs composed of genetic components derived from any organism, irrespective of its taxonomic relationship to the recipient

organism. A combination of purified, exogenous enzymes, isolated from various sources, can be used to construct a linear assemblage of genetic elements that would not occur naturally. While any single element of the genetic construct may be capable of moving into the recipient by horizontal gene transfer, the odds of the recipient naturally containing all of the genetic elements arranged in a linear fashion, immediately adjacent to one another, are so remote it is inappropriate to view the inserted genetic construct as something that could be found in nature.

Question 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))

Response: No disclosure within the USDA-AMS mandatory marketing program should be required if a food does not meet the applicable statutory definition set forth in Section 291. Also, question 4 is directed toward "bioengineered crops," but USDA-AMS should be mindful that the precise definition of "food" is not limited to plant-derived foods, but also includes a subset of foods from animals; the agency should take that fact into account generally throughout rulemaking.

BIO notes that USDA-AMS should not use the term "highly refined products" to refer to food products such as sugar and oils. Rather, the more appropriate term is simply "refined ingredients." The terms "highly processed" or "highly refined" typically refer to multi-ingredient mixtures processed to the extent that they are no longer recognizable as their original plant/animal source, e.g., candy, tomato sauce, ice cream, etc. In contrast, when a single isolated food component, such as sugar or oil, is obtained by extraction or purification using physical or chemical processes, it is typically referred to as "refined."¹ For these reasons, we urge USDA-AMS to use the term "refined ingredients" when referring to single food components such as sugar and oils.

Additional information: According to the bipartisan Senate Report, "the definition of bioengineering is set in statute and establishes the scope of the disclosure standard. Congress intends an item of food "to be subject to the definition if it contains genetic material that has been modified through in vitro recombinant DNA techniques and this same modification could not be otherwise obtained through conventional plant breeding or found in nature." (Senate Report). This is consistent with the definition of "bioengineering" in Section 291 of the Law. Nothing in the law prevents food manufacturers wanting to highlight the use of bioengineered ingredients from making

¹ See e.g., Poti, J.M., et al., Is the degree of food processing and convenience linked with the quality of food purchased by US households?, 101 Am. J. Clin. Nutr. 1251-1262 (June 2015). See also, Monteiro, CA, et al., A new classification of foods based on the extent and purpose of their processing, 11 Cad Saude Publica, 2039049 (Nov. 2010) (describing three categories of processed foods: (1) minimally processed foods (physical processes applied to single basic foods such as cleaning, chilling, etc.); (2) processed foods (extraction of one specific component of a single basic food, such as oils and fats, sugar, high fructose corn syrup, and milk and soy proteins); and (3) ultra-processed foods (processing of several foodstuffs, including ingredients from group 2 and unprocessed or minimally processed basic foods from group 1).

additional voluntary disclosures that are truthful, not misleading, and that are consistent with the national mandatory disclosure standard.

Question 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))

Response: There may be consumer confusion if regulations implementing the National Bioengineered Disclosure Law are not clear that the bioengineered disclosure standard is a marketing standard, while similar terms used by other agencies may be focused on health and safety issues. Accordingly, USDA-AMS's regulations and all associated guidance and other government references to the regulations and disclosure standard should clearly and unequivocally restate the definition of bioengineering laid out in Section 291(1) and repeat the statutory prohibition on affecting any other federal statute, definition, program, rule, regulation or guidance.

Additionally, the statute directs the USDA-AMS to consider establishing consistency between the eventual National Bioengineered Food Disclosure Standard and the Organic Foods Production Act of 1990. BIO supports consistency, where appropriate, to help reduce consumer confusion and refers USDA-AMS to the CFSAF's responses, to which BIO is a signatory.

Question 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))

Response: Per Section 293(b)(2)(A), a food derived from an animal is not considered bioengineered solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance. To avoid consumer confusion, USDA-AMS must acknowledge the clear statutory intent that food is not subject to the mandatory disclosure requirements solely because it is derived from animals fed bioengineered substances. It would be appropriate for USDA-AMS to adopt via regulation the language in Section 293(b)(2)(A). As to invertebrates, BIO refers the Agency to its response to Question 11, below.

Additional information: According to the bipartisan Senate Report, "it is the intent of Congress that the mandatory disclosure provisions not apply to animal feed, pet food, or ingredients used in animal feed or pet food. The language prohibits the Secretary from considering any food product derived from an animal to be bioengineered solely because the animal may have eaten bioengineered feed." BIO supports Congress' conclusion.

