

**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.

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.

1 **SEC. 2. SAVINGS CLAUSE.**

2 Nothing in this Act (or the amendments made by this
3 Act) is intended to alter or affect the authorities or regu-
4 latory programs, policies, and procedures otherwise avail-
5 able to, or the definitions used by, the Food and Drug
6 Administration under the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 301 et seq.) or the Animal and Plant
8 Health Inspection Service under the Plant Protection Act
9 (7 U.S.C. 7701 et seq.), to ensure the safety of the food
10 supply and the protection of plant health.

11 **TITLE I—FOOD SAFETY AFFIR-**
12 **MATION FOR CERTAIN PLANT**
13 **PRODUCTS**

14 **Subtitle A—Food and Drug**
15 **Administration**

16 **SEC. 101. CONSULTATION PROCESS.**

17 Chapter IV of the Federal Food, Drug, and Cosmetic
18 Act is amended by inserting after section 423 of such Act
19 (21 U.S.C. 350l) the following:

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

21 “(a) IN GENERAL.—The Secretary shall continue to
22 administer the consultation process established under the
23 Food and Drug Administration’s policy statement entitled
24 ‘Statement of Policy: Food Derived from New Plant Vari-

1 eties' published in the Federal Register on May 29, 1992
2 (57 Fed. Reg. 22,984).

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

6 “(1) IN GENERAL.—For purposes of subsection
7 (a), the use of genetic engineering does not, by
8 itself, constitute information that is material for
9 purposes of determining whether there is a dif-
10 ference between a food produced from, containing,
11 or consisting of a genetically engineered plant and a
12 comparable food.

13 “(2) LABELING REQUIRED.—The Secretary
14 may require that the labeling of a food produced
15 from, containing, or consisting of a genetically engi-
16 neered plant contain a statement to adequately in-
17 form consumers of a difference between the food so
18 produced and its comparable food if the Secretary
19 determines that—

20 “(A) there is a material difference in the
21 functional, nutritional, or compositional charac-
22 teristics, allergenicity, or other attributes be-
23 tween the food so produced and its comparable
24 food; and

1 “(B) the disclosure of such material dif-
2 ference is necessary to protect public health and
3 safety or to prevent the label or labeling of the
4 food so produced from being false or misleading
5 in any particular.”.

6 **Subtitle B—Department of** 7 **Agriculture**

8 **SEC. 111. REGULATION.**

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

11 **“Subtitle F—Coordination of Food** 12 **Safety and Agriculture Programs**

13 **“SEC. 461. NOTIFICATION RELATING TO CERTAIN GENETI-** 14 **CALLY ENGINEERED PLANTS.**

15 “(a) IN GENERAL.—Subject to subsection (b), it shall
16 be unlawful to introduce or deliver for introduction into
17 interstate commerce a nonregulated genetically engineered
18 plant for use or application in food or a food produced
19 from, containing, or consisting of a nonregulated geneti-
20 cally engineered plant unless—

21 “(1)(A) the Secretary of Health and Human
22 Services notified the entity seeking evaluation of a
23 food produced from, containing, or consisting of the
24 genetically engineered plant in writing that the Sec-
25 retary of Health and Human Services, in evaluating

1 the food through the consultation process referred to
2 in section 424(a) of the Federal Food, Drug, and
3 Cosmetic Act, has no objections to the entity's deter-
4 mination that food produced from, containing, or
5 consisting of the genetically engineered plant that is
6 the subject of the notification is as safe for use by
7 humans or animals, as applicable, as one or more
8 comparable foods; and

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

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

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

23 “(B) notified the consulting party in writ-
24 ing that all questions with respect to the safety
25 of food produced from, containing, or consisting

1 of the genetically engineered plant have been re-
2 solved; and

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

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

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

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

16 “(B) research involving multiplication of
17 seed or hybrid and variety development con-
18 ducted before submitting a notification under
19 subsection (a)(1)(B);

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

23 “(3) solely because the genetically engineered
24 plant is used as a nutrient source for microorga-
25 nisms.

1 “(c) RULE OF CONSTRUCTION.—Nothing in sub-
2 section (b)(1) may be construed as authorizing the intro-
3 duction or delivery for introduction into interstate com-
4 merce of a nonregulated genetically engineered plant for
5 use or application in food or a food produced from, con-
6 taining, or consisting of a nonregulated genetically engi-
7 neered plant.

