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H. R. 4080

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 18, 1998

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 Commerce

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Imported Food Safety
5 Act of 1998”.

6 **SEC. 2. ADDITIONAL AUTHORITIES OF FOOD AND DRUG AD-**
7 **MINISTRATION REGARDING FOOD SAFETY.**

8 (a) REQUIREMENT FOR PRIOR APPROVAL OF SEC-
9 RETARY FOR COMMERCIAL DISTRIBUTION AND RELATED

1 ACTIVITIES.—Section 801 of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 381) is amended—

3 (1) by striking “(b) Pending decision” and in-
4 sserting “(b)(1) Pending decision”, and by redesignig-
5 nating subsection (c) as paragraph (2) of subsection
6 (b); and

7 (2) by inserting after subsection (b) the follow-
8 ing subsection:

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

11 “(A) transferred from the control of the person
12 who held control when the food entered the United
13 States;

14 “(B) commercially distributed within the
15 United States; or

16 “(C) removed from its intact state, with respect
17 to the manner in which the food was packed for
18 transport.

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

21 “(A) Whether the person or persons preparing,
22 packing, holding, manufacturing, or processing the
23 food involved cooperate with the Secretary in inspec-
24 tions regarding the food that are conducted by the

1 Secretary (including inspections conducted in foreign
2 countries).

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

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

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

10 “(E) Whether the system of regulating food
11 maintained in the foreign country provides at least
12 the same level of protection as domestic laws that
13 affect the safety of the food supply.

14 “(F) Whether the foreign country permits the
15 Secretary to conduct within the country inspections
16 regarding food.

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

19 “(3)(A) If the system of regulating food maintained
20 in a foreign country does not provide at least the same
21 level of protection as domestic laws that affect the safety
22 of the food supply, or if the foreign country does not per-
23 mit the Secretary to conduct within the country inspec-
24 tions regarding food, the Secretary shall deny approval
25 under paragraph (1) for all food prepared, packed, held,

1 manufactured, or processed in the foreign country, except
2 as provided in subparagraph (B).

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

15 “(4) The Secretary shall by regulation provide for the
16 marking of any shipment of food that has been denied ap-
17 proval under paragraph (1) in a manner making it readily
18 apparent that the food has been refused admission into
19 the United States.

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

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

4 “(B) Each report under subparagraph (A) shall, for
5 each port of entry into the United States, specify the num-
6 ber of inspections and tests that were conducted under
7 this section with respect to food during the preceding fis-
8 cal year, and the extent to which such number is an in-
9 crease over the number of such inspections specified for
10 such port in the preceding report under subparagraph (A).

11 “(C) Each report under subparagraph (A) shall state
12 the statistical methodologies used by the Secretary in sam-
13 pling food for purposes of inspections under this section,
14 including the testing of imported food for pesticide and
15 microbial contamination, and the levels of confidence asso-
16 ciated with the methodologies.

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

20 (b) CRIMINAL PENALTIES.—

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

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

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

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

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

16 “(t) If it is a food intended for human consumption,
17 it is grown, prepared, packed, manufactured, or processed
18 in a foreign country, and it fails, at the time the food is
19 offered for retail sale, to bear or be accompanied by label-
20 ing that identifies the country or countries in which the
21 food was grown, prepared, packed, manufactured, or proc-
22 essed, except that this paragraph does not apply to food
23 offered for retail sale by restaurants or other eating estab-
24 lishments.”.

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

5 **SEC. 3. RESEARCH ON TESTING TECHNIQUES FOR USE IN**
6 **INSPECTIONS OF FOOD SAFETY.**

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

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

14 “(i) whose purpose is to determine whether food
15 is adulterated by reason of being contaminated with
16 microorganisms or pesticide chemicals or related res-
17 idues; and

18 “(ii) whose results are available not later than
19 approximately 60 minutes after the administration
20 of the tests.

21 “(B) In providing for research under subparagraph
22 (A), the Secretary shall give priority to conducting re-
23 search on the development of tests that are suitable for
24 inspections of food at ports of entry into the United
25 States.

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

15 “(ii) The Secretary shall submit to the Congress peri-
16 odic reports describing the progress that has been made
17 toward the goal referred to in clause (i) and describing
18 plans for future research toward the goal. Each of the re-
19 ports shall provide an estimate by the Secretary of the
20 amount of funds needed to meet such goal, and shall pro-
21 vide a determination by the Secretary of whether there
22 is a need for further research under this paragraph. The
23 first such report shall be submitted not later than March
24 1, 1999, and subsequent reports shall be submitted semi-

1 annually after the submission of the first report until the
2 goal is met.

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

14 “(E) Of the amounts reserved under section
15 801A(a)(2)(B)(ii) for a fiscal year for carrying out the
16 program of research under subparagraph (A), the Sec-
17 retary shall make available not less than 50 percent for
18 making awards of grants or contracts to private entities
19 to conduct such research.”.

