

111TH CONGRESS  
1ST SESSION

# S. 425

To amend the Federal Food, Drug, and Cosmetic Act to provide for the establishment of a traceability system for food, to amend the Federal Meat Inspection Act, the Poultry Products Inspections Act, the Egg Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act to provide for improved public health and food safety through enhanced enforcement, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2009

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

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the establishment of a traceability system for food, to amend the Federal Meat Inspection Act, the Poultry Products Inspections Act, the Egg Products Inspection Act, and the Federal Food, Drug, and Cosmetic Act to provide for improved public health and food safety through enhanced enforcement, 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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the  
3 Food Safety and Tracking Improvement Act.

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

Sec. 1. Short title; table of contents.

TITLE I—TRACEABILITY OF FOOD

Sec. 101. Traceability of food.

TITLE II—ENFORCEMENT AND RECALL FOR MEAT, POULTRY,  
AND FOOD

Sec. 201. Food safety enforcement for meat and meat food products.

Sec. 202. Food safety enforcement for poultry and poultry food products.

Sec. 203. Notification, nondistribution, and recall of adulterated or misbranded  
eggs and egg products.

Sec. 204. Notification, nondistribution, and recall of adulterated or misbranded  
articles of food.

6 **TITLE I—TRACEABILITY OF**  
7 **FOOD**

8 **SEC. 101. TRACEABILITY OF FOOD.**

9 The Federal Food, Drug, and Cosmetic Act (21  
10 U.S.C. 301 et seq.) is amended—

11 (1) in section 301, by inserting at the end the  
12 following:

13 “(oo) The failure to comply with any requirement of  
14 section 414A (relating to the traceability of food).”; and

15 (2) in chapter IV, by inserting after section 414  
16 the following:

17 **“SEC. 414A. TRACEABILITY OF FOOD.**

18 “(a) ESTABLISHMENT OF SYSTEM.—Not later than  
19 3 years after the date of the enactment of this section,

1 the Secretary shall establish a traceability system de-  
2 scribed in subsection (b) for all stages of manufacturing,  
3 processing, packaging, and distribution of food.

4 “(b) DESCRIPTION OF SYSTEM.—The traceability  
5 system required by subsection (a) shall require each article  
6 of food shipped in interstate commerce to be identified in  
7 a manner that enables the Secretary to retrieve the his-  
8 tory, use, and location of the article through a record-  
9 keeping and audit system, a secure, online database, or  
10 registered identification.

11 “(c) RECORDS.—

12 “(1) IN GENERAL.—The Secretary may require  
13 that each person required to identify an article of  
14 food pursuant to subsection (b) maintain accurate  
15 records, as prescribed by the Secretary, regarding  
16 the purchase, sale, and identification of the article.

17 “(2) ACCESS.—Each person described in para-  
18 graph (1) shall, at all reasonable times, on notice by  
19 a duly authorized representative of the Secretary,  
20 allow the representative to access each place of busi-  
21 ness of the person to examine and copy the records  
22 described in paragraph (1).

23 “(3) DURATION.—Each person described in  
24 paragraph (1) shall maintain records as required

1 under this subsection for such period of time as the  
2 Secretary prescribes.

3 “(d) FALSE INFORMATION.—No person shall falsify  
4 or misrepresent to any other person or to the Secretary,  
5 any information as to any location at which any article  
6 of food was held.

7 “(e) ALTERATION OR DESTRUCTION OF RECORDS.—  
8 No person shall, without authorization from the Secretary,  
9 alter, detach, or destroy any records or other means of  
10 identification prescribed by the Secretary for use in deter-  
11 mining the location at which any article of food was held.

12 “(f) ADVISORY COMMITTEE.—

13 “(1) IN GENERAL.—In order to assist the Sec-  
14 retary in implementing the traceability system under  
15 subsection (a), the Secretary shall convene an advi-  
16 sory committee (referred to in this subsection as the  
17 ‘Committee’).

18 “(2) MEMBERSHIP.—The Committee shall con-  
19 sist of 13 members appointed by the Secretary which  
20 shall include—

21 “(A) an equitable number of food safety  
22 and tracking technology experts, representatives  
23 of the food industry, and consumer advocates;  
24 and

1           “(B) officials from the Center for Food  
2           Safety and Applied Nutrition and the Office of  
3           Regulatory Affairs of the Food and Drug Ad-  
4           ministration and the Agriculture Marketing  
5           Service of the Department of Agriculture.

6           “(3) CHAIRPERSON.—The Secretary shall ap-  
7           point a Chairperson of the Committee.

8           “(4) MEETING.—The Committee shall convene  
9           not later than 180 days after the date of enactment  
10          of this section and periodically thereafter at the call  
11          of the Chairperson.

12          “(5) REPORT OF COMMITTEE.—

13                 “(A) IN GENERAL.—Not later than 1 year  
14                 after the date of enactment of this section, the  
15                 Committee shall submit to the Secretary and  
16                 the Office of the Commissioner a report that  
17                 describes the recommendations regarding the  
18                 most practicable approach to providing for the  
19                 traceability of food, including the most efficient  
20                 means of implementing the traceback of con-  
21                 taminated foods.