8 “(d) PUBLIC DISCLOSURE.—

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

14 “(A) a list of each nonregulated genetically
15 engineered plant intended for a use or applica-
16 tion in food that may be introduced or delivered
17 for introduction in interstate commerce, in ac-
18 cordance with subsection (a);

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

22 “(C) the notifications of findings issued by
23 the Secretary of Health and Human Services
24 with respect to such a plant or the use or appli-
25 cation of such a plant in food.

1 “(2) TRADE SECRETS AND CONFIDENTIAL IN-
2 FORMATION.—Notwithstanding paragraph (1), noth-
3 ing in this section shall be construed to alter the
4 protections offered by laws, regulations, and policies
5 governing disclosure of confidential commercial or
6 trade secret information, and any other information
7 exempt from disclosure pursuant to section 552(b)
8 of title 5, United States Code, as such provisions
9 would be applied to the documents and information
10 referred to in subparagraphs (A) through (C) of
11 paragraph (1).

12 “(e) IMPORTED FOOD.—In the case of food imported
13 into the United States that is food produced from, con-
14 taining, or consisting of a plant that meets the definition
15 of a nonregulated genetically engineered plant or a plant
16 that, if introduced in interstate commerce, would be sub-
17 ject to regulation under part 340 of title 7, Code of Fed-
18 eral Regulations (or any successor regulations), the provi-
19 sions of this section shall apply to such food in the same
20 manner and to the same extent as such provisions apply
21 to a food that is not so imported.

22 **“SEC. 462. DEFINITIONS.**

23 “In this subtitle:

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

4 “(2) NONREGULATED GENETICALLY ENGI-
5 NEERED PLANT.—The term ‘nonregulated geneti-
6 cally engineered plant’ means a genetically engi-
7 neered plant—

8 “(A) for which the Secretary of Agri-
9 culture has approved a petition under section
10 340.6 of title 7, Code of Federal Regulations
11 (or any successor regulations), for a determina-
12 tion that the genetically engineered plant should
13 not be regulated under this Act; or

14 “(B) that—

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

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

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

22 **SEC. 112. REGULATIONS.**

23 Not later than one year after the date of the enact-
24 ment of this Act, the Secretary of Agriculture shall pro-

1 mulgate interim final regulations to carry out the amend-
2 ments made by section 111.

3 **SEC. 113. PREEMPTION.**

4 Regardless of whether regulations have been promul-
5 gated under section 112, beginning on the date of the en-
6 actment of this Act, no State or political subdivision of
7 a State may directly or indirectly establish under any au-
8 thority or continue in effect as to any food in interstate
9 commerce any requirement with respect to genetically en-
10 gineered plants for use or application in food that is not
11 identical to the requirement of section 461 of the Plant
12 Protection Act (as added by section 111 of this Act).

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

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

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

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

1 **SEC. 115. IMPLEMENTATION REPORT.**

2 (a) STUDY.—Not later than 1 year after the date of
3 the enactment of this Act, the Secretary of Agriculture,
4 in consultation with the Secretary of Health and Human
5 Services, shall submit to Congress a report evaluating the
6 progress made in the implementation of subtitle F of the
7 Plant Protection Act, as added by section 111. Such re-
8 port shall include—

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

11 (2) an analysis of the extent to which the provi-
12 sions of such subtitle establish an appropriate scope
13 of regulatory oversight for the Animal and Plant
14 Health Inspection Service and the Food and Drug
15 Administration, including their oversight of public
16 research programs; and

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

21 (b) COORDINATION WITH OTHER EFFORTS TO MOD-
22 ERNIZE REGULATION.—The report under subsection (a)
23 shall be prepared, to the greatest extent practicable, in
24 accordance with the process described in the memorandum
25 issued by the Executive Office of the President on July
26 2, 2015, entitled “Modernizing the Regulatory System for

1 Biotechnology Products”, including the directive specified
2 in such memorandum to update the “Coordinated Frame-
3 work for Regulation of Biotechnology” published by the
4 Executive Office of the President, Office of Science and
5 Technology Policy, in the Federal Register on June 26,
6 1986 (51 Fed.Reg. 23302).

