

114TH CONGRESS
1ST SESSION

H. R. 1599

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

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Safe and Accurate
3 Food Labeling Act of 2015”.

4 **SEC. 2. TABLE OF CONTENTS.**

5 The table of contents of this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Ensuring safety of food supply.

TITLE I—FOOD PRODUCED FROM, CONTAINING, OR CONSISTING
OF A BIOENGINEERED ORGANISM

- Sec. 101. Definitions.
- Sec. 102. Mandatory premarket biotechnology notification program.
- Sec. 103. Labeling of whether food is bioengineered.
- Sec. 104. Preemption.

TITLE II—NATURAL FOODS

- Sec. 201. Labeling of natural foods.
- Sec. 202. Regulations.
- Sec. 203. Preemption.
- Sec. 204. Effective date.

TITLE III—NON-BIOENGINEERED FOOD CERTIFICATION

- Sec. 301. Non-bioengineered food certification.
- Sec. 302. Regulations.
- Sec. 303. Preemption.

6 **SEC. 3. ENSURING SAFETY OF FOOD SUPPLY.**

7 Nothing in this Act (or the amendments made by this
8 Act) is intended to alter or affect the authorities or regu-
9 latory programs, policies, and procedures otherwise avail-
10 able to the Food and Drug Administration to ensure the
11 safety of the food supply under the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 301 et seq.).

1 **TITLE I—FOOD PRODUCED**
2 **FROM, CONTAINING, OR CON-**
3 **SISTING OF A BIOENGI-**
4 **NEERED ORGANISM**

5 **SEC. 101. DEFINITIONS.**

6 Section 201 of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 321) is amended by adding at the end the
8 following:

9 “(ss) The term ‘bioengineered organism’ refers to an
10 organism if—

11 “(1) the organism is a plant (or a seed, a fruit,
12 or any other part thereof);

13 “(2) the organism contains genetic material
14 that has been modified through in vitro recombinant
15 deoxyribonucleic acid (DNA) techniques; and

16 “(3) the modification could not otherwise be ob-
17 tained using conventional breeding techniques.”.

18 **SEC. 102. MANDATORY PREMARKET BIOTECHNOLOGY NO-**
19 **TIFICATION PROGRAM.**

20 (a) **PROHIBITED ACT.**—Section 301 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
22 ed by adding at the end the following:

23 “(ddd) The initial introduction or delivery for intro-
24 duction in interstate commerce of a bioengineered orga-
25 nism intended for a food use or application, unless the

1 developer of the organism has complied with the notifica-
2 tion requirements, to the extent applicable, under section
3 424.”.

4 (b) NOTIFICATION PROGRAM.—Chapter IV of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341
6 et seq.) is amended by adding at the end the following:

7 **“SEC. 424. NOTIFICATION RELATING TO CERTAIN BIOENGI-
8 NEERED ORGANISMS.**

9 “(a) IN GENERAL.—A bioengineered organism shall
10 not be introduced or delivered for introduction into inter-
11 state commerce for a food use or application unless—

12 “(1) the use or application of the bioengineered
13 organism in food has been addressed by the devel-
14 oper of the bioengineered organism in a premarket
15 biotechnology notification, to which the Secretary
16 has responded under subsection (d)(2)(A) by stating
17 no objections; or

18 “(2)(A) food produced from, containing, or con-
19 sisting of the bioengineered organism was evaluated
20 by the Secretary pursuant to the Food and Drug
21 Administration’s voluntary consultation process for
22 foods and food products from genetically engineered
23 plants in effect prior to the date of enactment of the
24 Safe and Accurate Food Labeling Act of 2015; and

1 “(B) the Secretary informed the developer of
2 the bioengineered organism that all questions about
3 safety have been resolved.

4 “(b) EXCEPTIONS.—This section does not apply with
5 respect to the introduction or delivery for introduction into
6 interstate commerce of a bioengineered organism—

7 “(1) for the purpose of development or testing
8 conducted to generate data and information that
9 could be used in a premarket biotechnology notifica-
10 tion or other regulatory submission; or

11 “(2) solely because a processing aid or enzyme
12 produced from the bioengineered organism is in-
13 tended to be used to produce food.

