

112TH CONGRESS  
1ST SESSION

# H. R. 3553

To amend the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly.

---

## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 2, 2011

Mr. KUCINICH (for himself, Mr. GRIJALVA, Ms. LEE of California, Mr. MORAN, Mr. POLIS, Ms. PINGREE of Maine, Ms. SLAUGHTER, Ms. SPEIER, Mr. STARK, Mr. THOMPSON of California, Ms. WATERS, Ms. WOOLSEY, and Mr. YOUNG of Alaska) introduced the following bill; which was referred to the Committee on Agriculture, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

## A BILL

To amend the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, 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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the  
3 “Genetically Engineered Food Right to Know Act”.

4 (b) TABLE OF CONTENTS.—The table of contents of  
5 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Labeling regarding genetically engineered material; amendments to Federal Food, Drug, and Cosmetic Act.

Sec. 4. Labeling regarding genetically engineered material; amendments to Federal Meat Inspection Act.

Sec. 5. Labeling regarding genetically engineered material; amendments to Poultry Products Inspection Act.

Sec. 6. Effective date.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) The process of genetically engineering foods  
9 results in the material change of such foods.

10 (2) The Congress has previously required that  
11 all foods bear labels that reveal material facts to  
12 consumers.

13 (3) Federal agencies have failed to uphold Con-  
14 gressional intent by allowing genetically engineered  
15 foods to be marketed, sold and otherwise used with-  
16 out labeling that reveals material facts to the public.

17 (4) Consumers wish to know whether the food  
18 they purchase and consume contains or is produced  
19 with a genetically engineered material for a variety  
20 of reasons, including the potential transfer of aller-  
21 gens into food and other health risks, concerns

1 about potential environmental risks associated with  
2 the genetic engineering of crops, and religiously and  
3 ethically based dietary restrictions.

4 (5) Consumers have a right to know whether  
5 the food they purchase contains or was produced  
6 with genetically engineered material.

7 (6) Labels voluntarily placed on foods are insuf-  
8 ficient to provide consumers with adequate informa-  
9 tion on whether or not all the food they are pur-  
10 chasing contains or was produced with genetically  
11 engineered material.

12 (7) Mandatory labeling provides a critical sci-  
13 entific method necessary for the continual  
14 postmarket surveillance to study long-term health  
15 impacts and enforcement of food safety laws pre-  
16 venting adulterated foods from reaching consumers.

17 (8) Many of the United States key trading  
18 partners, including countries in the European  
19 Union, Japan, and the People's Republic of China,  
20 have established, or are in the process of imple-  
21 menting, mandatory labeling requirements for ge-  
22 netically engineered food.

23 (9) Adoption and implementation of mandatory  
24 labeling requirements for genetically engineered food  
25 produced in the United States would facilitate inter-

1 national trade by allowing American farmers and  
2 companies to export and appropriately market their  
3 products—both genetically engineered and non-ge-  
4 netically engineered—to foreign customers.

5 **SEC. 3. LABELING REGARDING GENETICALLY ENGINEERED**  
6 **MATERIAL; AMENDMENTS TO FEDERAL**  
7 **FOOD, DRUG, AND COSMETIC ACT.**

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

11 “(z)(1) If it contains a genetically engineered mate-  
12 rial, or was produced with a genetically engineered mate-  
13 rial, unless it bears a label (or labeling, in the case of a  
14 raw agricultural commodity, other than the sale of such  
15 a commodity at retail) that provides notices in accordance  
16 with the following:

17 “(A) A notice as follows: ‘GENETICALLY  
18 ENGINEERED’.

19 “(B) A notice as follows: ‘THIS PRODUCT  
20 CONTAINS A GENETICALLY ENGINEERED  
21 MATERIAL, OR WAS PRODUCED WITH A GE-  
22 NETICALLY ENGINEERED MATERIAL’.

23 “(C) The notice required in clause (A) imme-  
24 diately precedes the notice required in clause (B)

1 and is not less than twice the size of the notice re-  
2 quired in clause (B).

3 “(D) The notice required in clause (B) is of the  
4 same size as would apply if the notice provided nu-  
5 trition information that is required in paragraph  
6 (q)(1).

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

9 “(2) For purposes of subparagraph (1):

10 “(A) The term ‘genetically engineered material’  
11 means material derived from any part of a geneti-  
12 cally engineered organism, without regard to wheth-  
13 er the altered molecular or cellular characteristics of  
14 the organism are detectable in the material.

15 “(B) The term ‘genetically engineered orga-  
16 nism’ means—

17 “(i) an organism (including fish) that has  
18 been altered at the molecular or cellular level by  
19 means that are not possible under natural con-  
20 ditions or processes (including but not limited  
21 to recombinant DNA and RNA techniques, cell  
22 fusion, microencapsulation, macroencapsulation,  
23 gene deletion and doubling, introducing a for-  
24 eign gene, and changing the positions of genes),  
25 other than a means consisting exclusively of

1 breeding, conjugation, fermentation, hybridiza-  
2 tion, in vitro fertilization, tissue culture, or mu-  
3 tagenesis, and

4 “(ii) an organism made through sexual or  
5 asexual reproduction (or both) involving an or-  
6 ganism described in subclause (i), if possessing  
7 any of the altered molecular or cellular charac-  
8 teristics of the organism so described.

9 “(3) For purposes of subparagraph (1), a food shall  
10 be considered to have been produced with a genetically en-  
11 gineered material if—

12 “(A) the organism (including fish) from which  
13 the food is derived has been injected or otherwise  
14 treated with a genetically engineered material (ex-  
15 cept that the use of manure as a fertilizer for raw  
16 agricultural commodities may not be construed to  
17 mean that such commodities are produced with a ge-  
18 netically engineered material),

19 “(B) the animal (including fish) from which the  
20 food is derived has been fed genetically engineered  
21 material, or

22 “(C) the food contains an ingredient that is a  
23 food to which clause (A) or (B) applies.