Question 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))

Response: When determining any threshold or amount of a bioengineered substance present in food that triggers mandatory disclosure, USDA-AMS should reinforce that the bioengineered food disclosure standard is a marketing standard, and not a health and safety standard. As such, USDA-AMS should consider exploring a five percent cumulative threshold, which is consistent with the National Organic Program, another food marketing program administered by USDA-AMS.²

Additional information: When determining the amounts of a bioengineered substance that may be present in food, or the threshold requirement, USDA-AMS should adhere to the Congress' instruction in the bipartisan Senate Report to "minimize the impacts on all aspects of the domestic and international value chain." USDA-AMS should also ensure that the rule is consistent with Section 293(b)(3), which provides that "a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering." USDA-AMS must also ensure thresholds or amounts triggering mandatory disclosure do not imply, directly or indirectly, that a bioengineered substance is a contaminant or stigmatize foods with such substances. Furthermore, USDA-AMS should consider a threshold that supports continued use of bioengineered ingredients or substances, recognizing their contribution to a safe, affordable, abundant, and sustainable food supply, and does not encourage reformulation away from such ingredients or substances. The Agency should also take into account consumers' interest in information about their food and the impact of mandatory bioengineered food disclosure on costs to the food processor, food producer, supply chain, and consumer when determining what, if any, threshold or amount of bioengineered substances in a food triggers disclosure.

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

Response: Per Section 293(a)(1) of the Law, there are two categories of mandatory disclosure within the USDA-AMS marketing program: "food" that is "bioengineered" and food that "may be bioengineered," as those terms are defined in Section 291.

Additional information: The Law requires the Secretary to establish through rulemaking a mandatory uniform national disclosure standard for human food that is or may be bioengineered, a point which is confirmed throughout the bipartisan Senate Report. Use of the phrase "may be" should be permitted to reflect instances where companies use both bioengineered and non-bioengineered ingredients in the same product throughout the year. There may be other instances in which the "may be" designation is

² 7 C.F.R. § 205.301 states in part, "A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products."

appropriate, such as where a manufacturer is unsure of the source of an ingredient that could be bioengineered.

The Secretary has authority, as outlined in Section 293, to generate requirements and procedures to carry out the mandatory marketing disclosure program via USDA-AMS. Those requirements and procedures may inform USDA-AMS thinking on how to best elaborate on disclosure categories. The Agency should also consider different disclosure language for foods of single ingredients compared to foods comprising multiple ingredients in order to clarify to the consumer whether or not the food is entirely bioengineered (for example, an apple), or contains bioengineered ingredients (for example, an apple pie). See BIO's responses to Questions 10 and 11 for additional information related to requirements and procedures under Section 293.

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

Response: Any determinations made under Section 293(b)(2)(C) must be consistent with the statutory definition in Section 291. See Question 11 for more information related to Section 293(b)(2)(C).

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

Response: Yes, and as stated in BIO's answer to Question 10, any determinations made under Section 293(b)(2)(C) must be consistent with the statutory definition in Section 291. So, consistent with the statutory definition, USDA-AMS must establish requirements that guide the Agency in developing the mandatory disclosure standard. For example, such requirements could include a threshold under which a food is not considered bioengineered (see Question 8) or the exemption of certain classes of food or ingredients from mandatory disclosure. USDA-AMS should be transparent in this process and consider providing information on its website to help the public and developers of bioengineered food or ingredients understand if their products are bioengineered and thereby subject to mandatory disclosure. Any exemption from the mandatory program should be based on criteria that are clear and scientifically and legally justified.

Additional information: According to the bipartisan Senate Report, "Congress intends the Secretary to provide exemptions and other determinations under which a food is not considered bioengineered." The Report noted examples of exemptions provided by various states to their labeling mandates, including for food products that (i) may include enzymes, additives, and processing aids and/or (ii) have medicinal and supplementary applications. We agree with the Congressional interpretation and urge USDA-AMS to provide exemptions for products that (i) may have used enzymes, additives, and processing aids and/or (ii) have medicinal and supplementary applications, to the extent those products would otherwise be subject to mandatory disclosure. We also urge USDA-AMS to use this provision of the Law to ensure the following foods and food ingredients do not trigger mandatory disclosure:

