

110TH CONGRESS  
2D SESSION

# H. R. 5827

To amend the Federal Food, Drug, and Cosmetic Act to improve food safety.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 16, 2008

Mr. ROSKAM (for himself and Mr. KIRK) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve food safety.

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 “Keeping America’s  
5 Food Safe Act of 2008”.

6 **SEC. 2. CERTIFICATION OF PRIVATE LABORATORIES AND**  
7 **SAMPLING SERVICES.**

8 (a) AMENDMENT.—Chapter IV of the Federal Food,  
9 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-  
10 ed by adding at the end the following:

1 **“SEC. 418. FOOD SAFETY LABORATORIES AND SAMPLING**  
2 **SERVICES.**

3 “(a) DEFINITIONS.—In this section:

4 “(1) FOOD SAFETY LABORATORY.—The term  
5 ‘food safety laboratory’ means an establishment that  
6 analyzes or tests samples of imported food to ensure  
7 the safety of such food.

8 “(2) SAMPLING SERVICE.—The term ‘sampling  
9 service’ means an establishment that collects sam-  
10 ples of an imported food.

11 “(b) CERTIFICATION REQUIREMENT.—

12 “(1) IN GENERAL.—Any entity that is a food  
13 safety laboratory or a sampling service shall submit  
14 to the Secretary an application for certification.  
15 Upon review, the Secretary may grant or deny cer-  
16 tification to the food safety laboratory or sampling  
17 service.

18 “(2) CERTIFICATION STANDARDS.—The Sec-  
19 retary shall establish criteria and methodologies for  
20 the evaluation of an application for certification sub-  
21 mitted under paragraph (1). Such criteria shall in-  
22 clude the requirements that a food safety laboratory  
23 or sampling service—

24 “(A) be accredited as being in compliance  
25 with standards set by the International Organi-  
26 zation for Standardization;

1           “(B) agree to permit the Secretary to con-  
2           duct an inspection of the facilities of the food  
3           safety laboratory or sampling service and the  
4           procedures of such facilities before making a  
5           certification determination;

6           “(C) agree to permit the Secretary to con-  
7           duct routine audits of the facilities to ensure  
8           ongoing compliance with accreditation and cer-  
9           tification requirements;

10           “(D) submit with such application a fee es-  
11           tablished by the Secretary in an amount suffi-  
12           cient to cover the cost of application review, in-  
13           cluding inspection; and

14           “(E) agree to submit to the Secretary, in  
15           accordance with the process established, the re-  
16           sults of tests conducted by such food safety lab-  
17           oratory or sampling service on behalf of an im-  
18           porter.

19           “(c) SUBMISSION OF TEST RESULTS.—The Sec-  
20           retary shall establish a process by which a food safety lab-  
21           oratory or sampling service certified under this section  
22           shall submit to the Secretary the results of all tests con-  
23           ducted by such food safety laboratory or sampling service  
24           on behalf of an importer.

1       “(d) CERTIFICATION OF IMPORTERS FOR TESTING  
2 AND SAMPLING OWN PRODUCTS.—An importer shall not  
3 be federally certified for the purposes of analyzing, testing,  
4 or sampling its own food products for import unless the  
5 Secretary establishes a process under this section by which  
6 an importer can become certified for such purposes.”.

7       (b) ENFORCEMENT.—Section 303(f) of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is  
9 amended—

10           (1) by redesignating paragraphs (5), (6), and  
11           (7) as paragraphs (7), (8), and (9), respectively;

12           (2) by inserting after paragraph (4) the fol-  
13           lowing:

14       “(5) An importer (as such term is used in section  
15 418) shall be subject to a civil penalty in an amount not  
16 to exceed \$1,000,000 if such importer knowingly engages  
17 in the falsification of test results submitted to the Sec-  
18 retary by a food safety laboratory or sampling service cer-  
19 tified under section 418.