7 **TITLE II—GENETIC**
8 **ENGINEERING CERTIFICATION**

9 **SEC. 201. GENETIC ENGINEERING CERTIFICATION.**

10 The Agricultural Marketing Act of 1946 (7 U.S.C.
11 1621 et seq.) is amended by adding at the end the fol-
12 lowing new subtitle:

13 **“Subtitle E—Genetic Engineering**
14 **Certification**

15 **“SEC. 291. DEFINITIONS.**

16 “In this subtitle:

17 “(1) The term ‘certifying agent’ means the
18 chief executive officer of a State or, in the case of
19 a State that provides for the statewide election of an
20 official to be responsible solely for the administra-
21 tion of the agricultural operations of the State, such
22 official, and any person (including a private entity)
23 who is accredited by the Secretary as a certifying
24 agent for the purpose of certifying a covered product
25 as a product the labeling of which may indicate

1 whether the product is produced with or without the
2 use of genetic engineering.

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

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

9 “(B) any other food (as defined in section
10 201 of the Federal Food, Drug, and Cosmetic
11 Act) not derived from an agricultural product;
12 and

13 “(C) seed or other propagative material.

14 “(3) The term ‘genetically engineered plant’ re-
15 fers to a plant or plant product (as those terms are
16 defined in section 403 of the Plant Protection Act
17 (7 U.S.C. 7702)), if—

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

21 “(B) the modification could not otherwise
22 be obtained using conventional breeding tech-
23 niques.

24 “(4) The term ‘comparable food’ means, with
25 respect to a covered product produced from, con-

1 taining, or consisting of a genetically engineered
2 plant—

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

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

6 “(C) a commonly consumed covered prod-
7 uct or food with properties comparable to the
8 agricultural product or food produced from,
9 containing, or consisting of the plant that is a
10 genetically engineered plant.

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

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

16 “(7) The term ‘Secretary’ means the Secretary
17 of Agriculture, acting through the Agricultural Mar-
18 keting Service.

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

21 “(a) IN GENERAL.—The Secretary shall establish a
22 genetically engineered food certification program for cov-
23 ered products with respect to the use of genetic engineer-
24 ing in the production of such products, as provided for
25 in this subtitle. The Secretary shall establish the require-

1 ments and procedures as the Secretary determines are
2 necessary to carry out such program.

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

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

12 “(d) SEAL.—The Secretary shall establish a seal to
13 identify covered products in interstate commerce using
14 terminology the Secretary considers appropriate, including
15 terminology commonly used in interstate commerce or es-
16 tablished 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 derived
11 from genetically engineered plants; and

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

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

23 “(3) labeling or advertising material on, or in
24 conjunction with, such covered product shall not
25 suggest either expressly or by implication that cov-

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

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

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

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

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

16 “(c) NONGENETICALLY ENGINEERED FOOD PLAN.—

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

23 “(2) CONTENTS.—A nongenetically engineered
24 food 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 nongenetically 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 **“SEC. 291C. NATIONAL STANDARDS FOR LABELING GENETI-
13 CALLY ENGINEERED FOOD.**

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

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

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

23 “(A) not expressly or impliedly claim that
24 a covered product developed with the use of ge-
25 netic engineering is safer or of higher quality

1 solely because the covered product is a product
2 developed with the use of genetic engineering;

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

5 “(C) contain such information as the Sec-
6 retary considers appropriate.

7 “(b) GENETICALLY ENGINEERED FOOD PLAN.—

8 “(1) IN GENERAL.—A producer or handler
9 seeking certification under this section shall submit
10 a genetically engineered food plan to the certifying
11 agent and such plan shall be reviewed by the certi-
12 fying agent who shall determine if such plan meets
13 the requirements of this section.

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

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

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

20 “(C) any corrective actions that will be im-
21 plemented in the event there is a deviation from
22 the plan.

23 “(3) AVAILABILITY.—The genetically engi-
24 neered food plan and the records maintained under

1 the plan shall be available for review and copying by
2 the Secretary or a certifying agent.

