

# `Genetically Engineered Food Right to Know Act'.

Tuesday, 29 July 2008

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. SANCHEZ 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,  
SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title- This Act may be cited as the `Genetically Engineered Food Right to Know Act'.

(b) Table of Contents- The table of contents of 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.

SEC. 2. FINDINGS.

The Congress finds as follows:

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

(2) The Congress has previously required that all foods bear labels that reveal material

facts to consumers.

(3) Federal agencies have failed to uphold Congressional intent by allowing genetically engineered foods to be marketed, sold and otherwise used without labeling that reveals material facts to the public.

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

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

(6) Labels voluntarily placed on foods are insufficient to provide consumers with adequate information on whether or not all the food they are purchasing contains or was produced with genetically engineered material.

(7) Mandatory labeling provides a critical scientific method necessary for the continual postmarket surveillance to study long-term health impacts and enforcement of food safety laws preventing adulterated foods from reaching consumers.

(8) Many of the United States' key trading partners, including countries in the European Union, Japan, and the People's Republic of China, have established, or are in the process of implementing, mandatory labeling requirements for genetically engineered food.

(9) Adoption and implementation of mandatory labeling requirements for genetically engineered food produced in the United States would facilitate international trade by allowing American farmers and companies to export and appropriately market their products--both genetically engineered and non-genetically engineered--to foreign customers.

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

(a) In General- Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following paragraphs:

(y)(1) If it contains a genetically engineered material, or was produced with a genetically engineered material, unless it bears a label (or labeling, in the case of a raw agricultural commodity, other than the sale of such a commodity at retail) that provides notices in accordance with the following:

(A) A notice as follows: 'GENETICALLY ENGINEERED'.

(B) A notice as follows: 'THIS PRODUCT CONTAINS A GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL'.

(C) The notice required in clause (A) immediately precedes the notice required in clause (B) and is not less than twice the size of the notice required in clause (B).

(D) The notice required in clause (B) is of the same size as would apply if the notice provided nutrition information that is required in paragraph (q)(1).

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

(2) For purposes of subparagraph (1):

(A) The term 'genetically engineered material'

means material derived from any part of a genetically engineered organism, without regard to whether the altered molecular or cellular characteristics of the organism are detectable in the material.

organism' means--

(B) The term 'genetically engineered

(i) an organism that has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes (including but not limited to recombinant DNA and RNA techniques, cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling, introducing a foreign gene, 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

(ii) an organism made through sexual or asexual reproduction (or both) involving an organism described in subclause (i), if possessing any of the altered molecular or cellular characteristics of the organism so described.

(3) For purposes of subparagraph (1), a food shall be considered to have been produced with a genetically engineered material if--

(A) the organism from which the food is derived has been injected or otherwise treated with a genetically engineered material (except that the use of manure as a fertilizer for raw agricultural commodities may not be construed to mean that such commodities are produced with a genetically engineered material),

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

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

(4) This paragraph does not apply to food that--

(A) is served in restaurants or other establishments in which food is served for immediate human consumption,

(B) is processed and prepared primarily in a retail establishment, is ready for human consumption, which is of the type described in clause (A), and is offered for sale to consumers but not for immediate human consumption in such establishment and is not offered for sale outside such establishment, or

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

(5) In the case of the transfer of food from manufacturers or producers to distributors, and from distributors to other distributors or to other persons in the chain of distribution, including persons who hold food for sale to consumers, regulations under this paragraph and paragraph (z) shall require periodic testing of foods by the Secretary for purposes of determining the accuracy of labels under such paragraphs. Such regulations shall require the use of the best available technology for such testing, and shall identify tests that meet such requirement. This subparagraph and subparagraph (6) do not apply to (A) foods that are certified and comply with the Organic Foods Production Act and its implementing regulations; or (B) foods produced with genetically engineered material if the Secretary has not through such regulations identified a validated method of testing for such material in the food; or (C) genetically engineered material contained in a food if the Secretary has not through such regulations identified a validated method of testing for such material in the food.

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

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

(B) the food contains an adventitious genetically engineered material and the amount of the material in the food is one percent or less, except that a lower percentage designated by the Secretary shall apply for purposes of this subparagraph if the Secretary determines that a test identified under subparagraph (5) can detect a percentage lower than one percent.

