

111<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6325

To amend the Federal Food, Drug, and Cosmetic Act and the Federal Meat Inspection Act to require that food that contains bioengineered products be labeled accordingly, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 29, 2010

Ms. DELAURO (for herself, Mr. FRANK of Massachusetts, and Ms. WOOLSEY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Agriculture, 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 and the Federal Meat Inspection Act to require that food that contains bioengineered products be labeled accordingly, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Consumer Right To  
5 Know Food Labeling Act of 2010”.

1 **SEC. 2. TABLE OF CONTENTS.**

2 The table of contents of this Act is as follows:

- Sec. 1. Short title.  
 Sec. 2. Table of contents.  
 Sec. 3. Effective date.

TITLE I—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND  
 COSMETIC ACT REGARDING CLONED PRODUCTS

Sec. 101. Labeling of products from cloned animals.

TITLE II—AMENDMENTS TO THE FEDERAL MEAT INSPECTION  
 ACT REGARDING CLONED PRODUCTS

Sec. 201. Requirements for labeling regarding cloned products.

TITLE III—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND  
 COSMETIC ACT REGARDING GENETICALLY-ENGINEERED SALMON

Sec. 301. Labeling of food products that contain genetically-engineered salmon.

3 **SEC. 3. EFFECTIVE DATE.**

4 This Act and the amendments made by this Act shall  
 5 take effect upon the expiration of the 180-day period be-  
 6 ginning on the date of enactment of this Act.

7 **TITLE I—AMENDMENTS TO THE**  
 8 **FEDERAL FOOD, DRUG, AND**  
 9 **COSMETIC ACT REGARDING**  
 10 **CLONED PRODUCTS**

11 **SEC. 101. LABELING OF PRODUCTS FROM CLONED ANI-**  
 12 **MALS.**

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:

16 “(z)(1) If it contains cloned product unless it bears  
 17 a label that provides notice in accordance with the fol-  
 18 lowing:

1           “(A) A notice as follows: ‘THIS PRODUCT IS  
2 FROM A CLONED ANIMAL OR ITS PROGENY’.

3           “(B) The notice required in clause (A) 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           “(C) The notice required under clause (A) is  
8 clearly legible and conspicuous.

9           “(2) For purposes of this paragraph:

10           “(A) The term ‘cloned animal’ means—

11                   “(i) an animal produced as the result of  
12 somatic cell nuclear transfer; and

13                   “(ii) the progeny of such an animal.

14           “(B) The term ‘cloned product’ means a prod-  
15 uct or byproduct derived from or containing any  
16 part of a cloned animal.

17           “(3) This paragraph does not apply to food that is  
18 a medical food as defined in section 5(b) of the Orphan  
19 Drug Act.

20           “(4)(A) The Secretary, in consultation with the Sec-  
21 retary of Agriculture, shall require that any person that  
22 prepares, stores, handles, or distributes a cloned product  
23 for retail sale maintain a verifiable recordkeeping audit  
24 trail that will permit the Secretary to verify compliance  
25 with this paragraph and subsection (aa).

1       “(B) The Secretary, in consultation with the Sec-  
2 retary of Agriculture, shall publish in the Federal Register  
3 the procedures established by such Secretaries to verify  
4 compliance with the recordkeeping audit trail system re-  
5 quired under clause (A).

6       “(C) The Secretary, in consultation with the Sec-  
7 retary of Agriculture, shall, on annual basis, submit to  
8 Congress a report that describes the progress and activi-  
9 ties of the recordkeeping audit trail system and compli-  
10 ance verification procedures required under this subpara-  
11 graph.

12       “(aa) If it bears a label indicating (within the mean-  
13 ing of subsection (z)) that it does not contain cloned prod-  
14 uct, unless the label is in accordance with regulations pro-  
15 mulgated by the Secretary. With respect to such regula-  
16 tions:

17               “(1) The regulations may not require such a  
18 label to include any statement indicating that the  
19 fact that a food does not contain such product has  
20 no bearing on the safety of the food for human con-  
21 sumption.

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

1       mercial distribution that does contain such prod-  
2       uct.”.

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

6       “(g)(1) With respect to a violation of section 301(a),  
7       301(b), or 301(c) involving the misbranding of food within  
8       the meaning of section 403(z) or 403(aa), any person en-  
9       gaging in such a violation shall be liable to the United  
10      States for a civil penalty in an amount not to exceed  
11      \$100,000 for each such violation.

