

SAFE AND ACCURATE FOOD LABELING ACT OF 2015

—————  
JULY 16, 2015.—Ordered to be printed  
—————

Mr. CONAWAY, from the Committee on Agriculture,  
submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 1599]

The Committee on Agriculture, to whom was referred the bill (H.R. 1599) to amend the Federal Food, Drug, and Cosmetic Act with respect to food produced from, containing, or consisting of a bioengineered organism, the labeling of natural foods, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) **SHORT TITLE.**—This Act may be cited as the “Safe and Accurate Food Labeling Act of 2015”.

(b) **TABLE OF CONTENTS.**—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Savings clause.

**TITLE I—FOOD SAFETY AFFIRMATION FOR CERTAIN PLANT PRODUCTS**

Subtitle A—Food and Drug Administration

Sec. 101. Consultation process.

Subtitle B—Department of Agriculture

Sec. 111. Regulation.

Sec. 112. Regulations.

Sec. 113. Preemption.

Sec. 114. Rule of construction.

Sec. 115. Implementation report.

**TITLE II—GENETIC ENGINEERING CERTIFICATION**

Sec. 201. Genetic engineering certification.

Sec. 202. Regulations.

Sec. 203. Preemption.

Sec. 204. Applicability.

## TITLE III—NATURAL FOODS

Sec. 301. Labeling of natural foods.  
 Sec. 302. Regulations.  
 Sec. 303. Preemption.  
 Sec. 304. Effective date.

**SEC. 2. SAVINGS CLAUSE.**

Nothing in this Act (or the amendments made by this Act) is intended to alter or affect the authorities or regulatory programs, policies, and procedures otherwise available to, or the definitions used by, the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Animal and Plant Health Inspection Service under the Plant Protection Act (7 U.S.C. 7701 et seq.), to ensure the safety of the food supply and the protection of plant health.

## **TITLE I—FOOD SAFETY AFFIRMATION FOR CERTAIN PLANT PRODUCTS**

### **Subtitle A—Food and Drug Administration**

**SEC. 101. CONSULTATION PROCESS.**

Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 423 of such Act (21 U.S.C. 350l) the following:

**“SEC. 424. FOOD DERIVED FROM NEW PLANT VARIETIES.**

“(a) **IN GENERAL.**—The Secretary shall continue to administer the consultation process established under the Food and Drug Administration’s policy statement entitled ‘Statement of Policy: Food Derived from New Plant Varieties’ published in the Federal Register on May 29, 1992 (57 Fed. Reg. 22,984).

“(b) **DETERMINATION OF MATERIAL DIFFERENCE BETWEEN FOOD FROM GENETICALLY ENGINEERED PLANTS AND COMPARABLE FOODS.**—

“(1) **IN GENERAL.**—For purposes of subsection (a), the use of genetic engineering 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.

“(2) **LABELING REQUIRED.**—The Secretary 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 determines that—

“(A) 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

“(B) the disclosure of such material difference 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 in any particular.”.

### **Subtitle B—Department of Agriculture**

**SEC. 111. REGULATION.**

The Plant Protection Act (7 U.S.C. 7701 et seq.) is amended by adding at the end the following new subtitle:

### **“Subtitle F—Coordination of Food Safety and Agriculture Programs**

**“SEC. 461. NOTIFICATION RELATING TO CERTAIN GENETICALLY ENGINEERED PLANTS.**

“(a) **IN GENERAL.**—Subject to subsection (b), it shall be unlawful to introduce or deliver for introduction into interstate commerce 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 unless—

“(1)(A) the Secretary of Health and Human Services notified the entity seeking evaluation of a food produced from, containing, or consisting of the genetically engineered plant in writing that the Secretary of Health and Human Services, in evaluating the food from the genetically engineered plant through the consultation process referred to in section 424(a) of the Federal Food, Drug, and

Cosmetic Act, has no objections to the entity’s determination that food produced from, containing, or consisting of the genetically engineered plant that is the subject of the notification is as safe for use by humans or animals, as applicable, as one or more comparable foods; and

“(B) the entity seeking evaluation of a food produced from, containing, or consisting of the genetically engineered plant submits to the Secretary of Agriculture the notification of the finding of the Secretary of Health and Human Services under subparagraph (A); or

“(2) before the date of the enactment of the Safe and Accurate Food Labeling Act of 2015, the Secretary of Health and Human Services—

“(A) considered the consultation process referred to in section 424(a) of the Federal Food, Drug, and Cosmetic Act with respect to such genetically engineered plant to be complete;

“(B) notified the consulting party in writing that all questions with respect to the safety of food produced from, containing, or consisting of the genetically engineered plant have been resolved; and

“(C) published such notification on the public Internet website of the Food and Drug Administration.

“(b) EXCEPTIONS.—Notwithstanding subsection (a), this section does not apply with respect to the introduction or delivery for introduction into interstate commerce of a genetically engineered plant—

“(1) for the purpose of research or development testing, including—

“(A) testing conducted to generate data and information that could be used in a submission to the Secretary under this title or other regulatory submission; or

“(B) research involving multiplication of seed or hybrid and variety development conducted before submitting a notification under subsection (a)(1)(B);

“(2) solely because a processing aid or enzyme produced from the genetically engineered plant is intended to be used to produce food; or

“(3) solely because the genetically engineered plant is used as a nutrient source for microorganisms.

“(c) RULE OF CONSTRUCTION.—Nothing in subsection (b)(1) may be construed as authorizing the introduction or delivery for introduction 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.

“(d) PUBLIC DISCLOSURE.—

“(1) IN GENERAL.—Subject to paragraph (2), the Secretary of Agriculture shall publish on the public Internet website of the Department of Agriculture, and update as necessary, a registry that includes—

“(A) a list of each nonregulated genetically engineered plant intended for a use or application in food that may be introduced or delivered for introduction in interstate commerce, in accordance with subsection (a);

“(B) the petitions submitted to, and determinations made by, the Secretary of Agriculture with respect to such a plant; and

“(C) the notifications of findings issued by the Secretary of Health and Human Services with respect to such a plant or the use or application of such a plant in food.

“(2) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Notwithstanding paragraph (1), nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to the documents and information referred to in subparagraphs (A) through (C) of paragraph (1).

“(e) IMPORTED FOOD.—In the case of food imported into the United States that is food produced from, containing, or consisting of a plant that meets the definition of 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), the provisions of this section shall apply to such food in the same manner and to the same extent as such provisions apply to a food that is not so imported.

“SEC. 462. DEFINITIONS.

“In this subtitle:

“(1) FOOD.—The term ‘food’ has the meaning given such term in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)).

“(2) NONREGULATED GENETICALLY ENGINEERED PLANT.—The term ‘nonregulated genetically engineered plant’ means a genetically engineered plant—

“(A) for which the Secretary of Agriculture has approved a petition under section 340.6 of title 7, Code of Federal Regulations (or any successor regulations), for a determination that the genetically engineered plant should not be regulated under this Act; or

“(B) that—

“(i) is not subject to regulation as a plant pest under this Act;

“(ii) contains genetic material from a different species; and

“(iii) has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.”.

**SEC. 112. REGULATIONS.**

Not later than one year after the date of the enactment of this Act, the Secretary of Agriculture shall promulgate interim final regulations to carry out the amendments made by section 111.

**SEC. 113. PREEMPTION.**

Regardless of whether regulations have been promulgated under section 112, beginning on the date of the enactment of this Act, 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 with respect to genetically engineered plants for use or application in food that is not identical to the requirement of section 461 of the Plant Protection Act (as added by section 111 of this Act).

**SEC. 114. RULE OF CONSTRUCTION.**

Nothing in the amendments made by this subtitle is intended to alter or affect the ability of—

(1) the Secretary of Health and Human Services to take enforcement actions with respect to a violation of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including section 301 of such Act (21 U.S.C. 331); or

(2) the Secretary of Agriculture to take enforcement actions with respect to a violation of the Plant Protection Act (7 U.S.C. 7701 et seq.), including section 411 of such Act (7 U.S.C. 7711).

**SEC. 115. IMPLEMENTATION REPORT.**

(a) STUDY.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Agriculture and the Secretary of Health and Human Services shall jointly submit to Congress a report evaluating the progress made in the implementation of subtitle F of the Plant Protection Act, as added by section 111. Such report shall include—

(1) an analysis of plants over which regulatory oversight under such subtitle is required;

(2) an analysis of the extent to which the provisions of such subtitle establish an appropriate scope of regulatory oversight for the Animal and Plant Health Inspection Service and the Food and Drug Administration, including their oversight of public research programs; and

(3) any potential changes to the Plant Protection Act that would better facilitate implementation of a coordinated, predictable, and efficient science-based regulatory process.

(b) COORDINATION WITH OTHER EFFORTS TO MODERNIZE REGULATION.—The report under subsection (a) shall be prepared, to the greatest extent practicable, 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 specified in such memorandum 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.**

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) is amended by adding at the end the following new subtitle:

## **“Subtitle E—Genetic Engineering Certification**

### **“SEC. 291. DEFINITIONS.**

“In this subtitle:

“(1) The term ‘certifying agent’ means the chief executive officer of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official, and 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, the labeling of which may indicate whether the product is produced with or without the use of genetic engineering.

“(2) The term ‘covered product’ means—

“(A) an 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 (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) not derived from an agricultural product; and

“(C) seed or other propagative material.

“(3) The term ‘genetically engineered plant’ refers to a plant or plant product (as those terms are defined in section 403 of the Plant Protection Act (7 U.S.C. 7702)), if—

“(A) it contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and

“(B) the modification could not otherwise be obtained using conventional breeding techniques.

“(4) The term ‘comparable food’ means, with respect to a covered product produced from, containing, or consisting of a genetically engineered plant—

“(A) the parental variety of the plant;

“(B) another commonly consumed variety of the plant; or

“(C) a commonly consumed covered product with properties comparable to the covered product produced from, containing, or consisting of the plant that is a genetically engineered plant.

“(5) The term ‘handle’ means to sell, process or package covered products.

“(6) The term ‘producer’ means a person who engages in the business of growing or producing covered products.

“(7) The term ‘Secretary’ means the Secretary of Agriculture, acting through the Agricultural Marketing Service.

