

114TH CONGRESS  
1ST SESSION

# S. 511

To amend the Federal Food, Drug, and Cosmetic Act to require that genetically engineered food and foods that contain genetically engineered ingredients be labeled accordingly.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2015

Mrs. BOXER (for herself, Mr. LEAHY, Mr. SANDERS, Mr. BLUMENTHAL, Mrs. FEINSTEIN, Mr. MURPHY, Mr. MERKLEY, Ms. MIKULSKI, Mr. REED, Mrs. SHAHEEN, Mr. HEINRICH, Ms. WARREN, Mr. TESTER, and Mr. BOOKER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that genetically engineered food and foods that contain genetically engineered ingredients be labeled accordingly.

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 “Genetically Engineered  
5       Food Right-to-Know Act”.

6       **SEC. 2. PURPOSE AND FINDINGS.**

7       (a) **PURPOSE.**—The purposes of this Act are to—

1           (1) establish a consistent and enforceable  
2 standard for labeling of foods produced using genetic  
3 engineering, thereby providing consumers with  
4 knowledge of how their food is produced; and

5           (2) prevent consumer confusion and deception  
6 by prohibiting the labeling of products produced  
7 from genetic engineering as “natural”, and by pro-  
8 moting the disclosure of factual information on food  
9 labels to allow consumers to make informed deci-  
10 sions.

11 (b) FINDINGS.—Congress finds that—

12           (1) the process of genetically engineering food  
13 organisms results in material changes and the fact  
14 that foods are genetically engineered is of material  
15 importance to consumers;

16           (2) the Food and Drug Administration requires  
17 the labeling of more than 3,000 ingredients, addi-  
18 tives, and processes;

19           (3) individuals in the United States have a  
20 right to know if their food was produced with ge-  
21 netic engineering for a variety of reasons, including  
22 health, economic, environmental, religious, and eth-  
23 ical;

24           (4) more than 60 countries, including the  
25 United Kingdom and all other countries of the Euro-

1       pean Union, South Korea, Japan, Brazil, Australia,  
2       India, China, and other key United States trading  
3       partners have laws or regulations mandating disclo-  
4       sure of genetically engineered food on food labels;

5               (5) in 2011, Codex Alimentarius, the food  
6       standards organization of the United Nations,  
7       adopted a text that indicates that governments can  
8       decide on whether and how to label foods produced  
9       with genetic engineering;

10              (6) mandatory identification of food produced  
11       with genetic engineering can be a critical method of  
12       preserving the economic value of exports or domesti-  
13       cally sensitive markets with labeling requirements  
14       for genetically engineered foods; and

15              (7) the cultivation of genetically engineered  
16       crops can have adverse effects on the environment in  
17       the form of cross-pollination of native plants, in-  
18       creased herbicide usage, and impacts on non-target  
19       and beneficial organisms, including the Monarch  
20       butterfly.

21 **SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**  
22 **COSMETIC ACT.**

23       (a) IN GENERAL.—Section 403 of the Federal Food,  
24       Drug, and Cosmetic Act (21 U.S.C. 343) is amended by  
25       adding at the end the following:

1       “(z)(1) If it is a food that has been genetically engi-  
2 neered or contains 1 or more genetically engineered ingre-  
3 dients, unless the ingredients label clearly states that the  
4 food has been genetically engineered or identifies any ge-  
5 netically engineered ingredients, as applicable.

6       “(2) This paragraph does not apply to food that—

7           “(A) is served in restaurants or other similar  
8 eating establishments, such as cafeterias and  
9 carryouts;

10          “(B) is a medical food (as defined in section  
11 5(b) of the Orphan Drug Act);

12          “(C) would be subject to this paragraph solely  
13 because it was produced using a genetically engi-  
14 neered vaccine or drug;

15          “(D) is a food or processed food that would be  
16 subject to this paragraph solely because it includes  
17 the use of a genetically engineered processing aid  
18 (including yeast) or enzyme; or

19          “(E) is a packaged food consisting of materials  
20 produced through genetic engineering that do not  
21 account for more than nine-tenths of 1 percent of  
22 the total weight of the packaged food.

23       “(3) In this paragraph and in paragraph (aa):

24           “(A) The term ‘genetic engineering’ means a  
25 process—

1           “(i) involving the application of in vitro  
2           nucleic acid techniques, including recombinant  
3           deoxyribonucleic acid (DNA) and direct injec-  
4           tion of nucleic acid into cells or organelles;

5           “(ii) involving the application of fusion of  
6           cells beyond the taxonomic family; or

7           “(iii) that overcomes natural physiological,  
8           reproductive, or recombinant barriers and that  
9           is not a process used in traditional breeding  
10          and selection.

11          “(B) The term ‘genetically engineered’, used  
12          with respect to a food, means a material intended  
13          for human consumption that is—

14               “(i) an organism that is produced through  
15               the intentional use of genetic engineering; or

16               “(ii) the progeny of intended sexual or  
17               asexual reproduction (or both) of 1 or more or-  
18               ganisms that is the product of genetic engineer-  
19               ing.

20          “(C) The term ‘genetically engineered ingre-  
21          dient’ means a material that is an ingredient in a  
22          food that is derived from any part of an organism  
23          that has been genetically engineered, without regard  
24          to whether—

1           “(i) the altered molecular or cellular char-  
2           acteristics of the organism are detectable in the  
3           material; and

4           “(ii) the organism is capable for use as  
5           human food.”.