24 “(4) This paragraph does not apply to food that—

1           “(A) is served in restaurants or other establish-  
2           ments in which food is served for immediate human  
3           consumption,

4           “(B) is processed and prepared primarily in a  
5           retail establishment, is ready for human consump-  
6           tion, which is of the type described in clause (A),  
7           and is offered for sale to consumers but not for im-  
8           mediate human consumption in such establishment  
9           and is not offered for sale outside such establish-  
10          ment, or

11          “(C) is a medical food as defined in section 5(b)  
12          of the Orphan Drug Act.

13          “(5) In the case of the transfer of food from manu-  
14          facturers or producers to distributors, and from distribu-  
15          tors to other distributors or to other persons in the chain  
16          of distribution, including persons who hold food for sale  
17          to consumers, regulations under this paragraph and para-  
18          graph (z) shall require periodic testing of foods by the Sec-  
19          retary for purposes of determining the accuracy of labels  
20          under such paragraphs. Such regulations shall require the  
21          use of the best available technology for such testing, and  
22          shall identify tests that meet such requirement. This sub-  
23          paragraph and subparagraph (6) do not apply to (A) foods  
24          that are certified and comply with the Organic Foods Pro-  
25          duction Act and its implementing regulations; or (B) foods

1 produced with genetically engineered material if the Sec-  
2 retary has not through such regulations identified a vali-  
3 dated method of testing for such material in the food; or  
4 (C) genetically engineered material contained in a food if  
5 the Secretary has not through such regulations identified  
6 a validated method of testing for such material in the food.

7 “(6) For purposes of this paragraph and paragraph  
8 (z), a food with respect to which a test has been identified  
9 under subparagraph (5) shall not be considered to contain  
10 a genetically engineered material if, as indicated by such  
11 a test—

12 “(A) the food does not contain any genetically  
13 engineered material, or

14 “(B) the food contains an adventitious geneti-  
15 cally engineered material and the amount of the ma-  
16 terial in the food is one percent or less, except that  
17 a lower percentage designated by the Secretary shall  
18 apply for purposes of this subparagraph if the Sec-  
19 retary determines that a test identified under sub-  
20 paragraph (5) can detect a percentage lower than  
21 one percent.

22 “(aa) If it bears a label indicating (within the mean-  
23 ing of paragraph (z)) that it does not contain a genetically  
24 engineered material, or that it was not produced with a  
25 genetically engineered material, unless the label is in ac-



1 cordance with regulations promulgated by the Secretary.

2 With respect to such regulations:

3           “(1) The regulations may not require such a  
4 label to include any statement indicating that the  
5 fact that a food does not contain such material, or  
6 was not produced with such material, has no bearing  
7 on the safety of the food for human consumption.

8           “(2) The regulations may not prohibit such a  
9 label on the basis that, in the case of the type of  
10 food involved, there is no version of the food in com-  
11 mercial distribution that does contain a genetically  
12 engineered material.”.

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

16           “(h)(1) With respect to a violation of section 301(a),  
17 301(b), or 301(c) involving the misbranding of food within  
18 the meaning of section 403(z) or 403(aa), any person en-  
19 gaging in such a violation shall be liable to the United  
20 States for a civil penalty in an amount not to exceed  
21 \$100,000 for each such violation.

22           “(2) Paragraphs (5) through (7) of subsection (f)  
23 apply with respect to a civil penalty under paragraph (1)  
24 of this subsection to the same extent and in the same man-  
25 ner as such paragraphs (5) through (7) apply with respect

1 to a civil penalty under paragraph (1), (2), (3), (4), or  
2 (9) of subsection (f).”.

3 (c) GUARANTY.—

4 (1) IN GENERAL.—Section 303(d) of the Fed-  
5 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
6 333(d)) is amended—

7 (A) by striking “(d)” and inserting  
8 “(d)(1)”; and

9 (B) by adding at the end the following new  
10 paragraph:

11 “(2)(A) Subject to subparagraph (C) and section  
12 403(z)(5), no person shall be subject to the penalties of  
13 subsection (a)(1) or (h) for a violation of section 301(a),  
14 301(b), or 301(c) involving the misbranding of food within  
15 the meaning of section 403(z) and 403(aa) if such person  
16 (referred to in this paragraph as the ‘recipient’) estab-  
17 lishes a guaranty or undertaking signed by, and con-  
18 taining the name and address of, the person residing in  
19 the United States from whom the recipient received in  
20 good faith the food (including the receipt of seeds to grow  
21 raw agricultural commodities), to the effect that (within  
22 the meaning of section 403(z)) the food does not contain  
23 a genetically engineered material or was not produced with  
24 a genetically engineered material.

1       “(B) In the case of a recipient who with respect to  
2 a food establishes a guaranty or undertaking in accord-  
3 ance with subparagraph (A), the exclusion under such sub-  
4 paragraph from being subject to penalties applies to the  
5 recipient without regard to the use of the food by the re-  
6 cipient, including—

7               “(i) processing the food,

8               “(ii) using the food as an ingredient in a food  
9 product,

10              “(iii) repacking the food, or

11              “(iv) growing, raising, or otherwise producing  
12 the food.”.

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 “303(c)(2)”.

