

114TH CONGRESS
1ST SESSION

H. R. 1599

[Report No. 114–208, Part I]

To amend the Federal Food, Drug, and Cosmetic Act with respect to food produced from, containing, or consisting of a bioengineered organism, the labeling of natural foods, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 25, 2015

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

JULY 16, 2015

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

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

JULY 16, 2015

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

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

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to food produced from, containing, or consisting of a bioengineered organism, the labeling of natural foods, and for other purposes.

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

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

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

6 (b) *TABLE OF CONTENTS.*—*The table of contents of this*
 7 *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.

8 **SEC. 2. SAVINGS CLAUSE.**

9 *Nothing in this Act (or the amendments made by this*
 10 *Act) is intended to alter or affect the authorities or regu-*
 11 *latory programs, policies, and procedures otherwise avail-*
 12 *able to, or the definitions used by, the Food and Drug Ad-*

1 *ministration under the Federal Food, Drug, and Cosmetic*
2 *Act (21 U.S.C. 301 et seq.) or the Animal and Plant Health*
3 *Inspection Service under the Plant Protection Act (7 U.S.C.*
4 *7701 et seq.), to ensure the safety of the food supply and*
5 *the protection of plant health.*

6 **TITLE I—FOOD SAFETY AFFIR-**
7 **MATION FOR CERTAIN PLANT**
8 **PRODUCTS**

9 **Subtitle A—Food and Drug**
10 **Administration**

11 **SEC. 101. CONSULTATION PROCESS.**

12 *Chapter IV of the Federal Food, Drug, and Cosmetic*
13 *Act is amended by inserting after section 423 of such Act*
14 *(21 U.S.C. 350l) the following:*

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

16 *“(a) IN GENERAL.—The Secretary shall continue to*
17 *administer the consultation process established under the*
18 *Food and Drug Administration’s policy statement entitled*
19 *‘Statement of Policy: Food Derived from New Plant Vari-*
20 *eties’ published in the Federal Register on May 29, 1992*
21 *(57 Fed. Reg. 22,984).*

22 *“(b) DETERMINATION OF MATERIAL DIFFERENCE BE-*
23 *TWEEN FOOD FROM GENETICALLY ENGINEERED PLANTS*
24 *AND COMPARABLE FOODS.—*

1 “(1) *IN GENERAL.*—For purposes of subsection
2 (a), the use of genetic engineering does not, by itself,
3 constitute information that is material for purposes of
4 determining whether there is a difference between a
5 food produced from, containing, or consisting of a ge-
6 netically engineered plant and a comparable food.

7 “(2) *LABELING REQUIRED.*—The Secretary may
8 require that the labeling of a food produced from, con-
9 taining, or consisting of a genetically engineered
10 plant contain a statement to adequately inform con-
11 sumers of a difference between the food so produced
12 and its comparable food if the Secretary determines
13 that—

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

19 “(B) the disclosure of such material dif-
20 ference is necessary to protect public health and
21 safety or to prevent the label or labeling of the
22 food so produced from being false or misleading
23 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 introduce or deliver for introduction into*
12 *interstate commerce a nonregulated genetically engineered*
13 *plant for use or application in food or a food produced*
14 *from, containing, or consisting of a nonregulated geneti-*
15 *cally engineered plant 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 through*
22 *the consultation process referred to in section 424(a)*
23 *of the Federal Food, Drug, and Cosmetic Act, has no*
24 *objections to the entity’s determination that food pro-*
25 *duced from, containing, or consisting of the geneti-*

1 *cally engineered plant that is the subject of the notifi-*
2 *cation is as safe for use by humans or animals, as*
3 *applicable, as one or more comparable foods; and*

4 *“(B) the entity seeking evaluation of a food pro-*
5 *duced from, containing, or consisting of the geneti-*
6 *cally engineered plant submits to the Secretary of Ag-*
7 *riculture the notification of the finding of the Sec-*
8 *retary of Health and Human Services under subpara-*
9 *graph (A); or*

10 *“(2) before the date of the enactment of the Safe*
11 *and Accurate Food Labeling Act of 2015, the Sec-*
12 *retary of Health and Human Services—*

13 *“(A) considered the consultation process re-*
14 *ferred to in section 424(a) of the Federal Food,*
15 *Drug, and Cosmetic Act with respect to such ge-*
16 *netically engineered plant to be complete;*