12      “(2) Paragraphs (3) through (5) of subsection (f)  
13      apply with respect to a civil penalty under paragraph (1)  
14      of this subsection to the same extent and in the same man-  
15      ner as such paragraphs (3) through (5) apply with respect  
16      to a civil penalty under paragraph (1) or (2) of subsection  
17      (f).”.

18      (c) GUARANTY.—

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

22           (A) by striking “(d)” and inserting  
23           “(d)(1)”; and

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

1       “(2) Subject to section 403(z)(4), no person shall be  
2 subject to the penalties of subsection (a)(1) or (h) for a  
3 violation of section 301(a), 301(b), or 301(c) involving the  
4 misbranding of food within the meaning of section 403(z)  
5 and 403(aa) if such person (referred to in this paragraph  
6 as the ‘recipient’) establishes a guaranty or undertaking  
7 signed by, and containing the name and address of, the  
8 person residing in the United States from whom the re-  
9 cipient received in good faith the food to the effect that  
10 (within the meaning of section 403(z)) the food does not  
11 contain any cloned product.”.

12               (2) FALSE GUARANTY.—Section 301(h) of the  
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
14 331(h)) is amended by inserting “or 303(d)(2)”  
15 after “303(c)(2)”.

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

19 **“SEC. 311. CITIZEN SUITS REGARDING MISBRANDING OF**  
20 **FOOD WITH RESPECT TO PRODUCT FROM**  
21 **CLONED ANIMALS.**

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

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

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

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

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

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

16           “(c) LIMITATIONS.—

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

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

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

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

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

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

1 **TITLE II—AMENDMENTS TO THE**  
2 **FEDERAL MEAT INSPECTION**  
3 **ACT REGARDING CLONED**  
4 **PRODUCTS**

5 **SEC. 201. REQUIREMENTS FOR LABELING REGARDING**  
6 **CLONED PRODUCTS.**

7 (a) REQUIREMENTS FOR LABELING REGARDING  
8 CLONED MEAT FOOD PRODUCTS.—The Federal Meat In-  
9 spection Act is amended by inserting after section 7 (21  
10 U.S.C. 607) the following:

11 **“SEC. 7A. REQUIREMENTS FOR LABELING REGARDING**  
12 **CLONED MEAT FOOD PRODUCTS.**

13 “(a) DEFINITIONS.—In this section:

14 “(1) CLONED ANIMAL.—The term ‘cloned ani-  
15 mal’ means—

16 “(A) an animal produced as the result of  
17 somatic cell nuclear transfer; and

18 “(B) the progeny of such an animal.

19 “(2) CLONED PRODUCT.—The term ‘cloned  
20 product’ means a product or byproduct derived from  
21 or containing any part of a cloned animal.

22 “(3) CLONED MEAT FOOD PRODUCT.—The  
23 term ‘cloned meat food product’ means a meat food  
24 product that contains a cloned product.

25 “(b) LABELING REQUIREMENT.—

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

3           “(A) INVOLVEMENT OF CLONED MEAT  
4           FOOD PRODUCT.—For purposes of sections 1(n)  
5           and 10, a meat food product is misbranded if  
6           the meat food product—

7                   “(i) is a cloned meat food product;  
8                   and

9                   “(ii) does not bear a label (or include  
10                  labeling, in the case of a meat food product  
11                  that is not packaged in a container) that  
12                  provides, in a clearly legible and con-  
13                  spicuous manner, the notice described in  
14                  subsection (c).

15           “(B) NO INVOLVEMENT OF CLONED MEAT  
16           FOOD PRODUCT.—

17                   “(i) IN GENERAL.—For purposes of  
18                  sections 1(n) and 10, a meat food product  
19                  is misbranded if the meat food product  
20                  bears a label indicating that the meat food  
21                  product is not a cloned meat food product,  
22                  unless the label is in accordance with regu-  
23                  lations promulgated by the Secretary.

1           “(ii) REQUIREMENTS.—In promul-  
2           gating regulations referred to in clause (i),  
3           the Secretary may not—

4                   “(I) require a label to include  
5                   any statement indicating that the fact  
6                   that a meat food product is not a  
7                   cloned meat food product has no bear-  
8                   ing on the safety of the food for  
9                   human consumption; or

10                   “(II) prohibit a label on the basis  
11                   that, in the case of the type of meat  
12                   food product involved, there is no  
13                   version of the meat food product in  
14                   commercial distribution that is not a  
15                   cloned meat food product.