17              (d) UNINTENDED CONTAMINATION.—Section 303(d)  
18 of the Federal Food, Drug, and Cosmetic Act, as amended  
19 by subsection (c)(1) of this section, is amended by adding  
20 at the end the following paragraph:

21              “(3)(A) No person shall be subject to the penalties  
22 of subsection (a)(1) or (h) for a violation of section 301(a),  
23 301(b), or 301(c) involving the misbranding of food within  
24 the meaning of section 403(z) or 403(aa) if—

1           “(i) such person is an agricultural producer and  
2           the violation occurs because food that is grown,  
3           raised, or otherwise produced by such producer,  
4           which food does not contain a genetically engineered  
5           material and was not produced with a genetically en-  
6           gineered material, is contaminated with a food that  
7           contains a genetically engineered material or was  
8           produced with a genetically engineered material (in-  
9           cluding contamination by mingling the two), and

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

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

15           (e) CITIZEN SUITS.—Chapter III of the Federal  
16           Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.)  
17           is amended by adding at the end the following section:

18           **“SEC. 311. CITIZEN SUITS REGARDING MISBRANDING OF**  
19                               **FOOD WITH RESPECT TO GENETICALLY ENGI-**  
20                               **NEERED MATERIAL.**

21           “(a) IN GENERAL.—Except as provided in subsection  
22           (c), any person may on his or her behalf commence a civil  
23           action in an appropriate district court of the United States  
24           against—

1           “(1) a person who is alleged to have engaged in  
2 a violation of section 301(a), 301(b), or 301(c) in-  
3 volving the misbranding of food within the meaning  
4 of section 403(z) or 403(aa); or

5           “(2) the Secretary where there is alleged a fail-  
6 ure of the Secretary to perform any act or duty  
7 under section 403(z) or 403(aa) that is not discre-  
8 tionary.

9           “(b) RELIEF.—In a civil action under subsection (a),  
10 the district court involved may, as the case may be—

11           “(1) enforce the compliance of a person with  
12 the applicable provisions referred to paragraph (1)  
13 of such subsection; or

14           “(2) order the Secretary to perform an act or  
15 duty referred to in paragraph (2) of such subsection.

16           “(c) LIMITATIONS.—

17           “(1) NOTICE TO SECRETARY.—A civil action  
18 may not be commenced under subsection (a)(1) prior  
19 to 60 days after the plaintiff has provided to the  
20 Secretary notice of the violation involved.

21           “(2) RELATION TO ACTIONS OF SECRETARY.—  
22 A civil action may not be commenced under sub-  
23 section (a)(2) if the Secretary has commenced and  
24 is diligently prosecuting a civil or criminal action in  
25 a district court of the United States to enforce com-

1       pliance with the applicable provisions referred to in  
2       subsection (a)(1).

3       “(d) RIGHT OF SECRETARY TO INTERVENE.—In any  
4       civil action under subsection (a), the Secretary, if not a  
5       party, may intervene as a matter of right.

6       “(e) AWARD OF COSTS; FILING OF BOND.—In a civil  
7       action under subsection (a), the district court involved  
8       may award costs of litigation (including reasonable attor-  
9       ney and expert witness fees) to any party whenever the  
10      court determines such an award is appropriate. The court  
11      may, if a temporary restraining order or preliminary in-  
12      junction is sought, require the filing of a bond or equiva-  
13      lent security in accordance with the Federal Rules of Civil  
14      Procedure.

15      “(f) SAVINGS PROVISION.—This section does not re-  
16      strict any right that a person (or class of persons) may  
17      have under any statute or common law to seek enforce-  
18      ment of the provisions referred to subsection (a)(1), or to  
19      seek any other relief (including relief against the Sec-  
20      retary).”.

1 **SEC. 4. LABELING REGARDING GENETICALLY ENGINEERED**  
2 **MATERIAL; AMENDMENTS TO FEDERAL MEAT**  
3 **INSPECTION ACT.**

4 (a) REQUIREMENTS.—The Federal Meat Inspection  
5 Act is amended by inserting after section 7 (21 U.S.C.  
6 607) the following section:

7 **“SEC. 7A. REQUIREMENTS FOR LABELING REGARDING GE-**  
8 **NETICALLY ENGINEERED MATERIAL.**

9 “(a) DEFINITIONS.—In this section:

10 “(1) The term ‘meat food’ means a carcass,  
11 part of a carcass, meat, or meat food product that  
12 is derived from cattle, sheep, swine, goats, horses,  
13 mules, or other equines and is capable of use as  
14 human food.

15 “(2) The term ‘genetically engineered material’  
16 means material derived from any part of a geneti-  
17 cally engineered organism, without regard to wheth-  
18 er the altered molecular or cellular characteristics of  
19 the organism are detectable in the material (and  
20 without regard to whether the organism is capable  
21 of use as human food).

22 “(3) The term ‘genetically engineered organism’  
23 means—

24 “(A) an organism that has been altered at  
25 the molecular or cellular level by means that are  
26 not possible under natural conditions or proc-

1           esses (including but not limited to recombinant  
2           DNA and RNA techniques, cell fusion, micro-  
3           encapsulation, macroencapsulation, gene dele-  
4           tion and doubling, introducing a foreign gene,  
5           and changing the positions of genes), other  
6           than a means consisting exclusively of breeding,  
7           conjugation, fermentation, hybridization, in  
8           vitro fertilization, tissue culture, or mutagene-  
9           sis; and

10           “(B) an organism made through sexual or  
11           asexual reproduction (or both) involving an or-  
12           ganism described in subparagraph (A), if pos-  
13           sessing any of the altered molecular or cellular  
14           characteristics of the organism so described.

15           “(b) LABELING REQUIREMENT.—

16           “(1) REQUIRED LABELING TO AVOID MIS-  
17           BRANDING.—

18           “(A) INVOLVEMENT OF GENETICALLY EN-  
19           GINEERED MATERIAL.—For purposes of sec-  
20           tions 1(n) and 10, a meat food is misbranded  
21           if it—

22           “(i) contains a genetically engineered  
23           material or was produced with a geneti-  
24           cally engineered material; and



1           “(ii) does not bear a label (or include  
2           labeling, in the case of a meat food that is  
3           not packaged in a container) that provides,  
4           in a clearly legible and conspicuous man-  
5           ner, the notices described in subsection (c).