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

22 *“(C) published such notification on the pub-*
23 *lic Internet website of the Food and Drug Ad-*
24 *ministration.*

1 “(b) *EXCEPTIONS.*—*Notwithstanding subsection (a),*
2 *this section does not apply with respect to the introduction*
3 *or delivery for introduction into interstate commerce of a*
4 *genetically engineered plant—*

5 “(1) *for the purpose of research or development*
6 *testing, including—*

7 “(A) *testing conducted to generate data and*
8 *information that could be used in a submission*
9 *to the Secretary under this title or other regu-*
10 *latory submission; or*

11 “(B) *research involving multiplication of*
12 *seed or hybrid and variety development con-*
13 *ducted before submitting a notification under*
14 *subsection (a)(1)(B);*

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

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

21 “(c) *RULE OF CONSTRUCTION.*—*Nothing in subsection*
22 *(b)(1) may be construed as authorizing the introduction or*
23 *delivery for introduction into interstate commerce of a non-*
24 *regulated genetically engineered plant for use or application*

1 *in food or a food produced from, containing, or consisting*
2 *of a nonregulated genetically engineered plant.*

3 “(d) *PUBLIC DISCLOSURE.*—

4 “(1) *IN GENERAL.*—Subject to paragraph (2), the
5 *Secretary of Agriculture shall publish on the public*
6 *Internet website of the Department of Agriculture,*
7 *and update as necessary, a registry that includes—*

8 “(A) *a list of each nonregulated genetically*
9 *engineered plant intended for a use or applica-*
10 *tion in food that may be introduced or delivered*
11 *for introduction in interstate commerce, in ac-*
12 *cordance with subsection (a);*

13 “(B) *the petitions submitted to, and deter-*
14 *minations made by, the Secretary of Agriculture*
15 *with respect to such a plant; and*

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

20 “(2) *TRADE SECRETS AND CONFIDENTIAL INFOR-*
21 *MATION.*—Notwithstanding paragraph (1), nothing in
22 *this section shall be construed to alter the protections*
23 *offered by laws, regulations, and policies governing*
24 *disclosure of confidential commercial or trade secret*
25 *information, and any other information exempt from*

1 *disclosure pursuant to section 552(b) of title 5,*
2 *United States Code, as such provisions would be ap-*
3 *plied to the documents and information referred to in*
4 *subparagraphs (A) through (C) of paragraph (1).*

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

15 **“SEC. 462. DEFINITIONS.**

16 *“In this subtitle:*

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

20 *“(2) NONREGULATED GENETICALLY ENGINEERED*
21 *PLANT.—The term ‘nonregulated genetically engi-*
22 *neered plant’ means a genetically engineered plant—*

23 *“(A) for which the Secretary of Agriculture*
24 *has approved a petition under section 340.6 of*
25 *title 7, Code of Federal Regulations (or any suc-*

1 cessor regulations), for a determination that the
2 genetically engineered plant should not be regu-
3 lated under this Act; or

4 “(B) that—

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

7 “(ii) contains genetic material from a
8 different species; and

9 “(iii) has been modified through in
10 vitro recombinant deoxyribonucleic acid
11 (DNA) techniques.”.

12 **SEC. 112. REGULATIONS.**

13 Not later than one year after the date of the enactment
14 of this Act, the Secretary of Agriculture shall promulgate
15 interim final regulations to carry out the amendments
16 made by section 111.

17 **SEC. 113. PREEMPTION.**

18 Regardless of whether regulations have been promul-
19 gated under section 112, beginning on the date of the enact-
20 ment of this Act, no State or political subdivision of a State
21 may directly or indirectly establish under any authority
22 or continue in effect as to any food in interstate commerce
23 any requirement with respect to genetically engineered
24 plants for use or application in food that is not identical

1 *to the requirement of section 461 of the Plant Protection*
2 *Act (as added by section 111 of this Act).*

3 **SEC. 114. RULE OF CONSTRUCTION.**

4 *Nothing in the amendments made by this subtitle is*
5 *intended to alter or affect the ability of—*

