

110TH CONGRESS
2D SESSION

H. R. 6636

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

JULY 29, 2008

Mr. KUCINICH (for himself, Mr. SHAYS, Ms. SCHAKOWSKY, Mr. GRIJALVA, Ms. LEE, Ms. LINDA T. SÁNCHEZ of California, Mr. DEFAZIO, Mr. McDERMOTT, Mr. STARK, and Mr. HINCHEY) 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,*

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

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

1 (b) TABLE OF CONTENTS.—The table of contents of
 2 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.

3 **SEC. 2. FINDINGS.**

4 The Congress finds as follows:

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

7 (2) The Congress has previously required that
 8 all foods bear labels that reveal material facts to
 9 consumers.

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

14 (4) Consumers wish to know whether the food
 15 they purchase and consume contains or is produced
 16 with a genetically engineered material for a variety
 17 of reasons, including the potential transfer of aller-
 18 gens into food and other health risks, concerns
 19 about potential environmental risks associated with
 20 the genetic engineering of crops, and religiously and
 21 ethically based dietary restrictions.

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

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

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

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

20 (9) Adoption and implementation of mandatory
21 labeling requirements for genetically engineered food
22 produced in the United States would facilitate inter-
23 national trade by allowing American farmers and
24 companies to export and appropriately market their

1 products—both genetically engineered and non-ge-
2 netically engineered—to foreign customers.

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

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

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

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

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

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

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

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

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

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

13 “(B) The term ‘genetically engineered orga-
14 nism’ means—

15 “(i) an organism that has been altered at
16 the molecular or cellular level by means that are
17 not possible under natural conditions or proc-
18 esses (including but not limited to recombinant
19 DNA and RNA techniques, cell fusion, micro-
20 encapsulation, macroencapsulation, gene dele-
21 tion and doubling, introducing a foreign gene,
22 and changing the positions of genes), other
23 than a means consisting exclusively of breeding,
24 conjugation, fermentation, hybridization, in

1 vitro fertilization, tissue culture, or
2 mutagenesis, and

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

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

11 “(A) the organism from which the food is de-
12 rived has been injected or otherwise treated with a
13 genetically engineered material (except that the use
14 of manure as a fertilizer for raw agricultural com-
15 modities may not be construed to mean that such
16 commodities are produced with a genetically engi-
17 neered material),

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

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

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

23 “(A) is served in restaurants or other establish-
24 ments in which food is served for immediate human
25 consumption,

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

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

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

1 (C) genetically engineered material contained in a food if
2 the Secretary has not through such regulations identified
3 a validated method of testing for such material in the food.

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

9 “(A) the food does not contain any genetically
10 engineered material, or

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

19 “(z) If it bears a label indicating (within the meaning
20 of paragraph (y)) that it does not contain a genetically
21 engineered material, or that it was not produced with a
22 genetically engineered material, unless the label is in ac-
23 cordance with regulations promulgated by the Secretary.
24 With respect to such regulations:

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

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

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

14 “(g)(1) With respect to a violation of section 301(a),
15 301(b), or 301(c) involving the misbranding of food within
16 the meaning of section 403(y) or 403(z), any person en-
17 gaging in such a violation shall be liable to the United
18 States for a civil penalty in an amount not to exceed
19 \$100,000 for each such violation.

20 “(2) Paragraphs (3) through (5) of subsection (f)
21 apply with respect to a civil penalty under paragraph (1)
22 of this subsection to the same extent and in the same man-
23 ner as such paragraphs (3) through (5) apply with respect
24 to a civil penalty under paragraph (1) or (2) of subsection
25 (f).”.

1 (c) GUARANTY.—

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

5 (A) by striking “(d)” and inserting
6 “(d)(1)”; and

7 (B) by adding at the end the following
8 paragraph:

9 “(2)(A) Subject to subparagraph (C) and section
10 403(y)(5), no person shall be subject to the penalties of
11 subsection (a)(1) or (h) for a violation of section 301(a),
12 301(b), or 301(c) involving the misbranding of food within
13 the meaning of section 403(y) and 403(z) if such person
14 (referred to in this paragraph as the ‘recipient’) estab-
15 lishes a guaranty or undertaking signed by, and con-
16 taining the name and address of, the person residing in
17 the United States from whom the recipient received in
18 good faith the food (including the receipt of seeds to grow
19 raw agricultural commodities), to the effect that (within
20 the meaning of section 403(y)) the food does not contain
21 a genetically engineered material or was not produced with
22 a genetically engineered material.