6           “(B) NO INVOLVEMENT OF GENETICALLY  
7           ENGINEERED MATERIAL.—For purposes of sec-  
8           tions 1(n) and 10, a meat food is misbranded  
9           if it bears a label indicating that it does not  
10          contain a genetically engineered material, or  
11          that it was not produced with a genetically en-  
12          gineered material, unless the label is in accord-  
13          ance with regulations promulgated by the Sec-  
14          retary. With respect to such regulations:

15               “(i) The regulations may not require  
16               such a label to include any statement indi-  
17               cating that the fact that a meat food does  
18               not contain such material, or was not pro-  
19               duced with such material, has no bearing  
20               on the safety of the food for human con-  
21               sumption.

22               “(ii) The regulations may not prohibit  
23               such a label on the basis that, in the case  
24               of the type of meat food involved, there is  
25               no version of the food in commercial dis-

1                   tribution that does contain a genetically  
2                   engineered material.

3                   “(2) RULE OF CONSTRUCTION.—For purposes  
4                   of subparagraphs (A)(i) and (B) of paragraph (1),  
5                   a meat food shall be considered to have been pro-  
6                   duced with a genetically engineered material if—

7                   “(A) the organism from which the food is  
8                   derived has been injected or otherwise treated  
9                   with a genetically engineered material;

10                  “(B) the animal from which the food is de-  
11                  rived has been fed genetically engineered mate-  
12                  rial; or

13                  “(C) the food contains an ingredient that  
14                  is a food to which subparagraph (A) or (B) of  
15                  this paragraph applies.

16                  “(3) TESTING.—For purposes of sections 1(n)  
17                  and 10:

18                  “(A) In the case of the transfer of meat  
19                  foods from manufacturers or producers to dis-  
20                  tributors, and from distributors to other dis-  
21                  tributors or to other persons in the chain of dis-  
22                  tribution, including persons who hold meat food  
23                  for sale to consumers, regulations under sub-  
24                  paragraphs (A)(i) and (B) of paragraph (1)  
25                  shall require periodic testing of meat foods by

1 the Secretary for purposes of determining the  
2 accuracy of labels under such subparagraphs.  
3 Such regulations shall require the use of the  
4 best available technology for such testing, and  
5 shall identify tests that meet such requirement.  
6 This subparagraph and subparagraph (B) of  
7 this paragraph do not apply to (i) meat foods  
8 that are certified and comply with the Organic  
9 Foods Production Act and its implementing  
10 regulations; or (ii) meat foods produced with  
11 genetically engineered material if the Secretary  
12 has not through such regulations identified a  
13 validated method of testing for such material in  
14 the food; or (iii) genetically engineered material  
15 contained in a meat food if the Secretary has  
16 not through such regulations identified a vali-  
17 dated method of testing for such material in the  
18 food.

19 “(B) A meat food with respect to which a  
20 test has been identified under subparagraph (A)  
21 shall not be considered to contain a genetically  
22 engineered material for purposes of subpara-  
23 graphs (A)(i) and (B) of paragraph (1) if, as  
24 indicated by such a test—

1                   “(i) the food does not contain any ge-  
2                   netically engineered material; or

3                   “(ii) the food contains an adventitious  
4                   genetically engineered material and the  
5                   amount of the material in the food is one  
6                   percent or less, except that a lower per-  
7                   centage designated by the Secretary shall  
8                   apply for purposes of this subparagraph if  
9                   the Secretary determines that a test identi-  
10                  fied under subparagraph (A) can detect a  
11                  percentage lower than one percent.

12                  “(c) SPECIFICS OF LABEL NOTICES.—

13                  “(1) REQUIRED NOTICES.—The notices referred  
14                  to in subsection (b)(1)(B) are the following:

15                  “(A) A notice as follows: ‘GENETICALLY  
16                  ENGINEERED’.

17                  “(B) A notice as follows: ‘THIS PROD-  
18                  UCT CONTAINS A GENETICALLY ENGI-  
19                  NEERED MATERIAL, OR WAS PRO-  
20                  DUCED WITH A GENETICALLY ENGI-  
21                  NEERED MATERIAL’.

22                  “(2) LOCATION AND SIZE.—(A) The notice re-  
23                  quired in paragraph (1)(A) shall immediately pre-  
24                  cede the notice required in paragraph (1)(B) and

1 shall be not less than twice the size of the notice re-  
2 quired in paragraph (1)(B).

3 “(B) The notice required in paragraph (1)(B)  
4 shall be of the same size as would apply if the notice  
5 provided nutrition information that is required in  
6 section 403(q)(1) of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 343).

8 “(d) EXCEPTIONS TO REQUIREMENTS.—Subsection  
9 (a) does not apply to any meat food that—

10 “(1) is served in restaurants or other establish-  
11 ments in which food is served for immediate human  
12 consumption; or

13 “(2) is processed and prepared primarily in a  
14 retail establishment, is ready for human consump-  
15 tion, is offered for sale to consumers but not for im-  
16 mediate human consumption in such establishment,  
17 and is not offered for sale outside such establish-  
18 ment.

19 “(e) GUARANTY.—

20 “(1) IN GENERAL.—Subject to subsection  
21 (b)(3)(A) and paragraph (3), a packer, processor, or  
22 other person shall not be considered to have violated  
23 the requirements of this section with respect to the  
24 labeling of meat food if the packer, processor, or  
25 other person (referred to in this subsection as the

1       ‘recipient’) establishes a guaranty or undertaking  
2       signed by, and containing the name and address of,  
3       the person residing in the United States from whom  
4       the recipient received in good faith the meat food or  
5       the animal from which the meat food was derived,  
6       or received in good faith food intended to be fed to  
7       such animal, to the effect that the meat food, or  
8       such animal, or such food, respectively, does not con-  
9       tain genetically engineered material or was not pro-  
10      duced with a genetically engineered material.

