

“Safe and Accurate Food Labeling Act of 2015”

Section by Section Summary of the Amendment in the Nature of a Substitute to H.R. 1599

Section 1 is the short title of the bill and table of contents.

Sec. 2. Savings Clause

Section 2 preserves current jurisdiction and regulatory authority, regulations, policies, definitions, and procedures of the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA) and Animal and the Plant Health Inspection Service (APHIS) under the Plant Protection Act (PPA).

TITLE I – Food Safety Affirmation for Certain Plant Products

Subtitle A – Food and Drug Administration

Sec. 101. Consultation Process

Sec. 101 creates a new section 424 in the Federal Food, Drug, and Cosmetic Act (FFDCA) recognizing the Food and Drug Administration’s (FDA’s) current premarket consultation process for food derived from new plant varieties, including genetically engineered plants, and directing the Secretary of Health and Human Services (HHS) to continue to administer that process. Under this subsection, the use of genetic engineered does not, by itself, constitute information that is material for purposes of determining whether there is a difference between a food produced from, containing, or consisting of a genetically engineered plant and a comparable food. FDA may require that the labeling of a food produced from, containing, or consisting of a genetically engineered plant contain a statement to adequately inform consumers of a difference between the food so produced and its comparable food if the Secretary of FDA determines that 1) there is a material difference in the functional, nutritional, or compositional characteristics, allergenicity, or other attributes between the food so produced and its comparable food; and 2) the disclosure of such material is necessary to protect public health and safety or to prevent the label or labeling of the food so produced from being false or misleading.

Subtitle B – Department of Agriculture

Sec. 111. Regulation

Subsection (a) amends the PPA by adding a new subtitle F, Coordination of Food Safety and Agriculture Programs, to further the objectives of the Coordinated Framework for Regulation of Biotechnology established in 1986 and provide consumers, the food industry, trading partners, and other interested parties with a clear affirmation of safety for food produced from, containing, or consisting of genetically engineered plants.

A new section 461 is added to create a notification program for genetically engineered plants prior to use or application in food. Under this section, it is unlawful to introduce into interstate

commerce a nonregulated genetically engineered plant for a use or application in food unless: (1) FDA has notified the entity seeking evaluation of the genetically engineered plant in writing that it has no objections to the entity's determination that the food is as safe for use by humans or animals as one or more comparable foods and the entity provides the notification of FDA's finding to USDA; or (2) FDA had previously evaluated the food pursuant to the voluntary consultation process established in FDA's 1992 policy statement, informed the entity in writing that all questions with respect to the safety of the genetically engineered plant have been resolved, and published the notification on the public website of the FDA. The USDA premarket notification program would not apply to genetically engineered plants that are introduced into commerce for the purpose of research and development. The notification program would also not apply solely because a processing aid or enzyme produced from a genetically engineered plant is intended to be used to produce food, or because the GE plant is used as a nutrient source for microorganisms.

Nothing in section 461 may be construed as authorizing the introduction or delivery into interstate commerce of a nonregulated genetically engineered plant for use or application in food or a food produced from, containing, or consisting of a nonregulated genetically engineered plant.

USDA is required to publish on its website a registry listing of each nonregulated genetically engineered plant intended for a use or application in food, the petitions and determinations made by USDA related to the plants, and the FDA notifications related to the plants. Nothing in this section is intended to alter current confidential commercial or trade secrets protections.

The provisions of this section apply to foods imported into the United States that are produced from, contain, or consist of a plant that is a nonregulated genetically engineered plant or a plant that if introduced in interstate commerce would be subject to regulation under part 340 of title 7, Code of Federal Regulations, or any successor regulations, in the same manner and to the same extent as the provisions apply to a food that is not imported.

A new section 462 is added to the PPA to re-designate and define terms and phrases within the PPA. The term "food" has the same meaning given to it under the FFDCA. A "nonregulated genetically engineered plant" is defined as a genetically engineered plant for which the Secretary of Agriculture has approved a petition under 7 C.F.R. § 340.6 for a determination that the plant should not be regulated under the PPA; or that 1) is not subject to regulation as a plant pest under the PPA, 2) contains genetic material from a different species, and 3) has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques.