23 “(B) In the case of a recipient who with respect to
24 a food establishes a guaranty or undertaking in accord-
25 ance with subparagraph (A), the exclusion under such sub-

1 paragraph from being subject to penalties applies to the
2 recipient without regard to the use of the food by the re-
3 cipient, including—

4 “(i) processing the food,

5 “(ii) using the food as an ingredient in a food
6 product,

7 “(iii) repacking the food, or

8 “(iv) growing, raising, or otherwise producing
9 the food.”.

10 (2) FALSE GUARANTY.—Section 301(h) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 331(h)) is amended by inserting “or 303(d)(2)”
13 after “303(c)(2)”.

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

18 “(3)(A) No person shall be subject to the penalties
19 of subsection (a)(1) or (g) for a violation of section 301(a),
20 301(b), or 301(c) involving the misbranding of food within
21 the meaning of section 403(y) or 403(z) if—

22 “(i) such person is an agricultural producer and
23 the violation occurs because food that is grown,
24 raised, or otherwise produced by such producer,
25 which food does not contain a genetically engineered

1 material and was not produced with a genetically en-
2 gineered material, is contaminated with a food that
3 contains a genetically engineered material or was
4 produced with a genetically engineered material (in-
5 cluding contamination by mingling the two), and

6 “(ii) such contamination is not intended by the
7 agricultural producer.

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

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

14 **“SEC. 311. CITIZEN SUITS REGARDING MISBRANDING OF**
15 **FOOD WITH RESPECT TO GENETICALLY ENGI-**
16 **NEERED MATERIAL.**

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

21 “(1) a person who is alleged to have engaged in
22 a violation of section 301(a), 301(b), or 301(c) in-
23 volving the misbranding of food within the meaning
24 of section 403(y) or 403(z); or

1 “(2) the Secretary where there is alleged a fail-
2 ure of the Secretary to perform any act or duty
3 under section 403(y) or 403(z) that is not discre-
4 tionary.

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

7 “(1) enforce the compliance of a person with
8 the applicable provisions referred to paragraph (1)
9 of such subsection; or

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

12 “(c) LIMITATIONS.—

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

17 “(2) RELATION TO ACTIONS OF SECRETARY.—
18 A civil action may not be commenced under sub-
19 section (a)(2) if the Secretary has commenced and
20 is diligently prosecuting a civil or criminal action in
21 a district court of the United States to enforce com-
22 pliance with the applicable provisions referred to in
23 subsection (a)(1).

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

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

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

19 **SEC. 4. LABELING REGARDING GENETICALLY ENGINEERED**
20 **MATERIAL; AMENDMENTS TO FEDERAL MEAT**
21 **INSPECTION ACT.**

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

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

3 “(a) DEFINITIONS.—In this section:

4 “(1) The term ‘meat food’ means a carcass,
5 part of a carcass, meat, or meat food product that
6 is derived from cattle, sheep, swine, goats, horses,
7 mules, or other equines and is capable of use as
8 human food.

9 “(2) The term ‘genetically engineered material’
10 means material derived from any part of a geneti-
11 cally engineered organism, without regard to wheth-
12 er the altered molecular or cellular characteristics of
13 the organism are detectable in the material (and
14 without regard to whether the organism is capable
15 of use as human food).

16 “(3) The term ‘genetically engineered organism’
17 means—

18 “(A) an organism that has been altered at
19 the molecular or cellular level by means that are
20 not possible under natural conditions or proc-
21 esses (including but not limited to recombinant
22 DNA and RNA techniques, cell fusion, micro-
23 encapsulation, macroencapsulation, gene dele-
24 tion and doubling, introducing a foreign gene,
25 and changing the positions of genes), other
26 than a means consisting exclusively of breeding,

1 conjugation, fermentation, hybridization, in
2 vitro fertilization, tissue culture, or
3 mutagenesis; and

4 “(B) an organism made through sexual or
5 asexual reproduction (or both) involving an or-
6 ganism described in subparagraph (A), if pos-
7 sessing any of the altered molecular or cellular
8 characteristics of the organism so described.

