

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Food and Drug Import Safety Act of 2007”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Research on testing techniques for use in inspections of imported food safety; priority regarding detection of intentional adulteration.

Sec. 3. User fees regarding inspections of imported food safety.

- Sec. 4. User fees regarding inspections of imported drug safety.
 Sec. 5. Authority to restrict food importation to specific ports of entry.
 Sec. 6. Country of origin labeling.
 Sec. 7. Safe and secure food importation program.
 Sec. 8. Civil penalties.
 Sec. 9. Continued operation of field laboratories.
 Sec. 10. Recall authority.
 Sec. 11. Inspection and other standards; applicability, enforcement; certifications.
 Sec. 12. Regulations on adequate testing of processed food.
 Sec. 13. Records of interstate shipment.
 Sec. 14. Labeling requirement for meat, poultry products, and seafood that contain carbon monoxide.

1 **SEC. 2. RESEARCH ON TESTING TECHNIQUES FOR USE IN**
 2 **INSPECTIONS OF IMPORTED FOOD SAFETY;**
 3 **PRIORITY REGARDING DETECTION OF INTEN-**
 4 **TIONAL ADULTERATION.**

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

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

10 “(1) IN GENERAL.—The Secretary shall (di-
 11 rectly or through grants or contracts) provide for re-
 12 search on the development of tests and sampling
 13 methodologies, for use in inspections of food under
 14 this section—

15 “(A) whose purpose is to determine wheth-
 16 er food is adulterated by reason of being con-
 17 taminated with microorganisms, chemical tox-
 18 ins, or pesticide chemicals or related residues;
 19 and

1 “(B) whose results are available not later
2 than approximately 60 minutes after the ad-
3 ministration of the tests.

4 “(2) PRIORITY.—In providing for research
5 under paragraph (1), the Secretary shall give pri-
6 ority to conducting research on the development of
7 tests that are suitable for inspections of food at
8 ports of entry into the United States, with the great-
9 est priority given to the development of such tests
10 that the Secretary determines would be useful in de-
11 tecting the intentional adulteration of food. In pro-
12 viding for research under paragraph (1), the Sec-
13 retary shall under the preceding sentence give pri-
14 ority to conducting research on the development of
15 tests for detecting the presence in food of the patho-
16 gens *E. coli*, salmonella, cyclospora, cryptosporidium,
17 hepatitis A, or listeria, the presence in or on food of
18 pesticide chemicals and related residues, the pres-
19 ence in or on food of chemical toxins, and the pres-
20 ence in or on food of such other pathogens or sub-
21 stances as the Secretary determines to be appro-
22 priate, including any pathogen or substance that the
23 Secretary determines is a candidate for use to inten-
24 tionally adulterate food. The Secretary shall estab-
25 lish the goal of developing, by the expiration of the

1 3-year period beginning on the date of the enact-
2 ment of the this subsection, tests under paragraph
3 (1) for each of the pathogens and substances receiv-
4 ing priority under the preceding sentence.

5 “(3) PERIODIC REPORTS.—The Secretary shall
6 submit to the Congress periodic reports describing
7 the progress that has been made toward the goal re-
8 ferred to in paragraph (1) and describing plans for
9 future research toward the goal. Each of the reports
10 shall provide an estimate by the Secretary of the
11 amount of funds needed to meet such goal, and shall
12 provide a determination by the Secretary of whether
13 there is a need for further research under this sub-
14 section. The first such report shall be submitted not
15 later than March 1, 2008, and subsequent reports
16 shall be submitted semiannually after the submission
17 of the first report until the goal is met.

18 “(4) CONSULTATION.—The Secretary shall
19 carry out the program of research under paragraph
20 (1) in consultation with the Director of the Centers
21 for Disease Control and Prevention, the Director of
22 the National Institutes of Health, and the Adminis-
23 trator of the Environmental Protection Agency. The
24 Secretary shall with respect to such research coordi-
25 nate the activities of the Department of Health and

1 Human Services. The Secretary shall in addition
2 consult with the Secretary of Agriculture (acting
3 through the Food Safety and Inspection Service of
4 the Department of Agriculture) in carrying out the
5 program.”.