### **“SEC. 291A. NATIONAL GENETICALLY ENGINEERED FOOD CERTIFICATION PROGRAM.**

“(a) **IN GENERAL.**—The Secretary shall establish a voluntary genetically engineered food certification program for covered products with respect to the use of genetic engineering in the production of such products, as provided for in this subtitle. The Secretary shall establish the requirements and procedures as the Secretary determines are necessary to carry out such program.

“(b) **CONSULTATION.**—In developing the program under subsection (a), the Secretary shall consult with such other parties as are necessary to develop such program.

“(c) **CERTIFICATION.**—The Secretary shall implement the program established under subsection (a) through certifying agents. Such certifying agents may certify that covered products were or were not produced with the use of genetic engineering or a genetically engineered plant, in accordance with this subtitle.

“(d) **SEAL.**—The Secretary shall 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.

### **“SEC. 291B. NATIONAL STANDARDS FOR LABELING NONGENETICALLY ENGINEERED FOOD.**

“(a) **IN GENERAL.**—To be sold or labeled as a covered product produced without the use of genetic engineering—

“(1) the covered product shall—

“(A) be subject to supply chain process controls that address—

“(i) the producer planting seed that is not genetically engineered;

“(ii) the producer keeping the crop separated during growth, harvesting, storage, and transportation; and

“(iii) 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

- “(B) be produced and handled in compliance with a nongenetically engineered food plan developed and approved in accordance with subsection (c);
- “(2) in the case of a covered product derived from livestock that is marketed in the United States for human consumption, the covered product and the livestock, products consumed by such livestock, and products used in processing the products consumed by such livestock shall be produced without the use of products derived from genetic engineering; and
- “(3) labeling or advertising material on, or in conjunction with, such covered product shall not suggest either expressly or by implication that covered products developed without the use of genetic engineering are safer or of higher quality than covered products produced from, containing, or consisting of a genetically engineered plant.
- “(b) EXCEPTIONS.—A covered product shall not be considered as not meeting the criteria specified in subsection (a) solely because the covered product—
- “(1) is produced with a genetically engineered microorganism or a processing aid or enzyme;
- “(2) is 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).
- “(c) NONGENETICALLY ENGINEERED FOOD PLAN.—
- “(1) IN GENERAL.—A producer or handler seeking certification under this section shall submit a nongenetically engineered food plan to the certifying agent and such plan shall be reviewed by the certifying agent who shall determine if such plan meets the requirements of this section.
- “(2) CONTENTS.—A nongenetically engineered food plan shall contain a description of—
- “(A) the procedures that will be followed to assure compliance with this section;
- “(B) a description of the monitoring records that will be maintained; and
- “(C) any corrective actions that will be implemented in the event there is a deviation from the plan.
- “(3) AVAILABILITY.—The nongenetically engineered food plan and the records maintained under the plan shall be available for review and copying by the Secretary or a certifying agent.
- “SEC. 291C. NATIONAL STANDARDS FOR LABELING GENETICALLY ENGINEERED FOOD.**
- “(a) IN GENERAL.—To be sold or labeled as a covered product produced with the use of genetic engineering—
- “(1) the covered product shall be produced and handled in compliance with a genetically engineered food plan developed and approved in accordance with subsection (b); and
- “(2) the labeling of or advertising material on, or in conjunction with, such covered product shall—
- “(A) not expressly or impliedly claim that a covered product developed with the use of genetic engineering is safer or of higher quality solely because the covered product is a product developed with the use of genetic engineering;
- “(B) not make any claims that are false or misleading; and
- “(C) contain such information as the Secretary considers appropriate.
- “(b) GENETICALLY ENGINEERED FOOD PLAN.—
- “(1) IN GENERAL.—A producer or handler seeking certification under this section shall submit a genetically engineered food plan to the certifying agent and such plan shall be reviewed by the certifying agent who shall determine if such plan meets the requirements of this section.
- “(2) CONTENTS.—A genetically engineered food plan shall contain a description of—
- “(A) the procedures that will be followed to assure compliance with this section;
- “(B) a description of the monitoring records that will be maintained; and
- “(C) any corrective actions that will be implemented in the event there is a deviation from the plan.
- “(3) AVAILABILITY.—The genetically engineered food plan and the records maintained under the plan shall be available for review and copying by the Secretary or a certifying agent.
- “(c) PROHIBITION AGAINST RESTRICTING CERTAIN DISCLOSURES.—With respect to a covered product that otherwise meets the criteria specified in subsection (a), the Secretary may not prevent a person—

“(1) from disclosing voluntarily on the labeling of such a covered product developed 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 in the labeling, that a covered product was developed with the use of genetic engineering.

**“SEC. 291D. IMPORTED PRODUCTS.**

“Imported covered products may be sold or labeled as produced with or without the use of genetic engineering if the Secretary determines that such products have been produced and handled under a genetic engineering certification program that provides safeguards and guidelines governing the production and handling of such products that are at least equivalent to the requirements of this subtitle.

**“SEC. 291E. ACCREDITATION PROGRAM.**

“(a) IN GENERAL.—The Secretary shall establish and implement a program to accredit a governing State official, and any private person, that meets the requirements of this section as a certifying agent for the purpose of certifying a covered product as having been produced with or without the use of genetic engineering or a genetically engineered plant, in accordance with this subtitle.

“(b) REQUIREMENTS.—To be accredited as a certifying agent under this section, a governing State official or private person shall—

“(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.

“(c) DURATION OF ACCREDITATION.—An accreditation made under this section shall be for a period of not to exceed 5 years, as determined appropriate by the Secretary, and may be renewed.

“(d) COORDINATION WITH EXISTING ORGANIC PROGRAM ACCREDITATION.—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) shall be deemed to be accredited to certify covered products under this subtitle.

**“SEC. 291F. RECORDKEEPING, INVESTIGATIONS, AND ENFORCEMENT.**

“(a) RECORDKEEPING.—

“(1) IN GENERAL.—Except as otherwise provided in this title, 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 shall—

“(A) maintain records in a manner prescribed by the Secretary; and

“(B) make available to the Secretary, on request by the Secretary, all records associated with the covered product.

“(2) CERTIFYING AGENTS.—

“(A) IN GENERAL.—A certifying agent shall—

“(i) 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

“(ii) make available to the Secretary, on request by the Secretary, all records associated with such activities.

“(B) TRANSFERENCE OF RECORDS.—If a private person that was certified under this subtitle is dissolved or loses accreditation, all records and copies of records concerning the activities of the person under this subtitle shall be transferred to the Secretary.

“(b) INVESTIGATIONS.—

“(1) IN GENERAL.—The Secretary may take such investigative actions as the Secretary considers to be necessary—

“(A) to verify the accuracy of any information reported or made available under this subtitle; and

“(B) to determine whether a person covered by this subtitle has committed a violation of any provision of this subtitle, including an order or regulation promulgated by the Secretary pursuant to this subtitle.

“(2) SPECIFIC INVESTIGATIVE POWERS.—In carrying out this subtitle, the Secretary may—

“(A) administer oaths and affirmations;

“(B) subpoena witnesses;

“(C) compel attendance of witnesses;

- “(D) take evidence; and  
“(E) require the production of any records required to be maintained under this subtitle that are relevant to an investigation.
- “(c) VIOLATIONS OF SUBTITLE.—
- “(1) UNLAWFUL ACT.—Any person covered by this subtitle who, after notice and an opportunity to be heard, has been found by the Secretary to have failed or refused to provide accurate information (including a delay in the timely delivery of such information) required by the Secretary under this subtitle, shall be subject to a civil penalty of not more than \$10,000.
- “(2) MISUSE OF LABEL.—
- “(A) IN GENERAL.—Any person who knowingly sells or labels 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, except in accordance with this subtitle, shall be subject to a civil penalty of not more than \$10,000.
- “(B) CONTINUING VIOLATION.—Each day during which a violation described in subparagraph (A) occurs shall be considered to be a separate violation.
- “(3) INELIGIBILITY.—
- “(A) IN GENERAL.—Except as provided in subparagraph (C), any person that carries out an activity described in subparagraph (B), after notice and an opportunity to be heard, shall 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.
- “(B) DESCRIPTION OF ACTIVITIES.—An activity referred to in subparagraph (A) is—
- “(i) making a false statement;
- “(ii) a violation described in paragraph (2)(A);
- “(iii) attempting to have a label indicating that a covered product has 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 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
- “(iv) otherwise violating the purposes of the genetically engineered food certification program established under section 291A, as determined by the Secretary.
- “(C) WAIVER.—Notwithstanding subparagraph (A), the Secretary may modify or waive a period of ineligibility under this paragraph if the Secretary determines that the modification or waiver is in the best interests of the genetically engineered food certification program established under section 291A.
- “(4) REPORTING OF VIOLATIONS.—A certifying agent shall immediately report any violation of this subtitle to the Secretary.
- “(5) CEASE-AND-DESIST ORDERS.—
- “(A) IN GENERAL.—The Secretary may, after providing notice and an opportunity to be heard, 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.
- “(B) FINAL AND CONCLUSIVE.—The order of the Secretary imposing a cease-and-desist order under this paragraph shall be final and conclusive unless the affected person files an appeal from the Secretary’s order with the appropriate district court of the United States not later than 30 days after the date of the issuance of the order.
- “(6) VIOLATIONS BY CERTIFYING AGENT.—A certifying agent that is a private person that violates the provisions of this subtitle or falsely or negligently 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, shall, after notice and an opportunity to be heard—
- “(A) lose accreditation as a certifying agent under this subtitle; and
- “(B) be ineligible to be accredited as a certifying agent under this subtitle for a period of not less than 3 years, beginning on the date of the determination.
- “(7) SUSPENSION.—



“(A) IN GENERAL.—The Secretary may, after first providing the certifying agent notice and an opportunity to be heard, suspend the accreditation of the certifying agent for a period specified in subparagraph (B) for a violation of this subtitle.

“(B) PERIOD OF SUSPENSION.—The period of a suspension under subparagraph (A) shall terminate on the date the Secretary makes a final determination with respect to the violation that is the subject of the suspension.

“(8) ENFORCEMENT BY ATTORNEY GENERAL.—On request of the Secretary, the Attorney General may bring a civil action against a person in a district court of the United States to enforce this subtitle or a requirement or regulation prescribed, or an order issued, under this subtitle. The action may be brought in the judicial district in which the person does business or in which the violation occurred.

