

110TH CONGRESS
1ST SESSION

S. 1274

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food for humans and pets.

IN THE SENATE OF THE UNITED STATES

MAY 2, 2007

Mr. DURBIN 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 with respect to the safety of food for humans and pets.

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 “Human and Pet Food
5 Safety Act of 2007”.

6 **SEC. 2. FOOD SAFETY FOR HUMANS AND PETS.**

7 (a) ADVERSE EVENTS; INSPECTIONS; RECALL.—
8 Chapter IV of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 341 et seq.) is amended by adding at the end
10 the following:

1 **“SEC. 417. NOTIFICATION AND RECALL.**

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

3 “(1) IN GENERAL.—A person that has reason
4 to believe that any food introduced into or in inter-
5 state commerce, or held for sale (whether or not the
6 first sale) after shipment in interstate commerce,
7 may be in violation of this Act shall immediately no-
8 tify the Secretary of the identity and location of the
9 food.

10 “(2) MANNER OF NOTIFICATION.—Notification
11 under paragraph (1) shall be made in such manner
12 and by such means as the Secretary may require by
13 regulation.

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

25 “(1) cease distribution of the food;

26 “(2) notify all persons—

1 “(A) processing, distributing, or otherwise
 2 handling the food to immediately cease such ac-
 3 tivities with respect to the food; or

4 “(B) to which the food has been distrib-
 5 uted, transported, or sold, to immediately cease
 6 distribution of the food;

7 “(3) recall the food;

8 “(4) in conjunction with the Secretary, provide
 9 notice of the finding of the Secretary—

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

12 “(B) to State and local public health offi-
 13 cials; or

14 “(5) take any combination of the measures de-
 15 scribed in this paragraph, as determined by the Sec-
 16 retary to be appropriate in the circumstances.

17 “(c) CIVIL AND CRIMINAL PENALTIES.—

18 “(1) CIVIL SANCTIONS.—

19 “(A) CIVIL PENALTY.—Any person that
 20 commits an act that violates the notification
 21 and recall standards under subsection (b) (in-
 22 cluding a regulation promulgated or order
 23 issued under this Act) may be assessed a civil
 24 penalty by the Secretary of not more than
 25 \$10,000 for each such act.

1 “(B) SEPARATE OFFENSE.—Each act de-
 2 scribed in subparagraph (A) and each day dur-
 3 ing which that act continues shall be considered
 4 a separate offense.

5 “(2) OTHER REQUIREMENTS.—

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

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

16 “(i) the gravity of the violation;

17 “(ii) the degree of culpability of the
 18 person;

19 “(iii) the size and type of the business
 20 of the person; and

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

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

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

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

9 “(i) the name, address and contact in-
10 formation of the person from whom that
11 person purchased or received the food;

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

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

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

24 “(d) JUDICIAL REVIEW.—

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

4 “(A) not later than 30 days after the effec-
5 tive date of the order, files a petition for judi-
6 cial review of the order in the United States
7 court of appeals for the circuit in which that
8 person resides or has its principal place of busi-
9 ness or the United States Court of Appeals for
10 the District of Columbia; and

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

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

18 “(3) STANDARD OF REVIEW.—The findings of
19 the Secretary relating to the order shall be set aside
20 only if found to be unsupported by substantial evi-
21 dence on the record as a whole.

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

23 “(1) IN GENERAL.—If any person fails to pay
24 a civil penalty assessed under subsection (c) after
25 the order assessing the penalty has become a final

1 order, or after the court of appeals described in sub-
 2 section (d) has entered final judgment in favor of
 3 the Secretary, the Secretary shall refer the matter to
 4 the Attorney General, who shall institute in a United
 5 States district court of competent jurisdiction a civil
 6 action to recover the amount assessed.