20       “(6) A food safety laboratory or sampling service cer-  
21 tified under section 418 shall be subject to a civil penalty  
22 in an amount not to exceed \$1,000,000 for knowingly sub-  
23 mitting to the Secretary false test results under section  
24 418.”.

1           (3) in paragraph (2)(C), by striking “paragraph  
2           (5)(A)” and inserting “paragraph (7)(A)”;

3           (4) in paragraph (7), as so redesignated, by  
4           striking “paragraph (1), (2), (3), or (4)” each place  
5           it appears and inserting “paragraph (1), (2), (3),  
6           (4), (5), or (6)”;

7           (5) in paragraph (8), as so redesignated, by  
8           striking “paragraph (5)(A)” and inserting “para-  
9           graph (7)(A)”;

10          (6) in paragraph (9), by striking “paragraph  
11          (6)” each place it appears and inserting “paragraph  
12          (8)”.

13 **SEC. 3. FOREIGN CERTIFICATION AND EQUIVALENCY.**

14          (a) AMENDMENT.—Chapter VIII of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)  
16 is amended by adding at the end the following:

17 **“SEC. 805. CERTIFICATION OF FOOD IMPORTERS.**

18          “(a) IN GENERAL.—Not later than 2 years after the  
19 date of enactment of this section, the Secretary shall es-  
20 tablish a certification program in accordance with this sec-  
21 tion to ensure that food imported into the United States  
22 meets the food safety standards applied to food produced  
23 in the United States.

24          “(b) CERTIFICATION STANDARD.—A foreign facility  
25 or foreign country requesting a certification to import food

1 to the United States shall demonstrate, in a manner deter-  
2 mined appropriate by the Secretary, that food produced  
3 under the supervision of the foreign facility or foreign  
4 country has met standards for food safety, inspection, la-  
5 beling, and consumer protection that are at least equiva-  
6 lent to standards applicable to food produced in the  
7 United States. In determining whether standards are so  
8 equivalent, the Secretary shall consider—

9           “(1) the potential for health, sanitary, environ-  
10           mental, or other conditions within the foreign coun-  
11           try involved to adversely affect the safety of food  
12           products exported from such nation; and

13           “(2) how well the food safety programs of the  
14           foreign country function to minimize any adverse ef-  
15           fects on such safety.

16           “(c) REQUIREMENT OF CERTIFICATION FOR IMPORT-  
17           ING.—

18           “(1) IN GENERAL.—Except as provided in para-  
19           graph (2), no food shall be permitted entry into the  
20           United States from a foreign facility in a foreign  
21           country unless there is—

22                   “(A) a certification for such facility in ef-  
23                   fect under subsection (d)(1); or

24                   “(B) a certification for such country in ef-  
25                   fect under subsection (d)(2).

1           “(2) EQUIVALENCY DETERMINATION BY SEC-  
2           RETARY.—Notwithstanding paragraph (1), the Sec-  
3           retary shall have authority, to determine that the  
4           certification process under subsection (d) is not  
5           needed for the Secretary’s understanding of the fa-  
6           cility’s or country’s standards for food safety, in-  
7           spection, labeling, and consumer protection for food  
8           imported to the United States to be at least equiva-  
9           lent to standards applicable to food produced in the  
10          United States.

11          “(d) CERTIFICATION.—

12                 “(1) FOREIGN FACILITY.—Each foreign facility  
13                 seeking to import food into the United States may  
14                 obtain a certification by the Secretary stating that  
15                 the facility maintains a program using reliable ana-  
16                 lytical methods to ensure compliance with all the  
17                 food safety standards described in subsection (a) to  
18                 import such food.

