

106TH CONGRESS
1ST SESSION

S. 1126

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of imported food, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 26, 1999

Ms. MIKULSKI (for herself, Mr. KENNEDY, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of imported food, 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.**

4 This Act may be cited as the “Imported Food Safety
5 Improvement Act of 1999”.

1 **TITLE I—IMPROVEMENTS TO**
2 **THE FOOD SAFETY IMPORT**
3 **SYSTEM**

4 **SEC. 101. EQUIVALENCE AUTHORITY TO PROTECT THE**
5 **PUBLIC HEALTH FROM CONTAMINATED IM-**
6 **PORTED FOODS.**

7 (a) EQUIVALENCE DETERMINATIONS, AND MEAS-
8 URES, SYSTEMS, AND CONDITIONS TO ACHIEVE PUBLIC
9 HEALTH PROTECTION.—Section 801 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

11 (1) by redesignating subsections (d), (e), and
12 (f) as subsections (f), (g), and (h), respectively; and

13 (2) by inserting after subsection (c) the fol-
14 lowing:

15 “(d)(1) Subject to paragraphs (2) and (3), any food
16 offered for import into the United States shall be prepared
17 (including produced), packed, and held under a system or
18 conditions, or subject to measures, that meet the require-
19 ments of this Act or that have been determined by the
20 Secretary to be equivalent to a system, conditions, or
21 measures for such food in the United States and to achieve
22 the level of public health protection for such food pre-
23 pared, packed, and held in the United States. Consistent
24 with section 492 of the Trade Agreements Act of 1979
25 (19 U.S.C. 2578a), the Secretary shall make, where ap-

1 appropriate, equivalence determinations described in that
2 section relating to sanitary or phytosanitary measures (in-
3 cluding systems and conditions) that apply to the prepara-
4 tion, packing, and holding of food offered for import into
5 the United States.

6 “(2) In carrying out this subsection, the Secretary
7 shall conduct systematic evaluations of the systems, condi-
8 tions, and measures in foreign countries that apply to the
9 preparation, packing, and holding of food offered for im-
10 port into the United States.

11 “(3) The Secretary shall develop a plan for the imple-
12 mentation of the authority under this subsection within
13 2 years after the date of enactment of the Imported Food
14 Safety Improvement Act of 1999. In developing the plan,
15 the Secretary shall provide an opportunity for, and take
16 into consideration, public comment on a proposed plan.”.

17 (b) GENERAL AUTHORITY.—Section 801 of the Fed-
18 eral Food, Drug, and Cosmetic Act (21 U.S.C. 381), as
19 amended in subsection (a), is further amended by insert-
20 ing after subsection (d) the following:

21 “(e)(1)(A) The Secretary shall establish a system, for
22 use by the Secretary of the Treasury, to deny the entry
23 of any food offered for import into the United States if
24 the Secretary of Health and Human Services makes and
25 publishes—

1 “(i) a written determination that the food—

2 “(I) has been associated with repeated and
3 separate outbreaks of foodborne disease or has
4 been repeatedly determined by the Secretary to
5 be adulterated within the meaning of section
6 402;

7 “(II) presents a reasonable probability of
8 causing significant adverse health consequences
9 or death; and

10 “(III) is likely, without systemic interven-
11 tion or changes, to cause disease or be adulter-
12 ated again; or

13 “(ii) an emergency written determination that
14 the food has been strongly associated with a single
15 outbreak of foodborne disease that has caused seri-
16 ous adverse health consequences or death.

17 “(B)(i) The Secretary shall make a determination de-
18 scribed in subparagraph (A) with respect to—

19 “(I) a food from a specific producer, manufac-
20 turer, or shipper; or

21 “(II) a food from a specific growing area or
22 country;

23 that meets the criteria described in subparagraph (A).

24 “(ii) Only the food from the specific producer, manu-
25 facturer, shipper, growing area, or country for which the

1 Secretary makes the determination shall be subject to de-
2 nial of entry under this subsection.

3 “(C) The denial of entry of any food under this para-
4 graph shall be done in a manner consistent with bilateral,
5 regional, and multilateral trade agreements and the rights
6 and obligations of the United States under the agree-
7 ments.

