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(Original Signature of Member)

113TH CONGRESS  
2D SESSION

# H. R.

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.

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## IN THE HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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# 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.