AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 1599
OFFERED BY M__.

Strike all after the enacting clause and insert the following:

1 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. Food safety affirmation.

TITLE I—GENETICALLY ENGINEERED PLANTS INTENDED FOR A FOOD USE OR APPLICATION

Subtitle A—Food and Drug Administration
Sec. 101. Consultation process.
Sec. 102. Misbranding.
Sec. 103. Preemption.

Subtitle B—Department of Agriculture
Sec. 111. Regulation.
Sec. 112. Regulations.
Sec. 113. Preemption.
Sec. 114. Rule of construction.

TITLE II—GENETIC ENGINEERING CERTIFICATION

Sec. 201. Genetic engineering certification.
Sec. 203. Preemption.
SEC. 2. FOOD SAFETY AFFIRMATION.

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 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—GENETICALLY ENGINEERED PLANTS INTENDED FOR A FOOD USE OR APPLICATION

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 Vari-

“(b) **Determination of Material Difference Between Food from Genetically Engineered Plants and Comparable Marketed Foods.**—For purposes of subsection (a)—

“(1) 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 marketed food; and

“(2) the Secretary may specify labeling that would adequately inform consumers of such material difference if the Secretary determines that—

“(A) there is a material difference between a food produced from, containing, or consisting of a genetically engineered plant and its comparable marketed food that—

“(i) significantly alters the characteristics of the food so produced, including the functional or compositional characteristics, such that the common or usual name no longer adequately describes the food;
“(ii) results in a significantly different nutritional property in the food so produced; or

“(iii) results in the food so produced containing an allergen that consumers would not expect to be present based on the name of the food; and

“(B) disclosure of such material difference is necessary to protect health and safety or to prevent the label or labeling of the food so produced from being false or misleading.”.

SEC. 102. MISBRANDING.

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) If it bears labeling indicating that genetic engineering was or was not used in the production of the food, except in compliance with sections 291B and 291C of the Agricultural Marketing Act of 1946.”.

SEC. 103. 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 at the end and inserting “; or”; and

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

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

Subtitle B—Department of Agriculture

SEC. 111. REGULATION.

(a) DEFINITIONS.—Section 403 of the Plant Protection Act (7 U.S.C. 7702) is amended—

(1) by redesignating paragraphs (5) through (20) as paragraphs (6) through (21), respectively;

(2) by inserting after paragraph (4) the following new paragraph:

“(5) 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)).”;

(3) by redesignating paragraphs (11) through (21) (as redesignated by paragraph (1)) as paragraphs (12) through (22), respectively; and

(4) by inserting after paragraph (9) the following new paragraph:
“(10) NONREGULATED GENETICALLY ENGINEERED PLANT.—The term ‘nonregulated genetically engineered plant’ means a genetically engineered plant (as defined in section 291 of the Agricultural Marketing Act of 1946) for which the Secretary of Agriculture has—

“(A) approved a petition under section 340.6 of title 7, Code of Federal Regulations (as in effect on June 1, 2015), for a determination that the genetically engineered plant is not a plant pest; or

“(B) has otherwise determined that such plant is not subject to regulation as a plant pest under this Act, including a determination made by the Secretary on or after the date of enactment of the Safe and Accurate Food Labeling Act of 2015.”.

(b) COORDINATION OF FOOD SAFETY AND AGRICULTURE PROGRAMS.—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.—It shall be unlawful to introduce or deliver for introduction into interstate commerce a non-regulated genetically engineered plant or a food produced from, containing, or consisting of a genetically engineered plant for a food use or application unless—

“(1)(A) the Secretary of Health and Human Services notified the developer of the genetically engineered plant in writing that the Secretary of Health and Human Services has no objections to the developer’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 marketed foods; and

“(B) the developer of the genetically engineered plant submits to the Secretary of Agriculture—

“(i) the notification of the finding of the Secretary of Health and Human Services under subparagraph (A); and
“(ii) any documentation the Secretary of Health and Human Services issues to the developer with respect to such finding; or

“(2)(A) the Secretary of Health and Human Services evaluated food produced from, containing, or consisting of the genetically engineered plant pursuant to the consultation process referred to in section 424(a) of the Federal Food, Drug, and Cosmetic Act; and

“(B) the Secretary of Health and Human Services informed the developer of the genetically engineered plant that all questions with respect to the safety of the genetically engineered plant have been resolved.

