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

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 20, 2007

Mr. HARKIN (for himself, Mr. KOHL, 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 fresh 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 “Fresh Produce 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—Minimally Processed Produce

Sec. 111. Good manufacturing practices.

Sec. 112. Inspections of processors.

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 system.

Sec. 203. Research.

TITLE III—IMPORTED PRODUCE AND OTHER PROVISIONS

Sec. 301. Imported produce.

Sec. 302. Authorization of appropriations.

1 **SEC. 2. FINDINGS.**

2 Congress finds that—

3 (1) consumption of fresh fruits and vegetables
4 can promote health and prevent disease, and should
5 be encouraged;

6 (2) an estimated 76,000,000 cases of foodborne
7 disease occur each year in the United States, caus-
8 ing about 325,000 hospitalizations and 5,000 deaths
9 annually, according to the Centers for Disease Con-
10 trol and Prevention (referred to in this section as
11 the “CDC”);

12 (3) data reported to the CDC indicate that out-
13 breaks of foodborne illness in the United States as-
14 sociated with fruits and vegetables have increased in
15 absolute numbers and as a proportion of all reported
16 foodborne outbreaks;

1 (4) illnesses caused by *E. coli* O157: H7, *Sal-*
2 *monella* spp., and norovirus have been traced to a
3 wide variety of produce, including lettuce, salads,
4 melons, sprouts, tomatoes, and many fruit- and veg-
5 etable-containing dishes;

6 (5) outbreaks of food-borne illness associated
7 with produce in the United States have been docu-
8 mented from both imported produce and domesti-
9 cally grown produce;

10 (6) large scale processing of produce can easily
11 spread pathogens into minimally processed food and
12 a single outbreak can affect hundreds of people;

13 (7) persons who process produce for human
14 consumption have the responsibility to prevent or
15 minimize food safety hazards related to their prod-
16 ucts;

17 (8) rising consumer demand for minimally proc-
18 essed produce, the growing market for various kinds
19 of domestic and imported minimally processed
20 produce, and the increasing variety of processing
21 techniques for produce, are causing newly recognized
22 or unpredicted safety hazards; and

23 (9) risk-based sanitation practices, and com-
24 modity-specific good agricultural and manufacturing
25 practices, tailored to the hazards and the level of

1 risk that a specific food product presents, should be
2 applied to the processing of produce to minimize
3 these hazards.

4 **SEC. 3. DEFINITIONS.**

5 In this Act:

6 (1) CONTAMINANT.—The term “contaminant”
7 includes a bacterium, chemical, natural or manufac-
8 tured toxin, virus, parasite, physical hazard, or other
9 human pathogen that, when in food, can cause
10 human illness, injury, or death.

11 (2) MINIMALLY PROCESS.—

12 (A) IN GENERAL.—The term “minimally
13 process” means—

14 (i) to carry out the commercial prepa-
15 ration or manufacture of produce, includ-
16 ing—

17 (I) the peeling, coring, stemming,
18 trimming, mashing, or shredding of
19 produce;

20 (II) the cutting of produce after
21 harvesting;

22 (III) the preparation of fresh
23 produce so to as to appear ready for
24 consumption without further washing
25 or preparation; and

1 (IV) the mixing or blending of
2 minimally processed produce with
3 other produce; and

4 (ii) does not include carrying out the
5 harvesting, washing (except as provided in
6 clause (i)(III)), waxing, packing, or sort-
7 ing, of a raw agricultural commodity.

8 (B) EXCEPTION.—The term “minimally
9 process” shall not apply to a raw agricultural
10 commodity that is stemmed but not subject to
11 further commercial preparation.

12 (3) PROCESSOR OF PRODUCE.—The term
13 “processor of produce” means a person that mini-
14 mally processes produce.

15 (4) PRODUCE.—

16 (A) IN GENERAL.—The term “produce”
17 means any perishable agricultural commodity,
18 as defined in section 1(b) of the Perishable Ag-
19 ricultural Commodities Act, 1930 (7 U.S.C.
20 499a(b)).

