

106TH CONGRESS  
1ST SESSION

# H. R. 3377

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.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 16, 1999

Mr. KUCINICH (for himself, Mr. METCALF, Mr. BONIOR, Mr. DEFazio, Mr. SANDERS, Mr. SMITH of New Jersey, Mr. DOYLE, Mr. LIPINSKI, Mr. BROWN of Ohio, Mr. HINCHEY, Ms. SCHAKOWSKY, Ms. NORTON, Mr. STARK, Ms. WOOLSEY, Mrs. MINK of Hawaii, Mr. MARTINEZ, Mr. McDERMOTT, Ms. LEE, and Ms. WATERS) introduced the following bill; which was referred to the Committee on Agriculture, and in addition to the Committee on 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

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## 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) Reasonably available technology permits the  
 8 detection in food of genetically engineered material,  
 9 generally acknowledged to be as low as 0.1 percent.

10 **SEC. 3. LABELING REGARDING GENETICALLY ENGINEERED**  
 11 **MATERIAL; AMENDMENTS TO FEDERAL**  
 12 **FOOD, DRUG, AND COSMETIC ACT.**

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

16 “(t)(1) If it contains a genetically engineered mate-  
 17 rial, or was produced with a genetically engineered mate-  
 18 rial, unless it bears a label (or labeling, in the case of a  
 19 raw agricultural commodity, other than the sale of such  
 20 a commodity at retail) that provides notices in accordance  
 21 with the following:

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

24 “(B) A notice as follows: ‘UNITED STATES  
 25 GOVERNMENT NOTICE: THIS PRODUCT

1       CONTAINS A GENETICALLY ENGINEERED  
2       MATERIAL, OR WAS PRODUCED WITH A GE-  
3       NETICALLY ENGINEERED MATERIAL’.

4           “(C) The notice required in clause (A) imme-  
5       diately precedes the notice required in clause (B)  
6       and is not less than twice the size of the notice re-  
7       quired in clause (B).

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

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

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

15          “(A) 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.

20          “(B) The term ‘genetically engineered orga-  
21      nism’ means—

22              “(i) an organism that has been altered at  
23              the molecular or cellular level by means that are  
24              not possible under natural conditions or proc-  
25              esses (including but not limited to recombinant

1 DNA and RNA techniques, cell fusion, micro-  
2 encapsulation, macroencapsulation, gene dele-  
3 tion and doubling, introducing a foreign gene,  
4 and changing the positions of genes), other  
5 than a means consisting exclusively of breeding,  
6 conjugation, fermentation, hybridization, in  
7 vitro fertilization, or tissue culture, and

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

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

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

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

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

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

4           “(A) is served in restaurants or other establish-  
5           ments in which food is served for immediate human  
6           consumption,

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

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

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

19          “(h)(1) With respect to a violation of section 301(a),  
20          301(b), or 301(c) involving the misbranding of food within  
21          the meaning of section 403(t), any person engaging in  
22          such a violation shall be liable to the United States for  
23          a civil penalty in an amount not to exceed \$100,000 for  
24          each such violation.

1       “(2) Paragraphs (3) through (5) of subsection (g)  
 2       apply with respect to a civil penalty under paragraph (1)  
 3       of this subsection to the same extent and in the same man-  
 4       ner as such paragraphs (3) through (5) apply with respect  
 5       to a civil penalty under paragraph (1) or (2) of subsection  
 6       (g).”.

7       (c) GUARANTY.—

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

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

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

15       “(2)(A) No person shall be subject to the penalties  
 16       of subsection (a)(1) or (h) for a violation of section 301(a),  
 17       301(b), or 301(c) involving the misbranding of food within  
 18       the meaning of section 403(t) if such person (referred to  
 19       in this paragraph as the ‘recipient’) establishes a guaranty  
 20       or undertaking signed by, and containing the name and  
 21       address of, the person residing in the United States from  
 22       whom the recipient received in good faith the food (includ-  
 23       ing the receipt of seeds to grow raw agricultural commod-  
 24       ities), to the effect that (within the meaning of section  
 25       403(t)) the food does not contain a genetically engineered

1 material or was not produced with a genetically engineered  
2 material.

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

9 “(i) processing the food,

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

12 “(iii) repacking the food, or

13 “(iv) growing, raising, or otherwise producing  
14 the food.”.

15 (2) FALSE GUARANTY.—Section 301(h) of the  
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 331(h)) is amended by inserting “or 303(d)(2)”  
18 after “303(c)(2)”.