6           (b) RESTRICTIONS ON THE TERM “NATURAL”.—Sec-  
7           tion 403 of the Federal Food, Drug, and Cosmetic Act  
8           (21 U.S.C. 343), as amended by subsection (a), is further  
9           amended by adding at the end the following:

10          “(aa) If it is a food intended for human consumption  
11          that has been produced using genetic engineering or that  
12          contains one or more genetically engineered ingredients  
13          and it bears a label, or for which there is signage or adver-  
14          tising, containing a claim that the food is ‘natural’, ‘natu-  
15          rally made’, ‘naturally grown’, ‘all natural’, or using any  
16          similar words that would be misleading to a consumer.”.

17          (c) GUARANTY.—

18               (1) IN GENERAL.—Section 303(d) of the Fed-  
19               eral Food, Drug, and Cosmetic Act (21 U.S.C.  
20               333(d)) is amended—

21                   (A) by striking “(d)” and inserting  
22                   “(d)(1)”; and

23                   (B) by adding at the end the following:

24                   “(2)(A) No person shall be subject to the pen-  
25                   alties of subsection (a)(1) for a violation of sub-

1 section (a), (b), or (c) of section 301 involving food  
2 that is misbranded within the meaning of paragraph  
3 (z) or (aa) of section 403 if such person (referred  
4 to in this paragraph as the ‘recipient’) establishes a  
5 guaranty or undertaking that—

6 “(i) is signed by, and contains the name  
7 and address of, a person residing in the United  
8 States from whom the recipient received in good  
9 faith the food (including the receipt of seeds to  
10 grow raw agricultural commodities); and

11 “(ii) contains a statement to the effect  
12 that the food is not genetically engineered or  
13 does not contain a genetically engineered ingre-  
14 dient.

15 “(B) In the case of a recipient who, with re-  
16 spect to a food, establishes a guaranty or under-  
17 taking in accordance with subparagraph (A), the ex-  
18 clusion under such subparagraph from being subject  
19 to penalties applies to the recipient without regard  
20 to the manner in which the recipient uses the food,  
21 including whether the recipient is—

22 “(i) processing the food;

23 “(ii) using the food as an ingredient in a  
24 food product;

25 “(iii) repacking the food; or

1           “(iv) growing, raising, or otherwise pro-  
2           ducing the food.

3           “(C) No person may avoid responsibility or li-  
4           ability for a violation of subsection (a), (b), or (c)  
5           of section 301 involving food that is misbranded  
6           within the meaning of paragraph (z) or (aa) of sec-  
7           tion 403 by entering into a contract or other agree-  
8           ment that specifies that another person shall bear  
9           such responsibility or liability, except that a recipi-  
10          ent may require a guaranty or undertaking as de-  
11          scribed in this subsection.

12          “(D) For purposes of this Act, food will be con-  
13          sidered not to have been produced with the knowing  
14          or intentional use of genetic engineering if—

15                 “(i) such food is lawfully certified to be la-  
16                 beled, marketed, and offered for sale as ‘or-  
17                 ganic’ pursuant to the Organic Foods Produc-  
18                 tion Act of 1990; or

19                 “(ii) an independent organization has de-  
20                 termined that the food has not been knowingly  
21                 or intentionally genetically engineered and has  
22                 been segregated from, and not knowingly or in-  
23                 tentionally commingled with, foods that may  
24                 have been genetically engineered at any time, if

1 such a determination has been made pursuant  
2 to a sampling and testing procedure that—

3 “(I) is consistent with sampling and  
4 testing principles recommended by inter-  
5 nationally recognized standards organiza-  
6 tions; and

7 “(II) does not rely on testing proc-  
8 essed foods in which no DNA is detectable.

9 “(E) In this subsection, the terms ‘genetically  
10 engineered’ and ‘genetically engineered ingredient’  
11 have the meanings given the terms in section  
12 403(z).”.

13 (2) FALSE GUARANTY.—Section 301(h) of the  
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 331(h)) is amended by inserting “or 303(d)(2)”  
16 after “section 303(c)(2)”.

17 (d) UNINTENDED CONTAMINATION.—Section 303(d)  
18 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19 333(d)), as amended by subsection (b), is further amended  
20 by adding at the end the following:

21 “(3)(A) No person shall be subject to the pen-  
22 alties of subsection (a)(1) for a violation of sub-  
23 section (a), (b), or (c) of section 301 involving food  
24 that is misbranded within the meaning of section  
25 403(z) if—

1           “(i) such person is an agricultural pro-  
2           ducer and the violation occurs because food that  
3           is grown, raised, or otherwise produced by such  
4           producer, which food does not contain a geneti-  
5           cally engineered material and was not produced  
6           with a genetically engineered material, is con-  
7           taminated with a food that contains a geneti-  
8           cally engineered material or was produced with  
9           a genetically engineered material; and

10           “(ii) such contamination is not intended by  
11           the agricultural producer.

12           “(B) Subparagraph (A) does not apply to an  
13           agricultural producer to the extent that the contami-  
14           nation occurs as a result of the negligence of the  
15           producer.”.

16           (e) PROMULGATION OF REGULATIONS.—Not later  
17           than 1 year after the date of enactment of this Act, the  
18           Secretary shall promulgate proposed regulations estab-  
19           lishing labeling requirements for compliance in accordance  
20           with section 403(z) of the Federal Food, Drug, and Cos-  
21           metic Act, as added by subsection (a).

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