6 **SEC. 3. USER FEES REGARDING INSPECTIONS OF IM-**
7 **PORTED FOOD SAFETY.**

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

11 “USER FEES REGARDING FOOD SAFETY

12 “SEC. 801A. (a) IN GENERAL.—

13 “(1) ASSESSMENT.—Beginning in fiscal year
14 2008, the Secretary shall in accordance with this
15 section assess and collect fees on food imported into
16 the United States.

17 “(2) PURPOSE OF FEES.—

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

1 “(B) ALLOCATIONS BY SECRETARY.—Of
2 the total fee revenues collected under paragraph
3 (1) for a fiscal year, the Secretary shall reserve
4 and expend amounts in accordance with the fol-
5 lowing:

6 “(i) The Secretary shall reserve not
7 less than 90 percent for carrying out sec-
8 tion 801 with respect to food, other than
9 research under section 801(p). In expend-
10 ing the amount so reserved, the Secretary
11 shall give priority to inspections conducted
12 at ports of entry into the United States,
13 with the greatest priority given to inspec-
14 tions to detect the intentional adulteration
15 of food.

16 “(ii) The Secretary shall reserve not
17 more than 10 percent for carrying out re-
18 search under section 801(p).

19 “(C) LABORATORY TESTING.—In this
20 paragraph, the term ‘costs of carrying out sec-
21 tion 801’ with respect to food being imported or
22 offered for import includes the costs of labora-
23 tory testing of such food, including laboratory
24 personnel costs.

1 “(3) AMOUNT OF FEE; COLLECTION.—A fee
2 under paragraph (1) shall be assessed on each line
3 item of food, as defined by the Secretary by regula-
4 tion. The amount of the fee shall be based on the
5 number of line items, and may not exceed \$50 per
6 line item, notwithstanding subsection (b). The liabil-
7 ity for the fee constitutes a personal debt due to the
8 United States, and such liability accrues on the date
9 on which the Secretary approves the food under sec-
10 tion 801(c)(1). The Secretary may coordinate with
11 and seek the cooperation of other agencies of the
12 Federal Government regarding the collection of such
13 fees.

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

17 “(c) ADJUSTMENTS.—

18 “(1) INFLATION ADJUSTMENT.—With respect
19 to the amount of total fee revenues referred to in
20 subsection (b), the amount authorized in subsection
21 (f)(3) for a fiscal year shall be adjusted by the Sec-
22 retary (and as adjusted shall be published in the
23 Federal Register) to reflect the greater of—

24 “(A) the total percentage change that oc-
25 curred during the preceding fiscal year in the

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

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

10 “(2) ANNUAL FEE ADJUSTMENT.—Not later
11 than 60 days after the end of each fiscal year begin-
12 ning after fiscal year 2008, the Secretary, subject to
13 not exceeding the maximum fee amount specified in
14 subsection (a)(3), shall adjust the amounts that oth-
15 erwise would under subsection (a) be assessed as
16 fees during the fiscal year in which the adjustment
17 occurs so that the total revenues collected in such
18 fees for such fiscal year equal the amount applicable
19 pursuant to subsection (b) for the fiscal year.

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

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

3 “(e) ASSESSMENT OF FEES.—

4 “(1) LIMITATION.—Fees may not be assessed
5 under subsection (a) for a fiscal year beginning after
6 fiscal year 2008 unless the amount appropriated for
7 salaries and expenses of the Food and Drug Admin-
8 istration for such fiscal year is equal to or greater
9 than the amount appropriated for salaries and ex-
10 penses of the Food and Drug Administration for fis-
11 cal year 2008 multiplied by the adjustment factor
12 applicable to the fiscal year involved, except that in
13 making determinations under this paragraph for the
14 fiscal years involved there shall be excluded—

15 “(A) the amounts appropriated under sub-
16 section (f)(3) for the fiscal years involved;

17 “(B) the amounts appropriated under sec-
18 tion 801B(f)(3) for such fiscal years; and

19 “(C) the amounts appropriated under sec-
20 tion 736(g) for such fiscal years.