8 “(D)(i) Before making any written determination
9 under subparagraph (A)(i), the Secretary shall consider
10 written comments, on a proposed determination, made by
11 any party affected by the proposed determination and any
12 remedial actions taken to address the findings made in
13 the proposed determination. In making the written deter-
14 mination, the Secretary may modify or rescind the pro-
15 posed determination in accordance with such comments.

16 “(ii)(I) The Secretary may immediately issue an
17 emergency written determination under subparagraph
18 (A)(ii) without first considering comments on a proposed
19 determination.

20 “(II) Within 30 days after the issuance of the emer-
21 gency determination, the Secretary shall consider written
22 comments on the determination that are made by a party
23 described in clause (i) and received within the 30-day pe-
24 riod. The Secretary may affirm, modify, or rescind the

1 emergency determination in accordance with the com-
2 ments.

3 “(III) The emergency determination shall be in
4 effect—

5 “(aa) for the 30-day period; or

6 “(bb) if the Secretary affirms or modifies the
7 determination, until the Secretary rescinds the de-
8 termination.

9 “(2)(A) The food initially denied entry under para-
10 graph (1) may be imported into the United States if the
11 Secretary finds that—

12 “(i) the written determination made under
13 paragraph (1) no longer justifies the denial of entry
14 of the food; or

15 “(ii) evidence of remedial action submitted from
16 the producer, manufacturer, shipper, specific grow-
17 ing area, or country for which the Secretary made
18 the written determination under paragraph (1) ad-
19 dresses the determination.

20 “(B)(i) The Secretary shall take action on evidence
21 submitted under subparagraph (A)(ii) within 90 days after
22 the date of the submission of the evidence.

23 “(ii) The Secretary’s action may include—

24 “(I) lifting the denial of entry of the food; or

1 “(II) continuing to deny entry of the food while
2 requesting additional information or specific reme-
3 dial action from the producer, manufacturer, ship-
4 per, specific growing area, or country.

5 “(iii) If the Secretary does not take action on evi-
6 dence submitted under subparagraph (A)(ii) within 90
7 days after the date of submission, effective on the 91st
8 day after the date of submission, the food initially denied
9 entry under paragraph (1) may be imported into the
10 United States.

11 “(3) The Secretary shall by regulation establish cri-
12 teria and procedures for the system described in para-
13 graph (1). The Secretary may by regulation modify those
14 criteria and procedures, as the Secretary determines ap-
15 propriate.”.

16 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

17 (1) Section 351(h) of the Public Health Service
18 Act (42 U.S.C. 262(h)) is amended by striking “sec-
19 tion 801(e)(1) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 381(e))” and inserting “sec-
21 tion 801(g)(1) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 381(g)(1))”.

23 (2) Section 301 of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 331) is amended—

1 (A) in paragraph (t), by striking “section
 2 801(d)(1)” and inserting “section 801(f)(1)”;
 3 and

4 (B) in paragraph (w)—

5 (i) by striking “sections 801(d)(3)(A)
 6 and 801(d)(3)(B)” and inserting “sub-
 7 paragraphs (A) and (B) of section
 8 801(f)(3)”;

9 (ii) except as provided in clause (i), by
 10 striking “section 801(d)(3)” each place it
 11 appears and inserting “section 801(f)(3)”;
 12 and

13 (iii) by striking “section 801(e)” and
 14 inserting “section 801(g)”.

15 (3) Section 303(b)(1)(A) of the Federal Food,
 16 Drug, and Cosmetic Act (21 U.S.C. 333(b)(1)(A)) is
 17 amended by striking “section 801(d)(1)” and insert-
 18 ing “section 801(f)(1)”.

19 (4) Section 304(d)(1) of the Federal Food,
 20 Drug, and Cosmetic Act (21 U.S.C. 334(d)(1)) is
 21 amended—

22 (A) by striking “section 801(e)(1)” and in-
 23 serting “section 801(g)(1)”;

1 (B) except as provided in subparagraph
2 (A), by striking “section 801(e)” each place it
3 appears and inserting “section 801(g)”.

