

110TH CONGRESS  
1ST SESSION

# 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.

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## 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

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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 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           “(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.

○