11           “(2) SCOPE OF GUARANTY.—In the case of a  
12      recipient who establishes a guaranty or undertaking  
13      in accordance with paragraph (1), the exclusion  
14      under such paragraph from being subject to pen-  
15      alties applies to the recipient without regard to the  
16      use of the meat food by the recipient (or the use by  
17      the recipient of the animal from which the meat food  
18      was derived, or of food intended to be fed to such  
19      animal), including—

20                   “(A) processing the meat food;

21                   “(B) using the meat food as an ingredient  
22      in another food product;

23                   “(C) packing or repacking the meat food;

24                   or

1           “(D) raising the animal from which the  
2           meat food was derived.

3           “(3) TESTING.—In the case of recipients who  
4           establish guaranties or undertakings in accordance  
5           with paragraph (1), regulations under subsection  
6           (b)(3)(A) may exempt the recipients from the re-  
7           quirement under such subsection regarding testing  
8           of the meat food involved (relating to the accuracy  
9           of labels regarding genetically engineered material).  
10          In determining whether to establish such exemp-  
11          tions, the Secretary shall, with respect to the meat  
12          food involved, take into account the number of times  
13          the food has been transferred from one recipient to  
14          another, the number of recipients who took any of  
15          the actions described in paragraph (2), and such  
16          other factors as the Secretary determines to be ap-  
17          propriate.

18          “(4) FALSE GUARANTY.—It is a violation of  
19          this Act for a person to give a guaranty or under-  
20          taking in accordance with paragraph (1) that the  
21          person knows or has reason to know is false.

22          “(f) CIVIL PENALTIES.—

23          “(1) IN GENERAL.—The Secretary may assess  
24          a civil penalty against a person that violates sub-

1 section (b) or (c)(2) in an amount not to exceed  
2 \$100,000 for each such violation.

3 “(2) NOTICE AND OPPORTUNITY FOR HEAR-  
4 ING.—A civil penalty under paragraph (1) shall be  
5 assessed by the Secretary by an order made on the  
6 record after opportunity for a hearing provided in  
7 accordance with this subparagraph and section 554  
8 of title 5, United States Code. Before issuing such  
9 an order, the Secretary shall give written notice to  
10 the person to be assessed a civil penalty under such  
11 order of the Secretary’s proposal to issue such order  
12 and provide such person an opportunity for a hear-  
13 ing on the order. In the course of any investigation,  
14 the Secretary may issue subpoenas requiring the at-  
15 tendance and testimony of witnesses and the produc-  
16 tion of evidence that relates to the matter under in-  
17 vestigation.

18 “(3) CONSIDERATIONS REGARDING AMOUNT OF  
19 PENALTY.—In determining the amount of a civil  
20 penalty under paragraph (1), the Secretary shall  
21 take into account the nature, circumstances, extent,  
22 and gravity of the violation or violations and, with  
23 respect to the violator, ability to pay, effect on abil-  
24 ity to continue to do business, any history of prior



1 such violations, the degree of culpability, and such  
2 other matters as justice may require.

3 “(4) CERTAIN AUTHORITIES.—The Secretary  
4 may compromise, modify, or remit, with or without  
5 conditions, any civil penalty under paragraph (1).  
6 The amount of such penalty, when finally deter-  
7 mined, or the amount agreed upon in compromise,  
8 may be deducted from any sums owing by the  
9 United States to the person charged.

10 “(5) JUDICIAL REVIEW.—Any person who re-  
11 quested, in accordance with paragraph (2), a hearing  
12 respecting the assessment of a civil penalty under  
13 paragraph (1) and who is aggrieved by an order as-  
14 sessing a civil penalty may file a petition for judicial  
15 review of such order with the United States Court  
16 of Appeals for the District of Columbia Circuit or  
17 for any other circuit in which such person resides or  
18 transacts business. Such a petition may only be filed  
19 within the 60-day period beginning on the date the  
20 order making such assessment was issued.

21 “(6) FAILURE TO PAY.—If a person fails to pay  
22 an assessment of a civil penalty—

23 “(A) after the order making the assess-  
24 ment becomes final, and if such person does not

1 file a petition for judicial review of the order in  
2 accordance with paragraph (5); or

3 “(B) after a court in an action brought  
4 under paragraph (4) has entered a final judg-  
5 ment in favor of the Secretary;

6 the Attorney General shall recover the amount as-  
7 sessed (plus interest at currently prevailing rates  
8 from the date of the expiration of the 60-day period  
9 referred to in paragraph (5) or the date of such final  
10 judgment, as the case may be) in an action brought  
11 in any appropriate district court of the United  
12 States. In such an action, the validity, amount, and  
13 appropriateness of such penalty shall not be subject  
14 to review.

15 “(g) CITIZEN SUITS.—

16 “(1) IN GENERAL.—Except as provided in para-  
17 graph (3), any person may on his or her behalf com-  
18 mence a civil action in an appropriate district court  
19 of the United States against—

20 “(A) a person who is alleged to have en-  
21 gaged in a violation of subsection (b) or (c)(2);

22 or

23 “(B) the Secretary where there is alleged  
24 a failure of the Secretary to perform any act or

1 duty under subsection (b) or (c)(2) that is not  
2 discretionary.

3 “(2) RELIEF.—In a civil action under para-  
4 graph (1), the district court involved may, as the  
5 case may be—

6 “(A) enforce the compliance of a person  
7 with the applicable provisions referred to sub-  
8 paragraph (A) of such paragraph; or

9 “(B) order the Secretary to perform an act  
10 or duty referred to in subparagraph (B) of such  
11 paragraph.

12 “(3) LIMITATIONS.—

13 “(A) NOTICE TO SECRETARY.—A civil ac-  
14 tion may not be commenced under paragraph  
15 (1)(A) prior to 60 days after the plaintiff has  
16 provided to the Secretary notice of the violation  
17 involved.

18 “(B) RELATION TO ACTIONS OF SEC-  
19 RETARY.—A civil action may not be commenced  
20 under paragraph (1)(B) if the Secretary has  
21 commenced and is diligently prosecuting a civil  
22 or criminal action in a district court of the  
23 United States to enforce compliance with the  
24 applicable provisions referred to in paragraph  
25 (1)(A).

