

110TH CONGRESS
1ST SESSION

H. R. 3937

To amend the Federal Food, Drug, and Cosmetic Act to ensure the safety
of imported food.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 23, 2007

Ms. DELAURO introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to
ensure the safety of imported food.

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 “Food Import Safety
5 Act of 2007”.

6 **SEC. 2. SAFETY OF IMPORTED FOOD.**

7 (a) **PATTERN OF VIOLATIONS.**—Section 801 of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)
9 is amended by adding at the end the following:

1 “(p) If there is a pattern of violations of this Act with
 2 respect to food generally or any type of food imported or
 3 offered for import into the United States from a particular
 4 country, the Secretary by regulation may prohibit the im-
 5 portation of food or such type of food, respectively, from
 6 such country, as determined appropriate by the Secretary
 7 to protect the public health.”.

8 (b) CERTIFICATION OF FOREIGN FACILITIES AND
 9 FOREIGN COUNTRIES.—Chapter IV of the Federal Food,
 10 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
 11 ed by adding at the end the following:

12 **“SEC. 418. CERTIFICATION OF FOREIGN FACILITIES AND**
 13 **FOREIGN COUNTRIES.**

14 “(a) IN GENERAL.—The Secretary shall establish a
 15 certification program in accordance with this section to
 16 ensure that food imported into the United States meets
 17 the food safety standards applied to food produced in the
 18 United States.

19 “(b) REQUIREMENT.—No food shall be permitted
 20 entry into the United States from a foreign facility in a
 21 foreign country unless there is—

22 “(1) a certification for such facility in effect
 23 under subsection (c)(1); or

24 “(2) a certification for such country in effect
 25 under subsection (c)(2).

1 “(c) CERTIFICATION.—

2 “(1) FOREIGN FACILITY.—Each foreign facility
3 seeking to import food into the United States may
4 obtain a certification by the Secretary stating that
5 the facility maintains a program using reliable ana-
6 lytical methods to ensure compliance with all the
7 food safety standards described in subsection (a).

8 “(2) FOREIGN COUNTRY.—A foreign country
9 may obtain a certification by the Secretary stating
10 that—

11 “(A) the country has in effect and is en-
12 forcing food safety standards at least as protec-
13 tive of food safety as the standards applicable
14 to food in the United States; and

15 “(B) the country has a program in effect
16 to monitor and enforce its food safety standards
17 with respect to food being exported from such
18 country to the United States.

19 “(d) REVOCATION OF CERTIFICATION.—The Sec-
20 retary may, with respect to a foreign facility or foreign
21 country, revoke a certification under subsection (c) if—

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

1 “(2) the Secretary determines that the foreign
2 facility or foreign country is no longer meeting the
3 requirements described in subsection (c); or

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

7 “(e) PERIODIC REVIEW.—The Secretary shall peri-
8 odically review certifications under subsection (c) for com-
9 pliance with the requirements of this section.

10 “(f) DURATION OF CERTIFICATION.—Each certifi-
11 cation under subsection (c) shall be for a period of not
12 more than 5 years.

13 “(g) INSPECTION; INDEPENDENT AUDITS.—In deter-
14 mining whether to issue a certification under subsection
15 (c) or revoke a certification under subsection (d), the Sec-
16 retary is authorized to—

17 “(1) inspect foreign facilities to ensure compli-
18 ance with the food safety standards described in
19 subsection (a); and

20 “(2) consider independent audits, product test
21 data, and other relevant information generated by
22 the facility, importer, or foreign country involved.

23 “(h) COOPERATION WITH FOREIGN COUNTRIES.—
24 The Commissioner of Food and Drugs and other appro-
25 priate Federal agencies shall work with foreign countries

1 that are major trading partners of the United States to
 2 establish certification programs described in subsection
 3 (c)(2).

4 “(i) TECHNICAL ASSISTANCE TO SMALL BUSI-
 5 NESSES.—The Secretary may provide technical assistance
 6 to small businesses in developing countries to assist such
 7 businesses in complying with the requirements of this sec-
 8 tion and meeting the food safety standards described in
 9 subsection (a).

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

14 “(k) EFFECTIVE DATE.—This section takes effect
 15 beginning on the date that is 2 years after the date of
 16 the enactment of the Food Import Safety Act of 2007.”.

17 **SEC. 3. NOTIFICATION AND RECALL.**

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

21 **“SEC. 419. NOTIFICATION AND RECALL.**

22 “(a) NOTICE TO SECRETARY OF VIOLATION.—

23 “(1) IN GENERAL.—A person that has reason
 24 to believe that any food introduced into or in inter-
 25 state commerce, or held for sale (whether or not the

1 first sale) after shipment in interstate commerce,
2 may be in violation of this Act shall immediately no-
3 tify the Secretary of the identity and location of the
4 food.

5 “(2) MANNER OF NOTIFICATION.—Notification
6 under paragraph (1) shall be made in such manner
7 and by such means as the Secretary may require by
8 regulation.

