

114TH CONGRESS
1ST SESSION

H. R. 1599

AN ACT

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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

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

4 (b) **TABLE OF CONTENTS.**—The table of contents of
 5 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.

6 **SEC. 2. SAVINGS CLAUSE.**

7 Nothing in this Act (or the amendments made by this
 8 Act) is intended to alter or affect the authorities or regu-
 9 latory programs, policies, and procedures otherwise avail-
 10 able to, or the definitions used by, the Food and Drug
 11 Administration under the Federal Food, Drug, and Cos-
 12 metic Act (21 U.S.C. 301 et seq.) or the Animal and Plant

1 Health Inspection Service under the Plant Protection Act
2 (7 U.S.C. 7701 et seq.), to ensure the safety of the food
3 supply and the protection of plant health.

4 **TITLE I—FOOD SAFETY AFFIR-**
5 **MATION FOR CERTAIN PLANT**
6 **PRODUCTS**

7 **Subtitle A—Food and Drug**
8 **Administration**

9 **SEC. 101. CONSULTATION PROCESS.**

10 Chapter IV of the Federal Food, Drug, and Cosmetic
11 Act is amended by inserting after section 423 of such Act
12 (21 U.S.C. 350l) the following:

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

14 “(a) IN GENERAL.—The Secretary shall continue to
15 administer the consultation process established under the
16 Food and Drug Administration’s policy statement entitled
17 ‘Statement of Policy: Food Derived from New Plant Vari-
18 eties’ published in the Federal Register on May 29, 1992
19 (57 Fed. Reg. 22,984).

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

23 “(1) IN GENERAL.—For purposes of subsection
24 (a), the use of genetic engineering does not, by
25 itself, constitute information that is material for

1 purposes of determining whether there is a dif-
2 ference between a food produced from, containing,
3 or consisting of a genetically engineered plant and a
4 comparable food.

5 “(2) LABELING REQUIRED.—The Secretary
6 may require that the labeling of a food produced
7 from, containing, or consisting of a genetically engi-
8 neered plant contain a statement to adequately in-
9 form consumers of a difference between the food so
10 produced and its comparable food if the Secretary
11 determines that—

12 “(A) there is a material difference in the
13 functional, nutritional, or compositional charac-
14 teristics, allergenicity, or other attributes be-
15 tween the food so produced and its comparable
16 food; and

17 “(B) the disclosure of such material dif-
18 ference is necessary to protect public health and
19 safety or to prevent the label or labeling of the
20 food so produced from being false or misleading
21 in any particular.”.

1 **Subtitle B—Department of**
2 **Agriculture**

3 **SEC. 111. REGULATION.**

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

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

8 **“SEC. 461. NOTIFICATION RELATING TO CERTAIN GENETI-**
9 **CALLY ENGINEERED PLANTS.**

10 “(a) IN GENERAL.—Subject to subsection (b), it shall
11 be unlawful to sell or offer for sale in interstate commerce
12 a nonregulated genetically engineered plant for use or ap-
13 plication in food or a food produced from, containing, or
14 consisting of a nonregulated genetically engineered plant
15 unless—

16 “(1)(A) the Secretary of Health and Human
17 Services notified the entity seeking evaluation of a
18 food produced from, containing, or consisting of the
19 genetically engineered plant in writing that the Sec-
20 retary of Health and Human Services, in evaluating
21 the food from the genetically engineered plant
22 through the consultation process referred to in sec-
23 tion 424(a) of the Federal Food, Drug, and Cos-
24 metic Act, has no objections to the entity’s deter-
25 mination that food produced from, containing, or

1 consisting of the genetically engineered plant that is
2 the subject of the notification is safe for use by hu-
3 mans or animals, as applicable, and lawful under the
4 Federal Food, Drug, and Cosmetic Act; and