6 *(1) the Secretary of Health and Human Services*
7 *to take enforcement actions with respect to a violation*
8 *of the Federal Food, Drug, and Cosmetic Act (21*
9 *U.S.C. 301 et seq.), including section 301 of such Act*
10 *(21 U.S.C. 331); or*

11 *(2) the Secretary of Agriculture to take enforce-*
12 *ment actions with respect to a violation of the Plant*
13 *Protection Act (7 U.S.C. 7701 et seq.), including sec-*
14 *tion 411 of such Act (7 U.S.C. 7711).*

15 **SEC. 115. IMPLEMENTATION REPORT.**

16 *(a) STUDY.—Not later than 1 year after the date of*
17 *the enactment of this Act, the Secretary of Agriculture and*
18 *the Secretary of Health and Human Services shall jointly*
19 *submit to Congress a report evaluating the progress made*
20 *in the implementation of subtitle F of the Plant Protection*
21 *Act, as added by section 111. Such report shall include—*

22 *(1) an analysis of plants over which regulatory*
23 *oversight under such subtitle is required;*

24 *(2) an analysis of the extent to which the provi-*
25 *sions of such subtitle establish an appropriate scope*

1 *of regulatory oversight for the Animal and Plant*
2 *Health Inspection Service and the Food and Drug*
3 *Administration, including their oversight of public re-*
4 *search programs; and*

5 *(3) any potential changes to the Plant Protection*
6 *Act that would better facilitate implementation of a*
7 *coordinated, predictable, and efficient science-based*
8 *regulatory process.*

9 **(b) COORDINATION WITH OTHER EFFORTS TO MOD-**
10 **ERNIZE REGULATION.**—*The report under subsection (a)*
11 *shall be prepared, to the greatest extent practicable, in ac-*
12 *cordance with the process described in the memorandum*
13 *issued by the Executive Office of the President on July 2,*
14 *2015, entitled “Modernizing the Regulatory System for Bio-*
15 *technology Products”, including the directive specified in*
16 *such memorandum to update the “Coordinated Framework*
17 *for Regulation of Biotechnology” published by the Executive*
18 *Office of the President, Office of Science and Technology*
19 *Policy, in the Federal Register on June 26, 1986 (51*
20 *Fed.Reg. 23302).*

1 **TITLE II—GENETIC**
2 **ENGINEERING CERTIFICATION**

3 **SEC. 201. GENETIC ENGINEERING CERTIFICATION.**

4 *The Agricultural Marketing Act of 1946 (7 U.S.C.*
5 *1621 et seq.) is amended by adding at the end the following*
6 *new subtitle:*

7 **“Subtitle E—Genetic Engineering**
8 **Certification**

9 **“SEC. 291. DEFINITIONS.**

10 *“In this subtitle:*

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

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

23 *“(A) an agricultural product, whether raw*
24 *or processed (including any product derived from*

1 *livestock that is marketed in the United States*
2 *for consumption by humans or other animals);*

3 “(B) *any other food (as defined in section*
4 *201 of the Federal Food, Drug, and Cosmetic*
5 *Act) not derived from an agricultural product;*
6 *and*

7 “(C) *seed or other propagative material.*

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

12 “(A) *it contains genetic material that has*
13 *been modified through in vitro recombinant*
14 *deoxyribonucleic acid (DNA) techniques; and*

15 “(B) *the modification could not otherwise be*
16 *obtained using conventional breeding techniques.*

17 “(4) *The term ‘comparable food’ means, with re-*
18 *spect to a covered product produced from, containing,*
19 *or consisting of a genetically engineered plant—*

20 “(A) *the parental variety of the plant;*

21 “(B) *another commonly consumed variety of*
22 *the plant; or*

23 “(C) *a commonly consumed covered product*
24 *with properties comparable to the covered prod-*

1 *uct produced from, containing, or consisting of*
2 *the plant that is a genetically engineered plant.*

3 *“(5) The term ‘handle’ means to sell, process or*
4 *package covered products.*

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

8 *“(7) The term ‘Secretary’ means the Secretary of*
9 *Agriculture, acting through the Agricultural Mar-*
10 *keting Service.*

