

109TH CONGRESS
2^D SESSION

H. R. 5269

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

MAY 2, 2006

Mr. KUCINICH (for himself, Mr. CONYERS, Ms. LEE, Mr. SANDERS, Ms. WATERS, Mr. OLVER, Mrs. MALONEY, Mr. NADLER, Mr. GEORGE MILLER of California, Mr. GUTIERREZ, Mr. BROWN of Ohio, and Mr. SHAYS) 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 The 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 paragraphs:

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

1 conjugation, fermentation, hybridization, in
2 vitro fertilization, tissue culture, or
3 mutagenesis, 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 from which the food is de-
13 rived has been injected or otherwise treated with a
14 genetically engineered material (except that the use
15 of manure as a fertilizer for raw agricultural com-
16 modities may not be construed to mean that such
17 commodities are produced with a genetically engi-
18 neered material),

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

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

23 “(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 “(z) If it bears a label indicating (within the meaning
23 of paragraph (y)) 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 “(g)(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(y) or 403(z), 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 (3) through (5) 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 (3) through (5) apply with respect

1 to a civil penalty under paragraph (1) or (2) of subsection
2 (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
10 paragraph:

11 “(2)(A) Subject to subparagraph (C) and section
12 403(y)(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(y) and 403(z) 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(y)) 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 (g) 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(y) or 403(z) 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(y) or 403(z); 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(y) or 403(z) 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
9 mutagenesis; 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.

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
14 mutagenesis; 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 paragraph subparagraphs (A)(i) and (B) of para-
11 graph (1), a poultry product shall be considered to
12 have been produced with a genetically engineered
13 material if—

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

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

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

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

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

1 regulations identified a validated method of
2 testing for such material in the product.

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

9 “(i) the product does not contain any
10 genetically engineered material; or

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

21 “(c) SPECIFICS OF LABEL NOTICES.—

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

24 “(A) A notice as follows: ‘GENETICALLY
25 ENGINEERED’.

1 “(B) A notice as follows: ‘THIS PROD-
2 UCT CONTAINS A GENETICALLY ENGI-
3 NEERED MATERIAL, OR WAS PRO-
4 DUCED WITH A GENETICALLY ENGI-
5 NEERED MATERIAL’.

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

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

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

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

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

1 and is not offered for sale outside such establish-
2 ment.

3 “(e) GUARANTY.—

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

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

1 use of the poultry product by the recipient (or the
2 use by the recipient of the poultry from which the
3 poultry product was derived, or of food intended to
4 be fed to such poultry), including—

5 “(A) processing the poultry;

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

8 “(C) packing or repacking the poultry
9 product; or

10 “(D) raising the poultry from which the
11 poultry product was derived.

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

1 (2), and such other factors as the Secretary deter-
2 mines to be appropriate.

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

7 “(f) CIVIL PENALTIES.—

8 “(1) IN GENERAL.—The Secretary may assess
9 a civil penalty against a person that violates sub-
10 section (b) or (c)(2) in an amount not to exceed
11 \$100,000 for each such violation.

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

1 tion of evidence that relates to the matter under in-
2 vestigation.

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

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

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

1 for any other circuit in which such person resides or
2 transacts business. Such a petition may only be filed
3 within the 60-day period beginning on the date the
4 order making such assessment was issued.

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

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

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

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

23 “(g) CITIZEN SUITS.—

24 “(1) IN GENERAL.—Except as provided in para-
25 graph (3), any person may on his or her behalf com-

1 mence a civil action in an appropriate district court
2 of the United States against—

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

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

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

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

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

19 “(3) LIMITATIONS.—

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

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

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

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

23 “(6) SAVINGS PROVISION.—This subsection
24 does not restrict any right that a person (or class of
25 persons) may have under any statute or common law

1 to seek enforcement of the provisions referred to in
2 paragraph (1)(A), or to seek any other relief (includ-
3 ing relief against the Secretary).”.

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

8 (1) by striking “or” at the end of paragraph
9 (11);

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

12 (3) by adding at the end the following para-
13 graph:

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

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

17 This Act and the amendments made by this Act take
18 effect upon the expiration of the 180-day period beginning
19 on the date of the enactment of this Act.

○