

105TH CONGRESS
2D SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

Mr. DINGELL (for himself, Mr. BROWN of Ohio, Mr. STUPAK, Mr. PALLONE, Mr. WAXMAN, Mr. MARKEY, Mr. BOUCHER, Mr. MANTON, Mr. GORDON, Ms. FURSE, Mr. RUSH, Mr. KLINK, Mr. WYNN, Mr. GREEN, Ms. MCCARTHY of Missouri, and Ms. DEGETTE) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food from foreign countries.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Imported Food Safety
3 Act of 1998”.

4 **SEC. 2. ADDITIONAL AUTHORITIES OF FOOD AND DRUG AD-
5 MINISTRATION REGARDING FOOD SAFETY.**

6 (a) REQUIREMENT FOR PRIOR APPROVAL OF SEC-
7 RETARY FOR COMMERCIAL DISTRIBUTION AND RELATED
8 ACTIVITIES.—Section 801 of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 381) is amended—

10 (1) by striking “(b) Pending decision” and in-
11 sserting “(b)(1) Pending decision”, and by redesign-
12 ating subsection (c) as paragraph (2) of subsection
13 (b); and

14 (2) by inserting after subsection (b) the follow-
15 ing subsection:

16 “(c)(1) Food entering the United States shall not,
17 without the prior approval of the Secretary, be—

18 “(A) transferred from the control of the person
19 who held control when the food entered the United
20 States;

21 “(B) commercially distributed within the Unit-
22 ed States; or

23 “(C) removed from its intact state, with respect
24 to the manner in which the food was packed for
25 transport.

1 “(2) In determining whether to grant approval under
2 paragraph (1), the Secretary shall consider the following:

3 “(A) Whether the person or persons preparing,
4 packing, holding, manufacturing, or processing the
5 food involved cooperate with the Secretary in inspec-
6 tions regarding the food that are conducted by the
7 Secretary (including inspections conducted in foreign
8 countries).

9 “(B) Whether the person or persons have a his-
10 tory of failing to comply with applicable provisions
11 of this Act regarding food.

12 “(C) Whether the food (as a particular type of
13 product) has such a history.

14 “(D) Whether there is such a history with re-
15 spect to a particular foreign country.

16 “(E) Whether the system of regulating food
17 maintained in the foreign country provides at least
18 the same level of protection as domestic laws that
19 affect the safety of the food supply.

20 “(F) Whether the foreign country permits the
21 Secretary to conduct within the country inspections
22 regarding food.

23 “(G) Such other factors as the Secretary deter-
24 mines to be appropriate.

1 “(3)(A) If the system of regulating food maintained
2 in a foreign country does not provide at least the same
3 level of protection as domestic laws that affect the safety
4 of the food supply, or if the foreign country does not per-
5 mit the Secretary to conduct within the country inspec-
6 tions regarding food, the Secretary shall deny approval
7 under paragraph (1) for all food prepared, packed, held,
8 manufactured, or processed in the foreign country, except
9 as provided in subparagraph (B).

10 “(B) In the case of a foreign country with respect
11 to which approval under paragraph (1) has been denied
12 under subparagraph (A), a shipment of food prepared,
13 packed, held, manufactured, or processed in the foreign
14 country may be granted approval under such paragraph
15 if the Secretary receives proof satisfactory to the Secretary
16 that food in the shipment is not adulterated. The Sec-
17 retary shall require for purposes of the preceding sentence
18 that proof be presented that the shipment has been tested
19 for the presence of microbial pathogens and pesticide
20 chemicals or related residues, and for such other sub-
21 stances as the Secretary determines to be appropriate.

22 “(4) The Secretary shall by regulation provide for the
23 marking of any shipment of food that has been denied ap-
24 proval under paragraph (1) in a manner making it readily

1 apparent that the food has been refused admission into
2 the United States.

3 “(5) The Secretary shall give high priority to increas-
4 ing significantly, relative to fiscal year 1998, the number
5 of inspections under this section, including the testing of
6 imported food for pesticide and microbial contamination,
7 that are conducted with respect to food at ports of entry
8 into the United States.

9 “(6)(A) The Secretary shall submit to the Congress
10 periodic reports describing the activities of the Secretary
11 under this section with respect to the safety of food.

12 “(B) Each report under subparagraph (A) shall, for
13 each port of entry into the United States, specify the num-
14 ber of inspections and tests that were conducted under
15 this section with respect to food during the preceding fis-
16 cal year, and the extent to which such number is an in-
17 crease over the number of such inspections specified for
18 such port in the preceding report under subparagraph (A).