11 **“SEC. 291A. NATIONAL GENETICALLY ENGINEERED FOOD**
12 **CERTIFICATION PROGRAM.**

13 *“(a) IN GENERAL.—The Secretary shall establish a*
14 *voluntary genetically engineered food certification program*
15 *for covered products with respect to the use of genetic engi-*
16 *neering in the production of such products, as provided for*
17 *in this subtitle. The Secretary shall establish the require-*
18 *ments and procedures as the Secretary determines are nec-*
19 *essary to carry out such program.*

20 *“(b) CONSULTATION.—In developing the program*
21 *under subsection (a), the Secretary shall consult with such*
22 *other parties as are necessary to develop such program.*

23 *“(c) CERTIFICATION.—The Secretary shall implement*
24 *the program established under subsection (a) through certi-*
25 *fying agents. Such certifying agents may certify that cov-*

1 *ered products were or were not produced with the use of*
 2 *genetic engineering or a genetically engineered plant, in ac-*
 3 *cordance with this subtitle.*

4 “(d) *SEAL.*—*The Secretary shall establish a seal to*
 5 *identify covered products in interstate commerce using ter-*
 6 *minology the Secretary considers appropriate, including*
 7 *terminology commonly used in interstate commerce or es-*
 8 *tablished by the Secretary in regulations.*

9 “**SEC. 291B. NATIONAL STANDARDS FOR LABELING NON-**
 10 **GENETICALLY ENGINEERED FOOD.**

11 “(a) *IN GENERAL.*—*To be sold or labeled as a covered*
 12 *product produced without the use of genetic engineering—*

13 “(1) *the covered product shall—*

14 “(A) *be subject to supply chain process con-*
 15 *trols that address—*

16 “(i) *the producer planting seed that is*
 17 *not genetically engineered;*

18 “(ii) *the producer keeping the crop sep-*
 19 *arated during growth, harvesting, storage,*
 20 *and transportation; and*

21 “(iii) *persons in direct contact with*
 22 *such crop or products derived from such*
 23 *crop during transportation, storage, or*
 24 *processing keeping the product separated*

1 *from other products that are or are derived*
2 *from genetically engineered plants; and*

3 “(B) *be produced and handled in compli-*
4 *ance with a nongenetically engineered food plan*
5 *developed and approved in accordance with sub-*
6 *section (c);*

7 “(2) *in the case of a covered product derived*
8 *from livestock that is marketed in the United States*
9 *for human consumption, the covered product and the*
10 *livestock, products consumed by such livestock, and*
11 *products used in processing the products consumed by*
12 *such livestock shall be produced without the use of*
13 *products derived from genetic engineering; and*

14 “(3) *labeling or advertising material on, or in*
15 *conjunction with, such covered product shall not sug-*
16 *gest either expressly or by implication that covered*
17 *products developed without the use of genetic engi-*
18 *neering are safer or of higher quality than covered*
19 *products produced from, containing, or consisting of*
20 *a genetically engineered plant.*

21 “(b) *EXCEPTIONS.—A covered product shall not be*
22 *considered as not meeting the criteria specified in sub-*
23 *section (a) solely because the covered product—*

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

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

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

7 “(c) *NONGENETICALLY ENGINEERED FOOD PLAN.*—

8 “(1) *IN GENERAL.*—A producer or handler seek-
9 ing certification under this section shall submit a
10 nongenetically 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 nongenetically engineered
15 food plan shall contain a description of—

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

18 “(B) a description of the monitoring records
19 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 nongenetically 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 ***“SEC. 291C. NATIONAL STANDARDS FOR LABELING GENETI-***
 4 ***CALLY ENGINEERED FOOD.***

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

7 *“(1) the covered product shall be produced and*
 8 *handled in compliance with a genetically engineered*
 9 *food plan developed and approved in accordance with*
 10 *subsection (b); and*

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

13 *“(A) not expressly or impliedly claim that*
 14 *a covered product developed with the use of ge-*
 15 *netic engineering is safer or of higher quality*
 16 *solely because the covered product is a product*
 17 *developed with the use of genetic engineering;*

18 *“(B) not make any claims that are false or*
 19 *misleading; and*

20 *“(C) contain such information as the Sec-*
 21 *retary considers appropriate.*

22 *“(b) GENETICALLY ENGINEERED FOOD PLAN.—*

23 *“(1) IN GENERAL.—A producer or handler seek-*
 24 *ing certification under this section shall submit a ge-*
 25 *netically engineered food plan to the certifying agent*

