

106TH CONGRESS  
2D SESSION

# S. 2080

To amend the Federal Food, Drug, and Cosmetic Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 22, 2000

Mrs. BOXER introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly, 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 “Genetically Engineered  
5        Food Right-to-Know Act”.

6        **SEC. 2. FINDINGS.**

7        Congress finds the following:

1           (1) In 1999, 98,600,000 acres in the United  
2 States were planted with genetically engineered  
3 crops, and more than  $\frac{1}{3}$  of the soybean crop, and  
4  $\frac{1}{4}$  of the corn crop, in the United States was geneti-  
5 cally engineered.

6           (2) The process of genetically engineering foods  
7 results in the material change of such foods.

8           (3) The health and environmental effects of ge-  
9 netically engineered foods are not yet known.

10           (4) Individuals in the United States have the  
11 right to know whether food contains or has been  
12 produced with genetically engineered material.

13           (5) Federal law gives individuals in the United  
14 States the right to know whether food contains arti-  
15 ficial colors and flavors, chemical preservatives, and  
16 artificial sweeteners by requiring the labeling of such  
17 food.

18           (6) Requirements that genetically engineered  
19 food be labeled as genetically engineered would in-  
20 crease consumer knowledge about, and consumer  
21 control over consumption of, genetically engineered  
22 food.

23           (7) Genetically engineered material can be de-  
24 tected in food at levels as low as 0.1 percent by rea-  
25 sonably available technology.

1 **SEC. 3. LABELING REGARDING GENETICALLY ENGINEERED**  
2 **MATERIAL; AMENDMENTS TO FEDERAL**  
3 **FOOD, DRUG, AND COSMETIC ACT.**

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

7 “(t)(1) If it contains a genetically engineered mate-  
8 rial, or was produced with a genetically engineered mate-  
9 rial, unless it bears a label (or labeling, in the case of a  
10 raw agricultural commodity) that provides notices in ac-  
11 cordance with each of the following requirements:

12 “(A) The label or labeling bears the following  
13 notice: ‘GENETICALLY ENGINEERED’.

14 “(B) The label or labeling bears the following  
15 notice: ‘THIS PRODUCT CONTAINS A GENETI-  
16 CALLY ENGINEERED MATERIAL, OR WAS  
17 PRODUCED WITH A GENETICALLY ENGI-  
18 NEERED MATERIAL’.

19 “(C) The notice required in clause (A) imme-  
20 diately precedes the notice required in clause (B)  
21 and the type for the notice required in clause (A) is  
22 not less than twice the size of the type for the notice  
23 required in clause (B).

24 “(D) The notice required in clause (B) is the  
25 same size as would be required if the notice provided

1 nutrition information that is required in paragraph  
2 (q)(1).

3 “(E) The notices required in clauses (A) and  
4 (B) are clearly legible and conspicuous.

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

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

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

11 “(C) was grown on a tree that was planted be-  
12 fore the date of enactment of the Genetically Engi-  
13 neered Food Right-to-Know Act, in a case in which  
14 the producer of the food does not know if the food  
15 contains a genetically engineered material, or was  
16 produced with a genetically engineered material.

17 “(3) In this paragraph:

18 “(A) The term ‘genetically engineered material’  
19 means material derived from any part of a geneti-  
20 cally engineered organism, without regard to wheth-  
21 er the altered molecular or cellular characteristics of  
22 the organism are detectable in the material.

23 “(B) The term ‘genetically engineered orga-  
24 nism’ means—

1           “(i) an organism that has been altered at  
2           the molecular or cellular level by means that are  
3           not possible under natural conditions or proc-  
4           esses (including recombinant DNA and RNA  
5           techniques, cell fusion, microencapsulation,  
6           macroencapsulation, gene deletion and doubling,  
7           introduction of a foreign gene, and a process  
8           that changes the positions of genes), other than  
9           a means consisting exclusively of breeding, con-  
10          jugation, fermentation, hybridization, in vitro  
11          fertilization, or tissue culture; and

12           “(ii) an organism made through sexual or  
13          asexual reproduction, or both, involving an or-  
14          ganism described in subclause (i), if possessing  
15          any of the altered molecular or cellular charac-  
16          teristics of the organism so described.