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

7 “(1) from disclosing voluntarily on the labeling
8 of such a covered product developed with the use of
9 genetic engineering the manner in which the product
10 has been modified to express traits or characteristics
11 that differ from its comparable food; or

12 “(2) from disclosing in advertisements, on the
13 Internet, in response to consumer inquiries, or on
14 other communications, other than in the labeling,
15 that a covered product was developed with the use
16 of genetic engineering.

17 **“SEC. 291D. IMPORTED PRODUCTS.**

18 “Imported covered products may be sold or labeled
19 as produced with or without the use of genetic engineering
20 if the Secretary determines that such products have been
21 produced and handled under a genetic engineering certifi-
22 cation program that provides safeguards and guidelines
23 governing the production and handling of such products
24 that are at least equivalent to the requirements of this
25 subtitle.

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

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

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

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

14 “(2) have sufficient expertise in agricultural
15 production and handling techniques as determined
16 by the Secretary; and

17 “(3) comply with the requirements of this sec-
18 tion.

19 “(c) DURATION OF ACCREDITATION.—An accredita-
20 tion made under this section shall be for a period of not
21 to exceed 5 years, as determined appropriate by the Sec-
22 retary, and may be renewed.

23 “(d) COORDINATION WITH EXISTING ORGANIC PRO-
24 GRAM ACCREDITATION.—A governing State official or pri-
25 vate person who is accredited to certify a farm or handling
26 operation as a certified organic farm or handling operation

1 pursuant to section 2115 of the Organic Foods Production
2 Act of 1990 (7 U.S.C. 6415) (and such accreditation is
3 in effect) shall be deemed to be accredited to certify cov-
4 ered products under this subtitle.

5 **“SEC. 291F. RECORDKEEPING, INVESTIGATIONS, AND EN-**
6 **FORCEMENT.**

7 “(a) RECORDKEEPING.—

8 “(1) IN GENERAL.—Except as otherwise pro-
9 vided in this title, each person who sells, labels, or
10 represents any covered product as having been pro-
11 duced without the use of genetic engineering or a ge-
12 netically engineered plant or with the use of genetic
13 engineering or a genetically engineered plant shall—

14 “(A) maintain records in a manner pre-
15 scribed by the Secretary; and

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

19 “(2) CERTIFYING AGENTS.—

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

22 “(i) maintain all records concerning
23 the activities of the certifying agent with
24 respect to the certification of covered prod-

1 ucts under this subtitle in a manner pre-
2 scribed by the Secretary; and

3 “(ii) make available to the Secretary,
4 on request by the Secretary, all records as-
5 sociated with such activities.

6 “(B) TRANSFERENCE OF RECORDS.—If a
7 private person that was certified under this sub-
8 title is dissolved or loses accreditation, all
9 records and copies of records concerning the ac-
10 tivities of the person under this subtitle shall be
11 transferred to the Secretary.

12 “(3) UNLAWFUL ACT.—It shall be unlawful and
13 a violation of this subtitle for any person covered by
14 this subtitle to fail or refuse to provide accurate in-
15 formation (including a delay in the timely delivery of
16 such information) required by the Secretary under
17 this subtitle.

18 “(b) INVESTIGATIONS.—

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

22 “(A) to verify the accuracy of any informa-
23 tion reported or made available under this sub-
24 title; and

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

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

8 “(A) administer oaths and affirmations;

9 “(B) subpoena witnesses;

10 “(C) compel attendance of witnesses;

11 “(D) take evidence; and

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

15 “(c) VIOLATIONS OF SUBTITLE.—

16 “(1) MISUSE OF LABEL.—

17 “(A) IN GENERAL.—Any person who
18 knowingly sells or labels any covered product as
19 having been produced without the use of genetic
20 engineering or a genetically engineered plant or
21 with the use of genetic engineering or a geneti-
22 cally engineered plant, except in accordance
23 with this subtitle, shall be subject to a civil pen-
24 alty of not more than \$10,000.

1 “(B) CONTINUING VIOLATION.—Each day
2 during which a violation described in subpara-
3 graph (A) occurs shall be considered to be a
4 separate violation.

5 “(2) INELIGIBILITY.—

6 “(A) IN GENERAL.—Except as provided in
7 subparagraph (C), any person that carries out
8 an activity described in subparagraph (B), after
9 notice and an opportunity to be heard, shall not
10 be eligible, for the 5-year period beginning on
11 the date of the occurrence, to receive a certifi-
12 cation under this subtitle with respect to any
13 covered product.