22                 “(B) CONSIDERATIONS.—In developing the  
23                 report under subparagraph (A), the Committee  
24                 shall consider the following approaches to pro-  
25                 viding for the traceability of food:

1           “(i) A national database or registry  
2 operated by the Food and Drug Adminis-  
3 tration.

4           “(ii) Electronic records identifying  
5 each prior sale, purchase, or trade of the  
6 food and its ingredients, and establishing  
7 that the food and its ingredients were  
8 grown, prepared, handled, manufactured,  
9 processed, distributed, shipped,  
10 warehoused, imported, and conveyed under  
11 conditions that ensure the safety of the  
12 food. The records should include an elec-  
13 tronic statement with the date of, and the  
14 names and addresses of all parties to, each  
15 prior sale, purchase, or trade, and any  
16 other information as appropriate.

17           “(iii) Standardized tracking numbers  
18 on all shipments. These numbers would  
19 identify the country of origin, the unique  
20 facility registration number, date of pro-  
21 duction, and lot number (if applicable).

22           “(iv) Recall performance standards  
23 for each food or commodity type.

1 “(v) Safeguards for the combining, re-  
2 packing, or otherwise mixing of items of  
3 food, particularly fresh produce.

4 “(vi) Other approaches that enable  
5 the reliable tracking of food and food prod-  
6 ucts.

7 “(g) AUTHORIZATION OF APPROPRIATIONS.—For the  
8 purpose of carrying out this section, there is authorized  
9 to be appropriated \$40,000,000 for the period of fiscal  
10 years 2010 through 2012.”.

11 **TITLE II—ENFORCEMENT AND**  
12 **RECALL FOR MEAT, POULTRY,**  
13 **AND FOOD**

14 **SEC. 201. FOOD SAFETY ENFORCEMENT FOR MEAT AND**  
15 **MEAT FOOD PRODUCTS.**

16 (a) IN GENERAL.—The Federal Meat Inspection Act  
17 (21 U.S.C. 601 et seq.) is amended—

18 (1) by redesignating section 411 (21 U.S.C.  
19 680) as section 414; and

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

22 **“SEC. 411. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
23 **OF ADULTERATED OR MISBRANDED ARTI-**  
24 **CLES.**

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 carcass, part of a carcass, meat, or meat food  
4 product of an amenable species (referred to in this  
5 section as an ‘article’) transported, stored, distrib-  
6 uted, or otherwise handled by the person is adulter-  
7 ated or misbranded shall, as soon as practicable, no-  
8 tify the Secretary of the identity and location of the  
9 article.

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.—

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

25           “(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 public  
7           health 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;

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

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

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

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

22           **“SEC. 412. REFUSAL OR WITHDRAWAL OF INSPECTION OF**  
23           **ESTABLISHMENTS.**

24           “(a) IN GENERAL.—The Secretary may, for such pe-  
25           riod, or indefinitely, as the Secretary considers necessary

1 to carry out this Act, refuse to provide or withdraw inspec-  
2 tion under title I with respect to an establishment if the  
3 Secretary determines, after opportunity for a hearing on  
4 the record is provided to the applicant for, or recipient  
5 of, inspection, that the applicant or recipient, or any per-  
6 son responsibly connected with the applicant or recipient  
7 (within the meaning of section 401), has committed a will-  
8 ful violation or repeated violations of this Act (including  
9 a regulation promulgated under this Act).

10       “(b) DENIAL OR SUSPENSION OF INSPECTION PEND-  
11 ING HEARING.—The Secretary may deny or suspend in-  
12 spection under title I, pending opportunity for an expe-  
13 dited hearing, with respect to an action under subsection  
14 (a), if the Secretary determines that the denial or suspen-  
15 sion is in the public interest to protect the health or wel-  
16 fare of consumers or to ensure the effective performance  
17 of an official duty under this Act.

18       “(c) JUDICIAL REVIEW.—

19               “(1) IN GENERAL.—A determination and order  
20 of the Secretary with respect to the refusal or with-  
21 drawal of inspection under this section shall be final  
22 unless, not later than 30 days after the effective  
23 date of the order, the affected applicant for, or re-  
24 cipient of, inspection—

1           “(A) files a petition for judicial review of  
2           the order; and

3           “(B) simultaneously sends a copy of the  
4           petition by certified mail to the Secretary.

5           “(2) REFUSAL OR WITHDRAWAL OF INSPEC-  
6           TION PENDING REVIEW.—Inspection shall be refused  
7           or withdrawn as of the effective date of the order  
8           pending any judicial review of the order unless the  
9           Secretary directs otherwise.

10          “(3) VENUE; RECORD.—Judicial review of the  
11          order shall be—

12                 “(A) in—

13                         “(i) the United States court of ap-  
14                         peals for the circuit in which the applicant  
15                         for, or recipient of, inspection resides or  
16                         has its principal place of business; or

17                         “(ii) the United States Court of Ap-  
18                         peals for the District of Columbia Circuit;

19                         and

20                         “(B) on the record on which the deter-  
21                         mination and order are based.

22          “(d) REMEDIES NOT EXCLUSIVE.—The remedies au-  
23          thorized by this section shall be in addition to any other  
24          remedies that may be available.

1 **“SEC. 413. CIVIL PENALTIES.**

2 “(a) IN GENERAL.—

3 “(1) ASSESSMENT.—The Secretary may assess  
4 against a person that violates section 411 (including  
5 a regulation promulgated or order issued under that  
6 section) a civil penalty for each violation of not more  
7 than \$100,000.