9 “(b) LABELING REQUIREMENT.—

10 “(1) REQUIRED LABELING TO AVOID MIS-
11 BRANDING.—

12 “(A) INVOLVEMENT OF GENETICALLY EN-
13 GINEERED MATERIAL.—For purposes of sec-
14 tions 1(n) and 10, a meat food is misbranded
15 if it—

16 “(i) contains a genetically engineered
17 material or was produced with a geneti-
18 cally engineered material; and

19 “(ii) does not bear a label (or include
20 labeling, in the case of a meat food that is
21 not packaged in a container) that provides,
22 in a clearly legible and conspicuous man-
23 ner, the notices described in subsection (c).

24 “(B) NO INVOLVEMENT OF GENETICALLY
25 ENGINEERED MATERIAL.—For purposes of sec-

1 tions 1(n) and 10, a meat food is misbranded
2 if it bears a label indicating that it does not
3 contain a genetically engineered material, or
4 that it was not produced with a genetically en-
5 gineered material, unless the label is in accord-
6 ance with regulations promulgated by the Sec-
7 retary. With respect to such regulations:

8 “(i) The regulations may not require
9 such a label to include any statement indi-
10 cating that the fact that a meat food does
11 not contain such material, or was not pro-
12 duced with such material, has no bearing
13 on the safety of the food for human con-
14 sumption.

15 “(ii) The regulations may not prohibit
16 such a label on the basis that, in the case
17 of the type of meat food involved, there is
18 no version of the food in commercial dis-
19 tribution that does contain a genetically
20 engineered material.

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

1 “(A) the organism from which the food is
2 derived has been injected or otherwise treated
3 with a genetically engineered material;

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

7 “(C) the food contains an ingredient that
8 is a food to which subparagraph (A) or (B) of
9 this paragraph applies.

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

12 “(A) In the case of the transfer of meat
13 foods from manufacturers or producers to dis-
14 tributors, and from distributors to other dis-
15 tributors or to other persons in the chain of dis-
16 tribution, including persons who hold meat food
17 for sale to consumers, regulations under sub-
18 paragraphs (A)(i) and (B) of paragraph (1)
19 shall require periodic testing of meat foods by
20 the Secretary for purposes of determining the
21 accuracy of labels under such subparagraphs.
22 Such regulations shall require the use of the
23 best available technology for such testing, and
24 shall identify tests that meet such requirement.
25 This subparagraph and subparagraph (B) of

1 this paragraph do not apply to (i) meat foods
2 that are certified and comply with the Organic
3 Foods Production Act and its implementing
4 regulations; or (ii) meat foods produced with
5 genetically engineered material if the Secretary
6 has not through such regulations identified a
7 validated method of testing for such material in
8 the food; or (iii) genetically engineered material
9 contained in a meat food if the Secretary has
10 not through such regulations identified a vali-
11 dated method of testing for such material in the
12 food.

13 “(B) A meat food with respect to which a
14 test has been identified under subparagraph (A)
15 shall not be considered to contain a genetically
16 engineered material for purposes of subpara-
17 graphs (A)(i) and (B) of paragraph (1) if, as
18 indicated by such a test—

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

21 “(ii) the food contains an adventitious
22 genetically engineered material and the
23 amount of the material in the food is one
24 percent or less, except that a lower per-
25 centage designated by the Secretary shall

1 apply for purposes of this subparagraph if
2 the Secretary determines that a test identi-
3 fied under subparagraph (A) can detect a
4 percentage lower than one percent.

5 “(c) SPECIFICS OF LABEL NOTICES.—

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

8 “(A) A notice as follows: ‘GENETICALLY
9 ENGINEERED’.

10 “(B) A notice as follows: ‘THIS PROD-
11 UCT CONTAINS A GENETICALLY ENGI-
12 NEERED MATERIAL, OR WAS PRO-
13 DUCED WITH A GENETICALLY ENGI-
14 NEERED MATERIAL’.

15 “(2) LOCATION AND SIZE.—(A) The notice re-
16 quired in paragraph (1)(A) shall immediately pre-
17 cede the notice required in paragraph (1)(B) and
18 shall be not less than twice the size of the notice re-
19 quired in paragraph (1)(B).

20 “(B) The notice required in paragraph (1)(B)
21 shall be of the same size as would apply if the notice
22 provided nutrition information that is required in
23 section 403(q)(1) of the Federal Food, Drug, and
24 Cosmetic Act.