5 “(B) the entity seeking evaluation of a food
6 produced from, containing, or consisting of the ge-
7 netically engineered plant submits to the Secretary
8 of Agriculture the notification of the finding of the
9 Secretary of Health and Human Services under sub-
10 paragraph (A); or

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

14 “(A) considered the consultation process
15 referred to in section 424(a) of the Federal
16 Food, Drug, and Cosmetic Act with respect to
17 such genetically engineered plant to be com-
18 plete;

19 “(B) notified the consulting party in writ-
20 ing that all questions with respect to the safety
21 of food produced from, containing, or consisting
22 of the genetically engineered plant have been re-
23 solved; and

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

4 “(b) EXCEPTIONS.—Notwithstanding subsection (a),
5 this section does not apply with respect to the sale or of-
6 fering for sale in interstate commerce of a genetically engi-
7 neered plant—

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

10 “(A) testing conducted to generate data
11 and information that could be used in a submis-
12 sion to the Secretary under this title or other
13 regulatory submission; or

14 “(B) multiplication of seed or hybrid and
15 variety development conducted before submit-
16 ting a notification under subsection (a)(1)(B);

17 “(2) solely because a processing aid or enzyme
18 produced from the genetically engineered plant is in-
19 tended to be used to produce food; or

20 “(3) solely because the genetically engineered
21 plant is used as a nutrient source for microorga-
22 nisms.

23 “(c) RULE OF CONSTRUCTION.—Nothing in sub-
24 section (b)(1) may be construed as authorizing the sale
25 or offering for sale in interstate commerce of a nonregu-

1 lated genetically engineered plant for use or application
2 in food or a food produced from, containing, or consisting
3 of a nonregulated genetically engineered plant.

4 “(d) PUBLIC DISCLOSURE.—

5 “(1) IN GENERAL.—Subject to paragraph (2),
6 the Secretary of Agriculture shall publish on the
7 public Internet website of the Department of Agri-
8 culture, and update as necessary, a registry that in-
9 cludes—

10 “(A) a list of each nonregulated genetically
11 engineered plant intended for a use or applica-
12 tion in food that may be sold or offered for sale
13 in interstate commerce, in accordance with sub-
14 section (a);

15 “(B) the petitions submitted to, and deter-
16 minations made by, the Secretary of Agri-
17 culture with respect to such a plant; and

18 “(C) the notifications of findings issued by
19 the Secretary of Health and Human Services
20 with respect to such a plant or the use or appli-
21 cation of such a plant in food.

22 “(2) TRADE SECRETS AND CONFIDENTIAL IN-
23 FORMATION.—Notwithstanding paragraph (1), noth-
24 ing in this section shall be construed to alter the
25 protections offered by laws, regulations, and policies

1 governing disclosure of confidential commercial or
2 trade secret information, and any other information
3 exempt from disclosure pursuant to section 552(b)
4 of title 5, United States Code, as such provisions
5 would be applied to the documents and information
6 referred to in subparagraphs (A) through (C) of
7 paragraph (1).

8 “(e) IMPORTED FOOD.—In the case of food imported
9 into the United States that is food produced from, con-
10 taining, or consisting of a plant that meets the definition
11 of a nonregulated genetically engineered plant or a plant
12 that, if sold in interstate commerce, would be subject to
13 regulation under part 340 of title 7, Code of Federal Reg-
14 ulations (or any successor regulations), the provisions of
15 this section shall apply to such food in the same manner
16 and to the same extent as such provisions apply to a food
17 that is not so imported.

18 **“SEC. 462. DEFINITIONS.**

19 “In this subtitle:

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

23 “(2) NONREGULATED GENETICALLY ENGI-
24 NEERED PLANT.—The term ‘nonregulated geneti-

1 cally engineered plant’ means a genetically engi-
2 neered plant—

3 “(A) for which the Secretary of Agri-
4 culture has approved a petition under section
5 340.6 of title 7, Code of Federal Regulations
6 (or any successor regulations), for a determina-
7 tion that the genetically engineered plant should
8 not be regulated under this Act; or

9 “(B) that—

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

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

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

17 **SEC. 112. REGULATIONS.**

18 Not later than 1 year after the date of the enactment
19 of this Act, the Secretary of Agriculture shall promulgate
20 interim final regulations to carry out the amendments
21 made by section 111.

