

106TH CONGRESS
1ST SESSION

S. 823

To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 15, 1999

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

A BILL

To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Fruit and Vegetable Safety Act”.

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

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

Sec. 3. Definitions.

TITLE I—FOOD SAFETY ACTIVITIES

Sec. 101. Administration of national program.

Subtitle A—Processed Produce

Sec. 111. Good manufacturing practices.

Sec. 112. Inspections of processors.

Sec. 113. State and Federal cooperation.

Subtitle B—Raw Agricultural Commodities

Sec. 121. Good agricultural practices.

Sec. 122. Inspections of facilities.

TITLE II—RESEARCH AND EDUCATION

Sec. 201. Public health assessment system.

Sec. 202. Public education and advisory system.

Sec. 203. Research.

TITLE III—IMPORTED FOOD

Sec. 301. Criteria for deeming imported food adulterated.

1 **SEC. 2. FINDINGS.**

2 Congress finds that—

3 (1) persons who process produce for human
4 consumption have the responsibility to prevent or
5 minimize food safety hazards related to their prod-
6 ucts;

7 (2) consumption of fresh fruits and vegetables
8 can promote health and prevent disease, and should
9 be encouraged;

10 (3) rising consumer demand for processed
11 produce, the growing market for various kinds of do-
12 mestic and imported processed produce, and the in-
13 creasing variety of processing techniques for
14 produce, are causing newly recognized or
15 unpredicted safety hazards; and

1 (4) uniform sanitation practices, applied to
2 processing of produce, will minimize these hazards.

3 **SEC. 3. DEFINITIONS.**

4 In this Act:

5 (1) CONTAMINANT.—The term “contaminant”
6 includes a bacterium, a chemical contaminant, a nat-
7 ural toxin, a virus, a parasite, a physical hazard, or
8 other substance, that when found on or in produce
9 can cause human illness or injury.

10 (2) PROCESS.—The term “process”—

11 (A) means to carry out the commercial
12 preparation or manufacture of produce,
13 including—

14 (i) the freezing, dehydration, salting,
15 sprouting, peeling, coring, stemming, trim-
16 ming, fermentation, mashing, or shredding
17 of produce;

18 (ii) the cutting of produce after har-
19 vesting;

20 (iii) the final washing of produce that
21 will be presented for sale so as appear to
22 the average consumer to be ready for con-
23 sumption without further washing or prep-
24 aration; and

1 (iv) the mixing or blending of produce
2 with other produce; and

3 (B) does not include carrying out the har-
4 vesting, washing (except as provided in sub-
5 paragraph (A)(iii)), waxing, packing, or sorting,
6 of a raw agricultural commodity.

7 (3) PRODUCE.—The term “produce”—

8 (A) means any perishable agricultural com-
9 modity, as defined in section 1(b) of the Perish-
10 able Agricultural Commodities Act, 1930 (7
11 U.S.C. 499a(b));

12 (B)(i) includes, except as provided in
13 clause (ii), a mixture of—

14 (I) a commodity described in subpara-
15 graph (A); and

16 (II) any other food, as defined in sec-
17 tion 201 of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 321); and

19 (ii) does not include the other food in the
20 mixture described in clause (i)(II); and

21 (C) does not include an article used for
22 food or drink for animals, or an article used for
23 a component of such an article.

24 (4) RAW AGRICULTURAL COMMODITY.—The
25 term “raw agricultural commodity” means a perish-

able agricultural commodity, as defined in section 1(b) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 499a(b)) that is a raw agricultural commodity, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(5) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

TITLE I—FOOD SAFETY ACTIVITIES

SEC. 101. ADMINISTRATION OF NATIONAL PROGRAM.

(a) IN GENERAL.—

(1) NATIONAL PROGRAM.—The Secretary shall administer a national program for the purpose of protecting human health by ensuring that—

(i) the produce processing industry has effective programs in place to assure the safety of produce processed in the United States; and

(ii) producers of raw agricultural commodities have effective programs in place to assure the safety of those commodities produced in the United States.

(2) BASIS FOR PROGRAM.—The program shall take into consideration the distinctive characteristics of produce processing and the production of raw agricultural commodities.