**SEC. 291G. AUTHORIZATION OF APPROPRIATIONS; FEES.**

“(a) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to establish the genetically engineered food program under section 291A, \$2,000,000, to remain available until expended.

“(b) FEES.—

“(1) IN GENERAL.—Upon establishment of the genetically engineered food certification program under section 291A, the Secretary shall establish by notice, charge, and collect fees to cover the estimated costs to the Secretary of carrying out this subtitle.

“(2) AVAILABILITY.—Fees collected under paragraph (1) shall be deposited into a fund in the Treasury of the United States and shall remain available until expended, without further appropriation, to carry out this subtitle.”.

**SEC. 202. REGULATIONS.**

In promulgating regulations to carry out the amendments made by section 201, the Secretary of Agriculture shall—

(1) provide a process to account for certified nongenetically engineered covered products containing material from genetically engineered plants due to the inadvertent presence of such material;

(2) to the greatest extent practicable, establish consistency between the certification programs established under subtitle E of the Agricultural Marketing Act of 1946 (as added by section 201 of this Act), the organic certification program established under the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.), and other voluntary labeling programs administered by the Secretary;

(3) with respect to regulations for 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 from the requirements of subtitle E of the Agricultural Marketing Act of 1946 (as added by section 201 of this Act) under conditions established by the Secretary.

**SEC. 203. EFFECTIVE DATE; PREEMPTION.**

(a) EFFECTIVE DATE.—Regardless of whether regulations have been promulgated under section 202 of this Act, the amendments made by section 201 shall take effect beginning on the date of the enactment of this Act.

(b) PROHIBITIONS AGAINST MANDATORY LABELING OF FOOD DEVELOPED USING GENETIC ENGINEERING.—No State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any covered product (as defined in section 291 of the Agricultural Marketing Act of 1946, as added by section 201 of this Act) in interstate commerce, any requirement for the labeling of a covered product indicating the product as 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 the State (or a political subdivision thereof) establishes either of the following programs for the regulation of such claims:

(1) A program that relates to voluntary claims to which paragraph (1) of section 204(a) of this Act applies.

(2) A program that—

(A) is voluntary;

(B) is accredited by the Secretary pursuant to section 291E of the Agricultural Marketing Act of 1946 (as added by section 201 of this Act); and

(C) establishes standards that are identical to the standards established under section 291B or 291C of the Agricultural Marketing Act of 1946, as applicable (as added by section 201 of this Act).

**SEC. 204. APPLICABILITY.**

(a) **EXISTING CLAIMS.**—A voluntary claim made with respect to whether a covered product (as defined in section 291 of the Agricultural Marketing Act of 1946, as added by section 201 of this Act) was produced with or without the use of genetic engineering or genetically engineered plants before the date of the enactment of this Act—

(1) may be made for such a product during the 36-month period that begins on the date of the enactment of this Act; and

(2) after the expiration of such 36-month period, may be made so long as the labels associated with such a claim meet the standards specified in section 291B or 291C of the Agricultural Marketing Act of 1946, as applicable (as added by section 201 of this Act).

(b) **ORGANIC CERTIFICATION.**—In the case of a covered product (as defined in section 291 of the Agricultural Marketing Act of 1946, as added by section 201 of this Act) produced by a farm or handling operation that is certified as an organic 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 (as added by section 201 of this Act).

## **TITLE III—NATURAL FOODS**

**SEC. 301. LABELING OF NATURAL FOODS.**

Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

“(z)(1) If its labeling contains an express or implied claim that the food is ‘natural’ unless the claim is made in accordance with subparagraph (2).

“(2) A claim described in subparagraph (1) may be made only if the claim uses terms that have been defined by, and the food meets the requirements that have been established in, regulations promulgated to carry out this paragraph.

“(3) Notwithstanding subparagraph (2), prior to the finalization of regulations to carry out this paragraph, the use of any claim that a food is ‘natural’ shall be allowed if consistent with the Secretary’s existing policy for such claims.

“(4) In promulgating regulations to carry out this paragraph, the Secretary shall differentiate between food for human consumption and food intended for consumption by animals other than humans.

“(5) For purposes of subparagraph (1), a natural claim includes the use of—

“(A) the terms ‘natural’, ‘100% natural’, ‘naturally grown’, ‘all natural’, and ‘made with natural ingredients’; and

“(B) any other terms specified by the Secretary.”.

**SEC. 302. REGULATIONS.**

(a) **PROPOSED REGULATIONS.**—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(z) of the Federal Food, Drug, and Cosmetic Act, as added by section 301 of this Act.

(b) **FINAL REGULATIONS.**—Not later than 30 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue final regulations to implement such section 403(z).

**SEC. 303. PREEMPTION.**

Section 403A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)) is amended—

(1) in paragraph (4), by striking “or” at the end;

(2) in paragraph (5), by striking the period and inserting a comma; and

(3) by inserting after paragraph (5) the following:

“(6) any requirement for the labeling of food of the type required by section 403(z) that is not identical to the requirement of such section.”.

**SEC. 304. EFFECTIVE DATE.**

The labeling requirements of section 403(z) of the Federal Food, Drug, and Cosmetic Act, as added by section 301 of this Act, shall take effect on the effective date of final regulations promulgated under section 302(b) of this Act. The provisions of

section 403A(a)(6) of the Federal Food, Drug, and Cosmetic Act, as added by section 303 of this Act, take effect on the date of enactment of this Act.

#### BRIEF EXPLANATION

The Safe and Accurate Food Labeling Act of 2015 would ensure national uniformity regarding labeling of foods derived from genetically engineered plants by preventing a patchwork of conflicting State or local labeling laws which inherently interfere with interstate and foreign commerce.

#### PURPOSE AND NEED

Agricultural biotechnology is one of the important tools available to producers to cope with an increasing world population and increasing production risks in the 21st century. Despite the need for this technology, an ever more vocal minority of citizens are creating doubt in the minds of many consumers and policymakers through misinformation regarding the safety and wise use of genetically engineered inputs.

In Washington and across the country, we are hearing about “GMOs” and the use of biotechnology in food and agricultural production. There is a great deal of misinformation that can be confusing to consumers and policymakers alike.

This misinformation is influencing policymakers at the local, state, and federal levels and could threaten our farmers’ ability to feed an ever growing population and increase the cost of food for consumers. Right now, biotechnology is helping farmers grow more food with less—less water, less land, and less energy.

Over the past several years, political activists in a growing number of states have attempted to pass ballot initiatives and legislative proposals that would require labeling of certain foods that contain genetically engineered (GE) ingredients. In November 2014, voters in Oregon and Colorado defeated mandatory labeling initiatives. In previous years, voters in California and Washington have defeated similar proposals. To date, Vermont is the only state that has passed a unilateral labeling law, which is scheduled to take effect in 2016, although it is currently being challenged in court. Maine and Connecticut each have a labeling law that can be fully enacted if neighboring states pass similar legislation. Anti-biotechnology activists continue to advocate for these proposals despite the clear scientific consensus on the issue.

State labeling initiatives would produce a state-by-state patchwork of laws that lead to misinformation and confusion for consumers as well as costly disruptions to the food supply chain. The exemptions that have been included in every proposal have raised questions about what, exactly, defines “Right-to-Know.” Under Vermont’s labeling law, for example, vegetable soup would be labeled “GE” while vegetable beef soup would not because it contains meat. A proposal pushed by anti-biotechnology activists in California would have required “GE” labels on soymilk but not cow’s milk. In Colorado, chewing gum would have been exempt from “GE” labeling but breath mints would not.

Food supply chain stakeholders are navigating the consequences of mandatory labeling laws. Farmers have to segregate non-GE crops from GE crops and use more water and pesticides. Food manufacturers have to set up separate food processing units and ware-

house space—not to mention additional transportation routes for products. All of these additional steps would add up to higher costs for farmers, manufacturers, and consumers. According to a recent study out of Cornell, state labeling laws would lead to a \$500 increase in grocery prices for the average family of four.

In a June 17, 2015 letter to Vermont Governor Peter Shumlin, one food industry trade association laid out the high costs associated with compliance of the state’s labeling law which is set to go into effect next July. The letter states that:

In addition to the large costs associated with changing labels, companies will be subject to costly fines due to errors in the supply chain that are no fault of the manufacturer. Under the Vermont law, manufacturers are strictly liable for violations under the law for all instances of a product exhibiting the wrong label on store shelves—regardless of whether the violation was inadvertent; the violation was fault of some other participant in the supply chain; the manufacturers have no legal custody or any control over the product once it leaves their own distribution center; or the violation was a deliberate act by someone who purchased product out of state and placed it on shelves.

The letter continues:

Even with the best of intentions, excellent supply chain logistics and herculean efforts, product will be in the wrong place at any given time, resulting in millions upon millions of dollars in potential fines. For example, assume a 90–95% success rate that the properly labeled products are on shelves. This means that 5% to 10% of products will be mislabeled, or have “slipped” through the supply chain (i.e., slippage rate). Vermont’s law imposes a \$1,000 daily fine for each item that does not bear the legally designated label. For a company that has 2,500 items that require the Vermont label, that slippage rate of products would translate to a \$125,000 to \$250,000 daily fine. We estimate that industry wide, there could be over 100,000 items sold in Vermont that would require Vermont-specific labels. That means our industry could be facing fines as much as \$10 million per day.

#### THE SOLUTION: THE SAFE AND ACCURATE FOOD LABELING ACT

The Safe and Accurate Food Labeling Act was introduced in the U.S. House of Representatives in March 2015.

Participants in the market typically employ measures to promote and distinguish their products utilizing a number of marketing tools. Regarding the use or non-use of biotechnology, a voluntary marketing claim is permitted so long as the label is truthful and not misleading. There is, however, no standard definition for the terminology proliferating in commerce generating confusion and inconsistency which is inherently misleading to consumers.

This legislation will create a consumer-friendly, science-based, uniform food labeling framework for products produced using genetically engineered ingredients. By ensuring that food labeling is the sole purview of the federal government, the bill guarantees that state labeling mandates do not mislead and misinform consumers. Additionally, the bill will prevent the costly price hikes associated with a patchwork of state labeling laws.

