

107TH CONGRESS
1ST SESSION

S. 1634

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of perishable products whose import is regulated by the Commissioner of Food and Drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 5, 2001

Ms. COLLINS introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the safety of perishable products whose import is regulated by the Commissioner of Food and Drugs, 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 Perishable
5 Product Safety Improvement Act”.

1 **TITLE I—IMPROVEMENTS TO**
 2 **THE SAFETY SYSTEM FOR IM-**
 3 **PORTED PERISHABLE PROD-**
 4 **UCTS**

5 **SEC. 101. AUTHORITY TO PROTECT THE PUBLIC HEALTH**
 6 **FROM CONTAMINATED IMPORTED PERISH-**
 7 **ABLE PRODUCTS.**

8 (a) GENERAL AUTHORITY.—Section 801 of the Fed-
 9 eral Food, Drug, and Cosmetic Act (21 U.S.C. 381) is
 10 amended—

11 (1) by redesignating subsections (d), (e), (f),
 12 and (g) as subsections (e), (f), (g), and (h), respec-
 13 tively; and

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

16 “(d)(1)(A) The Secretary shall establish a system, for
 17 use by the Secretary of the Treasury, to deny the entry
 18 of any perishable product offered for import into the
 19 United States if the Secretary of Health and Human Serv-
 20 ices makes and publishes—

21 “(i) a written determination that the perishable
 22 product—

23 “(I) has been associated with repeated and
 24 separate outbreaks of disease borne in a perish-
 25 able product or has been repeatedly determined

1 by the Secretary to be adulterated within the
2 meaning of section 402;

3 “(II) presents a reasonable probability of
4 causing serious adverse health consequences or
5 death; and

6 “(III) is likely, without systemic interven-
7 tion or changes, to cause disease or be adulter-
8 ated again; or

9 “(ii) an emergency written determination that
10 the perishable product has been strongly associated
11 with a single outbreak of disease borne in a perish-
12 able product that has caused serious adverse health
13 consequences or death.

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

16 “(I) a perishable product from a specific pro-
17 ducer, manufacturer, or transporter; or

18 “(II) a perishable product from a specific grow-
19 ing area or country;

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

21 “(ii) Only the perishable product from the specific
22 producer, manufacturer, transporter, growing area, or
23 country for which the Secretary makes the determination
24 shall be subject to denial of entry under this subsection.

1 “(C) The denial of entry of any perishable product
2 under this paragraph shall be done in a manner consistent
3 with bilateral, regional, and multilateral trade agreements
4 and the rights and obligations of the United States under
5 the agreements.

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

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

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

1 “(III) The emergency determination shall be in
2 effect—

3 “(aa) for the 30-day period; or

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

7 “(2)(A) The perishable product initially denied entry
8 under paragraph (1) may be imported into the United
9 States if the Secretary finds that—

10 “(i) the written determination made under
11 paragraph (1) no longer justifies the denial of entry
12 of the perishable product; or

13 “(ii) evidence of remedial action submitted from
14 the producer, manufacturer, transporter, specific
15 growing area, or country for which the Secretary
16 made the written determination under paragraph (1)
17 addresses the determination.

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

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

22 “(I) lifting the denial of entry of the perishable
23 product; or

24 “(II) continuing to deny entry of the perishable
25 product while requesting additional information or

1 specific remedial action from the producer, manufac-
 2 turer, transporter, specific growing area, or country.

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

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

14 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

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

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

23 (A) in paragraph (t), by striking “section
 24 801(d)(1)” and inserting “section 801(e)(1)”;
 25 and

1 (B) in paragraph (w)—

2 (i) by striking “sections 801(d)(3)(A)
3 and 801(d)(3)(B)” and inserting “sub-
4 paragraphs (A) and (B) of section
5 801(e)(3)”;

6 (ii) except as provided in clause (i), by
7 striking “section 801(d)(3)” each place it
8 appears and inserting “section 801(e)(3)”;
9 and

10 (iii) by striking “section 801(e)” and
11 inserting “section 801(f)”.