1 (b) PROGRAM ELEMENTS.—The program shall pro-
 2 vide for implementation of the authorities described in—

3 (1) sections 402A, 402B, 407A, and 407B of
 4 the Federal Food, Drug, and Cosmetic Act, as
 5 added in subtitles A and B;

6 (2) section 113; and

7 (3) title II.

8 **Subtitle A—Processed Produce**

9 **SEC. 111. GOOD MANUFACTURING PRACTICES.**

10 (a) IN GENERAL.—Chapter IV of the Federal Food,
 11 Drug, and Cosmetic Act is amended by inserting after sec-
 12 tion 402 (21 U.S.C. 342) the following:

13 **“SEC. 402A. GOOD MANUFACTURING PRACTICES FOR** 14 **PRODUCE.**

15 “(a) GOOD MANUFACTURING PRACTICE REGULA-
 16 TIONS.—Not later than 1 year after the date of enactment
 17 of this section, the Secretary shall by regulation issue
 18 standards for good manufacturing practices for the proc-
 19 essing of produce.

20 “(b) APPLICATION.—

21 “(1) IN GENERAL.—The regulations issued
 22 under subsection (a) shall be the same as the provi-
 23 sions of the good manufacturing practice regulations
 24 that apply to the processing of food (notwith-
 25 standing any exclusions in Federal law relating to

1 establishments engaged solely in the harvesting,
 2 storage, or distribution of raw agricultural commod-
 3 ities), except as provided in paragraph (2).

4 “(2) EXCEPTIONS.—In issuing regulations
 5 under subsection (a), the Secretary may modify the
 6 provisions described in paragraph (1) if the Sec-
 7 retary determines, for good cause shown and stated
 8 together with the regulations, that—

9 “(A) a modification of such provisions
 10 would be more effective to prevent the contami-
 11 nation of, or promote the sanitation of, proc-
 12 essed produce; or

13 “(B) the application of a portion of such
 14 provisions would not result in the prevention of
 15 contamination of, or promotion of sanitation of,
 16 processed produce.

17 “(c) EFFECTIVE DATE.—The regulations described
 18 in subsection (a) take effect 2 years after the date of en-
 19 actment of this section.

20 “(d) DEFINITIONS.—In this section:

21 “(1) CONTAMINANT; PROCESS; PRODUCE.—The
 22 terms ‘contaminant’, ‘process’, and ‘produce’ have
 23 the meanings given the terms in section 3 of the
 24 Fruit and Vegetable Safety Act.

1 “(2) GOOD MANUFACTURING PRACTICE REGU-
 2 LATIONS.—The term ‘good manufacturing practice
 3 regulations’ means the good manufacturing practice
 4 regulations for manufacturing, packing, or holding
 5 food, issued under sections 402, 701, and 704 and
 6 under section 361 of the Public Health Service Act
 7 (42 U.S.C. 264).”.

8 (b) VIOLATION.—Section 402 of the Federal Food,
 9 Drug, and Cosmetic Act (21 U.S.C. 342) is amended by
 10 adding at the end the following:

11 “(h) It is an article of produce processed in violation
 12 of section 402A.”.

13 **SEC. 112. INSPECTIONS OF PROCESSORS.**

14 (a) IN GENERAL.—Chapter VII of the Federal Food,
 15 Drug, and Cosmetic Act is amended by inserting after sec-
 16 tion 704 (21 U.S.C. 374) the following:

17 **“SEC. 704A. INSPECTIONS OF PROCESSORS.**

18 “(a) NATURE OF INSPECTIONS.—

19 “(1) IN GENERAL.—The Secretary shall provide
 20 for unannounced inspections of processing facilities
 21 to determine if produce processed in the facilities is
 22 in compliance with the requirements of this Act that
 23 relate to produce.

24 “(2) SCHEDULE.—

1 “(A) IN GENERAL.—The Secretary shall
2 establish a schedule for the unannounced in-
3 spections, which shall provide for—

4 “(i) annual inspections for the facili-
5 ties, except as provided in clause (ii); and

6 “(ii) less frequent inspections for fa-
7 cilities classified as low-risk facilities under
8 subparagraph (B).

9 “(B) LOW-RISK FACILITIES.—The Sec-
10 retary may classify processing facilities as low-
11 risk facilities. In making the classification, the
12 Secretary shall classify facilities by considering
13 the hazards associated with the type of produce
14 being processed at a facility, the facility’s his-
15 tory of compliance and food safety problems,
16 and such other factors as the Secretary may de-
17 termine to be appropriate.