22 **SEC. 113. PREEMPTION.**

23 Regardless of whether regulations have been promul-
24 gated under section 112, beginning on the date of the en-
25 actment of this Act, no State or political subdivision of

1 a State may directly or indirectly establish under any au-
2 thority or continue in effect as to any food in interstate
3 commerce any requirement with respect to the sale or of-
4 fering for sale in interstate commerce of a genetically engi-
5 neered plant for use or application in food that is not iden-
6 tical to the requirement of section 461 of the Plant Protec-
7 tion Act (as added by section 111 of this Act).

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

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

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

16 (2) the Secretary of Agriculture to take enforce-
17 ment actions with respect to a violation of the Plant
18 Protection Act (7 U.S.C. 7701 et seq.), including
19 section 411 of such Act (7 U.S.C. 7711).

20 **SEC. 115. IMPLEMENTATION REPORT.**

21 (a) STUDY.—Not later than 1 year after the date of
22 the enactment of this Act, the Secretary of Agriculture
23 and the Secretary of Health and Human Services shall
24 jointly submit to Congress a report evaluating the
25 progress made in the implementation of subtitle F of the

1 Plant Protection Act, as added by section 111. Such re-
2 port shall include—

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

5 (2) an analysis of the extent to which the provi-
6 sions of such subtitle establish an appropriate scope
7 of regulatory oversight for the Animal and Plant
8 Health Inspection Service and the Food and Drug
9 Administration, including their oversight of public
10 research programs; and

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

15 (b) COORDINATION WITH OTHER EFFORTS TO MOD-
16 ERNIZE REGULATION.—The report under subsection (a)
17 shall be prepared, to the greatest extent practicable, in
18 accordance with the process described in the memorandum
19 issued by the Executive Office of the President on July
20 2, 2015, entitled “Modernizing the Regulatory System for
21 Biotechnology Products”, including the directive specified
22 in such memorandum to update the “Coordinated Frame-
23 work for Regulation of Biotechnology” published by the
24 Executive Office of the President, Office of Science and

1 Technology Policy, in the Federal Register on June 26,
2 1986 (51 Fed. Reg. 23302).

3 **TITLE II—GENETIC**
4 **ENGINEERING CERTIFICATION**

5 **SEC. 201. GENETIC ENGINEERING CERTIFICATION.**

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

9 **“Subtitle E—Genetic Engineering**
10 **Certification**

11 **“SEC. 291. DEFINITIONS.**

12 “In this subtitle:

13 “(1) The term ‘certifying agent’ means the
14 chief executive officer of a State or, in the case of
15 a State that provides for the statewide election of an
16 official to be responsible solely for the administra-
17 tion of the agricultural operations of the State, such
18 official, and any person (including a private entity)
19 who is accredited by the Secretary as a certifying
20 agent for the purpose of certifying a covered product
21 as a product, the labeling of which may indicate
22 whether the product is produced with or without the
23 use of genetic engineering.

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

1 “(A) an agricultural product, whether raw
2 or processed (including any product derived
3 from livestock that is marketed in the United
4 States for consumption by humans or other ani-
5 mals);

6 “(B) any other food (as defined in section
7 201 of the Federal Food, Drug, and Cosmetic
8 Act) not derived from an agricultural product;
9 and

10 “(C) seed or other propagative material.

11 “(3) The term ‘genetically engineered plant’ re-
12 fers to a plant or plant product (as those terms are
13 defined in section 403 of the Plant Protection Act
14 (7 U.S.C. 7702)), if—

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

18 “(B) the modification could not otherwise
19 be obtained using conventional breeding tech-
20 niques.

