114TH CONGRESS
1ST SESSION

H. R. 1599

[Report No. 114–208, Part I]

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.

IN THE HOUSE OF REPRESENTATIVES

MARCH 25, 2015

Mr. POMPEO (for himself, Mr. BUTTERFIELD, Mr. DAVID SCOTT of Georgia, Mr. ASHFORD, Mrs. KIRKPATRICK, Ms. ADAMS, Ms. PLASKETT, Mr. HASTINGS, Mr. SCHRADER, Mr. WHITFIELD, Mrs. ELLMERS of North Carolina, Mr. COLLINS of New York, Mrs. WAGNER, Mr. CRAMER, Mr. VALADAO, Mr. NEWHOUSE, Mr. NUNES, and Mr. BLUM) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

JULY 16, 2015

Additional sponsors: Mr. LONG, Mr. HUELSKAMP, Mr. LUETKEMEYER, Mr. DESJARLAIS, Mr. PERRY, Mr. SIMPSON, Mr. SMITH of Nebraska, Mr. YOUNG of Iowa, Mr. CHABOT, Mrs. LAWRENCE, Mr. LAMBORN, Mr. FLEISCHMANN, Mr. BYRNE, Mr. ZINKE, Mr. GRAVES of Missouri, Mr. SHIMKUS, Mr. AMODEI, Mr. THOMPSON of Mississippi, Mr. GROTHMAN, Mr. ROONEY of Florida, Mr. CLEAVER, Mr. MESSER, Mr. JONES, Mr. ROKITA, Mr. GUTHRIE, Mr. RIBBLE, Mr. FINCHER, Mr. COSTA, Mr. POE of Texas, Mr. ROSS, Mr. TIBERI, Mr. MACARTHUR, Mr. WENSTRUP, Mr. JOHNSON of Ohio, Mr. COLLINS of Georgia, Mr. YOUNG of Indiana, Mr. BARR, Mr. CARTER of Georgia, Mr. MARINO, Mr. HOLDING, Mr. HARRIS, Mr. KNIGHT, Mr. RENACCI, Mr. WESTERMAN, Mr. THOMPSON of Pennsylvania, Mr. DENT, Mr. BRIDENSTINE, Mr. MULVANEY, Mrs. HARTZLER, Ms. MICHELLE LUJAN GRISHAM of New Mexico, Mr. NORCROSS, Mr. FRANKS of Arizona, Mr. WOODALL, Mr. PITTENGER, Mr. ABRAHAM, Mr. STIVERS, Mr. JORDAN, Mr. BUCK, Mr. BUCSHON, Mr. PETERSON, Mr. CONAWAY, Mr. CRAWFORD, Mr. RODNEY DAVIS of Illinois, Mr. MOOLENAAR, Mr. ROUZER, Mr. BOST, Mr. ROGERS of Alabama, Mr. GOODLATTE, Mr. NEUGEBAUER, Mr. GIBBS, Mr. EMMER of

Minnesota, Mr. LUCAS, Mr. KELLY of Mississippi, Mr. BENISHEK, Mr. AUSTIN SCOTT of Georgia, Mr. LAMALFA, Mr. YOHO, Mrs. WALORSKI, Mr. ALLEN, Mrs. NOEM, Mr. KINZINGER of Illinois, Mr. GOSAR, Mr. HURT of Virginia, Mr. BROOKS of Alabama, Mr. STUTZMAN, Mr. SCHWEIKERT, Mr. SHUSTER, Mr. DENHAM, and Mrs. MILLER of Michigan

JULY 16, 2015

Reported from the Committee on Agriculture with an amendment and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on March 25, 2015]

A BILL

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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. 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 Ad-

ministration 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 geneti-

cally 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 suc-

cessor 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 prod-

uct 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 cov-

ered 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 NON-GENETICALLY 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 regula-

tions 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.

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