

113TH CONGRESS  
1ST SESSION

# S. 809

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

APRIL 24, 2013

Mrs. BOXER (for herself, Ms. MURKOWSKI, Mrs. GILLIBRAND, Mr. BLUMENTHAL, Mr. BEGICH, Mr. TESTER, Mr. SANDERS, Mr. MERKLEY, Mr. SCHATZ, and Mr. HEINRICH) 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”.

1 **SEC. 2. PURPOSE AND FINDINGS.**

2 (a) PURPOSE.—The purpose of this Act is to estab-  
3 lish a consistent and enforceable standard for labeling of  
4 foods produced using genetic engineering, including fish,  
5 thereby providing consumers with knowledge of how their  
6 food is produced.

7 (b) FINDINGS.—Congress finds that—

8 (1) the process of genetically engineering food  
9 organisms results in material changes to food de-  
10 rived from those organisms;

11 (2) the Food and Drug Administration requires  
12 the labeling of more than 3,000 ingredients, addi-  
13 tives, and processes;

14 (3) individuals in the United States have a  
15 right to know if their food was produced with ge-  
16 netic engineering for a variety of reasons, including  
17 health, economic, environmental, religious, and eth-  
18 ical;

19 (4) more than 60 countries, including the  
20 United Kingdom and all other countries of the Euro-  
21 pean Union, South Korea, Japan, Brazil, Australia,  
22 India, China, and other key United States trading  
23 partners have laws or regulations mandating disclo-  
24 sure of genetically engineered food on food labels;

25 (5) in 2011, Codex Alimentarius, the food  
26 standards organization of the United Nations,

1       adopted a text that indicates that governments can  
2       decide on whether and how to label foods produced  
3       with genetic engineering; and

4               (6) mandatory identification of food produced  
5       with genetic engineering can be a critical method of  
6       preserving the economic value of exports or domesti-  
7       cally sensitive markets with labeling requirements  
8       for genetically engineered foods.

9       **SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**  
10                                   **COSMETIC ACT.**

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

14               “(z)(1) If it is a food that has been genetically engi-  
15       neered or contains 1 or more genetically engineered ingre-  
16       dients, unless such information is clearly disclosed, as de-  
17       termined by the Secretary.

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

19                       “(A) is served in restaurants or other similar  
20       eating establishments, such as cafeterias and  
21       carryouts;

22                       “(B) is a medical food (as defined in section  
23       5(b) of the Orphan Drug Act);

1           “(C) is a food that would be subject to this  
2 paragraph solely because it was produced using a ge-  
3 netically engineered vaccine; or

4           “(D) is a food or processed food that would be  
5 subject to this paragraph solely because it includes  
6 the use of a genetically engineered processing aid  
7 (including yeast) or enzyme.

8           “(3) In this paragraph:

9           “(A) The term ‘genetic engineering’ means a  
10 process involving the application of—

11                   “(i) in vitro nucleic acid techniques, includ-  
12 ing recombinant deoxyribonucleic acid (DNA)  
13 and direct injection of nucleic acid into cells or  
14 organelles; or

15                   “(ii) fusion of cells beyond the taxonomic  
16 family that—

17                           “(I) overcome natural physiological  
18 reproductive or recombinant barriers; and

19                           “(II) are not techniques used in tradi-  
20 tional breeding and selection.

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

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

1           “(ii) the progeny of intended sexual or  
2           asexual reproduction (or both) of 1 or more or-  
3           ganisms that is the product of genetic engineer-  
4           ing.

5           “(C) The term ‘genetically engineered ingre-  
6           dient’ means a material that is an ingredient in a  
7           food that is derived from any part of an organism  
8           that has been genetically engineered, without regard  
9           to whether—

10           “(i) the altered molecular or cellular char-  
11           acteristics of the organism are detectable in the  
12           material; and

13           “(ii) the organism is capable for use as  
14           human food.”.

15           (b) GUARANTY.—

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

19           (A) by striking “(d)” and inserting  
20           “(d)(1)”; and

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

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

1 403(z) if such person (referred to in this paragraph  
2 as the ‘recipient’) establishes a guaranty or under-  
3 taking that—

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

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

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

20 “(i) processing the food;

21 “(ii) using the food as an ingredient in a  
22 food product;

23 “(iii) repacking the food; or

24 “(iv) growing, raising, or otherwise pro-  
25 ducing the food.

1           “(C) No person may avoid responsibility or li-  
2           ability for a violation of subsection (a), (b), or (c)  
3           of section 301 involving food that is misbranded  
4           within the meaning of section 403(z) by entering  
5           into a contract or other agreement that specifies  
6           that another person shall bear such responsibility or  
7           liability, except that a recipient may require a guar-  
8           anty or undertaking as described in this subsection.

9           “(D) 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          (c) 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           (d) 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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