19 “(C) Each report under subparagraph (A) shall state
20 the statistical methodologies used by the Secretary in sam-
21 pling food for purposes of inspections under this section,
22 including the testing of imported food for pesticide and
23 microbial contamination, and the levels of confidence asso-
24 ciated with the methodologies.

1 “(D) The first report under subparagraph (A) shall
2 be submitted not later than December 1, 1999, and subse-
3 quent reports shall be submitted annually thereafter.”.

4 (b) CRIMINAL PENALTIES.—

5 (1) ACTING WITHOUT APPROVAL OF SEC-
6 RETARY.—Section 301 of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 331) is amended by
8 adding at the end the following:

9 “(aa)(1) In the case of food, the carrying out of any
10 act in violation of section 801(c)(1).”.

11 (2) FAILURE TO DISPOSE OF FOODS DENIED
12 ENTRY.—Section 301(aa) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 331(aa)), as
14 added by paragraph (1), is amended by adding at
15 the end the following:

16 “(2) The failure to comply with an order under sec-
17 tion 801 regarding the disposition of food that for pur-
18 poses of such section has been refused admission or denied
19 the approval of the Secretary.”.

20 (3) FAILURE TO PROVIDE COUNTRY-OF-ORIGIN
21 LABELING FOR CERTAIN FOODS.—Section 403 of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 343) is amended by adding at the end the following:

24 “(t) If it is a food intended for human consumption,
25 it is grown, prepared, packed, manufactured, or processed

1 in a foreign country, and it fails, at the time the food is
2 offered for retail sale, to bear or be accompanied by label-
3 ing that identifies the country or countries in which the
4 food was grown, prepared, packed, manufactured, or proc-
5 essed, except that this paragraph does not apply to food
6 offered for retail sale by restaurants or other eating estab-
7 lishments.”.

8 (c) CONFORMING AMENDMENT.—Section 801 of the
9 Federal Food, Drug, and Cosmetic Act, as amended by
10 subsection (a), is amended in subsection (b)(2) by striking
11 “subsection (b)” and inserting “paragraph (1)”.

12 **SEC. 3. RESEARCH ON TESTING TECHNIQUES FOR USE IN**
13 **INSPECTIONS OF FOOD SAFETY.**

14 Section 801 of the Federal Food, Drug, and Cosmetic
15 Act, as amended by section 2(a), is amended in subsection
16 (c) by adding at the end the following paragraph:

17 “(7)(A) The Secretary shall (directly or through
18 grants or contracts) provide for research on the develop-
19 ment of tests and sampling methodologies, for use in in-
20 spections of food under this section—

21 “(i) whose purpose is to determine whether food
22 is adulterated by reason of being contaminated with
23 microorganisms or pesticide chemicals or related res-
24 idues; and

1 “(ii) whose results are available not later than
2 approximately 60 minutes after the administration
3 of the tests.

4 “(B) In providing for research under subparagraph
5 (A), the Secretary shall give priority to conducting re-
6 search on the development of tests that are suitable for
7 inspections of food at ports of entry into the United
8 States.

9 “(C)(i) In providing for research under subparagraph
10 (A), the Secretary shall under subparagraph (B) give pri-
11 ority to conducting research on the development of tests
12 for detecting the presence in food of the pathogens *E. coli*,
13 salmonella, cyclospora, cryptosporidium, hepatitis A, or
14 listeria, the presence in or on food of pesticide chemicals
15 and related residues, and the presence in or on food of
16 such other pathogens or substances as the Secretary deter-
17 mines to be appropriate. The Secretary shall establish the
18 goal of developing, by the expiration of the three-year pe-
19 riod beginning on the date of the enactment of the Im-
20 ported Food Safety Act of 1998, tests under subparagraph
21 (A) for each of the pathogens and substances receiving
22 priority under the preceding sentence.

23 “(ii) The Secretary shall submit to the Congress peri-
24 odic reports describing the progress that has been made
25 toward the goal referred to in clause (i) and describing

1 plans for future research toward the goal. Each of the re-
2 ports shall provide an estimate by the Secretary of the
3 amount of funds needed to meet such goal, and shall pro-
4 vide a determination by the Secretary of whether there
5 is a need for further research under this paragraph. The
6 first such report shall be submitted not later than March
7 1, 1999, and subsequent reports shall be submitted semi-
8 annually after the submission of the first report until the
9 goal is met.