By creating a national non-GE certification program that is overseen by the U.S. Department of Agriculture (USDA), this bill

brings transparency and consistency to an area of food labeling where it is urgently needed. This program mimics the widely popular National Organic Program and will provide those who prefer to buy non-GE foods a reliable means of doing so. Similar to organics, non-GE foods also are a small percentage of the U.S. food market. The USDA Certified Organic program is a successful precedent for labeling the exception rather than the rule.

With the passage of this bill, farmers will feel confident an important technology they rely on is safe from unwarranted stigmatization; food producers will have the assurance that their interstate supply chains will remain intact and unhindered; and grocery shoppers across the United States will have the peace of mind that the costs associated with feeding their families are not increased due to misguided labeling laws.

#### SECTION-BY-SECTION SUMMARY OF THE MANAGER'S AMENDMENT TO H.R. 1599

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

The Committee intends that this legislation will provide consumers with assurance that the American food supply remains the safest in the world and that accurate, reliable information is readily available concerning the extent to which food is produced from, contains, or consists of genetically engineered plants. The Committee further intends to recognize and reinforce the valuable role that the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) and its nationally uniform, science-based regulatory review process have played and should continue to play in our national agricultural economy and in providing consumers with an adequate, wholesome, and economical food supply.

#### *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). In particular, the Committee intends for the Secretary of Health and Human Services and the Secretary of Agriculture to retain and use their respective authorities to ensure the safety of the food supply and the protection of plant health.

#### 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. The voluntary consultation process is derived from FDA's 1992 Statement of Policy (Policy), which provides guidance on how existing FDA authority related to food safety and food labeling should be applied to foods

derived from genetically engineered plants. FDA states in that Policy that it does not believe that the “method of development” of a food is material information under the FFDCA “and would not usually be required to be disclosed in labeling for the food.” Under the Policy, such labeling would be required under the same circumstances as it would for any other food product. A possible example of such material information would be the need to disclose information about the potential allergenicity of a food product that was not previously recognized by consumers as being allergenic. Such material differences between food from a genetically engineered plant and comparable (i.e., non-genetically engineered) food might also include those that alter the characteristics of a food product such that its common or usual name no longer adequately describes the food, or those that result in a significantly different nutritional property in the food. This section of the bill clarifies that the use of genetic engineering, by itself, is not information that is material for determining whether there is a difference between food from bioengineered plants and comparable food. FDA has the discretion to 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 produced and comparable food if the FDA determines 1) there is a material difference in the functional, nutritional, or compositional characteristics, allergenicity, or other attributes between the food produced and comparable food; and 2) the disclosure of the material difference is necessary to protect public health and safety or to prevent the label or labeling of the food from being false or misleading.

The Committee intends that this subtitle recognize the FDA’s 1992 Statement of Policy as to Foods Derived from New Plant Varieties and reinforce its purpose to provide consumers, the food industry, and trading partners with assurance that the foods reviewed under that Policy are as safe to eat as non-genetically engineered foods.

The Committee expects that, in continuing to administer the voluntary consultation process established by the 1992 policy, the FDA will continue to assess whether the use or application of a genetically engineered plant in the production of food raises any safety or regulatory issues under the FFDCA and, if no such issues are identified, promptly notify the consulting party that the FDA did not identify any such safety or regulatory issues that would require further evaluation, and considers the consultation to be complete, thereby providing affirmation of the safety of the foods reviewed.

#### 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 or a food produced from, containing, or consisting of such a plant unless: (1) FDA has notified the entity seeking evaluation of food from the genetically engineered plant in writing under FDA's 1992 policy statement 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 food from 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 testing, such as regulated field trials, or development activities, such as multiplication of seed. 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.

The Committee recognizes that the petition process established by APHIS for genetically engineered plants under the Coordinated Framework and the Plant Protection Act provides developers with the national clearance they need to commercialize their genetically engineered crops. It also provides farmers with confirmation that genetically engineered crops are as safe to grow as non-genetically engineered crops and gives them clarity with respect to the crops they can legally grow. The Committee further recognizes that the consultation process administered by FDA is an important step in obtaining national clearance to commercialize the crop from which genetically engineered foods are derived in conjunction with the petition process administered by the Secretary of Agriculture. The Committee intends that the notification and public disclosure process created by this Act will further the objectives of the existing processes already in place at APHIS and FDA.

Nothing in section 461(b)(1) 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 that may be introduced into commerce in accordance with section 461(a), the petitions to 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.

Congress intends that the provision of a public registry listing each nonregulated genetically engineered plant that has been cleared for introduction into commerce for use or application in food will further the goal of increased regulatory transparency set

by this Congress and recently identified by the Office of Science and Technology Policy in its July 2, 2015 Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture.

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 or application in food of genetically engineered plants that is not identical to the requirements 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 FFDCA 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 and 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.



The Committee recognizes that the development of valuable new breeding techniques is ongoing in both the public and private sectors and intends to exercise appropriate oversight to ensure that the regulation, if any, of products developed using these techniques is commensurate with any potential risks.

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 “Co-ordinated 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).

The Committee intends that implementation of Section 115 will ensure that the Secretary of Agriculture and the Secretary of Health and Human Services are provided with an opportunity to encourage and promote further innovation using new breeding technologies. The Committee further recognizes that the smooth movement of food and feed crops and other agricultural products into, out of, or within the United States is vital to the United States economy and should be facilitated to the greatest extent possible.

## 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.

The Committee intends this legislation to address the desires of some consumers to know, via food product labeling, whether they are purchasing or consuming food produced with or without genetic engineering. Some states and localities have attempted to mandate such labeling, creating the potential for a patchwork of regulatory approaches and increased costs of food for consumers and a substantial adverse economic effect on interstate commerce.

The Committee recognizes that the interests of consumers are protected and advanced when consumers have access to truthful and non-misleading food product information, and that the FDA has consistently found no basis to require special labeling for food produced using genetic engineering. The Committee further recognizes that food should be labeled in a way that is meaningful, accurate, and not deceptive or confusing to consumers.

A covered product is defined under this section as including a raw or processed agricultural product. The use of “processed” in the definition is intended to apply to any food that contains an ingredient derived from an agricultural product, regardless of the level of the ingredient in the product. Highly processed foods that contain even small amounts of ingredients derived from agricultural products would be considered a “processed” agricultural product under this definition. In addition, “covered products” are defined to

include any other foods as defined by Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA) that are not derived from agricultural products, and seed or other propagative material.

Section 201 requires the Secretary to implement the 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 in accordance with the standards established under the certification program. The Committee supports the creation of a single, unified food labeling standard for the presence or absence of genetically engineered plants in food. The Committee intends for the program created in Section 201 to provide the sole standard by which all food producers, processors and handlers may make claims regarding the use of genetic engineering in the production and processing of food, including claims for foods that fall within the definition of raw or processed agricultural products and for those foods that do not, as well as for seeds.

*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. The Committee expects the Secretary to establish the requirements and procedures that the Sec-

retary deems necessary to carry out the certification program such that entities seeking to make claims under section 291B or 291C receive the requisite certification.

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 entities that want to participate in the voluntary program for selling or labeling of 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) 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.

The legislation requires the Secretary to establish national standards for labeling non-genetically engineered food. In the case of covered products consumed by or derived from livestock, the Committee intends that a covered product will not be labeled as a covered product produced without the use of genetic engineering unless livestock, feed, feed ingredients, feed additives (including pharmaceuticals) and any other products consumed by livestock are produced without the use of products derived from genetic engineering. Additionally, the Committee fully intends that products used in the processing of covered agriculture products derived from livestock are produced without the use of products derived from genetic engineering. Exceptions to this provision include those items found on the National List established under Section 2118 of the Organic Foods Production Act of 1990 (7 U.S.C. 6517).

*AMA Sec. 291C. National standards for labeling genetically engineered food*

Subsection (a) establishes the standards for entities that want to participate in the voluntary program for selling or 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. The Committee intends for persons to be able to disclose voluntarily that the products they develop or sell have been developed with the use of genetic engineering and to do so without regard to whether such persons elect to participate in the certification program under section 291C. As an example, seed companies that otherwise comply with the Federal Seed Act requirements that set accurate labeling and purity standards for seed in commerce would not be prohibited from disclosing the manner in which those

seeds were developed to growers who intend to plant those seeds, as is standard practice today.

*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 person covered 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, after notice and opportunity to be heard, is found to have knowingly sold or labeled 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 is found, after notice and an opportunity to be heard, to have carried out any of the following activities, the person, 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 with or 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 this 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 plant material due to the inadvertent presence of such material, 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 covered products intended for consumption by non-food animals, to 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) to provide a process for requesting and granting exemptions under conditions established by the Secretary.

The Committee recognizes that cats and dogs rely on pet food as their primary source of nutrition, and that pet food manufacturers are required by law to include certain vitamins, minerals, amino acids, and fatty acids in their formulations to provide pets with a complete and balanced diet. This requirement exists without regard to the availability of these essential ingredients from any one specific source. The Committee expects that the Secretary, in promulgating regulations to carry out the amendments made by section 201, will ensure that such regulations strictly provide for animal well-being. Such regulations should authorize the use of alternative sources, as needed, for securing the essential vitamins, minerals and micronutrients. In providing for consistency between the NOP and the non-genetically engineered labeling program, the Secretary is expected to provide a process for requesting and granting exemptions from the requirements of subtitle E of the Agricultural Marketing Act of 1946, without penalty to pet food manufacturers who choose to sell or label covered products as produced without the use of genetic engineering under the provisions of proposed Section

291B of the AMA. The Committee also expects that such regulations promulgated by the Secretary will apply the same principles to food for other non-food animals.

*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 continuing in effect, as to any covered products in interstate commerce, any requirement for the labeling of a covered product indicating the product as 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, except that such State (or political subdivision thereof) may establish either of the following voluntary 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.

The Committee recognizes the hardship the food industry would face if each state were to adopt a different standard or separate requirements for labeling whether or not a covered product contains a genetically engineered plant. Section 203 is intended to give preemptive effect to the single national standard for such labeling established by USDA. No state or political subdivision could create a different standard for the voluntary labeling of foods that have or have not been developed through genetic engineering. In addition to creating a single standard for voluntary claims regarding the use of genetic engineering, Section 203 also is intended to preempt any state laws, such as those in place in Vermont, Connecticut, and Maine, that would mandate the labeling of foods that contain genetically engineered plants. These state laws as written today would be in conflict with the national standard because they are creating state requirements for covered products that are not identical to the federal standard. States that want to establish their own programs for the labeling of whether a food has or has not been produced with genetic engineering would be allowed to do so provided the state program (1) is voluntary, (2) is accredited by the Secretary, and (3) is identical to the standards established by the Secretary.