8 “(2) SEPARATE OFFENSES.—Each violation  
9 and each day during which the violation continues  
10 shall be considered to be a separate offense.

11 “(3) NOTICE AND OPPORTUNITY FOR HEAR-  
12 ING.—The Secretary shall not assess a civil penalty  
13 under this section against a person unless the person  
14 is given notice and opportunity for a hearing on the  
15 record before the Secretary in accordance with sec-  
16 tions 554 and 556 of title 5, United States Code.

17 “(4) DETERMINATION OF CIVIL PENALTY  
18 AMOUNT.—The amount of a civil penalty under this  
19 section—

20 “(A) shall be assessed by the Secretary by  
21 written order, taking into account—

22 “(i) the gravity of the violation;

23 “(ii) the degree of culpability of the  
24 person;

25 “(iii) the size and type of the business  
26 of the person; and

1           “(iv) any history of prior offenses by  
2           the person under this Act; and

3           “(B) shall be reviewed only in accordance  
4           with subsection (b).

5           “(b) JUDICIAL REVIEW.—

6           “(1) IN GENERAL.—An order assessing a civil  
7           penalty against a person under subsection (a) shall  
8           be final unless the person—

9           “(A) not later than 30 days after the effec-  
10          tive date of the order, files a petition for judi-  
11          cial review of the order in—

12           “(i) the United States court of ap-  
13           peals for the circuit in which the person re-  
14           sides or has its principal place of business;  
15           or

16           “(ii) the United States Court of Ap-  
17           peals for the District of Columbia Circuit;  
18           and

19           “(B) simultaneously sends a copy of the  
20           petition by certified mail to the Secretary.

21           “(2) FILING OF COPY OF RECORD.—The Sec-  
22           retary shall promptly file in the court a certified  
23           copy of the record on which the order was issued.

24           “(c) COLLECTION ACTIONS FOR FAILURE TO PAY  
25           ASSESSMENT.—



1           “(1) REFERRAL TO ATTORNEY GENERAL.—If a  
2           person fails to pay a civil penalty assessed under  
3           subsection (a) after the order assessing the civil pen-  
4           alty has become a final order, or after the court of  
5           appeals has entered final judgment in favor of the  
6           Secretary, the Secretary shall refer the matter to the  
7           Attorney General.

8           “(2) ACTION BY ATTORNEY GENERAL.—The  
9           Attorney General shall bring a civil action to recover  
10          the amount of the civil penalty in United States dis-  
11          trict court.

12          “(3) SCOPE OF REVIEW.—In a civil action  
13          under paragraph (2), the validity and appropriate-  
14          ness of the order of the Secretary assessing the civil  
15          penalty shall not be subject to review.

16          “(d) REFUSAL OR WITHDRAWAL OF INSPECTION  
17          PENDING PAYMENT.—If a person fails to pay the amount  
18          of a civil penalty after the order assessing the civil penalty  
19          has become a final order, the Secretary may refuse to pro-  
20          vide or withdraw inspection under title I of the person  
21          until the civil penalty is paid or until the Secretary directs  
22          otherwise.

23          “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—  
24          Nothing in this Act requires the Secretary to report for  
25          prosecution, or for the commencement of an action, any

1 violation of section 411 in any case in which the Secretary  
2 believes that the public interest will be adequately served  
3 by the assessment of a civil penalty under this section.

4 “(f) REMEDIES NOT EXCLUSIVE.—The remedies au-  
5 thorized by this section shall be in addition to any other  
6 remedies that may be available.”.

7 (b) CONFORMING AMENDMENTS.—

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

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

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

16 (A) by striking “person, firm, or corpora-  
17 tion” each place it appears and inserting “per-  
18 son”;

19 (B) by striking “persons, firms, and cor-  
20 porations” each place it appears and inserting  
21 “persons”; and

22 (C) by striking “persons, firms, or corpora-  
23 tions” each place it appears and inserting “per-  
24 sons”.

1 **SEC. 202. FOOD SAFETY ENFORCEMENT FOR POULTRY AND**  
2 **POULTRY FOOD PRODUCTS.**

3 (a) IN GENERAL.—The Poultry Products Inspection  
4 Act (21 U.S.C. 451 et seq.) is amended by adding at the  
5 end the following:

6 **“SEC. 32. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
7 **OF ADULTERATED OR MISBRANDED ARTI-**  
8 **CLES.**

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

10 “(1) IN GENERAL.—A person (other than a  
11 household consumer) that has reason to believe that  
12 any poultry or poultry product (referred to in this  
13 section as an ‘article’) transported, stored, distrib-  
14 uted, or otherwise handled by the person is adulter-  
15 ated or misbranded shall, as soon as practicable, no-  
16 tify the Secretary of the identity and location of the  
17 article.

