

Calendar No. 379

114TH CONGRESS }
2d Session }

SENATE

{ REPORT
114-403

S. 2609, RELATED TO ROBERTS SENATE
AMENDMENT #4935 TO S. 764, A NATIONAL
BIOENGINEERING LABELING DISCLOSURE
STANDARD

R E P O R T

OF THE

COMMITTEE ON AGRICULTURE, NUTRITION,
AND FORESTRY

ON

S. 2609

together with

ADDITIONAL VIEWS



DECEMBER 9, 2016.—Ordered to be printed

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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

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany S. 2609]

The Committee on Agriculture, Nutrition and Forestry, having considered an original bill (S. 2609) to amend the Agricultural Marketing Act of 1946 to require the Secretary of Agriculture to establish a national voluntary labeling standard for bioengineered foods, and for other purposes, 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 characteris-

tics. 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	NAYS
Mr. Roberts	Ms. Stabenow
Mr. Cochran	Mr. Leahy ¹
Mr. McConnell ¹	Mr. Brown
Mr. Boozman ¹	Mr. Bennet
Mr. Hoeven	Mrs. Gillibrand
Mr. Perdue	Mr. Casey
Mrs. Ernst	
Mr. Tillis	
Mr. Sasse	
Mr. Grassley	
Mr. Thune	
Ms. Klobuchar	
Mr. Donnelly	
Ms. Heitkamp	

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.