1 *and such plan shall be reviewed by the certifying*
2 *agent who shall determine if such plan meets the re-*
3 *quirements of this section.*

4 “(2) *CONTENTS.—A genetically engineered food*
5 *plan shall contain a description of—*

6 “(A) *the procedures that will be followed to*
7 *assure compliance with this section;*

8 “(B) *a description of the monitoring records*
9 *that will be maintained; and*

10 “(C) *any corrective actions that will be im-*
11 *plemented in the event there is a deviation from*
12 *the plan.*

13 “(3) *AVAILABILITY.—The genetically engineered*
14 *food plan and the records maintained under the plan*
15 *shall be available for review and copying by the Sec-*
16 *retary or a certifying agent.*

17 “(c) *PROHIBITION AGAINST RESTRICTING CERTAIN*
18 *DISCLOSURES.—With respect to a covered product that oth-*
19 *erwise meets the criteria specified in subsection (a), the Sec-*
20 *retary may not prevent a person—*

21 “(1) *from disclosing voluntarily on the labeling*
22 *of such a covered product developed with the use of ge-*
23 *netic engineering the manner in which the product*
24 *has been modified to express traits or characteristics*
25 *that differ from its comparable food; or*

1 “(2) from disclosing in advertisements, on the
2 Internet, in response to consumer inquiries, or on
3 other communications, other than in the labeling, that
4 a covered product was developed with the use of ge-
5 netic engineering.

6 **“SEC. 291D. IMPORTED PRODUCTS.**

7 “Imported covered products may be sold or labeled as
8 produced with or without the use of genetic engineering if
9 the Secretary determines that such products have been pro-
10 duced and handled under a genetic engineering certification
11 program that provides safeguards and guidelines governing
12 the production and handling of such products that are at
13 least equivalent to the requirements of this subtitle.

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

15 “(a) *IN GENERAL.*—The Secretary shall establish and
16 implement a program to accredit a governing State official,
17 and any private person, that meets the requirements of this
18 section as a certifying agent for the purpose of certifying
19 a covered product as having been produced with or without
20 the use of genetic engineering or a genetically engineered
21 plant, in accordance with this subtitle.

22 “(b) *REQUIREMENTS.*—To be accredited as a certi-
23 fying agent under this section, a governing State official
24 or private person shall—

1 “(1) prepare and submit to the Secretary an ap-
2 plication for such accreditation;

3 “(2) have sufficient expertise in agricultural pro-
4 duction and handling techniques as determined by the
5 Secretary; and

6 “(3) comply with the requirements of this sec-
7 tion.

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

12 “(d) *COORDINATION WITH EXISTING ORGANIC PRO-*
13 *GRAM ACCREDITATION*.—A governing State official or pri-
14 vate person who is accredited to certify a farm or handling
15 operation as a certified organic farm or handling operation
16 pursuant to section 2115 of the Organic Foods Production
17 Act of 1990 (7 U.S.C. 6415) (and such accreditation is in
18 effect) shall be deemed to be accredited to certify covered
19 products under this subtitle.

20 “**SEC. 291F. RECORDKEEPING, INVESTIGATIONS, AND EN-**
21 **FORCEMENT.**

22 “(a) *RECORDKEEPING*.—

23 “(1) *IN GENERAL*.—Except as otherwise provided
24 in this title, each person who sells, labels, or rep-
25 resents any covered product as having been produced

1 *without the use of genetic engineering or a genetically*
2 *engineered plant or with the use of genetic engineer-*
3 *ing or a genetically engineered plant shall—*

4 *“(A) maintain records in a manner pre-*
5 *scribed by the Secretary; and*

6 *“(B) make available to the Secretary, on re-*
7 *quest by the Secretary, all records associated*
8 *with the covered product.*

9 *“(2) CERTIFYING AGENTS.—*

10 *“(A) IN GENERAL.—A certifying agent*
11 *shall—*

12 *“(i) maintain all records concerning*
13 *the activities of the certifying agent with re-*
14 *spect to the certification of covered products*
15 *under this subtitle in a manner prescribed*
16 *by the Secretary; and*

17 *“(ii) make available to the Secretary,*
18 *on request by the Secretary, all records asso-*
19 *ciated with such activities.*