21 (B) INCLUSIONS.—The term “produce” in-
22 cludes a mixture of—

23 (i) a commodity described in subpara-
24 graph (A); and

1 (ii) any other food, as defined in sec-
 2 tion 201 of the Federal Food, Drug, and
 3 Cosmetic Act (21 U.S.C. 321).

4 (C) EXCLUSIONS.—The term “produce”
 5 does not include—

6 (i) other food in the mixture described
 7 in subparagraph (B)(ii); and

8 (ii) an article used for food or drink
 9 for animals, or an article used for a com-
 10 ponent of such an article.

11 (5) RAW AGRICULTURAL COMMODITY.—The
 12 term “raw agricultural commodity” means a perish-
 13 able agricultural commodity, as defined in section
 14 1(b) of the Perishable Agricultural Commodities Act,
 15 1930 (7 U.S.C. 499a(b)) that is a raw agricultural
 16 commodity, as defined in section 201 of the Federal
 17 Food, Drug, and Cosmetic Act (21 U.S.C. 321).

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

20 **TITLE I—FOOD SAFETY**
 21 **ACTIVITIES**

22 **SEC. 101. ADMINISTRATION OF NATIONAL PROGRAM.**

23 (a) IN GENERAL.—

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

4 (A) there are effective programs in place to
5 assure the safety of produce minimally pro-
6 cessed in the United States; and

7 (B) producers of raw agricultural commod-
8 ities have effective programs in place to assure
9 the safety of those commodities produced in the
10 United States.

11 (2) BASIS FOR PROGRAM.—The program shall
12 take into consideration the distinctive characteristics
13 of minimal processing of produce and the differing
14 practices and levels of risk associated with the pro-
15 duction of different raw agricultural commodities.

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

18 (1) sections 402A, 402B, 704A, and 704B of
19 the Federal Food, Drug, and Cosmetic Act, as
20 added by subtitles A and B; and

21 (2) title II.

1 **Subtitle A—Minimally Processed**
 2 **Produce**

3 **SEC. 111. GOOD MANUFACTURING PRACTICES.**

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

7 **“SEC. 402A. GOOD MANUFACTURING PRACTICES FOR**
 8 **PRODUCE.**

9 “(a) GOOD MANUFACTURING PRACTICE REGULA-
 10 TIONS.—

11 “(1) IN GENERAL.—Not later than 1 year after
 12 the date of enactment of this section, the Secretary
 13 shall by regulation establish standards for good
 14 manufacturing practices for the minimal processing
 15 of produce.

16 “(2) CONTENT.—The regulations issued under
 17 paragraph (1) shall include the following require-
 18 ments:

19 “(A) SANITATION.—Processors of produce
 20 shall—

21 “(i) establish mandatory sanitation
 22 standard operating procedures, including
 23 cleaning procedures for equipment, storage
 24 areas, air systems, and water storage
 25 areas;

1 “(ii) design processing facilities to fa-
2 cilitate maintenance and good sanitation
3 practices so that contamination may be
4 controlled throughout receiving, cooling,
5 processing, packing, and storage oper-
6 ations; and

7 “(iii) ensure—

8 “(I) controlled access to the facil-
9 ity and to processing areas;

10 “(II) adequate space for oper-
11 ations;

12 “(III) adequate drainage of proc-
13 essing and wash water;

14 “(IV) food contact surfaces that
15 are easy to clean and maintain;

16 “(V) that areas and structures
17 designed to protect the product and
18 equipment from contamination; and

19 “(VI) that sanitation standards
20 established in clause (i) are adhered
21 to in the transportation of minimally
22 processed produce to the extent prac-
23 ticable.