- Food derived from animals, insects, or microorganisms that grow or feed on a bioengineered substrate, such as a bioengineered crop or other substance derived from a bioengineered product. Examples include milk, eggs, honey, alcohol, amino acids, citric acid, and vinegar.
- Food derived from animals treated with bioengineered animal drugs and pharmaceuticals.
- Food ingredients derived by the chemical transformation of materials directly obtained from a bioengineered crop. Examples include caramel flavoring and color, vitamin C, and sugar alcohols.
- Food produced with microbially-derived products, including fermentation products, should not be subject to the mandatory disclosure standard solely because they are produced using a bioengineered microorganism. Such products in food include ingredients, e.g., vitamins and amino acids, and processing aides.
- A processing aid, incidental additive, or secondary direct food additive that may be from a bioengineered source material. Examples include carriers (e.g., for flavor components), diluents, fermentation substrates, and substances that have a functional role in ingredients but no function in the final product. By their very definition, processing aids and incidental additives are present at insignificant levels in the finished food and have no technical or functional effect in that food. For that reason, FDA regulations do not require the declaration of processing aids or incidental additives in the ingredient statement on food labels. Therefore, their use in processing is not material to whether the finished food is bioengineered. Indeed, the European Union recognizes that processing aids are outside of the scope of disclosure regulation.³ Similar to processing aids and incidental additives, a secondary direct food additive has a technical effect in food during processing, but not in the finished food.

Question 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))

Response: Where a manufacturer chooses to use the on-package text to disclose a bioengineered food, USDA-AMS should require one of the following two options to be used:

1. Contains bioengineered ingredients; or
2. May contain bioengineered ingredients

³ Regulation (EC) No 1829/2003 (clause (16)), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF>.

The term "may be" should be permitted to reflect when food manufacturers alternate between the use of bioengineered and non-bioengineered ingredients in the same product throughout the year. There may be other instances in which the term "may be" is appropriate, such as where a manufacturer is unsure of the source of an ingredient for which bioengineered and non-bioengineered versions are available.

USDA-AMS should also consider providing flexibility for raw agricultural commodities intended for direct human consumption and other single-ingredient foods, such as papaya, that are otherwise subject to the mandatory disclosure standard, to be identified using a different term, such as "bioengineered product."

The agency should establish a compliance date that provides sufficient time for companies to revise their labels to comply with the new mandatory disclosure requirements. USDA-AMS should also consider harmonizing the compliance date with other relevant labeling changes required by new Federal regulations.

We thank you for consideration of our responses, and we look forward to working with the Agency on implementing the National Bioengineered Food Disclosure Standard Law.

Sincerely,

A handwritten signature in black ink, appearing to read "D.O'Brien", followed by a period.

Dana O'Brien
Executive Vice President, Food and Agriculture
Biotechnology Innovation Organization

S. 2609, related to Roberts Senate Amendment #4935 to S. 764, a national bioengineering labeling disclosure standard

REPORT
OF THE
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

To Accompany

S. 2609

December 9, 2016. _ Ordered to be printed

SENATE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

ONE HUNDRED FOURTEENTH CONGRESS
SECOND SESSION

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S. 2609, related to Roberts Senate Amendment #4935 to S. 764, a national bioengineering labeling disclosure standard

December 9, 2016. _Ordered to be printed

Mr. Roberts, from the Committee on Agriculture, Nutrition, and Forestry, submitted the following

REPORT

together with

ADDITIONAL VIEWS

To accompany S. 2609

The Committee on Agriculture, Nutrition and Forestry reported an original bill, S. 2609, to amend the Agricultural Marketing Act of 1946, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

Purpose of the Bill

The purpose of the bill is to preempt state and local actions that mandate labeling of whether a food or seed is genetically engineered, and establish a mandatory uniform national disclosure standard for human food that is or may be bioengineered. The disclosure requirement can be accomplished with several options—text on package, a symbol, or an electronic or digital link disclosure. The legislation allows for additional disclosure options for certain food manufacturers and provides for exemptions and other determinations by the Secretary.

Background and Needs

The solution to the state-by-state patchwork of regulations—express preemption—takes effect immediately and prevents states, tribal, or local governments from mandating labeling on food or seed that are genetically engineered. The first state law took effect on July 1, 2016 in Vermont and other states have also passed mandatory labeling laws.