18 “(3) EXAMINATION OF CLASSIFICATIONS.—
19 Each such inspection of a facility shall include an
20 examination of whether the facility is appropriately
21 classified under paragraph (2).

22 “(b) CONDUCT OF INSPECTIONS.—

23 “(1) SCOPE.—An inspection under subsection
24 (a) of any facility described in subsection (a) shall
25 extend to all things in the facility (including records

1 required to be maintained under subsection
2 (d)(1)(A)), processes, controls, and premises) that
3 bear on whether processed produce is in compliance
4 with the requirements of this Act that relate to
5 produce. Access to records may include the copying
6 of the records.

7 “(2) AUTHORITIES.—In conducting such an in-
8 spection, an officer or employee duly designated by
9 the Secretary shall have the same authorities and
10 duties as the officer or employee would have under
11 subsection (a)(1), (c), or (d) of section 704 to in-
12 spect establishments in which food is processed.

13 “(3) REPORT.—Immediately after completion of
14 the inspection, the officer or employee making the
15 inspection shall give to the owner, operator, or agent
16 in charge a written report setting forth any condi-
17 tions or practices observed that indicate that any
18 produce from the facility is in violation of the re-
19 quirements of this Act that relate to produce.

20 “(c) PRODUCT DETENTION AND CONDEMNATION.—

21 “(1) IN GENERAL.—If, during an inspection
22 conducted under this section, an officer or employee
23 making the inspection determines that processed
24 produce is in violation of the requirements of this
25 Act that relate to produce, the officer or employee

1 may order the produce segregated, impounded, and
2 if objection is not made within 48 hours after the
3 issuance of the impoundment order, condemned. If
4 objection is made within that 48 hours, processed
5 produce that is perishable may be processed to the
6 extent necessary to prevent spoilage, and the Sec-
7 retary shall expeditiously commence a hearing re-
8 garding the determination and any action required
9 for compliance with the requirements of this Act
10 that relate to produce. The decision of the Secretary
11 following the hearing shall be considered to be a
12 final agency action.

13 “(2) RELEASE.—If the Secretary determines
14 that, through relabeling or other action, the produce
15 can be brought into compliance with the require-
16 ments of this Act that relate to produce, the produce
17 may be released following a determination by the
18 Secretary that the relabeling or other action as spec-
19 ified by the Secretary has been performed.

20 “(3) DESTRUCTION.—Any processed produce
21 condemned under paragraph (1)—

22 “(A) in a case in which no objection is
23 made under paragraph (1);

24 “(B) after the hearing and any judicial re-
25 view; or

1 “(C) after failure of the owner, operator,
 2 or agent to perform relabeling or other action
 3 described in paragraph (2);
 4 shall be destroyed under supervision of the Sec-
 5 retary.

6 “(d) MAINTENANCE OF RECORDS.—

7 “(1) IN GENERAL.—The owner, operator, or
 8 agent in charge of each processing facility shall
 9 maintain such records as the Secretary may pre-
 10 scribe. The records shall be maintained for a reason-
 11 able period of time as determined by the Secretary.
 12 The records shall include information concerning—

13 “(A)(i) the origin, receipt, delivery, sale,
 14 movement, holding, and disposition of produce
 15 processed at the facility;

16 “(ii) the processing of the produce; and

17 “(iii) other matters reasonably related to
 18 whether produce processed at the facility may
 19 be in violation of the requirements of this Act
 20 that relate to produce; and

21 “(B)(i) the origin, receipt, delivery, sale,
 22 movement, holding, and disposition of ingredi-
 23 ents used in the produce processed at the facil-
 24 ity, including sufficient information to permit
 25 lot identification to facilitate traceback of

1 produce found to be adulterated under the re-
2 quirements of this Act that relate to produce,
3 or to be causing human illness or injury;

4 “(ii) the identity and amount of ingredi-
5 ents used in the produce;

6 “(iii) the results of laboratory, sanitation,
7 or other quality control tests performed on the
8 produce or in the facility; and

9 “(iv) consumer complaints concerning the
10 produce or the packaging of the produce.

