I

110TH CONGRESS
1ST SESSION

H. R. 3610

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food and drugs imported into the United States, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2007

Mr. DINGELL (for himself, Mr. PALLONE, and Mr. STUPAK) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food and drugs imported into the United States, 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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Food and Drug Import Safety Act of 2007''.

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

SEC. 2. RESEARCH ON TESTING TECHNIQUES FOR USE IN INSPECTIONS OF IMPORTED FOOD SAFETY; PRIORITY REGARDING DETECTION OF INTENTIONAL ADULTERATION.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

''(p) RESEARCH ON TESTING TECHNIQUES FOR USE IN INSPECTIONS OF IMPORTED FOOD SAFETY.—

''(1) IN GENERAL.—The Secretary shall (directly or through grants or contracts) provide for research on the development of tests and sampling methodologies, for use in inspections of food under this section—

''(A) whose purpose is to determine whether food is adulterated by reason of being contaminated with microorganisms, chemical toxins, or pesticide chemicals or related residues; and

"(B) whose results are available not later than approximately 60 minutes after the administration of the tests.

"(2) PRIORITY.—In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States, with the greatest priority given to the development of such tests that the Secretary determines would be useful in detecting the intentional adulteration of food. In providing for research under paragraph (1), the Secretary shall under the preceding sentence give priority to conducting research on the development of tests for detecting the presence in food of the pathogens E. coli, salmonella, cyclospora, cryptosporidium, hepatitis A, or listeria, the presence in or on food of pesticide chemicals and related residues, the presence in or on food of chemical toxins, and the presence in or on food of such other pathogens or substances as the Secretary determines to be appropriate, including any pathogen or substance that the Secretary determines is a candidate for use to intentionally adulterate food. The Secretary shall establish the goal of developing, by the expiration of the

3-year period beginning on the date of the enactment of the this subsection, tests under paragraph (1) for each of the pathogens and substances receiving priority under the preceding sentence.

''(3) PERIODIC REPORTS.—The Secretary shall submit to the Congress periodic reports describing the progress that has been made toward the goal referred to in paragraph (1) and describing plans for future research toward the goal. Each of the reports shall provide an estimate by the Secretary of the amount of funds needed to meet such goal, and shall provide a determination by the Secretary of whether there is a need for further research under this subsection. The first such report shall be submitted not later than March 1, 2008, and subsequent reports shall be submitted semiannually after the submission of the first report until the goal is met.

''(4) CONSULTATION.—The Secretary shall carry out the program of research under paragraph (1) in consultation with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Administrator of the Environmental Protection Agency. The Secretary shall with respect to such research coordinate the activities of the Department of Health and

Human Services. The Secretary shall in addition consult with the Secretary of Agriculture (acting through the Food Safety and Inspection Service of the Department of Agriculture) in carrying out the program.''.

SEC. 3. USER FEES REGARDING INSPECTIONS OF IMPORTED FOOD SAFETY.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by inserting after section 801 the following:

''USER FEES REGARDING FOOD SAFETY

''SEC. 801A. (a) IN GENERAL.—

''(1) ASSESSMENT.—Beginning in fiscal year 2008, the Secretary shall in accordance with this section assess and collect fees on food imported into the United States.

''(2) PURPOSE OF FEES.—

''(A) IN GENERAL.—The purpose of fees under paragraph (1) is to defray the costs of carrying out section 801 with respect to food over the costs of carrying out such section with respect to food in fiscal year 2007 multiplied by the adjustment factor. Fees under paragraph (1) may be used to pay for overseas inspection with respect to food by the Department of Health and Human Services.

"(B) ALLOCATIONS BY SECRETARY.—Of the total fee revenues collected under paragraph (1) for a fiscal year, the Secretary shall reserve and expend amounts in accordance with the following:

"(i) The Secretary shall reserve not less than 90 percent for carrying out section 801 with respect to food, other than research under section 801(p). In expending the amount so reserved, the Secretary shall give priority to inspections conducted at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

"(ii) The Secretary shall reserve not more than 10 percent for carrying out research under section 801(p).