*Sec. 204. Applicability*

Subsection (a) states that a voluntary 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. The Committee intends that covered products labeled with voluntary claims regarding genetic engineering should have a reasonable opportunity to clear the channels of trade prior to any changes made necessary in order to meet the national labeling standards established under this subtitle.

Subsection (b) states that if a covered product is produced by a farm or handling operation certified 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.

## COMMITTEE CONSIDERATION

### I. HEARINGS

On June 25, 2015, the Subcommittee on Biotechnology, Horticulture, and Research held a public hearing to review USDA marketing programs.

Members of the Subcommittee heard testimony and discussed programs that allow the Agricultural Marketing Service to help producers and processors address consumer demand through development of voluntary and unique marketing claims. During the hearing, the following witness testified on matters included in H.R. 1599:

- Mr. Craig Morris, Deputy Administrator, Livestock Poultry and Seed Program, Agricultural Marketing Service, USDA, Washington, D.C.

### II. FULL COMMITTEE

The Committee on Agriculture met, pursuant to notice, with a quorum present, on July 14, 2015, to consider H.R. 1599, the Safe and Accurate Food Labeling Act of 2015.

H.R. 1599 was placed before the Committee for consideration. Without objection, a first reading of the bill was waived and it was open for amendment at any point. Mr. Davis was recognized to offer an Amendment in the Nature of a Substitute to H.R. 1599. Without objection, Davis's Amendment in Nature of a Substitute was considered as original text for purposes of amendment.

Chairman Conaway, Mr. Peterson, and Mr. Davis were recognized for statements. There being no other amendments, Mr. Peterson was recognized to offer a motion that the Amendment in the Nature of a Substitute to H.R. 1599 be approved. The Amendment in the Nature of a Substitute was adopted by a voice vote. Mr. Peterson was then recognized to offer a motion that the bill H.R. 1599 be reported, as amended, favorably to the House with recommendation that it do pass. The motion was subsequently approved by voice vote.

At the conclusion of the meeting, Chairman Conaway advised Members that pursuant to the rules of the House of Representatives Members had until July 16, 2015, to file any supplemental, minority, additional, or dissenting views with the Committee.

Without objection, staff was given permission to make any necessary clerical, technical or conforming changes to reflect the intent of the Committee. Chairman Conaway thanked all the Members and adjourned the meeting.

### COMMITTEE VOTES

In compliance with clause 3(b) of rule XIII of the House of Representatives, H.R. 1599 was reported by voice vote with a majority quorum present. There was no request for a recorded vote.

#### COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee on Agriculture's oversight findings and recommendations are reflected in the body of this report.

#### BUDGET ACT COMPLIANCE (SECTIONS 308, 402, AND 423)

The provisions of clause 3(c)(2) of rule XIII of the Rules of the House of Representatives and section 308(a)(1) of the Congressional Budget Act of 1974 (relating to estimates of new budget authority, new spending authority, new credit authority, or increased or decreased revenues or tax expenditures) are not considered applicable. The estimate and comparison required to be prepared by the Director of the Congressional Budget Office under clause 3(c)(3) of rule XIII of the Rules of the House of Representatives and sections 402 and 423 of the Congressional Budget Act of 1974 were not received by the Committee prior to the filing of this report.

#### PERFORMANCE GOALS AND OBJECTIVES

With respect to the requirement of clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of this legislation are to provide for a consistent, uniform, national standard for voluntary food marketing claims related to the use or non-use of genetic engineering. This free market alternative to a 50-State patchwork of labeling requirements will allow consumers access to meaningful information, create market opportunities for those on the agricultural production and food processing side, and will facilitate future innovation.

#### COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee estimates that this bill would have no significant net effect on direct spending or revenues in this fiscal year or in each of the five fiscal years following this fiscal year. The Committee may revise this statement when the requested Congressional Budget Office cost estimate is received.

#### ADVISORY COMMITTEE STATEMENT

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

#### APPLICABILITY TO THE LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act (Public Law 104-1).

#### FEDERAL MANDATES STATEMENT

The Committee adopted as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act (Public Law 104-4).

EARMARK STATEMENT REQUIRED BY CLAUSE 9 OF RULE XXI OF THE  
RULES OF HOUSE OF REPRESENTATIVES

H.R. 1599 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(e), 9(f), or 9(g) of rule XXI of the Rules of the House Representatives.

DUPLICATION OF FEDERAL PROGRAMS

This bill does not establish or reauthorize a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111-139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that H.R. 1599 specifically directs USDA to conduct two rule making proceedings within the meaning of 5 U.S.C. 551.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

**FEDERAL FOOD, DRUG, AND COSMETIC ACT**

\* \* \* \* \*

CHAPTER IV—FOOD

\* \* \* \* \*

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2).

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(3) a food that is pasteurized unless—

(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation promulgated under this Act; or

(B)(i) such food has been subjected to a safe process or treatment that—

(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;

(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

(ii) at least 120 days have passed after the date of receipt of such notification by the Secretary without the Secretary making a determination that the process or treatment involved has not been shown to meet the requirements of subclauses (I) through (III) of clause (i).

For purposes of paragraph (3), a determination by the Secretary that a process or treatment has not been shown to meet the requirements of subclauses (I) through (III) of subparagraph (B)(i) shall constitute final agency action under such subclauses.

(i) Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or

more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 721(c) unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(l) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical, except that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721.

(n) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(q)(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories—

(i) derived from any source, and

(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this Act before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

(2)(A) If the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.

(B) If the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

(3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

(4)(A) The Secretary shall provide for furnishing the nutrition information required by subparagraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by clause (B) or by issuing regulations that are mandatory as provided by clause (D).

(B)(i) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990, the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in subparagraphs (1) and (2). Such guidelines shall take into account the actions taken by food retailers during such 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply—

(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and

(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

(ii) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subclause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.

(C)(i) Upon the expiration of 30 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990, the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under clause (A). Such report shall include a determination of whether there is substantial compliance with the guidelines.

(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subclause (i) every two years.

(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under clause (A), the Secretary shall at the time such determination is made issue proposed regulations requiring that any person who offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by subparagraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.

(ii) Regulations issued under subclause (i) may require that the nutrition information required by subparagraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by subparagraphs (1) and (2).

(iii) Regulations issued under subclause (i) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for



sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.

(E) For purposes of this subparagraph, the term “fish” includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—

(i) except as provided in clause (H)(ii)(III), which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

(ii) except as provided in clause (H)(ii)(III), which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,

(iii) which is an infant formula subject to section 412,

(iv) which is a medical food as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)), or

(v) which is described in section 405(2).

(B) Subparagraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such subparagraphs is impracticable because the package of such food is too small to comply with the requirements of such subparagraphs and if the label of such food does not contain any nutrition information.

(C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

(D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than \$500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than \$50,000, the requirements of subparagraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

(E)(i) During the 12-month period for which an exemption from subparagraphs (1) and (2) is claimed pursuant to this subclause, the requirements of such subparagraphs shall not apply to any food product if—

(I) the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r),

(II) the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 100 full-time equivalent employees,

(III) such person provided the notice described in subclause (iii), and

(IV) in the case of a food product which was sold in the 12-month period preceding the period for which an exemption was claimed, fewer than 100,000 units of such product were sold in the United States during such preceding period, or in the case of a food product which was not sold in the 12-month period preceding the period for which such exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which such exemption is claimed.

(ii) During the 12-month period after the applicable date referred to in this sentence, the requirements of subparagraphs (1) and (2) shall not apply to any food product which was first introduced into interstate commerce before May 8, 1994, if the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r), if such person provided the notice described in subclause (iii), and if—

(I) during the 12-month period preceding May 8, 1994, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 600,000 units of such product were sold in the United States,

(II) during the 12-month period preceding May 8, 1995, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full-time equivalent employees and fewer than 400,000 units of such product were sold in the United States, or

(III) during the 12-month period preceding May 8, 1996, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 200 full-time equivalent employees and fewer than 200,000 units of such product were sold in the United States.

(iii) The notice referred to in subclauses (i) and (ii) shall be given to the Secretary prior to the beginning of the period during which the exemption under subclause (i) or (ii) is to be in effect, shall state that the person claiming such exemption for a food product has complied with the applicable requirements of subclause (i) or (ii), and shall—

(I) state the average number of full-time equivalent employees such person employed during the 12 months preceding the date such person claims such exemption,

(II) state the approximate number of units the person claiming the exemption sold in the United States,

(III) if the exemption is claimed for a food product which was sold in the 12-month period preceding the period for which the

exemption was claimed, state the approximate number of units of such product which were sold in the United States during such preceding period, and, if the exemption is claimed for a food product which was not sold in such preceding period, state the number of units of such product which such person reasonably anticipates will be sold in the United States during the period for which the exemption was claimed, and

(IV) contain such information as the Secretary may require to verify the information required by the preceding provisions of this subclause if the Secretary has questioned the validity of such information.

If a person is not an importer, has fewer than 10 full-time equivalent employees, and sells fewer than 10,000 units of any food product in any year, such person is not required to file a notice for such product under this subclause for such year.

(iv) In the case of a person who claimed an exemption under subclause (i) or (ii), if, during the period of such exemption, the number of full-time equivalent employees of such person exceeds the number in such subclause or if the number of food products sold in the United States exceeds the number in such subclause, such exemption shall extend to the expiration of 18 months after the date the number of full-time equivalent employees or food products sold exceeded the applicable number.

(v) For any food product first introduced into interstate commerce after May 8, 2002, the Secretary may by regulation lower the employee or units of food products requirement of subclause (i) if the Secretary determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to such lower requirement.

(vi) For purposes of subclauses (i), (ii), (iii), (iv), and (v)—

(I) the term “unit” means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers,

(II) the term “food product” means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and which has similar preparation methods, and

(III) the term “person” in the case of a corporation includes all domestic and foreign affiliates of the corporation.

(F) A dietary supplement product (including a food to which section 411 applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that—

(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.