11 “(2) AVAILABILITY OF RECORDS.—The owner,
12 operator, or agent shall—

13 “(A) make available, during an inspection
14 conducted under subsection (a), the records de-
15 scribed in paragraph (1)(A); and

16 “(B) at the request of the Secretary, if the
17 officer or employee finds as a result of the in-
18 spection that produce from the facility is associ-
19 ated with foodborne disease or poses an immi-
20 nent health hazard, make available for inspec-
21 tion the records described in paragraph (1)(B).

22 “(e) DEFINITIONS.—

23 “(1) FACILITY.—The term ‘facility’ includes
24 any factory, warehouse, or establishment, in which
25 produce is processed.

1 “(2) PROCESS; PRODUCE.—The terms ‘process’
2 and ‘produce’ have the meanings given the terms in
3 section 3 of the Fruit and Vegetable Safety Act.”.

4 (b) REMEDIES.—

5 (1) IN GENERAL.—Paragraphs (f) and (n) of
6 section 301, and section 304(g)(1), of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 331,
8 334(g)(1)) are amended by striking “section 704”
9 and inserting “section 704 or 704A”.

10 (2) PROHIBITED DISCLOSURES.—Section 301(j)
11 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 331(j)) is amended by striking “704,” and
13 inserting “704, 704A,”.

14 (c) CONFORMING AMENDMENT.—Section 742(a)(2)
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 379l(a)(2)) is amended by striking “section 704” and in-
17 serting “section 704 or 704A”.

18 **SEC. 113. STATE AND FEDERAL COOPERATION.**

19 (a) IN GENERAL.—The Secretary shall work with the
20 States in undertaking activities and programs that con-
21 tribute to the national program established under section
22 111 so that State food safety programs involving the safe-
23 ty of processed produce and the national program function
24 in a coordinated and cost-effective manner. With the as-

1 sistance provided under subsection (b), the Secretary shall
2 encourage States to—

3 (1) establish, continue, or strengthen State food
4 safety programs, especially with respect to the regu-
5 lation of retail commercial food establishments; and

6 (2) establish procedures and requirements for
7 ensuring that processed produce under the jurisdic-
8 tion of the State food safety programs is not unsafe
9 for human consumption.

10 (b) ASSISTANCE.—The Secretary may provide to a
11 State, for planning, developing, and implementing such a
12 food safety program—

13 (1) advisory assistance;

14 (2) technical assistance, training, and labora-
15 tory assistance (including necessary materials and
16 equipment); and

17 (3) financial and other assistance.

18 (c) SERVICE AGREEMENTS.—The Secretary may,
19 under an agreement entered into with a Federal, State,
20 or local agency, use, on a reimbursable basis or otherwise,
21 the personnel, services, and facilities of the agency to carry
22 out the responsibilities of the agency under this Act. The
23 agreement shall provide that any compliance records, no-
24 tices, or reports that are recorded or issued in connection
25 with activities under the agreement, and are in the posses-

1 sion of the agency that entered into the agreement shall
 2 be made available in accordance with section 552 of title
 3 5, United States Code. An agreement entered into with
 4 a State agency under this subsection may provide for
 5 training of State employees.

6 **Subtitle B—Raw Agricultural** 7 **Commodities**

8 **SEC. 121. GOOD AGRICULTURAL PRACTICES.**

9 (a) IN GENERAL.—Chapter IV of the Federal Food,
 10 Drug, and Cosmetic Act, as amended by section 111(a),
 11 is further amended by inserting after section 402A the fol-
 12 lowing:

13 **“SEC. 402B. GOOD AGRICULTURAL PRACTICES FOR RAW** 14 **AGRICULTURAL COMMODITIES.**

15 “(a) GOOD AGRICULTURAL PRACTICE REGULA-
 16 TIONS.—Not later than 2 years after the date of enact-
 17 ment of this section, the Secretary, in consultation with
 18 the Secretary of Agriculture, shall by regulation issue
 19 standards for good agricultural practices for the produc-
 20 tion of raw agricultural commodities, in order to minimize
 21 the adulteration and maximize the safety of those com-
 22 modities.

23 “(b) IMPLEMENTATION PLAN.—Not later than 3
 24 years after the date of enactment of this section, the Sec-
 25 retary, in consultation with the Secretary of Agriculture,

1 shall issue and carry out an implementation plan for the
2 implementation of the standards.