16           “(2) AUDIT VERIFICATION SYSTEM.—

17                   “(A) IN GENERAL.—The Secretary, in con-  
18                   sultation with the Secretary of Health and  
19                   Human Services, shall require that any person  
20                   that manufactures, produces, distributes, stores,  
21                   or handles a meat food product maintain a  
22                   verifiable recordkeeping audit trail that will per-  
23                   mit the Secretary to verify compliance with the  
24                   labeling requirements described in paragraph  
25                   (1).

1           “(B) PUBLICATION.—The Secretary, in  
2           consultation with the Secretary of Health and  
3           Human Services, shall publish in the Federal  
4           Register the procedures established by the Sec-  
5           retaries to verify compliance with the record-  
6           keeping audit trail system required under sub-  
7           paragraph (A).

8           “(C) REPORT.—The Secretary, in con-  
9           sultation with the Secretary of Health and  
10          Human Services, shall, on an annual basis, sub-  
11          mit to Congress a report that describes the  
12          progress and activities of the recordkeeping  
13          audit trail system and compliance verification  
14          procedures required under this paragraph.

15          “(c) SPECIFICS OF LABEL NOTICE.—

16                 “(1) REQUIRED NOTICE.—The notice referred  
17                 to in subsection (b)(1)(A)(ii) is the following: ‘THIS  
18                 PRODUCT IS FROM A CLONED ANIMAL OR  
19                 ITS PROGENY’.

20                 “(2) SIZE.—The notice required in paragraph  
21                 (1) shall be of the same size as if the notice provided  
22                 nutrition information that is required under section  
23                 403(q)(1) of the Federal Food, Drug, and Cosmetic  
24                 Act (21 U.S.C. 343(q)(1)).

25          “(d) GUARANTY.—

1           “(1) IN GENERAL.—Subject to subsection  
2           (b)(2) and paragraph (2), a person engaged in the  
3           business of manufacturing or processing meat food  
4           products, or selling or serving meat food products at  
5           retail or through a food service establishment (re-  
6           ferred to in this subsection as the ‘recipient’) shall  
7           not be considered to have violated this section with  
8           respect to the labeling of a meat food product if the  
9           recipient establishes a guaranty or undertaking  
10          signed by, and containing the name and address of,  
11          the person residing in the United States from whom  
12          the recipient received in good faith the meat food  
13          product or the animal from which the meat food  
14          product was derived, or received in good faith food  
15          intended to be fed to the animal, to the effect that  
16          the meat food product, or the animal, or the meat  
17          food product, respectively, does not contain a cloned  
18          product or was not produced with a cloned product.

19          “(2) AUDIT VERIFICATION SYSTEM.—In the  
20          case of recipients who establish guaranties or under-  
21          takings in accordance with paragraph (1), the Sec-  
22          retary may exempt the recipients from the require-  
23          ment under subsection (b)(2) regarding maintaining  
24          a verifiable recordkeeping audit trail.

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

5           “(e) CIVIL PENALTIES.—

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

10           “(2) NOTICE AND OPPORTUNITY FOR HEAR-  
11 ING.—

12           “(A) IN GENERAL.—A civil penalty under  
13 paragraph (1) shall be assessed by the Sec-  
14 retary by an order made on the record after op-  
15 portunity for a hearing provided in accordance  
16 with this paragraph and section 554 of title 5,  
17 United States Code.

18           “(B) WRITTEN NOTICE.—Before issuing  
19 an order under subparagraph (A), the Secretary  
20 shall—

21           “(i) give written notice to the person  
22 to be assessed a civil penalty under the  
23 order of the proposal of the Secretary to  
24 issue the order; and

1           “(ii) provide the person an oppor-  
2           tunity for a hearing on the order.

3           “(C) AUTHORIZATIONS.—In the course of  
4           any investigation, the Secretary may issue sub-  
5           poenas requiring the attendance and testimony  
6           of witnesses and the production of evidence that  
7           relates to the matter under investigation.