19                 “(2) FOREIGN COUNTRY.—A foreign country  
20                 may obtain a certification by the Secretary stating  
21                 that—

22                         “(A) the country has in effect and is en-  
23                         forcing food safety standards at least as protec-  
24                         tive of food safety as the standards applicable  
25                         to food in the United States; and

1           “(B) the country has a program in effect  
2           to monitor and enforce its food safety standards  
3           with respect to food being exported from such  
4           country to the United States, ensuring that the  
5           food products intended for export to the United  
6           States are safe for human consumption, and  
7           not adulterated or misbranded.

8           “(e) AGREEMENTS WITH FOREIGN NATIONS.—Any  
9           certification of a foreign country under subsection (d)(2)  
10          shall—

11           “(1) require the foreign country to promptly no-  
12          tify the Secretary of any violations affecting the  
13          safety of food products exported or intended for ex-  
14          port to the United States;

15           “(2) provide for such activities (whether in the  
16          foreign country or at the port of entry during impor-  
17          tation) by the Secretary, including analysis, testing,  
18          and sampling, at such stages in the growth or har-  
19          vest of food, or in the processing or handling of food  
20          products, as the Secretary considers appropriate to  
21          ensure that the foreign country has in effect and is  
22          enforcing food safety standards at least as protective  
23          of food safety as the standards applicable to food in  
24          the United States; and

1           “(3) provide for reciprocity with respect to the  
2           treatment of food imports and exports between the  
3           United States and the foreign country.

4           “(f) DOCUMENTATION.—The Secretary shall provide  
5           to the Congress annual documentation demonstrating the  
6           Secretary’s confidence in the standards of any foreign fa-  
7           cility or country for which the Secretary has made a deter-  
8           mination under paragraph (2) of subsection (c).

9           “(g) REVOCATION OF CERTIFICATION.—The Sec-  
10          retary may, with respect to a foreign facility or foreign  
11          country, revoke a certification under subsection (d) if—

12                 “(1) food from the foreign facility or foreign  
13                 country is linked to an outbreak of human illness;

14                 “(2) the Secretary determines that the foreign  
15                 facility or foreign country is no longer meeting the  
16                 requirements described in subsection (d); or

17                 “(3) United States officials are not allowed to  
18                 conduct such audits and investigations as may be  
19                 necessary to carry out this section.

20          “(h) DURATION OF CERTIFICATION.—Each certifi-  
21          cation under subsection (d) shall be for a period of not  
22          more than 5 years.

23          “(i) INSPECTION; INDEPENDENT AUDITS.—

24                 “(1) AUTHORIZATION.—In determining whether  
25                 to issue a certification under subsection (d) or re-

1       voke a certification under subsection (g), the Sec-  
2       retary is authorized to—

3               “(A) inspect foreign facilities to ensure  
4               compliance with the food safety standards de-  
5               scribed in subsection (a); and

6               “(B) consider independent audits, product  
7               test data, and other relevant information gen-  
8               erated by the facility, importer, or foreign coun-  
9               try involved.

10              “(2) RENEWAL OF CERTIFICATION.—The Sec-  
11              retary shall audit foreign countries and foreign fa-  
12              cilities at least every 5 years to ensure the continued  
13              compliance with the standards set forth in this sec-  
14              tion.

15              “(j) ENFORCEMENT.—The Secretary is authorized  
16              to—

17                      “(1) deny importation of food from any foreign  
18                      country that does not permit United States officials  
19                      to enter the foreign country to conduct such audits  
20                      and inspections as may be necessary to fulfill the re-  
21                      quirements of this section;

22                      “(2) deny importation of food from any foreign  
23                      country or foreign facility that does not consent to  
24                      an investigation by the Secretary when food from  
25                      that foreign country or foreign facility is linked to

1 a food-borne illness outbreak or is otherwise found  
2 to be adulterated or mislabeled; and

3 “(3) promulgate rules and regulations to carry  
4 out the purposes of this section, including setting  
5 terms and conditions for the destruction of products  
6 that fail to meet the standards of this Act.