(G) Subparagraphs (1), (2), (3), and (4) shall not apply to food which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

(H) RESTAURANTS, RETAIL FOOD ESTABLISHMENTS, AND VENDING MACHINES.—

(i) GENERAL REQUIREMENTS FOR RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS.—Except for food described in subclause (vii), in the case of food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items, the restaurant or similar retail food establishment shall disclose the information described in subclauses (ii) and (iii).

(ii) INFORMATION REQUIRED TO BE DISCLOSED BY RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—Except as provided in subclause (vii), the restaurant or similar retail food establishment shall disclose in a clear and conspicuous manner—

(I)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu listing the item for sale, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu and designed to enable the public to understand, in the context of a total daily diet, the significance of the caloric information that is provided on the menu;

(II)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu board, including a drive-through menu board, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu board, designed to enable the public to understand, in the context of a total daily diet, the significance of the nutrition information that is provided on the menu board;

(III) in a written form, available on the premises of the restaurant or similar retail establishment and to the consumer upon request, the nutrition information required under clauses (C) and (D) of subparagraph (1); and

(IV) on the menu or menu board, a prominent, clear, and conspicuous statement regarding the availability of the information described in item (III).

(iii) SELF-SERVICE FOOD AND FOOD ON DISPLAY.—Except as provided in subclause (vii), in the case of food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers, a restaurant or similar retail food establishment shall place adjacent to each food offered a sign that lists calories per displayed food item or per serving.

(iv) REASONABLE BASIS.—For the purposes of this clause, a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of title 21, Code of Federal Regulations (or any successor regulation) or in a related guidance of the Food and Drug Administration.

(v) MENU VARIABILITY AND COMBINATION MEALS.—The Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children's combination meals, through means determined by the Secretary, including ranges, averages, or other methods.

(vi) ADDITIONAL INFORMATION.—If the Secretary determines that a nutrient, other than a nutrient required under subclause (ii)(III), should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, disclosure of such nutrient in the written form required under subclause (ii)(III).

(vii) NONAPPLICABILITY TO CERTAIN FOOD.—

(I) IN GENERAL.—Subclauses (i) through (vi) do not apply to—

(aa) items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use);

(bb) daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; or

(cc) such other food that is part of a customary market test appearing on the menu for less than 90 days, under terms and conditions established by the Secretary.

(II) WRITTEN FORMS.—Subparagraph (5)(C) shall apply to any regulations promulgated under subclauses (ii)(III) and (vi).

(viii) VENDING MACHINES.—

(I) IN GENERAL.—In the case of an article of food sold from a vending machine that—

(aa) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and

(bb) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines,

the vending machine operator shall provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.

(ix) VOLUNTARY PROVISION OF NUTRITION INFORMATION.—

(I) IN GENERAL.—An authorized official of any restaurant or similar retail food establishment or vending machine operator not subject to the requirements of this clause may elect to be subject to the requirements of such clause, by registering biannually the name and address of such restaurant or similar retail food establishment or vending machine operator with the Secretary, as specified by the Secretary by regulation.

(II) REGISTRATION.—Within 120 days of enactment of this clause, the Secretary shall publish a notice in the Federal Register specifying the terms and conditions for implementation of item (I), pending promulgation of regulations.

(III) RULE OF CONSTRUCTION.—Nothing in this subclause shall be construed to authorize the Secretary to require an application, review, or licensing process for any entity to register with the Secretary, as described in such item.

(x) REGULATIONS.—

(I) PROPOSED REGULATION.—Not later than 1 year after the date of enactment of this clause, the Secretary shall promulgate proposed regulations to carry out this clause.

(II) CONTENTS.—In promulgating regulations, the Secretary shall—

(aa) consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines; and

(bb) specify the format and manner of the nutrient content disclosure requirements under this subclause.

(III) REPORTING.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a quarterly report that describes the Secretary's progress toward promulgating final regulations under this subparagraph.

(xi) DEFINITION.—In this clause, the term “menu” or “menu board” means the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection.

(r)(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or

labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)—

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless—

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food,

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless—

(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and a requirement that the statement disclose that cholesterol is not usually present in the food, and

(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,

(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the

label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: "See nutrition information for \_\_\_\_\_ content." The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.

(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

(D) Subparagraph (2) does not apply to a claim described in subparagraph (1)(A) which uses the term "diet" and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use of the term "diet" was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to paragraph (a).

(E) Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;



(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(H) A claim submitted under the requirements of clause (G) may be made until—

(i) such time as the Secretary issues a regulation—

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.

(3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made—

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and

(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available sci-

entific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(ii) A regulation described in subclause (i) shall describe—

(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health-related condition, and

(II) the significance of each such nutrient in affecting such disease or health-related condition.

(iii) A regulation described in subclause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(D) A claim submitted under the requirements of clause (C) may be made until—

(i) such time as the Secretary issues a regulation under the standard in clause (B)(i)—

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary denies the petition or the petition is deemed to be denied, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision. If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be con-

sidered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this paragraph and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This paragraph does not apply to infant formulas subject to section 412(h) and medical foods as defined in section 5(b) of the Orphan Drug Act.

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 401 shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”.

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

(i) enable consumers to develop and maintain healthy dietary practices;

(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.

(s) If—

(1) it is a dietary supplement; and

(2)(A) the label or labeling of the supplement fails to list—

(i) the name of each ingredient of the supplement that is described in section 201(ff); and

(ii)(I) the quantity of each such ingredient; or

(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to identify the product by using the term “dietary supplement”, which term may be modified with the name of such an ingredient;

(C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

(D) the supplement—

(i) is covered by the specifications of an official compendium;

(ii) is represented as conforming to the specifications of an official compendium; and

(iii) fails to so conform; or

(E) the supplement—

(i) is not covered by the specifications of an official compendium; and

(ii)(I) fails to have the identity and strength that the supplement is represented to have; or

(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.

A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.

(t) If it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae.

(u) If it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus *Panax*.

(v) If—

(1) it fails to bear a label required by the Secretary under section 801(n)(1) (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) upon or after notifying the owner or consignee involved that the label is required under section 801, the Secretary informs the owner or consignee that the food presents such a threat.

(w)(1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either—

(A) the word “Contains”, followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under subsections (g) and (i); or

(B) the common or usual name of the major food allergen in the list of ingredients required under subsections (g) and (i) is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when—

(i) the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived; or

(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen under section 201(qq)(2)(A) or (B).

(2) As used in this subsection, the term “name of the food source from which the major food allergen is derived” means the name described in section 201(qq)(1); provided that in the case of a tree nut, fish, or Crustacean shellfish, the term “name of the food source from which the major food allergen is derived” means the name of the specific type of nut or species of fish or Crustacean shellfish.

(3) The information required under this subsection may appear in labeling in lieu of appearing on the label only if the Secretary finds that such other labeling is sufficient to protect the public health. A finding by the Secretary under this paragraph (including any change in an earlier finding under this paragraph) is effective upon publication in the Federal Register as a notice.

(4) Notwithstanding subsection (g), (i), or (k), or any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection.

(5) The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of paragraph (1), or eliminate either the requirement of subparagraph (A) or the requirements of subparagraph (B) of paragraph (1), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A)

or the requirements of subparagraph (B) is necessary to protect the public health.

(6)(A) Any person may petition the Secretary to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection.

(B) The Secretary shall approve or deny such petition within 180 days of receipt of the petition or the petition shall be deemed denied, unless an extension of time is mutually agreed upon by the Secretary and the petitioner.

(C) The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

(D) A determination regarding a petition under this paragraph shall constitute final agency action.

(E) The Secretary shall promptly post to a public site all petitions received under this paragraph within 14 days of receipt and the Secretary shall promptly post the Secretary's response to each.

(7)(A) A person need not file a petition under paragraph (6) to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection, if the person files with the Secretary a notification containing—

(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or

(ii) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409.

(B) The food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this paragraph, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergenic response that poses a risk to human health.

(C) The Secretary shall promptly post to a public site all notifications received under this subparagraph within 14 days of receipt and promptly post any objections thereto by the Secretary.

(x) Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.

(y) If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes a domestic address or domestic phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplement.

(2)(1) *If its labeling contains an express or implied claim that the food is “natural” unless the claim is made in accordance with subparagraph (2).*

(2) *A claim described in subparagraph (1) may be made only if the claim uses terms that have been defined by, and the food meets the requirements that have been established in, regulations promulgated to carry out this paragraph.*

(3) *Notwithstanding subparagraph (2), prior to the finalization of regulations to carry out this paragraph, the use of any claim that a food is “natural” shall be allowed if consistent with the Secretary’s existing policy for such claims.*

(4) *In promulgating regulations to carry out this paragraph, the Secretary shall differentiate between food for human consumption and food intended for consumption by animals other than humans.*

(5) *For purposes of subparagraph (1), a natural claim includes the use of—*

(A) *the terms “natural”, “100% natural”, “naturally grown”, “all natural”, and “made with natural ingredients”; and*

(B) *any other terms specified by the Secretary.*

SEC. 403A. (a) Except as provided in subsection (b), 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—

(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g), except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 401 and 403(g),

(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), 403(i)(2), 403(w), or 403(x) that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(c) and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(h)(1) and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q), except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 403(q)(5)(H)(ix), **[or]**

(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food



that is not identical to the requirement of section 403(r), except a requirement respecting a claim made in the label or labeling of food which is exempt under section 403(r)(5)(B) **[.]**,

(6) any requirement for the labeling of food of the type required by section 403(z) that is not identical to the requirement of such section.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a).

\* \* \* \* \*

**SEC. 424. FOOD DERIVED FROM NEW PLANT VARIETIES.**

(a) *IN GENERAL.*—The Secretary shall continue to administer the consultation process established under the Food and Drug Administration’s policy statement entitled “Statement of Policy: Food Derived from New Plant Varieties” published in the Federal Register on May 29, 1992 (57 Fed. Reg. 22,984).

(b) *DETERMINATION OF MATERIAL DIFFERENCE BETWEEN FOOD FROM GENETICALLY ENGINEERED PLANTS AND COMPARABLE FOODS.*—

(1) *IN GENERAL.*—For purposes of subsection (a), the use of genetic engineering 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.

(2) *LABELING REQUIRED.*—The Secretary 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 determines that—

(A) 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

(B) the disclosure of such material difference 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 in any particular.