8           “(3) CONSIDERATIONS REGARDING AMOUNT OF  
9           PENALTY.—In determining the amount of a civil  
10          penalty under paragraph (1), the Secretary shall  
11          consider—

12           “(A) the nature, circumstances, extent,  
13           and gravity of the 1 or more violations; and

14           “(B) with respect to the violator—

15           “(i) ability to pay;

16           “(ii) effect on ability to continue to do  
17           business;

18           “(iii) any history of prior violations;

19           “(iv) the degree of culpability; and

20           “(v) such other matters as justice  
21           may require.

22          “(4) CERTAIN AUTHORITIES.—

23           “(A) IN GENERAL.—The Secretary may  
24           compromise, modify, or remit, with or without

1 conditions, any civil penalty under paragraph  
2 (1).

3 “(B) DEDUCTION FROM SUMS OWED.—  
4 The amount of a civil penalty under this sub-  
5 section, when finally determined, or the amount  
6 agreed upon in compromise, may be deducted  
7 from any sums owing by the United States to  
8 the person charged.

9 “(5) JUDICIAL REVIEW.—

10 “(A) IN GENERAL.—Any person who re-  
11 quested, in accordance with paragraph (2), a  
12 hearing respecting the assessment of a civil  
13 penalty under paragraph (1) and who is ag-  
14 grieved by an order assessing a civil penalty  
15 may file a petition for judicial review of the  
16 order with—

17 “(i) the United States Court of Ap-  
18 peals for the District of Columbia Circuit;  
19 or

20 “(ii) any other circuit in which the  
21 person resides or transacts business.

22 “(B) FILING DEADLINE.—A petition de-  
23 scribed in subparagraph (A) may only be filed  
24 within the 60-day period beginning on the date  
25 the order making the assessment was issued.

1 “(6) FAILURE TO PAY.—

2 “(A) IN GENERAL.—The Attorney General  
3 shall recover the amount assessed under a civil  
4 penalty (plus interest at prevailing rates from  
5 the date of the expiration of the 60-day period  
6 referred to in paragraph (5)(B) or the date of  
7 the final judgment, as appropriate) in an action  
8 brought in any appropriate district court of the  
9 United States if a person fails to pay the as-  
10 sessment—

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

16 “(ii) after a court in an action  
17 brought under paragraph (5) has entered a  
18 final judgment in favor of the Secretary;

19 “(B) EXEMPTIONS FROM REVIEW.—In an  
20 action described in subparagraph (A), the valid-  
21 ity, amount, and appropriateness of the civil  
22 penalty shall not be subject to review.

23 “(f) 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); or

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

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

12 “(A) enforce the compliance of a person  
13 with the applicable provisions referred to para-  
14 graph (1)(A); or

15 “(B) order the Secretary to perform an act  
16 or duty referred to in paragraph (1)(B).

17 “(3) LIMITATIONS.—

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

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

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

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

10 “(5) AWARD OF COSTS; FILING OF BOND.—

11 “(A) AWARD OF COSTS.—In a civil action  
12 under paragraph (1), the district court involved  
13 may award costs of litigation (including reason-  
14 able attorney and expert witness fees) to any  
15 party in any case in which the court determines  
16 such an award is appropriate.

17 “(B) FILING OF BOND.—The court may, if  
18 a temporary restraining order or preliminary in-  
19 junction is sought, require the filing of a bond  
20 or equivalent security in accordance with the  
21 Federal Rules of Civil Procedure.

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

1           “(A) to seek enforcement of the provisions  
2 referred to in paragraph (1)(A); or

3           “(B) to seek any other relief (including re-  
4 lief against the Secretary).”.

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

9           (1) by striking “or” at the end of paragraph  
10 (11);

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

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

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

16 **TITLE III—AMENDMENTS TO**  
17 **THE FEDERAL FOOD, DRUG,**  
18 **AND COSMETIC ACT REGARD-**  
19 **ING GENETICALLY-ENGI-**  
20 **NEERED SALMON**

21 **SEC. 301. LABELING OF FOOD PRODUCTS THAT CONTAIN**  
22 **GENETICALLY-ENGINEERED SALMON.**

23           Section 403 of the Federal Food, Drug, and Cosmetic  
24 Act (21 U.S.C. 343), as amended by section 3, is further  
25 amended by adding at the end the following:

1           “(bb) If it contains genetically-engineered salmon un-  
2 less the food bears a label stating that fact.”.

○