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

22 “(b) RECALL AND CONSUMER NOTIFICATION.—

23 “(1) VOLUNTARY ACTIONS.—On receiving noti-  
24 fication under subsection (a) or by other means, if  
25 the Secretary finds that an article is adulterated or  
26 misbranded and that there is a reasonable prob-

1 ability that human consumption of the article would  
2 present a threat to public health (as determined by  
3 the Secretary), the Secretary shall provide all appropriate  
4 persons (as determined by the Secretary),  
5 that transported, stored, distributed, or otherwise  
6 handled the article with an opportunity—

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

8 “(B) to notify all persons that transport,  
9 store, distribute, or otherwise handle the article,  
10 or to which the article has been transported,  
11 sold, distributed, or otherwise handled, to cease  
12 immediately distribution of the article;

13 “(C) to recall the article;

14 “(D) in consultation with the Secretary, to  
15 provide notice of the finding of the Secretary to  
16 all consumers to which the article was, or may  
17 have been, distributed; or

18 “(E) to notify State and local public health  
19 officials.

20 “(2) MANDATORY ACTIONS.—If the appropriate  
21 person referred to in paragraph (1) does not carry  
22 out the actions described in that paragraph with respect  
23 to an article within the time period and in the  
24 manner prescribed by the Secretary, the Secretary—

25 “(A) shall require the person—

1                   “(i) to immediately cease distribution  
2                   of the article; and

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

5                   “(B) may take control or possession of the  
6                   article.

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

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

21                  “(5) AVAILABILITY OF RECORDS TO SEC-  
22                  RETARY.—Each appropriate person referred to in  
23                  paragraph (1) that transported, stored, distributed,  
24                  or otherwise handled an article shall make available  
25                  to the Secretary information necessary to carry out

1 this subsection, as determined by the Secretary, re-  
2 garding—

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

5 “(B) persons to which the article has been  
6 transported, sold, distributed, or otherwise han-  
7 dled.

8 “(c) INFORMAL HEARINGS ON ORDERS.—

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

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

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

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

21 “(d) POST-HEARING RECALL ORDERS.—

22 “(1) AMENDMENT OF ORDERS.—If, after pro-  
23 viding an opportunity for an informal hearing under  
24 subsection (c), the Secretary determines that there is  
25 a reasonable probability that human consumption of

1 the article that is the subject of an order under sub-  
2 section (b) presents a threat to public health, the  
3 Secretary may, as the Secretary determines to be  
4 necessary—

5 “(A) amend the order under subsection  
6 (b)—

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

9 “(ii) to specify a timetable during  
10 which the recall shall occur;

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

13 “(C) provide notice of the recall to con-  
14 sumers to which the article 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 (c), 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 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-  
22 thorized by this section shall be in addition to any other  
23 remedies that may be available.

1 **“SEC. 33. REFUSAL OR WITHDRAWAL OF INSPECTION OF**  
2 **ESTABLISHMENTS.**

3 “(a) IN GENERAL.—The Secretary may, for such pe-  
4 riod, or indefinitely, as the Secretary considers necessary  
5 to carry out this Act, refuse to provide or withdraw inspec-  
6 tion under this Act with respect to an establishment if the  
7 Secretary determines, after opportunity for a hearing on  
8 the record is provided to the applicant for, or recipient  
9 of, inspection, that the applicant or recipient, or any per-  
10 son responsibly connected with the applicant or recipient  
11 (within the meaning of section 18(a)), has committed a  
12 willful violation or repeated violations of this Act (includ-  
13 ing a regulation promulgated under this Act).

14 “(b) DENIAL OR SUSPENSION OF INSPECTION PEND-  
15 ING HEARING.—The Secretary may deny or suspend in-  
16 spection under this Act, pending opportunity for an expe-  
17 dited hearing, with respect to an action under subsection  
18 (a), if the Secretary determines that the denial or suspen-  
19 sion is in the public interest to protect the health or wel-  
20 fare of consumers or to ensure the effective performance  
21 of an official duty under this Act.

22 “(c) JUDICIAL REVIEW.—

23 “(1) IN GENERAL.—A determination and order  
24 of the Secretary with respect to the refusal or with-  
25 drawal of inspection under this section shall be final  
26 unless, not later than 30 days after the effective



1 date of the order, the affected applicant for, or re-  
2 cipient of, inspection—

3 “(A) files a petition for judicial review of  
4 the order; and

5 “(B) simultaneously sends a copy of the  
6 petition by certified mail to the Secretary.

7 “(2) REFUSAL OR WITHDRAWAL OF INSPEC-  
8 TION PENDING REVIEW.—Inspection shall be refused  
9 or withdrawn as of the effective date of the order  
10 pending any judicial review of the order unless the  
11 Secretary directs otherwise.

12 “(3) VENUE; RECORD.—Judicial review of the  
13 order shall be—

14 “(A) in—

15 “(i) the United States court of ap-  
16 peals for the circuit in which the applicant  
17 for, or recipient of, inspection resides or  
18 has its principal place of business; or

19 “(ii) the United States Court of Ap-  
20 peals for the District of Columbia Circuit;  
21 and

22 “(B) on the record on which the deter-  
23 mination and order are based.

1       “(d) REMEDIES NOT EXCLUSIVE.—The remedies au-  
2 thORIZED by this section shall be in addition to any other  
3 remedies that may be available.

4 **“SEC. 34. CIVIL PENALTIES.**

5       “(a) IN GENERAL.—

6           “(1) ASSESSMENT.—The Secretary may assess  
7 against a person that violates section 32 (including  
8 a regulation promulgated or order issued under that  
9 section) a civil penalty for each violation of not more  
10 than \$100,000.