The Secretary of Agriculture is directed to establish a mandatory uniform national disclosure standard for human food that is or may be bioengineered. For this purpose, the definition of bioengineering is set in statute and establishes the scope of the disclosure standard. The comprehensive federal regulatory review process has determined that there is no difference in safety between a

bioengineered food and its non-bioengineered counterpart. The legislation ensures that the disclosure standard and USDA's implementing regulations treat a bioengineered food the same as its non-bioengineered counterpart by precluding any statements that would suggest or imply that one is safer than the other. The legislation requires mandatory disclosure with several options for compliance—text, a symbol, or an electronic or digital link disclosure. This will replace state laws, including those which mandate on-package labeling. The only language that is required to accompany the electronic or digital link disclosure option is “scan here for more food information”. Nothing in the requirement can be used to denigrate biotechnology.

Within one year of passage, USDA is directed to study any potential technological concerns related to using electronic means of disclosure that are dependent on wireless and telephone networks, unique to small or rural retailers, voluntary activities in place or under consideration to address potential challenges, and relevant costs and benefits. If necessary, the Secretary could allow for additional and comparable disclosure options only if they conclude that consumers lack sufficient access through electronic or digital disclosure.

In addition, the legislation allows website addresses or telephone numbers to satisfy the requirement for small food manufacturers. Very small food manufacturers and restaurants are exempt from the requirement. The disclosure requirement only applies to human food solely subject to the Food, Drug, and Cosmetic Act labeling requirements as well as some meat and poultry products. Those foods where a meat, poultry, or egg product is the main ingredient are exempt. Furthermore, the legislation prohibits the Secretary from considering any food product derived from an animal to be bioengineered solely because the animal may have eaten bioengineered feed. Enforcement of the disclosure requirement is accomplished through an examination and audit process that allows for a hearing before a summary of the audit is made public. Recall authority is not authorized for this standard and no Federal fines or other penalties are permitted. A food that is not subject to the disclosure requirement cannot automatically claim to be “non-biotech.” Separately from the disclosure standard, the law permits organic products to make a “non-biotech” claim. The legislation does not impact the authorities or obligations under the Federal Food, Drug, and Cosmetic Act, the Federal Alcohol Administration Act, or the Organic Foods Production Act. And, the legislation shall be implemented in a manner that is consistent with U.S. trade obligations under international agreements.

Summary of Provisions

The Secretary of Agriculture is directed to establish through rulemaking a mandatory uniform national disclosure standard for human food that is or may be bioengineered. For this purpose, the definition of bioengineering is set in statute and establishes the scope of the disclosure standard. Congress intends an item of food to be subject to the definition if it contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and this same modification could not be otherwise obtained through conventional plant breeding or found in nature. Subparagraph (A) limits application of the definition to a particular type of genetic material (a food containing genetic material modified through recombinant DNA techniques). On the other hand, food that is not genetically modified is not intended to be included in the scope of the definition. Use of some gene editing or breeding technologies during product development would lead to certain food products that would not be subject to the standard because the foods do not contain genetic material modified through recombinant DNA techniques or because the modification could be obtained

through conventional breeding or found in nature. The statutory definition of bioengineering is fully consistent with the approach adopted by most countries to date.

The disclosure requirement applies to human food subject to the Food, Drug, and Cosmetic Act labeling requirements as well as some meat and poultry products. It is the intent of Congress that the disclosure requirement applies only to those foods subject solely to the labeling requirements under the Federal Food, Drug, and Cosmetic Act and excludes from its scope alcoholic beverage products over which the Tax & Trade Bureau has labeling authority pursuant to Section 205 of the Federal Alcohol Administration Act. Unpackaged foods and food processed or prepared in a restaurant or similar retail food establishment are also excluded from the scope of the disclosure requirement. It is the intent of Congress that such products also are covered by the preemption provisions set forth in Subtitle F, Section 295.

It is the intent of Congress that the mandatory disclosure provisions not apply to animal feed, pet food or ingredients used in animal feed or pet food. The language prohibits the Secretary from considering any food product derived from an animal to be bioengineered solely because the animal may have eaten bioengineered feed. Further, Congress intends that meat, milk, eggs and other human food products derived from animals that consume bioengineered feed or feed ingredients are not considered to be bioengineered food subject to mandatory disclosure.

