

110TH CONGRESS
1ST SESSION

S. 2081

To require manufacturers to demonstrate sufficient means to cover, for certain products distributed in commerce, costs of potential recalls, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 20, 2007

Mr. BROWN (for himself and Mr. CASEY) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To require manufacturers to demonstrate sufficient means to cover, for certain products distributed in commerce, costs of potential recalls, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Food and Product Responsibility Act of 2007”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Requirement that manufacturers demonstrate sufficient means to cover, for certain products, costs of potential recalls.

Sec. 3. Notification, nondistribution, and recall of adulterated or misbranded meat and meat food products.

Sec. 4. Notification, nondistribution, and recall of adulterated or misbranded poultry and poultry food products.

Sec. 5. Notification, nondistribution, and recall of adulterated or misbranded eggs and egg products.

Sec. 6. Notification, nondistribution, and recall of adulterated or misbranded foods.

1 **SEC. 2. REQUIREMENT THAT MANUFACTURERS DEM-**
 2 **ONSTRATE SUFFICIENT MEANS TO COVER,**
 3 **FOR CERTAIN PRODUCTS, COSTS OF POTEN-**
 4 **TIAL RECALLS.**

5 (a) DEFINITIONS.—In this section:

6 (1) COMMERCE.—The term “commerce” means
 7 trade, traffic, commerce, or transportation—

8 (A) between a place in a State and any
 9 place outside thereof, or

10 (B) which affects trade, traffic, commerce,
 11 or transportation described in subparagraph
 12 (A).

13 (2) COVERED PRODUCT.—The term “covered
 14 product” means any of the following:

15 (A) Replacement equipment, as such term
 16 is used in section 30102 of title 49, United
 17 States Code.

18 (B) Food, drugs, devices, and cosmetics as
 19 such terms are defined in section 201 of the
 20 Federal Food, Drug, and Cosmetic Act (21
 21 U.S.C. 321).

1 (C) A biological product as such term is
2 defined in section 351(i) of the Public Health
3 Service Act (42 U.S.C. 262(i)).

4 (D) A consumer product, as such term is
5 used in section 3(a) of the Consumer Product
6 Safety Act (15 U.S.C. 2052).

7 (E)(i) Meat or meat food product (within
8 the meaning of the Federal Meat Inspection Act
9 (21 U.S.C. 601 et seq.)).

10 (ii) Poultry or poultry product (as defined
11 in section 4 of the Poultry Products Inspection
12 Act (21 U.S.C. 453)).

13 (iii) Egg or egg product (as defined in sec-
14 tion 4 of the Egg Products Inspection Act (21
15 U.S.C. 1033)).

16 (3) DISTRIBUTE IN COMMERCE.—The term
17 “distribute in commerce” means to sell in commerce,
18 to introduce or deliver for introduction into com-
19 merce, or to hold for sale or distribution after intro-
20 duction into commerce.

21 (4) IMPORT.—The term “import” includes re-
22 importing a covered product manufactured or proc-
23 essed, in whole or in part, in the United States.

24 (5) MANUFACTURER.—The term “manufac-
25 turer” means any person who manufactures or im-

1 ports a covered product. A common carrier, contract
2 carrier, or freight forwarder shall not, for purposes
3 of this Act, be deemed to be a manufacturer of a
4 covered product solely by reason of receiving or
5 transporting a covered product in the ordinary
6 course of its business as such a carrier or forwarder.

7 (6) RECALL.—With respect to a covered prod-
8 uct, the term “recall” means the following:

9 (A) In the case that the Secretary of
10 Transportation makes a determination under
11 section 30118(b)(1) of title 49, United States
12 Code, that a covered product described in para-
13 graph (2)(A) contains a defect related to motor
14 vehicle safety or does not comply with an appli-
15 cable motor vehicle safety standard prescribed
16 under chapter 301 of such title, giving notifica-
17 tion under section 30119 of such title and rem-
18 edying such defect or noncompliance under sec-
19 tion 30120 of such title.