“(b) EXCEPTIONS.—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 notification submitted under subsection (a)(2)(A) or other regulatory submission;

“(B) research involving multiplication of seed or hybrid and variety development con-
ducted before submitting a notification to the Secretary of Agriculture under subsection (a)(2)(A); or

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

“(c) RULE OF CONSTRUCTION.—Nothing in subsection (b)(2)(B) may be construed as authorizing the introduction or delivery for introduction into interstate commerce a nonregulated genetically engineered plant or a food produced from, containing, or consisting of a genetically engineered plant for a food use or application.

“(d) PUBLIC DISCLOSURE.—

“(1) IN GENERAL.—Subject to paragraph (2), not later than 180 days after the date of the enactment of the Safe and Accurate Food Labeling Act of 2015, the Secretary of Agriculture shall publish on the public Website of the Department of Agriculture, and update as necessary, a registry that contains—

“(A) a list of each nonregulated genetically engineered plant intended for a food use or application 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 plants; and

“(C) the submissions made to, and notifications of findings issued by, the Secretary of Health and Human Services, with respect to such plants.

“(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 consultation with individuals and organizations prior to the date of enactment of this section.”.

SEC. 112. REGULATIONS.

Not later than one year after the date of the enactment of this Act, the Secretary of Agriculture shall promulgate 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 the use of genetically engineered plants for a food use or application 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).
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 any person (including a private entity) who is accredited by the Secretary as a certifying agent for the purpose of certifying a covered agricultural product as a product to be labeled to indicate whether the product is produced with or without the use of genetic engineering.

“(2) The term ‘covered agricultural product’ means any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption and seed or other propagative material.

“(3) The term ‘genetically engineered plant’ refers to a plant (as defined in section 403 of the
Plant Protection Act (7 U.S.C. 7702)) or a seed, a fruit, or any other part thereof, 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 marketed food’ means with respect to an agricultural 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 plant variety from which is derived a commonly consumed agricultural product with properties comparable to the agricultural 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 agricultural products.

“(6) The term ‘producer’ means a person who engages in the business of growing or producing covered agricultural 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 genetically engineered food certification program for covered agricultural 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 agricultural products were or were not produced with the use of genetic engineering, in accordance with this subtitle.
SEC. 291B. NATIONAL STANDARDS FOR LABELING NON-GENETICALLY ENGINEERED FOOD.

(a) In General.—To be sold or labeled as a covered agricultural product produced without the use of genetic engineering—

(1) the agricultural product shall—

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

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

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

(iii) persons in direct contact with such crop or agricultural products derived from such crop during transportation, storage, or processing keeping the agricultural product separated from other agricultural products that are or are derived from genetically engineered plants; and

(B) be produced and handled in compliance with a non-genetically engineered food plan developed and approved in accordance with subsection (e); and

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

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

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

“(2) is derived from microorganisms that consumed a nutrient source produced from, containing, or consisting of a genetically engineered plant.

“(c) Non-genetically Engineered Food Plan.—

“(1) In General.—A producer or handler seeking certification under this section shall submit a non-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 non-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 non-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.

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

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

“(1) the covered agricultural 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 such covered agricultural product shall—

“(A) not expressly or impliedly claim that a covered agricultural product developed with the use of genetic engineering is safer or of
higher quality solely because the covered agricultural 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) 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 agricultural 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 agricultural 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 com-
parable marketed 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 agricultural product was developed
with the use of genetic engineering.

“SEC. 291D. IMPORTED PRODUCTS.

“Imported agricultural products may be sold or la-
beled as produced with or without the use of genetic engi-
neering if the Secretary determines that such products
have been produced and handled under a genetic engineer-
ing 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. 202. REGULATIONS.

(a) IN GENERAL.—Not later than one year after the
date of the enactment of this Act, the Secretary of Agri-
culture shall, in consultation with stakeholders as the Sec-
retary determines appropriate, promulgate final regula-
tions to carry out the amendments made by section 201.
(b) CONSIDERATIONS.—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 non-genetically engineered covered agricultural products containing a genetically engineered plant due to the inadvertent presence of such plant;

(2) take into account other voluntary labeling programs administered by the Secretary, and, to the greatest extent practicable, establish consistency among such programs and the certification program established under subtitle E of the Agricultural Marketing Act of 1946 (as added by section 201); and

(3) with respect to regulations for covered agricultural products intended for consumption by animals other than humans—

(A) 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

(B) provide a process for requesting and granting exemptions under conditions established by the Secretary.
21

SEC. 203. PREEMPTION.

Regardless of whether regulations have been promulgated under section 202, 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 agricultural product in interstate commerce any requirement for the labeling of covered agricultural products of the type described in section 291B or 291C of the Agricultural Marketing Act of 1946 (as added by section 201 of this Act) that is not identical to the requirements of such respective section.