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H. R. 815

To amend the Federal Meat Inspection Act, the Poultry 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.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 3, 2009

Ms. DEGETTE (for herself, Mr. NADLER of New York, and Ms. DELAURO) introduced the following bill; which was referred to the Committee on Agriculture, and in addition to the Committee on Energy and Commerce, 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 amend the Federal Meat Inspection Act, the Poultry 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Safe And Fair Enforcement and Recall for Meat, Poultry, and Food Act of

2009'' or ''SAFER Meat, Poultry, and Food Act of 2009''.

SEC. 2. FOOD SAFETY ENFORCEMENT FOR MEAT AND MEAT FOOD PRODUCTS.

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

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

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

''SEC. 411. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES.

''(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

''(1) IN GENERAL.—A person (other than a household consumer) that has reason to believe that any carcass, part of a carcass, meat, or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines (referred to in this section as an 'article') transported, stored, distributed, or otherwise handled by the person is adulterated or misbranded shall, as soon as practicable, notify the Secretary of the identity and location of the article.

''(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner

and by such means as the Secretary may require by regulation.

"(b) RECALL AND CONSUMER NOTIFICATION.—

"(1) VOLUNTARY ACTIONS.—On receiving notification under subsection (a) or by other means, if the Secretary finds that an article is adulterated or misbranded and that there is a reasonable probability that human consumption of the article would present a threat to public health (as determined by the Secretary), the Secretary shall provide all appropriate persons (as determined by the Secretary), that transported, stored, distributed, or otherwise handled the article with an opportunity—

"(A) to cease distribution of the article;

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

"(C) to recall the article;

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

"(E) to notify State and local public health officials.

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

"(A) shall require the person—

"(i) to immediately cease distribution of the article; and

"(ii) to immediately make the notification described in paragraph (1)(B); and

"(B) may take control or possession of the article.

"(3) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of the finding of the Secretary under paragraph (1) to consumers to which the article was, or may have been, distributed and to appropriate State and local public health officials.

"(4) NONDISTRIBUTION BY NOTIFIED PERSONS.—A person that transports, stores, distributes, or otherwise handles the article, or to which the article has been transported, sold, distributed, or other-

wise handled, and that is notified under paragraph (1)(B) or (2)(B) shall cease immediately distribution of the article.

"(5) AVAILABILITY OF RECORDS TO SECRETARY.—Each appropriate person referred to in paragraph (1) that transported, stored, distributed, or otherwise handled an article shall make available to the Secretary information necessary to carry out this subsection, as determined by the Secretary, regarding—

"(A) persons that transport, store, distribute, or otherwise handle the article; and

"(B) persons to which the article has been transported, sold, distributed, or otherwise handled.

"(c) INFORMAL HEARINGS ON ORDERS.—

"(1) IN GENERAL.—The Secretary shall provide a person subject to an order under subsection (b) with an opportunity for an informal hearing (in accordance with such rules or regulations as the Secretary shall prescribe) on—

"(A) the actions required by the order; and

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

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

"(d) POST-HEARING RECALL ORDERS.—

"(1) AMENDMENT OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (c), the Secretary determines that there is a reasonable probability that human consumption of the article that is the subject of an order under subsection (b) presents a threat to public health, the Secretary may, as the Secretary determines to be necessary—

"(A) amend the order under subsection (b)—

"(i) to require recall of the article or other appropriate action; and

"(ii) to specify a timetable during which the recall shall occur;

"(B) require periodic reports to the Secretary describing the progress of the recall;

"(C) provide notice of the recall to consumers to which the article was, or may have been, distributed; or

"(D) take any combination of actions described in subparagraphs (A) through (C).

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

"(e) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.

"SEC. 412. REFUSAL OR WITHDRAWAL OF INSPECTION OF ESTABLISHMENTS.