10 “(D) The Secretary shall carry out the program of
11 research under subparagraph (A) in consultation with the
12 Director of the Centers for Disease Control and Preven-
13 tion, the Director of the National Institutes of Health, and
14 the Administrator of the Environmental Protection Agen-
15 cy. The Secretary shall with respect to such research co-
16 ordinate the activities of the Department of Health and
17 Human Services. The Secretary shall in addition consult
18 with the Secretary of Agriculture (acting through the
19 Food Safety Inspection Service of the Department of Agri-
20 culture) in carrying out the program.

21 “(E) Of the amounts reserved under section
22 801A(a)(2)(B)(ii) for a fiscal year for carrying out the
23 program of research under subparagraph (A), the Sec-
24 retary shall make available not less than 50 percent for

1 making awards of grants or contracts to private entities
2 to conduct such research.”.

3 **SEC. 4. USER FEES REGARDING INSPECTIONS OF FOOD**
4 **SAFETY.**

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

8 “USER FEES REGARDING FOOD SAFETY

9 “SEC. 801A. (a) IN GENERAL.—

10 “(1) ASSESSMENT.—Beginning in fiscal year
11 1999, the Secretary shall in accordance with this
12 section assess and collect fees on food imported into
13 the United States.

14 “(2) PURPOSE OF FEES.—

15 “(A) IN GENERAL.—The purpose of fees
16 under paragraph (1) is to defray increases in
17 the costs of the resources allocated for carrying
18 out section 801 with respect to food over the
19 costs of carrying out such section with respect
20 to food in fiscal year 1998 multiplied by the ad-
21 justment factor. Increases referred to in the
22 preceding sentence include increases in such
23 costs for an additional number of full-time
24 equivalent positions in the Department of
25 Health and Human Services to be engaged in
26 carrying out such section.

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 50 percent for carrying out sec-
8 tion 801 with respect to food, other than
9 research under subsection (c)(7) of such
10 section. In expending the amount so re-
11 served, the Secretary shall give priority to
12 inspections conducted at ports of entry
13 into the United States.

14 “(ii) The Secretary shall reserve not
15 more than 50 percent for carrying out re-
16 search under section 801(c)(7).

17 “(3) AMOUNT OF FEE; COLLECTION.—A fee
18 under paragraph (1) shall be assessed on each line
19 item of food, as defined by the Secretary by regula-
20 tion. The amount of the fee shall be based on the
21 number of line items, and may not exceed \$20 per
22 line item, notwithstanding subsection (b). The liabil-
23 ity for the fee constitutes a personal debt due to the
24 United States, and such liability accrues on the date
25 on which the Secretary approves the food under sec-

1 tion 801(c)(1). The Secretary may coordinate with
2 and seek the cooperation of other agencies of the
3 Federal Government regarding the collection of such
4 fees.

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

8 “(c) ADJUSTMENTS.—

9 “(1) INFLATION ADJUSTMENT.—With respect
10 to the amount of total fee revenues referred to in
11 subsection (b), the amount authorized in subsection
12 (f)(3) for a fiscal year shall be adjusted by the Sec-
13 retary (and as adjusted shall be published in the
14 Federal Register) to reflect the greater of—

15 “(A) the total percentage change that oc-
16 curred during the preceding fiscal year in the
17 Consumer Price Index for all urban consumers
18 (all items; U.S. city average); or

19 “(B) the total percentage change for such
20 fiscal year in basic pay under the General
21 Schedule in accordance with section 5332 of
22 title 5, United States Code, as adjusted by any
23 locality-based comparability payment pursuant
24 to section 5304 of such title for Federal em-
25 ployees stationed in the District of Columbia.

1 “(2) ANNUAL FEE ADJUSTMENT.—Not later
2 than 60 days after the end of each fiscal year begin-
3 ning after fiscal year 1999, the Secretary, subject to
4 not exceeding the maximum fee amount specified in
5 subsection (a)(3), shall adjust the amounts that oth-
6 erwise would under subsection (a) be assessed as
7 fees during the fiscal year in which the adjustment
8 occurs so that the total revenues collected in such
9 fees for such fiscal year equal the amount applicable
10 pursuant to subsection (b) for the fiscal year.

11 “(d) FEE WAIVER OR REDUCTION.—The Secretary
12 shall grant a waiver from or a reduction of a fee assessed
13 under subsection (a) where the Secretary finds that the
14 fee to be paid will exceed the anticipated present and fu-
15 ture costs incurred by the Secretary in carrying out sec-
16 tion 801 with respect to food (which finding may be made
17 by the Secretary using standard costs).