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

6 (A) in subsection (a), in the third sentence,
7 by striking “subsection (b) of this section” and
8 inserting “subsection (b) or subsection
9 (e)(2)(A) (in the case of a food described in
10 that subsection)”;

11 (B) in paragraph (3)(A) of subsection (f),
12 as redesignated in subsection (a), by striking
13 “section 801(e) or 802” and inserting “sub-
14 section (g), section 802,”; and

15 (C) in paragraph (1) of subsection (h), as
16 redesignated in subsection (a), by striking “sub-
17 section (e)” and inserting “subsection (g)”.

18 (6) Section 802 of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 382) is amended—

20 (A) in subsection (a)(2)(C), by striking
21 “section 801(e)(2)” and inserting “section
22 801(g)(2)”;

23 (B) in subsection (f)(3), by striking “sec-
24 tion 801(e)(1)” and inserting “section
25 801(g)(1)”;

1 (C) in subsection (i), by striking “section
 2 801(e)(1)” and inserting “section 801(g)(1)”.

3 **SEC. 102. PROHIBITION AGAINST THE DISTRIBUTION OF**
 4 **CERTAIN FOOD.**

5 (a) ADULTERATED FOODS.—Section 402 of the Fed-
 6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 342) is
 7 amended by adding at the end the following:

8 “(h)(1) If—

9 “(A) it is a food being imported or offered for
 10 import into the United States;

11 “(B) the food has been designated by the Sec-
 12 retary for sampling, examination, or review for the
 13 purpose of determining whether the food is in com-
 14 pliance with this Act;

15 “(C) the Secretary requires, under section
 16 801(a)(2)(B), that the food not be distributed until
 17 the Secretary authorizes the distribution of the food;
 18 and

19 “(D) the food is distributed before the Sec-
 20 retary authorizes the distribution.

21 “(2) In this paragraph, the term ‘distributed’, used
 22 with respect to food, means—

23 “(A) moved for the purpose of selling the food,
 24 offering the food for sale, or delivering the food for

1 the purpose of selling the food or offering the food
2 for sale; or

3 “(B) delivered contrary to any bond require-
4 ment.”.

5 (b) PROHIBITION.—Section 801(a) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
7 amended—

8 (1) in the third sentence, by redesignating para-
9 graphs (1) through (3) as subparagraphs (A)
10 through (C), respectively;

11 (2) by striking “(a) The” and inserting “(a)(1)
12 The”;

13 (3) in the last sentence, by striking “Clause
14 (2)” and inserting “Subparagraph (B)”;

15 (4) by moving the fourth sentence to the end;

16 (5) in the sentence so moved, by striking “The
17 Secretary” and inserting the following:

18 “(2)(A) The Secretary”; and

19 (6) by adding at the end the following:

20 “(B) The Secretary of Health and Human Services
21 may require that a food being imported or offered for im-
22 port into the United States not be distributed until the
23 Secretary authorizes distribution of the food.”.

1 **SEC. 103. REQUIREMENT OF SECURE STORAGE OF CERTAIN**
2 **IMPORTED FOOD.**

3 (a) ADULTERATED FOODS.—Section 402 of the Fed-
4 eral Food, Drug, and Cosmetic Act, as amended in section
5 102(a), is further amended by adding at the end the fol-
6 lowing:

7 “(i) If—

8 “(1) it is a food being imported or offered for
9 import into the United States;

10 “(2) the Secretary requires, under section
11 801(a)(2)(C), that the food be held in a secure stor-
12 age facility until the Secretary authorizes distribu-
13 tion of the food; and

14 “(3) the food is not held in a secure storage fa-
15 cility as described in section 801(a)(2)(C) until the
16 Secretary authorizes the distribution.”.

17 (b) REQUIREMENT.—Section 801(a)(2) of the Fed-
18 eral Food, Drug, and Cosmetic Act, as amended in section
19 102(b), is further amended by adding at the end the fol-
20 lowing:

21 “(C)(i) The Secretary of Health and Human Services
22 may require that a food that is being imported or offered
23 for import into the United States be held, at the expense
24 of the owner or consignee of the food, in a secure storage
25 facility until the Secretary authorizes distribution of the

1 food, if the Secretary makes the determination that the
2 food is—

3 “(I) being imported or offered for import into
4 the United States by a person described in clause
5 (ii); or

6 “(II) owned by or consigned to a person de-
7 scribed in clause (ii).