"(a) IN GENERAL.—The Secretary may, for such period, or indefinitely, as the Secretary considers necessary to carry out this Act, refuse to provide or withdraw inspection under title I with respect to an establishment if the Secretary determines, after opportunity for a hearing on the record is provided to the applicant for, or recipient of, inspection, that the applicant or recipient, or any person responsibly connected with the applicant or recipient (within the meaning of section 401), has committed a willful violation or repeated violations of this Act (including a regulation promulgated under this Act).

"(b) DENIAL OR SUSPENSION OF INSPECTION PENDING HEARING.—The Secretary may deny or suspend in-

spection under title I, pending opportunity for an expedited hearing, with respect to an action under subsection (a), if the Secretary determines that the denial or suspension is in the public interest to protect the health or welfare of consumers or to ensure the effective performance of an official duty under this Act.

"(c) JUDICIAL REVIEW.—

"(1) IN GENERAL.—A determination and order of the Secretary with respect to the refusal or withdrawal of inspection under this section shall be final unless, not later than 30 days after the effective date of the order, the affected applicant for, or recipient of, inspection—

"(A) files a petition for judicial review of the order; and

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

"(2) REFUSAL OR WITHDRAWAL OF INSPECTION PENDING REVIEW.—Inspection shall be refused or withdrawn as of the effective date of the order pending any judicial review of the order unless the Secretary directs otherwise.

"(3) VENUE; RECORD.—Judicial review of the order shall be—

"(A) in—

"(i) the United States court of appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business; or

"(ii) the United States Court of Appeals for the District of Columbia Circuit; and

"(B) on the record on which the determination and order are based.

"(d) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.

"SEC. 413. CIVIL PENALTIES.

"(a) IN GENERAL.—

"(1) ASSESSMENT.—The Secretary may assess against a person that violates this Act (including a regulation promulgated or order issued under this Act) a civil penalty for each violation of not more than $100,000.

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

"(3) NOTICE AND OPPORTUNITY FOR HEARING.—The Secretary shall not assess a civil penalty under this section against a person unless the person

is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

"(4) DETERMINATION OF CIVIL PENALTY AMOUNT.—The amount of a civil penalty under this section—

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

"(i) the gravity of the violation;

"(ii) the degree of culpability of the person;

"(iii) the size and type of the business of the person; and

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

"(B) shall be reviewed only in accordance with subsection (b).

"(b) JUDICIAL REVIEW.—

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

"(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in—

"(i) the United States court of appeals for the circuit in which the person resides or has its principal place of business; or

"(ii) the United States Court of Appeals for the District of Columbia Circuit; and

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

"(2) FILING OF COPY OF RECORD.—The Secretary shall promptly file in the court a certified copy of the record on which the order was issued.

"(c) COLLECTION ACTIONS FOR FAILURE TO PAY ASSESSMENT.—

"(1) REFERRAL TO ATTORNEY GENERAL.—If a person fails to pay a civil penalty assessed under subsection (a) after the order assessing the civil penalty has become a final order, or after the court of appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General.

"(2) ACTION BY ATTORNEY GENERAL.—The Attorney General shall bring a civil action to recover the amount of the civil penalty in United States district court.

"(3) SCOPE OF REVIEW.—In a civil action under paragraph (2), the validity and appropriateness of the order of the Secretary assessing the civil penalty shall not be subject to review.

"(d) REFUSAL OR WITHDRAWAL OF INSPECTION PENDING PAYMENT.—If a person fails to pay the amount of a civil penalty after the order assessing the civil penalty has become a final order, the Secretary may refuse to provide or withdraw inspection under title I of the person until the civil penalty is paid or until the Secretary directs otherwise.

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

"(f) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.".

(b) CONFORMING AMENDMENTS.—

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

"(x) PERSON.—The term 'person' means any individual, partnership, corporation, association, or other business unit.".

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

(A) by striking "person, firm, or corporation" each place it appears and inserting "person";

(B) by striking "persons, firms, and corporations" each place it appears and inserting "persons"; and

(C) by striking "persons, firms, or corporations" each place it appears and inserting "persons".