20 *“(B) TRANSFERENCE OF RECORDS.—If a*
21 *private person that was certified under this sub-*
22 *title is dissolved or loses accreditation, all*
23 *records and copies of records concerning the ac-*
24 *tivities of the person under this subtitle shall be*
25 *transferred to the Secretary.*

1 “(b) *INVESTIGATIONS.*—

2 “(1) *IN GENERAL.*—*The Secretary may take such*
3 *investigative actions as the Secretary considers to be*
4 *necessary—*

5 “(A) *to verify the accuracy of any informa-*
6 *tion reported or made available under this sub-*
7 *title; and*

8 “(B) *to determine whether a person covered*
9 *by this subtitle has committed a violation of any*
10 *provision of this subtitle, including an order or*
11 *regulation promulgated by the Secretary pursu-*
12 *ant to this subtitle.*

13 “(2) *SPECIFIC INVESTIGATIVE POWERS.*—*In car-*
14 *rying out this subtitle, the Secretary may—*

15 “(A) *administer oaths and affirmations;*

16 “(B) *subpoena witnesses;*

17 “(C) *compel attendance of witnesses;*

18 “(D) *take evidence; and*

19 “(E) *require the production of any records*
20 *required to be maintained under this subtitle*
21 *that are relevant to an investigation.*

22 “(c) *VIOLATIONS OF SUBTITLE.*—

23 “(1) *UNLAWFUL ACT.*—*Any person covered by*
24 *this subtitle who, after notice and an opportunity to*
25 *be heard, has been found by the Secretary to have*

1 *failed or refused to provide accurate information (in-*
2 *cluding a delay in the timely delivery of such infor-*
3 *mation) required by the Secretary under this subtitle,*
4 *shall be subject to a civil penalty of not more than*
5 *\$10,000.*

6 “(2) *MISUSE OF LABEL.—*

7 “(A) *IN GENERAL.—Any person who know-*
8 *ingly sells or labels any covered product as hav-*
9 *ing been produced without the use of genetic en-*
10 *gineering or a genetically engineered plant or*
11 *with the use of genetic engineering or a geneti-*
12 *cally engineered plant, except in accordance with*
13 *this subtitle, shall be subject to a civil penalty of*
14 *not more than \$10,000.*

15 “(B) *CONTINUING VIOLATION.—Each day*
16 *during which a violation described in subpara-*
17 *graph (A) occurs shall be considered to be a sepa-*
18 *rate violation.*

19 “(3) *INELIGIBILITY.—*

20 “(A) *IN GENERAL.—Except as provided in*
21 *subparagraph (C), any person that carries out*
22 *an activity described in subparagraph (B), after*
23 *notice and an opportunity to be heard, shall not*
24 *be eligible, for the 5-year period beginning on the*
25 *date of the occurrence, to receive a certification*

1 *under this subtitle with respect to any covered*
2 *product.*

3 “(B) *DESCRIPTION OF ACTIVITIES.*—*An ac-*
4 *tivity referred to in subparagraph (A) is—*

5 “(i) *making a false statement;*

6 “(ii) *a violation described in para-*
7 *graph (2)(A);*

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

18 “(iv) *otherwise violating the purposes*
19 *of the genetically engineered food certifi-*
20 *cation program established under section*
21 *291A, as determined by the Secretary.*

22 “(C) *WAIVER.*—*Notwithstanding subpara-*
23 *graph (A), the Secretary may modify or waive*
24 *a period of ineligibility under this paragraph if*
25 *the Secretary determines that the modification or*

1 *waiver is in the best interests of the genetically*
2 *engineered food certification program established*
3 *under section 291A.*

4 “(4) *REPORTING OF VIOLATIONS.—A certifying*
5 *agent shall immediately report any violation of this*
6 *subtitle to the Secretary.*

7 “(5) *CEASE-AND-DESIST ORDERS.—*

8 “(A) *IN GENERAL.—The Secretary may,*
9 *after providing notice and an opportunity to be*
10 *heard, issue an order, requiring any person who*
11 *the Secretary reasonably believes is selling or la-*
12 *beling a covered product in violation of this sub-*
13 *title to cease and desist from selling or labeling*
14 *such covered product as having been produced*
15 *without the use of genetic engineering or a ge-*
16 *netically engineered plant or as having been pro-*
17 *duced with the use of genetic engineering or a ge-*
18 *netically engineered plant.*

19 “(B) *FINAL AND CONCLUSIVE.—The order of*
20 *the Secretary imposing a cease-and-desist order*
21 *under this paragraph shall be final and conclu-*
22 *sive unless the affected person files an appeal*
23 *from the Secretary’s order with the appropriate*
24 *district court of the United States not later than*

1 30 days after the date of the issuance of the
2 order.