8 “(ii) An importer, owner, or consignee referred to in
9 subclause (I) or (II) of clause (i) is a person against whom
10 the Secretary of the Treasury has assessed liquidated
11 damages not less than twice under subsection (b) for fail-
12 ure to redeliver, at the request of the Secretary of the
13 Treasury, food subject to a bond under subsection (b).”.

14 **SEC. 104. REQUIREMENT OF ADMINISTRATIVE DESTRUC-**
15 **TION OF CERTAIN IMPORTED FOOD.**

16 (a) ADULTERATED FOODS.—Section 402 of the Fed-
17 eral Food, Drug, and Cosmetic Act, as amended in section
18 103(a), is further amended by adding at the end the fol-
19 lowing:

20 “(j) Notwithstanding subsections (a)(2)(A) and (b) of
21 section 801, if—

22 “(1) it is a food being imported or offered for
23 import into the United States;

1 “(2) the food presents a reasonable probability
 2 of causing significant adverse health consequences or
 3 death;

4 “(3) the Secretary, after the food has been re-
 5 fused admission under section 801(a), requires
 6 under section 801(a)(2)(D) that the food be de-
 7 stroyed; and

8 “(4) the owner or consignee of the food fails to
 9 comply with that destruction requirement.”.

10 (b) REQUIREMENT.—Section 801(a)(2) of the Fed-
 11 eral Food, Drug, and Cosmetic Act, as amended in section
 12 103(b), is further amended by adding at the end the fol-
 13 lowing:

14 “(D) The Secretary of Health and Human Services
 15 may require destruction, at the expense of the owner or
 16 consignee, of food imported or offered for import into the
 17 United States that presents a reasonable probability of
 18 causing significant adverse health consequences or
 19 death.”.

20 **SEC. 105. PROHIBITION AGAINST PORT SHOPPING.**

21 Section 402 of the Federal Food, Drug, and Cosmetic
 22 Act, as amended in section 104(a), is further amended by
 23 adding at the end the following:

24 “(k) If it is an article of food being imported or of-
 25 fered for import into the United States, and the article

1 of food previously has been refused admission under sec-
 2 tion 801(a), unless the person reoffering the article affirm-
 3 atively establishes, at the expense of the owner or con-
 4 signee of the article, that the article complies with the ap-
 5 plicable requirements of this Act, as determined by the
 6 Secretary.”.

7 **SEC. 106. PROHIBITION OF IMPORTS BY DEBARRED PER-**
 8 **SONS.**

9 Section 402 of the Federal Food, Drug, and Cosmetic
 10 Act, as amended in section 105, is further amended by
 11 adding at the end the following:

12 “(l) If it is a food being imported or offered for im-
 13 port into the United States by a person debarred under
 14 section 306(b)(4).”.

15 **SEC. 107. AUTHORITY TO MARK REFUSED ARTICLES.**

16 (a) MISBRANDED FOODS.—Section 403 of the Fed-
 17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 343) is
 18 amended by adding at the end the following:

19 “(t) If—

20 “(1) it has been refused admission under sec-
 21 tion 801(a);

22 “(2) the food has not been required to be de-
 23 stroyed under subparagraph (A) or (B) of section
 24 801(a)(2); and

1 “(3) the packaging of the food does not bear a
2 label or labeling described in section 801(a)(2)(E).”.

3 (b) REQUIREMENT.—Section 801(a)(2) of the Fed-
4 eral Food, Drug, and Cosmetic Act, as amended in section
5 104(b), is further amended by adding at the end the fol-
6 lowing:

7 “(E) The Secretary of Health and Human Services
8 may require the owner or consignee of food that has been
9 refused admission under paragraph (1), and has not been
10 required to be destroyed under subparagraph (A) or (B),
11 to affix to the packaging of the food a label or labeling
12 that—

13 “(i) clearly and conspicuously bears the fol-
14 lowing statement: ‘United States: Refused Entry.’;

15 “(ii) is affixed to the packaging until the food
16 is brought into compliance with this Act; and

17 “(iii) has been provided at the expense of the
18 owner or consignee of the food.”.