1           “(4) RIGHT OF SECRETARY TO INTERVENE.—  
2           In any civil action under paragraph (1), the Sec-  
3           retary, if not a party, may intervene as a matter of  
4           right.

5           “(5) AWARD OF COSTS; FILING OF BOND.—In  
6           a civil action under paragraph (1), the district court  
7           involved may award costs of litigation (including rea-  
8           sonable attorney and expert witness fees) to any  
9           party whenever the court determines such an award  
10          is appropriate. The court may, if a temporary re-  
11          straining order or preliminary injunction is sought,  
12          require the filing of a bond or equivalent security in  
13          accordance with the Federal Rules of Civil Proce-  
14          dure.

15          “(6) SAVINGS PROVISION.—This subsection  
16          does not restrict any right that a person (or class of  
17          persons) may have under any statute or common law  
18          to seek enforcement of the provisions referred to in  
19          paragraph (1)(A), or to seek any other relief (includ-  
20          ing relief against the Secretary).”.

21          (b) INCLUSION OF LABELING REQUIREMENTS IN  
22          DEFINITION OF MISBRANDED.—Section 1(n) of the Fed-  
23          eral Meat Inspection Act (21 U.S.C. 601(n)) is amend-  
24          ed—

1           (1) by striking “or” at the end of paragraph  
2           (11);

3           (2) by striking the period at the end of para-  
4           graph (12) and inserting “; or”; and

5           (3) by adding at the end the following para-  
6           graph:

7           “(13) if it fails to bear a label or labeling as re-  
8           quired by section 7A.”.

9   **SEC. 5. LABELING REGARDING GENETICALLY ENGINEERED**  
10                   **MATERIAL; AMENDMENTS TO POULTRY**  
11                   **PRODUCTS INSPECTION ACT.**

12           (a) REQUIREMENTS.—The Poultry Products Inspec-  
13           tion Act is amended by inserting after section 8 (21  
14           U.S.C. 457) the following section:

15   **“SEC. 8A. REQUIREMENTS FOR LABELING REGARDING GE-**  
16                   **NETICALLY ENGINEERED MATERIAL.**

17           “(a) DEFINITIONS.—In this section:

18           “(1) 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 (and  
23           without regard to whether the organism is capable  
24           of use as human food).

1           “(2) The term ‘genetically engineered organism’  
2 means—

3           “(A) an organism that has been altered at  
4 the molecular or cellular level by means that are  
5 not possible under natural conditions or proc-  
6 esses (including but not limited to recombinant  
7 DNA and RNA techniques, cell fusion, micro-  
8 encapsulation, macroencapsulation, gene dele-  
9 tion and doubling, introducing a foreign gene,  
10 and changing the positions of genes), other  
11 than a means consisting exclusively of breeding,  
12 conjugation, fermentation, hybridization, in  
13 vitro fertilization, tissue culture, or mutagene-  
14 sis; and

15           “(B) an organism made through sexual or  
16 asexual reproduction (or both) involving an or-  
17 ganism described in subparagraph (A), if pos-  
18 sessing any of the altered molecular or cellular  
19 characteristics of the organism so described.

20           “(b) LABELING REQUIREMENT.—

21           “(1) REQUIRED LABELING TO AVOID MIS-  
22 BRANDING.—

23           “(A) INVOLVEMENT OF GENETICALLY EN-  
24 GINEERED MATERIAL.—For purposes of sec-

1 tions 4(h) and 9(a), a poultry product is mis-  
2 branded if it—

3 “(i) contains a genetically engineered  
4 material or was produced with a geneti-  
5 cally engineered material; and

6 “(ii) does not bear a label (or include  
7 labeling, in the case of a poultry product  
8 that is not packaged in a container) that  
9 provides, in a clearly legible and con-  
10 spicuous manner, the notices described in  
11 subsection (c).

12 “(B) NO INVOLVEMENT OF GENETICALLY  
13 ENGINEERED MATERIAL.—For purposes of sec-  
14 tions 4(h) and 9(a), a poultry product is mis-  
15 branded if it bears a label indicating that it  
16 does not contain a genetically engineered mate-  
17 rial, or that it was not produced with a geneti-  
18 cally engineered material, unless the label is in  
19 accordance with regulations promulgated by the  
20 Secretary. With respect to such regulations:

21 “(i) The regulations may not require  
22 such a label to include any statement indi-  
23 cating that the fact that a poultry product  
24 does not contain such material, or was not  
25 produced with such material, has no bear-

1           ing on the safety of the product for human  
2           consumption.

3           “(ii) The regulations may not prohibit  
4           such a label on the basis that, in the case  
5           of the type of poultry product involved,  
6           there is no version of the product in com-  
7           mercial distribution that does contain a ge-  
8           netically engineered material.

9           “(2) RULE OF CONSTRUCTION.—For purposes  
10          of subparagraphs (A)(i) and (B) of paragraph (1),  
11          a poultry product shall be considered to have been  
12          produced with a genetically engineered material if—

13               “(A) the poultry from which the food is de-  
14               rived has been injected or otherwise treated  
15               with a genetically engineered material;

16               “(B) the poultry from which the food is  
17               derived has been fed genetically engineered ma-  
18               terial; or

19               “(C) the food contains an ingredient that  
20               is a food to which subparagraph (A) or (B) of  
21               this paragraph applies.