20 (B) In the case of—

21 (i) a device, as defined in section 201
22 of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 321), an order under sub-
24 section (b)(1)(a) or (e) of section 518 of
25 such Act (21 U.S.C. 360h (b), (e));

1 (ii) infant formula, as such term is
2 defined in section 201 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 321),
4 a recall of infant formula begun by a man-
5 ufacturer of infant formula that is carried
6 out in accordance with section 412(f) of
7 such Act (21 U.S.C. 350a(f)); and

8 (iii) any other covered product de-
9 scribed in paragraph (2)(B), a recall of the
10 covered product by the manufacturer or
11 distributor in response to an advisory or
12 other alert issued by the Commissioner of
13 Food and Drugs that advises consumers to
14 avoid the covered product.

15 (C) In the case of a biological product, as
16 defined in section 351(i) of the Public Health
17 Service Act (42 U.S.C. 262(i)), an order under
18 section 351(d) of such Act (42 U.S.C. 262(d).

19 (D) In the case of a covered product de-
20 scribed in paragraph (2)(D), an action under
21 subsection (c) and (d) of section 15 of the Con-
22 sumer Product Safety Act (15 U.S.C. 2064).

23 (E) In the case of a covered product de-
24 scribed in paragraph (1)(E), a recall of the cov-
25 ered product under—

- 1 (i) the Federal Meat Inspection Act
2 (21 U.S.C. 601 et seq.);
3 (ii) the Poultry Products Inspection
4 Act (21 U.S.C. 451 et seq.); or
5 (iii) the Egg Products Inspection Act
6 (21 U.S.C. 1031 et seq.).

7 (b) FINANCIAL RESPONSIBILITY REQUIRED.—

8 (1) IN GENERAL.—Beginning on the date that
9 is 2 years after the date of the enactment of this
10 Act, a manufacturer may not distribute in commerce
11 a covered product unless the manufacturer holds a
12 recall responsibility certificate described in para-
13 graph (2) for such covered product.

14 (2) RECALL RESPONSIBILITY CERTIFICATE.—A
15 recall responsibility certificate described in this para-
16 graph is a certification from the U.S. Customs and
17 Border Protection that a manufacturer possess suffi-
18 cient means (through insurance or otherwise), for
19 the 5-year period beginning on the date the manu-
20 facturer begins to distribute in commerce a covered
21 product, to cover—

22 (A) the entire cost of a recall of that prod-
23 uct, including any administrative costs associ-
24 ated with such recall; and

1 (B) compensatory damages and costs (in-
2 cluding reasonable attorneys fees) of any prod-
3 uct liability or other lawsuit filed for claims
4 arising out of, relating to, or resulting from any
5 defect in that product.

6 (c) ANNUAL REPORT.—

7 (1) IN GENERAL.—Not later than 2 years after
8 the date of the enactment of this Act and each year
9 thereafter, the Secretary of Homeland Security shall
10 submit to Congress a report on the implementation
11 of this Act, including an assessment of the com-
12 ments received from the public in accordance with
13 paragraph (3).

14 (2) CONSULTATION.—In preparing the annual
15 report required by paragraph (1), the Secretary of
16 Homeland Security shall consult with the following:

17 (A) The Secretary of State.

18 (B) The Consumer Product Safety Com-
19 mission.

20 (C) Secretary of Health and Human Serv-
21 ices.

22 (D) The Secretary of Agriculture.

23 (E) The Secretary of Commerce.

24 (3) PUBLIC COMMENTS.—In preparing the an-
25 nual report required by paragraph (1), the Secretary

1 of Homeland Security shall solicit comments from
2 the public on the implementation of this Act.

3 **SEC. 3. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
4 **OF ADULTERATED OR MISBRANDED MEAT**
5 **AND MEAT FOOD PRODUCTS.**

6 (a) IN GENERAL.—The Federal Meat Inspection Act
7 (21 U.S.C. 601 et seq.) is amended—

8 (1) by redesignating section 411 (21 U.S.C.
9 680) as section 412; and

10 (2) by inserting after section 410 (21 U.S.C.
11 679a) the following:

12 **“SEC. 411. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
13 **OF ADULTERATED OR MISBRANDED MEAT**
14 **AND MEAT FOOD PRODUCTS.**

15 **“(a) NOTIFICATION TO SECRETARY OF VIOLATION.—**

16 **“(1) IN GENERAL.—**A person (other than a
17 household consumer) that has reason to believe that
18 any carcass, part of a carcass, meat, or meat food
19 product of cattle, sheep, swine, goats, horses, mules,
20 or other equines (referred to in this section as an
21 ‘article’) transported, stored, distributed, or other-
22 wise handled by the person is adulterated or mis-
23 branded shall, as soon as practicable, notify the Sec-
24 retary of the identity and location of the article.