21 “(4) The term ‘comparable food’ means, with
22 respect to a covered product produced from, con-
23 taining, or consisting of a genetically engineered
24 plant—

25 “(A) the parental variety of the plant;

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

3 “(C) a commonly consumed covered prod-
4 uct with properties comparable to the covered
5 product produced from, containing, or con-
6 sisting of the genetically engineered plant.

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

9 “(6) The term ‘producer’ means a person who
10 engages in the business of growing or producing cov-
11 ered products.

12 “(7) The term ‘Secretary’ means the Secretary
13 of Agriculture, acting through the Agricultural Mar-
14 keting Service.

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

17 “(a) IN GENERAL.—The Secretary shall establish a
18 voluntary genetically engineered food certification pro-
19 gram for covered products with respect to the use of ge-
20 netic engineering in the production of such products, as
21 provided for in this subtitle. The Secretary shall establish
22 the requirements and procedures as the Secretary deter-
23 mines are necessary to carry out such program.

24 “(b) CONSULTATION.—In developing the program
25 under subsection (a), the Secretary shall consult with such

1 other parties as are necessary to develop such program
2 to ensure that producers or handlers seeking to make
3 claims under section 291B or 291C are certified to make
4 such claims.

5 “(c) CERTIFICATION.—The Secretary shall imple-
6 ment the program established under subsection (a)
7 through certifying agents. Such certifying agents may cer-
8 tify that covered products were or were not produced with
9 the use of genetic engineering or a genetically engineered
10 plant, in accordance with this subtitle.

11 “(d) SEAL.—The Secretary shall establish a seal to
12 identify covered products in interstate commerce using
13 terminology the Secretary considers appropriate for cov-
14 ered products certified under this title, including termi-
15 nology commonly used in interstate commerce or estab-
16 lished by the Secretary in regulations.

17 **“SEC. 291B. NATIONAL STANDARDS FOR LABELING NON-**
18 **GENETICALLY ENGINEERED FOOD.**

19 “(a) IN GENERAL.—To be sold or labeled as a cov-
20 ered product produced without the use of genetic engineer-
21 ing—

22 “(1) the covered product shall—

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

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

3 “(ii) the producer keeping the crop
4 separated during growth, harvesting, stor-
5 age, and transportation; and

6 “(iii) persons in direct contact with
7 such crop or products derived from such
8 crop during transportation, storage, or
9 processing keeping the product separated
10 from other products that are, or are de-
11 rived from, genetically engineered plants;
12 and

13 “(B) be produced and handled in compli-
14 ance with a nongenetically engineered food plan
15 developed and approved in accordance with sub-
16 section (c);

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

24 “(3) labeling or advertising material on, or in
25 conjunction with, such covered product shall not

1 suggest either expressly or by implication that cov-
2 ered products developed without the use of genetic
3 engineering are safer or of higher quality than cov-
4 ered products produced from, containing, or con-
5 sisting of a genetically engineered plant.

6 “(b) EXCEPTIONS.—A covered product shall not be
7 considered as not meeting the criteria specified in sub-
8 section (a) solely because the covered product—

9 “(1) is manufactured or processed using a ge-
10 netically engineered microorganism or a processing
11 aid or enzyme;

12 “(2) is derived from microorganisms that con-
13 sumed a nutrient source produced from, containing,
14 or consisting of a genetically engineered plant; or

15 “(3) is an approved substance on the National
16 List established under section 2118 of the Organic
17 Foods Production Act of 1990 (7 U.S.C. 6517).

18 “(c) NONGENETICALLY ENGINEERED FOOD PLAN.—

19 “(1) IN GENERAL.—A producer or handler
20 seeking certification under this section shall submit
21 a nongenetically engineered food plan to the certi-
22 fying agent and such plan shall be reviewed by the
23 certifying agent who shall determine if such plan
24 meets the requirements of this section.