24 “(B) WATER.—

1 “(i) IN GENERAL.—Processors of
2 produce shall ensure that—

3 “(I) the water supply used in
4 food processing plants is suitable for
5 its intended use;

6 “(II) facilities have an environ-
7 mental monitoring program that in-
8 cludes sampling for pathogens to de-
9 tect areas of harborage and to verify
10 the effectiveness of cleaning and sani-
11 tizing programs in preventing cross-
12 contamination; and

13 “(III) each sanitizer used for
14 washing vegetables is appropriate for
15 its intended use.

16 “(ii) SAMPLING PROGRAMS FOR
17 WATER.—If the Secretary determines that
18 effective sampling programs can be devel-
19 oped, processors of produce shall ensure
20 that the water used for washing produce is
21 monitored for the presence of pathogens at
22 a rate adequate to ensure highly contami-
23 nated batches are identified and elimi-
24 nated.

1 “(C) ADDITIONAL REQUIREMENTS.—Other
2 requirements as determined appropriate by the
3 Secretary.

4 “(3) RISK ASSESSMENT.—The standards estab-
5 lished under paragraph (1) shall be based on risk as-
6 sessment tools and metrics developed by the Food
7 and Drug Administration in consultation with the
8 Department of Agriculture and processors of
9 produce. The risk assessments shall include—

10 “(A) identification of existing and potential
11 hazards at facilities;

12 “(B) evaluation of human health risks
13 posed by hazards identified in subparagraph
14 (A); and

15 “(C) proposed controls to minimize haz-
16 ards based on subparagraph (B).

17 “(4) RISK CLASSIFICATION.—The Secretary
18 shall classify facilities as high-, medium-, or low-risk
19 according to the risk assessments in paragraph (3),
20 and by considering the hazards associated with the
21 type of produce being minimally processed at a facil-
22 ity, the facility’s history of compliance and food safe-
23 ty problems, and such other factors as the Secretary
24 may determine to be appropriate. Such risk classi-

1 fication shall determine the specific standards and
2 controls required at each facility.

3 “(5) SCIENCE-BASED STANDARDS.—The stand-
4 ards established under paragraph (1) shall—

5 “(A) reflect the best available science; and

6 “(B) be subject to change through regula-
7 tions promulgated by the Secretary as new sci-
8 entific evidence on risk becomes available.

9 “(b) IMPLEMENTATION PLAN FOR PROCESSORS.—

10 “(1) IN GENERAL.—Not later than 2 years
11 after the date of enactment of this section, the Sec-
12 retary shall require every processor of produce to
13 have a written plan detailing the controls utilized the
14 processor of produce.

15 “(2) CONTENT.—A plan under paragraph (1)
16 shall—

17 “(A) address good manufacturing stand-
18 ards set forth by the Secretary;

19 “(B) require recordkeeping to monitor
20 compliance;

21 “(C) require the sampling of products and
22 process to be tested, at a frequency and in a
23 manner commensurate with the risk presented
24 by the facility and produce processed, as deter-
25 mined in subsection (a)(3), if the Secretary

1 deems this appropriate, and sufficient to ensure
2 that the standards or process controls are effec-
3 tive on an on-going basis and that regulatory
4 standards are met; and

5 “(D) provide access to the Food and Drug
6 Administration to records maintained by the fa-
7 cility pursuant to section 414.

8 “(3) SPECIFIC CONTROLS.—In addition to com-
9 plying with standards established under section
10 402A(a)(1), the Secretary may require processors to
11 adopt specific process controls identified in section
12 402A(a)(3), if the process controls are needed to en-
13 sure the protection of the public health.

14 “(4) TIERED IMPLEMENTATION.—The Sec-
15 retary shall require such a plan for high-risk facili-
16 ties first, and then for medium-risk facilities, and
17 then for low-risk facilities, as classified under sub-
18 section (a)(4).