"(C) LABORATORY TESTING.—In this paragraph, the term 'costs of carrying out section 801' with respect to food being imported or offered for import includes the costs of laboratory testing of such food, including laboratory personnel costs.

''(3) AMOUNT OF FEE; COLLECTION.—A fee under paragraph (1) shall be assessed on each line item of food, as defined by the Secretary by regulation. The amount of the fee shall be based on the number of line items, and may not exceed $50 per line item, notwithstanding subsection (b). The liability for the fee constitutes a personal debt due to the United States, and such liability accrues on the date on which the Secretary approves the food under section 801(c)(1). The Secretary may coordinate with and seek the cooperation of other agencies of the Federal Government regarding the collection of such fees.

''(b) TOTAL FEE REVENUES.—The total fee revenues collected under subsection (a) for a fiscal year shall be the amount appropriated under subsection (f)(3).

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—With respect to the amount of total fee revenues referred to in subsection (b), the amount authorized in subsection (f)(3) for a fiscal year shall be adjusted by the Secretary (and as adjusted shall be published in the Federal Register) to reflect the greater of—

''(A) the total percentage change that occurred during the preceding fiscal year in the

Consumer Price Index for all urban consumers (all items; U.S. city average); or

''(B) the total percentage change for such fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

''(2) ANNUAL FEE ADJUSTMENT.—Not later than 60 days after the end of each fiscal year beginning after fiscal year 2008, the Secretary, subject to not exceeding the maximum fee amount specified in subsection (a)(3), shall adjust the amounts that otherwise would under subsection (a) be assessed as fees during the fiscal year in which the adjustment occurs so that the total revenues collected in such fees for such fiscal year equal the amount applicable pursuant to subsection (b) for the fiscal year.

''(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of a fee assessed under subsection (a) where the Secretary finds that the fee to be paid will exceed the anticipated present and future costs incurred by the Secretary in carrying out sec-

tion 801 with respect to food (which finding may be made by the Secretary using standard costs).

''(e) ASSESSMENT OF FEES.—

''(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless the amount appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year is equal to or greater than the amount appropriated for salaries and expenses of the Food and Drug Administration for fiscal year 2008 multiplied by the adjustment factor applicable to the fiscal year involved, except that in making determinations under this paragraph for the fiscal years involved there shall be excluded—

''(A) the amounts appropriated under subsection (f)(3) for the fiscal years involved;

''(B) the amounts appropriated under section 801B(f)(3) for such fiscal years; and

''(C) the amounts appropriated under section 736(g) for such fiscal years.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect

such fees, without any modification in the rate of the fees, at any time in such fiscal year notwithstanding the provisions of subsection (a)(3) relating to the time at which fees are to be paid.

''(f) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for carrying out section 801 with respect to food, and the sums are subject to allocations under subsection (a)(2)(B).

''(2) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized in subsection (a)—

''(A) shall be collected in each fiscal year in accordance with subsections (a)(3) and (b); and

"(B) shall only be collected and available for the purpose specified in subsection (a)(2).

"(3) AUTHORIZATION OF APPROPRIATIONS; ALLOCATIONS BY SECRETARY.—Subject to paragraph (4) and subsection (c)(1), there is authorized to be appropriated for fees under this section $500,000,000 for each of the fiscal years 2008 through 2012.

"(4) OFFSET.—Any amount of fees collected for a fiscal year under subsection (a) that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

"(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(h) CONSTRUCTION.—This section may not be construed as requiring that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in carrying out section 801 with respect to food be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(i) DEFINITION OF ADJUSTMENT FACTOR.—For purposes of this section, the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April 2007.''.

SEC. 4. USER FEES REGARDING INSPECTIONS OF IMPORTED DRUG SAFETY.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section 3, is further amended by inserting after section 801A the following:

''USER FEES REGARDING DRUG SAFETY

''SEC. 801B. (a) IN GENERAL.—

''(1) ASSESSMENT.—Beginning in fiscal year 2008, the Secretary shall in accordance with this section assess and collect fees on drugs imported into the United States.