21 “(2) AUTHORITY.—If the Secretary does not
22 assess fees under subsection (a) during any portion
23 of a fiscal year because of paragraph (1) and if at
24 a later date in such fiscal year the Secretary may as-
25 sess such fees, the Secretary may assess and collect

1 such fees, without any modification in the rate of
2 the fees, at any time in such fiscal year notwith-
3 standing the provisions of subsection (a)(3) relating
4 to the time at which fees are to be paid.

5 “(f) CREDITING AND AVAILABILITY OF FEES.—

6 “(1) IN GENERAL.—Fees collected for a fiscal
7 year pursuant to subsection (a) shall be credited to
8 the appropriation account for salaries and expenses
9 of the Food and Drug Administration and shall be
10 available in accordance with appropriation Acts until
11 expended without fiscal year limitation. Such sums
12 as may be necessary may be transferred from the
13 Food and Drug Administration salaries and ex-
14 penses appropriation account without fiscal year lim-
15 itation to such appropriation account for salaries
16 and expenses with such fiscal year limitation. The
17 sums transferred shall be available solely for car-
18 rying out section 801 with respect to food, and the
19 sums are subject to allocations under subsection
20 (a)(2)(B).

21 “(2) COLLECTIONS AND APPROPRIATION
22 ACTS.—The fees authorized in subsection (a)—

23 “(A) shall be collected in each fiscal year
24 in accordance with subsections (a)(3) and (b);
25 and

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

3 “(3) AUTHORIZATION OF APPROPRIATIONS; AL-
4 LOCATIONS BY SECRETARY.—Subject to paragraph
5 (4) and subsection (c)(1), there is authorized to be
6 appropriated for fees under this section
7 \$500,000,000 for each of the fiscal years 2008
8 through 2012.

9 “(4) OFFSET.—Any amount of fees collected
10 for a fiscal year under subsection (a) that exceeds
11 the amount of fees specified in appropriation Acts
12 for such fiscal year shall be credited to the appro-
13 priation account of the Food and Drug Administra-
14 tion as provided in paragraph (1), and shall be sub-
15 tracted from the amount of fees that would other-
16 wise be authorized to be collected under this section
17 pursuant to appropriation Acts for a subsequent fis-
18 cal year.

19 “(g) COLLECTION OF UNPAID FEES.—In any case
20 where the Secretary does not receive payment of a fee as-
21 sessed under subsection (a) within 30 days after it is due,
22 such fee shall be treated as a claim of the United States
23 Government subject to subchapter II of chapter 37 of title
24 31, United States Code.

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

10 “(B) PRIORITY.—In expending the fee rev-
11 enue amounts collected under paragraph (1),
12 the Secretary shall give priority to—

13 “(i) inspections conducted at ports of
14 entry into the United States, with the
15 greatest priority given to inspections to de-
16 tect the intentional adulteration or mis-
17 branding of drugs; and

18 “(ii) inspections of good manufac-
19 turing practices conducted abroad.

20 “(C) LABORATORY TESTING.—In this
21 paragraph, the term ‘costs of carrying out sec-
22 tion 801’ with respect to drugs being imported
23 or offered for import includes the costs of lab-
24 oratory testing of such drugs, including labora-
25 tory personnel costs.

1 “(3) AMOUNT OF FEE; COLLECTION.—A fee
2 under paragraph (1) shall be assessed on each line
3 item of drugs, as defined by the Secretary by regula-
4 tion. The amount of the fee shall be based on the
5 number of line items, and may not exceed \$1000 per
6 line item, notwithstanding subsection (b). The liabil-
7 ity for the fee constitutes a personal debt due to the
8 United States, and such liability accrues on the date
9 on which the Secretary approves the drugs under
10 section 801(c)(1). The Secretary may coordinate
11 with and seek the cooperation of other agencies of
12 the Federal Government regarding the collection of
13 such fees.

