

113TH CONGRESS
2^D SESSION

H. R. 4432

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

APRIL 9, 2014

Mr. POMPEO (for himself, Mr. BUTTERFIELD, Mr. MATHESON, Mrs. BLACKBURN, and Mr. WHITFIELD) introduced the following bill; which was referred to the Committee on Energy and Commerce

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.**

4 This Act may be cited as the “Safe and Accurate
5 Food Labeling Act of 2014”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 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.

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

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 the Food and Drug Administration to ensure the
 6 safety of the food supply under the Federal Food, Drug,
 7 and Cosmetic Act (21 U.S.C. 301 et seq.).

8 **TITLE I—FOOD PRODUCED**
 9 **FROM, CONTAINING, OR CON-**
 10 **SISTING OF A BIOENGI-**
 11 **NEERED ORGANISM**

12 **SEC. 101. DEFINITIONS.**

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

16 “(ss) The term ‘bioengineered organism’ refers to an
 17 organism if—

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

3 “(2) the organism contains genetic material
4 that has been modified through in vitro recombinant
5 deoxyribonucleic acid (DNA) techniques; and

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

8 **SEC. 102. MANDATORY PREMARKET BIOTECHNOLOGY NO-**
9 **TIFICATION PROGRAM.**

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

13 “(ddd) The initial introduction or delivery for intro-
14 duction in interstate commerce of a bioengineered orga-
15 nism intended for a food use or application, unless the
16 developer of the organism has complied with the notifica-
17 tion requirements, to the extent applicable, under section
18 424.”.

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

1 **“SEC. 424. NOTIFICATION RELATING TO CERTAIN BIOENGI-**
2 **NEERED ORGANISMS.**

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

6 “(1) the use or application of the bioengineered
7 organism in food has been addressed by the devel-
8 oper of the bioengineered organism in a premarket
9 biotechnology notification, to which the Secretary
10 has responded under subsection (d)(2)(A) by stating
11 no objections; or

12 “(2)(A) food produced from, containing, or con-
13 sisting of the bioengineered organism was evaluated
14 by the Secretary pursuant to the Food and Drug
15 Administration’s voluntary consultation process for
16 foods and food products from genetically engineered
17 plants in effect prior to the date of enactment of the
18 Safe and Accurate Food Labeling Act of 2014; and

19 “(B) the Secretary informed the developer of
20 the bioengineered organism that all questions about
21 safety have been resolved.

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

25 “(1) for the purpose of development or testing
26 conducted to generate data and information that

1 could be used in a premarket biotechnology notifica-
2 tion or other regulatory submission; or

3 “(2) solely because—

4 “(A) a processing aid or enzyme produced
5 from the bioengineered organism is intended to
6 be used to produce food; or

7 “(B) food produced from, containing, or
8 consisting of the bioengineered organism is in-
9 tended to be fed to an animal from which food
10 is intended to be produced or derived.

11 “(c) PREMARKET BIOTECHNOLOGY NOTIFICA-
12 TION.—

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

20 “(A) the basis for the notifier’s determina-
21 tion that food produced from, containing, or
22 consisting of such bioengineered organism is as
23 safe for use by humans or animals, as applica-
24 ble, as one or more comparable marketed foods
25 that are not produced from, do not contain, or

1 do not consist of such bioengineered organism;
2 and

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

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

12 “(d) RESPONSE TO A PREMARKET BIOTECHNOLOGY
13 NOTIFICATION.—

14 “(1) PRELIMINARY RESPONSE.—Within 30
15 days of receipt of a premarket biotechnology notifi-
16 cation, the Secretary shall—

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

19 “(B) inform the notifier in writing of any
20 missing elements that prevent the Secretary
21 from filing and reviewing the notification.

22 The Secretary shall limit any request under subpara-
23 graph (B) to data or information necessary to per-
24 form the evaluation specified in paragraph (2) and

1 shall not delay informing the notifier under para-
2 graph (1)(A) for any other purpose.

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

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

18 “(B) shall—

19 “(i) respond in writing to the notifier
20 that the Secretary has evaluated the notifi-
21 cation and has determined the notification
22 does not provide an adequate basis for the
23 notifier’s determination; and

1 “(ii) include in such response the Sec-
2 retary’s basis for the Secretary’s deter-
3 mination.

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

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

19 “(e) LABELING.—If the Secretary determines that
20 there is a material difference between a food produced
21 from, containing, or consisting of a bioengineered orga-
22 nism and its comparable marketed food and that disclo-
23 sure of such difference is necessary to protect health and
24 safety or to prevent the label or labeling of such food from
25 being false or misleading, the Secretary may, in a response

1 under subsection (d)(2)(A), specify labeling that would
2 adequately inform consumers of such material difference.
3 The use of bioengineering does not, by itself, constitute
4 a material difference.

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

12 “(g) DEFINITIONS.—In this section:

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

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

18 “(ii) another commonly consumed variety
19 of the plant; or

20 “(iii) a plant variety from which is derived
21 a commonly consumed food with properties
22 comparable to the food produced from, con-
23 taining, or consisting of the plant that is a bio-
24 engineered organism.