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

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

19 (A) by striking “section 801(e)(1)” and in-
20 serting “section 801(f)(1)”;

21 (B) except as provided in subparagraph
22 (A), by striking “section 801(e)” each place it
23 appears and inserting “section 801(f)”.

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

1 (A) in subsection (a), in the third sentence,
 2 by striking “subsection (b) of this section” and
 3 inserting “subsection (b) or subsection
 4 (d)(2)(A) (in the case of a perishable product
 5 described in that subsection)”;

6 (B) in paragraph (3)(A) of subsection (f),
 7 as redesignated in subsection (a), by striking
 8 “section 801(e) or 802” and inserting “sub-
 9 section (f), section 802,”; and

10 (C) in paragraph (1) of subsection (h), as
 11 redesignated in subsection (a), by striking “sub-
 12 section (e)” and inserting “subsection (f)”.

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

15 (A) in subsection (a)(2)(C), by striking
 16 “section 801(e)(2)” and inserting “section
 17 801(f)(2)”;

18 (B) in subsection (f)(3), by striking “sec-
 19 tion 801(e)(1)” and inserting “section
 20 801(f)(1)”;

21 (C) in subsection (i), by striking “section
 22 801(e)(1)” and inserting “section 801(f)(1)”.

1 **SEC. 102. PROHIBITION AGAINST THE DISTRIBUTION OF**
2 **CERTAIN PERISHABLE PRODUCTS.**

3 (a) ADULTERATED PERISHABLE PRODUCTS.—Sec-
4 tion 402 of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 342) is amended by adding at the end the fol-
6 lowing:

7 “(h)(1) If—

8 “(A) it is a perishable product being imported
9 or offered for import into the United States;

10 “(B) the perishable product has been des-
11 ignated by the Secretary for sampling, examination,
12 or review for the purpose of determining whether the
13 perishable product is in compliance with this Act;

14 “(C) the Secretary requires, under section
15 801(a)(2)(B), that the perishable product not be dis-
16 tributed until the Secretary authorizes the distribu-
17 tion of the perishable product; and

18 “(D) the perishable product is distributed be-
19 fore the Secretary authorizes the distribution.

20 “(2) In this paragraph, the term ‘distributed’, used
21 with respect to a perishable product, means—

22 “(A) moved for the purpose of selling the per-
23 ishable product, offering the product for sale, or de-
24 livering the product for the purpose of selling the
25 product or offering the product for sale; or

1 “(B) delivered contrary to any bond require-
2 ment.”.

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

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

9 (2) by striking “(a) The” and inserting “(a)(1)
10 The”;

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

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

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

16 “(2)(A) The Secretary”; and

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

18 “(B) The Secretary of Health and Human Services
19 may require that a perishable product being imported or
20 offered for import into the United States not be distrib-
21 uted until the Secretary authorizes distribution of the per-
22 ishable product.”.

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

3 (a) ADULTERATED PERISHABLE PRODUCTS.—Sec-
4 tion 402 of the Federal Food, Drug, and Cosmetic Act,
5 as amended in section 102(a), is further amended by add-
6 ing at the end the following:

7 “(i) If—

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

10 “(2) the Secretary requires, under section
11 801(a)(2)(C), that the perishable product be held in
12 a secure storage facility until the Secretary author-
13 izes distribution of the perishable product; and

14 “(3) the perishable product is not held in a se-
15 cure storage facility as described in section
16 801(a)(2)(C) until the Secretary authorizes the dis-
17 tribution.”.