(z) If it bears a label indicating (within the meaning of paragraph (y)) 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:

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

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

(b) Civil Penalties- Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following subsection:

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

(2) Paragraphs (3) through (5) of subsection (f) apply with respect to a civil penalty under paragraph (1) of this subsection to the same extent and in the same manner as such paragraphs (3) through (5) apply with respect to a civil penalty under paragraph (1) or (2) of subsection (f).'

(c) Guaranty-

(1) IN GENERAL- Section 303(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(d)) is amended--

(A) by striking '(d)' and inserting '(d)(1)'; and

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

(2)(A) Subject to subparagraph (C) and section 403(y)(5), no person shall be subject to the penalties of subsection (a)(1) or (h) for a violation of section 301(a), 301(b), or 301(c) involving the misbranding of food within the meaning of section 403(y) and 403(z) if such person (referred to in this paragraph as the 'recipient') establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom the recipient received in good faith the food (including the receipt of seeds to grow raw agricultural commodities), to the effect that (within the meaning of section 403(y)) the food does not contain a genetically engineered material or was not produced with a genetically engineered material.

(B) In the case of a recipient who with respect to a food establishes a guaranty or undertaking in accordance with subparagraph (A), the exclusion under such subparagraph from being subject to penalties applies to the recipient without regard to the use of the food by the recipient, including--

(i) processing the food,

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

(iii) repacking the food, or

(iv) growing, raising, or otherwise producing the food.'.

(2) FALSE GUARANTY- Section 301(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(h)) is amended by inserting 'or 303(d)(2)' after '303(c)(2)'.

(d) Unintended Contamination- Section 303(d) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (c)(1) of this section, is amended by adding at the end the following paragraph:

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

(i) such person is an agricultural producer and the violation occurs because food that is grown, raised, or otherwise produced by such producer, which food does not contain a genetically engineered material and was not produced with a genetically engineered material, is contaminated with a food that contains a genetically engineered material or was produced with a genetically engineered material (including contamination by mingling the two), and

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

`(B) Subparagraph (A) does not apply to an agricultural producer to the extent that the contamination occurs as a result of the negligence of the producer.'

(e) Citizen Suits- Chapter III of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331 et seq.) is amended by adding at the end the following section:

`SEC. 311. CITIZEN SUITS REGARDING MISBRANDING OF FOOD WITH RESPECT TO GENETICALLY ENGINEERED MATERIAL.

`(a) In General- Except as provided in subsection (c), any person may on his or her behalf commence a civil action in an appropriate district court of the United States against--

`(1) a person who is alleged to have engaged in a violation of section 301(a), 301(b), or 301(c) involving the misbranding of food within the meaning of section 403(y) or 403(z); or

`(2) the Secretary where there is alleged a failure of the Secretary to perform any act or duty under section 403(y) or 403(z) that is not discretionary.

`(b) Relief- In a civil action under subsection (a), the district court involved may, as the case may be--

`(1) enforce the compliance of a person with the applicable provisions referred to paragraph (1) of such subsection; or

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

`(c) Limitations-

`(1) NOTICE TO SECRETARY- A civil action may not be commenced under subsection (a)(1) prior to 60 days after the plaintiff has provided to the Secretary notice of the violation involved.

`(2) RELATION TO ACTIONS OF SECRETARY- A civil action may not be commenced under subsection (a)(2) if the Secretary has commenced and is diligently prosecuting a civil or criminal action in a district court of the United States to enforce compliance with the applicable provisions referred to in subsection (a)(1).

`(d) Right of Secretary To Intervene- In any civil action under subsection (a), the Secretary, if not a party, may intervene as a matter of right.

`(e) Award of Costs; Filing of Bond- In a civil action under subsection (a), the district court involved may award costs of litigation (including reasonable attorney and expert witness fees) to any party whenever the court determines such an award is appropriate. The court may, if a temporary restraining order or preliminary injunction is sought, require the filing of a bond or equivalent security in accordance with the Federal Rules of Civil Procedure.

`(f) Savings Provision- This section does not restrict any right that a person (or class of persons) may have under any statute or common law to seek enforcement of the provisions referred to subsection (a)(1), or to seek any other relief (including relief against the Secretary).'