18 “(e) ASSESSMENT OF FEES.—

19 “(1) LIMITATION.—Fees may not be assessed
20 under subsection (a) for a fiscal year beginning after
21 fiscal year 1999 unless the amount appropriated for
22 salaries and expenses of the Food and Drug Admin-
23 istration for such fiscal year is equal to or greater
24 than the amount appropriated for salaries and ex-
25 penses of the Food and Drug Administration for fis-

1 cal year 1999 multiplied by the adjustment factor
2 applicable to the fiscal year involved, except that in
3 making determinations under this subparagraph for
4 the fiscal years involved there shall be excluded—

5 “(A) the amounts appropriated under sub-
6 section (f)(3) for the fiscal years involved; and

7 “(B) the amounts appropriated under sec-
8 tion 736(g) for such fiscal years.

9 “(2) AUTHORITY.—If the Secretary does not
10 assess fees under subsection (a) during any portion
11 of a fiscal year because of paragraph (1) and if at
12 a later date in such fiscal year the Secretary may as-
13 sess such fees, the Secretary may assess and collect
14 such fees, without any modification in the rate of
15 the fees, at any time in such fiscal year notwith-
16 standing the provisions of subsection (a)(3) relating
17 to the time at which fees are to be paid.

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

19 “(1) IN GENERAL.—Fees collected for a fiscal
20 year pursuant to subsection (a) shall be credited to
21 the appropriation account for salaries and expenses
22 of the Food and Drug Administration and shall be
23 available in accordance with appropriation Acts until
24 expended without fiscal year limitation. Such sums
25 as may be necessary may be transferred from the

1 Food and Drug Administration salaries and ex-
2 penses appropriation account without fiscal year lim-
3 itation to such appropriation account for salaries
4 and expenses with such fiscal year limitation. The
5 sums transferred shall be available solely for carry-
6 ing out section 801 with respect to food, and the
7 sums are subject to allocations under subsection
8 (a)(2)(B).

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

11 “(A) shall be collected in each fiscal year
12 in accordance with subsections (a)(3) and (b);
13 and

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

16 “(3) AUTHORIZATION OF APPROPRIATIONS; AL-
17 LOCATIONS BY SECRETARY.—Subject to paragraph
18 (4) and subsection (c)(1), there is authorized to be
19 appropriated for fees under this section \$56,000,000
20 for each of the fiscal years 1999 through 2003.

21 “(4) OFFSET.—Any amount of fees collected
22 for a fiscal year under subsection (a) that exceeds
23 the amount of fees specified in appropriation Acts
24 for such fiscal year shall be credited to the appro-
25 priation account of the Food and Drug Administra-

1 tion as provided in paragraph (1), and shall be sub-
2 tracted from the amount of fees that would other-
3 wise be authorized to be collected under this section
4 pursuant to appropriation Acts for a subsequent fis-
5 cal year.

6 “(g) COLLECTION OF UNPAID FEES.—In any case
7 where the Secretary does not receive payment of a fee as-
8 sessed under subsection (a) within 30 days after it is due,
9 such fee shall be treated as a claim of the United States
10 Government subject to subchapter II of chapter 37 of title
11 31, United States Code.

12 “(h) CONSTRUCTION.—This section may not be con-
13 strued as requiring that the number of full-time equivalent
14 positions in the Department of Health and Human Serv-
15 ices, for officers, employers, and advisory committees not
16 engaged in carrying out section 801 with respect to food
17 be reduced to offset the number of officers, employees, and
18 advisory committees so engaged.

19 “(i) DEFINITION OF ADJUSTMENT FACTOR.—For
20 purposes of this section, the term ‘adjustment factor’ ap-
21 plicable to a fiscal year is the lower of—

22 “(1) the Consumer Price Index for all urban
23 consumers (all items; United States city average) for
24 April of the preceding fiscal year divided by such
25 Index for April 1998; or

1 “(2) the total of discretionary budget authority
2 provided for programs in categories other than the
3 defense category for the immediately preceding fiscal
4 year (as reported in the Office of Management and
5 Budget sequestration preview report, if available, re-
6 quired under section 254(c) of the Balanced Budget
7 and Emergency Deficit Control Act of 1985) divided
8 by such budget authority for fiscal year 1998 (as re-
9 ported in the Office of Management and Budget
10 final sequestration report submitted after the end of
11 the 105th Congress, 2d Session).

12 The terms ‘budget authority’ and ‘category’ in subpara-
13 graph (B) are as defined in the Balanced Budget and
14 Emergency Deficit Control Act of 1985.”.