14 “(c) PREMARKET BIOTECHNOLOGY NOTIFICA-
15 TION.—

16 “(1) SUBMISSION.—At least 210 days before a
17 bioengineered organism is first introduced or deliv-
18 ered for introduction into interstate commerce for a
19 food use or application, a premarket biotechnology
20 notification shall be submitted to the Secretary by
21 the developer of the bioengineered organism. Such
22 notification shall provide—

23 “(A) the basis for the notifier’s determina-
24 tion that food produced from, containing, or
25 consisting of such bioengineered organism is as

1 safe for use by humans or animals, as applica-
2 ble, as one or more comparable marketed foods
3 that are not produced from, do not contain, or
4 do not consist of such bioengineered organism;
5 and

6 “(B) whether any other Federal agency is
7 conducting or has conducted any review of the
8 bioengineered organism and the status or con-
9 clusions of any such review.

10 “(2) CONSULTATION PRIOR TO SUBMISSION.—A
11 prospective notifier may consult informally with the
12 Secretary concerning a bioengineered organism in-
13 tended for a food use or application before submit-
14 ting a premarket biotechnology notification.

15 “(d) RESPONSE TO A PREMARKET BIOTECHNOLOGY
16 NOTIFICATION.—

17 “(1) PRELIMINARY RESPONSE.—Within 30
18 days of receipt of a premarket biotechnology notifi-
19 cation, the Secretary shall—

20 “(A) inform the notifier in writing that the
21 notification is complete and has been filed; or

22 “(B) inform the notifier in writing of any
23 missing elements that prevent the Secretary
24 from filing and reviewing the notification.

1 The Secretary shall limit any request under subpara-
2 graph (B) to data or information necessary to per-
3 form the evaluation specified in paragraph (2) and
4 shall not delay informing the notifier under para-
5 graph (1)(A) for any other purpose.

6 “(2) SUBSTANTIVE RESPONSE.—Within 180
7 days of the Secretary informing the notifier under
8 paragraph (1)(A) that the premarket biotechnology
9 notification is complete, the Secretary—

10 “(A) shall respond in writing to the noti-
11 fier that the Secretary has evaluated the notifi-
12 cation and has no objections to the notifier’s
13 determination that food produced from, con-
14 taining, or consisting of the bioengineered orga-
15 nism that is the subject of the notification is as
16 safe for use by humans or animals, as applica-
17 ble, as one or more comparable marketed foods
18 that are not produced from, do not contain, or
19 do not consist of such bioengineered organism;
20 or

21 “(B) shall—

22 “(i) respond in writing to the notifier
23 that the Secretary has evaluated the notifi-
24 cation and has determined the notification

1 does not provide an adequate basis for the
2 notifier's determination; and

3 “(ii) include in such response the Sec-
4 retary's basis for the Secretary's deter-
5 mination.

6 “(3) WITHDRAWAL BY NOTIFIER.—At any
7 point before receiving a written response from the
8 Secretary under subparagraph (A) or (B) of para-
9 graph (2), the notifier may withdraw a premarket
10 biotechnology notification without prejudice as to
11 any future notifications.

12 “(4) EFFECTIVE DATE.—A notification sub-
13 mitted under subsection (c) shall become effective on
14 the date that is 180 days after the Secretary in-
15 forms the notifier under paragraph (1)(A) that the
16 notification is complete, and as of such date the bio-
17 engineered organism that is the subject of the notifi-
18 cation may be introduced or delivered for introduc-
19 tion into interstate commerce, unless the Secretary
20 provides a response under paragraph (2)(B).

21 “(e) LABELING.—If the Secretary determines that
22 there is a material difference between a food produced
23 from, containing, or consisting of a bioengineered orga-
24 nism and its comparable marketed food and that disclo-
25 sure of such difference is necessary to protect health and

1 safety or to prevent the label or labeling of such food from
2 being false or misleading, the Secretary may, in a response
3 under subsection (d)(2)(A), specify labeling that would
4 adequately inform consumers of such material difference.
5 The use of bioengineering does not, by itself, constitute
6 a material difference.

7 “(f) PUBLIC DISCLOSURE.—The existence and con-
8 tents of a premarket biotechnology notification shall be
9 made available to the public as of the date the Secretary
10 issues a written response under subsection (d)(2)(A), sub-
11 ject to review by the Secretary pursuant to the provisions
12 on exemptions from disclosure under chapter 5 of title 5,
13 United States Code.

14 “(g) DEFINITIONS.—In this section:

15 “(1)(A) The term ‘comparable marketed food’
16 means, with respect to the food produced from, con-
17 taining, or consisting of a plant that is a bioengi-
18 neered organism—

19 “(i) the parental variety of the plant;

20 “(ii) another commonly consumed variety
21 of the plant; or

22 “(iii) a plant variety from which is derived
23 a commonly consumed food with properties
24 comparable to the food produced from, con-

1 taining, or consisting of the plant that is a bio-
2 engineered organism.