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

11 “(f) PENALTIES PAID INTO ACCOUNT.—The Sec-
 12 retary—

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

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

17 “(A) to carry out enforcement activities
 18 under food safety law; or

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

1 “(g) DISCRETION OF THE SECRETARY TO PROS-
 2 ECUTE.—Nothing in this section, section 418, or section
 3 419 requires the Secretary to report for prosecution, or
 4 for the commencement of an action, the violation of this
 5 Act in a case in which the Secretary finds that the public
 6 interest will be adequately served by the assessment of a
 7 civil penalty under this section.

8 “(h) REMEDIES NOT EXCLUSIVE.—The remedies
 9 provided in this section may be in addition to, and not
 10 exclusive of, other remedies that may be available.

11 **“SEC. 418. MANDATORY RECALL ACTION.**

12 “(a) MANDATORY ACTIONS.—If a person referred to
 13 in section 417(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 paragraph (1)—

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

1 417(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 417 that processed, dis-
 5 tributed, or otherwise handled food shall make available
 6 to the Secretary information necessary to carry out this
 7 subsection, 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.

1 **“SEC. 419. FOREIGN INSPECTIONS; IMPORTS.**

2 “(a) **AUTHORITY TO INSPECT.**—The Secretary shall
3 have the authority to visit any foreign country that im-
4 ports to the United States human or pet food. Such a visit
5 shall be for the purpose of auditing the food safety or pet
6 food programs of such foreign country or to conduct inves-
7 tigations in the event that a food or ingredient of a food
8 is found to violate this Act.

9 “(b) **IMPORTS.**—

10 “(1) **IN GENERAL.**—Not later than 2 years
11 after the date of enactment of this section, the Sec-
12 retary shall establish a system under which a foreign
13 government or foreign manufacturer, importer, dis-
14 tributor, or retailer that seeks to import food to the
15 United States shall submit a request for certification
16 to the Secretary.

17 “(2) **CERTIFICATION STANDARD.**—A foreign
18 government or foreign manufacturer, importer, dis-
19 tributor, or retailer requesting a certification to im-
20 port food to the United States shall demonstrate, in
21 a manner determined appropriate by the Secretary,
22 that food produced under the supervision of a for-
23 eign government or by the foreign manufacturer, im-
24 porter, distributor, or retailer has met standards for
25 food safety, inspection, labeling, and consumer pro-

1 tection that are at least equivalent to standards ap-
2 plicable to food produced in the United States.

3 “(3) CERTIFICATION APPROVAL.—

4 “(A) REQUEST BY FOREIGN GOVERN-
5 MENT.—Prior to granting the certification re-
6 quest of a foreign government, the Secretary
7 shall review, audit, and certify the food safety
8 program of a requesting foreign government
9 (including all statutes, regulations, and inspec-
10 tion authority) as at least equivalent to the food
11 safety program in the United States, as dem-
12 onstrated by the foreign government.

13 “(B) REQUEST BY FOREIGN ESTABLISH-
14 MENT.—Prior to granting the certification re-
15 quest of a foreign manufacturer, importer, dis-
16 tributor, or retailer that seeks to import food to
17 the United States, the Secretary shall certify,
18 based on an onsite inspection, the food safety
19 programs and procedures of a requesting for-
20 eign firm as at least equivalent to the food safe-
21 ty programs and procedures of the United
22 States.

23 “(4) LIMITATION.—A foreign government or
24 foreign manufacturer, importer, distributor, or re-
25 tailer approved by the Secretary to import food to

1 the United States under this section shall be cer-
2 tified to export only the approved food products to
3 the United States for a period not to exceed 5 years.

4 “(5) WITHDRAWAL OF CERTIFICATION.—The
5 Secretary may withdraw certification of any food
6 from a foreign government or foreign manufacturer,
7 importer, distributor, or retailer that seeks to import
8 food to the United States—

9 “(A) if such food is linked to an outbreak
10 of human illness;

11 “(B) following an investigation by the Sec-
12 retary that finds that the food safety programs
13 and procedures of the foreign government or
14 foreign manufacturer, importer, distributor, or
15 retailer are no longer equivalent to the food
16 safety programs and procedures in the United
17 States; or

18 “(C) following a refusal to allow United
19 States officials to conduct such audits and in-
20 vestigations as may be necessary to fulfill the
21 requirements under this section.