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

3 “(1) is served in restaurants or other establish-
4 ments in which food is served for immediate human
5 consumption; or

6 “(2) is processed and prepared primarily in a
7 retail establishment, is ready for human consump-
8 tion, is offered for sale to consumers but not for im-
9 mediate human consumption in such establishment,
10 and is not offered for sale outside such establish-
11 ment.

12 “(e) GUARANTY.—

13 “(1) IN GENERAL.—Subject to subsection
14 (b)(3)(A) and paragraph (3), a packer, processor, or
15 other person shall not be considered to have violated
16 the requirements of this section with respect to the
17 labeling of meat food if the packer, processor, or
18 other person (referred to in this subsection as the
19 ‘recipient’) establishes a guaranty or undertaking
20 signed by, and containing the name and address of,
21 the person residing in the United States from whom
22 the recipient received in good faith the meat food or
23 the animal from which the meat food was derived,
24 or received in good faith food intended to be fed to
25 such animal, to the effect that the meat food, or

1 such animal, or such food, respectively, does not con-
2 tain genetically engineered material or was not pro-
3 duced with a genetically engineered material.

4 “(2) SCOPE OF GUARANTY.—In the case of a
5 recipient who establishes a guaranty or undertaking
6 in accordance with paragraph (1), the exclusion
7 under such paragraph from being subject to pen-
8 alties applies to the recipient without regard to the
9 use of the meat food by the recipient (or the use by
10 the recipient of the animal from which the meat food
11 was derived, or of food intended to be fed to such
12 animal), including—

13 “(A) processing the meat food;

14 “(B) using the meat food as an ingredient
15 in another food product;

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

17 or

18 “(D) raising the animal from which the
19 meat food was derived.

20 “(3) TESTING.—In the case of recipients who
21 establish guaranties or undertakings in accordance
22 with paragraph (1), regulations under subsection
23 (b)(3)(A) may exempt the recipients from the re-
24 quirement under such subsection regarding testing
25 of the meat food involved (relating to the accuracy

1 of labels regarding genetically engineered material).
2 In determining whether to establish such exemp-
3 tions, the Secretary shall, with respect to the meat
4 food involved, take into account the number of times
5 the food has been transferred from one recipient to
6 another, the number of recipients who took any of
7 the actions described in paragraph (2), and such
8 other factors as the Secretary determines to be ap-
9 propriate.

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

14 “(f) CIVIL PENALTIES.—

15 “(1) IN GENERAL.—The Secretary may assess
16 a civil penalty against a person that violates sub-
17 section (b) or (c)(2) in an amount not to exceed
18 \$100,000 for each such violation.

19 “(2) NOTICE AND OPPORTUNITY FOR HEAR-
20 ING.—A civil penalty under paragraph (1) shall be
21 assessed by the Secretary by an order made on the
22 record after opportunity for a hearing provided in
23 accordance with this subparagraph and section 554
24 of title 5, United States Code. Before issuing such
25 an order, the Secretary shall give written notice to

1 the person to be assessed a civil penalty under such
2 order of the Secretary's proposal to issue such order
3 and provide such person an opportunity for a hear-
4 ing on the order. In the course of any investigation,
5 the Secretary may issue subpoenas requiring the at-
6 tendance and testimony of witnesses and the produc-
7 tion of evidence that relates to the matter under in-
8 vestigation.

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

18 “(4) CERTAIN AUTHORITIES.—The Secretary
19 may compromise, modify, or remit, with or without
20 conditions, any civil penalty under paragraph (1).
21 The amount of such penalty, when finally deter-
22 mined, or the amount agreed upon in compromise,
23 may be deducted from any sums owing by the
24 United States to the person charged.

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

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

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

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

21 the Attorney General shall recover the amount as-
22 sessed (plus interest at currently prevailing rates
23 from the date of the expiration of the 60-day period
24 referred to in paragraph (5) or the date of such final
25 judgment, as the case may be) in an action brought

1 in any appropriate district court of the United
2 States. In such an action, the validity, amount, and
3 appropriateness of such penalty shall not be subject
4 to review.

5 “(g) CITIZEN SUITS.—

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

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

13 “(B) the Secretary where there is alleged
14 a failure of the Secretary to perform any act or
15 duty under subsection (b) or (c)(2) that is not
16 discretionary.

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

20 “(A) enforce the compliance of a person
21 with the applicable provisions referred to sub-
22 paragraph (A) of such paragraph; or

23 “(B) order the Secretary to perform an act
24 or duty referred to in subparagraph (B) of such
25 paragraph.