11           “(2) SEPARATE OFFENSES.—Each violation  
12 and each day during which the violation continues  
13 shall be considered to be a separate offense.

14           “(3) NOTICE AND OPPORTUNITY FOR HEAR-  
15 ING.—The Secretary shall not assess a civil penalty  
16 under this section against a person unless the person  
17 is given notice and opportunity for a hearing on the  
18 record before the Secretary in accordance with sec-  
19 tions 554 and 556 of title 5, United States Code.

20           “(4) DETERMINATION OF CIVIL PENALTY  
21 AMOUNT.—The amount of a civil penalty under this  
22 section—

23           “(A) shall be assessed by the Secretary by  
24 written order, taking into account—

25           “(i) the gravity of the violation;

1                   “(ii) the degree of culpability of the  
2                   person;

3                   “(iii) the size and type of the business  
4                   of the person; and

5                   “(iv) any history of prior offenses by  
6                   the person under this Act; and

7                   “(B) shall be reviewed only in accordance  
8                   with subsection (b).

9                   “(b) JUDICIAL REVIEW.—

10                   “(1) IN GENERAL.—An order assessing a civil  
11                   penalty against a person under subsection (a) shall  
12                   be final unless the person—

13                   “(A) not later than 30 days after the effec-  
14                   tive date of the order, files a petition for judi-  
15                   cial review of the order in—

16                   “(i) the United States court of ap-  
17                   peals for the circuit in which the person re-  
18                   sides or has its principal place of business;  
19                   or

20                   “(ii) the United States Court of Ap-  
21                   peals for the District of Columbia Circuit;  
22                   and

23                   “(B) simultaneously sends a copy of the  
24                   petition by certified mail to the Secretary.

1           “(2) FILING OF COPY OF RECORD.—The Sec-  
2           retary shall promptly file in the court a certified  
3           copy of the record on which the order was issued.

4           “(c) COLLECTION ACTIONS FOR FAILURE TO PAY  
5 ASSESSMENT.—

6           “(1) REFERRAL TO ATTORNEY GENERAL.—If a  
7           person fails to pay a civil penalty assessed under  
8           subsection (a) after the order assessing the civil pen-  
9           alty has become a final order, or after the court of  
10          appeals has entered final judgment in favor of the  
11          Secretary, the Secretary shall refer the matter to the  
12          Attorney General.

13          “(2) ACTION BY ATTORNEY GENERAL.—The  
14          Attorney General shall bring a civil action to recover  
15          the amount of the civil penalty in United States dis-  
16          trict court.

17          “(3) SCOPE OF REVIEW.—In a civil action  
18          under paragraph (2), the validity and appropriate-  
19          ness of the order of the Secretary assessing the civil  
20          penalty shall not be subject to review.

21          “(d) REFUSAL OR WITHDRAWAL OF INSPECTION  
22 PENDING PAYMENT.—If a person fails to pay the amount  
23 of a civil penalty after the order assessing the civil penalty  
24 has become a final order, the Secretary may refuse to pro-  
25 vide or withdraw inspection under this Act of the person

1 until the civil penalty is paid or until the Secretary directs  
2 otherwise.

3 “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—  
4 Nothing in this Act requires the Secretary to report for  
5 prosecution, or for the commencement of an action, any  
6 violation of section 32 in any case in which the Secretary  
7 believes that the public interest will be adequately served  
8 by the assessment of a civil penalty under this section.

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

12 (b) CONFORMING AMENDMENTS.—Section 5(c)(1) of  
13 the Poultry Products Inspection Act (21 U.S.C.  
14 454(c)(1)) is amended in the first sentence—

15 (1) by striking “, by thirty days prior to the ex-  
16 piration of two years after enactment of the Whole-  
17 some Poultry Products Act,”; and

18 (2) by striking “sections 1–4, 6–10, and 12–22  
19 of this Act” and inserting “sections 1 through 4, 6  
20 through 10, 12 through 22, and 32 through 34”;  
21 and

1 **SEC. 203. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
 2 **OF ADULTERATED OR MISBRANDED EGGS**  
 3 **AND EGG PRODUCTS.**

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

6 **“SEC. 20A. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
 7 **OF ADULTERATED OR MISBRANDED EGGS**  
 8 **AND EGG PRODUCTS.**

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

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

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

21 “(b) RECALL AND CONSUMER NOTIFICATION.—

22 “(1) VOLUNTARY ACTIONS.—On receiving noti-  
 23 fication under subsection (a) or by other means, if  
 24 the Secretary finds that an article is adulterated or  
 25 misbranded and that there is a reasonable prob-  
 26 ability that human consumption of the article would

1 present a threat to public health (as determined by  
2 the Secretary), the Secretary shall provide all appro-  
3 priate persons (as determined by the Secretary),  
4 that transported, stored, distributed, or otherwise  
5 handled the article with an opportunity—

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

7 “(B) to notify all persons that transport,  
8 store, distribute, or otherwise handle the article,  
9 or to which the article has been transported,  
10 sold, distributed, or otherwise handled, to cease  
11 immediately distribution of the article;

12 “(C) to recall the article;

13 “(D) in consultation with the Secretary, to  
14 provide notice of the finding of the Secretary to  
15 all consumers to which the article was, or may  
16 have been, distributed; or

17 “(E) to notify State and local public health  
18 officials.