''(2) PURPOSE OF FEES.—

"(A) IN GENERAL.—The purpose of fees under paragraph (1) is to defray the costs of carrying out section 801 with respect to drugs over the costs of carrying out such section with respect to drugs in fiscal year 2007 multiplied by the adjustment factor. Fees under paragraph (1) may be used to pay for overseas inspection with respect to drugs by the Department of Health and Human Services.

"(B) PRIORITY.—In expending the fee revenue amounts collected under paragraph (1), the Secretary shall give priority to—

"(i) inspections conducted at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration or misbranding of drugs; and

"(ii) inspections of good manufacturing practices conducted abroad.

"(C) LABORATORY TESTING.—In this paragraph, the term 'costs of carrying out section 801' with respect to drugs being imported or offered for import includes the costs of laboratory testing of such drugs, including laboratory personnel costs.

''(3) AMOUNT OF FEE; COLLECTION.—A fee under paragraph (1) shall be assessed on each line item of drugs, as defined by the Secretary by regulation. The amount of the fee shall be based on the number of line items, and may not exceed $1000 per line item, notwithstanding subsection (b). The liability for the fee constitutes a personal debt due to the United States, and such liability accrues on the date on which the Secretary approves the drugs under section 801(c)(1). The Secretary may coordinate with and seek the cooperation of other agencies of the Federal Government regarding the collection of such fees.

''(b) TOTAL FEE REVENUES.—The total fee revenues collected under subsection (a) for a fiscal year shall be the amount appropriated under subsection (f)(3).

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—With respect to the amount of total fee revenues referred to in subsection (b), the amount authorized in subsection (f)(3) for a fiscal year shall be adjusted by the Secretary (and as adjusted shall be published in the Federal Register) to reflect the greater of—

''(A) the total percentage change that occurred during the preceding fiscal year in the

Consumer Price Index for all urban consumers (all items; U.S. city average); or

"(B) the total percentage change for such fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

"(2) ANNUAL FEE ADJUSTMENT.—Not later than 60 days after the end of each fiscal year beginning after fiscal year 2008, the Secretary, subject to not exceeding the maximum fee amount specified in subsection (a)(3), shall adjust the amounts that otherwise would under subsection (a) be assessed as fees during the fiscal year in which the adjustment occurs so that the total revenues collected in such fees for such fiscal year equal the amount applicable pursuant to subsection (b) for the fiscal year.

"(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of a fee assessed under subsection (a) where the Secretary finds that the fee to be paid will exceed the anticipated present and future costs incurred by the Secretary in carrying out sec-

tion 801 with respect to drugs (which finding may be made by the Secretary using standard costs).

''(e) ASSESSMENT OF FEES.—

''(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless the amount appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year is equal to or greater than the amount appropriated for salaries and expenses of the Food and Drug Administration for fiscal year 2008 multiplied by the adjustment factor applicable to the fiscal year involved, except that in making determinations under this paragraph for the fiscal years involved there shall be excluded—

''(A) the amounts appropriated under subsection (f)(3) for the fiscal years involved;

''(B) the amounts appropriated under section 801A(f)(3) for such fiscal years; and

''(C) the amounts appropriated under section 736(g) for such fiscal years.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect

such fees, without any modification in the rate of the fees, at any time in such fiscal year notwithstanding the provisions of subsection (a)(3) relating to the time at which fees are to be paid.

''(f) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for carrying out section 801 with respect to drugs.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized in subsection (a)—

''(A) shall be collected in each fiscal year in accordance with subsections (a)(3) and (b); and

''(B) shall only be collected and available for the purpose specified in subsection (a)(2).

''(3) AUTHORIZATION OF APPROPRIATIONS; ALLOCATIONS BY SECRETARY.—Subject to paragraph (4) and subsection (c)(1), there is authorized to be appropriated for fees under this section $300,000,000 for each of the fiscal years 2008 through 2012.