1 “(3) LIMITATIONS.—

2 “(A) NOTICE TO SECRETARY.—A civil ac-
3 tion may not be commenced under paragraph
4 (1)(A) prior to 60 days after the plaintiff has
5 provided to the Secretary notice of the violation
6 involved.

7 “(B) RELATION TO ACTIONS OF SEC-
8 RETARY.—A civil action may not be commenced
9 under paragraph (1)(B) if the Secretary has
10 commenced and is diligently prosecuting a civil
11 or criminal action in a district court of the
12 United States to enforce compliance with the
13 applicable provisions referred to in paragraph
14 (1)(A).

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

19 “(5) AWARD OF COSTS; FILING OF BOND.—In
20 a civil action under paragraph (1), the district court
21 involved may award costs of litigation (including rea-
22 sonable attorney and expert witness fees) to any
23 party whenever the court determines such an award
24 is appropriate. The court may, if a temporary re-
25 straining order or preliminary injunction is sought,

1 require the filing of a bond or equivalent security in
2 accordance with the Federal Rules of Civil Proce-
3 dure.

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

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

14 (1) by striking “or” at the end of paragraph
15 (11);

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

18 (3) by adding at the end the following para-
19 graph:

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

1 **SEC. 5. LABELING REGARDING GENETICALLY ENGINEERED**
2 **MATERIAL; AMENDMENTS TO POULTRY**
3 **PRODUCTS INSPECTION ACT.**

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

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

9 “(a) DEFINITIONS.—In this section:

10 “(1) 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 (and
15 without regard to whether the organism is capable
16 of use as human food).

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

19 “(A) an organism that has been altered at
20 the molecular or cellular level by means that are
21 not possible under natural conditions or proc-
22 esses (including but not limited to recombinant
23 DNA and RNA techniques, cell fusion, micro-
24 encapsulation, macroencapsulation, gene dele-
25 tion and doubling, introducing a foreign gene,
26 and changing the positions of genes), other

than a means consisting exclusively of breeding, conjugation, fermentation, hybridization, in vitro fertilization, tissue culture, or mutagenesis; and

“(B) an organism made through sexual or asexual reproduction (or both) involving an organism described in subparagraph (A), if possessing any of the altered molecular or cellular characteristics of the organism so described.

“(b) LABELING REQUIREMENT.—

“(1) REQUIRED LABELING TO AVOID MISBRANDING.—

“(A) INVOLVEMENT OF GENETICALLY ENGINEERED MATERIAL.—For purposes of sections 4(h) and 9(a), a poultry product is misbranded if it—

“(i) contains a genetically engineered material or was produced with a genetically engineered material; and

“(ii) does not bear a label (or include labeling, in the case of a poultry product that is not packaged in a container) that provides, in a clearly legible and conspicuous manner, the notices described in subsection (c).

“(B) NO INVOLVEMENT OF GENETICALLY ENGINEERED MATERIAL.—For purposes of sections 4(h) and 9(a), a poultry product is misbranded if it bears a label indicating that it does not contain a genetically engineered material, or that it was not produced with a genetically engineered material, unless the label is in accordance with regulations promulgated by the Secretary. With respect to such regulations:

“(i) The regulations may not require such a label to include any statement indicating that the fact that a poultry product does not contain such material, or was not produced with such material, has no bearing on the safety of the product for human consumption.

“(ii) The regulations may not prohibit such a label on the basis that, in the case of the type of poultry product involved, there is no version of the product in commercial distribution that does contain a genetically engineered material.

“(2) RULE OF CONSTRUCTION.—For purposes of paragraph subparagraphs (A)(i) and (B) of paragraph (1), a poultry product shall be considered to

1 have been produced with a genetically engineered
2 material if—

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

6 “(B) the poultry from which the food is
7 derived has been fed genetically engineered ma-
8 terial; or

9 “(C) the food contains an ingredient that
10 is a food to which subparagraph (A) or (B) of
11 this paragraph applies.