Those foods where a meat, poultry, or egg product is the main ingredient are expressly exempt. Very small food manufacturers, restaurants, and similar retail food establishments are exempt from the disclosure requirement. And, Congress intends the Secretary to provide exemptions and other determinations under which a food is not considered bioengineered. Congress recognizes that states that had passed labeling mandates provided exceptions for a range of food products including those sold online; those that may include enzymes, additives, and processing aids; foods with medicinal and supplementary applications; and other characteristics. In order to meet the legislative intent, the Secretary, when determining the amounts of a bioengineered substance that may be present in food, or the threshold requirement, shall minimize the impacts on all aspects of the domestic and international value chain.

The comprehensive federal regulatory review process has determined that foods produced using bioengineering are safe and not materially different in any way from those made using other methods. This is consistent with scientific research conducted and reviewed by both federal agencies and private entities. Consequently, the legislation ensures that the national disclosure standard and USDA's implementing regulations treat the safety of a bioengineered food the same as its non-bioengineered counterpart. The mandatory disclosure requirement is designed solely to address marketing matters, not based on any concerns with respect to safety of bioengineered foods or ingredients, which is why authority for implementation of this program is given to the Secretary under the Agricultural Marketing Act. The legislation does not change the authority of the FDA to require that a bioengineered food be accurately labeled should any material difference arise with respect to safety or nutrition. FDA's authority over bioengineered foods remains the same.

The legislation directs the Secretary to provide manufacturers with three particular disclosure options – text on package, a symbol, or an electronic or digital link disclosure – with alternative reasonable options for food in small or very small packages. Congress directs USDA to be impartial on a manufacturer's selection of options as those manufacturers shall have sole discretion in choosing from whatever disclosure options are available. In addition, the legislation allows website addresses or

telephone numbers to satisfy the requirement for small food manufacturers. In considering definitions of terms, package sizes, types of manufacturers, and similar decisions, Congress expects efforts be taken to ensure consistency with other federal requirements and definitions. The legislation directs the Secretary to ensure that any language on the food package that accompanies a telephone number or an electronic or digital link is limited to indicating that those sources will provide “more food information.” When a consumer accesses one of the electronic or digital link disclosure sources, the legislation requires the bioengineering disclosure to be consistent and conspicuous.

Congress intends USDA to establish any text or the symbol that could appear on packaging to solely satisfy the disclosure requirement and not be used as a tool to denigrate biotechnology. In doing so, USDA should identify the symbol, its placement, and its type size. With regard to the placement and type size, Congress does not believe the symbol should be given more prominence than the required label elements, including ingredient statement, nutrition information, and statement of manufacturer, packer, and distributor. Congress does not intend the electronic or digital link disclosure option to include any text on the package, other than the language expressly stated in statute, which could be used to denigrate biotechnology.

Congress intends for the standard to be technology neutral and reflect technological changes over time. Congress recognizes that consumers are interested in increased access to information about their food. We understand that consumers increasingly research and make purchases online and in this scenario, they are accessing product information and disclosures online and not directly via the product packaging. The Secretary, as part of the implementation of this act, should consider the ways consumers access product information for online sales. The Secretary should look at the opportunities associated with electronic disclosures where the point of sale is online, and may provide for comparable options to access disclosure information.

Congress is aware that some food manufacturers have voluntarily responded to the growing number of consumers who are seeking detailed information about the products they purchase when consumers are interested in getting that information. Consumers expect a wealth of information at their fingertips and have become accustomed to getting the answers to any questions they may have about a product they wish to purchase via their smartphone or computer. As such, current private sector initiatives led by food manufacturers reflect the change in the type of information consumers expect and how they expect to receive it. These efforts provide access to detailed information on thousands of food products, and consumers will be able to access more detail about their food than ever before. Additionally, these efforts are intended to satisfy the disclosure requirement and will be helpful tools to members of the agriculture community who are interested in voluntarily providing more information to the consumers about the science and resources necessary to provide the safest, most affordable, and abundant food supply in the world.

Congress recognizes that some food manufacturers are already voluntarily disclosing the use of bioengineered ingredients either digitally or on package. Additional manufacturers may want to disclose information about ingredients prior to USDA establishing the uniform bioengineered disclosure standard. Congress does not intend to prevent food manufacturers from voluntarily disclosing ingredient information prior to or after USDA establishes the disclosure standard and compliance date for meeting such standard. Additionally, Congress understands that some manufacturers may not disclose information until a uniform disclosure standard has been finalized by USDA. However, food manufacturers must meet the USDA disclosure standard when the compliance dates are effective.