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

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

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

7 “(C) any corrective actions that will be im-
8 plemented in the event there is a deviation from
9 the plan.

10 “(3) AVAILABILITY.—The nongenetically engi-
11 neered food plan and the records maintained under
12 the plan shall be available for review and copying by
13 the Secretary or a certifying agent.

14 “(d) TREATMENT OF LIVESTOCK.—In the case of a
15 covered product derived from livestock that is marketed
16 in the United States for human consumption, the covered
17 product shall not be considered to be genetically engi-
18 neered solely because the livestock consumed feed pro-
19 duced from containing, or consisting of a genetically engi-
20 neered plant.

21 **“SEC. 291C. NATIONAL STANDARDS FOR LABELING GENETI-
22 CALLY ENGINEERED FOOD.**

23 “(a) IN GENERAL.—To be sold or labeled as a cov-
24 ered product produced with the use of genetic engineer-
25 ing—

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

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

7 “(A) not expressly or impliedly claim that
8 a covered product developed with the use of ge-
9 netic engineering is safer or of higher quality
10 solely because the covered product is a product
11 developed with the use of genetic engineering;

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

14 “(C) contain such information as the Sec-
15 retary considers appropriate.

16 “(b) GENETICALLY ENGINEERED FOOD PLAN.—

17 “(1) IN GENERAL.—A producer or handler
18 seeking certification under this section shall submit
19 a genetically engineered food plan to the certifying
20 agent and such plan shall be reviewed by the certi-
21 fying agent who shall determine if such plan meets
22 the requirements of this section.

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

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

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

5 “(C) any corrective actions that will be im-
6 plemented in the event there is a deviation from
7 the plan.

8 “(3) AVAILABILITY.—The genetically engi-
9 neered food plan and the records maintained under
10 the plan shall be available for review and copying by
11 the Secretary or a certifying agent.

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

16 “(1) from disclosing voluntarily on the labeling
17 of such a covered product developed with the use of
18 genetic engineering the manner in which the product
19 has been modified to express traits or characteristics
20 that differ from its comparable food; or

21 “(2) from disclosing in advertisements, on the
22 Internet, in response to consumer inquiries, or on
23 other communications, other than in the labeling,
24 that a covered product was developed with the use
25 of genetic engineering.

1 **“SEC. 291D. IMPORTED PRODUCTS.**

2 “Imported covered products may be sold or labeled
3 as produced with or without the use of genetic engineering
4 if the Secretary determines that such products have been
5 produced and handled under a genetic engineering certifi-
6 cation program that provides safeguards and guidelines
7 governing the production and handling of such products
8 that are at least equivalent to the requirements of this
9 subtitle.

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

11 “(a) IN GENERAL.—The Secretary shall establish
12 and implement a program to accredit a governing State
13 official, and any private person, that meets the require-
14 ments of this section as a certifying agent for the purpose
15 of certifying a covered product as having been produced
16 with or without the use of genetic engineering or a geneti-
17 cally engineered plant, in accordance with this subtitle.

18 “(b) REQUIREMENTS.—To be accredited as a certi-
19 fying agent under this section, a governing State official
20 or private person shall—

21 “(1) prepare and submit to the Secretary an
22 application for such accreditation;

23 “(2) have sufficient expertise in agricultural
24 production and handling techniques as determined
25 by the Secretary; and

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

4 “(2) CERTIFYING AGENTS.—

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

7 “(i) maintain all records concerning
8 the activities of the certifying agent with
9 respect to the certification of covered prod-
10 ucts under this subtitle in a manner pre-
11 scribed by the Secretary; and

12 “(ii) make available to the Secretary,
13 on request by the Secretary, all records as-
14 sociated with such activities.

15 “(B) TRANSFERENCE OF RECORDS.—If a
16 private person that was certified under this sub-
17 title is dissolved or loses accreditation, all
18 records and copies of records concerning the ac-
19 tivities of the person under this subtitle shall be
20 transferred to the Secretary.