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

17 “(c) ADJUSTMENTS.—

18 “(1) INFLATION ADJUSTMENT.—With respect
19 to the amount of total fee revenues referred to in
20 subsection (b), the amount authorized in subsection
21 (f)(3) for a fiscal year shall be adjusted by the Sec-
22 retary (and as adjusted shall be published in the
23 Federal Register) to reflect the greater of—

24 “(A) the total percentage change that oc-
25 curred during the preceding fiscal year in the

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

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

10 “(2) ANNUAL FEE ADJUSTMENT.—Not later
11 than 60 days after the end of each fiscal year begin-
12 ning after fiscal year 2008, the Secretary, subject to
13 not exceeding the maximum fee amount specified in
14 subsection (a)(3), shall adjust the amounts that oth-
15 erwise would under subsection (a) be assessed as
16 fees during the fiscal year in which the adjustment
17 occurs so that the total revenues collected in such
18 fees for such fiscal year equal the amount applicable
19 pursuant to subsection (b) for the fiscal year.

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

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

3 “(e) ASSESSMENT OF FEES.—

4 “(1) LIMITATION.—Fees may not be assessed
5 under subsection (a) for a fiscal year beginning after
6 fiscal year 2008 unless the amount appropriated for
7 salaries and expenses of the Food and Drug Admin-
8 istration for such fiscal year is equal to or greater
9 than the amount appropriated for salaries and ex-
10 penses of the Food and Drug Administration for fis-
11 cal year 2008 multiplied by the adjustment factor
12 applicable to the fiscal year involved, except that in
13 making determinations under this paragraph for the
14 fiscal years involved there shall be excluded—

15 “(A) the amounts appropriated under sub-
16 section (f)(3) for the fiscal years involved;

17 “(B) the amounts appropriated under sec-
18 tion 801A(f)(3) for such fiscal years; and

19 “(C) the amounts appropriated under sec-
20 tion 736(g) for such fiscal years.

21 “(2) AUTHORITY.—If the Secretary does not
22 assess fees under subsection (a) during any portion
23 of a fiscal year because of paragraph (1) and if at
24 a later date in such fiscal year the Secretary may as-
25 sess such fees, the Secretary may assess and collect

1 such fees, without any modification in the rate of
2 the fees, at any time in such fiscal year notwith-
3 standing the provisions of subsection (a)(3) relating
4 to the time at which fees are to be paid.

5 “(f) CREDITING AND AVAILABILITY OF FEES.—

6 “(1) IN GENERAL.—Fees collected for a fiscal
7 year pursuant to subsection (a) shall be credited to
8 the appropriation account for salaries and expenses
9 of the Food and Drug Administration and shall be
10 available in accordance with appropriation Acts until
11 expended without fiscal year limitation. Such sums
12 as may be necessary may be transferred from the
13 Food and Drug Administration salaries and ex-
14 penses appropriation account without fiscal year lim-
15 itation to such appropriation account for salaries
16 and expenses with such fiscal year limitation. The
17 sums transferred shall be available solely for car-
18 rying out section 801 with respect to drugs.

19 “(2) COLLECTIONS AND APPROPRIATION
20 ACTS.—The fees authorized in subsection (a)—

21 “(A) shall be collected in each fiscal year
22 in accordance with subsections (a)(3) and (b);
23 and

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

1 “(3) AUTHORIZATION OF APPROPRIATIONS; AL-
2 LOCATIONS BY SECRETARY.—Subject to paragraph
3 (4) and subsection (c)(1), there is authorized to be
4 appropriated for fees under this section
5 \$300,000,000 for each of the fiscal years 2008
6 through 2012.

7 “(4) OFFSET.—Any amount of fees collected
8 for a fiscal year under subsection (a) that exceeds
9 the amount of fees specified in appropriation Acts
10 for such fiscal year shall be credited to the appro-
11 priation account of the Food and Drug Administra-
12 tion as provided in paragraph (1), and shall be sub-
13 tracted from the amount of fees that would other-
14 wise be authorized to be collected under this section
15 pursuant to appropriation Acts for a subsequent fis-
16 cal year.