22          “(3) TESTING.—For purposes of sections 4(h)  
23          and 9(a):

24               “(A) In the case of the transfer of poultry  
25               products from manufacturers or producers to



1 distributors, and from distributors to other dis-  
2 tributors or to other persons in the chain of dis-  
3 tribution, including persons who hold poultry  
4 products for sale to consumers, regulations  
5 under subparagraphs (A)(i) and (B) of para-  
6 graph (1) shall require periodic testing of poul-  
7 try products by the Secretary for purposes of  
8 determining the accuracy of labels under such  
9 subparagraphs. Such regulations shall require  
10 the use of the best available technology for such  
11 testing, and shall identify tests that meet such  
12 requirement. This subparagraph and subpara-  
13 graph (B) of this paragraph do not apply to (i)  
14 poultry products that are certified and comply  
15 with the Organic Foods Production Act and its  
16 implementing regulations; or (ii) poultry prod-  
17 ucts produced with genetically engineered mate-  
18 rial if the Secretary has not through such regu-  
19 lations identified a validated method of testing  
20 for such material in the food; or (iii) genetically  
21 engineered material contained in a poultry  
22 products if the Secretary has not through such  
23 regulations identified a validated method of  
24 testing for such material in the product.

1           “(B) A poultry product with respect to  
2           which a test has been identified under subpara-  
3           graph (A) shall not be considered to contain a  
4           genetically engineered material for purposes of  
5           subparagraphs (A)(i) and (B) of paragraph (1)  
6           if, as indicated by such a test—

7                   “(i) the product does not contain any  
8                   genetically engineered material; or

9                   “(ii) the product contains an adven-  
10                  titious genetically engineered material and  
11                  the amount of the material in the product  
12                  is one percent or less, except that a lower  
13                  percentage designated by the Secretary  
14                  shall apply for purposes of this subpara-  
15                  graph if the Secretary determines that a  
16                  test identified under subparagraph (A) can  
17                  detect a percentage lower than one per-  
18                  cent.

19           “(c) SPECIFICS OF LABEL NOTICES.—

20                   “(1) REQUIRED NOTICES.—The notices referred  
21           to in subsection (b)(1)(B) are the following:

22                           “(A) A notice as follows: ‘GENETICALLY  
23                           ENGINEERED’.

24                           “(B) A notice as follows: ‘THIS PROD-  
25                           UCT CONTAINS A GENETICALLY ENGI-

1           NEERED MATERIAL, OR WAS PRO-  
2           DUCED WITH A GENETICALLY ENGI-  
3           NEERED MATERIAL’.

4           “(2) LOCATION AND SIZE.—(A) The notice re-  
5           quired in paragraph (1)(A) shall immediately pre-  
6           cede the notice required in paragraph (1)(B) and  
7           shall be not less than twice the size of the notice re-  
8           quired in paragraph (1)(B).

9           “(B) The notice required in paragraph (1)(B)  
10          shall be of the same size as would apply if the notice  
11          provided nutrition information that is required in  
12          section 403(q)(1) of the Federal Food, Drug, and  
13          Cosmetic Act.

14          “(d) EXCEPTIONS TO REQUIREMENTS.—Subsection  
15 (a) does not apply to any poultry product that—

16               “(1) is served in restaurants or other establish-  
17               ments in which food is served for immediate human  
18               consumption; or

19               “(2) is processed and prepared primarily in a  
20               retail establishment, is ready for human consump-  
21               tion, is offered for sale to consumers but not for im-  
22               mediate human consumption in such establishment,  
23               and is not offered for sale outside such establish-  
24               ment.

25          “(e) GUARANTY.—

1           “(1) IN GENERAL.—Subject to subsection  
2           (b)(3)(A) and paragraph (3), an official establish-  
3           ment or other person shall not be considered to have  
4           violated the requirements of this section with respect  
5           to the labeling of a poultry product if the official es-  
6           tablishment or other person (referred to in this sub-  
7           section as the ‘recipient’) establishes a guaranty or  
8           undertaking signed by, and containing the name and  
9           address of, the person residing in the United States  
10          from whom the recipient received in good faith the  
11          poultry product or the poultry from which the poul-  
12          try product was derived, or received in good faith  
13          food intended to be fed to poultry, to the effect that  
14          the poultry product, poultry, or such food, respec-  
15          tively, does not contain genetically engineered mate-  
16          rial or was not produced with a genetically engi-  
17          neered material.

18          “(2) SCOPE OF GUARANTY.—In the case of a  
19          recipient who establishes a guaranty or undertaking  
20          in accordance with paragraph (1), the exclusion  
21          under such paragraph from being subject to pen-  
22          alties applies to the recipient without regard to the  
23          use of the poultry product by the recipient (or the  
24          use by the recipient of the poultry from which the

1 poultry product was derived, or of food intended to  
2 be fed to such poultry), including—

3 “(A) processing the poultry;

4 “(B) using the poultry product as an in-  
5 gredient in another food product;

6 “(C) packing or repacking the poultry  
7 product; or

8 “(D) raising the poultry from which the  
9 poultry product was derived.

10 “(3) TESTING.—In the case of recipients who  
11 establish guaranties or undertakings in accordance  
12 with paragraph (1), regulations under subsection  
13 (b)(3)(A) may exempt the recipients from the re-  
14 quirement under such subsection regarding testing  
15 of the poultry product involved (relating to the accu-  
16 racy of labels regarding genetically engineered mate-  
17 rial). In determining whether to establish such ex-  
18 emptions, the Secretary shall, with respect to the  
19 poultry product involved, take into account the num-  
20 ber of times the product has been transferred from  
21 one recipient to another, the number of recipients  
22 who took any of the actions described in paragraph  
23 (2), and such other factors as the Secretary deter-  
24 mines to be appropriate.

1           “(4) FALSE GUARANTY.—It is a violation of  
2 this Act for a person to give a guaranty or under-  
3 taking in accordance with paragraph (1) that the  
4 person knows or has reason to know is false.

5           “(f) CIVIL PENALTIES.—

6           “(1) IN GENERAL.—The Secretary may assess  
7 a civil penalty against a person that violates sub-  
8 section (b) or (c)(2) in an amount not to exceed  
9 \$100,000 for each such violation.