21 “(b) INVESTIGATIONS.—

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

1 “(A) to verify the accuracy of any informa-
2 tion reported or made available under this sub-
3 title; and

4 “(B) to determine whether a person cov-
5 ered by this subtitle has committed a violation
6 of any provision of this subtitle, including an
7 order or regulation promulgated by the Sec-
8 retary pursuant to this subtitle.

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

11 “(A) administer oaths and affirmations;

12 “(B) subpoena witnesses;

13 “(C) compel attendance of witnesses;

14 “(D) take evidence; and

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

18 “(c) VIOLATIONS OF SUBTITLE.—

19 “(1) FAILURE TO PROVIDE INFORMATION.—

20 Any person covered by this subtitle who, after notice
21 and an opportunity to be heard, has been found by
22 the Secretary to have failed or refused to provide ac-
23 curate information (including a delay in the timely
24 delivery of such information) required by the Sec-

1 retary under this subtitle, shall be assessed a civil
2 penalty of not more than \$10,000.

3 “(2) MISUSE OF LABEL.—

4 “(A) IN GENERAL.—Any person who, after
5 notice and an opportunity to be heard, is found
6 by the Secretary to have knowingly sold or la-
7 beled any covered product as having been pro-
8 duced with or without the use of genetic engi-
9 neering or a genetically engineered plant, except
10 in accordance with this subtitle, shall be as-
11 sessed a civil penalty of not more than \$10,000.

12 “(B) CONTINUING VIOLATION.—Each day
13 during which a violation described in subpara-
14 graph (A) occurs shall be considered to be a
15 separate violation.

16 “(3) INELIGIBILITY.—

17 “(A) IN GENERAL.—Except as provided in
18 subparagraph (C), any person that carries out
19 an activity described in subparagraph (B), after
20 notice and an opportunity to be heard, shall not
21 be eligible, for the 5-year period beginning on
22 the date of the occurrence, to receive a certifi-
23 cation under this subtitle with respect to any
24 covered product.

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

3 “(i) making a false statement;

4 “(ii) a violation described in para-
5 graph (2)(A);

6 “(iii) attempting to have a label indi-
7 cating that a covered product has been
8 produced with or without the use of genetic
9 engineering or a genetically engineered
10 plant affixed to a covered product that a
11 person knows, or should have reason to
12 know, to have been produced in a manner
13 that is not in accordance with this subtitle;
14 or

15 “(iv) otherwise violating the purposes
16 of the genetically engineered food certifi-
17 cation program established under section
18 291A, as determined by the Secretary.

19 “(C) WAIVER.—Notwithstanding subpara-
20 graph (A), the Secretary may modify or waive
21 a period of ineligibility under this paragraph if
22 the Secretary determines that the modification
23 or waiver is in the best interests of the geneti-
24 cally engineered food certification program es-
25 tablished under section 291A.

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

4 “(5) CEASE-AND-DESIST ORDERS.—

5 “(A) IN GENERAL.—The Secretary may,
6 after providing notice and an opportunity to be
7 heard, issue an order, require any person who
8 the Secretary reasonably believes is selling or
9 labeling a covered product in violation of this
10 subtitle to cease and desist from selling or la-
11 beling such covered product as having been pro-
12 duced with or without the use of genetic engi-
13 neering or a genetically engineered plant.

14 “(B) FINAL AND CONCLUSIVE.—The order
15 of the Secretary imposing a cease-and-desist
16 order under this paragraph shall be final and
17 conclusive unless the affected person files an
18 appeal from the Secretary’s order with the ap-
19 propriate district court of the United States not
20 later than 30 days after the date of the
21 issuance of the order.