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

16 “(i) making a false statement;

17 “(ii) a violation described in para-
18 graph (1)(A);

19 “(iii) attempting to have a label indi-
20 cating that a covered product has been
21 produced without the use of genetic engi-
22 neering or a genetically engineered plant or
23 with the use of genetic engineering or a ge-
24 netically engineered plant affixed to a cov-
25 ered product that a person knows, or

1 should have reason to know, to have been
2 produced in a manner that is not in ac-
3 cordance with this subtitle; or

4 “(iv) otherwise violating the purposes
5 of the genetically engineered food certifi-
6 cation program established under section
7 291A, as determined by the Secretary.

8 “(C) WAIVER.—Notwithstanding subpara-
9 graph (A), the Secretary may modify or waive
10 a period of ineligibility under this paragraph if
11 the Secretary determines that the modification
12 or waiver is in the best interests of the geneti-
13 cally engineered food certification program es-
14 tablished under section 291A.

15 “(3) REPORTING OF VIOLATIONS.—A certifying
16 agent shall immediately report any violation of this
17 subtitle to the Secretary.

18 “(4) CEASE-AND-DESIST ORDERS.—

19 “(A) IN GENERAL.—The Secretary may,
20 after providing notice and an opportunity to be
21 heard, issue an order, requiring any person who
22 the Secretary reasonably believes is selling or
23 labeling a covered product in violation of this
24 subtitle to cease and desist from selling or la-
25 beling such covered product as having been pro-

1 duced without the use of genetic engineering or
2 a genetically engineered plant or as having been
3 produced with the use of genetic engineering or
4 a genetically engineered plant.

5 “(B) FINAL AND CONCLUSIVE.—The order
6 of the Secretary imposing a cease-and-desist
7 order under this paragraph shall be final and
8 conclusive unless the affected person files an
9 appeal from the Secretary’s order with the ap-
10 propriate district court of the United States not
11 later than 30 days after the date of the
12 issuance of the order.

13 “(5) VIOLATIONS BY CERTIFYING AGENT.—A
14 certifying agent that is a private person that violates
15 the provisions of this subtitle or falsely or neg-
16 ligently certifies any covered product that does not
17 meet the terms and conditions of the genetically en-
18 gineered food certification program established
19 under section 291A, as determined by the Secretary,
20 shall, after notice and an opportunity to be heard—

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

23 “(B) be ineligible to be accredited as a cer-
24 tifying agent under this subtitle for a period of

1 not less than 3 years, beginning on the date of
2 the determination.

3 “(6) SUSPENSION.—

4 “(A) IN GENERAL.—The Secretary may,
5 after first providing the certifying agent notice
6 and an opportunity to be heard, suspend the ac-
7 creditation of the certifying agent for a period
8 specified in subparagraph (B) for a violation of
9 this subtitle.

10 “(B) PERIOD OF SUSPENSION.—The pe-
11 riod of a suspension under subparagraph (A)
12 shall terminate on the date the Secretary makes
13 a final determination with respect to the viola-
14 tion that is the subject of the suspension.

15 “(7) ENFORCEMENT BY ATTORNEY GEN-
16 ERAL.—On request of the Secretary, the Attorney
17 General may bring a civil action against a person in
18 a district court of the United States to enforce this
19 subtitle or a requirement or regulation prescribed, or
20 an order issued, under this subtitle. The action may
21 be brought in the judicial district in which the per-
22 son does business or in which the violation occurred.

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

24 “(a) AUTHORIZATION OF APPROPRIATIONS.—There
25 are authorized to be appropriated to establish the geneti-

1 cally engineered food program under section 291A,
2 \$2,000,000, to remain available until expended.

3 “(b) FEES.—

4 “(1) IN GENERAL.—Upon establishment of the
5 genetically engineered food certification program
6 under section 291A, the Secretary shall establish by
7 notice, charge, and collect fees to cover the esti-
8 mated costs to the Secretary of carrying out this
9 subtitle.