9 “(b) RECALL AND CONSUMER NOTIFICATION; VOL-
10 UNTARY ACTIONS.—If the Secretary determines that food
11 is in violation of this Act when introduced into or while
12 in interstate commerce or while held for sale (whether or
13 not the first sale) after shipment in interstate commerce
14 and that there is a reasonable probability that the food,
15 if consumed, would present a threat to public health, as
16 determined by the Secretary, the Secretary shall give the
17 appropriate persons (including the manufacturers, import-
18 ers, distributors, or retailers of the food) an opportunity
19 to—

20 “(1) cease distribution of the food;

21 “(2) notify all persons—

22 “(A) processing, distributing, or otherwise
23 handling the food to immediately cease such ac-
24 tivities with respect to the food; or

1 “(B) to which the food has been distrib-
2 uted, transported, or sold, to immediately cease
3 distribution of the food;

4 “(3) recall the food;

5 “(4) in conjunction with the Secretary, provide
6 notice of the finding of the Secretary—

7 “(A) to consumers to whom the food was,
8 or may have been, distributed; and

9 “(B) to State and local public health offi-
10 cials; or

11 “(5) take any combination of the measures de-
12 scribed in this subsection, as determined by the Sec-
13 retary to be appropriate in the circumstances.

14 “(c) CIVIL AND CRIMINAL PENALTIES.—

15 “(1) CIVIL SANCTIONS.—

16 “(A) CIVIL PENALTY.—Any person that
17 commits an act that violates the notification
18 and recall standards under subsection (b) (in-
19 cluding a regulation promulgated or order
20 issued under this Act) may be assessed a civil
21 penalty by the Secretary of not more than
22 \$10,000 for each such act.

23 “(B) SEPARATE OFFENSE.—Each act de-
24 scribed in subparagraph (A) and each day dur-

1 ing which that act continues shall be considered
2 a separate offense.

3 “(2) OTHER REQUIREMENTS.—

4 “(A) WRITTEN ORDER.—The civil penalty
5 described in paragraph (1) shall be assessed by
6 the Secretary by a written order, which shall
7 specify the amount of the penalty and the basis
8 for the penalty under subparagraph (B) consid-
9 ered by the Secretary.

10 “(B) AMOUNT OF PENALTY.—Subject to
11 paragraph (1)(A), the amount of the civil pen-
12 alty shall be determined by the Secretary, after
13 considering—

14 “(i) the gravity of the violation;

15 “(ii) the degree of culpability of the
16 person;

17 “(iii) the size and type of the business
18 of the person; and

19 “(iv) any history of prior offenses by
20 the person under this Act.

21 “(C) REVIEW OF ORDER.—The order may
22 be reviewed only in accordance with subsection
23 (d).

24 “(3) EXCEPTION.—No person shall be subject
25 to the penalties of this subsection—

1 “(A) for having received, proffered, or de-
2 livered in interstate commerce any food, if the
3 receipt, proffer, or delivery was made in good
4 faith, unless that person refuses to furnish (on
5 request of an officer or employee designated by
6 the Secretary)—

7 “(i) the name, address, and contact
8 information of the person from whom that
9 person purchased or received the food;

10 “(ii) copies of all documents relating
11 to the person from whom that person pur-
12 chased or received the food; and

13 “(iii) copies of all documents per-
14 taining to the delivery of the food to that
15 person; or

16 “(B) if that person establishes a guaranty
17 signed by, and containing the name and address
18 of, the person from whom that person received
19 in good faith the food, stating that the food is
20 not adulterated or misbranded within the mean-
21 ing of this Act.

22 “(d) JUDICIAL REVIEW.—

23 “(1) IN GENERAL.—An order assessing a civil
24 penalty under subsection (c) shall be a final order
25 unless the person—

1 “(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in the United States court of appeals for the circuit in which that person resides or has its principal place of business or the United States Court of Appeals for the District of Columbia; and

8 “(B) simultaneously serves a copy of the petition by certified mail to the Secretary.

10 “(2) FILING OF RECORD.—Not later than 45 days after the service of a copy of the petition under paragraph (1)(B), the Secretary shall file in the court a certified copy of the administrative record upon which the order was issued.

15 “(3) STANDARD OF REVIEW.—The findings of the Secretary relating to the order shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

19 “(e) COLLECTION ACTIONS FOR FAILURE TO PAY.—

20 “(1) IN GENERAL.—If any person fails to pay a civil penalty assessed under subsection (c) after the order assessing the penalty has become a final order, or after the court of appeals described in subsection (d) has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to

1 the Attorney General, who shall institute in a United
2 States district court of competent jurisdiction a civil
3 action to recover the amount assessed.

4 “(2) LIMITATION ON REVIEW.—In a civil action
5 under paragraph (1), the validity and appropriate-
6 ness of the order of the Secretary assessing the civil
7 penalty shall not be subject to judicial review.