''(4) OFFSET.—Any amount of fees collected for a fiscal year under subsection (a) that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

''(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(h) CONSTRUCTION.—This section may not be construed as requiring that the number of full-time equivalent positions in the Department of Health and Human Serv-

ices, for officers, employees, and advisory committees not engaged in carrying out section 801 with respect to drugs be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(i) DEFINITION OF ADJUSTMENT FACTOR.—For purposes of this section, the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April 2007.''.

SEC. 5. AUTHORITY TO RESTRICT FOOD IMPORTATION TO SPECIFIC PORTS OF ENTRY.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended by section 2, is further amended by adding at the end the following:

''(q) AUTHORITY TO RESTRICT FOOD IMPORTATION TO SPECIFIC PORTS OF ENTRY.—

''(1) IN GENERAL.—The Secretary shall restrict the importation of all food to ports of entry that are located in a metropolitan area with a laboratory of the Food and Drug Administration for testing such food.

''(2) WAIVER.—The Secretary may waive the requirement of paragraph (1) and authorize the im-

portation of food to a port of entry not described in such paragraph if the Secretary certifies that—

''(A) the importation of such food through such port will not increase the probability that such food will cause serious, adverse health consequences or death; or

''(B) there is a reasonable probability that the type food involved will not cause serious, adverse health consequences or death.

''(3) IMPLEMENTATION.—The Secretary shall implement this subsection beginning not later than 5 years after the date of the enactment of this subsection.''.

SEC. 6. COUNTRY OF ORIGIN LABELING.

(a) FOOD.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(z) If the labeling of the food fails to identify the country of origin of the food.''.

(b) DRUGS AND DEVICES.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(y) If it is a drug or device and its labeling fails to identify the country of origin of the drug or device.''.

(c) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall promulgate final regulations to carry out sections 403(z) and 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), respectively.

(d) EFFECTIVE DATE.—The requirements of sections 403(z) and 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), respectively, take effect on the date that is 180 days after the date of the enactment of this Act.

SEC. 7. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

"SEC. 805. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

''(a) IN GENERAL.—Beginning not later than 2 years after the date of the enactment of this section, the Secretary shall establish by regulation and carry out a program under which—

''(1) persons importing food into the United States voluntarily agree to abide by the food safety and security guidelines developed under subsection (b); and

''(2) the Secretary agrees to expedite the movement of such food through the inspection process.

''(b) GUIDELINES.—

''(1) DEVELOPMENT.—For purposes of the program established under subsection (a), the Secretary shall develop safety and security guidelines applicable to the importation of food.

''(2) FACTORS.—The guidelines developed under paragraph (1) shall take into account the following factors:

''(A) The personnel of the person importing the food.

''(B) The physical and procedural safety and security of such person's food supply chain.

''(C) The sufficiency of access controls for food and ingredients purchased by such person.

''(D) The need for tracking and maintaining records on food and ingredients purchased by such person or moved through the supply chain.

''(E) Documentation processing through such person's supply chain.

''(F) Access by the Secretary to such person's business records for review.

''(G) Vendor and supplier information.

''(H) Such other factors as the Secretary determines necessary.''.

SEC. 8. CIVIL PENALTIES.

Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

(1) by redesignating subsection (g) (relating to civil penalties) as subsection (f): and

(2) in subparagraph (A) of paragraph (2) of subsection (f), as so redesignated, by striking ''Any person who introduces'' and all that follows through the end of the subparagraph and inserting the following: ''Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil money penalty of—

''(i) not more than $50,000 in the case of any individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding; or

''(ii) notwithstanding clause (i), if such person is the manufacturer or the importer of the food, not more than $100,000 in the case of any individual and $500,000 in the case of

any other person for such introduction or delivery, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.''.

SEC. 9. CONTINUED OPERATION OF FIELD LABORATORIES.