22 “(6) RENEWAL OF CERTIFICATION.—The Sec-
23 retary shall audit a foreign government and a for-
24 eign manufacturer, importer, distributor, or retailer
25 that seeks to import food to the United States at

1 least every 5 years to ensure the continued compli-
2 ance with the standards set forth in this section.

3 “(7) REQUIRED ROUTINE INSPECTION.—The
4 Secretary shall routinely inspect food and food ani-
5 mals (via a physical examination) before it enters
6 the United States to ensure that it is—

7 “(A) safe;

8 “(B) labeled as required for food produced
9 in the United States; and

10 “(C) otherwise meets requirements under
11 this Act.

12 “(8) RECORDS INSPECTION.—

13 “(A) IN GENERAL.—The responsible party
14 or importer shall permit an authorized person
15 to have access to records required to be main-
16 tained under this section during an inspection
17 pursuant to section 704.

18 “(B) DEFINITIONS.—For purposes of this
19 paragraph—

20 “(i) the term ‘authorized person’
21 means an officer or employee of the De-
22 partment of Health and Human Services,
23 who has—

24 “(I) appropriate credentials, as
25 determined by the Secretary; and

1 “(II) been duly designated by the
2 Secretary to have access to the
3 records required under this section;
4 and

5 “(ii) the term ‘responsible party’
6 means, with respect to an article of food,
7 any person responsible for the manufac-
8 turing, processing, packaging, or holding
9 for such food for consumption in the
10 United States.

11 “(9) ENFORCEMENT.—The Secretary is author-
12 ized to—

13 “(A) deny importation of food from any
14 foreign government that does not permit United
15 States officials to enter the foreign country to
16 conduct such audits and inspections as may be
17 necessary to fulfill the requirements under this
18 section;

19 “(B) deny importation of food from any
20 foreign government or foreign manufacturer,
21 importer, distributor, or retailer that does not
22 consent to an investigation by the Administra-
23 tion when food from that foreign country or
24 foreign firm is linked to a food-borne illness

1 outbreak or is otherwise found to be adulterated
 2 or mislabeled; and

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

8 “(10) DETENTION AND SEIZURE.—Any food
 9 imported for consumption in the United States may
 10 be detained, seized, or condemned pursuant to sec-
 11 tion 418.”.

12 **SEC. 3. ENSURING EFFICIENT AND EFFECTIVE COMMU-**
 13 **NICATIONS DURING A RECALL.**

14 The Secretary shall, during an ongoing recall of
 15 human or pet food shall—

16 (1) work with companies, relevant professional
 17 associations, and other organizations to collect and
 18 aggregate information pertaining to the recall;

19 (2) use existing networks of communication in-
 20 cluding electronic forms of information dissemina-
 21 tion to enhance the quality and speed of communica-
 22 tion with the public; and

23 (3) post information regarding recalled prod-
 24 ucts on the Internet website of the Food and Drug

1 Administration in a consolidated, searchable form
 2 that is easily accessed and understood by the public.

3 **SEC. 4. ENSURING THE SAFETY OF PET FOOD.**

4 (a) PROCESSING AND INGREDIENT STANDARDS.—

5 Not later than 18 months after the date of enactment of
 6 this Act, the Secretary of Health and Human Services (re-
 7 ferred to in this section as the “Secretary”), in consulta-
 8 tion with the Association of American Feed Control Offi-
 9 cials, and other relevant stakeholder groups, including vet-
 10 erinary medical associations, animal health organizations,
 11 and pet food manufacturers, shall by regulation estab-
 12 lish—

13 (1) processing and ingredient standards with
 14 respect to feed, pet food, animal waste, and ingre-
 15 dient definitions; and

16 (2) updated standards for the labeling of pet
 17 food that includes nutritional information and ingre-
 18 dient information.