3 “(6) VIOLATIONS BY CERTIFYING AGENT.—A cer-
4 tifying agent that is a private person that violates the
5 provisions of this subtitle or falsely or negligently cer-
6 tifies any covered product that does not meet the
7 terms and conditions of the genetically engineered
8 food certification program established under section
9 291A, as determined by the Secretary, shall, after no-
10 tice and an opportunity to be heard—

11 “(A) lose accreditation as a certifying agent
12 under this subtitle; and

13 “(B) be ineligible to be accredited as a certi-
14 fying agent under this subtitle for a period of
15 not less than 3 years, beginning on the date of
16 the determination.

17 “(7) SUSPENSION.—

18 “(A) IN GENERAL.—The Secretary may,
19 after first providing the certifying agent notice
20 and an opportunity to be heard, suspend the ac-
21 creditation of the certifying agent for a period
22 specified in subparagraph (B) for a violation of
23 this subtitle.

24 “(B) PERIOD OF SUSPENSION.—The period
25 of a suspension under subparagraph (A) shall

1 *terminate on the date the Secretary makes a*
2 *final determination with respect to the violation*
3 *that is the subject of the suspension.*

4 “(8) *ENFORCEMENT BY ATTORNEY GENERAL.—*
5 *On request of the Secretary, the Attorney General*
6 *may bring a civil action against a person in a dis-*
7 *trict court of the United States to enforce this subtitle*
8 *or a requirement or regulation prescribed, or an order*
9 *issued, under this subtitle. The action may be brought*
10 *in the judicial district in which the person does busi-*
11 *ness or in which the violation occurred.*

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

13 “(a) *AUTHORIZATION OF APPROPRIATIONS.—There*
14 *are authorized to be appropriated to establish the geneti-*
15 *cally engineered food program under section 291A,*
16 *\$2,000,000, to remain available until expended.*

17 “(b) *FEES.—*

18 “(1) *IN GENERAL.—Upon establishment of the*
19 *genetically engineered food certification program*
20 *under section 291A, the Secretary shall establish by*
21 *notice, charge, and collect fees to cover the estimated*
22 *costs to the Secretary of carrying out this subtitle.*

23 “(2) *AVAILABILITY.—Fees collected under para-*
24 *graph (1) shall be deposited into a fund in the Treas-*
25 *ury of the United States and shall remain available*

1 *until expended, without further appropriation, to*
2 *carry out this subtitle.”.*

3 **SEC. 202. REGULATIONS.**

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

7 (1) *provide a process to account for certified*
8 *nongenetically engineered covered products containing*
9 *material from genetically engineered plants due to the*
10 *inadvertent presence of such material;*

11 (2) *to the greatest extent practicable, establish*
12 *consistency between the certification programs estab-*
13 *lished under subtitle E of the Agricultural Marketing*
14 *Act of 1946 (as added by section 201 of this Act), the*
15 *organic certification program established under the*
16 *Organic Foods Production Act of 1990 (7 U.S.C. 6501*
17 *et seq.), and other voluntary labeling programs ad-*
18 *ministered by the Secretary;*

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

1 (4) provide a process for requesting and granting
2 exemptions from the requirements of subtitle E of the
3 Agricultural Marketing Act of 1946 (as added by sec-
4 tion 201 of this Act) under conditions established by
5 the Secretary.

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

7 (a) *EFFECTIVE DATE.*—Regardless of whether regula-
8 tions have been promulgated under section 202 of this Act,
9 the amendments made by section 201 shall take effect begin-
10 ning on the date of the enactment of this Act.