(a) IN GENERAL.—Subject to subsections (b) and (d), the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall not—

(1) terminate any of the 13 field laboratories that were operated by the Office of Regulatory Affairs of the Food and Drug Administration as of January 1, 2007;

(2) consolidate any such laboratory with any other laboratory;

(3) terminate any of the 20 district offices or any of the inspection or compliance functions of any of the 20 district offices of the Food and Drug Administration functioning as of January 1, 2007; or

(4) consolidate—

(A) any such district office with an office in any other district; or

(B) transfer any of the compliance or inspection functions of any such district office to any other district.

(b) REPORT BY SECRETARY.—

(1) SUBMISSION.—The Secretary shall submit a reorganization plan involving the termination or consolidation of the laboratories, the district offices, or the functions of such district offices specified in subsection (a) to the Comptroller General, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

(2) CONSULTATION.—In preparing the reorganization plan described in paragraph (1), the Secretary shall consult with personnel and unions to be affected by the plan.

(c) REPORT BY GAO.—The Comptroller General shall study the cost effectiveness of the reorganization plan described in subsection (b) and its impact on the safety of food, drug, and other products regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) and report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(d) REORGANIZATION.—

(1) CONGRESSIONAL REVIEW.—The reorganization plan described in subsection (b) is deemed to be a major rule (as defined in section 804(2) of title 5,

United States Code) for purposes of chapter 8 of such title.

(2) EFFECTIVE DATE.—Notwithstanding section 801(a)(3) of title 5, United States Code, the reorganization plan described in subsection (b) shall take effect (unless disapproved under section 802 of such title) on the date that is 180 days after the date on which the Comptroller General submits the report required by subsection (c).

SEC. 10. RECALL AUTHORITY.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by section 6 of this Act, is amended by adding at the end the following:

"SEC. 418. RECALL AUTHORITY.

"(a) ORDER TO CEASE DISTRIBUTION.—

"(1) IN GENERAL.—If the Secretary finds that a food may cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the food) to immediately cease distribution of the food.

"(2) INFORMAL HEARING.—An order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing,

to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of the food involved. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(b) ORDER TO RECALL.—

''(1) IN GENERAL.—If, after providing an opportunity for an informal hearing under subsection (a)(2), the Secretary determines that the order should be amended to include a recall of the food with respect to which the order was issued, the Secretary shall, except as provided in paragraphs (2) and (3), amend the order to require a recall. The Secretary shall specify a timetable in which the food recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(2) CERTAIN ACTIONS.—An amended order under paragraph (1) shall not include recall of a food from individuals.''.

SEC. 11. INSPECTION AND OTHER STANDARDS; APPLICABILITY, ENFORCEMENT; CERTIFICATIONS.

Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by section 10 of this Act, is amended by adding at the end the following:

"SEC. 419. INSPECTION AND OTHER STANDARDS; APPLICABILITY, ENFORCEMENT; CERTIFICATIONS.

''(a) IN GENERAL.—Notwithstanding any other provision of law, all food that is offered for importation into the United States shall be subject to the food safety standards applied to such food produced in the United States.

''(b) ENFORCEMENT.—Any food that appears to not meet all the standards referred to in subsection (a) shall be considered adulterated and shall not be permitted entry into the United States.

''(c) RANDOM INSPECTIONS.—The Secretary shall enforce this section through appropriate random inspections, sampling, and testing.

''(d) CERTIFICATIONS REGARDING FOREIGN FACILITIES.—

''(1) REQUIREMENT.—No food shall be permitted entry into the United States from a foreign facility in a foreign country unless there is—

''(A) a certification for such facility in effect under paragraph (2)(A); or

''(B) a certification for such country under paragraph (2)(B).

''(2) CERTIFICATION.—

''(A) FOREIGN FACILITY.—Each foreign facility seeking to import food into the United States may obtain a certification by the Secretary stating that the facility maintains a program using reliable analytical methods to ensure compliance with all the standards referred to in subsection (a).

''(B) FOREIGN COUNTRY.—A foreign country may obtain a certification by the Secretary stating that—

''(i) the country has in effect and is enforcing food safety standards at least as protective of food safety as the standards applicable to food in the United States; and

''(ii) the country has a program in effect to monitor and enforce its food safety standards with respect to food being exported from such country to the United States.