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

22 “(C)(i) The Secretary of Health and Human Services
23 may require that a perishable product that is being im-
24 ported or offered for import into the United States be
25 held, at the expense of the owner or consignee of the per-
26 ishable product, in a secure storage facility until the Sec-

1 retary authorizes distribution of the perishable product,
 2 if the Secretary makes the determination that the perish-
 3 able product is—

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

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

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

16 **SEC. 104. REQUIREMENT OF ADMINISTRATIVE DESTRUC-**
 17 **TION OF CERTAIN PERISHABLE PRODUCTS.**

18 (a) ADULTERATED PERISHABLE PRODUCTS.—Sec-
 19 tion 402 of the Federal Food, Drug, and Cosmetic Act,
 20 as amended in section 103(a), is further amended by add-
 21 ing at the end the following:

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

24 “(1) it is a perishable product being imported
 25 or offered for import into the United States;

1 “(2) the perishable product poses a strong like-
2 lihood of causing serious adverse health con-
3 sequences or death;

4 “(3) the Secretary, after the perishable product
5 has been refused admission under section 801(a), re-
6 quires under section 801(a)(2)(D) that the perish-
7 able product be destroyed; and

8 “(4) the owner or consignee of the perishable
9 product fails to comply with that destruction re-
10 quirement.”.

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

15 “(D) The Secretary of Health and Human Services
16 may require destruction, at the expense of the owner or
17 consignee, of a perishable product imported or offered for
18 import into the United States that poses a strong likeli-
19 hood of causing serious adverse health consequences or
20 death.”.

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

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

1 “(k) If it is an article that is a perishable product
 2 being imported or offered for import into the United
 3 States, and the article previously has been refused admis-
 4 sion under section 801(a), unless the person reoffering the
 5 article affirmatively establishes, at the expense of the
 6 owner or consignee of the article, that the article complies
 7 with the applicable requirements of this Act, as deter-
 8 mined by the Secretary.”.

9 **SEC. 106. PROHIBITION OF IMPORTS BY DEBARRED PER-**
 10 **SONS.**

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

14 “(l) If it is a perishable product being imported or
 15 offered for import into the United States by a person
 16 debarred under section 306(b)(4).”.

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

18 (a) MISBRANDED PERISHABLE PRODUCTS.—Section
 19 403 of the Federal Food, Drug, and Cosmetic Act (21
 20 U.S.C. 343) is amended by adding at the end the fol-
 21 lowing:

22 “(t) If—

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

1 “(2) the perishable product has not been re-
2 quired to be destroyed under subparagraph (A) or
3 (B) of section 801(a)(2); and

4 “(3) the packaging of the perishable product
5 does not bear a label or labeling described in section
6 801(a)(2)(E).”.

7 (b) REQUIREMENT.—Section 801(a)(2) of the Fed-
8 eral Food, Drug, and Cosmetic Act, as amended in section
9 104(b), is further amended by adding at the end the fol-
10 lowing:

11 “(E) The Secretary of Health and Human Services
12 may require the owner or consignee of a perishable prod-
13 uct that has been refused admission under paragraph (1),
14 and has not been required to be destroyed under subpara-
15 graph (A) or (B), to affix to the packaging of the perish-
16 able product a label or labeling that—

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

19 “(ii) is affixed to the packaging until the per-
20 ishable product is brought into compliance with this
21 Act; and

22 “(iii) has been provided at the expense of the
23 owner or consignee of the perishable product.”.

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

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

6 **SEC. 109. COLLECTION AND ANALYSIS OF SAMPLES OF**
7 **CERTAIN IMPORTS.**

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

11 “(h) The Secretary may issue regulations or guidance
12 as necessary to govern the collection and analysis by enti-
13 ties other than the Food and Drug Administration of sam-
14 ples of perishable products imported or offered for import
15 into the United States to ensure the integrity of the sam-
16 ples collected and the validity of the analytical results.”.

17 **SEC. 110. DEFINITION.**

18 Section 201 of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 321) is amended by adding at the end the
20 following:

21 “(kk) The term ‘perishable product’ means an article
22 that is described in subparagraph (1), (2), or (3) of para-
23 graph (f) and that is not a dietary supplement. The term
24 shall not include an article to the extent that the Secretary
25 of Agriculture exercises inspection authority over the arti-
26 cle at the time of import into the United States.”.