19 “(c) EXCEPTIONS.—In issuing regulations under sub-
20 section (a), the Secretary may modify the good manufac-
21 turing process regulations if the Secretary determines, for
22 good cause shown and stated together with the regula-
23 tions, that for a specific product—

24 “(1) a modification of such provisions would be
25 more effective to prevent the contamination of, or

1 promote the sanitation of, minimally processed
2 produce; or

3 “(2) the application of a portion of such provi-
4 sions would not result in the prevention of contami-
5 nation of, or promotion of sanitation of, minimally
6 processed produce.

7 “(d) EFFECTIVE DATE.—The regulations promul-
8 gated under subsection (a) shall take effect 2 years after
9 the date of enactment of this section.

10 “(e) DEFINITIONS.—In this section:

11 “(1) CONTAMINANT; MINIMALLY PROCESS;
12 PRODUCE.—The terms ‘contaminant’, ‘minimally
13 process’, and ‘produce’ have the meanings given
14 those terms in section 3 of the Fresh Produce Safety
15 Act.

16 “(2) FACILITY.—The term ‘facility’ includes
17 any factory, warehouse, or establishment, in which
18 produce is minimally processed.

19 “(3) GOOD MANUFACTURING PRACTICE REGU-
20 LATIONS.—The term ‘good manufacturing practice
21 regulations’ means the good manufacturing practice
22 regulations for manufacturing, packing, or holding
23 food, issued under sections 402, 701, and 704 of
24 this Act and under section 361 of the Public Health
25 Service Act (42 U.S.C. 264).”.

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

4 “(j) It is an article of produce processed in violation
5 of section 402A.”

6 **SEC. 112. INSPECTIONS OF PROCESSORS.**

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

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

11 “(a) NATURE OF INSPECTIONS.—

12 “(1) IN GENERAL.—The Secretary shall provide
13 for unannounced inspections of processing facilities
14 to determine if produce processed in the facilities is
15 in compliance with the requirements of this Act that
16 relate to produce.

17 “(2) SCHEDULE.—The Secretary shall establish
18 a schedule for the unannounced inspections, which
19 shall provide for—

20 “(A) inspections at least once per growing
21 season for facilities classified as high-risk under
22 section 402A(a)(4); and

23 “(B) less frequent inspections, as deter-
24 mined by the Secretary, for facilities classified

1 as medium- or low-risk facilities under section
2 402A(a)(4).

3 “(3) EXAMINATION OF CLASSIFICATIONS.—

4 Each such inspection of a facility shall include an
5 examination of whether the facility is appropriately
6 classified under section 402A(a)(4).

7 “(b) CONDUCT OF INSPECTIONS.—

8 “(1) SCOPE.—An inspection under subsection
9 (a) of any facility described in subsection (a) shall
10 extend to all things in the facility, any required
11 records, processes, controls, and premises that bear
12 on whether minimally processed produce is in com-
13 pliance with the requirements of this Act that relate
14 to produce. Access to records may include the copy-
15 ing of the records.

16 “(2) AUTHORITIES.—In conducting such an in-
17 spection, an officer or employee duly designated by
18 the Secretary shall have the same authorities and
19 duties as the officer or employee would have under
20 subsection (a)(1), (c), or (d) of section 704 to in-
21 spect facilities in which food is minimally processed.

22 “(3) REPORT.—Not later than 48 hours after
23 completion of the inspection, the officer or employee
24 making the inspection shall give to the owner, oper-
25 ator, or agent in charge a written report setting

1 forth any conditions or practices observed that indi-
2 cate that any produce from the facility is in violation
3 of the requirements of this Act that relate to
4 produce.

5 “(c) PRODUCT DETENTION AND CONDEMNATION.—

6 “(1) IN GENERAL.—If, during an inspection
7 conducted under this section, an officer or employee
8 making the inspection determines that minimally
9 processed produce is in violation of the requirements
10 of this Act that relate to produce, the officer or em-
11 ployee may order the produce segregated, im-
12 pounded, and if objection is not made no later than
13 48 hours after the issuance of the impoundment
14 order, condemned. If objection is made during such
15 48-hour period, minimally processed produce that is
16 perishable may be processed to the extent necessary
17 to prevent spoilage, and the Secretary shall expedi-
18 tiously commence a hearing within 24 hours after
19 the objection regarding the determination and any
20 action required for compliance with the requirements
21 of this Act that relate to produce. The decision of
22 the Secretary following the hearing shall be consid-
23 ered to be a final agency action.