17 “(g) COLLECTION OF UNPAID FEES.—In any case
18 where the Secretary does not receive payment of a fee as-
19 sessed under subsection (a) within 30 days after it is due,
20 such fee shall be treated as a claim of the United States
21 Government subject to subchapter II of chapter 37 of title
22 31, United States Code.

23 “(h) CONSTRUCTION.—This section may not be con-
24 strued as requiring that the number of full-time equivalent
25 positions in the Department of Health and Human Serv-

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

5 “(i) DEFINITION OF ADJUSTMENT FACTOR.—For
 6 purposes of this section, the term ‘adjustment factor’ ap-
 7 plicable to a fiscal year is the Consumer Price Index for
 8 all urban consumers (all items; United States city average)
 9 for April of the preceding fiscal year divided by such Index
 10 for April 2007.”.

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

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

16 “(q) AUTHORITY TO RESTRICT FOOD IMPORTATION
 17 TO SPECIFIC PORTS OF ENTRY.—

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

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

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

3 “(A) the importation of such food through
4 such port will not increase the probability that
5 such food will cause serious, adverse health con-
6 sequences or death; or

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

10 “(3) IMPLEMENTATION.—The Secretary shall
11 implement this subsection beginning not later than
12 5 years after the date of the enactment of this sub-
13 section.”.

14 **SEC. 6. COUNTRY OF ORIGIN LABELING.**

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

18 “(z) If the labeling of the food fails to identify the
19 country of origin of the food.”.

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

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

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

6 (d) EFFECTIVE DATE.—The requirements of sections
7 403(z) and 502(y) of the Federal Food, Drug, and Cos-
8 metic Act, as added by subsections (a) and (b), respec-
9 tively, take effect on the date that is 180 days after the
10 date of the enactment of this Act.

11 **SEC. 7. SAFE AND SECURE FOOD IMPORTATION PROGRAM.**

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

15 **“SEC. 805. SAFE AND SECURE FOOD IMPORTATION PRO-**
16 **GRAM.**

17 “(a) IN GENERAL.—Beginning not later than 2 years
18 after the date of the enactment of this section, the Sec-
19 retary shall establish by regulation and carry out a pro-
20 gram under which—

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

1 “(2) the Secretary agrees to expedite the move-
2 ment of such food through the inspection process.

3 “(b) GUIDELINES.—

4 “(1) DEVELOPMENT.—For purposes of the pro-
5 gram established under subsection (a), the Secretary
6 shall develop safety and security guidelines applica-
7 ble to the importation of food.

8 “(2) FACTORS.—The guidelines developed
9 under paragraph (1) shall take into account the fol-
10 lowing factors:

11 “(A) The personnel of the person import-
12 ing the food.

13 “(B) The physical and procedural safety
14 and security of such person’s food supply chain.

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

17 “(D) The need for tracking and maintain-
18 ing records on food and ingredients purchased
19 by such person or moved through the supply
20 chain.

21 “(E) Documentation processing through
22 such person’s supply chain.

23 “(F) Access by the Secretary to such per-
24 son’s business records for review.

25 “(G) Vendor and supplier information.

1 “(H) Such other factors as the Secretary
2 determines necessary.”.

3 **SEC. 8. CIVIL PENALTIES.**

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

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

8 (2) in subparagraph (A) of paragraph (2) of
9 subsection (f), as so redesignated, by striking “Any
10 person who introduces” and all that follows through
11 the end of the subparagraph and inserting the fol-
12 lowing: “Any person who introduces into interstate
13 commerce or delivers for introduction into interstate
14 commerce an article of food that is adulterated with-
15 in the meaning of section 402(a)(2)(B) shall be sub-
16 ject to a civil money penalty of—

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

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

1 any other person for such introduction or deliv-
2 ery, not to exceed \$1,000,000 for all such viola-
3 tions adjudicated in a single proceeding.”.