Sec. 112. Regulations

Section 112 requires the Secretary of Agriculture to promulgate interim final regulations to carry out the premarket notification program within one year of enactment of the bill.

Sec. 113. Preemption

Under Section 113, no state or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement regarding the use of genetically engineered plants for a use or application in food that is not identical to the notification program established under Section 111 of this Act. This is true regardless of whether regulations have been promulgated under section 112.

Sec. 114. Rule of Construction

Section 114 clarifies that nothing in this Act is intended to alter the ability of the Secretary of Health and Human Services (HHS) to take enforcement actions with respect to a violation of the FFDCFA or the ability of the Secretary of Agriculture to take enforcement actions with respect to a violation of the PPA.

Sec. 115. Implementation Report

Subsection (a) requires the Secretary of Agriculture, in consultation with the Secretary of HHS, to submit a report to Congress evaluating the progress made in the implementation of subtitle F of the PPA, as added by section 111. The report should include 1) an analysis of plants requiring regulatory oversight under subtitle F; 2) an analysis of the extent to which the provisions of subtitle F establish an appropriate scope of regulatory oversight for APHIS and FDA, including their oversight of public research programs; and 3) any potential changes to the relevant provisions of the PPA that would better facilitate implementation of a coordinated, predictable, and efficient science-based regulatory process.

Subsection (b) requires that the report should be prepared to the greatest extent possible in accordance with the process described in the memorandum issued by the Executive Office of the President on July 2, 2015, entitled “Modernizing the Regulatory System for Biotechnology Products,” including the directive to update the “Coordinated Framework for Regulation of Biotechnology” published by the Executive Office of the President, Office of Science and Technology Policy, in the Federal Register on June 26, 1986 (51 Fed. Reg. 23302).

TITLE II – Genetic Engineering Certification

Sec. 201. Genetic Engineering Certification

Section 201 establishes a voluntary genetically engineered food certification program within USDA to govern label claims with respect to the use or non-use of genetic engineering in the production and processing of food in a nationally uniform manner. Section 201 would amend the Agricultural Marketing Act of 1946 (AMA) to add new sections 291, 291A, 291B, 291C, 291D, 291E, 291F, and 291G.

AMA Sec. 291. Definitions

Section 291 of the AMA is amended by adding several new definitions to the Act.

In this subtitle, the term ‘certifying agent’ means the chief executive officer of a State or, in the case of an official to be responsible solely for the administration of the agricultural operations of the State, such official, or any person (including a private entity) who is accredited by the Secretary as a certifying agent for the purpose of certifying a covered product as a product whose label may indicate whether the product is produced with or without the use of genetic engineering.

In this subtitle, the term ‘covered product’ means A) any agricultural product, whether raw or processed, including any product derived from livestock that is marketed in the United States for consumption by humans or other animals, B) any other food not derived from agricultural products; and C) seed or other propagative material.

In this subtitle, the term ‘genetically engineered plant’ means a plant or plant product (as defined in section 403 of the PPA) if it contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and the modification could not otherwise be obtained using conventional breeding techniques.

In this subtitle, the term ‘comparable food’ means, with respect to a covered product produced from, containing, or consisting of a genetically engineered plant 1) the parental variety of the plant; 2) another commonly consumed variety of the plant; or 3) a commonly consumed covered product with properties comparable to the covered product produced from, containing, or consisting of the plant that is genetically engineered.

AMA Sec. 291A. National Genetically Engineered Food Certification Program

Subsection (a) of section 291A of the AMA directs the Secretary of Agriculture to establish a voluntary genetically engineered food certification program for covered products to govern labeling with respect to the use of genetic engineering in the production of food in a nationally uniform manner.

Subsection (b) requires the Secretary to consult with such other parties as are necessary to develop the certification program.

Subsection (c) requires the Secretary to implement the certification program through the use of certifying agents, who would certify that a covered product is or is not produced with the use of genetic engineering or a genetically engineered plant, in accordance with the standards established under the program.

Subsection (d) requires the Secretary to establish a seal to identify covered products in interstate commerce using terminology the Secretary considers appropriate, including terminology commonly used in interstate commerce or established by the Secretary in regulations.