1 **TITLE II—ENFORCEMENT AND**
 2 **PENALTIES FOR IMPORTING**
 3 **CONTAMINATED PERISHABLE**
 4 **PRODUCTS**

5 **SEC. 201. ENHANCED BONDING REQUIREMENTS FOR PRIOR**
 6 **INVOLVEMENT IN IMPORTING ADULTERATED**
 7 **OR MISBRANDED PERISHABLE PRODUCTS.**

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

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

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

12 “(2)(A) The Secretary of the Treasury, acting
 13 through the Commissioner of Customs, shall issue regula-
 14 tions that establish a rate for a bond required to be exe-
 15 cuted under paragraph (1) for an article that is a perish-
 16 able product if an owner, consignee, or importer of the
 17 article has committed a covered violation.

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

20 “(i) at twice the usual rate; or

21 “(ii) if the owner, consignee, or importer has
 22 committed more than 1 covered violation, at a rate
 23 that increases with the number of covered violations
 24 committed, as determined in accordance with a slid-
 25 ing scale established in the regulations.

1 “(C) In this paragraph:

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

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

7 “(I) importing or offering for import into
8 the United States—

9 “(aa) an article that is a perishable
10 product during a period of debarment
11 under section 306(b)(4);

12 “(bb) an article that is a perishable
13 product and that is adulterated within the
14 meaning of paragraph (h), (i), (j), (k), or
15 (l) of section 402; or

16 “(cc) an article that is a perishable
17 product and that is misbranded within the
18 meaning of section 403(t); or

19 “(II) making a false or misleading state-
20 ment in conduct relating to the import or offer-
21 ing for import of a perishable product into the
22 United States.

23 “(iii) The term ‘usual rate’, used with respect
24 to a bond, means the rate that would be required

1 under paragraph (1) for the bond by a person who
 2 has not committed a covered violation.”.

3 **SEC. 202. DEBARMENT OF REPEAT OFFENDERS AND SERI-**
 4 **OUS OFFENDERS.**

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

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

11 (2) in paragraph (2), in the paragraph heading,
 12 by striking “PERSONS SUBJECT TO PERMISSIVE DE-
 13 BARMENT.—” and inserting “PERSONS SUBJECT TO
 14 PERMISSIVE DEBARMENT FOR VIOLATIONS RELAT-
 15 ING TO DRUGS.—”;

16 (3) in paragraph (3), in the paragraph heading,
 17 by striking “STAY OF CERTAIN ORDERS.—” and in-
 18 serting “STAY OF CERTAIN ORDERS RELATING TO
 19 DEBARMENT FOR VIOLATIONS RELATING TO
 20 DRUGS.—”; and

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

22 “(4) DEBARMENT FOR VIOLATIONS RELATING
 23 TO IMPORTS OF PERISHABLE PRODUCTS.—

24 “(A) IN GENERAL.—The Secretary may
 25 debar a person from importing a perishable

1 product or offering a perishable product for im-
2 port into the United States, if—

3 “(i) the Secretary finds that the per-
4 son has been convicted for conduct that is
5 a felony under Federal law and relates to
6 the importation or offering for importation
7 of any perishable product into the United
8 States; or

9 “(ii) the Secretary makes a written
10 determination that the person has repeat-
11 edly or deliberately imported or offered for
12 import into the United States a perishable
13 product adulterated within the meaning of
14 paragraph (h), (i), (j), or (k) of section
15 402, or misbranded within the meaning of
16 section 403(t).

17 “(B) IMPACT.—On debarring a person
18 under subparagraph (A), the Secretary shall
19 provide notice of the debarment to the Sec-
20 retary of the Treasury, who shall deny entry of
21 a perishable product offered for import by the
22 person.”.