4 **SEC. 9. CONTINUED OPERATION OF FIELD LABORATORIES.**

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

8 (1) terminate any of the 13 field laboratories
9 that were operated by the Office of Regulatory Af-
10 fairs of the Food and Drug Administration as of
11 January 1, 2007;

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

14 (3) terminate any of the 20 district offices or
15 any of the inspection or compliance functions of any
16 of the 20 district offices of the Food and Drug Ad-
17 ministration functioning as of January 1, 2007; or

18 (4) consolidate—

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

21 (B) transfer any of the compliance or in-
22 spection functions of any such district office to
23 any other district.

24 (b) REPORT BY SECRETARY.—

1 (1) SUBMISSION.—The Secretary shall submit a
2 reorganization plan involving the termination or con-
3 solidation of the laboratories, the district offices, or
4 the functions of such district offices specified in sub-
5 section (a) to the Comptroller General, the Com-
6 mittee on Energy and Commerce of the House of
7 Representatives, and the Committee on Health, Edu-
8 cation, Labor, and Pensions of the Senate.

9 (2) CONSULTATION.—In preparing the reorga-
10 nization plan described in paragraph (1), the Sec-
11 retary shall consult with personnel and unions to be
12 affected by the plan.

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

22 (d) REORGANIZATION.—

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

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

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

10 **SEC. 10. RECALL AUTHORITY.**

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

14 **“SEC. 418. RECALL AUTHORITY.**

15 **“(a) ORDER TO CEASE DISTRIBUTION.—**

16 **“(1) IN GENERAL.—**If the Secretary finds that
17 a food may cause serious, adverse health con-
18 sequences or death, the Secretary shall issue an
19 order requiring the appropriate person (including
20 the manufacturers, importers, distributors, or retail-
21 ers of the food) to immediately cease distribution of
22 the food.

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

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

9 “(b) ORDER TO RECALL.—

10 “(1) IN GENERAL.—If, after providing an op-
11 portunity for an informal hearing under subsection
12 (a)(2), the Secretary determines that the order
13 should be amended to include a recall of the food
14 with respect to which the order was issued, the Sec-
15 retary shall, except as provided in paragraphs (2)
16 and (3), amend the order to require a recall. The
17 Secretary shall specify a timetable in which the food
18 recall will occur and shall require periodic reports to
19 the Secretary describing the progress of the recall.

20 “(2) CERTAIN ACTIONS.—An amended order
21 under paragraph (1) shall not include recall of a
22 food from individuals.”

1 **SEC. 11. INSPECTION AND OTHER STANDARDS; APPLICA-**
2 **BILITY, ENFORCEMENT; CERTIFICATIONS.**

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

6 **“SEC. 419. INSPECTION AND OTHER STANDARDS; APPLICA-**
7 **BILITY, ENFORCEMENT; CERTIFICATIONS.**

8 “(a) IN GENERAL.—Notwithstanding any other pro-
9 vision of law, all food that is offered for importation into
10 the United States shall be subject to the food safety stand-
11 ards applied to such food produced in the United States.

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

16 “(c) RANDOM INSPECTIONS.—The Secretary shall
17 enforce this section through appropriate random inspec-
18 tions, sampling, and testing.

19 “(d) CERTIFICATIONS REGARDING FOREIGN FACILI-
20 TIES.—

21 “(1) REQUIREMENT.—No food shall be per-
22 mitted entry into the United States from a foreign
23 facility in a foreign country unless there is—

24 “(A) a certification for such facility in ef-
25 fect under paragraph (2)(A); or

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

3 “(2) CERTIFICATION.—

4 “(A) FOREIGN FACILITY.—Each foreign
5 facility seeking to import food into the United
6 States may obtain a certification by the Sec-
7 retary stating that the facility maintains a pro-
8 gram using reliable analytical methods to en-
9 sure compliance with all the standards referred
10 to in subsection (a).