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

5 “(b) RECALL AND CONSUMER NOTIFICATION.—

6 “(1) VOLUNTARY ACTIONS.—On receiving noti-
7 fication under subsection (a) or by other means, if
8 the Secretary finds that an article is adulterated or
9 misbranded and that there is a reasonable prob-
10 ability that human consumption of the article would
11 present a threat to public health (as determined by
12 the Secretary), the Secretary shall provide all appro-
13 priate persons (as determined by the Secretary),
14 that transported, stored, distributed, or otherwise
15 handled the article with an opportunity—

16 “(A) to cease distribution of the article;

17 “(B) to notify all persons that transport,
18 store, distribute, or otherwise handle the article,
19 or to which the article has been transported,
20 sold, distributed, or otherwise handled, to cease
21 immediately distribution of the article;

22 “(C) to recall the article;

23 “(D) in consultation with the Secretary, to
24 provide notice of the finding of the Secretary to

1 all consumers to which the article was, or may
2 have been, distributed; or

3 “(E) to notify State and local public health
4 officials.

5 “(2) MANDATORY ACTIONS.—If the appropriate
6 person referred to in paragraph (1) does not carry
7 out the actions described in that paragraph with re-
8 spect to an article within the time period and in the
9 manner prescribed by the Secretary, the Secretary—

10 “(A) shall require the person—

11 “(i) to immediately cease distribution
12 of the article; and

13 “(ii) to immediately make the notifica-
14 tion described in paragraph (1)(B); and

15 “(B) may take control or possession of the
16 article.

17 “(3) NOTICE TO CONSUMERS AND HEALTH OF-
18 FICIALS.—The Secretary shall, as the Secretary de-
19 termines to be necessary, provide notice of the find-
20 ing of the Secretary under paragraph (1) to con-
21 sumers to which the article was, or may have been,
22 distributed and to appropriate State and local public
23 health officials.

24 “(4) NONDISTRIBUTION BY NOTIFIED PER-
25 SONS.—A person that transports, stores, distributes,

1 or otherwise handles the article, or to which the arti-
2 cle has been transported, sold, distributed, or other-
3 wise handled, and that is notified under paragraph
4 (1)(B) or (2)(B) shall cease immediately distribution
5 of the article.

6 “(5) AVAILABILITY OF RECORDS TO SEC-
7 RETARY.—Each appropriate person referred to in
8 paragraph (1) that transported, stored, distributed,
9 or otherwise handled an article shall make available
10 to the Secretary information necessary to carry out
11 this subsection, as determined by the Secretary, re-
12 garding—

13 “(A) persons that transport, store, dis-
14 tribute, or otherwise handle the article; and

15 “(B) persons to which the article has been
16 transported, sold, distributed, or otherwise han-
17 dled.

18 “(c) INFORMAL HEARINGS ON ORDERS.—

19 “(1) IN GENERAL.—The Secretary shall provide
20 a person subject to an order under subsection (b)
21 with an opportunity for an informal hearing (in ac-
22 cordance with such rules or regulations as the Sec-
23 retary shall prescribe) on—

24 “(A) the actions required by the order; and

1 “(B) any reasons why the article that is
2 the subject of the order should not be recalled.

3 “(2) TIMING OF HEARINGS.—The Secretary
4 shall hold a hearing under paragraph (1) as soon as
5 practicable, but not later than 2 business days, after
6 the date of issuance of the order.

7 “(d) POST-HEARING RECALL ORDERS.—

8 “(1) AMENDMENT OF ORDERS.—If, after pro-
9 viding an opportunity for an informal hearing under
10 subsection (c), the Secretary determines that there is
11 a reasonable probability that human consumption of
12 the article that is the subject of an order under sub-
13 section (b) presents a threat to public health, the
14 Secretary may, as the Secretary determines to be
15 necessary—

16 “(A) amend the order under subsection
17 (b)—

18 “(i) to require recall of the article or
19 other appropriate action; and

20 “(ii) to specify a timetable during
21 which the recall shall occur;

22 “(B) require periodic reports to the Sec-
23 retary describing the progress of the recall;

1 “(C) provide notice of the recall to con-
2 sumers to which the article was, or may have
3 been, distributed; or

4 “(D) take any combination of actions de-
5 scribed in subparagraphs (A) through (C).