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

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

6 “(3) The term ‘premarket biotechnology notifi-
7 cation’—

8 “(A) means a submission to the Secretary
9 under subsection (c); and

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

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

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

20 “(B) results in a significantly different nu-
21 tritional property in the food produced from,
22 containing, or consisting of the bioengineered
23 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 such
19 term is used in section 301(ddd) of the Federal
20 Food, Drug, and Cosmetic Act, as added by
21 subsection (a)); 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. 343–2(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, as such
13 term is used in section 301(ddd), or”.

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

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

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

21 “(a) IN GENERAL.—Except”; and

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

24 “(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 and

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

18 “(3) REGULATIONS.—

19 “(A) IN GENERAL.—The Secretary shall
20 promulgate regulations to carry out this sec-
21 tion. Such regulations shall specify a maximum
22 permissible level of food produced from, con-
23 taining, or consisting of a bioengineered orga-
24 nism that may be inadvertently present in food
25 bearing claims under paragraph (1).

1 “(B) SEPARATE CATEGORIES.—Such regu-
2 lations may specify different permissible levels
3 for separate categories of food.

4 “(C) CLAIMS PRIOR TO FINALIZATION OF
5 REGULATIONS.—This section does not limit the
6 ability of persons to make claims described in
7 paragraph (1) before the finalization of regula-
8 tions under this paragraph.

9 “(D) INITIAL REGULATIONS.—The Sec-
10 retary shall promulgate final regulations under
11 this paragraph not later than 24 months after
12 the date of enactment of the Safe and Accurate
13 Food Labeling Act of 2014.

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

15 “(1) IN GENERAL.—If a claim in the labeling of
16 food indicates, directly or indirectly, that bio-
17 engineering was used in the production of the food,
18 such claim shall be subject to this subsection.

19 “(2) REGULATIONS.—A claim described in
20 paragraph (1) may be made only in accordance with
21 regulations promulgated by the Secretary. Such reg-
22 ulations—

23 “(A) shall not require the labeling to de-
24 clare the use of bioengineering solely because

1 the food was developed with the use of bio-
2 engineering;

3 “(B) shall not allow the labeling to ex-
4 pressly or impliedly claim that food developed
5 with the use of bioengineering is safer solely be-
6 cause the food is a food developed with the use
7 of bioengineering;

8 “(C) shall allow any claims which the Sec-
9 retary deems necessary under section 424(e);
10 and

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

14 “(3) PROHIBITION AGAINST RESTRICTING CER-
15 TAIN DISCLOSURES.—The regulations under this
16 subsection shall not prevent a person—

17 “(A) from disclosing voluntarily on the la-
18 beling of food developed with the use of bio-
19 engineering the manner in which the food has
20 been modified to express traits or characteris-
21 tics that differ from its comparable marketed
22 food (as defined in section 424); or

23 “(B) from disclosing in advertisements, on
24 the Internet, in response to consumer inquiries,
25 or on other communications, other than in the

1 labeling, that a food was developed with the use
2 of bioengineering.

3 “(c) DEFINITION.—The term ‘bioengineered orga-
4 nism’ means a bioengineered organism, as such term is
5 used in section 301(ddd).”.

6 **SEC. 104. PREEMPTION.**

7 (a) IN GENERAL.—Section 403A(a) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 343–2(a)) is
9 amended by adding at the end the following:

10 “(7) any requirement for the labeling of food of
11 the type described in subsection (a)(1) or (b)(1) of
12 section 425 that is not identical to the requirement
13 of such section, or”.

14 (b) PROHIBITION AGAINST MANDATORY LABEL-
15 ING.—Section 403A of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 343–1) is amended by adding at the
17 end the following:

18 “(c) PROHIBITIONS AGAINST MANDATORY LABELING
19 OF FOOD DEVELOPED USING BIOENGINEERING.—Except
20 for claims under subsection (a)(1) or (b)(1) of section 425,
21 no State or political subdivision of a State may directly
22 or indirectly establish under any authority or continue in
23 effect as to any food in interstate commerce any require-
24 ment for the labeling of a food by virtue of its having been
25 developed using bioengineering, including any require-

1 ments for claims that a food is or contains an ingredient
2 that was developed using bioengineering.”.

3 **TITLE II—NATURAL FOODS**

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

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

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

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

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

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

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

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

6 “(B) any other terms specified by the Sec-
7 retary.”.

8 **SEC. 202. REGULATIONS.**

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

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

19 **SEC. 203. PREEMPTION.**

20 Section 403A(a) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 343–1(a)), as amended by section
22 104 of this Act, is further amended by adding at the end
23 the following:

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

4 **SEC. 204. EFFECTIVE DATE.**

5 The labeling requirements of section 403(aa) of the
6 Federal Food, Drug, and Cosmetic Act, as added by sec-
7 tion 201 of this Act, shall take effect on the effective date
8 of final regulations promulgated under section 202(b) of
9 this Act. The provisions of section 403A(a)(8) of the Fed-
10 eral Food, Drug, and Cosmetic Act, as added by section
11 203 of this Act, take effect on the date of enactment of
12 this Act.

○