#### SEC. 4. LABELING REGARDING GENETICALLY ENGINEERED MATERIAL; AMENDMENTS TO FEDERAL MEAT INSPECTION ACT.

(a) Requirements- The Federal Meat Inspection Act is amended by inserting after section 7 (21 U.S.C. 607) the following section:

#### `SEC. 7A. REQUIREMENTS FOR LABELING REGARDING GENETICALLY ENGINEERED MATERIAL.

`(a) Definitions- In this section:

`(1) The term 'meat food' means a carcass, part of a carcass, meat, or meat food product that is derived from cattle, sheep, swine, goats, horses, mules, or other equines and is capable of use as human food.

`(2) The term 'genetically engineered material' means material derived from any part of a genetically engineered organism, without regard to whether the altered molecular or cellular characteristics of the organism are detectable in the material (and without regard to whether the organism is capable of use as human food).

engineered organism' means--

`(3) The term 'genetically

`(A) an organism that has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes (including but not limited to recombinant DNA and RNA techniques, cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling, introducing a foreign gene, 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

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) an organism made

(b) Labeling Requirement-

LABELING TO AVOID MISBRANDING-

(1) REQUIRED

INVOLVEMENT OF GENETICALLY ENGINEERED MATERIAL- For purposes of sections 1(n) and 10, a meat food is misbranded if it-- (A)

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

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

`(B) NO

INVOLVEMENT OF GENETICALLY ENGINEERED MATERIAL- For purposes of sections 1(n) and 10, a meat food 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 meat food does not contain such material, or was not produced with such material, has no bearing on the safety of the food for human consumption.

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

`(2)

RULE OF CONSTRUCTION- For purposes of subparagraphs (A)(i) and (B) of paragraph (1), a meat food shall be considered to have been produced with a genetically engineered material if--

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

`(B) the animal from which the food is derived has been fed genetically engineered material; or

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

`(3) TESTING- For purposes of sections 1(n) and 10:

`(A) In the case of the transfer of meat foods from manufacturers or producers to distributors, and from distributors to other distributors or to other persons in the chain of distribution, including persons who hold meat food for sale to consumers, regulations under subparagraphs (A)(i) and (B) of paragraph (1) shall require periodic testing of meat foods by the Secretary for purposes of determining the accuracy of labels under such subparagraphs. Such regulations shall require the use of the best available technology for such testing, and shall identify tests that meet such requirement. This subparagraph and subparagraph (B) of this paragraph do not apply to (i) meat foods that are certified and comply with the Organic Foods Production Act and its implementing regulations; or (ii) meat foods produced with genetically engineered material if the Secretary has not through such regulations identified a validated method of testing for such material in the food; or (iii) genetically engineered material contained in a meat food if the Secretary has not through such regulations identified a validated method of testing for such material in the food.

`(B) A meat food with respect to which a test has been identified under subparagraph (A) shall not be considered to contain a genetically engineered material for purposes of subparagraphs (A)(i) and (B) of paragraph (1) if, as indicated by such a test--

`(i) the food does not contain any genetically engineered material; or

`(ii) the food contains an adventitious genetically engineered material and the amount of the material in the food is one percent or less, except that a lower percentage designated by the Secretary shall apply for purposes of this subparagraph if the Secretary determines that a test identified under subparagraph (A) can detect a percentage lower than one percent.

`(c) Specifics of Label Notices-

`(1) REQUIRED NOTICES- The notices referred to in subsection (b)(1)(B) are the following:

`(A) A notice as follows: `GENETICALLY ENGINEERED`.

`(B) A notice as follows: `THIS PRODUCT CONTAINS A GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL`.

`(2) LOCATION AND SIZE- (A) The notice required in paragraph (1)(A) shall immediately precede the notice required in paragraph (1)(B) and shall be not less than twice the size of the notice required in paragraph (1)(B).

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

`(d) Exceptions to Requirements- Subsection (a) does not apply to any meat food that--

`(1) is served in restaurants or other establishments in which food is served for immediate human consumption; or

`(2) is processed and prepared primarily in a retail establishment, is ready for human consumption, is offered for sale to consumers but not for immediate human consumption in such establishment, and is not offered for sale outside such establishment.