AMA Sec. 291B. National Standards for Labeling Non-Genetically Engineered Food

Subsection (a) establishes the standards for selling or labeling a covered product as produced without the use of genetic engineering. To be sold or labeled without the use of genetic engineering, covered products must be: 1) subjected to supply chain process controls that address the producer planting seed that is not genetically engineered, the producer and other individuals keeping the crop separated during growth, harvesting, storage, processing, and transportation, and persons in direct contact with such crop or products derived from such crop during transportation, storage, or processing keeping the product separated from other products that are or are derived from genetically engineered plants; and (2) produced and handled in compliance with a nongenetically engineered food plan, described in subsection (c) below. In the case of covered products derived from livestock that are marketed in the U.S. for human consumption, the product, the livestock, the products consumed by the livestock, and the products used in processing the products consumed by such livestock must be produced without the use of products derived from genetic engineering. This section prohibits labeling or advertising material from suggesting, either expressly or by implication, that covered products developed without genetic engineering are safer or of higher quality than those produced from, containing, or consisting of a genetically engineered plant.

Subsection (b) precludes a covered product from being considered as not meeting the criteria under subsection (a) solely because the product is 1) produced with a genetically engineered microorganism or a processing aid or enzyme; 2) derived from microorganisms that consumed a nutrient source produced from, containing, or consisting of a genetically engineered plant; or 3) is an approved substance on the National List established under section 2118 of the Organic Foods Production Act of 1990 (7 U.S.C. 6517).

Subsection (c) requires producers or handlers seeking certification under the non-GE labeling program to submit for review and approval by a certifying agent a non-GE food plan addressing the handling and processing procedures to be used. Producers and handlers are required to maintain the non-GE food plan and related records, which are subjected to review by USDA and certifying agents.

AMA Sec. 291C. National Standards for Labeling Genetically Engineered Food

Subsection (a) establishes standards for entities that want to participate in the voluntary program regarding the labeling of a covered product as having been produced using genetic engineering. To be sold or labeled as produced with genetic engineering, the covered product must be produced and handled in compliance with a genetically engineered food plan, and the labeling of or advertising material on, or in conjunction with such products may not claim that covered products produced with genetic engineering are safer or of higher quality than those produced without genetic engineering. Nor may the claims be false or misleading. The labeling of covered products produced with the use of genetic engineering also must contain any other information the Secretary considers appropriate.

Subsection (b) requires producers or handlers of covered products with the use of genetic engineering who want to participate in the program to submit a genetically engineered food plan, which would be subject to review by the USDA and certifying agents. Producers must adhere to

recordkeeping requirements and make such records available for review and copying by the Secretary or certifying agent.

Subsection (c) prohibits the Secretary of Agriculture from preventing a person from: 1) disclosing voluntarily on the labeling of a covered product produced with the use of genetic engineering the manner in which the product has been modified to express traits or characteristics that differ from its comparable food; or 2) from disclosing in advertisements, on the Internet, in response to consumer inquiries, or on other communications, other than labeling, that a covered product was developed with the use of genetic engineering.

AMA Sec. 291D. Imported Products

This section allows imported covered products to be sold or labeled as produced with or without the use of genetic engineering if the Secretary determines that they have been produced and handled under a genetic engineering certification program with safeguards and guidelines that are at least equivalent to the USDA labeling standards.

AMA Sec. 291E. Accreditation Program

Subsection (a) directs the Secretary of Agriculture to establish and implement a program to accredit any State official or private person that meets the requirements of a certifying agent under the requirements set forth in this section.

Subsection (b) sets forth requirements for a governing State official or private person to be accredited as a certifying agent under this section. In order to be accredited, a government State official or private person must 1) prepare and submit to the Secretary an application for such accreditation; 2) have sufficient expertise in agricultural production and handling techniques as determined by the Secretary; and 3) comply with the requirements of this section.

Subsection (c) states that the duration of an accreditation made under this section can only be for five years or less. The duration of accreditation is determined by the Secretary and the accreditation may be renewed once the accreditation expires.

Subsection (d) requires that a governing State official or private person who is accredited to certify a farm or handling operation as a certified organic farm or handling operation pursuant to section 2115 of the Organic Foods Production Act of 1990 (7 U.S.C. 6415), and such accreditation is in effect, be deemed to be accredited to certify covered products under this Section.