19 “(2) MANDATORY ACTIONS.—If the appropriate  
20 person referred to in paragraph (1) does not carry  
21 out the actions described in that paragraph with re-  
22 spect to an article within the time period and in the  
23 manner prescribed by the Secretary, the Secretary—

24 “(A) shall require the person—

1                   “(i) to immediately cease distribution  
2                   of the article; and

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

5                   “(B) may take control or possession of the  
6                   article.

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

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

21                  “(5) AVAILABILITY OF RECORDS TO SEC-  
22                  RETARY.—Each appropriate person referred to in  
23                  paragraph (1) that transported, stored, distributed,  
24                  or otherwise handled an article shall make available  
25                  to the Secretary information necessary to carry out



1 this subsection, as determined by the Secretary, re-  
2 garding—

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

5 “(B) persons to which the article has been  
6 transported, sold, distributed, or otherwise han-  
7 dled.

8 “(c) INFORMAL HEARINGS ON ORDERS.—

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

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

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

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

21 “(d) POST-HEARING RECALL ORDERS.—

22 “(1) AMENDMENT OF ORDERS.—If, after pro-  
23 viding an opportunity for an informal hearing under  
24 subsection (c), the Secretary determines that there is  
25 a reasonable probability that human consumption of

1 the article that is the subject of an order under sub-  
2 section (b) presents a threat to public health, the  
3 Secretary may, as the Secretary determines to be  
4 necessary—

5 “(A) amend the order under subsection  
6 (b)—

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

9 “(ii) to specify a timetable during  
10 which the recall shall occur;

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

13 “(C) provide notice of the recall to con-  
14 sumers to which the article 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 (c), 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 “(e) REMEDIES NOT EXCLUSIVE.—The remedies au-  
22 thorized by this section shall be in addition to any other  
23 remedies that may be available.

1 **“SEC. 20B. REFUSAL OR WITHDRAWAL OF INSPECTION OF**  
2 **ESTABLISHMENTS.**

3 “(a) IN GENERAL.—The Secretary may, for such pe-  
4 riod, or indefinitely, as the Secretary considers necessary  
5 to carry out this Act, refuse to provide or withdraw inspec-  
6 tion under this Act with respect to an establishment if the  
7 Secretary determines, after opportunity for a hearing on  
8 the record is provided to the applicant for, or recipient  
9 of, inspection, that the applicant or recipient, or any per-  
10 son responsibly connected with the applicant or recipient  
11 (within the meaning of section 18), has committed a will-  
12 ful violation or repeated violations of this Act (including  
13 a regulation promulgated under this Act).

14 “(b) DENIAL OR SUSPENSION OF INSPECTION PEND-  
15 ING HEARING.—The Secretary may deny or suspend in-  
16 spection under this Act, pending opportunity for an expe-  
17 dited hearing, with respect to an action under subsection  
18 (a), if the Secretary determines that the denial or suspen-  
19 sion is in the public interest to protect the health or wel-  
20 fare of consumers or to ensure the effective performance  
21 of an official duty under this Act.

22 “(c) JUDICIAL REVIEW.—

23 “(1) IN GENERAL.—A determination and order  
24 of the Secretary with respect to the refusal or with-  
25 drawal of inspection under this section shall be final  
26 unless, not later than 30 days after the effective

1 date of the order, the affected applicant for, or re-  
2 cipient of, inspection—

3 “(A) files a petition for judicial review of  
4 the order; and

5 “(B) simultaneously sends a copy of the  
6 petition by certified mail to the Secretary.

7 “(2) REFUSAL OR WITHDRAWAL OF INSPEC-  
8 TION PENDING REVIEW.—Inspection shall be refused  
9 or withdrawn as of the effective date of the order  
10 pending any judicial review of the order unless the  
11 Secretary directs otherwise.

12 “(3) VENUE; RECORD.—Judicial review of the  
13 order shall be—

14 “(A) in—

15 “(i) the United States court of ap-  
16 peals for the circuit in which the applicant  
17 for, or recipient of, inspection resides or  
18 has its principal place of business; or

19 “(ii) the United States Court of Ap-  
20 peals for the District of Columbia Circuit;  
21 and

22 “(B) on the record on which the deter-  
23 mination and order are based.

1       “(d) REMEDIES NOT EXCLUSIVE.—The remedies au-  
2 thORIZED by this section shall be in addition to any other  
3 remedies that may be available.

4 **“SEC. 20C. CIVIL PENALTIES.**

5       “(a) IN GENERAL.—

6           “(1) ASSESSMENT.—The Secretary may assess  
7 against a person that violates section 20A (including  
8 a regulation promulgated or order issued under that  
9 section) a civil penalty for each violation of not more  
10 than \$100,000.

11           “(2) SEPARATE OFFENSES.—Each violation  
12 and each day during which the violation continues  
13 shall be considered to be a separate offense.

14           “(3) NOTICE AND OPPORTUNITY FOR HEAR-  
15 ING.—The Secretary shall not assess a civil penalty  
16 under this section against a person unless the person  
17 is given notice and opportunity for a hearing on the  
18 record before the Secretary in accordance with sec-  
19 tions 554 and 556 of title 5, United States Code.