`(e) Guaranty-

`(1) IN GENERAL- Subject to subsection (b)(3)(A) and paragraph (3), a packer, processor, or other person shall not be considered to have violated the requirements of this section with respect to the labeling of meat food if the packer, processor, or other person (referred to in this subsection as the `recipient') establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom the recipient received in good faith the meat food or the animal from which the meat food was derived, or received in good faith food intended to be fed to such animal, to the effect that the meat food, or such animal, or such food, respectively, does not contain genetically engineered material or was not produced with a genetically engineered material.

`(2) SCOPE OF GUARANTY- In the case of a recipient who establishes a guaranty or undertaking in accordance with paragraph (1), the exclusion under such paragraph from being subject to penalties applies to the recipient without regard to the use of the meat food by the recipient (or the use by the recipient of the animal from which the meat food was derived, or of food intended to be fed to such animal), including--

`(A) processing the meat food;

`(B) using the meat food as an ingredient in another food product;

`(C) packing or repacking the meat food; or

`(D) raising the animal from which the meat food was derived.

`(3) TESTING- In the case of recipients who establish guaranties or undertakings in accordance with paragraph (1), regulations under subsection (b)(3)(A) may exempt the recipients from the requirement under such subsection regarding testing of the meat food involved (relating to the accuracy of labels regarding genetically engineered material). In determining whether to establish such exemptions, the Secretary shall, with respect to the meat food involved, take into account the number of times the food has been transferred from one recipient to another, the number of recipients who took any of the actions described in paragraph (2), and such other factors as the Secretary determines to be appropriate.

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

`(f) Civil Penalties-

`(1) IN GENERAL- The Secretary may assess a civil penalty against a person that violates subsection (b) or (c)(2) in an amount not to exceed \$100,000 for each such violation.

`(2) NOTICE AND OPPORTUNITY FOR HEARING- A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

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

`(4) CERTAIN AUTHORITIES- The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty under paragraph (1). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

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

pay an assessment of a civil penalty--

`(6) FAILURE TO PAY- If a person fails to

assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (5); or

`(A) after the order making the

brought under paragraph (4) has entered a final judgment in favor of the Secretary;

`(B) after a court in an action

the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (5) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

the Attorney General shall recover

`(g) Citizen Suits-

provided in paragraph (3), any person may on his or her behalf commence a civil action in an appropriate district court of the United States against--

“(1) IN GENERAL- Except as

alleged to have engaged in a violation of subsection (b) or (c)(2); or

“(A) a person who is

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

“(B) the Secretary

action under paragraph (1), the district court involved may, as the case may be--

“(2) RELIEF- In a civil

compliance of a person with the applicable provisions referred to subparagraph (A) of such paragraph; or

“(A) enforce the

Secretary to perform an act or duty referred to in subparagraph (B) of such paragraph.

`(B) order the

LIMITATIONS-

`(3)

NOTICE TO SECRETARY- A civil action may not be commenced under paragraph (1)(A) prior to 60 days after the plaintiff has provided to the Secretary notice of the violation involved.

`(A)

RELATION TO ACTIONS OF SECRETARY- A civil action may not be commenced under paragraph (1)(B) if the Secretary has commenced and is diligently prosecuting a civil or criminal action in a district court of the United States to enforce compliance with the applicable provisions referred to in paragraph (1)(A).

`(B)

`(4)

RIGHT OF SECRETARY TO INTERVENE- In any civil action under paragraph (1), the Secretary, if not a party, may intervene as a matter of right.

`(5)

AWARD OF COSTS; FILING OF BOND- In a civil action under paragraph (1), the district court involved may award costs of litigation (including reasonable attorney and expert witness fees) to any party whenever the court determines such an award is appropriate. The court may, if a temporary restraining order or preliminary injunction is sought, require the filing of a bond or equivalent security in accordance with the Federal Rules of Civil Procedure.

`(6)

SAVINGS PROVISION- This subsection does not restrict any right that a person (or class of persons) may have under any statute or common law to seek enforcement of the provisions referred to in paragraph (1)(A), or to seek any other relief (including relief against the Secretary).'

