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S. 414

To amend the Federal Food, Drug, and Cosmetic Act and the Federal Meat Inspection Act to require that food that contains product from a cloned animal be labeled accordingly, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 26, 2007

Ms. MIKULSKI introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Federal Meat Inspection Act to require that food that contains product from a cloned animal 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 “Cloned Food Labeling
5 Act”.

1 **SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**
 2 **COSMETIC ACT.**

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

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

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

11 “(B) The notice required in clause (A) is of the
 12 same size as would apply if the notice provided nu-
 13 trition information that is required in paragraph
 14 (q)(1).

15 “(C) The notice required under clause (A) is
 16 clearly legible and conspicuous.

17 “(2) For purposes of this paragraph:

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

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

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

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

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

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

10 “(B) The Secretary, in consultation with the Sec-
11 retary of Agriculture, shall publish in the Federal Register
12 the procedures established by such Secretaries to verify
13 compliance with the recordkeeping audit trail system re-
14 quired under clause (A).

15 “(C) The Secretary, in consultation with the Sec-
16 retary of Agriculture, shall, on annual basis, submit to
17 Congress a report that describes the progress and activi-
18 ties of the recordkeeping audit trail system and compli-
19 ance verification procedures required under this subpara-
20 graph.

21 “(aa) If it bears a label indicating (within the mean-
22 ing of paragraph (z)) that it does not contain cloned prod-
23 uct, unless the label is in accordance with regulations pro-
24 mulgated by the Secretary. With respect to such regula-
25 tions:

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

6 “(2) The regulations may not prohibit such a
7 label on the basis that, in the case of the type of
8 food involved, there is no version of the food in com-
9 mercial distribution that does contain such prod-
10 uct.”.

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

14 “(g)(1) With respect to a violation of section 301(a),
15 301(b), or 301(c) involving the misbranding of food within
16 the meaning of section 403(z) or 403(aa), any person en-
17 gaging in such a violation shall be liable to the United
18 States for a civil penalty in an amount not to exceed
19 \$100,000 for each such violation.

20 “(2) Paragraphs (3) through (5) of subsection (f)
21 apply with respect to a civil penalty under paragraph (1)
22 of this subsection to the same extent and in the same man-
23 ner as such paragraphs (3) through (5) apply with respect
24 to a civil penalty under paragraph (1) or (2) of subsection
25 (f).”.

1 (c) GUARANTY.—

2 (1) IN GENERAL.—Section 303(d) of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C.
4 333(d)) is amended—

5 (A) by striking “(d)” and inserting
6 “(d)(1)”; and

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

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

20 (2) FALSE GUARANTY.—Section 301(h) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 331(h)) is amended by inserting “or 303(d)(2)”
23 after “303(c)(2)”.

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

4 **“SEC. 311. CITIZEN SUITS REGARDING MISBRANDING OF**
 5 **FOOD WITH RESPECT TO PRODUCT FROM**
 6 **CLONED ANIMALS.**

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

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

15 “(2) the Secretary where there is alleged a fail-
 16 ure of the Secretary to perform any act or duty
 17 under section 403(z) or 403(aa) that is not discre-
 18 tionary.

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

21 “(1) enforce the compliance of a person with
 22 the applicable provisions referred to paragraph (1)
 23 of such subsection; or

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

1 “(c) LIMITATIONS.—

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

6 “(2) RELATION TO ACTIONS OF SECRETARY.—

7 A civil action may not be commenced under sub-
8 section (a)(2) if the Secretary has commenced and
9 is diligently prosecuting a civil or criminal action in
10 a district court of the United States to enforce com-
11 pliance with the applicable provisions referred to in
12 subsection (a)(1).

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

16 “(e) AWARD OF COSTS; FILING OF BOND.—In a civil
17 action under subsection (a), the district court involved
18 may award costs of litigation (including reasonable attor-
19 ney and expert witness fees) to any party whenever the
20 court determines such an award is appropriate. The court
21 may, if a temporary restraining order or preliminary in-
22 junction is sought, require the filing of a bond or equiva-
23 lent security in accordance with the Federal Rules of Civil
24 Procedure.