24 “(2) RELEASE.—If the Secretary determines
25 that, through relabeling or other action, the produce

1 can be brought into compliance with the require-
2 ments of this Act that relate to produce, the produce
3 may be released following a determination by the
4 Secretary that the relabeling or other action as spec-
5 ified by the Secretary has been performed.

6 “(3) DESTRUCTION.—Any minimally processed
7 produce condemned under paragraph (1)—

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

10 “(B) after the hearing and any judicial re-
11 view; or

12 “(C) after failure of the owner, operator,
13 or agent to perform relabeling or other action
14 described in paragraph (2),

15 shall be destroyed under supervision of the Sec-
16 retary.

17 “(d) MAINTENANCE OF RECORDS.—

18 “(1) IN GENERAL.—The owner, operator, or
19 agent in charge of each facility shall maintain such
20 records as the Secretary may prescribe. The records
21 shall be maintained for a reasonable period of time
22 as determined by the Secretary. The records shall
23 include information concerning—

1 “(A)(i) the origin, receipt, delivery, sale,
2 movement, holding, and disposition of produce
3 minimally processed at the facility;

4 “(ii) the minimal processing of the
5 produce; and

6 “(iii) other matters reasonably related to
7 whether produce minimally processed at the fa-
8 cility may be in violation of the requirements of
9 this Act that relate to produce; and

10 “(B)(i) the origin, receipt, delivery, sale,
11 movement, holding, and disposition of ingredi-
12 ents used in the produce minimally processed at
13 the facility, including sufficient information to
14 permit lot identification to facilitate traceback
15 of produce found to be in violation of the re-
16 quirements of this Act that relate to produce,
17 or to be causing human illness or injury;

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

20 “(iii) the results of laboratory, sanitation,
21 or other quality control tests performed on the
22 produce or in the facility; and

23 “(iv) consumer complaints concerning the
24 safety of the produce or the packaging of the
25 produce.

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

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

6 “(B) at the request of the Secretary, if the
7 officer or employee finds as a result of the in-
8 spection that produce from the facility is associ-
9 ated with foodborne disease or poses an immi-
10 nent health hazard, make available for inspec-
11 tion the records described in paragraph (1)(B).

12 “(3) REQUIRED DISCLOSURE.—The owner, op-
13 erator, or agent in charge of a facility shall have an
14 affirmative obligation to take corrective action, in-
15 cluding ensuring the product is not introduced into
16 commerce, as approved by the Commissioner of
17 Food and Drugs or the Secretary, if the results of
18 testing or sampling of produce, equipment, or mate-
19 rial in contact with produce are positive for any con-
20 taminant, in accordance with section 414. The
21 owner, operator, or agent in charge of a facility shall
22 have an affirmative obligation to disclose to the
23 Commissioner of Food and Drugs or the Secretary
24 if the results of testing finds a positive test result
25 and the product is in commerce.

1 “(e) DEFINITIONS.—

2 “(1) FACILITY.—The term ‘facility’ includes
3 any factory, warehouse, or establishment, in which
4 produce is minimally processed.

5 “(2) MINIMALLY PROCESS; PRODUCE.—The
6 terms ‘minimally process’ and ‘produce’ have the
7 meanings given those terms in section 3 of the
8 Fresh Produce Safety Act.”.

9 (b) REMEDIES.—

10 (1) IN GENERAL.—Paragraphs (f) and (n) of
11 section 301, and section 304(g)(1), of the Federal
12 Food, Drug, and Cosmetic Act (21 U.S.C. 331,
13 334(g)(1)) are amended by striking “section 704”
14 and inserting “section 704 or 704A”.