6 “(2) VACATION OF ORDERS.—If, after providing
7 an opportunity for an informal hearing under sub-
8 section (c), the Secretary determines that adequate
9 grounds do not exist to continue the actions required
10 by the order, the Secretary shall vacate the order.

11 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-
12 thorized by this section shall be in addition to any other
13 remedies that may be available.”.

14 (b) CONFORMING AMENDMENTS.—

15 (1) Section 1 of the Federal Meat Inspection
16 Act (21 U.S.C. 601) is amended by adding at the
17 end the following:

18 “(x) PERSON.—The term ‘person’ means any indi-
19 vidual, partnership, corporation, association, or other busi-
20 ness unit.”.

21 (2) The Federal Meat Inspection Act (21
22 U.S.C. 601 et seq.) is amended—

23 (A) by striking “person, firm, or corpora-
24 tion” each place it appears and inserting “per-
25 son”;

1 (B) by striking “persons, firms, and cor-
 2 porations” each place it appears and inserting
 3 “persons”; and

4 (C) by striking “persons, firms, or corpora-
 5 tions” each place it appears and inserting “per-
 6 sons”.

7 **SEC. 4. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
 8 **OF ADULTERATED OR MISBRANDED POUL-**
 9 **TRY AND POULTRY FOOD PRODUCTS.**

10 The Poultry Products Inspection Act (21 U.S.C. 451
 11 et seq.) is amended—

12 (1) in the first sentence of section 5(c)(1) (21
 13 U.S.C. 454(c)(1))—

14 (A) by striking “, by thirty days prior to
 15 the expiration of two years after enactment of
 16 the Wholesome Poultry Products Act,”; and

17 (B) by striking “sections 1-4, 6-10, and
 18 12-22 of this Act” and inserting “sections 1
 19 through 4, 6 through 10, 12 through 22, and
 20 31”; and

21 (2) by adding at the end the following:

22 **“SEC. 31. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
 23 **OF ADULTERATED OR MISBRANDED POUL-**
 24 **TRY AND POULTRY FOOD PRODUCTS.**

25 “(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

1 “(1) IN GENERAL.—A person (other than a
2 household consumer) that has reason to believe that
3 any poultry or poultry product (referred to in this
4 section as an ‘article’) transported, stored, distrib-
5 uted, or otherwise handled by the person is adulter-
6 ated or misbranded shall, as soon as practicable, no-
7 tify the Secretary of the identity and location of the
8 article.

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

13 “(b) RECALL AND CONSUMER NOTIFICATION.—

14 “(1) VOLUNTARY ACTIONS.—On receiving noti-
15 fication under subsection (a) or by other means, if
16 the Secretary finds that an article is adulterated or
17 misbranded and that there is a reasonable prob-
18 ability that human consumption of the article would
19 present a threat to public health (as determined by
20 the Secretary), the Secretary shall provide all appro-
21 priate persons (as determined by the Secretary),
22 that transported, stored, distributed, or otherwise
23 handled the article with an opportunity—

24 “(A) to cease distribution of the article;

1 “(B) to notify all persons that transport,
2 store, distribute, or otherwise handle the article,
3 or to which the article has been transported,
4 sold, distributed, or otherwise handled, to cease
5 immediately distribution of the article;

6 “(C) to recall the article;

7 “(D) in consultation with the Secretary, to
8 provide notice of the finding of the Secretary to
9 all consumers to which the article was, or may
10 have been, distributed; or

11 “(E) to notify State and local public health
12 officials.

13 “(2) MANDATORY ACTIONS.—If the appropriate
14 person referred to in paragraph (1) does not carry
15 out the actions described in that paragraph with re-
16 spect to an article within the time period and in the
17 manner prescribed by the Secretary, the Secretary—

18 “(A) shall require the person—

19 “(i) to immediately cease distribution
20 of the article; and

21 “(ii) to immediately make the notifica-
22 tion described in paragraph (1)(B); and

23 “(B) may take control or possession of the
24 article.

1 “(3) NOTICE TO CONSUMERS AND HEALTH OF-
2 FICIALS.—The Secretary shall, as the Secretary de-
3 termines to be necessary, provide notice of the find-
4 ing of the Secretary under paragraph (1) to con-
5 sumers to which the article was, or may have been,
6 distributed and to appropriate State and local health
7 officials.