17          “(C) The term ‘produced with a genetically en-  
18          gineered material’, used with respect to a food,  
19          means a food if—

20           “(i) the organism from which the food is  
21           derived has been injected or otherwise treated  
22           with a genetically engineered material (except  
23           that the use of manure as a fertilizer for raw  
24           agricultural commodities may not be construed

1 to be production with a genetically engineered  
2 material);

3 “(ii) the animal from which the food is de-  
4 rived has been fed genetically engineered mate-  
5 rial; or

6 “(iii) the food contains an ingredient that  
7 is a food to which subclause (i) or (ii) applies.”.

8 (b) GUARANTY.—

9 (1) IN GENERAL.—Section 303(d) of the Fed-  
10 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
11 333(d)) is amended—

12 (A) by striking “(d)” and inserting  
13 “(d)(1)”; and

14 (B) by adding at the end the following  
15 paragraph:

16 “(2)(A) No person shall be subject to the penalties  
17 of subsection (a)(1) or (h) for a violation of section 301(a),  
18 301(b), or 301(c) involving food that is misbranded within  
19 the meaning of section 403(t) if such person (referred to  
20 in this paragraph as the ‘recipient’) establishes a guaranty  
21 or undertaking that—

22 “(i) is signed by, and contains the name and  
23 address of, a person residing in the United States  
24 from whom the recipient received in good faith the

1 food (including the receipt of seeds to grow raw agri-  
2 cultural commodities); and

3 “(ii) contains a statement to the effect that the  
4 food does not contain a genetically engineered mate-  
5 rial or was not produced with a genetically engi-  
6 neered material.

7 “(B) In the case of a recipient who, with respect to  
8 a food, establishes a guaranty or undertaking in accord-  
9 ance with subparagraph (A), the exclusion under such sub-  
10 paragraph from being subject to penalties applies to the  
11 recipient without regard to the manner in which the recipi-  
12 ent uses the food, including whether the recipient is—

13 “(i) processing the food;

14 “(ii) using the food as an ingredient in a food  
15 product;

16 “(iii) repacking the food; or

17 “(iv) growing, raising, or otherwise producing  
18 the food.

19 “(C) No person may avoid responsibility or liability  
20 for a violation of section 301(a), 301(b), or 301(c) involv-  
21 ing food that is misbranded within the meaning of section  
22 403(t) by entering into a contract or other agreement that  
23 specifies that another person shall bear such responsibility  
24 or liability, except that a recipient may require a guaranty  
25 or undertaking as described in this subsection.

1 “(D) In this paragraph, the terms ‘genetically engi-  
2 neered material’ and ‘produced with a genetically engi-  
3 neered material’ have the meanings given the terms in sec-  
4 tion 403(t).”.

5 (2) FALSE GUARANTY.—Section 301(h) of the  
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
7 331(h)) is amended by inserting “or 303(d)(2)” be-  
8 fore “, which guaranty or undertaking is false” the  
9 first place it appears.

10 (c) UNINTENDED CONTAMINATION.—Section 303(d)  
11 of the Federal Food, Drug, and Cosmetic Act, as amended  
12 by subsection (b)(1), is further amended by adding at the  
13 end the following paragraph:

14 “(3)(A) No person shall be subject to the penalties  
15 of subsection (a)(1) or (h) for a violation of section 301(a),  
16 301(b), or 301(c) involving food that is misbranded within  
17 the meaning of section 403(t) if—

18 “(i) such person is an agricultural producer and  
19 the violation occurs because food that is grown,  
20 raised, or otherwise produced by such producer,  
21 which food does not contain a genetically engineered  
22 material and was not produced with a genetically en-  
23 gineered material, is contaminated with a food that  
24 contains a genetically engineered material or was

1 produced with a genetically engineered material (in-  
2 cluding contamination by mingling the 2 foods); and

3 “(ii) such contamination is not intended by the  
4 agricultural producer.

5 “(B) Subparagraph (A) does not apply to an agricul-  
6 tural producer to the extent that the contamination occurs  
7 as a result of the negligence of the producer.”.

8 (d) CIVIL PENALTIES.—Section 303 of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amend-  
10 ed by adding at the end the following subsection:

11 “(h)(1) With respect to a violation of section 301(a),  
12 301(b), or 301(c) involving food that is misbranded within  
13 the meaning of section 403(t), any person engaging in  
14 such a violation shall be liable to the United States for  
15 a civil penalty in an amount not to exceed \$1,000 for each  
16 such violation.