11 “(B) FOREIGN COUNTRY.—A foreign coun-
12 try may obtain a certification by the Secretary
13 stating that—

14 “(i) the country has in effect and is
15 enforcing food safety standards at least as
16 protective of food safety as the standards
17 applicable to food in the United States;
18 and

19 “(ii) the country has a program in ef-
20 fect to monitor and enforce its food safety
21 standards with respect to food being ex-
22 ported from such country to the United
23 States.

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

1 and shall revoke any certification if the Secretary
2 determines that the foreign facility or foreign coun-
3 try involved is no longer meeting the requirements
4 described in such paragraph.

5 “(4) INSPECTION.—The consideration of any
6 application for a certification under paragraph (2)
7 and the review of any such certification, by the Sec-
8 retary, may include the inspection of foreign facili-
9 ties to ensure that the inspection program of the for-
10 eign facility involved is meeting such standards.

11 “(5) FOREIGN FACILITY.—In this subsection,
12 the term ‘foreign facility’ means a foreign facility (as
13 defined in section 415(b)(3)) that is required to be
14 registered under section 415.

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

19 **SEC. 12. REGULATIONS ON ADEQUATE TESTING OF PROC-**
20 **ESSED FOOD.**

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

1 **“SEC. 420. REGULATIONS ON ADEQUATE TESTING OF PROC-**
2 **ESSED FOOD.**

3 “(a) IN GENERAL.—Not later than 2 years after the
4 date of the enactment of the Food and Drug Import Safe-
5 ty Act of 2007, the Secretary shall by regulation require
6 that, as good manufacturing practices, processed food un-
7 dergo testing to detect substances in the food that may
8 render the food adulterated, including microbial patho-
9 gens, toxic chemicals, and such other substances as the
10 Secretary determines to be appropriate.

11 “(b) REVIEW OF TEST RESULTS.—Regulations
12 under subsection (a) shall require that the results of tests
13 under such subsection be provided to the Secretary upon
14 demand.”.

15 **SEC. 13. RECORDS OF INTERSTATE SHIPMENT.**

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

18 (1) by striking “upon the request” and insert-
19 ing “upon the written or oral request”; and

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

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

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

7 (a) LABELING REQUIREMENT.—

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

12 “(4) In the case of food that is meat within the
13 meaning of the Federal Meat Inspection Act, a poul-
14 try product within the meaning of the Poultry Prod-
15 ucts Inspection Act, or seafood (including all fresh
16 or saltwater finfish, molluscan shellfish, crustaceans,
17 and other forms of aquatic animal life) intended for
18 human consumption as food within the meaning of
19 section 201(f) of this Act (referred to collectively in
20 this subsection as ‘seafood’), the term ‘color addi-
21 tive’ shall include carbon monoxide under conditions
22 of use that may impart, maintain, preserve, stabilize,
23 fix, or otherwise affect the color of fresh meat, poul-
24 try products, or seafood, unless the label of such
25 food bears, prominently and conspicuously in such

1 place and in such manner as to render it likely to
2 be read and understood by the ordinary person, the
3 following statement to prevent consumer deception
4 and serious risks to the public health: ‘SAFETY
5 NOTICE: Carbon monoxide has been used to pre-
6 serve the color of this product. Do not rely on color
7 or the “use or freeze by” date alone to judge the
8 freshness or safety of the product. Discard any prod-
9 uct with an unpleasant odor, slime, or a bulging
10 package.’”.

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

15 (b) DISCRETIONARY AUTHORITY.—If, not earlier
16 than 5 years after the effective date described in sub-
17 section (a)(1), the Secretary of Health and Human Serv-
18 ices finds, based on competent and reliable scientific evi-
19 dence, that the statement prescribed in section 201(t)(4)
20 of the Federal Food, Drug, and Cosmetic Act is no longer
21 required to prevent consumer deception and other harms,
22 then the Secretary is authorized to issue regulations estab-
23 lishing alternative labeling requirements that are shown
24 to be adequate and effective in preventing consumer de-
25 ception and other harms related to the conditions of use

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

○