SEC. 3. FOOD SAFETY ENFORCEMENT FOR POULTRY AND POULTRY FOOD PRODUCTS.

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

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

(A) by striking ", by thirty days prior to the expiration of two years after enactment of the Wholesome Poultry Products Act,"; and

(B) by striking "sections 1–4, 6–10, and 12–22 of this Act" and inserting "sections 1

through 4, 6 through 10, 12 through 22, and 31 through 33''; and

(2) by adding at the end the following:

"SEC. 31. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES.

''(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

''(1) IN GENERAL.—A person (other than a household consumer) that has reason to believe that any poultry or poultry product (referred to in this section as an 'article') transported, stored, distributed, or otherwise handled by the person is adulterated or misbranded shall, as soon as practicable, notify the Secretary of the identity and location of the article.

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

''(b) RECALL AND CONSUMER NOTIFICATION.—

''(1) VOLUNTARY ACTIONS.—On receiving notification under subsection (a) or by other means, if the Secretary finds that an article is adulterated or misbranded and that there is a reasonable probability that human consumption of the article would

present a threat to public health (as determined by the Secretary), the Secretary shall provide all appropriate persons (as determined by the Secretary), that transported, stored, distributed, or otherwise handled the article with an opportunity—

"(A) to cease distribution of the article;

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

"(C) to recall the article;

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

"(E) to notify State and local public health officials.

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

"(A) shall require the person—

"(i) to immediately cease distribution of the article; and

"(ii) to immediately make the notification described in paragraph (1)(B); and

"(B) may take control or possession of the article.

"(3) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of the finding of the Secretary under paragraph (1) to consumers to which the article was, or may have been, distributed and to appropriate State and local health officials.

"(4) NONDISTRIBUTION BY NOTIFIED PERSONS.—A person that transports, stores, distributes, or otherwise handles the article, or to which the article has been transported, sold, distributed, or otherwise handled, and that is notified under paragraph (1)(B) or (2)(B) shall cease immediately distribution of the article.

"(5) AVAILABILITY OF RECORDS TO SECRETARY.—Each appropriate person referred to in paragraph (1) that transported, stored, distributed, or otherwise handled an article shall make available to the Secretary information necessary to carry out

this subsection, as determined by the Secretary, regarding—

"(A) persons that transport, store, distribute, or otherwise handle the article; and

"(B) persons to which the article has been transported, sold, distributed, or otherwise handled.

"(c) INFORMAL HEARINGS ON ORDERS.—

"(1) IN GENERAL.—The Secretary shall provide a person subject to an order under subsection (b) with an opportunity for an informal hearing (in accordance with such rules or regulations as the Secretary shall prescribe) on—

"(A) the actions required by the order; and

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

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

"(d) POST-HEARING RECALL ORDERS.—

"(1) AMENDMENT OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (c), the Secretary determines that there is a reasonable probability that human consumption of

the article that is the subject of an order under subsection (b) presents a threat to public health, the Secretary may, as the Secretary determines to be necessary—

"(A) amend the order under subsection (b)—

"(i) to require recall of the article or other appropriate action; and

"(ii) to specify a timetable during which the recall shall occur;

"(B) require periodic reports to the Secretary describing the progress of the recall; or

"(C) provide notice of the recall to consumers to which the article was, or may have been, distributed.

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

"(e) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.

"SEC. 32. REFUSAL OR WITHDRAWAL OF INSPECTION OF ESTABLISHMENTS.

"(a) IN GENERAL.—The Secretary may, for such period, or indefinitely, as the Secretary considers necessary to carry out this Act, refuse to provide or withdraw inspection under this Act with respect to an establishment if the Secretary determines, after opportunity for a hearing on the record is provided to the applicant for, or recipient of, inspection, that the applicant or recipient, or any person responsibly connected with the applicant or recipient (within the meaning of section 18(a)), has committed a willful violation or repeated violations of this Act (including a regulation promulgated under this Act).