17 “(2) Paragraphs (3) through (5) of subsection (g)  
18 apply with respect to a civil penalty assessed under para-  
19 graph (1) to the same extent and in the same manner as  
20 such paragraphs (3) through (5) apply with respect to a  
21 civil penalty assessed under paragraph (1) or (2) of sub-  
22 section (g).”.

1 **SEC. 4. GRANTS FOR RESEARCH ON GENETICALLY ENGI-**  
2 **NEERED FOOD.**

3 Chapter IX of the Federal Food, Drug, and Cosmetic  
4 Act (21 U.S.C. 391 et seq.) is amended by adding at the  
5 end the following:

6 **“SEC. 908. GRANTS FOR RESEARCH ON GENETICALLY ENGI-**  
7 **NEERED FOOD.**

8 “(a) IN GENERAL.—The Secretary may make grants  
9 to appropriate individuals, organizations, and institutions  
10 to conduct research into the public health and environ-  
11 mental risks associated with genetically engineered mate-  
12 rials, food that contains a genetically engineered material,  
13 and food that is produced with a genetically engineered  
14 material, including risks related to—

15 “(1) increased allergenicity;

16 “(2) increased toxicity;

17 “(3) cross-pollination between genetically engi-  
18 neered materials and materials that are not geneti-  
19 cally engineered materials; and

20 “(4) interference with the soil ecosystem and  
21 other impacts on the ecosystem.

22 “(b) AUTHORIZATION OF APPROPRIATIONS.—

23 “(1) IN GENERAL.—There is authorized to be  
24 appropriated \$5,000,000 for fiscal year 2001 to  
25 carry out the objectives of this section.

1           “(2) AVAILABILITY.—Any sums appropriated  
2           under the authorization contained in this subsection  
3           shall remain available, without fiscal year limitation,  
4           until expended.

5           “(c) DEFINITIONS.—The terms ‘genetically engi-  
6           neered material’ and ‘produced with a genetically engi-  
7           neered material’ have the meanings given the terms in sec-  
8           tion 403(t)(3) of the Federal Food, Drug, and Cosmetic  
9           Act.”.

10 **SEC. 5. CONFORMING AMENDMENTS.**

11           (a) Section 1(n) of Public Law 90–201 is amended—

12                   (1) in paragraph (11), by striking “or” at the  
13                   end;

14                   (2) in paragraph (12), by striking the period at  
15                   the end and inserting “; or”; and

16                   (3) by adding at the end the following:

17                   “(13) if—

18                           “(A) it contains a genetically engineered  
19                           material, or was produced with a genetically en-  
20                           gineered material; and

21                           “(B)(i) it does not bear a label or labeling,  
22                           as appropriate, that provides the notices re-  
23                           quired under the terms and conditions of sec-  
24                           tion 403(t) of the Federal Food, Drug, and  
25                           Cosmetic Act (21 U.S.C. 343(t)); or

1           “(ii) it is the subject of a false guaranty or  
2           undertaking,  
3           subject to the terms and conditions of section 303(d)  
4           of that Act (21 U.S.C. 333(d)) and subject to the  
5           penalties described in section 303(h) of that Act (21  
6           U.S.C. 333(h)) and remedies available under this  
7           Act.”.

8           (b) Section 4(h) of Public Law 85–172 is amended—

9           (1) in paragraph (11), by striking “or” at the  
10          end;

11          (2) in paragraph (12), by striking the period at  
12          the end and inserting “; or”; and

13          (3) by adding at the end the following:

14          “(13) if—

15               “(A) it contains a genetically engineered  
16               material, or was produced with a genetically en-  
17               gineered material; and

18               “(B)(i) it does not bear a label or labeling,  
19               as appropriate, that provides the notices re-  
20               quired under the terms and conditions of sec-  
21               tion 403(t) of the Federal Food, Drug, and  
22               Cosmetic Act (21 U.S.C. 343(t)); or

23               “(ii) it is the subject of a false guaranty or  
24               undertaking,

1 subject to the terms and conditions of section 303(d)  
2 of that Act (21 U.S.C. 333(d)) and subject to the  
3 penalties described in section 303(h) of that Act (21  
4 U.S.C. 333(h)) and remedies available under this  
5 Act.”.

6 **SEC. 6. EFFECTIVE DATE.**

7 This Act and the amendments made by this Act take  
8 effect 180 days after the date of enactment of this Act.

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