The legislation directs the Secretary, within one year of passage, to conduct a study of any potential technological concerns related to using electronic or digital link disclosure. In particular, the study shall consider availability of wireless internet or cellular networks; availability of landline telephones; challenges facing small and rural retailers, efforts taken by retailers and other entities to address potential technological and infrastructure challenges, and the costs and benefits of installing evolving technology. Congress intends that this study will occur before USDA establishes the uniform disclosure standard and compliance deadline for such standard. Therefore, the Committee directs the Secretary that the study shall not measure the extent to which manufacturers disclose information or consumers choose to access information via electronic or digital disclosure methods. If the Secretary determines, based on the results of the study, that consumer access to the disclosure is not sufficient, the legislation authorizes the Secretary to provide additional and comparable disclosure options within the national bioengineered food disclosure standard and implementing regulations.

The ability of the FDA and the USDA to enforce food safety laws is not impacted by the legislation. Both agencies have authority to protect the consuming public from unsafe food products under their respective jurisdictions.

With respect to the requirement for disclosure of bioengineered foods, Congress intends USDA to have authority for an examination and audit process that allows for a hearing before a summary of the audit is made public. Recall authority is not authorized for this standard and no Federal fines or other penalties are permitted.

Congress intends USDA, FDA, the Federal Trade Commission, and any other relevant agency to maintain existing authorities to enforce against any claims that are false or misleading. The legislation does not affect the authority of States to enforce against claims that are false or misleading or that otherwise violate State consumer protection laws, except to the extent that any such enforcement would create a de facto labeling requirement that is not identical to the Federal bioengineered food disclosure standard and implementing regulations under this legislation. Specifically, Section 296 codifies the fact that the legislation does not preempt any State or Federal remedy under common law or statutory causes of action.

Although the Secretary may consider establishing consistency between the bioengineered food disclosure standard and the existing Organic Foods Production Act rules and regulations, nothing in this legislation would require USDA to take any action or make changes in the Organic Foods Production Act rules and regulations. Congress does not intend the legislation to impact the authorities or obligations under the Federal Food, Drug, and Cosmetic Act, the Federal Alcohol Administration Act, or the Organic Foods Production Act. Additionally, the legislation shall be implemented in a manner that is consistent with U.S. trade obligations.

Further, Congress does not intend a food that is not subject to the disclosure requirement to be able to automatically claim to be “non-biotech.” There is no intent to define or clarify those claims in the legislation.

Congress recognizes the importance of having a uniform national standard for the disclosure of whether a food is or may be genetically engineered to prevent a patchwork of state, tribal, and local requirements. The preemption provision in Section 295 applies to all disclosure requirements regarding whether a food or seed is genetically engineered. Congress selected the term “genetically

engineered” food or seed, rather than “bioengineering,” because it is the intent for the provision to broadly preempt state, tribal, and local requirements regarding genetically engineered foods or seed regardless of whether the technology used to develop the food or seed falls within the definition of bioengineering. The intended goal is national uniformity and avoiding the confusion and disputes that would arise if a jurisdiction could require disclosure relying on one or more other terms that might be used to refer in various ways to genetic engineering, biotechnology, or breeding techniques, now or in the future.

For seed, the only State and local requirements that are preempted are those for disclosure of whether seed is genetically engineered. All other seed labeling requirements, whether Federal, State or local, and whether existing or future, would be unaffected by the Act. Examples include, but are not limited to, requirements related to disclosure of information on kind, variety, type, hybrid, mixtures, lot numbers, origin, inert matter, germination, and presence of weed seed, treated seed, hard seed, and inoculated seed.

The Congress recognizes states have expressed an interest in regulating the disclosure of bioengineered foods. The language in section 293(e) provides states with the legal authority to establish disclosure requirements for bioengineered foods, provided, the state establishes a definition for bioengineered food and disclosure requirements that are identical to those established by USDA. The state would be preempted from establishing requirements that differ from the federal requirements for bioengineered foods.

Congress intends to preserve remedies available through private rights of action established by state or Federal statutory or common law. Some examples of state remedies that would be available under this clause include monetary damages and injunctive relief. However, the state remedy could not impose labeling or disclosure requirements regarding the presence of bioengineered material or establish a definition for bioengineered food, genetically engineered food, or any similar term or establish any other requirements that differs from the requirements established by USDA under the national bioengineered food disclosure standard.