"(b) DENIAL OR SUSPENSION OF INSPECTION PENDING HEARING.—The Secretary may deny or suspend inspection under this Act, pending opportunity for an expedited hearing, with respect to an action under subsection (a), if the Secretary determines that the denial or suspension is in the public interest to protect the health or welfare of consumers or to ensure the effective performance of an official duty under this Act.

"(c) JUDICIAL REVIEW.—

"(1) IN GENERAL.—A determination and order of the Secretary with respect to the refusal or withdrawal of inspection under this section shall be final unless, not later than 30 days after the effective

date of the order, the affected applicant for, or recipient of, inspection—

"(A) files a petition for judicial review of the order; and

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

"(2) REFUSAL OR WITHDRAWAL OF INSPECTION PENDING REVIEW.—Inspection shall be refused or withdrawn as of the effective date of the order pending any judicial review of the order unless the Secretary directs otherwise.

"(3) VENUE; RECORD.—Judicial review of the order shall be—

"(A) in—

"(i) the United States court of appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business; or

"(ii) the United States Court of Appeals for the District of Columbia Circuit; and

"(B) on the record on which the determination and order are based.

"(d) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.

"SEC. 33. CIVIL PENALTIES.

"(a) IN GENERAL.—

"(1) ASSESSMENT.—The Secretary may assess against a person that violates this Act (including a regulation promulgated or order issued under this Act) a civil penalty for each violation of not more than $100,000.

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

"(3) NOTICE AND OPPORTUNITY FOR HEARING.—The Secretary shall not assess a civil penalty under this section against a person unless the person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

"(4) DETERMINATION OF CIVIL PENALTY AMOUNT.—The amount of a civil penalty under this section—

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

"(i) the gravity of the violation;

"(ii) the degree of culpability of the person;

"(iii) the size and type of the business of the person; and

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

"(B) shall be reviewed only in accordance with subsection (b).

"(b) JUDICIAL REVIEW.—

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

"(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in—

"(i) the United States court of appeals for the circuit in which the person resides or has its principal place of business; or

"(ii) the United States Court of Appeals for the District of Columbia Circuit; and

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

"(2) FILING OF COPY OF RECORD.—The Secretary shall promptly file in the court a certified copy of the record on which the order was issued.

"(c) COLLECTION ACTIONS FOR FAILURE TO PAY ASSESSMENT.—

"(1) REFERRAL TO ATTORNEY GENERAL.—If a person fails to pay a civil penalty assessed under subsection (a) after the order assessing the civil penalty has become a final order, or after the court of appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General.

"(2) ACTION BY ATTORNEY GENERAL.—The Attorney General shall bring a civil action to recover the amount of the civil penalty in United States district court.

"(3) SCOPE OF REVIEW.—In a civil action under paragraph (2), the validity and appropriateness of the order of the Secretary assessing the civil penalty shall not be subject to review.

"(d) REFUSAL OR WITHDRAWAL OF INSPECTION PENDING PAYMENT.—If a person fails to pay the amount of a civil penalty after the order assessing the civil penalty has become a final order, the Secretary may refuse to provide or withdraw inspection under this Act of the person

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

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

"(f) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.".

SEC. 4. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD.

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

"(oo)(1) The failure to notify the Secretary in violation of section 311(a).

"(2) The failure to comply with—

"(A) an order issued under section 311(b) following any hearing requested under section 311(c); or

"(B) an amended order issued under section 311(d)(1).".

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

"SEC. 311. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD.

"(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

"(1) IN GENERAL.—A person (other than a household consumer or other individual who is the intended consumer of an article of food) that has reason to believe that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that, if consumed, may result in illness or injury shall, as soon as practicable, notify the Secretary of the identity and location of the article.