8 “(f) PENALTIES PAID INTO ACCOUNT.—The Sec-
9 retary—

10 “(1) shall deposit penalties collected under this
11 section in an account in the Treasury; and

12 “(2) may use the funds in the account, without
13 further appropriation or fiscal year limitation—

14 “(A) to carry out enforcement activities
15 under food safety law; or

16 “(B) to provide assistance to States to in-
17 spect retail commercial food establishments,
18 such as an establishment that holds, stores, or
19 transports food or food ingredients, or other
20 food or firms under the jurisdiction of State
21 food safety programs.

22 “(g) DISCRETION OF THE SECRETARY TO PROS-
23 ECUTE.—Nothing in this section, section 418, or section
24 420 requires the Secretary to report for prosecution, or
25 for the commencement of an action, the violation of this

1 Act in a case in which the Secretary finds that the public
2 interest will be adequately served by the assessment of a
3 civil penalty under this section.

4 “(h) REMEDIES NOT EXCLUSIVE.—The remedies
5 provided in this section may be in addition to, and not
6 exclusive of, other remedies that may be available.”.

7 **SEC. 4. MANDATORY RECALL AUTHORITY.**

8 Chapter IV of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 341 et seq.), as amended by section 3,
10 is amended by adding at the end the following:

11 **“SEC. 420. MANDATORY RECALL ACTION.**

12 “(a) MANDATORY ACTIONS.—If a person referred to
13 in section 419(b) refuses to or does not adequately carry
14 out the actions described in that section within the time
15 period and in the manner prescribed by the Secretary, the
16 Secretary shall—

17 “(1) have authority to control and possess the
18 food, including ordering the shipment of the food
19 from a food establishment, such as an establishment
20 that holds, stores, or transports food or food ingredi-
21 ents, to the Secretary—

22 “(A) at the expense of such food establish-
23 ment; or

1 “(B) in an emergency (as determined by
2 the Secretary), at the expense of the Secretary;
3 and

4 “(2) by order, require, as the Secretary deter-
5 mines to be necessary, the person to immediately—

6 “(A) cease distribution of the food; and

7 “(B) notify all persons—

8 “(i) processing, distributing, or other-
9 wise handling the food to immediately
10 cease such activities with respect to the
11 food; or

12 “(ii) if the food has been distributed,
13 transported, or sold, to immediately cease
14 distribution of the food.

15 “(b) NOTIFICATION TO CONSUMERS BY SEC-
16 RETARY.—The Secretary shall, as the Secretary deter-
17 mines to be necessary, provide notice of the finding of the
18 Secretary under subsection (a)—

19 “(1) to consumers to whom the food was, or
20 may have been, distributed; and

21 “(2) to State and local public health officials.

22 “(c) NONDISTRIBUTION BY NOTIFIED PERSONS.—A
23 person that processes, distributes, or otherwise handles
24 the food, or to which the food has been distributed, trans-
25 ported, or sold, and that is notified under section

1 419(b)(2) or subsection (a)(2)(B) of this section shall im-
2 mediately cease distribution of the food.

3 “(d) AVAILABILITY OF RECORDS TO SECRETARY.—

4 Each person referred to in section 419 that processed, dis-
5 tributed, or otherwise handled food shall make available
6 to the Secretary information necessary to carry out this
7 section, as determined by the Secretary, regarding—

8 “(1) persons that processed, distributed, or oth-
9 erwise handled the food; and

10 “(2) persons to which the food has been trans-
11 ported, sold, distributed, or otherwise handled.

12 “(e) INFORMAL HEARINGS ON ORDERS.—

13 “(1) IN GENERAL.—The Secretary shall provide
14 any person subject to an order under subsection (a)
15 with an opportunity for an informal hearing, to be
16 held as soon as practicable but not later than 2 busi-
17 ness days after the issuance of the order.

18 “(2) SCOPE OF THE HEARING.—In a hearing
19 under paragraph (1), the Secretary shall consider
20 the actions required by the order and any reasons
21 why the food that is the subject of the order should
22 not be recalled.

23 “(f) POST-HEARING RECALL ORDERS.—

24 “(1) AMENDMENT OF ORDER.—If, after pro-
25 viding an opportunity for an informal hearing under

1 subsection (e), the Secretary determines that there
2 is a reasonable probability that the food that is the
3 subject of an order under subsection (a), if con-
4 sumed, would present a threat to the public health,
5 the Secretary, as the Secretary determines to be nec-
6 essary, may—

7 “(A) amend the order to require recall of
8 the food or other appropriate action;

9 “(B) specify a timetable in which the recall
10 shall occur;

11 “(C) require periodic reports to the Sec-
12 retary describing the progress of the recall; and

13 “(D) provide notice of the recall to con-
14 sumers to whom the food was, or may have
15 been, distributed.

16 “(2) VACATION OF ORDERS.—If, after providing
17 an opportunity for an informal hearing under sub-
18 section (e), the Secretary determines that adequate
19 grounds do not exist to continue the actions required
20 by the order, the Secretary shall vacate the order.

21 “(g) REMEDIES NOT EXCLUSIVE.—The remedies
22 provided in this section shall be in addition to, and not
23 exclusive of, other remedies that may be available.”.

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