20           “(4) DETERMINATION OF CIVIL PENALTY  
21 AMOUNT.—The amount of a civil penalty under this  
22 section—

23           “(A) shall be assessed by the Secretary by  
24 written order, taking into account—

25           “(i) the gravity of the violation;

1                   “(ii) the degree of culpability of the  
2                   person;

3                   “(iii) the size and type of the business  
4                   of the person; and

5                   “(iv) any history of prior offenses by  
6                   the person under this Act; and

7                   “(B) shall be reviewed only in accordance  
8                   with subsection (b).

9                   “(b) JUDICIAL REVIEW.—

10                   “(1) IN GENERAL.—An order assessing a civil  
11                   penalty against a person under subsection (a) shall  
12                   be final unless the person—

13                   “(A) not later than 30 days after the effec-  
14                   tive date of the order, files a petition for judi-  
15                   cial review of the order in—

16                   “(i) the United States court of ap-  
17                   peals for the circuit in which the person re-  
18                   sides or has its principal place of business;  
19                   or

20                   “(ii) the United States Court of Ap-  
21                   peals for the District of Columbia Circuit;  
22                   and

23                   “(B) simultaneously sends a copy of the  
24                   petition by certified mail to the Secretary.

1           “(2) FILING OF COPY OF RECORD.—The Sec-  
2           retary shall promptly file in the court a certified  
3           copy of the record on which the order was issued.

4           “(c) COLLECTION ACTIONS FOR FAILURE TO PAY  
5 ASSESSMENT.—

6           “(1) REFERRAL TO ATTORNEY GENERAL.—If a  
7           person fails to pay a civil penalty assessed under  
8           subsection (a) after the order assessing the civil pen-  
9           alty has become a final order, or after the court of  
10          appeals has entered final judgment in favor of the  
11          Secretary, the Secretary shall refer the matter to the  
12          Attorney General.

13          “(2) ACTION BY ATTORNEY GENERAL.—The  
14          Attorney General shall bring a civil action to recover  
15          the amount of the civil penalty in United States dis-  
16          trict court.

17          “(3) SCOPE OF REVIEW.—In a civil action  
18          under paragraph (2), the validity and appropriate-  
19          ness of the order of the Secretary assessing the civil  
20          penalty shall not be subject to review.

21          “(d) REFUSAL OR WITHDRAWAL OF INSPECTION  
22 PENDING PAYMENT.—If a person fails to pay the amount  
23 of a civil penalty after the order assessing the civil penalty  
24 has become a final order, the Secretary may refuse to pro-  
25 vide or withdraw inspection under this Act of the person

1 until the civil penalty is paid or until the Secretary directs  
2 otherwise.

3 “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—  
4 Nothing in this Act requires the Secretary to report for  
5 prosecution, or for the commencement of an action, any  
6 violation of section 20A in any case in which the Secretary  
7 believes that the public interest will be adequately served  
8 by the assessment of a civil penalty under this section.

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

12 **SEC. 204. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
13 **OF ADULTERATED OR MISBRANDED ARTI-**  
14 **CLES OF FOOD.**

15 (a) PROHIBITED ACTS.—Section 301 of the Federal  
16 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
17 ed by adding at the end the following:

18 “(pp)(1) The failure to notify the Secretary in viola-  
19 tion of section 311(a).

20 “(2) The failure to comply with—

21 “(A) an order issued under section 311(b) fol-  
22 lowing any hearing requested under section 311(c);  
23 or

24 “(B) an amended order issued under section  
25 311(d)(1).”.



1 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL  
2 OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD;  
3 CIVIL PENALTIES RELATING TO FOODS.—Chapter III of  
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331  
5 et seq.) is amended by adding at the end the following:

6 **“SEC. 311. NOTIFICATION, NONDISTRIBUTION, AND RECALL**  
7 **OF ADULTERATED OR MISBRANDED ARTI-**  
8 **CLES OF FOOD.**

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

10 “(1) IN GENERAL.—A person (other than a  
11 household consumer or other individual who is the  
12 intended consumer of an article of food) that has  
13 reason to believe that an article of food when intro-  
14 duced into or while in interstate commerce, or while  
15 held for sale (regardless of whether the first sale)  
16 after shipment in interstate commerce, is adulter-  
17 ated or misbranded in a manner that, if consumed,  
18 may result in illness or injury shall, as soon as prac-  
19 ticable, notify the Secretary of the identity and loca-  
20 tion of the article.

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

25 “(b) RECALL AND CONSUMER NOTIFICATION.—

1           “(1) VOLUNTARY ACTIONS.—On receiving noti-  
2           fication under subsection (a) or by other means, if  
3           the Secretary finds that an article of food when in-  
4           troduced into or while in interstate commerce, or  
5           while held for sale (regardless of whether the first  
6           sale) after shipment in interstate commerce, is adul-  
7           terated or misbranded in a manner that, if con-  
8           sumed, may result in illness or injury (as determined  
9           by the Secretary), the Secretary shall provide all ap-  
10          propriate persons (including the manufacturer, im-  
11          porter, distributor, or retailer of the article) with an  
12          opportunity (as determined by the Secretary)—

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

14                   “(B) to notify all persons—

15                           “(i) that produce, manufacture, pack,  
16                           process, prepare, treat, package, distribute,  
17                           or hold the article, to cease immediately  
18                           those activities with respect to the article;

19                           or

20                           “(ii) to which the article has been dis-  
21                           tributed, transported, or sold, to cease im-  
22                           mediately distribution of the article;

23                   “(C) to recall the article;

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

1 all consumers to which the article was, or may  
2 have been, distributed and to appropriate State  
3 and local health officials; or

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

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

11 “(A) shall require the person—

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

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

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

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

25 “(c) HEARINGS ON ORDERS.—

1           “(1) IN GENERAL.—The Secretary shall provide  
2 a person subject to an order under subsection (b)  
3 with an opportunity for a hearing on—

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

5                   “(B) any reasons why the article of food  
6 that is the subject of the order should not be  
7 recalled.