8 “(4) NONDISTRIBUTION BY NOTIFIED PER-
9 SONS.—A person that transports, stores, distributes,
10 or otherwise handles the article, or to which the arti-
11 cle has been transported, sold, distributed, or other-
12 wise handled, and that is notified under paragraph
13 (1)(B) or (2)(B) shall cease immediately distribution
14 of the article.

15 “(5) AVAILABILITY OF RECORDS TO SEC-
16 RETARY.—Each appropriate person referred to in
17 paragraph (1) that transported, stored, distributed,
18 or otherwise handled an article shall make available
19 to the Secretary information necessary to carry out
20 this subsection, as determined by the Secretary, re-
21 garding—

22 “(A) persons that transport, store, dis-
23 tribute, or otherwise handle the article; and

1 “(B) persons to which the article has been
2 transported, sold, distributed, or otherwise han-
3 dled.

4 “(c) INFORMAL HEARINGS ON ORDERS.—

5 “(1) IN GENERAL.—The Secretary shall provide
6 a person subject to an order under subsection (b)
7 with an opportunity for an informal hearing (in ac-
8 cordance with such rules or regulations as the Sec-
9 retary shall prescribe) on—

10 “(A) the actions required by the order; and

11 “(B) any reasons why the article that is
12 the subject of the order should not be recalled.

13 “(2) TIMING OF HEARINGS.—The Secretary
14 shall hold a hearing under paragraph (1) as soon as
15 practicable, but not later than 2 business days, after
16 the date of issuance of the order.

17 “(d) POST-HEARING RECALL ORDERS.—

18 “(1) AMENDMENT OF ORDERS.—If, after pro-
19 viding an opportunity for an informal hearing under
20 subsection (c), the Secretary determines that there is
21 a reasonable probability that human consumption of
22 the article that is the subject of an order under sub-
23 section (b) presents a threat to public health, the
24 Secretary may, as the Secretary determines to be
25 necessary—

1 “(A) amend the order under subsection

2 (b)—

3 “(i) to require recall of the article or
4 other appropriate action; and

5 “(ii) to specify a timetable during
6 which the recall shall occur;

7 “(B) require periodic reports to the Sec-
8 retary describing the progress of the recall; or

9 “(C) provide notice of the recall to con-
10 sumers to which the article was, or may have
11 been, distributed.

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

17 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-
18 thorized by this section shall be in addition to any other
19 remedies that may be available.”.

20 **SEC. 5. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
21 **OF ADULTERATED OR MISBRANDED EGGS**
22 **AND EGG PRODUCTS.**

23 The Egg Products Inspection Act is amended by in-
24 serting after section 20 (21 U.S.C. 1049) the following:

1 **“SEC. 20A. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
2 **OF ADULTERATED OR MISBRANDED EGGS**
3 **AND EGG PRODUCTS.**

4 “(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

5 “(1) IN GENERAL.—A person (other than a
6 household consumer) that has reason to believe that
7 any egg or egg product (referred to in this section
8 as an ‘article’) transported, stored, distributed, or
9 otherwise handled by the person is adulterated or
10 misbranded shall, as soon as practicable, notify the
11 Secretary of the identity and location of the article.

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

16 “(b) RECALL AND CONSUMER NOTIFICATION.—

17 “(1) VOLUNTARY ACTIONS.—On receiving noti-
18 fication under subsection (a) or by other means, if
19 the Secretary finds that an article is adulterated or
20 misbranded and that there is a reasonable prob-
21 ability that human consumption of the article would
22 present a threat to public health (as determined by
23 the Secretary), the Secretary shall provide all appro-
24 priate persons (as determined by the Secretary),
25 that transported, stored, distributed, or otherwise
26 handled the article with an opportunity—

1 “(A) to cease distribution of the article;

2 “(B) to notify all persons that transport,
3 store, distribute, or otherwise handle the article,
4 or to which the article has been transported,
5 sold, distributed, or otherwise handled, to cease
6 immediately distribution of the article;

7 “(C) to recall the article;

8 “(D) in consultation with the Secretary, to
9 provide notice of the finding of the Secretary to
10 all consumers to which the article was, or may
11 have been, distributed; or

12 “(E) to notify State and local public health
13 officials.

