

JULY 15, 2015

**RULES COMMITTEE PRINT 114-24**  
**TEXT OF H.R. 1599, THE SAFE AND ACCURATE**  
**FOOD LABELING ACT OF 2015**

**[Showing the text of the bill as ordered reported by the  
Committee on Agriculture.]**

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

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

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

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

24 “(B) notified the consulting party in writ-  
25 ing that all questions with respect to the safety

1 of food produced from, containing, or consisting  
2 of the genetically engineered plant have been re-  
3 solved; and

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

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

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

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

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

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

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

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

11          “(d) PUBLIC DISCLOSURE.—

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

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

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

1           “(C) the notifications of findings issued by  
2           the Secretary of Health and Human Services  
3           with respect to such a plant or the use or appli-  
4           cation of such a plant in food.

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

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



1 **“SEC. 462. DEFINITIONS.**

2 “In this subtitle:

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

6 “(2) **NONREGULATED GENETICALLY ENGI-**  
7 **NEERED PLANT.**—The term ‘nonregulated geneti-

8 cally engineered plant’ means a genetically engi-

9 neered plant—

10 “(A) for which the Secretary of Agri-

11 culture has approved a petition under section

12 340.6 of title 7, Code of Federal Regulations

13 (or any successor regulations), for a determina-

14 tion that the genetically engineered plant should

15 not be regulated under this Act; or

16 “(B) that—

17 “(i) is not subject to regulation as a

18 plant pest under this Act;

19 “(ii) contains genetic material from a

20 different species; and

21 “(iii) has been modified through in

22 vitro recombinant deoxyribonucleic acid

23 (DNA) techniques.”.

24 **SEC. 112. REGULATIONS.**

25 Not later than one year after the date of the enact-

26 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 and the Secretary of Health and Human Services shall  
5 jointly 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 with properties comparable to the covered  
8 product produced from, containing, or con-  
9 sisting of the plant that is a genetically engi-  
10 neered 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 voluntary genetically engineered food certification pro-  
23 gram for covered products with respect to the use of ge-  
24 netic engineering in the production of such products, as  
25 provided for in this subtitle. The Secretary shall establish

1 the requirements and procedures as the Secretary deter-  
2 mines are 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 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                  “(b) INVESTIGATIONS.—

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

16                  “(A) to verify the accuracy of any informa-  
17                  tion reported or made available under this sub-  
18                  title; and

19                  “(B) to determine whether a person cov-  
20                  ered by this subtitle has committed a violation  
21                  of any provision of this subtitle, including an  
22                  order or regulation promulgated by the Sec-  
23                  retary pursuant to this subtitle.

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

1           “(A) administer oaths and affirmations;

2           “(B) subpoena witnesses;

3           “(C) compel attendance of witnesses;

4           “(D) take evidence; and

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

8           “(c) VIOLATIONS OF SUBTITLE.—

9           “(1) UNLAWFUL ACT.—Any person covered by  
10          this subtitle who, after notice and an opportunity to  
11          be heard, has been found by the Secretary to have  
12          failed or refused to provide accurate information (in-  
13          cluding a delay in the timely delivery of such infor-  
14          mation) required by the Secretary under this sub-  
15          title, shall be subject to a civil penalty of not more  
16          than \$10,000.

17          “(2) MISUSE OF LABEL.—

18          “(A) IN GENERAL.—Any person who  
19          knowingly sells or labels any covered product as  
20          having been produced without the use of genetic  
21          engineering or a genetically engineered plant or  
22          with the use of genetic engineering or a geneti-  
23          cally engineered plant, except in accordance  
24          with this subtitle, shall be subject to a civil pen-  
25          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           “(3) 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 (2)(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                  “(4) REPORTING OF VIOLATIONS.—A certifying  
16                  agent shall immediately report any violation of this  
17                  subtitle to the Secretary.

18                  “(5) 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          “(6) 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 “(7) 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 “(8) 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 voluntary claim made with  
5 respect to whether a covered product (as defined in section  
6 291 of the Agricultural Marketing Act of 1946, as added  
7 by section 201 of this Act) was produced with or without  
8 the use of genetic engineering or genetically engineered  
9 plants 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 uct 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.