15 (2) PROHIBITED DISCLOSURES.—Section 301(j)
16 of the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 331(j)) is amended by striking “704,” and
18 inserting “704, 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)) is amended by striking “section 704” and in-
22 serting “section 704 or 704A”.

1 **Subtitle B—Raw Agricultural**
 2 **Commodities**

3 **SEC. 121. GOOD AGRICULTURAL PRACTICES.**

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

8 **“SEC. 402B. GOOD AGRICULTURAL PRACTICES FOR RAW**
 9 **AGRICULTURAL COMMODITIES.**

10 “(a) GOOD AGRICULTURAL PRACTICE REGULA-
 11 TIONS.—

12 “(1) IN GENERAL.—Not later than 1 year after
 13 the date of enactment of this section, the Secretary,
 14 in consultation with the Secretary of Agriculture,
 15 shall by regulation establish general standards for
 16 good agricultural practices for the production of raw
 17 agricultural commodities, in order to minimize the
 18 violations of this Act and maximize the safety of
 19 those commodities.

20 “(2) CONTENTS.—The regulations issued under
 21 paragraph (1) shall include the following require-
 22 ments:

23 “(A) MANURE.—Growers of a raw agri-
 24 culture commodity shall—

1 “(i) manage the application of manure
2 to ensure that it does not contribute to the
3 contamination of crops, including limita-
4 tions on the crops where and when manure
5 may be applied; and

6 “(ii) monitor and maintain records re-
7 lating to use of manure in composting in-
8 tended for use on food crops to ensure ef-
9 fective controls are used to destroy patho-
10 gens.

11 “(B) ANIMALS, DOMESTIC AND WILD-
12 LIFE.—Growers of a raw agricultural com-
13 modity shall ensure that domestic animals
14 should be excluded, to the extent reasonably
15 practicable, from fields and orchards during the
16 growing and harvesting season, and growing
17 areas should have wildlife deterrents.

18 “(C) WATER.—Growers of a raw agricul-
19 tural commodity shall ensure that the water
20 supply used for irrigation and for washing is
21 suitable for its intended use and that ground
22 water is regularly monitored for the presence of
23 pathogens at a rate adequate to ensure that
24 contaminated water is identified and diverted
25 from use on food crops.

1 “(D) ENVIRONMENTAL CONDITIONS.—
2 Growers of a raw agricultural commodity shall
3 consider the unique environmental conditions
4 that might increase the likelihood of crop con-
5 tamination, including flooding, runoff, drought,
6 and other conditions and develop safety plans to
7 ensure contaminated crops are not distributed.

8 “(E) ADDITIONAL REQUIREMENTS.—Other
9 requirements as determined appropriate by the
10 Secretary.

11 “(3) RISK ASSESSMENT.—The standards estab-
12 lished under paragraph (1) shall be based on risk as-
13 sessment tools and metrics developed by the Food
14 and Drug Administration in consultation with the
15 Department of Agriculture and growers of produce.
16 The risk assessments shall include—

17 “(A) identification of existing and potential
18 hazards at facilities;

19 “(B) evaluation of human health risks
20 posed by hazards identified in subparagraph
21 (A); and

22 “(C) proposed controls to minimize haz-
23 ards based on subparagraph (B).

24 “(4) RISK CLASSIFICATION.—The Secretary
25 shall classify facilities as high-, medium-, or low-risk

1 according to the risk assessments in paragraph (3),
2 and by considering the hazards associated with the
3 type of produce being grown at a facility, the facili-
4 ty's history of compliance and food safety problems,
5 and such other factors as the Secretary may deter-
6 mine to be appropriate. Such risk classification shall
7 determine the specific standards and controls re-
8 quired at each facility.