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

"(b) RECALL AND CONSUMER NOTIFICATION.—

"(1) VOLUNTARY ACTIONS.—On receiving notification under subsection (a) or by other means, if the Secretary finds that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that, if consumed, may result in illness or injury (as determined by the Secretary), the Secretary shall provide all appropriate persons (including the manufacturer, importer, distributor, or retailer of the article) with an opportunity (as determined by the Secretary)—

"(A) to cease distribution of the article;

"(B) to notify all persons—

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

"(ii) to which the article has been distributed, transported, or sold, to cease immediately distribution of the article;

"(C) to recall the article;

"(D) in consultation with the Secretary, to provide notice of the finding of the Secretary to

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

"(E) to notify State and local public health officials.

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

"(A) shall require the person—

"(i) to immediately cease distribution of the article; and

"(ii) to immediately make the notification described in paragraph (1)(B); and

"(B) may take control or possession of the article.

"(3) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of the finding of the Secretary under paragraph (1) to consumers to which the article was, or may have been, distributed and to appropriate State and local health officials.

"(c) HEARINGS ON ORDERS.—

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

"(A) the actions required by the order; and

"(B) any reasons why the article of food that is the subject of the order should not be recalled.

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

"(d) POST-HEARING RECALL ORDERS.—

"(1) AMENDMENT OF ORDERS.—If, after providing an opportunity for a hearing under subsection (c), the Secretary determines that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that, if consumed, may result in illness or injury, the Secretary may, as the Secretary determines to be necessary—

"(A) amend the order under subsection (b)—

"(i) to require recall of the article or other appropriate action; and

"(ii) to specify a timetable during which the recall shall occur;

"(B) require periodic reports to the Secretary describing the progress of the recall; or

"(C) provide notice of the recall to consumers to which the article was, or may have been, distributed.

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

"(e) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.

"SEC. 312. CIVIL PENALTIES RELATING TO FOODS.

"(a) IN GENERAL.—

"(1) ASSESSMENT.—The Secretary may assess against a person that commits an act prohibited by section 301 with respect to an article of food a civil penalty for each such act of not more than—

"(A) $100,000, in the case of an individual; and

"(B) $500,000, in the case of any other person.

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

"(3) NOTICE AND OPPORTUNITY FOR HEARING.—The Secretary shall not assess a civil penalty under this section against a person unless the person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

"(4) DETERMINATION OF CIVIL PENALTY AMOUNT.—The amount of a civil penalty under this section—

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

"(i) the gravity of the violation;

"(ii) the degree of culpability of the person;

"(iii) the size and type of the business of the person; and

"(iv) any history of prior offenses by the person; and

"(B) shall be reviewed only in accordance with subsection (b).

"(b) JUDICIAL REVIEW.—

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

"(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in—

"(i) the United States court of appeals for the circuit in which the person resides or has its principal place of business; or

"(ii) the United States Court of Appeals for the District of Columbia Circuit; and

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

"(2) FILING OF COPY OF RECORD.—The Secretary shall promptly file in the court a certified copy of the record on which the order was issued.

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

"(c) COLLECTION ACTIONS FOR FAILURE TO PAY ASSESSMENT.—

"(1) REFERRAL TO ATTORNEY GENERAL.—If a person fails to pay a civil penalty assessed under subsection (a) after the order assessing the civil penalty has become a final order, or after the court of appeals has entered final judgment in favor of the Secretary, the Secretary may refer the matter to the Attorney General.

"(2) ACTION BY ATTORNEY GENERAL.—The Attorney General shall bring a civil action to recover the amount of the civil penalty in United States district court.

"(3) SCOPE OF REVIEW.—In a civil action under paragraph (2), the validity and appropriateness of the order of the Secretary assessing the civil penalty shall not be subject to review.

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

"(e) PENALTIES IN LIEU OF OTHER ACTIONS.—Nothing in this Act requires the Secretary to report for prosecution, or for the commencement of any libel or injunction proceeding, any violation of this Act in any case in which the Secretary believes that the public interest will be adequately served by the assessment of a 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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