19 **SEC. 108. EXPORT OF REFUSED ARTICLES.**

20 Paragraph (2)(A) of section 801(a) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as des-
22 ignated in section 102(b), is amended by striking “ninety
23 days” and inserting “30 days”.

1 **SEC. 109. COLLECTION AND ANALYSIS OF SAMPLES OF**
2 **FOOD IMPORTS.**

3 Section 801 of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 381), as amended in section 101(a), is fur-
5 ther amended by adding at the end the following:

6 “(i) The Secretary may issue regulations or guidance
7 as necessary to govern the collection and analysis by enti-
8 ties other than the Food and Drug Administration of sam-
9 ples of food imported or offered for import into the United
10 States to ensure the integrity of the samples collected and
11 the validity of the analytical results.”.

12 **TITLE II—ENFORCEMENT AND**
13 **PENALTIES FOR IMPORTING**
14 **CONTAMINATED FOOD**

15 **SEC. 201. ENHANCED BONDING REQUIREMENTS FOR PRIOR**
16 **INVOLVEMENT IN IMPORTING ADULTERATED**
17 **OR MISBRANDED FOOD.**

18 Section 801(b) of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 381(b)) is amended—

20 (1) by inserting “(1)” after “(b)”; and

21 (2) by adding at the end the following:

22 “(2)(A) The Secretary of the Treasury, acting
23 through the Commissioner of Customs, shall issue regula-
24 tions that establish a rate for a bond required to be exe-
25 cuted under paragraph (1) for an article of food if an

1 owner, consignee, or importer of the food has committed
 2 a covered violation.

3 “(B) The regulations shall require the owner or con-
 4 signee to execute such a bond—

5 “(i) at twice the usual rate; or

6 “(ii) if the owner, consignee, or importer has
 7 committed more than 1 covered violation, at a rate
 8 that increases with the number of covered violations
 9 committed, as determined in accordance with a slid-
 10 ing scale established in the regulations.

11 “(C) In this paragraph:

12 “(i) The term ‘committed’ means been con-
 13 victed of, or found liable for, a violation by an ap-
 14 propriate court or administrative officer.

15 “(ii) The term ‘covered violation’ means a viola-
 16 tion relating to—

17 “(I) importing or offering for import into
 18 the United States—

19 “(aa) an article of food during a pe-
 20 riod of debarment under section 306(b)(4);

21 “(bb) an article of food that is adul-
 22 terated within the meaning of paragraph
 23 (h), (i), (j), (k), or (l) of section 402; or

1 “(cc) an article of food that is mis-
 2 branded within the meaning of section
 3 403(t); or

4 “(II) making a false or misleading state-
 5 ment in conduct relating to the import or offer-
 6 ing for import of a food into the United States.

7 “(iii) The term ‘usual rate’, used with respect
 8 to a bond, means the rate that would be required
 9 under paragraph (1) for the bond by a person who
 10 has not committed a covered violation.”.

11 **SEC. 202. DEBARMENT OF REPEAT OFFENDERS AND SERI-**
 12 **OUS OFFENDERS.**

13 (a) IN GENERAL.—Section 306(b) of the Federal
 14 Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is
 15 amended—

16 (1) in paragraph (1), in the paragraph heading,
 17 by striking “IN GENERAL.—” and inserting “DE-
 18 BARMENT FOR VIOLATIONS RELATING TO DRUGS.—”;

19 (2) in paragraph (2), in the paragraph heading,
 20 by striking “PERSONS SUBJECT TO PERMISSIVE DE-
 21 BARMENT.—” and inserting “PERSONS SUBJECT TO
 22 PERMISSIVE DEBARMENT FOR VIOLATIONS RELAT-
 23 ING TO DRUGS.—”;

24 (3) in paragraph (3), in the paragraph heading,
 25 by striking “STAY OF CERTAIN ORDERS.—” and in-

1 serting “STAY OF CERTAIN ORDERS RELATING TO
2 DEBARMENT FOR VIOLATIONS RELATING TO
3 DRUGS.—”; and

4 (4) by adding at the end the following:

5 “(4) DEBARMENT FOR VIOLATIONS RELATING
6 TO FOOD IMPORTS.—

7 “(A) IN GENERAL.—The Secretary may
8 debar a person from importing a food or offer-
9 ing a food for import into the United States,
10 if—

11 “(i) the Secretary finds that the per-
12 son has been convicted for conduct that is
13 a felony under Federal law and relates to
14 the importation or offering for importation
15 of any food into the United States; or

16 “(ii) the Secretary makes a written
17 determination that the person has repeat-
18 edly or deliberately imported or offered for
19 import into the United States a food adul-
20 terated within the meaning of paragraph
21 (h), (i), (j), or (k) of section 402, or mis-
22 branded within the meaning of section
23 403(t).

24 “(B) IMPACT.—On debarring a person
25 under subparagraph (A), the Secretary shall

1 provide notice of the debarment to the Sec-
 2 retary of the Treasury, who shall deny entry of
 3 food offered for import by the person.”.

4 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

5 (1) IN GENERAL.—Section 306 of the Federal
 6 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is
 7 amended—

8 (A) in subsection (c)—

9 (i) in paragraph (1)—

10 (I) in subparagraph (B), by
 11 striking “, and” at the end and in-
 12 serting a comma;

13 (II) by redesignating subpara-
 14 graph (C) as subparagraph (D); and

15 (III) by inserting after subpara-
 16 graph (B) the following:

17 “(C) shall, during the period of a debar-
 18 ment under subsection (b)(4), prohibit the
 19 debarred person from importing a food or offer-
 20 ing a food for import into the United States,
 21 and”;

22 (ii) in paragraph (2)(A), by inserting
 23 after clause (iii) the following:

“(iv) The period of debarment of any person under subsection (b)(4) shall be not less than 1 year.”; and

(iii) in paragraph (3)—

(I) in subparagraph (C)—

(aa) by striking “suspect drugs” and inserting “suspect drugs or food”; and

(bb) by striking “fraudulently obtained” and inserting “fraudulently obtained or on food wrongfully imported into the United States”; and

(II) in subparagraph (E), by inserting “in the case of a debarment relating to a drug,” after “(E)”;

(B) in subsection (d)—

(i) in paragraph (3)—

(I) in subparagraph (A)—

(aa) in clause (i), by striking “or (b)(2)(A)” and inserting “or paragraph (2)(A) or (4) of subsection (b)”;

(bb) in clause (ii)(II), by inserting “in the case of a debar-

1 ment relating to a drug,” after
2 “(II)”; and
3 (II) in subparagraph (B)—
4 (aa) in clause (i), by striking
5 “or clause (i), (ii), (iii) or (iv) of
6 subsection (b)(2)(B)” and insert-
7 ing “, clause (i), (ii), (iii), or (iv)
8 of subsection (b)(2)(B), or sub-
9 section (b)(4)”; and
10 (bb) in clause (ii), by strik-
11 ing “subsection (b)(2)(B)” and
12 inserting “paragraph (2)(B) or
13 (4) of subsection (b)”; and
14 (ii) in paragraph (4)—
15 (I) in subparagraph (A), by strik-
16 ing “(a)(2)” and inserting “(a)(2) or
17 (b)(4)”;
18 (II) in subparagraph (B)—
19 (aa) in clause (ii), by strik-
20 ing “involving the development or
21 approval of any drug subject to
22 section 505” and inserting “in-
23 volving, as appropriate, the devel-
24 opment or approval of any drug

1 subject to section 505 or the im-
 2 portation of any food”; and

3 (bb) in clause (iv), by strik-
 4 ing “drug” each place it appears
 5 and inserting “drug or food”;
 6 and

7 (III) in subparagraph (D), in the
 8 matter following clause (ii), by insert-
 9 ing “, in the case of a debarment re-
 10 lating to a drug,” before “protects”;
 11 and

12 (C) in subsection (l)(2), in the second sen-
 13 tence, by striking “(b)(2)(B)” and inserting
 14 “(b)(2)(B), subsection (b)(4),”.