\* \* \* \* \*



## PLANT PROTECTION ACT

## TITLE II—AGRICULTURAL ASSISTANCE

\* \* \* \* \*

## SUBTITLE E—NUTRITION PROGRAMS

\* \* \* \* \*

***Subtitle F—Coordination of Food Safety  
and Agriculture Programs*****SEC. 461. NOTIFICATION RELATING TO CERTAIN GENETICALLY ENGINEERED PLANTS.**

(a) *IN GENERAL.*—Subject to subsection (b), it shall be unlawful to introduce or deliver for introduction into interstate commerce 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 unless—

(1)(A) the Secretary of Health and Human Services notified the entity seeking evaluation of a food produced from, containing, or consisting of the genetically engineered plant in writing that the Secretary of Health and Human Services, in evaluating the food from the genetically engineered plant through the consultation process referred to in section 424(a) of the Federal Food, Drug, and Cosmetic Act, has no objections to the entity's determination that food produced from, containing, or consisting of the genetically engineered plant that is the subject of the notification is as safe for use by humans or animals, as applicable, as one or more comparable foods; and

(B) the entity seeking evaluation of a food produced from, containing, or consisting of the genetically engineered plant submits to the Secretary of Agriculture the notification of the finding of the Secretary of Health and Human Services under subparagraph (A); or

(2) before the date of the enactment of the Safe and Accurate Food Labeling Act of 2015, the Secretary of Health and Human Services—

(A) considered the consultation process referred to in section 424(a) of the Federal Food, Drug, and Cosmetic Act with respect to such genetically engineered plant to be complete;

(B) notified the consulting party in writing that all questions with respect to the safety of food produced from, containing, or consisting of the genetically engineered plant have been resolved; and

(C) published such notification on the public Internet website of the Food and Drug Administration.

(b) *EXCEPTIONS.*— Notwithstanding subsection (a), this section does not apply with respect to the introduction or delivery for introduction into interstate commerce of a genetically engineered plant—

(1) for the purpose of research or development testing, including—

(A) testing conducted to generate data and information that could be used in a submission to the Secretary under this title or other regulatory submission; or

(B) research involving multiplication of seed or hybrid and variety development conducted before submitting a notification under subsection (a)(1)(B);

(2) solely because a processing aid or enzyme produced from the genetically engineered plant is intended to be used to produce food; or

(3) solely because the genetically engineered plant is used as a nutrient source for microorganisms.

(c) **RULE OF CONSTRUCTION.**—Nothing in subsection (b)(1) may be construed as authorizing the introduction or delivery for introduction 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.

(d) **PUBLIC DISCLOSURE.**—

(1) **IN GENERAL.**—Subject to paragraph (2), the Secretary of Agriculture shall publish on the public Internet website of the Department of Agriculture, and update as necessary, a registry that includes—

(A) a list of each nonregulated genetically engineered plant intended for a use or application in food that may be introduced or delivered for introduction in interstate commerce, in accordance with subsection (a);

(B) the petitions submitted to, and determinations made by, the Secretary of Agriculture with respect to such a plant; and

(C) the notifications of findings issued by the Secretary of Health and Human Services with respect to such a plant or the use or application of such a plant in food.

(2) **TRADE SECRETS AND CONFIDENTIAL INFORMATION.**—Notwithstanding paragraph (1), nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to the documents and information referred to in subparagraphs (A) through (C) of paragraph (1).

(e) **IMPORTED FOOD.**—In the case of food imported into the United States that is food produced from, containing, or consisting of a plant that meets the definition of 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), the provisions of this section shall apply to such food in the same manner and to the same extent as such provisions apply to a food that is not so imported.

**SEC. 462. DEFINITIONS.**

In this subtitle:

(1) **FOOD.**—The term “food” has the meaning given such term in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)).

(2) *NONREGULATED GENETICALLY ENGINEERED PLANT.*—The term “nonregulated genetically engineered plant” means a genetically engineered plant—

(A) for which the Secretary of Agriculture has approved a petition under section 340.6 of title 7, Code of Federal Regulations (or any successor regulations), for a determination that the genetically engineered plant should not be regulated under this Act; or

(B) that—  
(i) is not subject to regulation as a plant pest under this Act;  
(ii) contains genetic material from a different species; and  
(iii) has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.

\* \* \* \* \*

**AGRICULTURAL MARKETING ACT OF 1946**

**TITLE II**

\* \* \* \* \*

**Subtitle D—Country of Origin Labeling**

\* \* \* \* \*

**Subtitle E—Genetic Engineering Certification**

**SEC. 291. DEFINITIONS.**

*In this subtitle:*

(1) The term “certifying agent” means the chief executive officer of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official, and 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, the labeling of which may indicate whether the product is produced with or without the use of genetic engineering.

(2) The term “covered product” means—

(A) an 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 (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act) not derived from an agricultural product; and

(C) seed or other propagative material.

(3) The term “genetically engineered plant” refers to a plant or plant product (as those terms are defined in section 403 of the Plant Protection Act (7 U.S.C. 7702)), if—

(A) it contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (DNA) techniques; and

(B) the modification could not otherwise be obtained using conventional breeding techniques.

(4) The term “comparable food” means, with respect to a covered product produced from, containing, or consisting of a genetically engineered plant—

(A) the parental variety of the plant;

(B) another commonly consumed variety of the plant; or

(C) a commonly consumed covered product with properties comparable to the covered product produced from, containing, or consisting of the plant that is a genetically engineered plant.

(5) The term “handle” means to sell, process or package covered products.

(6) The term “producer” means a person who engages in the business of growing or producing covered products.

(7) The term “Secretary” means the Secretary of Agriculture, acting through the Agricultural Marketing Service.

**SEC. 291A. NATIONAL GENETICALLY ENGINEERED FOOD CERTIFICATION PROGRAM.**

(a) *IN GENERAL.*—The Secretary shall establish a voluntary genetically engineered food certification program for covered products with respect to the use of genetic engineering in the production of such products, as provided for in this subtitle. The Secretary shall establish the requirements and procedures as the Secretary determines are necessary to carry out such program.

(b) *CONSULTATION.*—In developing the program under subsection (a), the Secretary shall consult with such other parties as are necessary to develop such program.

(c) *CERTIFICATION.*—The Secretary shall implement the program established under subsection (a) through certifying agents. Such certifying agents may certify that covered products were or were not produced with the use of genetic engineering or a genetically engineered plant, in accordance with this subtitle.

(d) *SEAL.*—The Secretary shall 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.

**SEC. 291B. NATIONAL STANDARDS FOR LABELING NONGENETICALLY ENGINEERED FOOD.**

(a) *IN GENERAL.*—To be sold or labeled as a covered product produced without the use of genetic engineering—

(1) the covered product shall—

(A) be subject to supply chain process controls that address—

(i) the producer planting seed that is not genetically engineered;

(ii) the producer keeping the crop separated during growth, harvesting, storage, and transportation; and

(iii) 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*

*(B) be produced and handled in compliance with a nongenetically engineered food plan developed and approved in accordance with subsection (c);*

*(2) in the case of a covered product derived from livestock that is marketed in the United States for human consumption, the covered product and the livestock, products consumed by such livestock, and products used in processing the products consumed by such livestock shall be produced without the use of products derived from genetic engineering; and*

*(3) labeling or advertising material on, or in conjunction with, such covered product shall not suggest either expressly or by implication that covered products developed without the use of genetic engineering are safer or of higher quality than covered products produced from, containing, or consisting of a genetically engineered plant.*

*(b) EXCEPTIONS.—A covered product shall not be considered as not meeting the criteria specified in subsection (a) solely because the covered product—*

*(1) is produced with a genetically engineered microorganism or a processing aid or enzyme;*

*(2) is 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).*

*(c) NONGENETICALLY ENGINEERED FOOD PLAN.—*

*(1) IN GENERAL.—A producer or handler seeking certification under this section shall submit a nongenetically engineered food plan to the certifying agent and such plan shall be reviewed by the certifying agent who shall determine if such plan meets the requirements of this section.*

*(2) CONTENTS.—A nongenetically engineered food plan shall contain a description of—*

*(A) the procedures that will be followed to assure compliance with this section;*

*(B) a description of the monitoring records that will be maintained; and*

*(C) any corrective actions that will be implemented in the event there is a deviation from the plan.*

*(3) AVAILABILITY.—The nongenetically engineered food plan and the records maintained under the plan shall be available for review and copying by the Secretary or a certifying agent.*

**SEC. 291C. NATIONAL STANDARDS FOR LABELING GENETICALLY ENGINEERED FOOD.**

*(a) IN GENERAL.—To be sold or labeled as a covered product produced with the use of genetic engineering—*

*(1) the covered product shall be produced and handled in compliance with a genetically engineered food plan developed and approved in accordance with subsection (b); and*

*(2) the labeling of or advertising material on, or in conjunction with, such covered product shall—*

(A) not expressly or impliedly claim that a covered product developed with the use of genetic engineering is safer or of higher quality solely because the covered product is a product developed with the use of genetic engineering;

(B) not make any claims that are false or misleading; and

(C) contain such information as the Secretary considers appropriate.

(b) **GENETICALLY ENGINEERED FOOD PLAN.**—

(1) **IN GENERAL.**—A producer or handler seeking certification under this section shall submit a genetically engineered food plan to the certifying agent and such plan shall be reviewed by the certifying agent who shall determine if such plan meets the requirements of this section.

(2) **CONTENTS.**—A genetically engineered food plan shall contain a description of—

(A) the procedures that will be followed to assure compliance with this section;

(B) a description of the monitoring records that will be maintained; and

(C) any corrective actions that will be implemented in the event there is a deviation from the plan.

(3) **AVAILABILITY.**—The genetically engineered food plan and the records maintained under the plan shall be available for review and copying by the Secretary or a certifying agent.

(c) **PROHIBITION AGAINST RESTRICTING CERTAIN DISCLOSURES.**—With respect to a covered product that otherwise meets the criteria specified in subsection (a), the Secretary may not prevent a person—

(1) from disclosing voluntarily on the labeling of such a covered product developed 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 in the labeling, that a covered product was developed with the use of genetic engineering.