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

14 “(A) In the case of the transfer of poultry
15 products from manufacturers or producers to
16 distributors, and from distributors to other dis-
17 tributors or to other persons in the chain of dis-
18 tribution, including persons who hold poultry
19 products for sale to consumers, regulations
20 under subparagraphs (A)(i) and (B) of para-
21 graph (1) shall require periodic testing of poul-
22 try products by the Secretary for purposes of
23 determining the accuracy of labels under such
24 subparagraphs. Such regulations shall require
25 the use of the best available technology for such

1 testing, and shall identify tests that meet such
2 requirement. This subparagraph and subpara-
3 graph (B) of this paragraph do not apply to (i)
4 poultry products that are certified and comply
5 with the Organic Foods Production Act and its
6 implementing regulations; or (ii) poultry prod-
7 ucts produced with genetically engineered mate-
8 rial if the Secretary has not through such regu-
9 lations identified a validated method of testing
10 for such material in the food; or (iii) genetically
11 engineered material contained in a poultry
12 products if the Secretary has not through such
13 regulations identified a validated method of
14 testing for such material in the product.

15 “(B) A poultry product with respect to
16 which a test has been identified under subpara-
17 graph (A) shall not be considered to contain a
18 genetically engineered material for purposes of
19 subparagraphs (A)(i) and (B) of paragraph (1)
20 if, as indicated by such a test—

21 “(i) the product does not contain any
22 genetically engineered material; or

23 “(ii) the product contains an adven-
24 titious genetically engineered material and
25 the amount of the material in the product

1 is one percent or less, except that a lower
 2 percentage designated by the Secretary
 3 shall apply for purposes of this subpara-
 4 graph if the Secretary determines that a
 5 test identified under subparagraph (A) can
 6 detect a percentage lower than one per-
 7 cent.

8 “(c) SPECIFICS OF LABEL NOTICES.—

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

11 “(A) A notice as follows: ‘GENETICALLY
 12 ENGINEERED’.

13 “(B) A notice as follows: ‘THIS PROD-
 14 UCT CONTAINS A GENETICALLY ENGI-
 15 NEERED MATERIAL, OR WAS PRO-
 16 DUCED WITH A GENETICALLY ENGI-
 17 NEERED MATERIAL’.

18 “(2) LOCATION AND SIZE.—(A) The notice re-
 19 quired in paragraph (1)(A) shall immediately pre-
 20 cede the notice required in paragraph (1)(B) and
 21 shall be not less than twice the size of the notice re-
 22 quired in paragraph (1)(B).

23 “(B) The notice required in paragraph (1)(B)
 24 shall be of the same size as would apply if the notice
 25 provided nutrition information that is required in

1 section 403(q)(1) of the Federal Food, Drug, and
2 Cosmetic Act.

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

5 “(1) is served in restaurants or other establish-
6 ments in which food is served for immediate human
7 consumption; or

8 “(2) is processed and prepared primarily in a
9 retail establishment, is ready for human consump-
10 tion, is offered for sale to consumers but not for im-
11 mediate human consumption in such establishment,
12 and is not offered for sale outside such establish-
13 ment.

14 “(e) GUARANTY.—

15 “(1) IN GENERAL.—Subject to subsection
16 (b)(3)(A) and paragraph (3), an official establish-
17 ment or other person shall not be considered to have
18 violated the requirements of this section with respect
19 to the labeling of a poultry product if the official es-
20 tablishment or other person (referred to in this sub-
21 section as the ‘recipient’) establishes a guaranty or
22 undertaking signed by, and containing the name and
23 address of, the person residing in the United States
24 from whom the recipient received in good faith the
25 poultry product or the poultry from which the poul-

1 try product was derived, or received in good faith
2 food intended to be fed to poultry, to the effect that
3 the poultry product, poultry, or such food, respec-
4 tively, does not contain genetically engineered mate-
5 rial or was not produced with a genetically engi-
6 neered material.

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

16 “(A) processing the poultry;

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

19 “(C) packing or repacking the poultry
20 product; or

21 “(D) raising the poultry from which the
22 poultry product was derived.

23 “(3) TESTING.—In the case of recipients who
24 establish guaranties or undertakings in accordance
25 with paragraph (1), regulations under subsection

1 (b)(3)(A) may exempt the recipients from the re-
2 quirement under such subsection regarding testing
3 of the poultry product involved (relating to the accu-
4 racy of labels regarding genetically engineered mate-
5 rial). In determining whether to establish such ex-
6 emptions, the Secretary shall, with respect to the
7 poultry product involved, take into account the num-
8 ber of times the product has been transferred from
9 one recipient to another, the number of recipients
10 who took any of the actions described in paragraph
11 (2), and such other factors as the Secretary deter-
12 mines to be appropriate.