(b)

Inclusion of Labeling Requirements in Definition of Misbranded- Section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)) is amended--

(1) by striking `or' at the end of paragraph (11);

(2) by striking the period at the end of paragraph (12) and inserting `; or'; and

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

`(13) if it fails to bear a label or labeling as required by section 7A.'

SEC. 5. LABELING REGARDING GENETICALLY ENGINEERED MATERIAL; AMENDMENTS TO POULTRY PRODUCTS INSPECTION ACT.

(a) Requirements- The Poultry Products Inspection Act is amended by inserting after section 8 (21 U.S.C. 457) the following section:

`SEC. 8A. REQUIREMENTS FOR LABELING REGARDING GENETICALLY ENGINEERED MATERIAL.

`(a) Definitions- In this section:

`(1) The term `genetically engineered material' means material derived from any part of a genetically engineered organism, without regard to whether the altered molecular or cellular characteristics of the organism are detectable in the material (and without regard to whether the organism is capable of use as human food).

`(2) The term `genetically engineered organism' means--

`(A) an organism that has been altered at the molecular or cellular level by means that are not possible under natural conditions or processes (including but not limited to recombinant DNA and RNA techniques, cell fusion, microencapsulation, macroencapsulation, gene deletion and doubling, introducing a foreign gene, 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-



`(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 have been produced with a genetically engineered material if--

`(A) the poultry from which the food is derived has been injected or otherwise treated with a genetically engineered material;

genetically engineered material; or

`(B) the poultry from which the food is derived has been fed

subparagraph (A) or (B) of this paragraph applies.

`(C) the food contains an ingredient that is a food to which

`(3) TESTING- For purposes of sections 4(h) and 9(a):

`(A) In the case of the transfer of poultry products from

manufacturers or producers to distributors, and from distributors to other distributors or to other persons in the chain of distribution, including persons who hold poultry products for sale to consumers, regulations under subparagraphs (A)(i) and (B) of paragraph (1) shall require periodic testing of poultry products by the Secretary for purposes of determining the accuracy of labels under such subparagraphs. Such regulations shall require the use of the best available technology for such testing, and shall identify tests that meet such requirement. This subparagraph and subparagraph (B) of this paragraph do not apply to (i) poultry products that are certified and comply with the Organic Foods Production Act and its implementing regulations; or (ii) poultry products produced with genetically engineered material if the Secretary has not through such regulations identified a validated method of testing for such material in the food; or (iii) genetically engineered material contained in a poultry products if the Secretary has not through such regulations identified a validated method of testing for such material in the product.

(B) A poultry product with respect to which a test has been identified under subparagraph (A) shall not be considered to contain a genetically engineered material for purposes of subparagraphs (A)(i) and (B) of paragraph (1) if, as indicated by such a test--

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

(ii) the product contains an adventitious genetically engineered material and the amount of the material in the product is one percent or less, except that a lower percentage designated by the Secretary shall apply for purposes of this subparagraph if the Secretary determines that a test identified under subparagraph (A) can detect a percentage lower than one percent.

(c) Specifics of Label Notices-

to in subsection (b)(1)(B) are the following:

(1) REQUIRED NOTICES- The notices referred

ENGINEERED'.

(A) A notice as follows: 'GENETICALLY

(B) A notice as follows: `THIS PRODUCT CONTAINS A GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL`.

(2) LOCATION AND SIZE- (A) The notice required in paragraph (1)(A) shall immediately precede the notice required in paragraph (1)(B) and shall be not less than twice the size of the notice required in paragraph (1)(B).

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

(d) Exceptions to Requirements-  
Subsection (a) does not apply to any poultry product that--

other establishments in which food is served for immediate human consumption; or (1) is served in restaurants or

primarily in a retail establishment, is ready for human consumption, is offered for sale to consumers but not for immediate human consumption in such establishment, and is not offered for sale outside such establishment. (2) is processed and prepared

(e) Guaranty-

(1) IN GENERAL- Subject to subsection (b)(3)(A) and paragraph (3), an official establishment or other person shall not be considered to have violated the requirements of this section with respect to the labeling of a poultry product if the official establishment or other person (referred to in this subsection as the 'recipient') establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom the recipient received in good faith the poultry product or the poultry from which the poultry product was derived, or received in good faith food intended to be fed to poultry, to the effect that the poultry product, poultry, or such food, respectively, does not contain genetically engineered material or was not produced with a genetically engineered material.