23 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

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

4 (A) in subsection (c)—

5 (i) in paragraph (1)—

6 (I) in subparagraph (B), by
7 striking “, and” at the end and in-
8 serting a comma;

9 (II) by redesignating subpara-
10 graph (C) as subparagraph (D); and

11 (III) by inserting after subpara-
12 graph (B) the following:

13 “(C) shall, during the period of a debar-
14 ment under subsection (b)(4), prohibit the
15 debarred person from importing a perishable
16 product or offering a perishable product for im-
17 port into the United States, and”;

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

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

23 (iii) in paragraph (3)—

24 (I) in subparagraph (C)—

1 (aa) by striking “suspect
2 drugs” and inserting “suspect
3 drugs or perishable products”;
4 and

5 (bb) by striking “fraudu-
6 lently obtained” and inserting
7 “fraudulently obtained or on a
8 perishable product wrongfully im-
9 ported into the United States”;
10 and

11 (II) in subparagraph (E), by in-
12 serting “in the case of a debarment
13 relating to a drug,” after “(E)”;

14 (B) in subsection (d)—

15 (i) in paragraph (3)—

16 (I) in subparagraph (A)—

17 (aa) in clause (i), by striking
18 “or (b)(2)(A)” and inserting “or
19 paragraph (2)(A) or (4) of sub-
20 section (b)”;

21 (bb) in clause (ii)(II), by in-
22 serting “in the case of a debar-
23 ment relating to a drug,” after
24 “(II)”;

25 (II) in subparagraph (B)—

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

1 (bb) in clause (iv), by strik-
 2 ing “drug” each place it appears
 3 and inserting “drug or perishable
 4 product”; and

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

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

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

18 **SEC. 203. INCREASED ENFORCEMENT TO IMPROVE THE**
 19 **SAFETY OF IMPORTED PERISHABLE PROD-**
 20 **UCTS.**

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

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

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 perishable products through the creation of addi-
 8 tional employment positions for laboratory, inspection,
 9 and compliance 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) PERISHABLE PRODUCT.—The term ‘per-
 26 ishable product’ has the meaning given the term in

1 section 201 of the Federal Food, Drug, and Cos-
 2 metic Act (21 U.S.C. 321).

3 “(3) SECRETARY.—The term ‘Secretary’ means
 4 the Secretary of Health and Human Services, acting
 5 through the Director of the Centers for Disease
 6 Control and Prevention.

7 **“SEC. 252. PUBLIC HEALTH SURVEILLANCE ENHANCE-**
 8 **MENT.**

9 “(a) IN GENERAL.—The Secretary may—

10 “(1) make grants to, enter into cooperative
 11 agreements with, and provide technical assistance to
 12 eligible agencies to enable the agencies to enhance
 13 their capacity to carry out activities relating to sur-
 14 veillance and prevention of pathogen-related disease
 15 borne in a perishable product, particularly pathogen-
 16 related disease associated with imported perishable
 17 products, as described in subsection (b)(1); and

18 “(2) carry out the activities described in sub-
 19 section (b)(2).

20 “(b) USE OF ASSISTANCE.—

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

24 “(A) to identify, investigate, and contain
 25 threats of pathogen-related disease borne in a

1 perishable product, particularly pathogen-re-
2 lated disease associated with imported perish-
3 able products; and

4 “(B) to conduct additional surveillance and
5 studies to address prevention and control of the
6 disease.

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

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

16 “(B) to enhance national surveillance sys-
17 tems, including the ability of domestic and
18 international agencies and entities to respond to
19 safety issues associated with imported perish-
20 able products that are identified through such
21 systems.

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

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

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

10 **“SEC. 253. PATHOGEN DETECTION RESEARCH AND DEVEL-**
 11 **OPMENT.**

12 “(a) IN GENERAL.—The Secretary shall award
 13 grants to universities, nonprofit corporations, and indus-
 14 trial partners to develop new or improved methods for de-
 15 tecting and subtyping emerging pathogens (borne in per-
 16 ishable products) in human specimens, perishable prod-
 17 ucts, and relevant environmental samples and to encour-
 18 age the rapid development of food safety monitoring sen-
 19 sors capable of detecting biological and chemical contami-
 20 nants.