3 “(B) A food produced from, containing, or con-
4 sisting of a bioengineered organism may have more
5 than one comparable marketed food.

6 “(2) The term ‘notifier’ means the person who
7 submits a premarket biotechnology notification.

8 “(3) The term ‘premarket biotechnology notifi-
9 cation’—

10 “(A) means a submission to the Secretary
11 under subsection (c); and

12 “(B) includes all scientific data and other
13 information in the original submission and in
14 any amendments to the original submission.

15 “(4) The term ‘material difference’ means a dif-
16 ference that—

17 “(A) significantly alters the characteristics,
18 including the functional or compositional char-
19 acteristics, of a food, such that the common or
20 usual name no longer adequately describes the
21 food;

22 “(B) results in a significantly different nu-
23 tritional property in the food produced from,
24 containing, or consisting of the bioengineered
25 organism; or

1 “(C) results in the food containing an al-
2 lergen that consumers would not expect to be
3 present based upon the name of the food.”.

4 (c) APPLICABILITY.—The amendments made by this
5 section apply beginning on the date that is 30 days after
6 the date of enactment of this Act, irrespective of whether
7 regulations or guidance have been finalized or issued by
8 such date to carry out such amendments.

9 (d) PENDING SUBMISSIONS.—The Secretary shall—
10 (1) deem to be a premarket biotechnology noti-
11 fication under section 424 of the Federal Food,
12 Drug, and Cosmetic Act, as added by this section,
13 any submission that—

14 (A) is pending as of the date of enactment
15 of this Act; and

16 (B) is for voluntary consultation with re-
17 spect to food produced from, containing, or con-
18 sisting of a bioengineered organism (as defined
19 in section 201(ss) of the Federal Food, Drug,
20 and Cosmetic Act, as added by subsection (a));
21 and

22 (2) evaluate such notifications expeditiously.

23 (e) PREEMPTION.—Section 403A(a) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)) is
25 amended—

1 (1) by striking “or” at the end of paragraph
2 (4);

3 (2) by striking the period at the end of para-
4 graph (5) and inserting a comma; and

5 (3) by adding at the end the following:

6 “(6) any requirement respecting, prohibition
7 against, or restriction on, the sale, distribution, or
8 marketing of—

9 “(A) a bioengineered organism intended
10 for a food use or application, or

11 “(B) food produced from, containing, or
12 consisting of a bioengineered organism, or”.

13 (f) **TECHNICAL CORRECTIONS.**—Section 403A of the
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–
15 1) is amended—

16 (1) by striking the section designation and enu-
17 merator and all that follows through “(a) Except”
18 and inserting the following:

19 **“SEC. 403A. STATE REQUIREMENTS.**

20 “(a) **IN GENERAL.**—Except”; and

21 (2) in subsection (b), by striking “(b) Upon pe-
22 tition” and inserting the following:

23 “(b) **PETITIONS FOR EXEMPTIONS.**—Upon petition”.

1 **SEC. 103. LABELING OF WHETHER FOOD IS BIOENGI-**
2 **NEERED.**

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

6 “(z) If it bears labeling (indicating that bio-
7 engineering was or was not used in the production of the
8 food) in violation of section 425.”.

9 (b) LABELING REQUIREMENTS.—Chapter IV of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341
11 et seq.), as amended by section 102 of this Act, is further
12 amended by adding at the end the following:

13 **“SEC. 425. LABELING OF WHETHER FOOD IS BIOENGI-**
14 **NEERED.**

15 “(a) CLAIMS THAT BIOENGINEERING WAS NOT
16 USED.—

17 “(1) IN GENERAL.—If a claim in the labeling of
18 food indicates, directly or indirectly, that bio-
19 engineering was not used in the production of the
20 food, such claim shall be subject to this subsection.