**SEC. 291D. IMPORTED PRODUCTS.**

Imported covered products may be sold or labeled as produced with or without the use of genetic engineering if the Secretary determines that such products have been produced and handled under a genetic engineering certification program that provides safeguards and guidelines governing the production and handling of such products that are at least equivalent to the requirements of this subtitle.

**SEC. 291E. ACCREDITATION PROGRAM.**

(a) **IN GENERAL.**—The Secretary shall establish and implement a program to accredit a governing State official, and any private person, that meets the requirements of this section as a certifying agent for the purpose of certifying a covered product as having been produced with or without the use of genetic engineering or a genetically engineered plant, in accordance with this subtitle.

(b) **REQUIREMENTS.**—To be accredited as a certifying agent under this section, a governing State official or private person shall—

(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.

(c) *DURATION OF ACCREDITATION.*—An accreditation made under this section shall be for a period of not to exceed 5 years, as determined appropriate by the Secretary, and may be renewed.

(d) *COORDINATION WITH EXISTING ORGANIC PROGRAM ACCREDITATION.*—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) shall be deemed to be accredited to certify covered products under this subtitle.

**SEC. 291F. RECORDKEEPING, INVESTIGATIONS, AND ENFORCEMENT.**

(a) *RECORDKEEPING.*—

(1) *IN GENERAL.*—Except as otherwise provided in this title, 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 shall—

(A) maintain records in a manner prescribed by the Secretary; and

(B) make available to the Secretary, on request by the Secretary, all records associated with the covered product.

(2) *CERTIFYING AGENTS.*—

(A) *IN GENERAL.*—A certifying agent shall—

(i) 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

(ii) make available to the Secretary, on request by the Secretary, all records associated with such activities.

(B) *TRANSFERENCE OF RECORDS.*—If a private person that was certified under this subtitle is dissolved or loses accreditation, all records and copies of records concerning the activities of the person under this subtitle shall be transferred to the Secretary.

(b) *INVESTIGATIONS.*—

(1) *IN GENERAL.*—The Secretary may take such investigative actions as the Secretary considers to be necessary—

(A) to verify the accuracy of any information reported or made available under this subtitle; and

(B) to determine whether a person covered by this subtitle has committed a violation of any provision of this subtitle, including an order or regulation promulgated by the Secretary pursuant to this subtitle.

(2) *SPECIFIC INVESTIGATIVE POWERS.*—In carrying out this subtitle, the Secretary may—

(A) administer oaths and affirmations;

(B) subpoena witnesses;

(C) compel attendance of witnesses;

(D) take evidence; and



(E) require the production of any records required to be maintained under this subtitle that are relevant to an investigation.

(c) VIOLATIONS OF SUBTITLE.—

(1) UNLAWFUL ACT.—Any person covered by this subtitle who, after notice and an opportunity to be heard, has been found by the Secretary to have failed or refused to provide accurate information (including a delay in the timely delivery of such information) required by the Secretary under this subtitle, shall be subject to a civil penalty of not more than \$10,000.

(2) MISUSE OF LABEL.—

(A) IN GENERAL.—Any person who knowingly sells or labels 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, except in accordance with this subtitle, shall be subject to a civil penalty of not more than \$10,000.

(B) CONTINUING VIOLATION.—Each day during which a violation described in subparagraph (A) occurs shall be considered to be a separate violation.

(3) INELIGIBILITY.—

(A) IN GENERAL.—Except as provided in subparagraph (C), any person that carries out an activity described in subparagraph (B), after notice and an opportunity to be heard, shall 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.

(B) DESCRIPTION OF ACTIVITIES.—An activity referred to in subparagraph (A) is—

(i) making a false statement;

(ii) a violation described in paragraph (2)(A);

(iii) attempting to have a label indicating that a covered product has 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 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

(iv) otherwise violating the purposes of the genetically engineered food certification program established under section 291A, as determined by the Secretary.

(C) WAIVER.—Notwithstanding subparagraph (A), the Secretary may modify or waive a period of ineligibility under this paragraph if the Secretary determines that the modification or waiver is in the best interests of the genetically engineered food certification program established under section 291A.

(4) REPORTING OF VIOLATIONS.—A certifying agent shall immediately report any violation of this subtitle to the Secretary.

(5) CEASE-AND-DESIST ORDERS.—

(A) IN GENERAL.—The Secretary may, after providing notice and an opportunity to be heard, 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.

(B) *FINAL AND CONCLUSIVE.*—The order of the Secretary imposing a cease-and-desist order under this paragraph shall be final and conclusive unless the affected person files an appeal from the Secretary's order with the appropriate district court of the United States not later than 30 days after the date of the issuance of the order.

(6) *VIOLATIONS BY CERTIFYING AGENT.*—A certifying agent that is a private person that violates the provisions of this subtitle or falsely or negligently 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, shall, after notice and an opportunity to be heard—

(A) lose accreditation as a certifying agent under this subtitle; and

(B) be ineligible to be accredited as a certifying agent under this subtitle for a period of not less than 3 years, beginning on the date of the determination.

(7) *SUSPENSION.*—

(A) *IN GENERAL.*—The Secretary may, after first providing the certifying agent notice and an opportunity to be heard, suspend the accreditation of the certifying agent for a period specified in subparagraph (B) for a violation of this subtitle.

(B) *PERIOD OF SUSPENSION.*—The period of a suspension under subparagraph (A) shall terminate on the date the Secretary makes a final determination with respect to the violation that is the subject of the suspension.

(8) *ENFORCEMENT BY ATTORNEY GENERAL.*—On request of the Secretary, the Attorney General may bring a civil action against a person in a district court of the United States to enforce this subtitle or a requirement or regulation prescribed, or an order issued, under this subtitle. The action may be brought in the judicial district in which the person does business or in which the violation occurred.

**SEC. 291G. AUTHORIZATION OF APPROPRIATIONS; FEES.**

(a) *AUTHORIZATION OF APPROPRIATIONS.*—There are authorized to be appropriated to establish the genetically engineered food program under section 291A, \$2,000,000, to remain available until expended.

(b) *FEES.*—

(1) *IN GENERAL.*—Upon establishment of the genetically engineered food certification program under section 291A, the Secretary shall establish by notice, charge, and collect fees to cover the estimated costs to the Secretary of carrying out this subtitle.

(2) *AVAILABILITY.*—Fees collected under paragraph (1) shall be deposited into a fund in the Treasury of the United States and shall remain available until expended, without further appropriation, to carry out this subtitle.

\* \* \* \* \*

FRED UPTON, MICHIGAN  
CHAIRMAN

COMMITTEE CORRESPONDENCE

FRANK PALLONE, JR., NEW JERSEY  
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

July 15, 2015

The Honorable Michael K. Conaway  
Chairman  
Committee on Agriculture  
1301 Longworth House Office Building  
Washington, D.C. 20515

Dear Chairman Conaway:

I write in regard to H.R. 1599, Safe and Accurate Food Labeling Act of 2015, which was ordered reported by the Committee on Agriculture on July 14, 2015. As you are aware, the bill also was referred to the Committee on Energy and Commerce. I wanted to notify you that the Committee on Energy and Commerce will forgo action on H.R. 1599 so that it may proceed expeditiously to the House floor for consideration.

This is done with the understanding that the Committee on Energy and Commerce's jurisdictional interests over this and similar legislation are in no way diminished or altered. In addition, the Committee reserves the right to seek conferees on H.R. 1599 and requests your support when such a request is made.

I would appreciate your response confirming this understanding with respect to H.R. 1599 and ask that a copy of our exchange of letters on this matter be included in the Congressional Record during consideration of the bill on the House floor.

Sincerely,



Fred Upton  
Chairman

K MICHAEL CONAWAY TEXAS  
 CHAIRMAN  
 HANCOY NEUBERGER TEXAS  
 VICE CHAIRMAN  
 BOB GIBBS OHIO  
 AUSTIN SCOTT GEORGIA  
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 DAN NEWHOUSE WASHINGTON  
 TRENT KELLY MISSISSIPPI

**U.S. House of Representatives**  
**Committee on Agriculture**  
 Room 1301, Longworth House Office Building  
 Washington, DC 20515-6001  
 (202) 225-2171

June 15, 2015

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SCOTT C. GRAMES  
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 ROBERT L. LARREW  
 MINORITY STAFF DIRECTOR

The Honorable Fred Upton  
 Chairman, Committee on Energy and Commerce  
 2125 Rayburn House Office Building  
 Washington, D.C. 20515

Dear Chairman Upton:

Thank you for your letter regarding H.R. 1599, "Safe and Accurate Food Labeling Act of 2015." I appreciate your support in bringing this legislation before the House of Representatives, and accordingly, understand that the Committee on Energy and Commerce will forego action on the bill.

The Committee on Agriculture concurs in the mutual understanding that by foregoing consideration of the bill at this time, the Committee on Energy and Commerce does not waive any jurisdiction over the subject matter contained in this bill or similar legislation in the future. In addition, should a conference on this bill be necessary, I would support your request to have the Committee on the Energy and Commerce represented on the conference committee.

I will insert copies of this exchange in the *Congressional Record* during Floor consideration. I appreciate your cooperation regarding this legislation and look forward to continuing to work the Committee on Energy and Commerce as this bill moves through the legislative process.

Sincerely,

  
 K. Michael Conaway  
 Chairman

cc: The Honorable Frank Pallone, Jr., Ranking Member, Committee on Energy and Commerce  
 The Honorable Collin Peterson, Ranking Member, Committee on Agriculture  
 The Honorable John Boehner, Speaker  
 Mr. Thomas J. Wickham Jr., Parliamentarian

## DISSENTING VIEWS

Recent polling shows that nine out of ten Americans want the right to know whether their food has been produced with genetically modified food ingredients. Vermont, Connecticut and Maine have acted to give consumers the right to know what is in their food and how it is grown.

H.R. 1599 would preempt states from labeling GMO foods and would invalidate existing state laws.

H.R. 1599 would make it virtually impossible for the Food and Drug Administration to craft a national mandatory GMO labeling system. It would codify the existing voluntary non-GMO labeling policy that causes confusion among consumers.

H.R. 1599 also would allow “natural” claims on foods with GMOs, which adds to consumer confusion.

Consumers have the right to know what is in their food and how it is grown. H.R. 1599 makes it more difficult for consumers to know that information.

JAMES P. MCGOVERN.  
ANN McLANE KUSTER.