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

23 “(3)(A) No person shall be subject to the penalties  
24 of subsection (a)(1) or (h) for a violation of section 301(a),



1 301(b), or 301(c) involving the misbranding of food within  
 2 the meaning of section 403(t) if—

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

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

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

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

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

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

25 “(a) DEFINITIONS.—In this section:

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

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

13          “(3) The term ‘genetically engineered organism’  
14          means—

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

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

6           “(b) LABELING REQUIREMENT.—

7           “(1) REQUIRED LABELING TO AVOID MIS-  
8           BRANDING.—For purposes of sections 1(n) and 10,  
9           a meat food is misbranded if it—

10           “(A) contains a genetically engineered ma-  
11           terial or was produced with a genetically engi-  
12           neered material; and

13           “(B) does not bear a label (or include la-  
14           beling, in the case of a meat food that is not  
15           packaged in a container) that provides, in a  
16           clearly legible and conspicuous manner, the no-  
17           tices described in subsection (c).

18           “(2) RULE OF CONSTRUCTION.—For purposes  
19           of paragraph (1)(A), a meat food shall be considered  
20           to have been produced with a genetically engineered  
21           material if—

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

1           “(B) the animal from which the food is de-  
 2           rived has been fed genetically engineered mate-  
 3           rial; or

4           “(C) the food contains an ingredient that  
 5           is a food to which subparagraph (A) or (B) ap-  
 6           plies.

7           “(c) SPECIFICS OF LABEL NOTICES.—

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

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

12           “(B) A notice as follows: ‘UNITED  
 13           STATES GOVERNMENT NOTICE: THIS  
 14           PRODUCT CONTAINS A GENETICALLY  
 15           ENGINEERED MATERIAL, OR WAS PRO-  
 16           DUCED WITH A GENETICALLY ENGI-  
 17           NEERED MATERIAL’.

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

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

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

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

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

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

14 “(e) GUARANTY.—

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

1 such animal, to the effect that the meat food, or  
2 such animal, or such food, respectively, does not con-  
3 tain genetically engineered material or was not pro-  
4 duced with a genetically engineered material.

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

14 “(A) processing the meat food;

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

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

18 or

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

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

25 “(f) CIVIL PENALTIES.—

1           “(1) IN GENERAL.—The Secretary may assess  
2           a civil penalty against a person that violates sub-  
3           section (b) or (c)(3) in an amount not to exceed  
4           \$100,000 for each such violation.

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

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

1       ity to continue to do business, any history of prior  
2       such violations, the degree of culpability, and such  
3       other matters as justice may require.

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

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

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

24           “(A) after the order making the assess-  
25      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  
7 assessed (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 (b) INCLUSION OF LABELING REQUIREMENTS IN  
16 DEFINITION OF MISBRANDED.—Section 1(n) of the Fed-  
17 eral Meat Inspection Act (21 U.S.C. 601(n)) is  
18 amended—

19 (1) by striking “or” at the end of paragraph  
20 (11);

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

23 (3) by adding at the end the following para-  
24 graph:

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

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

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

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

11 “(a) DEFINITIONS.—In this section:

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

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

21 “(A) an organism that has been altered at  
22 the molecular or cellular level by means that are  
23 not possible under natural conditions or proc-  
24 esses (including but not limited to recombinant  
25 DNA and RNA techniques, cell fusion, micro-

encapsulation, 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, or tissue culture; 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.—For purposes of sections 4(h) and 9(a), a poultry product is misbranded if it—

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

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

“(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1)(A), a poultry product shall be con-

sidered 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;

“(B) the poultry 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) applies.

“(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: ‘UNITED STATES GOVERNMENT NOTICE: 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

1 shall be not less than twice the size of the notice  
2 required 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 poultry product 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.—An official establishment or  
21 other person shall not be considered to have violated  
22 the requirements of this section with respect to the  
23 labeling of a poultry product if the official establish-  
24 ment or other person (referred to in this subsection  
25 as the ‘recipient’) establishes a guaranty or under-

1 taking signed by, and containing the name and ad-  
2 dress of, the person residing in the United States  
3 from whom the recipient received in good faith the  
4 poultry product or the poultry from which the poul-  
5 try product was derived, or received in good faith  
6 food intended to be fed to poultry, to the effect that  
7 the poultry product, poultry, or such food, respec-  
8 tively, does not contain genetically engineered mate-  
9 rial or was not produced with a genetically engi-  
10 neered 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 poultry product by the recipient (or the  
17 use by the recipient of the poultry from which the  
18 poultry product was derived, or of food intended to  
19 be fed to such poultry), including—

20 “(A) processing the poultry;

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

23 “(C) packing or repacking the poultry  
24 product; or

1           “(D) raising the poultry from which the  
2           poultry product was derived.

3           “(3) 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)(3) 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  
15 assessed (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 (b) INCLUSION OF LABELING REQUIREMENTS IN  
24 DEFINITION OF MISBRANDED.—Section 4(h) of the Poul-

1 try Products Inspection Act (21 U.S.C. 453(h)) is  
2 amended—

3 (1) by striking “or” at the end of paragraph  
4 (11);

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

7 (3) by adding at the end the following para-  
8 graph:

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

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

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

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