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

7 **SEC. 3. AMENDMENTS TO THE FEDERAL MEAT INSPECTION**
 8 **ACT.**

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

13 **“SEC. 7A. REQUIREMENTS FOR LABELING REGARDING**
 14 **CLONED MEAT FOOD PRODUCTS.**

15 “(a) DEFINITIONS.—In this section:

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

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

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

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

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

4 “(b) LABELING REQUIREMENT.—

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

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

11 “(i) is a cloned meat food product;
 12 and

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

19 “(B) NO INVOLVEMENT OF CLONED MEAT
 20 FOOD PRODUCT.—

21 “(i) IN GENERAL.—For purposes of
 22 sections 1(n) and 10, a meat food product
 23 is misbranded if the meat food product
 24 bears a label indicating that the meat food
 25 product is not a cloned meat food product,

1 unless the label is in accordance with regu-
2 lations promulgated by the Secretary.

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

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

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

18 “(2) AUDIT VERIFICATION SYSTEM.—

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

1 labeling requirements described in paragraph
2 (1).

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

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

17 “(c) SPECIFICS OF LABEL NOTICE.—

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

22 “(2) SIZE.—The notice required in paragraph
23 (1) shall be of the same size as if the notice provided
24 nutrition information that is required under section

1 403(q)(1) of the Federal Food, Drug, and Cosmetic
2 Act (21 U.S.C. 343(q)(1)).

3 “(d) GUARANTY.—

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

22 “(2) AUDIT VERIFICATION SYSTEM.—In the
23 case of recipients who establish guaranties or under-
24 takings in accordance with paragraph (1), the Sec-
25 retary may exempt the recipients from the require-

1 ment under subsection (b)(2) regarding maintaining
2 a verifiable recordkeeping audit trail.

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 “(e) 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) in an amount not to exceed
11 \$100,000 for each violation.

12 “(2) NOTICE AND OPPORTUNITY FOR HEAR-
13 ING.—

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

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

23 “(i) give written notice to the person
24 to be assessed a civil penalty under the

1 order of the proposal of the Secretary to
2 issue the order; and

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

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

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

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

16 “(B) with respect to the violator—

17 “(i) ability to pay;

18 “(ii) effect on ability to continue to do
19 business;

20 “(iii) any history of prior violations;

21 “(iv) the degree of culpability; and

22 “(v) such other matters as justice
23 may require.

24 “(4) CERTAIN AUTHORITIES.—

1 “(A) IN GENERAL.—The Secretary may
2 compromise, modify, or remit, with or without
3 conditions, any civil penalty under paragraph
4 (1).

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

11 “(5) JUDICIAL REVIEW.—

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

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

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

24 “(B) FILING DEADLINE.—A petition de-
25 scribed in subparagraph (A) may only be filed

1 within the 60-day period beginning on the date
 2 the order making the assessment was issued.

3 “(6) FAILURE TO PAY.—

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

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

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

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

25 “(f) CITIZEN SUITS.—

1 “(1) IN GENERAL.—Except as provided in para-
 2 graph (3), any person may on his or her behalf com-
 3 mence a civil action in an appropriate district court
 4 of the United States against—

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

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

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

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

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

19 “(3) LIMITATIONS.—

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

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

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

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

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

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

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

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

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

9 (b) INCLUSION OF LABELING REQUIREMENTS IN
 10 DEFINITION OF MISBRANDED.—Section 1(n) of the Fed-
 11 eral Meat Inspection Act (21 U.S.C. 601(n)) is amend-
 12 ed—

13 (1) by striking “or” at the end of paragraph
 14 (11);

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

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

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

20 **SEC. 4. EFFECTIVE DATE.**

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

○