In Section 2, organic products are permitted to make a voluntary “non-biotech” claim. USDA is given no new authority under the biotechnology disclosure provisions related to “non-biotech” claims.

Furthermore, the Congress recognizes that food manufacturers are facing multiple, costly label changes with varying compliance dates. Thus, Congress urges the Secretary of Agriculture to consult with the Secretary of Health and Human Services so that food manufacturers will be able to minimize the number of label changes to comply with the national bioengineered food disclosure standard and other nutrition or health-related updates. New Federal requirements requiring label changes will impact virtually every food and beverage product on the market, thus it is essential that timeframes for compliance for these changes be considered and harmonized to the greatest extent possible. Congress requests that the Secretary of Agriculture keep the relevant Committees informed of efforts to coordinate the timeframes for compliance for federal label changes.

It is also Congress’s intent that USDA utilize and recognize other label changes and standards where appropriate to minimize burdens imposed by the mandatory disclosure program. This legislation is intended to address a consumer demand for marketing information in a manner that creates as little interruption in the value chain as possible. For instance, only the manufacturer decides how best to comply with the standard, including whether to indicate a product may contain bioengineered food or

may be bioengineered. It is not intended to increase the costs of food manufacturing or changes in distribution or handling. Furthermore, every effort was taken to ensure farmers access to seed technology and not limit the options available to agriculture production. Congress intends USDA to take every effort to minimize the impacts on growers, handlers, processors, manufacturers, distributors, retailers, and consumers.

Legislative History of Related Bills S. 2609 and S. 764

On Mar. 1, 2016, the Committee on Agriculture, Nutrition, and Forestry ordered to be reported favorably to the Senate, 14-6, S. 2609, an original measure amending the Agricultural Marketing Act of 1946.

On July 23, 2015, the Committee on Commerce, Science, and Transportation reported S. 764, with an amendment in the nature of a substitute reauthorizing and amending the National Sea Grant College Program Act, with written report No. 114-90.

S. 764 passed the Senate with an amendment by Unanimous Consent on July 28, 2015. On Sept. 18, 2015, the House passed the bill with further amendment pursuant to H. Res. 421.

On July 7, 2016, the Senate concurred in the House amendment to S. 764 with Senate amendment #4935, an amendment in the nature of a substitute, submitted by Senator Roberts, which consisted of a national bioengineering labeling disclosure standard, 63-30 margin. The House agreed to the Senate proposal on July 14, 2016.

The resulting enactment P.L. 114-116, establishes a national bioengineering labeling disclosure standard.

Estimated Costs

In compliance with subsection (a)(3) of paragraph 11 of rule XXVI of the Standing Rules of the Senate, the Committee states that, in its opinion, it is necessary to dispense with the requirements of paragraphs (1) and (2) of that subsection in order to expedite the business of the Senate.

Regulatory Impact Statement

In compliance with subsection (b)(2) of paragraph 11 of rule XXVI of the Standing Rules of the Senate, the Committee states that, in its opinion, it is necessary to dispense with the requirements of paragraph (1) of that subsection in order to expedite the business of the Senate.

Congressionally Directed Spending

In compliance with paragraph 4(b) of rule XLIV of the Standing Rules of the Senate, the Committee provides that no provisions contained in the bill, as reported, meet the definition of congressionally directed spending items under the rule.

Section-by-Section Analysis of Amendment #4935 to S. 764, the Agreement on an Agriculture Biotechnology Disclosure Solution

Section 1

Subtitle E of the Agricultural Marketing Act of 1946-

Section 291 amends the Agricultural Marketing Act of 1946 by providing definitions for a national bioengineered food disclosure standard.

Section 292 provides that the national bioengineered food disclosure standard will apply to claims indicating that food is bioengineered and the standard specifically applies to food subject either to the Federal Food, Drug, and Cosmetic Act (FDCA), or the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act (FSIS authorities) only if the food subject to the FSIS authorities falls under at least one of two possible criterion.

The first criteria is whether the FSIS food's most predominant ingredient is, by itself, subject to FDCA jurisdiction. If the most predominant ingredient is subject to FDCA jurisdiction, the FSIS regulated food will fall under the national standard.