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

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

13                   “(1) AMENDMENT OF ORDERS.—If, after pro-  
14 viding an opportunity for a hearing under subsection  
15 (c), the Secretary determines that an article of food  
16 when introduced into or while in interstate com-  
17 merce, or while held for sale (regardless of whether  
18 the first sale) after shipment in interstate commerce,  
19 is adulterated or misbranded in a manner that, if  
20 consumed, may result in illness or injury, the Sec-  
21 retary may, as the Secretary determines to be nec-  
22 essary—

23                   “(A) amend the order under subsection

24                   (b)—

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

3                   “(ii) to specify a timetable during  
4                   which the recall shall occur;

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

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

10                  “(2) VACATION OF ORDERS.—If, after providing  
11                  an opportunity for a hearing under subsection (c),  
12                  the Secretary determines that adequate grounds do  
13                  not exist to continue the actions required by the  
14                  order, the Secretary shall vacate the order.

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

18                  **“SEC. 312. CIVIL PENALTIES RELATING TO FOODS.**

19                  “(a) IN GENERAL.—

20                         “(1) ASSESSMENT.—The Secretary may assess  
21                         against a person that commits an act prohibited by  
22                         section 301(pp) a civil penalty for each such act of  
23                         not more than—

24                                 “(A) \$100,000, in the case of an indi-  
25                                 vidual; and

1           “(B) \$500,000, in the case of any other  
2           person.

3           “(2) SEPARATE OFFENSES.—Each prohibited  
4           act and each day during which the act continues  
5           shall be considered to be a separate offense.

6           “(3) NOTICE AND OPPORTUNITY FOR HEAR-  
7           ING.—The Secretary shall not assess a civil penalty  
8           under this section against a person unless the person  
9           is given notice and opportunity for a hearing on the  
10          record before the Secretary in accordance with sec-  
11          tions 554 and 556 of title 5, United States Code.

12          “(4) DETERMINATION OF CIVIL PENALTY  
13          AMOUNT.—The amount of a civil penalty under this  
14          section—

15                 “(A) shall be assessed by the Secretary by  
16                 written order, taking into account—

17                         “(i) the gravity of the violation;

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

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

22                         “(iv) any history of prior offenses by  
23                         the person; and

24                 “(B) shall be reviewed only in accordance  
25                 with subsection (b).

1 “(b) JUDICIAL REVIEW.—

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

5 “(A) not later than 30 days after the effec-  
6 tive date of the order, files a petition for judi-  
7 cial review of the order in—

8 “(i) the United States court of ap-  
9 peals for the circuit in which the person re-  
10 sides or has its principal place of business;  
11 or

12 “(ii) the United States Court of Ap-  
13 peals for the District of Columbia Circuit;  
14 and

15 “(B) simultaneously sends a copy of the  
16 petition by certified mail to the Secretary.

17 “(2) FILING OF COPY OF RECORD.—The Sec-  
18 retary shall promptly file in the court a certified  
19 copy of the record on which the order was issued.

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

24 “(c) COLLECTION ACTIONS FOR FAILURE TO PAY  
25 ASSESSMENT.—

1           “(1) REFERRAL TO ATTORNEY GENERAL.—If a  
2           person fails to pay a civil penalty assessed under  
3           subsection (a) after the order assessing the civil pen-  
4           alty has become a final order, or after the court of  
5           appeals has entered final judgment in favor of the  
6           Secretary, the Secretary may refer the matter to the  
7           Attorney General.

8           “(2) ACTION BY ATTORNEY GENERAL.—The  
9           Attorney General shall bring a civil action to recover  
10          the amount of the civil penalty in United States dis-  
11          trict court.

12          “(3) SCOPE OF REVIEW.—In a civil action  
13          under paragraph (2), the validity and appropriate-  
14          ness of the order of the Secretary assessing the civil  
15          penalty shall not be subject to review.

16          “(d) PENALTIES DEPOSITED IN TREASURY.—All  
17          amounts collected as civil penalties under this section shall  
18          be deposited in the Treasury of the United States.

19          “(e) PENALTIES IN LIEU OF OTHER ACTIONS.—  
20          Nothing in this Act requires the Secretary to report for  
21          prosecution, or for the commencement of any libel or in-  
22          junction proceeding, any violation of section 301(pp) in  
23          any case in which the Secretary believes that the public  
24          interest will be adequately served by the assessment of a  
25          civil penalty under this section.



1       “(f) REMEDIES NOT EXCLUSIVE.—The remedies au-  
2       thorized by this section shall be in addition to any other  
3       remedies that may be available.”.

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