

110TH CONGRESS  
2D SESSION

# H. R. 5069

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

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 17, 2008

Mr. VISCLOSKY (for himself, Mr. WILSON of Ohio, Mr. COHEN, Mr. MOLLOHAN, Ms. DELAURO, Mr. PASTOR, Ms. KAPTUR, Mr. MURTHA, and Mr. ALLEN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## 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 2008”.

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

1 Federal Food, Drug, and Cosmetic Act (21  
2 U.S.C. 321).

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

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

9 (E)(i) Meat or meat food product (within  
10 the meaning of the Federal Meat Inspection Act  
11 (21 U.S.C. 601 et seq.)).

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

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

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

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

1           (5) MANUFACTURER.—The term “manufac-  
2           turer” means any person who manufactures or im-  
3           ports a covered product. A common carrier, contract  
4           carrier, or freight forwarder shall not, for purposes  
5           of this Act, be deemed to be a manufacturer of a  
6           covered product solely by reason of receiving or  
7           transporting a covered product in the ordinary  
8           course of its business as such a carrier or forwarder.

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

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

22           (B) In the case of—

23           (i) a device, as defined in section 201  
24          of the Federal Food, Drug, and Cosmetic  
25          Act (21 U.S.C. 321), an order under sub-

1 section (b)(1)(A) or (e) of section 518 of  
2 such Act (21 U.S.C. 360h (b)(1)(A), (e));

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

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

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

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

1           (E) In the case of a covered product de-  
2           scribed in paragraph (2)(E), a recall of the cov-  
3           ered product under—

4                   (i) the Federal Meat Inspection Act  
5                   (21 U.S.C. 601 et seq.);

6                   (ii) the Poultry Products Inspection  
7                   Act (21 U.S.C. 451 et seq.); or

8                   (iii) the Egg Products Inspection Act  
9                   (21 U.S.C. 1031 et seq.).

10       (b) FINANCIAL RESPONSIBILITY REQUIRED.—

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

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

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

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

9 (c) ANNUAL REPORT.—

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

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

20 (A) The Secretary of State.

21 (B) The Consumer Product Safety Com-  
22 mission.

23 (C) Secretary of Health and Human Serv-  
24 ices.

25 (D) The Secretary of Agriculture.

1 (E) The Secretary of Commerce.

2 (3) PUBLIC COMMENTS.—In preparing the an-  
3 nual report required by paragraph (1), the Secretary  
4 of Homeland Security shall solicit comments from  
5 the public on the implementation of this Act.

6 **SEC. 3. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
7 **OF ADULTERATED OR MISBRANDED MEAT**  
8 **AND MEAT FOOD PRODUCTS.**

9 (a) IN GENERAL.—The Federal Meat Inspection Act  
10 (21 U.S.C. 601 et seq.) is amended—

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

13 (2) by inserting after section 410 (21 U.S.C.  
14 679a) the following:

15 **“SEC. 411. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
16 **OF ADULTERATED OR MISBRANDED MEAT**  
17 **AND MEAT FOOD PRODUCTS.**

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

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



1       branded shall, as soon as practicable, notify the Sec-  
2       retary of the identity and location of the article.

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

7               “(b) RECALL AND CONSUMER NOTIFICATION.—

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

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

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

24                       “(C) to recall the article;

1           “(D) in consultation with the Secretary, to  
2           provide notice of the finding of the Secretary to  
3           all consumers to which the article was, or may  
4           have been, distributed; or

5           “(E) to notify State and local public health  
6           officials.

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

12           “(A) shall require the person—

13                   “(i) to immediately cease distribution  
14                   of the article; and

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

17           “(B) may take control or possession of the  
18          article.

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

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

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

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

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

20          “(c) INFORMAL HEARINGS ON ORDERS.—

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

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

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

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

8           “(d) POST-HEARING RECALL ORDERS.—

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

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

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

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

23                 “(B) require periodic reports to the Sec-  
24                 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)(A)(ii) shall cease immediately distribu-  
14          tion 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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