11 (b) *PROHIBITIONS AGAINST MANDATORY LABELING OF*
12 *FOOD DEVELOPED USING GENETIC ENGINEERING.*—No
13 State or political subdivision of a State may directly or
14 indirectly establish under any authority or continue in ef-
15 fect as to any covered product (as defined in section 291
16 of the Agricultural Marketing Act of 1946, as added by sec-
17 tion 201 of this Act) in interstate commerce, any require-
18 ment for the labeling of a covered product indicating the
19 product as having been produced from, containing, or con-
20 sisting of a genetically engineered plant, including any re-
21 quirements for claims that a covered product is or contains
22 an ingredient that was produced from, contains, or consists
23 of a genetically engineered plant unless the State (or a po-
24 litical subdivision thereof) establishes either of the following
25 programs for the regulation of such claims:

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

4 (2) *A program that—*

5 *(A) is voluntary;*

6 *(B) is accredited by the Secretary pursuant*
7 *to section 291E of the Agricultural Marketing*
8 *Act of 1946 (as added by section 201 of this Act);*
9 *and*

10 *(C) establishes standards that are identical*
11 *to the standards established under section 291B*
12 *or 291C of the Agricultural Marketing Act of*
13 *1946, as applicable (as added by section 201 of*
14 *this Act).*

15 **SEC. 204. APPLICABILITY.**

16 *(a) EXISTING CLAIMS.—A voluntary claim made with*
17 *respect to whether a covered product (as defined in section*
18 *291 of the Agricultural Marketing Act of 1946, as added*
19 *by section 201 of this Act) was produced with or without*
20 *the use of genetic engineering or genetically engineered*
21 *plants before the date of the enactment of this Act—*

22 *(1) may be made for such a product during the*
23 *36-month period that begins on the date of the enact-*
24 *ment of this Act; and*

1 (2) after the expiration of such 36-month period,
2 may be made so long as the labels associated with
3 such a claim meet the standards specified in section
4 291B or 291C of the Agricultural Marketing Act of
5 1946, as applicable (as added by section 201 of this
6 Act).

7 (b) *ORGANIC CERTIFICATION.*—In the case of a covered
8 product (as defined in section 291 of the Agricultural Mar-
9 keting Act of 1946, as added by section 201 of this Act)
10 produced by a farm or handling operation that is certified
11 as an organic farm or handling operation under the Or-
12 ganic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.),
13 such product is deemed to be certified as a product produced
14 without the use of genetic engineering under the genetically
15 engineered food certification program established under sec-
16 tion 291A of the Agricultural Marketing Act of 1946 (as
17 added by section 201 of this Act).

18 **TITLE III—NATURAL FOODS**

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

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

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

1 “(2) A claim described in subparagraph (1) may be
2 made only if the claim uses terms that have been defined
3 by, and the food meets the requirements that have been es-
4 tablished in, regulations promulgated to carry out this
5 paragraph.

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

11 “(4) In promulgating regulations to carry out this
12 paragraph, the Secretary shall differentiate between food for
13 human consumption and food intended for consumption by
14 animals other than humans.

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

17 “(A) the terms ‘natural’, ‘100% natural’, ‘natu-
18 rally grown’, ‘all natural’, and ‘made with natural
19 ingredients’; and

20 “(B) any other terms specified by the Sec-
21 retary.”.

22 **SEC. 302. REGULATIONS.**

23 (a) *PROPOSED REGULATIONS.*—Not later than 18
24 months after the date of enactment of this Act, the Secretary
25 of Health and Human Services shall issue proposed regula-

1 tions to implement section 403(z) of the Federal Food,
2 Drug, and Cosmetic Act, as added by section 301 of this
3 Act.

4 (b) *FINAL REGULATIONS.*—Not later than 30 months
5 after the date of enactment of this Act, the Secretary of
6 Health and Human Services shall issue final regulations
7 to implement such section 403(z).

8 **SEC. 303. PREEMPTION.**

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

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

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

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

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

20 **SEC. 304. EFFECTIVE DATE.**

21 The labeling requirements of section 403(z) of the Fed-
22 eral Food, Drug, and Cosmetic Act, as added by section 301
23 of this Act, shall take effect on the effective date of final
24 regulations promulgated under section 302(b) of this Act.
25 The provisions of section 403A(a)(6) of the Federal Food,

- 1 *Drug, and Cosmetic Act, as added by section 303 of this*
- 2 *Act, take effect on the date of enactment of this Act.*