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

15 **SEC. 202. REGULATIONS.**

16 In promulgating regulations to carry out the amend-
17 ments made by section 201, the Secretary of Agriculture
18 shall—

19 (1) provide a process to account for certified
20 nongenetically engineered covered products con-
21 taining material from genetically engineered plants
22 due to the inadvertent presence of such material;

23 (2) to the greatest extent practicable, establish
24 consistency between the certification programs es-
25 tablished under subtitle E of the Agricultural Mar-

1 keting Act of 1946 (as added by section 201 of this
2 Act), the organic certification program established
3 under the Organic Foods Production Act of 1990 (7
4 U.S.C. 6501 et seq.), and other voluntary labeling
5 programs administered by the Secretary;

6 (3) with respect to regulations for covered prod-
7 ucts intended for consumption by non-food animals,
8 take into account the inherent differences between
9 food intended for animal and human consumption,
10 including the essential vitamins, minerals, and
11 micronutrients required to be added to animal food
12 to formulate a complete and balanced diet; and

13 (4) provide a process for requesting and grant-
14 ing exemptions from the requirements of subtitle E
15 of the Agricultural Marketing Act of 1946 (as added
16 by section 201 of this Act) under conditions estab-
17 lished by the Secretary.

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

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

23 (b) **PROHIBITIONS AGAINST MANDATORY LABELING**
24 **OF FOOD DEVELOPED USING GENETIC ENGINEERING.**—
25 No State or political subdivision of a State may directly

1 or indirectly establish under any authority or continue in
2 effect as to any covered product (as defined in section 291
3 of the Agricultural Marketing Act of 1946, as added by
4 section 201 of this Act) in interstate commerce, any re-
5 quirement for the labeling of a covered product indicating
6 the product as having been produced from, containing, or
7 consisting of a genetically engineered plant, including any
8 requirements for claims that a covered product is or con-
9 tains an ingredient that was produced from, contains, or
10 consists of a genetically engineered plant unless the State
11 (or a political subdivision thereof) establishes either of the
12 following programs for the regulation of such claims:

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

16 (2) A program that—

17 (A) is voluntary;

18 (B) is accredited by the Secretary pursu-
19 ant to section 291E of the Agricultural Mar-
20 keting Act of 1946 (as added by section 201 of
21 this Act); and

22 (C) establishes standards that are identical
23 to the standards established under section
24 291B or 291C of the Agricultural Marketing

1 Act of 1946, as applicable (as added by section
2 201 of this Act).

3 **SEC. 204. APPLICABILITY.**

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

10 (1) may be made for such a product during the
11 36-month period that begins on the date of the en-
12 actment of this Act; and

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

19 (b) ORGANIC CERTIFICATION.—In the case of a cov-
20 ered product (as defined in section 291 of the Agricultural
21 Marketing Act of 1946, as added by section 201 of this
22 Act) produced by a farm or handling operation that is cer-
23 tified as an organic farm or handling operation under the
24 Organic Foods Production Act of 1990 (7 U.S.C. 6501
25 et seq.), such product is deemed to be certified as a prod-

1 ict produced without the use of genetic engineering under
2 the genetically engineered food certification program es-
3 tablished under section 291A of the Agricultural Mar-
4 keting Act of 1946 (as added by section 201 of this Act).

5 **TITLE III—NATURAL FOODS**

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

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

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

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

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

23 “(4) In promulgating regulations to carry out this
24 paragraph, the Secretary shall differentiate between food

1 for human consumption and food intended for consump-
2 tion by animals other than humans.

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

5 “(A) the terms ‘natural’, ‘100% natural’, ‘natu-
6 rally grown’, ‘all natural’, and ‘made with natural
7 ingredients’; and

8 “(B) any other terms specified by the Sec-
9 retary.”.

10 **SEC. 302. REGULATIONS.**

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

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

21 **SEC. 303. PREEMPTION.**

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

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

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

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

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

8 **SEC. 304. EFFECTIVE DATE.**

9 The labeling requirements of section 403(z) of the
10 Federal Food, Drug, and Cosmetic Act, as added by sec-
11 tion 301 of this Act, shall take effect on the effective date
12 of final regulations promulgated under section 302(b) of
13 this Act. The provisions of section 403A(a)(6) of the Fed-
14 eral Food, Drug, and Cosmetic Act, as added by section
15 303 of this Act, take effect on the date of enactment of
16 this Act.