15 (2) CIVIL PENALTIES.—Paragraphs (6) and (7)
 16 of section 307(a) of the Federal Food, Drug, and
 17 Cosmetic Act (21 U.S.C. 335b(a)) are amended by
 18 striking “306” and inserting “306 (except section
 19 306(b)(4))”.

20 **SEC. 203. INCREASED ENFORCEMENT TO IMPROVE THE**
 21 **SAFETY OF IMPORTED FOOD.**

22 Subchapter A of chapter VII of the Federal Food,
 23 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
 24 ed by adding at the end the following:

1 **“SEC. 712. POSITIONS TO IMPROVE THE SAFETY OF IM-**
 2 **PORTED FOOD.**

3 “There is authorized to be appropriated such sums
 4 as may be necessary for each of fiscal years 2000 through
 5 2002 to enable the Commissioner, in carrying out chapters
 6 IV and VIII, to decrease the health risks associated with
 7 imported food through the creation of additional employ-
 8 ment positions for laboratory, inspection, and compliance
 9 personnel.”.

10 **TITLE III—IMPROVEMENTS TO**
 11 **PUBLIC HEALTH INFRA-**
 12 **STRUCTURE AND AWARENESS**

13 **SEC. 301. IMPROVEMENTS.**

14 Title II of the Public Health Service Act (42 U.S.C.
 15 202 et seq.) is amended by adding at the end the fol-
 16 lowing:

17 **“PART C—PUBLIC HEALTH INFRASTRUCTURE**
 18 **AND AWARENESS**

19 **“SEC. 251. DEFINITIONS.**

20 “In this part:

21 “(1) INSTITUTION OF HIGHER EDUCATION.—

22 The term ‘institution of higher education’ has the
 23 meaning given the term in section 101(a) of the
 24 Higher Education Act of 1965 (20 U.S.C. 1001(a)).

25 “(2) SECRETARY.—The term ‘Secretary’ means
 26 the Secretary of Health and Human Services, acting

1 through the Director of the Centers for Disease
2 Control and Prevention.

3 **“SEC. 252. PUBLIC HEALTH SURVEILLANCE ENHANCE-**
4 **MENT.**

5 “(a) IN GENERAL.—The Secretary may—

6 “(1) make grants to, enter into cooperative
7 agreements with, and provide technical assistance to
8 eligible agencies to enable the agencies to enhance
9 their capacity to carry out activities relating to sur-
10 veillance and prevention of foodborne pathogen-re-
11 lated disease, particularly pathogen-related disease
12 associated with imported food, as described in sub-
13 section (b)(1); and

14 “(2) carry out the activities described in sub-
15 section (b)(2).

16 “(b) USE OF ASSISTANCE.—

17 “(1) AGENCIES.—An eligible agency that re-
18 ceives assistance under subsection (a) shall use the
19 assistance to enhance the capacity of the agency—

20 “(A) to identify, investigate, and contain
21 threats of foodborne pathogen-related disease,
22 particularly pathogen-related disease associated
23 with imported food; and

1 “(B) to conduct additional surveillance and
2 studies to address prevention and control of the
3 disease.

4 “(2) CENTERS FOR DISEASE CONTROL AND
5 PREVENTION.—The Secretary may use not more
6 than 30 percent of the funds appropriated to carry
7 out this section—

8 “(A) to assist an agency described in para-
9 graph (1) in enhancing the capacity described
10 in paragraph (1) by providing standards, tech-
11 nologies, information, materials, and other re-
12 sources; and

13 “(B) to enhance national surveillance sys-
14 tems, including the ability of domestic and
15 international agencies and entities to respond to
16 food safety issues associated with imported food
17 that are identified through such systems.

18 “(c) ELIGIBLE AGENCIES.—To be eligible to receive
19 assistance under subsection (a)(1), an agency shall be a
20 State or local health department.

21 “(d) APPLICATION.—To be eligible to receive assist-
22 ance under subsection (a)(1), an agency shall submit an
23 application to the Secretary at such time, in such manner,
24 and containing such information as the Secretary may re-
25 quire.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 such sums as may be necessary for fiscal years 2000
4 through 2002.