7 “(k) FOREIGN FACILITY.—In this section, the term  
8 ‘foreign facility’ means a foreign facility (as defined in sec-  
9 tion 415(b)(3)) that is required to be registered under sec-  
10 tion 415.”.

11 (b) TRANSITIONAL PROGRAM.—Not later than 180  
12 days after the date of enactment of this Act, the Secretary  
13 shall promulgate regulations to establish a transitional  
14 food safety import review program, with minimal disrup-  
15 tion to commerce, that shall be in effect until the date  
16 of implementation of the food import certification program  
17 under section 805 of the Federal Food, Drug, and Cos-  
18 metic Act, as added by subsection (a) of this section.

19 **SEC. 4. INFORMATION CLEARINGHOUSES.**

20 Chapter IV of the Federal Food, Drug, and Cosmetic  
21 Act (21 U.S.C. 341 et seq.), as amended by section 2 of  
22 this Act, is amended by adding at the end the following:

23 **“SEC. 419. INFORMATION CLEARINGHOUSES.**

24 “(a) WEBSITE ON FOOD SAFETY ISSUES.—

1           “(1) IN GENERAL.—The Secretary, in consulta-  
2           tion with the Secretary of Agriculture, shall develop  
3           and maintain a Website with public information  
4           that—

5                   “(A) provides information on Federal food  
6                   standards and best practice requirements for  
7                   food preparation;

8                   “(B) assists health professionals to im-  
9                   prove their ability—

10                           “(i) to diagnose and treat food-related  
11                           illness; and

12                           “(ii) to advise individuals whose  
13                           health conditions place them at particular  
14                           risk; and

15                   “(C) promotes the public awareness of food  
16                   safety issues.

17           “(2) RESOURCES.—The Secretary shall utilize  
18           the resources of the Food and Drug Administration  
19           and the Centers for Disease Control and Prevention  
20           to carry out this subsection.

21           “(b) WEBSITE ON SCHOOL CURRICULA REGARDING  
22           FOOD SAFETY.—The Secretary, in consultation with the  
23           Secretary of Education, shall develop and maintain a  
24           Website to provide the public with appropriate information

1 on developing school curriculum regarding food safety  
2 issues.”.

3 **SEC. 5. WHISTLEBLOWER PROTECTION.**

4 Chapter IV of the Federal Food, Drug, and Cosmetic  
5 Act (21 U.S.C. 341 et seq.), as amended by sections 2  
6 and 4 of this Act, is amended by adding at the end the  
7 following:

8 **“SEC. 420. WHISTLEBLOWER PROTECTION.**

9 “(a) PROHIBITION.—No employee or other person  
10 may be harassed, prosecuted, held liable, or discriminated  
11 against in any way because that person—

12 “(1) has commenced, caused to be commenced,  
13 or is about to commence a proceeding, testified or is  
14 about to testify at a proceeding, or assisted or par-  
15 ticipated or is about to assist or participate in any  
16 manner in such a proceeding or in any other action  
17 to carry out the purposes, functions, or responsibil-  
18 ities of this Act; or

19 “(2) is refusing to violate or assist in violation  
20 of this Act.

21 “(b) PROCEDURES.—The process and procedures  
22 with respect to prohibited discrimination under subsection  
23 (a) shall be governed by the applicable provisions of sec-  
24 tion 31105 of title 49, United States Code, unless the  
25 party bringing an action under this subsection chooses al-

1 ternative dispute resolution procedures such as mediation  
2 or arbitration.

3 “(c) BURDENS OF PROOF.—The legal burdens of  
4 proof with respect to prohibited discrimination under sub-  
5 section (a) shall be governed by the applicable provisions  
6 of sections 1214 and 1221 of title 5, United States  
7 Code.”.

8 **SEC. 6. AUTHORIZATION OF APPROPRIATIONS.**

9 There are authorized to be appropriated to carry out  
10 this Act and the amendments made by this Act such sums  
11 as may be necessary for each of fiscal years 2009 through  
12 2013.

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