19 (b) EARLY WARNING SURVEILLANCE SYSTEMS AND
 20 NOTIFICATION DURING PET FOOD RECALLS.—

21 (1) IN GENERAL.—Not later than 180 days
 22 after the date of enactment of this Act, the Sec-
 23 retary shall by regulation establish an early warning
 24 and surveillance system to identify contaminations of
 25 the pet food supply and outbreaks of illness from pet

1 food. In establishing such system, the Secretary
2 shall—

3 (A) use surveillance and monitoring mech-
4 anisms similar to, or in coordination with, those
5 mechanisms used by the Centers for Disease
6 Control and Prevention to monitor human
7 health, such as the Foodborne Diseases Active
8 Surveillance Network (FoodNet) and PulseNet;

9 (B) consult with relevant professional asso-
10 ciations and private sector veterinary hospitals;
11 and

12 (C) work with Health Alert Networks and
13 other notification networks to inform veterinar-
14 ians and relevant stakeholders during any recall
15 of pet food.

16 (2) AUTHORIZATION OF APPROPRIATIONS.—

17 There are authorized to be appropriated to carry out
18 paragraph (1) such sums as may be necessary.

19 **SEC. 5. SENSE OF THE SENATE.**

20 (a) FINDINGS.—Congress finds that—

21 (1) the safety and integrity of the United
22 States food supply is vital to the public health, to
23 public confidence in the food supply, and to the suc-
24 cess of the food sector of the Nation's economy;

1 (2) illnesses and deaths of individuals and com-
2 panion pets caused by contaminated food—

3 (A) have contributed to a loss of public
4 confidence in food safety; and

5 (B) have caused significant economic losses
6 to manufactures and producers not responsible
7 for contaminated food items;

8 (3) the task of preserving the safety of the food
9 supply of the United States faces tremendous pres-
10 sures with regard to—

11 (A) emerging pathogens and other con-
12 taminants and the ability to detect all forms of
13 contamination; and

14 (B) an increasing volume of imported food,
15 without adequate monitoring and inspection;

16 (4) the United States is increasing the amount
17 of food that it imports such that —

18 (A) from 2003 to the present, the value of
19 food imports has increased from
20 \$45,600,000,000 to \$64,000,000,000; and

21 (B) imported food accounts for 13 percent
22 of the average Americans diet including 31 per-
23 cent of fruits, juices, and nuts, 9.5 percent of
24 red meat and 78.6 percent of fish and shellfish;
25 and

1 (5) the number of full time equivalent Food and
 2 Drug Administration employees conducting inspec-
 3 tions has decreased from 2003 to 2007.

4 (b) SENSE OF THE SENATE.—It is the sense of the
 5 Senate that—

6 (1) it is vital for Congress to provide the Food
 7 and Drug Administration with additional resources,
 8 authorities, and direction with respect to ensuring
 9 the safety of the food supply of the United States;

10 (2) additional Food and Drug Administration
 11 inspectors are required if we are to improve Food
 12 and Drug Administration’s ability to safeguard the
 13 food supply of the United States; and

14 (3) because of the increasing volume of inter-
 15 national trade in food products the Secretary of
 16 Health and Human Services should make it a pri-
 17 ority to enter into agreements, including memoranda
 18 of understanding, with the trading partners of the
 19 United States with respect to food safety.

20 **SEC. 6. ANNUAL REPORT TO CONGRESS.**

21 The Secretary of Health and Human Service shall,
 22 on an annual basis, submit to the Committee on Health,
 23 Education, Labor, and Pensions and the Committee on
 24 Appropriations of the Senate and the Committee on En-
 25 ergy and Commerce and the Committee on Appropriations

1 of the House of Representatives a report that includes,
2 with respect to the preceding 1-year period—

3 (1) the number and amount of food products
4 imported into the United States, aggregated by
5 country, and type of food, if any;

6 (2) a listing of the number of inspectors of im-
7 ported food products and the number of inspections
8 performed on such products; and

9 (3) aggregated data on the findings of such in-
10 spections, including data related to violations of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 201 et seq.), and enforcement mechanisms used to
13 follow-up on such findings and violations.

○