''(3) PERIODIC REVIEW.—The Secretary shall periodically review certifications under paragraph (2)

and shall revoke any certification if the Secretary determines that the foreign facility or foreign country involved is no longer meeting the requirements described in such paragraph.

''(4) INSPECTION.—The consideration of any application for a certification under paragraph (2) and the review of any such certification, by the Secretary, may include the inspection of foreign facilities to ensure that the inspection program of the foreign facility involved is meeting such standards.

''(5) FOREIGN FACILITY.—In this subsection, the term 'foreign facility' means a foreign facility (as defined in section 415(b)(3)) that is required to be registered under section 415.

''(6) EFFECTIVE DATE.—This subsection takes effect beginning on the date that is 5 years after the date of the enactment of the Food and Drug Import Safety Act of 2007.''.

SEC. 12. REGULATIONS ON ADEQUATE TESTING OF PROCESSED FOOD.

Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by section 11 of this Act, is amended by adding at the end the following:

"SEC. 420. REGULATIONS ON ADEQUATE TESTING OF PROCESSED FOOD.

''(a) IN GENERAL.—Not later than 2 years after the date of the enactment of the Food and Drug Import Safety Act of 2007, the Secretary shall by regulation require that, as good manufacturing practices, processed food undergo testing to detect substances in the food that may render the food adulterated, including microbial pathogens, toxic chemicals, and such other substances as the Secretary determines to be appropriate.

''(b) REVIEW OF TEST RESULTS.—Regulations under subsection (a) shall require that the results of tests under such subsection be provided to the Secretary upon demand.''.

SEC. 13. RECORDS OF INTERSTATE SHIPMENT.

Subsection (a) of section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

(1) by striking ''upon the request'' and inserting ''upon the written or oral request''; and

(2) by striking '', except that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained, and except that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food,

drugs, devices, or cosmetics in the usual course of business as carriers, except as provided in subsection (b)''.

SEC. 14. LABELING REQUIREMENT FOR MEAT, POULTRY PRODUCTS, AND SEAFOOD THAT CONTAIN CARBON MONOXIDE.

(a) LABELING REQUIREMENT.—

(1) IN GENERAL.—Paragraph (t) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(t)) is amended by adding at the end the following new paragraph:

''(4) In the case of food that is meat within the meaning of the Federal Meat Inspection Act, a poultry product within the meaning of the Poultry Products Inspection Act, or seafood (including all fresh or saltwater finfish, molluscan shellfish, crustaceans, and other forms of aquatic animal life) intended for human consumption as food within the meaning of section 201(f) of this Act (referred to collectively in this subsection as 'seafood'), the term 'color additive' shall include carbon monoxide under conditions of use that may impart, maintain, preserve, stabilize, fix, or otherwise affect the color of fresh meat, poultry products, or seafood, unless the label of such food bears, prominently and conspicuously in such

place and in such manner as to render it likely to be read and understood by the ordinary person, the following statement to prevent consumer deception and serious risks to the public health: 'SAFETY NOTICE: Carbon monoxide has been used to preserve the color of this product. Do not rely on color or the ''use or freeze by'' date alone to judge the freshness or safety of the product. Discard any product with an unpleasant odor, slime, or a bulging package.' ''.

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply to food labeled on or after the date that is 30 days after the date of the enactment of this Act.

(b) DISCRETIONARY AUTHORITY.—If, not earlier than 5 years after the effective date described in subsection (a)(1), the Secretary of Health and Human Services finds, based on competent and reliable scientific evidence, that the statement prescribed in section 201(t)(4) of the Federal Food, Drug, and Cosmetic Act is no longer required to prevent consumer deception and other harms, then the Secretary is authorized to issue regulations establishing alternative labeling requirements that are shown to be adequate and effective in preventing consumer deception and other harms related to the conditions of use

of carbon monoxide, including with respect to preventing any consumer deception or other harm that may result from the actual conditions of carbon monoxide use and its potential to impart a persistent color to meat, poultry products, or seafood described in such section through a reaction with natural pigment.

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