21 “(2) REQUIREMENTS.—A claim described in
22 paragraph (1)—

23 “(A) may be made only if the food bearing
24 the claim is comprised of ingredients subject to
25 supply chain process controls that address—

1 “(i) the producer planting a seed de-
2 veloped by means other than through the
3 use of bioengineering;

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

7 “(iii) persons in direct contact with
8 such crop or foods derived from such crop
9 during transportation, storage, or proc-
10 essing keeping the product separated from
11 foods or food ingredients derived through
12 bioengineering;

13 “(B) may be made for a food produced in
14 accordance with subparagraph (A) in which
15 food produced from, containing, or consisting of
16 a bioengineered organism is inadvertently
17 present;

18 “(C) may not suggest either expressly or
19 by implication that foods developed without the
20 use of bioengineering are safer than foods pro-
21 duced from, containing, or consisting of a bio-
22 engineered organism;

23 “(D) may be made on dairy products de-
24 rived from cows or other milk-producing ani-
25 mals, on shell eggs derived from chickens and

1 other birds, and on products consisting of or
2 derived from fish or animals (that are under
3 the jurisdiction of the Food and Drug Adminis-
4 tration) that consumed feed or a feed ingre-
5 dient, or received a drug or biological product,
6 that—

7 “(i) was developed with the use of bio-
8 engineering; and

9 “(ii) has been authorized for such use
10 by the Secretary;

11 “(E) may be made on a food produced
12 with a bioengineered processing aid or enzyme;

13 “(F) shall comply with any other require-
14 ments established by the Secretary by regula-
15 tion to ensure that the food’s labeling is not
16 false or misleading; and

17 “(G) may be made if—

18 “(i) the food is an agricultural prod-
19 uct, as such term is defined in section 207
20 of the Agricultural Marketing Act of 1946;
21 and

22 “(ii) such agricultural product has
23 been certified as an agricultural product
24 produced without the use of bioengineering
25 under subtitle E of such Act.

1 “(3) REGULATIONS.—

2 “(A) IN GENERAL.—The Secretary shall
3 promulgate regulations to carry out this sec-
4 tion. Such regulations shall specify a maximum
5 permissible level of food produced from, con-
6 taining, or consisting of a bioengineered orga-
7 nism that may be inadvertently present in food
8 bearing claims under paragraph (1).

9 “(B) SEPARATE CATEGORIES.—Such regu-
10 lations may specify different permissible levels
11 for separate categories of food.

12 “(C) CLAIMS PRIOR TO FINALIZATION OF
13 REGULATIONS.—This section does not limit the
14 ability of persons to make claims described in
15 paragraph (1) before the finalization of regula-
16 tions under this paragraph.

17 “(D) INITIAL REGULATIONS.—The Sec-
18 retary shall promulgate final regulations under
19 this paragraph not later than 24 months after
20 the date of enactment of the Safe and Accurate
21 Food Labeling Act of 2015.

22 “(b) CLAIMS THAT BIOENGINEERING WAS USED.—

23 “(1) IN GENERAL.—If a claim in the labeling of
24 food indicates, directly or indirectly, that bio-

1 engineering was used in the production of the food,
2 such claim shall be subject to this subsection.

3 “(2) REGULATIONS.—A claim described in
4 paragraph (1) may be made only in accordance with
5 regulations promulgated by the Secretary. Such reg-
6 ulations—

7 “(A) shall not require the labeling to de-
8clare the use of bioengineering solely because
9 the food was developed with the use of bio-
10 engineering;

11 “(B) shall not allow the labeling to ex-
12pressly or impliedly claim that food developed
13 with the use of bioengineering is safer solely be-
14 cause the food is a food developed with the use
15 of bioengineering;

16 “(C) shall allow any claims which the Sec-
17retary deems necessary under section 424(e);
18 and

19 “(D) may contain other requirements es-
20tablished by the Secretary to ensure that the
21 food’s labeling is not false or misleading.

22 “(3) PROHIBITION AGAINST RESTRICTING CER-
23TAIN DISCLOSURES.—The regulations under this
24 subsection shall not prevent a person—

1 “(A) from disclosing voluntarily on the la-
2 beling of food developed with the use of bio-
3 engineering the manner in which the food has
4 been modified to express traits or characteris-
5 tics that differ from its comparable marketed
6 food (as defined in section 424); or

7 “(B) from disclosing in advertisements, on
8 the Internet, in response to consumer inquiries,
9 or on other communications, other than in the
10 labeling, that a food was developed with the use
11 of bioengineering.

12 “(c) DEFINITION.—The term ‘bioengineered orga-
13 nism’ means a bioengineered organism, as such term is
14 used in section 201(ss).”.

15 **SEC. 104. PREEMPTION.**

16 (a) IN GENERAL.—Section 403A(a) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)) is
18 amended by adding at the end the following:

19 “(7) any requirement for the labeling of food of
20 the type described in subsection (a)(1) or (b)(1) of
21 section 425 that is not identical to the requirement
22 of such section, or”.