AMA Sec. 291F. Recordkeeping, Investigations, and Enforcement

Subsection (a) requires each person who sells, labels, or represents any covered product as having been produced without the use of genetic engineering or a genetically engineered plant or with the use of genetic engineering or a genetically engineered plant to 1) maintain records in a manner prescribed by the Secretary; and 2) upon request by the Secretary, make available to the Secretary all records associated with the covered product. A certifying agent is required to 1)

maintain all records concerning the activities of the certifying agent with respect to the certification of covered products under this subtitle in a manner prescribed by the Secretary; and 2) upon request by the Secretary, make available to the Secretary all records associated with such activities. If a private person who was a certifying agent is dissolved or loses accreditation, all records or copies of records concerning the activities of the person shall be transferred to the Secretary as it relates to this subtitle. This subsection makes it unlawful for any covered person by this subtitle to fail or refuse to provide accurate information in a timely manner as required by the Secretary under this subtitle.

Subsection (b) allows the Secretary to take investigative actions as the Secretary considers to be necessary in order to 1) verify the accuracy of any information reported or made available under this subtitle; and 2) determine whether a person covered by this subtitle has committed a violation, including an order or regulation promulgated by the Secretary pursuant to this subtitle. In order to carry out this subtitle, the Secretary can, but is not required to, 1) administer oaths and affirmations; 2) subpoena witnesses; 3) compel attendance of witnesses; 4) take evidence; and 5) require the production of any records required to be maintained under this subtitle that are relevant to an investigation.

Subsection (c) states that any person who knowingly sells or labels any covered product as having been produced without or with the use of genetic engineering or a genetically engineered plant, except in accordance with this subtitle, would be subject to a civil penalty of not more than \$10,000. Each day in which this violation occurs is considered to be a separate violation.

If a person carries out the following activities, the person, after notice and an opportunity to be heard, will not be eligible for the 5-year period beginning on the date of the occurrence to receive a certification under this subtitle with respect to any covered product: 1) makes a false statement; 2) performs a violation described in paragraph (1)(A) of this subtitle; 3) attempts to have a label indicating that a covered product has been produced without the use of genetic engineering or a genetically engineered plant affixed to a covered product that a person knows, or should have reason to know, to have been produced in a manner that is not in accordance with this subtitle; or 4) otherwise violates the purposes of the genetically engineered food certification program under section 291A, as determined by the Secretary. The Secretary may modify or waive a period of ineligibility if the Secretary determines that the modification or waiver is in the best interests of the genetically engineered food certification program.

A certifying agent must immediately report any violation of this subtitle to the Secretary.

After providing notice and an opportunity to be heard, the Secretary may issue an order, requiring any person who the Secretary reasonably believes is selling or labeling a covered product in violation of this subtitle to cease and desist from selling or labeling such covered product as having been produced without the use of genetic engineering or a genetically engineered plant or as having been produced with the use of genetic engineering or a genetically engineered plant. The order imposing a cease-and-desist order must be final and conclusive unless the affected person files an appeal from the Secretary's order with the appropriate district court in the U.S. within 30 days after the date of the issuance of the order.

If a certifying agent that is a private person violates provisions of this subtitle or falsely or negatively certifies any covered product that does not meet the terms and conditions of the genetically engineered food certification program established under section 291A, as determined by the Secretary, after notice and an opportunity to be heard, the certifying agent will lose accreditation as a certifying agent, and be ineligible to be accredited as a certifying agent for at least three years, beginning on the date of determination. The Secretary may suspend the accreditation of the certifying agent for a violation of this subtitle after providing notice and an opportunity to be heard until the Secretary makes a final determination with respect to the violation that is the subject of the suspension.

The Attorney General may bring a civil action against a person in a district court of the U.S. to enforce the subtitle or a requirement under the subtitle, with the action being brought in the judicial district where the person does business or in which the violation occurred.

AMA Sec. 291G. Authorization of Appropriations, Fees

Subsection (a) authorizes \$2 million to be appropriated to establish the genetically engineered food program under section 291A.

Subsection (b) directs the Secretary of Agriculture to notice, charge, and collect fees in order to cover the estimated costs to the Secretary of carrying out this subtitle after establishment of the genetically engineered food certification program. Fees collected under this subsection must be deposited into a fund in the Treasury of the United States and must remain available until expended, without further appropriations, to carry out this subtitle.