3 “(c) EFFECTIVE DATE.—The regulations described
4 in subsection (a) take effect 3 years after the date of en-
5 actment of this section.

6 “(d) DEFINITION.—The term ‘raw agricultural com-
7 modity’ means a perishable agricultural commodity, as de-
8 fined in section 1(b) of the Perishable Agricultural Com-
9 modities Act, 1930 (7 U.S.C. 499a(b)) that is a raw agri-
10 cultural commodity, as defined in section 201.”.

11 (b) VIOLATION.—Section 402(h) of the Federal
12 Food, Drug, and Cosmetic Act, as added by section
13 111(b), is amended by inserting before the period the fol-
14 lowing: “or a raw agricultural commodity produced in vio-
15 lation of section 402B”.

16 **SEC. 122. INSPECTIONS OF FACILITIES.**

17 (a) IN GENERAL.—Chapter VII of the Federal Food,
18 Drug, and Cosmetic Act, as amended by section 112(a),
19 is further amended by inserting after section 704A the fol-
20 lowing:

21 **“SEC. 704B. INSPECTIONS OF FACILITIES.**

22 “(a) NATURE OF INSPECTIONS.—Officers and em-
23 ployees duly designated by the Secretary shall have the
24 authority to inspect appropriate facilities to determine
25 compliance with the standards described in section 402B.

1 “(b) REGULATIONS.—Not later than 2 years after
 2 the date of enactment of this section, the Secretary, in
 3 consultation with the Secretary of Agriculture, shall by
 4 regulation issue procedures for conducting the inspections.

5 “(c) EFFECTIVE DATE.—Subsection (a) and the reg-
 6 ulations described in subsection (b) take effect 3 years
 7 after the date of enactment of this section.”.

8 (b) REMEDIES.—

9 (1) IN GENERAL.—Paragraphs (f) and (n) of
 10 section 301, and section 304(g)(1), of the Federal
 11 Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)),
 12 as amended in section 112(b), are further amended
 13 by striking “or 704A” and inserting “, 704A, or
 14 704B”.

15 (2) PROHIBITED DISCLOSURES.—Section 301(j)
 16 of the Federal Food, Drug, and Cosmetic Act (21
 17 U.S.C. 333(j)), as amended in section 112(b), is fur-
 18 ther amended by inserting “704B,” after “704A,”.

19 (c) CONFORMING AMENDMENT.—Section 742(a)(2)
 20 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 21 379l(a)(2)), as amended in section 112(c), is further
 22 amended by striking “or 704A” and inserting “, 704A,
 23 or 704B”.

1 **TITLE II—RESEARCH AND**
2 **EDUCATION**

3 **SEC. 201. PUBLIC HEALTH ASSESSMENT SYSTEM.**

4 (a) COOPERATION WITH THE CENTERS FOR DISEASE
5 CONTROL AND PREVENTION.—The Commissioner of Food
6 and Drugs, in cooperation with the Secretary of Agri-
7 culture, the Director of the Centers for Disease Control
8 and Prevention, and the Administrator of the Environ-
9 mental Protection Agency, shall establish and maintain an
10 active surveillance system, for surveillance of a representa-
11 tive proportion of the population of the United States, to
12 assess more accurately the frequency and sources of
13 human illness in the United States associated with the
14 consumption of produce.

15 (b) PUBLIC HEALTH SAMPLING.—

16 (1) GUIDELINES.—Not later than 12 months
17 after the date of enactment of this Act, the Commis-
18 sioner of Food and Drugs, in cooperation with the
19 Secretary of Agriculture, the Director of the Centers
20 for Disease Control and Prevention, and the Admin-
21 istrator of the Environmental Protection Agency,
22 shall establish guidelines for a sampling system
23 under which the Commissioner and the Secretary of
24 Agriculture shall collect and analyze samples of
25 produce to assist the Commissioner in carrying out

1 this Act and the requirements of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
3 that relate to produce, and to assess more accurately
4 the nature, frequency of occurrence, and amounts of
5 contaminants in the produce.

