

111TH CONGRESS
2^D 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.

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

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.”.

○