22 “(6) VIOLATIONS BY CERTIFYING AGENT.—A
23 certifying agent that is a private person that violates
24 the provisions of this subtitle or falsely or neg-
25 ligently certifies any covered product that does not

1 meet the terms and conditions of the genetically en-
2 gineered food certification program established
3 under section 291A, as determined by the Secretary,
4 shall, after notice and an opportunity to be heard—

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

7 “(B) be ineligible to be accredited as a cer-
8 tifying agent under this subtitle for a period of
9 not less than 3 years, beginning on the date of
10 the determination.

11 “(7) SUSPENSION.—

12 “(A) IN GENERAL.—The Secretary may,
13 after first providing the certifying agent notice
14 and an opportunity to be heard, suspend the ac-
15 creditation of the certifying agent for a period
16 specified in subparagraph (B) for a violation of
17 this subtitle.

18 “(B) PERIOD OF SUSPENSION.—The pe-
19 riod of a suspension under subparagraph (A)
20 shall terminate on the date the Secretary makes
21 a final determination with respect to the viola-
22 tion that is the subject of the suspension.

23 “(8) ENFORCEMENT BY ATTORNEY GEN-
24 ERAL.—On request of the Secretary, the Attorney
25 General may bring a civil action against a person in

1 a district court of the United States to enforce this
2 subtitle or a requirement or regulation prescribed, or
3 an order issued, under this subtitle. The action may
4 be brought in the judicial district in which the per-
5 son does business or in which the violation occurred.

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

7 “(a) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated to establish the geneti-
9 cally engineered food certification program under section
10 291A, \$2,000,000, to remain available until expended.

11 “(b) FEES.—

12 “(1) IN GENERAL.—Upon establishment of the
13 genetically engineered food certification program
14 under section 291A, the Secretary shall establish by
15 notice, charge, and collect fees to cover the esti-
16 mated costs to the Secretary of carrying out this
17 subtitle.

18 “(2) AVAILABILITY.—Fees collected under
19 paragraph (1) shall be deposited into a fund in the
20 Treasury of the United States and shall remain
21 available until expended, subject to appropriation, to
22 carry out this subtitle.”.

1 **SEC. 202. REGULATIONS.**

2 In promulgating regulations to carry out the amend-
3 ments made by section 201, the Secretary of Agriculture
4 shall—

5 (1) provide a process to account for certified
6 nongenetically engineered covered products con-
7 taining material from genetically engineered plants
8 due to the inadvertent presence of such material;

9 (2) to the greatest extent practicable, establish
10 consistency between the certification programs es-
11 tablished under subtitle E of the Agricultural Mar-
12 keting Act of 1946 (as added by section 201 of this
13 Act), the organic certification program established
14 under the Organic Foods Production Act of 1990 (7
15 U.S.C. 6501 et seq.), and other voluntary labeling
16 programs administered by the Secretary;

17 (3) with respect to regulations for covered prod-
18 ucts intended for consumption by non-food animals,
19 take into account the inherent differences between
20 food intended for animal and human consumption,
21 including the essential vitamins, minerals, and
22 micronutrients required to be added to animal food
23 to formulate a complete and balanced diet; and

24 (4) provide a process for requesting and grant-
25 ing exemptions from the requirements of subtitle E
26 of the Agricultural Marketing Act of 1946 (as added

1 by section 201 of this Act) under conditions estab-
2 lished by the Secretary.

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

4 (a) **EFFECTIVE DATE.**—Regardless of whether regu-
5 lations have been promulgated under section 202 of this
6 Act, the amendments made by section 201 shall take effect
7 beginning on the date of the enactment of this Act.

8 (b) **PROHIBITIONS AGAINST MANDATORY LABELING**
9 **OF FOOD DEVELOPED USING GENETIC ENGINEERING.**—

10 (1) **IN GENERAL.**—Subject to paragraph (2), no
11 State or political subdivision of a State may directly
12 or indirectly establish under any authority or con-
13 tinue in effect as to any covered product (as defined
14 in section 291 of the Agricultural Marketing Act of
15 1946, as added by section 201 of this Act) in inter-
16 state commerce, any requirement for the labeling of
17 a covered product indicating the product as having
18 been produced from, containing, or consisting of a
19 genetically engineered plant, including any require-
20 ments for claims that a covered product is or con-
21 tains an ingredient that was produced from, con-
22 tains, or consists of a genetically engineered plant.