6 (2) MONITORING AND OTHER INFORMATION.—

7 In carrying out the sampling system, the Commis-
8 sioner of Food and Drugs and the Secretary of Agri-
9 culture shall provide for—

10 (A) statistically valid monitoring, including
11 the conduct of market-basket studies, on the
12 nature, frequency of occurrence, and amounts
13 of contaminants in produce available to con-
14 sumers; and

15 (B) at the request of the Commissioner,
16 the collection and analysis of such other infor-
17 mation, including analysis of information from
18 monitoring and verification samples, as the
19 Commissioner determines may be useful in as-
20 sessing the occurrence of contaminants in
21 produce.

22 (3) PROCESS VERIFICATION STANDARD.—The
23 Commissioner of Food and Drugs and the Secretary
24 of Agriculture shall conduct sampling to identify—

1 (A) a contaminant, or other substance,
2 that is commonly found on processed produce
3 and, when present at low levels, accurately indi-
4 cates that the produce has been appropriately
5 processed, with adequate sanitation; and

6 (B) a standard for the level of that sub-
7 stance that indicates that the produce has been
8 processed as described in subparagraph (A).

9 **SEC. 202. PUBLIC EDUCATION AND ADVISORY SYSTEM.**

10 (a) PUBLIC EDUCATION.—The Commissioner of
11 Food and Drugs, in cooperation with private and public
12 organizations, including the State cooperative extension
13 services and appropriate State entities, shall design and
14 implement a national public education program on food
15 safety relating to produce. In carrying out the program,
16 the Commissioner shall—

17 (1) provide information to the public regarding
18 Federal standards and good manufacturing practice
19 requirements relating to food safety and promote
20 public awareness, understanding, and acceptance of
21 the standards and requirements; and

22 (2) provide such other information or advice to
23 the produce processing industry, the food service and
24 retail industry, consumers, and other persons as the

1 Commissioner determines will promote the purposes
2 of this Act.

3 (b) HEALTH ADVISORIES.—The Commissioner of
4 Food and Drugs, in cooperation with the Secretary of Ag-
5 riculture, the Director of the Centers for Disease Control
6 and Prevention, the Administrator of the Environmental
7 Protection Agency, States, and other appropriate entities,
8 shall—

9 (1) develop and distribute regional and national
10 advisories concerning food safety relating to
11 produce;

12 (2) develop standardized formats for written
13 and broadcast advisories concerning food safety re-
14 lating to produce; and

15 (3) incorporate State and local advisories, at
16 the election of the States and local entities, con-
17 cerning food safety relating to produce into the na-
18 tional public education program required under sub-
19 section (a).

20 **SEC. 203. RESEARCH.**

21 (a) IN GENERAL.—The Commissioner of Food and
22 Drugs shall conduct research to assist in the implementa-
23 tion of this Act and the requirements of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that re-
25 late to produce, including studies relating to—

19 **TITLE III—IMPORTED FOOD**

(a) AMENDMENT TO THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT.—Section 402 of the Federal Food,
Drug, and Cosmetic Act (21 U.S.C. 342), as amended by

1 sections 111(b) and 121(b), is further amended by adding
2 at the end the following:

3 “(i) If it is food consisting of processed produce or
4 a raw agricultural commodity (as defined in section 402A
5 or 402B) that is offered for import into the United States
6 and that has not been prepared, packed, and held under
7 a system or conditions, or subject to measures, that meet
8 the requirements of this Act (including sections 402A and
9 402B), or that otherwise achieve the level of protection
10 required, as determined by the Secretary, for such food
11 prepared, packed, or held in the United States. In deter-
12 mining whether a system, conditions, or measures meet
13 the requirements of this Act or otherwise achieve the level
14 of protection required, the Secretary may consider whether
15 an officer or employee duly designated by the Secretary
16 has requested, and has been refused, access to the estab-
17 lishment or location where such food was prepared,
18 packed, or held for the purpose of inspection (including
19 sample collection), including inspection under subsection
20 (a)(1), (b), or (d) of section 704A or section 704B, test-
21 ing, or other relevant procedures, at a reasonable time and
22 in a reasonable manner, and may deny the importation
23 of such food from such establishment or location on the
24 basis of such refusal and other relevant factors.”.

1 (b) IMPLEMENTATION OF AUTHORITY; PLAN.—The
2 Secretary of Health and Human Services shall develop a
3 plan for the initial implementation of the authority under
4 section 402(i) of the Federal Food, Drug, and Cosmetic
5 Act, as added by subsection (a), and shall carry out the
6 authority of such section consistent with such plan.

○