21 “(b) 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 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
 2 are authorized to be appropriated to carry out this
 3 section—

4 “(1) \$50,000,000 for fiscal year 2002; and

5 “(2) such sums as are necessary for each subse-
 6 quent fiscal year.

7 **“SEC. 254. TRAINING, EDUCATION, AND PUBLIC INFORMA-**
 8 **TION.**

9 “(a) IN GENERAL.—The Secretary may—

10 “(1) make grants and enter into contracts with
 11 eligible entities, to support training activities and
 12 other collaborative activities with the entities to in-
 13 form health professionals about disease borne in per-
 14 ishable products, including strengthening training
 15 networks serving State, local, and private entities;
 16 and

17 “(2) increase and improve the activities carried
 18 out by the Centers for Disease Control and Preven-
 19 tion to provide information to the public on disease
 20 borne in perishable products.

21 “(b) ELIGIBLE ENTITIES.—To be eligible to receive
 22 a grant or enter into a contract under subsection (a), an
 23 entity shall be a medical school, a nursing school, an entity
 24 carrying out clinical laboratory training programs, a
 25 school of public health, another institution of higher edu-

1 cation, a professional organization, or an international or-
2 ganization.

3 “(c) APPLICATION.—To be eligible to receive a grant
4 or enter into a contract under subsection (a), an entity
5 shall submit an application to the Secretary at such time,
6 in such manner, and containing such information as the
7 Secretary may require.

8 “(d) CONSULTATION.—In carrying out this section,
9 the Secretary shall consult with Federal, State, and local
10 agencies, international organizations, and other interested
11 parties.

12 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated to carry out this section
14 such sums as may be necessary for fiscal years 2000
15 through 2002.

16 **“SEC. 255. INTERNATIONAL PUBLIC HEALTH TRAINING AND**
17 **TECHNICAL ASSISTANCE.**

18 “(a) IN GENERAL.—The Secretary shall, directly or
19 by agreement, provide training and technical assistance to
20 agencies and entities in foreign countries, to strengthen
21 the surveillance and investigation capacities of the agen-
22 cies and entities relating to disease borne in perishable
23 products, including establishing or expanding activities or
24 programs such as the Field Epidemiology and Training

1 Program of the Centers for Disease Control and Preven-
2 tion.

3 “(b) APPLICATION.—To be eligible to enter into an
4 agreement under subsection (a), an entity shall submit an
5 application to the Secretary at such time, in such manner,
6 and containing such information as the Secretary may re-
7 quire.

8 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
9 are authorized to be appropriated to carry out this section
10 such sums as may be necessary for fiscal years 2000
11 through 2002.

12 **“SEC. 256. SUPPLIES AND SERVICES IN LIEU OF GRANT**
13 **FUNDS.**

14 “(a) IN GENERAL.—On the request of a recipient of
15 assistance under section 252, 253, 254, or 255, the Sec-
16 retary may, subject to subsection (b), provide supplies,
17 equipment, and services for the purpose of aiding the re-
18 cipient in carrying out the section involved and, for such
19 purpose, may detail to the grant recipient any officer or
20 employee of the Department of Health and Human Serv-
21 ices. Such detail shall be without interruption or loss of
22 civil service status or privilege.

23 “(b) CORRESPONDING REDUCTION IN PAYMENTS.—
24 With respect to a request described in subsection (a), the
25 Secretary shall reduce the amount of payments under the

1 section involved by an amount equal to the cost of detail-
2 ing the officer or employee and the fair market value of
3 the supplies, equipment, or services provided by the Sec-
4 retary. The Secretary shall, for the payment of expenses
5 incurred in complying with such a request, expend the
6 amounts withheld.”.

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