23 (b) PROHIBITION AGAINST MANDATORY LABEL-
24 ING.—Section 403A of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 343–1) is amended by adding at the
2 end the following:

3 “(c) PROHIBITIONS AGAINST MANDATORY LABELING
4 OF FOOD DEVELOPED USING BIOENGINEERING.—Except
5 for claims under subsection (a)(1) or (b)(1) of section 425,
6 no State or political subdivision of a State may directly
7 or indirectly establish under any authority or continue in
8 effect as to any food in interstate commerce any require-
9 ment for the labeling of a food by virtue of its having been
10 developed using bioengineering, including any require-
11 ments for claims that a food is or contains an ingredient
12 that was developed using bioengineering.”.

13 **TITLE II—NATURAL FOODS**

14 **SEC. 201. LABELING OF NATURAL FOODS.**

15 Section 403 of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 343), as amended by section 103 of this
17 Act, is further amended by adding at the end the fol-
18 lowing:

19 “(aa)(1) If its labeling contains an express or implied
20 claim that the food is ‘natural’ unless the claim is made
21 in accordance with subparagraph (2).

22 “(2) A claim described in subparagraph (1) may be
23 made only if the claim uses terms that have been defined
24 by, and the food meets the requirements that have been

1 established in, regulations promulgated to carry out this
2 paragraph.

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

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

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

14 “(A) the terms ‘natural’, ‘100% natural’, ‘natu-
15 rally grown’, ‘all natural’, and ‘made with natural
16 ingredients’; and

17 “(B) any other terms specified by the Sec-
18 retary.”.

19 **SEC. 202. REGULATIONS.**

20 (a) PROPOSED REGULATIONS.—Not later than 12
21 months after the date of enactment of this Act, the Sec-
22 retary of Health and Human Services shall issue proposed
23 regulations to implement section 403(aa) of the Federal
24 Food, Drug, and Cosmetic Act, as added by section 201
25 of this Act.

1 (b) FINAL REGULATIONS.—Not later than 24 months
2 after the date of enactment of this Act, the Secretary of
3 Health and Human Services shall issue final regulations
4 to implement such section 403(aa).

5 **SEC. 203. PREEMPTION.**

6 Section 403A(a) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 343–1(a)), as amended by section
8 104 of this Act, is further amended by adding at the end
9 the following:

10 “(8) any requirement for the labeling of food of
11 the type required by section 403(aa) that is not
12 identical to the requirement of such section.”.

13 **SEC. 204. EFFECTIVE DATE.**

14 The labeling requirements of section 403(aa) of the
15 Federal Food, Drug, and Cosmetic Act, as added by sec-
16 tion 201 of this Act, shall take effect on the effective date
17 of final regulations promulgated under section 202(b) of
18 this Act. The provisions of section 403A(a)(8) of the Fed-
19 eral Food, Drug, and Cosmetic Act, as added by section
20 203 of this Act, take effect on the date of enactment of
21 this Act.

1 **TITLE III—NON-BIOENGINEERED**
2 **FOOD CERTIFICATION**

3 **SEC. 301. NON-BIOENGINEERED FOOD CERTIFICATION.**

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

7 **“Subtitle E—Non-bioengineered**
8 **Food Certification**

9 **“SEC. 291. DEFINITIONS.**

10 “In this subtitle:

11 “(1) The term ‘bioengineered organism’ refers
12 to an organism if—

13 “(A) the organism is a plant (or a seed, a
14 fruit, or any other part thereof);

15 “(B) the organism contains genetic mate-
16 rial that has been modified through in vitro re-
17 combinant deoxyribonucleic acid (DNA) tech-
18 niques; and

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

22 “(2) The term ‘certifying agent’ means any per-
23 son (including a private entity) who is accredited by
24 the Secretary as a certifying agent for the purpose
25 of certifying an agricultural product as a product to

1 be labeled to indicate that the product is produced
2 without the use of bioengineering.

3 “(3) The term ‘comparable marketed food’
4 means with respect to an agricultural product pro-
5 duced from, containing, or consisting of a plant that
6 is a bioengineered organism—

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

8 “(B) another commonly consumed variety
9 of the plant; or

10 “(C) a plant variety from which is derived
11 a commonly consumed agricultural product with
12 properties comparable to the agricultural prod-
13 uct produced from, containing, or consisting of
14 the plant that is a bioengineered organism.

15 “(4) The term ‘handle’ means to sell, process or
16 package agricultural products.

17 “(5) The term ‘producer’ means a person who
18 engages in the business of growing or producing ag-
19 ricultural products.