20 **SEC. 4. USER FEES REGARDING INSPECTIONS OF FOOD**
21 **SAFETY.**

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

25 “USER FEES REGARDING FOOD SAFETY

26 “SEC. 801A. (a) IN GENERAL.—

1 “(1) ASSESSMENT.—Beginning in fiscal year
2 1999, the Secretary shall in accordance with this
3 section assess and collect fees on food imported into
4 the United States.

5 “(2) PURPOSE OF FEES.—

6 “(A) IN GENERAL.—The purpose of fees
7 under paragraph (1) is to defray increases in
8 the costs of the resources allocated for carrying
9 out section 801 with respect to food over the
10 costs of carrying out such section with respect
11 to food in fiscal year 1998 multiplied by the ad-
12 justment factor. Increases referred to in the
13 preceding sentence include increases in such
14 costs for an additional number of full-time
15 equivalent positions in the Department of
16 Health and Human Services to be engaged in
17 carrying out such section.

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

23 “(i) The Secretary shall reserve not
24 less than 50 percent for carrying out sec-
25 tion 801 with respect to food, other than

1 research under subsection (c)(7) of such
2 section. In expending the amount so re-
3 served, the Secretary shall give priority to
4 inspections conducted at ports of entry
5 into the United States.

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

9 “(3) AMOUNT OF FEE; COLLECTION.—A fee
10 under paragraph (1) shall be assessed on each line
11 item of food, as defined by the Secretary by regula-
12 tion. The amount of the fee shall be based on the
13 number of line items, and may not exceed \$20 per
14 line item, notwithstanding subsection (b). The liabil-
15 ity for the fee constitutes a personal debt due to the
16 United States, and such liability accrues on the date
17 on which the Secretary approves the food under sec-
18 tion 801(c)(1). The Secretary may coordinate with
19 and seek the cooperation of other agencies of the
20 Federal Government regarding the collection of such
21 fees.

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

25 “(c) ADJUSTMENTS.—

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

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

11 “(B) the total percentage change for such
12 fiscal year in basic pay under the General
13 Schedule in accordance with section 5332 of
14 title 5, United States Code, as adjusted by any
15 locality-based comparability payment pursuant
16 to section 5304 of such title for Federal em-
17 ployees stationed in the District of Columbia.

18 “(2) ANNUAL FEE ADJUSTMENT.—Not later
19 than 60 days after the end of each fiscal year begin-
20 ning after fiscal year 1999, the Secretary, subject to
21 not exceeding the maximum fee amount specified in
22 subsection (a)(3), shall adjust the amounts that oth-
23 erwise would under subsection (a) be assessed as
24 fees during the fiscal year in which the adjustment
25 occurs so that the total revenues collected in such

1 fees for such fiscal year equal the amount applicable
2 pursuant to subsection (b) for the fiscal year.

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

10 “(e) ASSESSMENT OF FEES.—

11 “(1) LIMITATION.—Fees may not be assessed
12 under subsection (a) for a fiscal year beginning after
13 fiscal year 1999 unless the amount appropriated for
14 salaries and expenses of the Food and Drug Admin-
15 istration for such fiscal year is equal to or greater
16 than the amount appropriated for salaries and ex-
17 penses of the Food and Drug Administration for fis-
18 cal year 1999 multiplied by the adjustment factor
19 applicable to the fiscal year involved, except that in
20 making determinations under this subparagraph for
21 the fiscal years involved there shall be excluded—

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

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

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

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

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

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

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

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

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

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

23 “(g) COLLECTION OF UNPAID FEES.—In any case
24 where the Secretary does not receive payment of a fee as-
25 sessed under subsection (a) within 30 days after it is due,

1 such fee shall be treated as a claim of the United States
2 Government subject to subchapter II of chapter 37 of title
3 31, United States Code.

4 “(h) CONSTRUCTION.—This section may not be con-
5 strued as requiring that the number of full-time equivalent
6 positions in the Department of Health and Human Serv-
7 ices, for officers, employers, and advisory committees not
8 engaged in carrying out section 801 with respect to food
9 be reduced to offset the number of officers, employees, and
10 advisory committees so engaged.

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

14 “(1) the Consumer Price Index for all urban
15 consumers (all items; United States city average) for
16 April of the preceding fiscal year divided by such
17 Index for April 1998; or

18 “(2) the total of discretionary budget authority
19 provided for programs in categories other than the
20 defense category for the immediately preceding fiscal
21 year (as reported in the Office of Management and
22 Budget sequestration preview report, if available, re-
23 quired under section 254(c) of the Balanced Budget
24 and Emergency Deficit Control Act of 1985) divided
25 by such budget authority for fiscal year 1998 (as re-

1 ported in the Office of Management and Budget
2 final sequestration report submitted after the end of
3 the 105th Congress, 2d Session).

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

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