Sec. 202. Regulations

Subsection (a) requires USDA, in promulgating regulations to carry out the amendments made in section 201, 1) to provide a process to account for certified non-genetically engineered covered products that contain genetically engineered plants due to the inadvertent presence of such plants, 2) to the greatest extent practicable, to establish consistency between the certification program established under section 201 of this Act, the organic certification program, and other USDA voluntary labeling programs, and 3) regarding regulations as covered products intended for consumption by non-food animals, take into account the inherent differences between food intended for animal and human consumption, including the essential vitamins, minerals, and micronutrients required to be added to animal food to formulate a complete and balanced diet; and 4) provide a process for requesting and granting exemptions under conditions established by the Secretary.

Sec. 203. Preemption

Subsection (a) requires that the amendments made by section 201 of the Act take effect beginning on the date of enactment of this Act regardless of whether regulation have been promulgated under section 202.

Subsection (b) prohibits States or political subdivisions of a State from directly or indirectly establishing under any authority, or continue in effect, as to any covered products in interstate commerce, any requirement for the labeling of a covered product indicating the product having been produced from, containing, or consisting of a genetically engineered plant, including any requirements for claims that a covered product is or contains an ingredient that was produced from, contains, or consists of a genetically engineered plant unless such State (or political subdivision thereof) establishes either of the following programs for the regulation of such claims. 1) A program that relates to a voluntary claim to which paragraph (1) of section 204(a) of the Act applies; or 2) a program that is A) voluntary, B) accredited by the Secretary pursuant to Section 291E of the Act, and C) identical to the standards established under section 291B or 291C of the Agricultural Marketing Act, as added by section 201 of the Act.

Sec. 204. Applicability

Subsection (a) states that a claim made with respect to whether a covered product was produced with or without the use of genetic engineering or a genetically engineered plant before this Act is enacted 1) may be made for such a product during the 36-month period beginning on the date of enactment of the Safe and Accurate Food Labeling Act; and 2) after the expiration of the 36-month period, may be made so long as the labels associated with such claims meet the standards specified in section 291B or 291C of the Agricultural Marketing Act of 1946.

Subsection (b) states that if a covered product is produced by a farm or handling operation under the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.), such product is deemed to be certified as a product produced without the use of genetic engineering under the genetically engineered food certification program established under section 291A of the Agricultural Marketing Act of 1946.

TITLE III—Natural Foods

Sec. 301. Labeling of Natural Foods

Section 301 of the Act amends section 403 of the FFDCA, to deem a food misbranded if its labeling contains an express or implied claim that the food is ‘natural’ unless the claim uses terms that have been defined by, and the food meets the requirements that have been established in, regulations promulgated by FDA. Prior to finalization of regulations to carry out this section, the use of any claim that the food is ‘natural’ is allowed if it is consistent with the Secretary’s existing policy for such claims. This section directs the Secretary to differentiate between food for human consumption and food intended for consumption by animals other than humans when promulgating regulations to carry out this section. A ‘natural claim’ includes 1) the use of the terms ‘natural,’ ‘100% natural,’ ‘naturally grown,’ ‘all natural,’ ‘made with natural ingredients,’ and any other terms specified by the Secretary.

Sec. 302. Regulations

Subsection (a) directs the Secretary of Health and Human Services (HHS) to issue proposed regulations to implement section 403(aa) of the FFDCa (as added by section 301 of this Act) not later than 18 months after the date of enactment of this Act.

Subsection (b) directs the Secretary of HHS to issue final regulations to implement such Section 403(z) not later than 30 months after the date of enactment of this Act.

Sec. 303 Preemption

Section 303 of this Act amends Section 403(A) of the FFDCa, as amended by section 103 of this Act, by requiring that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as any food in interstate commerce any requirement for the labeling of food of the type required by section 403(z) that is not identical to the requirement by such section.

Sec. 304. Effective Date

The labeling requirements of section 403(z) of the FFDCa, as added by section 301 of this Act, will take effect on the effective date of final regulations promulgated under section 302(b) of this Act. The provisions of section 403A(a)(7), as added by section 303 of this Act, take effect upon the date of enactment of this Act.