20 “(6) The term ‘Secretary’ means the Secretary
21 of Agriculture, acting through the Agricultural Mar-
22 keting Service.

1 **“SEC. 291A. NATIONAL NON-BIOENGINEERED FOOD CER-**
2 **TIFICATION PROGRAM.**

3 “(a) IN GENERAL.—The Secretary shall establish a
4 non-bioengineered food certification program for agricul-
5 tural products with respect to the use of bioengineering
6 in the production of such products, as provided for in this
7 subtitle. The Secretary shall establish the requirements
8 and procedures as the Secretary determines are necessary
9 to carry out such program.

10 “(b) CONSULTATION.—In developing the program
11 under subsection (a), the Secretary—

12 “(1) may consult with such other parties as are
13 necessary to develop such program; and

14 “(2) shall coordinate with the Secretary of
15 Health and Human Services to ensure that the pro-
16 gram is consistent with any requirements established
17 by the Secretary of Health and Human Services
18 under section 425 of the Federal Food, Drug, and
19 Cosmetic Act (relating to claims that bioengineering
20 was not used in the production of food).

21 “(c) CERTIFICATION.—The Secretary shall imple-
22 ment the program established under subsection (a)
23 through certifying agents. Such certifying agents may cer-
24 tify that agricultural products were produced without the
25 use of bioengineering, in accordance with this subtitle.

1 **“SEC. 291B. NATIONAL STANDARDS FOR LABELING NON-**
2 **BIOENGINEERED FOOD.**

3 “(a) IN GENERAL.—To be sold or labeled as an agri-
4 cultural product produced without the use of bio-
5 engineering—

6 “(1) the agricultural product shall—

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

9 “(i) the producer planting a seed de-
10 veloped by means other than through the
11 use of bioengineering;

12 “(ii) the producer keeping the crop
13 separated during growth, harvesting, stor-
14 age, and transportation; and

15 “(iii) persons in direct contact with
16 such crop or agricultural products derived
17 from such crop during transportation, stor-
18 age, or processing keeping the agricultural
19 product separated from other agricultural
20 products derived through bioengineering;
21 and

22 “(B) be produced and handled in compli-
23 ance with a non-bioengineered food plan devel-
24 oped and approved in accordance with sub-
25 section (c); and

1 “(2) the labeling of such agricultural product
2 may not suggest either expressly or by implication
3 that agricultural products developed without the use
4 of bioengineering are safer than agricultural prod-
5 ucts produced from, containing, or consisting of a
6 bioengineered organism.

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

10 “(1) is derived from animals that consumed
11 feed or a feed ingredient or received a drug or bio-
12 logical product that—

13 “(A) was developed with the use of bio-
14 engineering; and

15 “(B) has been authorized for such use;

16 “(2) contains minor amounts of a bioengineered
17 organism due to the inadvertent presence of such or-
18 ganism;

19 “(3) is produced with a bioengineered proc-
20 essing aid, enzyme, or microorganism; or

21 “(4) is derived from microorganisms that con-
22 sumed a nutrient source produced from, containing,
23 or consisting of a bioengineered organism.

24 “(c) NON-BIOENGINEERED FOOD PLAN.—

1 “(1) IN GENERAL.—A producer or handler
2 seeking certification under this section shall submit
3 a non-bioengineered food plan to the certifying agent
4 and such plan shall be reviewed by the certifying
5 agent who shall determine if such plan meets the re-
6 quirements of this section.

7 “(2) CONTENTS.—A non-bioengineered food
8 plan shall contain a description of—

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

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

13 “(C) any corrective actions that will be im-
14 plemented in the event there is a deviation from
15 the plan.

16 “(3) AVAILABILITY.—The non-bioengineered
17 food plan and the records maintained under the plan
18 shall be available for review and copying by the Sec-
19 retary or a certifying agent.”.

20 **SEC. 302. REGULATIONS.**

21 Not later than 2 years after the date of the enact-
22 ment of this Act, the Secretary of Agriculture shall issue
23 final regulations to carry out the amendments made by
24 section 301.

1 **SEC. 303. PREEMPTION.**

2 No State or political subdivision of a State may di-
3 rectly or indirectly establish under any authority or con-
4 tinue in effect as to any agricultural product in interstate
5 commerce any requirement for the labeling of agricultural
6 products of the type described in section 291B of the Agri-
7 cultural Marketing Act of 1946, as added by section 301,
8 that is not identical to the requirement of such section.

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