14 “(2) MANDATORY ACTIONS.—If the appropriate
15 person referred to in paragraph (1) does not carry
16 out the actions described in that paragraph with re-
17 spect to an article within the time period and in the
18 manner prescribed by the Secretary, the Secretary—

19 “(A) shall require the person—

20 “(i) to immediately cease distribution
21 of the article; and

22 “(ii) to immediately make the notifica-
23 tion described in paragraph (1)(B); and

24 “(B) may take control or possession of the
25 article.

1 “(3) NOTICE TO CONSUMERS AND HEALTH OF-
2 FICIALS.—The Secretary shall, as the Secretary de-
3 termines to be necessary, provide notice of the find-
4 ing of the Secretary under paragraph (1) to con-
5 sumers to which the article was, or may have been,
6 distributed and to appropriate State and local health
7 officials.

8 “(4) NONDISTRIBUTION BY NOTIFIED PER-
9 SONS.—A person that transports, stores, distributes,
10 or otherwise handles the article, or to which the arti-
11 cle has been transported, sold, distributed, or other-
12 wise handled, and that is notified under paragraph
13 (1)(B) or (2)(B) shall cease immediately distribution
14 of the article.

15 “(5) AVAILABILITY OF RECORDS TO SEC-
16 RETARY.—Each appropriate person referred to in
17 paragraph (1) that transported, stored, distributed,
18 or otherwise handled an article shall make available
19 to the Secretary information necessary to carry out
20 this subsection, as determined by the Secretary, re-
21 garding—

22 “(A) persons that transport, store, dis-
23 tribute, or otherwise handle the article; and

1 “(B) persons to which the article has been
2 transported, sold, distributed, or otherwise han-
3 dled.

4 “(c) INFORMAL HEARINGS ON ORDERS.—

5 “(1) IN GENERAL.—The Secretary shall provide
6 a person subject to an order under subsection (b)
7 with an opportunity for an informal hearing (in ac-
8 cordance with such rules or regulations as the Sec-
9 retary shall prescribe) on—

10 “(A) the actions required by the order; and

11 “(B) any reasons why the article that is
12 the subject of the order should not be recalled.

13 “(2) TIMING OF HEARINGS.—The Secretary
14 shall hold a hearing under paragraph (1) as soon as
15 practicable, but not later than 2 business days, after
16 the date of issuance of the order.

17 “(d) POST-HEARING RECALL ORDERS.—

18 “(1) AMENDMENT OF ORDERS.—If, after pro-
19 viding an opportunity for an informal hearing under
20 subsection (c), the Secretary determines that there is
21 a reasonable probability that human consumption of
22 the article that is the subject of an order under sub-
23 section (b) presents a threat to public health, the
24 Secretary may, as the Secretary determines to be
25 necessary—

1 “(A) amend the order under subsection

2 (b)—

3 “(i) to require recall of the article or
4 other appropriate action; and

5 “(ii) to specify a timetable during
6 which the recall shall occur;

7 “(B) require periodic reports to the Sec-
8 retary describing the progress of the recall; or

9 “(C) provide notice of the recall to con-
10 sumers to which the article was, or may have
11 been, distributed.

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

17 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-
18 thorized by this section shall be in addition to any other
19 remedies that may be available.”.

20 **SEC. 6. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
21 **OF ADULTERATED OR MISBRANDED FOODS.**

22 Chapter III of the Federal, Food, Drug, and Cos-
23 metic Act (21 U.S.C. 331 et seq.) is amended by inserting
24 after section 304 the following:

1 **“SEC. 304A. NOTIFICATION, NONDISTRIBUTION, AND RE-**
2 **CALL OF ADULTERATED OR MISBRANDED**
3 **FOODS.**

4 “(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

5 “(1) IN GENERAL.—A person (other than a
6 household consumer) that has reason to believe that
7 any food (referred to in this section as an ‘article’)
8 transported, stored, distributed, or otherwise han-
9 dled by the person is adulterated or misbranded
10 shall, as soon as practicable, notify the Secretary of
11 the identity and location of the article.

