

113TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mrs. BOXER introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that genetically engineered food and foods that contains 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 purpose of this Act is to estab-
8 lish a consistent and enforceable standard for labeling of

1 foods produced using genetic engineering, including fish,
2 thereby providing consumers with knowledge of how their
3 food is produced.

4 (b) FINDINGS.—Congress finds that—

5 (1) the process of genetically engineering food
6 organisms results in material changes to food de-
7 rived from those organisms;

8 (2) the Food and Drug Administration requires
9 the labeling of more than 3,000 ingredients, addi-
10 tives, and processes;

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

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

22 (5) in 2011, Codex Alimentarius, the food
23 standards organization of the United Nations,
24 adopted a text that indicates that governments can

1 decide on whether and how to label foods produced
2 with genetic engineering; and

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

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

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

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

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

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

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

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

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

5 “(3) In this paragraph:

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

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

12 “(ii) fusion of cells beyond the taxonomic
13 family that—

14 “(I) overcome natural physiological
15 reproductive or recombinant barriers; and

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

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

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

23 “(ii) the progeny of intended sexual or
24 asexual reproduction (or both) of 1 or more or-

1 ganisms that is the product of genetic engineer-
2 ing.

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

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

11 “(ii) the organism is capable for use as
12 human food.”.

13 (b) GUARANTY.—

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

17 (A) by striking “(d)” and inserting
18 “(d)(1)”; and

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

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

1 as the ‘recipient’) establishes a guaranty or under-
2 taking that—

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

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

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

19 “(i) processing the food;

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

22 “(iii) repacking the food; or

23 “(iv) growing, raising, or otherwise pro-
24 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).