The second criteria is whether the FSIS food's most predominant ingredient is broth, stock, water, or a similar solution, and the second most predominant ingredient is, by itself, subject to FDCA jurisdiction. If the first ingredient is broth, stock, water, or a similar solution, and the second ingredient is subject to FDCA jurisdiction, the FSIS regulated food will fall under the national standard.

It also clarifies that the definition of "bioengineering" does not affect other Federal authority or programs.

Section 293 authorizes the Secretary of Agriculture to promulgate regulations establishing a mandatory national bioengineered food disclosure standard for food that contains or may contain bioengineering.

Subsection (b)(2) provides for various requirements in the regulations including authorization for the Secretary to determine as appropriate, an amount of bioengineered substance for food to be a bioengineered food under the national standard, and provides for exemptions and other determinations by the Secretary.. It also authorizes three particular disclosure options, reasonable options to address package sizing, and options for small food manufacturers.

Subsection (b)(3) does not allow regulations promulgated and food disclosures made pursuant to paragraph (2) within the disclosure standard to treat a bioengineered food differently than its non-bioengineered counterpart based on its safety notification through the Federal regulatory review process.

Subsection (c) authorizes a study of factors that would affect access to bioengineering disclosures through electronic or digital link methods.

Subsection (d) includes various disclosure requirements, including direction to the Secretary requiring on-package language to accompany an electronic or digital link and telephone number disclosure, protection for personal consumer information, and a minimum size requirement.

Subsection (e) intends to allow a State to have an identical standard and mandatory disclosure requirements as provided through Section 293. Here, the requirement that a State standard must be identical to the national bioengineered food disclosure standard furthers the purpose of national uniformity on bioengineering food disclosure.

Subsection (f) requires the Secretary to consider establishing consistency between the national standard and the Organic Foods Production Act of 1990.

Subsection (g) provides the Secretary with enforcement authority for examination, audit, and disclosure. The Secretary may not recall any food under the authority of this subtitle.

Section 294 requires consistency with US trade obligations and preserves specific other authorities. It also prevents the Secretary from authorizing a “non-GMO” or similar claim because the national standard does not require that the food bear a disclosure that the food is bioengineered.

Subtitle F of the Agricultural Marketing Act of 1946-

Section 295 takes two actions. The section first defines food according to the Federal Food, Drug, and Cosmetic Act. Secondly, the provision preempts any state or political subdivision law relating to the labeling of whether food or seed is genetically engineered or developed or produced using genetic engineering. Here, preemption furthers the purpose of national uniformity on genetic engineering food disclosure, including the prohibition of any state or local requirements that would prevent uniformity in any disclosure of this type.

Section 296 codifies language regarding exemptions from Federal preemption.

Section 2

Certification of food under the Organic Foods Production Act of 1990 is sufficient to allow a “non-GMO” or similar claim.

Rollcall Votes in Committee

By a rollcall vote of 14 yeas and 6 nays as follows, the bill was ordered reported without amendment:

YEAS

Mr. Roberts
Mr. Cochran
Mr. McConnell¹
Mr. Boozman¹
Mr. Hoeven
Mr. Perdue
Mrs. Ernst
Mr. Tillis
Mr. Sasse
Mr. Grassley
Mr. Thune
Ms. Klobuchar
Mr. Donnelly
Ms. Heitkamp

NAYS

Ms. Stabenow
Mr. Leahy¹
Mr. Brown
Mr. Bennet
Mrs. Gillibrand
Mr. Casey

¹By proxy

Additional Views of Senator Stabenow

I respectfully file dissenting views to this report that accompanies S. 2609. On March 1, 2016, the Committee on Agriculture, Nutrition, and Forestry ordered to be reported favorably to the Senate, by a vote of 14-6, an original measure amending the Agricultural Marketing Act of 1946, which I, along with five members of the Committee opposed. This measure subsequently failed to advance on the floor of the Senate. The content of this committee report however, has been used to describe the Roberts Senate Amendment #4935 to the House amendment to S.764, which was a legislative product agreed to by me and Mr. Roberts. That bill became P.L. 114-116, which creates a national bioengineering disclosure standard within the Agricultural Marketing Act of the Department of Agriculture. As such, I respectfully dissent solely because this report accompanying S. 2609 includes information on legislative text never referred to or acted on by the Committee on Agriculture, Nutrition, and Forestry.

Changes in Existing Law

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, the Committee states that, in its opinion, it is necessary to dispense with the requirements of that paragraph in order to expedite the business of the Senate.