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

17 “(f) CIVIL PENALTIES.—

18 “(1) IN GENERAL.—The Secretary may assess
19 a civil penalty against a person that violates sub-
20 section (b) or (c)(2) in an amount not to exceed
21 \$100,000 for each such violation.

22 “(2) NOTICE AND OPPORTUNITY FOR HEAR-
23 ING.—A civil penalty under paragraph (1) shall be
24 assessed by the Secretary by an order made on the
25 record after opportunity for a hearing provided in

1 accordance with this subparagraph and section 554
2 of title 5, United States Code. Before issuing such
3 an order, the Secretary shall give written notice to
4 the person to be assessed a civil penalty under such
5 order of the Secretary's proposal to issue such order
6 and provide such person an opportunity for a hear-
7 ing on the order. In the course of any investigation,
8 the Secretary may issue subpoenas requiring the at-
9 tendance and testimony of witnesses and the produc-
10 tion of evidence that relates to the matter under in-
11 vestigation.

12 “(3) CONSIDERATIONS REGARDING AMOUNT OF
13 PENALTY.—In determining the amount of a civil
14 penalty under paragraph (1), the Secretary shall
15 take into account the nature, circumstances, extent,
16 and gravity of the violation or violations and, with
17 respect to the violator, ability to pay, effect on abil-
18 ity to continue to do business, any history of prior
19 such violations, the degree of culpability, and such
20 other matters as justice may require.

21 “(4) CERTAIN AUTHORITIES.—The Secretary
22 may compromise, modify, or remit, with or without
23 conditions, any civil penalty under paragraph (1).
24 The amount of such penalty, when finally deter-
25 mined, or the amount agreed upon in compromise,

1 may be deducted from any sums owing by the
2 United States to the person charged.

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

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

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

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

23 the Attorney General shall recover the amount as-
24 sessed (plus interest at currently prevailing rates
25 from the date of the expiration of the 60-day period

1 referred to in paragraph (5) or the date of such final
2 judgment, as the case may be) in an action brought
3 in any appropriate district court of the United
4 States. In such an action, the validity, amount, and
5 appropriateness of such penalty shall not be subject
6 to review.

7 “(g) CITIZEN SUITS.—

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

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

15 “(B) the Secretary where there is alleged
16 a failure of the Secretary to perform any act or
17 duty under subsection (b) or (c)(2) that is not
18 discretionary.

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

22 “(A) enforce the compliance of a person
23 with the applicable provisions referred to sub-
24 paragraph (A) of such paragraph; or

1 “(B) order the Secretary to perform an act
2 or duty referred to in subparagraph (B) of such
3 paragraph.

4 “(3) LIMITATIONS.—

5 “(A) NOTICE TO SECRETARY.—A civil ac-
6 tion may not be commenced under paragraph
7 (1)(A) prior to 60 days after the plaintiff has
8 provided to the Secretary notice of the violation
9 involved.

10 “(B) RELATION TO ACTIONS OF SEC-
11 RETARY.—A civil action may not be commenced
12 under paragraph (1)(B) if the Secretary has
13 commenced and is diligently prosecuting a civil
14 or criminal action in a district court of the
15 United States to enforce compliance with the
16 applicable provisions referred to in paragraph
17 (1)(A).

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

22 “(5) AWARD OF COSTS; FILING OF BOND.—In
23 a civil action under paragraph (1), the district court
24 involved may award costs of litigation (including rea-
25 sonable attorney and expert witness fees) to any

1 party whenever the court determines such an award
2 is appropriate. The court may, if a temporary re-
3 straining order or preliminary injunction is sought,
4 require the filing of a bond or equivalent security in
5 accordance with the Federal Rules of Civil Proce-
6 dure.

7 “(6) SAVINGS PROVISION.—This subsection
8 does not restrict any right that a person (or class of
9 persons) may have under any statute or common law
10 to seek enforcement of the provisions referred to in
11 paragraph (1)(A), or to seek any other relief (includ-
12 ing relief against the Secretary).”.

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

17 (1) by striking “or” at the end of paragraph
18 (11);

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

21 (3) by adding at the end the following para-
22 graph:

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

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

2 This Act and the amendments made by this Act take
3 effect upon the expiration of the 180-day period beginning
4 on the date of the enactment of this Act.