(2) SCOPE OF GUARANTY- In the case of a recipient who establishes a guaranty or undertaking in accordance with paragraph (1), the exclusion under such paragraph from being subject to penalties applies to the recipient without regard to the use of the poultry product by the recipient (or the use by the recipient of the poultry from which the poultry product was derived, or of food intended to be fed to such poultry), including--

the poultry;

`(A) processing

poultry product as an ingredient in another food product;

`(B) using the

or repacking the poultry product; or

`(C) packing

the poultry from which the poultry product was derived.

`(D) raising

TESTING- In the case of recipients who establish guaranties or undertakings in accordance with paragraph (1), regulations under subsection (b)(3)(A) may exempt the recipients from the requirement under such subsection regarding testing of the poultry product involved (relating to the accuracy of labels regarding genetically engineered material). In determining whether to establish such exemptions, the Secretary shall, with respect to the poultry product involved, take into account the number of times the product has been transferred from one recipient to another, the number of recipients who took any of the actions described in paragraph (2), and such other factors as the Secretary determines to be appropriate.

`(3)

FALSE GUARANTY- It is a violation of this Act for a person to give a guaranty or undertaking in accordance with paragraph (1) that the person knows or has reason to know is false.

`(4)

Penalties-

`(f) Civil

IN GENERAL- The Secretary may assess a civil penalty against a person that violates subsection (b) or (c)(2) in an

`(1)

amount not to exceed \$100,000 for each such violation.

`(2) NOTICE AND OPPORTUNITY FOR HEARING- A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

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

`(4) CERTAIN AUTHORITIES- The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty under paragraph (1). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

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

`(6) FAILURE TO PAY- If a person fails to pay an assessment of a civil penalty--

`(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (5); or

Secretary; (B) after a court in an action brought under paragraph (4) has entered a final judgment in favor of the

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

(g) Citizen Suits-

(1) IN GENERAL- Except as provided in paragraph (3), any person may on his or her behalf commence a civil action in an appropriate district court of the United States against--

`(A) a person who is alleged to have engaged in a violation of subsection (b) or (c)(2); or

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

case may be-- `(2) RELIEF- In a civil action under paragraph (1), the district court involved may, as the

`(A) enforce the compliance of a person with the applicable provisions referred to subparagraph (A) of such paragraph; or

such paragraph. `(B) order the Secretary to perform an act or duty referred to in subparagraph (B) of

`(3) LIMITATIONS-

`(A) NOTICE TO SECRETARY- A civil action may not be commenced under paragraph (1)(A) prior to 60 days after the plaintiff has provided to the Secretary notice of the violation involved.

`(B) RELATION TO ACTIONS OF SECRETARY- A civil action may not be commenced under paragraph (1)(B) if the Secretary has commenced and is diligently prosecuting a civil or criminal action in a district court of the United States to enforce compliance with the applicable provisions referred to in paragraph (1)(A).

`(4) RIGHT OF SECRETARY TO INTERVENE- In any civil action under paragraph (1), the Secretary, if not a party, may intervene as a matter of right.

`(5) AWARD OF COSTS; FILING OF BOND- In a civil action under paragraph (1), the district court involved may award costs of litigation (including reasonable attorney and expert witness fees) to any party whenever the court determines such an award is appropriate. The court may, if a temporary restraining order or preliminary injunction is sought, require the filing of a bond or equivalent security in accordance with the Federal Rules of Civil Procedure.

`(6) SAVINGS PROVISION- This subsection does not restrict any right that a person (or class of persons) may have under any statute or common law to seek enforcement of the provisions referred to in paragraph (1)(A), or to seek any other relief (including relief against the Secretary).'

(b) Inclusion of Labeling Requirements in Definition of Misbranded-  
Section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)) is amended--

(1) by striking `or' at the end of paragraph (11);

inserting `; or'; and  
(2) by striking the period at the end of paragraph (12) and

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

section 8A.:

(13) if it fails to bear a label or labeling as required by

#### SEC. 6. EFFECTIVE DATE.

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

END