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

16 “(b) RECALL AND CONSUMER NOTIFICATION.—

17 “(1) VOLUNTARY ACTIONS.—On receiving noti-
18 fication under subsection (a) or by other means, if
19 the Secretary finds that an article is adulterated or
20 misbranded and that there is a reasonable prob-
21 ability that human consumption of the article would
22 present a threat to public health (as determined by
23 the Secretary), the Secretary shall provide all appro-
24 priate persons (as determined by the Secretary),
25 that transported, stored, distributed, or otherwise
26 handled the article with an opportunity—

1 “(A) to cease distribution of the article;

2 “(B) to notify all persons that transport,
3 store, distribute, or otherwise handle the article,
4 or to which the article has been transported,
5 sold, distributed, or otherwise handled, to cease
6 immediately distribution of the article;

7 “(C) to recall the article;

8 “(D) in consultation with the Secretary, to
9 provide notice of the finding of the Secretary to
10 all consumers to which the article was, or may
11 have been, distributed; or

12 “(E) to notify State and local public health
13 officials.

14 “(2) MANDATORY ACTIONS.—If the appropriate
15 person referred to in paragraph (1) does not carry
16 out the actions described in that paragraph with re-
17 spect to an article within the time period and in the
18 manner prescribed by the Secretary, the Secretary—

19 “(A) shall require the person—

20 “(i) to immediately cease distribution
21 of the article; and

22 “(ii) to immediately make the notifica-
23 tion described in paragraph (1)(B); and

24 “(B) may take control or possession of the
25 article.

1 “(3) NOTICE TO CONSUMERS AND HEALTH OF-
2 FICIALS.—The Secretary shall, as the Secretary de-
3 termines to be necessary, provide notice of the find-
4 ing of the Secretary under paragraph (1) to con-
5 sumers to which the article was, or may have been,
6 distributed and to appropriate State and local health
7 officials.

8 “(4) NONDISTRIBUTION BY NOTIFIED PER-
9 SONS.—A person that transports, stores, distributes,
10 or otherwise handles the article, or to which the arti-
11 cle has been transported, sold, distributed, or other-
12 wise handled, and that is notified under paragraph
13 (1)(B) or (2)(B) shall cease immediately distribution
14 of the article.

15 “(5) AVAILABILITY OF RECORDS TO SEC-
16 RETARY.—Each appropriate person referred to in
17 paragraph (1) that transported, stored, distributed,
18 or otherwise handled an article shall make available
19 to the Secretary information necessary to carry out
20 this subsection, as determined by the Secretary, re-
21 garding—

22 “(A) persons that transport, store, dis-
23 tribute, or otherwise handle the article; and

1 “(B) persons to which the article has been
2 transported, sold, distributed, or otherwise han-
3 dled.

4 “(c) INFORMAL HEARINGS ON ORDERS.—

5 “(1) IN GENERAL.—The Secretary shall provide
6 a person subject to an order under subsection (b)
7 with an opportunity for an informal hearing (in ac-
8 cordance with such rules or regulations as the Sec-
9 retary shall prescribe) on—

10 “(A) the actions required by the order; and

11 “(B) any reasons why the article that is
12 the subject of the order should not be recalled.

13 “(2) TIMING OF HEARINGS.—The Secretary
14 shall hold a hearing under paragraph (1) as soon as
15 practicable, but not later than 2 business days, after
16 the date of issuance of the order.

17 “(d) POST-HEARING RECALL ORDERS.—

18 “(1) AMENDMENT OF ORDERS.—If, after pro-
19 viding an opportunity for an informal hearing under
20 subsection (c), the Secretary determines that there is
21 a reasonable probability that human consumption of
22 the article that is the subject of an order under sub-
23 section (b) presents a threat to public health, the
24 Secretary may, as the Secretary determines to be
25 necessary—

1 “(A) amend the order under subsection

2 (b)—

3 “(i) to require recall of the article or

4 other appropriate action; and

5 “(ii) to specify a timetable during

6 which the recall shall occur;

7 “(B) require periodic reports to the Sec-

8 retary describing the progress of the recall; or

9 “(C) provide notice of the recall to con-

10 sumers to which the article was, or may have

11 been, distributed.

12 “(2) VACATION OF ORDERS.—If, after providing

13 an opportunity for an informal hearing under sub-

14 section (c), the Secretary determines that adequate

15 grounds do not exist to continue the actions required

16 by the order, the Secretary shall vacate the order.

17 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-

18 thorized by this section shall be in addition to any other

19 remedies that may be available.”.

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