23 (2) **EXCEPTION.**—Notwithstanding paragraph
24 (1), a State (or a political subdivision thereof) may
25 establish either of the following voluntary programs

1 for the regulation of claims described in such para-
2 graph:

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

6 (B) A program that—

7 (i) is voluntary;

8 (ii) is accredited by the Secretary pur-
9 suant to section 291E of the Agricultural
10 Marketing Act of 1946 (as added by sec-
11 tion 201 of this Act); and

12 (iii) establishes standards that are
13 identical to the standards established
14 under section 291B or 291C of the Agri-
15 cultural Marketing Act of 1946, as appli-
16 cable (as added by section 201 of this Act).

17 (c) **RULE OF CONSTRUCTION.**—For the sole purpose
18 of subsection (b)(1), a covered product derived from live-
19 stock that consumed genetically engineered plants shall be
20 deemed as having been produced from, containing, or con-
21 sisting of a genetically engineered plant.

22 **SEC. 204. APPLICABILITY.**

23 (a) **EXISTING CLAIMS.**—A voluntary claim made with
24 respect to whether a covered product (as defined in section
25 291 of the Agricultural Marketing Act of 1946, as added

1 by section 201 of this Act) was produced with or without
2 the use of genetic engineering or genetically engineered
3 plants before the date of the enactment of this Act—

4 (1) may be made for such a product during the
5 36-month period that begins on the date of the en-
6 actment of this Act; and

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

13 (b) ORGANIC CERTIFICATION.—In the case of a cov-
14 ered product (as defined in section 291 of the Agricultural
15 Marketing Act of 1946, as added by section 201 of this
16 Act) produced by a farm or handling operation that is cer-
17 tified as an organic farm or handling operation under the
18 Organic Foods Production Act of 1990 (7 U.S.C. 6501
19 et seq.), such product is deemed to be certified as a prod-
20 uct produced without the use of genetic engineering under
21 the genetically engineered food certification program es-
22 tablished under section 291A of the Agricultural Mar-
23 keting Act of 1946 (as added by section 201 of this Act).

1 **TITLE III—NATURAL FOODS**

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

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

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

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

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

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

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

1 “(A) the terms ‘natural’, ‘100% natural’, ‘natu-
2 rally grown’, ‘all natural’, and ‘made with natural
3 ingredients’; and

4 “(B) any other terms specified by the Sec-
5 retary.”.

6 **SEC. 302. REGULATIONS.**

7 (a) PROPOSED REGULATIONS.—Not later than 18
8 months after the date of enactment of this Act, the Sec-
9 retary of Health and Human Services shall issue proposed
10 regulations to implement section 403(z) of the Federal
11 Food, Drug, and Cosmetic Act, as added by section 301
12 of this Act.

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

17 **SEC. 303. PREEMPTION.**

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

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

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

24 (3) by inserting after paragraph (5) the fol-
25 lowing:

1 “(6) any requirement for the labeling of food of
2 the type required by section 403(z) that is not iden-
3 tical to the requirement of such section.”.

4 **SEC. 304. EFFECTIVE DATE.**

5 The labeling requirements of section 403(z) of the
6 Federal Food, Drug, and Cosmetic Act, as added by sec-
7 tion 301 of this Act, shall take effect on the effective date
8 of final regulations promulgated under section 302(b) of
9 this Act. The provisions of section 403A(a)(6) of the Fed-
10 eral Food, Drug, and Cosmetic Act, as added by section
11 303 of this Act, take effect on the date of enactment of
12 this Act.

Passed the House of Representatives July 23, 2015.

Attest:

Clerk.

114TH CONGRESS
1ST SESSION

H. R. 1599

AN ACT

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.