5 **“SEC. 253. PATHOGEN DETECTION RESEARCH AND DEVEL-**
6 **OPMENT.**

7 “(a) IN GENERAL.—The Secretary may conduct ap-
8 plied research, directly or by grant or contract, to develop
9 new or improved methods for detecting and subtyping
10 emerging foodborne pathogens in human specimens, food,
11 and relevant environmental samples. The Secretary may
12 use funds appropriated to carry out this section to support
13 applied research by State health departments or institu-
14 tions of higher education.

15 “(b) APPLICATION.—To be eligible to receive a grant
16 or enter into a contract under subsection (a), an entity
17 shall submit an application to the Secretary at such time,
18 in such manner, and containing such information as the
19 Secretary may require.

20 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
21 are authorized to be appropriated to carry out this section
22 such sums as may be necessary for fiscal years 2000
23 through 2002.

1 **“SEC. 254. TRAINING, EDUCATION, AND PUBLIC INFORMA-**
2 **TION.**

3 “(a) IN GENERAL.—The Secretary may—

4 “(1) make grants and enter into contracts with
5 eligible entities, to support training activities and
6 other collaborative activities with the entities to in-
7 form health professionals about foodborne disease,
8 including strengthening training networks serving
9 State, local, and private entities; and

10 “(2) increase and improve the activities carried
11 out by the Centers for Disease Control and Preven-
12 tion to provide information to the public on
13 foodborne disease.

14 “(b) ELIGIBLE ENTITIES.—To be eligible to receive
15 a grant or enter into a contract under subsection (a), an
16 entity shall be a medical school, a nursing school, an entity
17 carrying out clinical laboratory training programs, a
18 school of public health, another institution of higher edu-
19 cation, a professional organization, or an international or-
20 ganization.

21 “(c) APPLICATION.—To be eligible to receive a grant
22 or enter into a contract under subsection (a), an entity
23 shall submit an application to the Secretary at such time,
24 in such manner, and containing such information as the
25 Secretary may require.

1 “(d) CONSULTATION.—In carrying out this section,
2 the Secretary shall consult with Federal, State, and local
3 agencies, international organizations, and other interested
4 parties.

5 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated to carry out this section
7 such sums as may be necessary for fiscal years 2000
8 through 2002.

9 **“SEC. 255. INTERNATIONAL PUBLIC HEALTH TRAINING AND**
10 **TECHNICAL ASSISTANCE.**

11 “(a) IN GENERAL.—The Secretary shall, directly or
12 by agreement, provide training and technical assistance to
13 agencies and entities in foreign countries, to strengthen
14 the foodborne disease surveillance and investigation capac-
15 ities of the agencies and entities, including establishing or
16 expanding activities or programs such as the Field Epide-
17 miology and Training Program of the Centers for Disease
18 Control and Prevention.

19 “(b) APPLICATION.—To be eligible to enter into an
20 agreement under subsection (a), an entity shall submit an
21 application to the Secretary at such time, in such manner,
22 and containing such information as the Secretary may re-
23 quire.

24 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
25 are authorized to be appropriated to carry out this section

1 such sums as may be necessary for fiscal years 2000
2 through 2002.

3 **“SEC. 256. SUPPLIES AND SERVICES IN LIEU OF GRANT**
4 **FUNDS.**

5 “(a) IN GENERAL.—On the request of a recipient of
6 assistance under section 252, 253, 254, or 255, the Sec-
7 retary may, subject to subsection (b), provide supplies,
8 equipment, and services for the purpose of aiding the re-
9 cipient in carrying out the section involved and, for such
10 purpose, may detail to the grant recipient any officer or
11 employee of the Department of Health and Human Serv-
12 ices. Such detail shall be without interruption or loss of
13 civil service status or privilege.

14 “(b) CORRESPONDING REDUCTION IN PAYMENTS.—
15 With respect to a request described in subsection (a), the
16 Secretary shall reduce the amount of payments under the
17 section involved by an amount equal to the cost of detail-
18 ing the officer or employee and the fair market value of
19 the supplies, equipment, or services provided by the Sec-
20 retary. The Secretary shall, for the payment of expenses
21 incurred in complying with such a request, expend the
22 amounts withheld.”.

○