10           “(2) NOTICE AND OPPORTUNITY FOR HEAR-  
11 ING.—A civil penalty under paragraph (1) shall be  
12 assessed by the Secretary by an order made on the  
13 record after opportunity for a hearing provided in  
14 accordance with this subparagraph and section 554  
15 of title 5, United States Code. Before issuing such  
16 an order, the Secretary shall give written notice to  
17 the person to be assessed a civil penalty under such  
18 order of the Secretary’s proposal to issue such order  
19 and provide such person an opportunity for a hear-  
20 ing on the order. In the course of any investigation,  
21 the Secretary may issue subpoenas requiring the at-  
22 tendance and testimony of witnesses and the produc-  
23 tion of evidence that relates to the matter under in-  
24 vestigation.

1           “(3) CONSIDERATIONS REGARDING AMOUNT OF  
2 PENALTY.—In determining the amount of a civil  
3 penalty under paragraph (1), the Secretary shall  
4 take into account the nature, circumstances, extent,  
5 and gravity of the violation or violations and, with  
6 respect to the violator, ability to pay, effect on abil-  
7 ity to continue to do business, any history of prior  
8 such violations, the degree of culpability, and such  
9 other matters as justice may require.

10           “(4) CERTAIN AUTHORITIES.—The Secretary  
11 may compromise, modify, or remit, with or without  
12 conditions, any civil penalty under paragraph (1).  
13 The amount of such penalty, when finally deter-  
14 mined, or the amount agreed upon in compromise,  
15 may be deducted from any sums owing by the  
16 United States to the person charged.

17           “(5) JUDICIAL REVIEW.—Any person who re-  
18 quested, in accordance with paragraph (2), a hearing  
19 respecting the assessment of a civil penalty under  
20 paragraph (1) and who is aggrieved by an order as-  
21 sessing a civil penalty may file a petition for judicial  
22 review of such order with the United States Court  
23 of Appeals for the District of Columbia Circuit or  
24 for any other circuit in which such person resides or  
25 transacts business. Such a petition may only be filed

1 within the 60-day period beginning on the date the  
2 order making such assessment was issued.

3 “(6) FAILURE TO PAY.—If a person fails to pay  
4 an assessment of a civil penalty—

5 “(A) after the order making the assess-  
6 ment becomes final, and if such person does not  
7 file a petition for judicial review of the order in  
8 accordance with paragraph (5); or

9 “(B) after a court in an action brought  
10 under paragraph (4) has entered a final judg-  
11 ment in favor of the Secretary;

12 the Attorney General shall recover the amount as-  
13 sessed (plus interest at currently prevailing rates  
14 from the date of the expiration of the 60-day period  
15 referred to in paragraph (5) or the date of such final  
16 judgment, as the case may be) in an action brought  
17 in any appropriate district court of the United  
18 States. In such an action, the validity, amount, and  
19 appropriateness of such penalty shall not be subject  
20 to review.

21 “(g) CITIZEN SUITS.—

22 “(1) IN GENERAL.—Except as provided in para-  
23 graph (3), any person may on his or her behalf com-  
24 mence a civil action in an appropriate district court  
25 of the United States against—



1           “(A) a person who is alleged to have en-  
2           gaged in a violation of subsection (b) or (c)(2);  
3           or

4           “(B) the Secretary where there is alleged  
5           a failure of the Secretary to perform any act or  
6           duty under subsection (b) or (c)(2) that is not  
7           discretionary.

8           “(2) RELIEF.—In a civil action under para-  
9           graph (1), the district court involved may, as the  
10          case may be—

11           “(A) enforce the compliance of a person  
12           with the applicable provisions referred to sub-  
13           paragraph (A) of such paragraph; or

14           “(B) order the Secretary to perform an act  
15           or duty referred to in subparagraph (B) of such  
16           paragraph.

17          “(3) LIMITATIONS.—

18           “(A) NOTICE TO SECRETARY.—A civil ac-  
19           tion may not be commenced under paragraph  
20           (1)(A) prior to 60 days after the plaintiff has  
21           provided to the Secretary notice of the violation  
22           involved.

23           “(B) RELATION TO ACTIONS OF SEC-  
24           RETARY.—A civil action may not be commenced  
25           under paragraph (1)(B) if the Secretary has

1 commenced and is diligently prosecuting a civil  
2 or criminal action in a district court of the  
3 United States to enforce compliance with the  
4 applicable provisions referred to in paragraph  
5 (1)(A).

6 “(4) RIGHT OF SECRETARY TO INTERVENE.—  
7 In any civil action under paragraph (1), the Sec-  
8 retary, if not a party, may intervene as a matter of  
9 right.

10 “(5) AWARD OF COSTS; FILING OF BOND.—In  
11 a civil action under paragraph (1), the district court  
12 involved may award costs of litigation (including rea-  
13 sonable attorney and expert witness fees) to any  
14 party whenever the court determines such an award  
15 is appropriate. The court may, if a temporary re-  
16 straining order or preliminary injunction is sought,  
17 require the filing of a bond or equivalent security in  
18 accordance with the Federal Rules of Civil Proce-  
19 dure.

20 “(6) SAVINGS PROVISION.—This subsection  
21 does not restrict any right that a person (or class of  
22 persons) may have under any statute or common law  
23 to seek enforcement of the provisions referred to in  
24 paragraph (1)(A), or to seek any other relief (includ-  
25 ing relief against the Secretary).”.

1 (b) INCLUSION OF LABELING REQUIREMENTS IN  
2 DEFINITION OF MISBRANDED.—Section 4(h) of the Poul-  
3 try Products Inspection Act (21 U.S.C. 453(h)) is amend-  
4 ed—

5 (1) by striking “or” at the end of paragraph  
6 (11);

7 (2) by striking the period at the end of para-  
8 graph (12) and inserting “; or”; and

9 (3) by adding at the end the following para-  
10 graph:

11 “(13) if it fails to bear a label or labeling as re-  
12 quired by section 8A.”.

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

14 This Act and the amendments made by this Act take  
15 effect upon the expiration of the 180-day period beginning  
16 on the date of the enactment of this Act.

○