9 “(5) SCIENCE-BASED STANDARDS.—The stand-
10 ards established under paragraph (1) shall—

11 “(A) reflect the best available science; and

12 “(B) be subject to change as new scientific
13 evidence on risk becomes available.

14 “(b) IMPLEMENTATION PLAN.—

15 “(1) IN GENERAL.—Not later than 2 years
16 after the date of enactment of this section, the Sec-
17 retary shall require growers of a raw agricultural
18 commodity to have a written plan detailing the con-
19 trols utilized by the grower that limit the presence
20 and growth of contaminants.

21 “(2) CONTENT.—A plan under paragraph (1)
22 shall—

23 “(A) address standards for good agricul-
24 tural practices developed under subsection (a);

1 “(B) require recordkeeping to monitor
2 compliance;

3 “(C) require sampling of product to be
4 tested at a frequency and in a manner commensurate with the risk presented by the facility
5 and produce grown as determined in subsection
6 (a)(3), if the Secretary deems this appropriate,
7 and sufficient to ensure that the standards or
8 process controls are effective on an on-going
9 basis and that regulatory standards are met;
10 and
11

12 “(D) provide access to the Food and Drug
13 Administration to records maintained by the facility.
14

15 “(3) SPECIFIC CONTROLS.—The Secretary may
16 require growers of a raw agricultural commodity to
17 adopt as part of a plan under paragraph (1) specific
18 process controls, if the process controls are needed
19 to ensure the protection of the public health.

20 “(4) TIERED IMPLEMENTATION.—The Secretary shall require such a plan for high-risk facilities first, and then for medium-risk facilities, and
21 then for low-risk facilities, as classified under subsection (a)(4).
22
23
24

1 “(c) EFFECTIVE DATE.—The regulations described
2 in subsection (a) shall take effect 2 years after the date
3 of enactment of this section.

4 “(d) DEFINITIONS.—In this section:

5 “(1) FACILITY.—The term ‘facility’ means a
6 farm or other facility of a grower of a raw agricul-
7 tural commodity.

8 “(2) RAW AGRICULTURAL COMMODITY.—The
9 term ‘raw agricultural commodity’ means a perish-
10 able agricultural commodity, as defined in section
11 1(b) of the Perishable Agricultural Commodities Act,
12 1930 (7 U.S.C. 499a(b)) that is a raw agricultural
13 commodity, as defined in section 201.”.

14 (b) VIOLATION.—Section 402(j) of the Federal Food,
15 Drug, and Cosmetic Act, as added by section 111(b), is
16 amended by inserting before the period the following: “or
17 a raw agricultural commodity produced in violation of sec-
18 tion 402B”.

19 **SEC. 122. INSPECTIONS OF FACILITIES.**

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

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

2 “(a) NATURE OF INSPECTIONS.—Officers and em-
3 ployees duly designated by the Secretary shall have the
4 authority to inspect appropriate facilities (as defined in
5 section 402B) to determine compliance with the standards
6 described in section 402B.

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

11 “(c) EFFECTIVE DATE.—Subsection (a) and the reg-
12 ulations promulgated under subsection (b) shall take effect
13 3 years after the date of enactment of this section.”.

14 (b) REMEDIES.—

15 (1) IN GENERAL.—Paragraphs (f) and (n) of
16 section 301, and section 304(g)(1), of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)),
18 as amended in section 112(b), are further amended
19 by striking “or 704A” and inserting “, 704A, or
20 704B”.

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

25 (c) CONFORMING AMENDMENT.—Section 742(a)(2)
26 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 3791(a)(2)), as amended in section 112(c), is further
2 amended by striking “or 704A” and inserting “, 704A,
3 or 704B”.

4 **TITLE II—RESEARCH AND** 5 **EDUCATION**

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

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

18 (b) PUBLIC HEALTH SAMPLING.—

19 (1) GUIDELINES.—Not later than 3 years after
20 the date of enactment of this Act, the Commissioner
21 of Food and Drugs, in cooperation with the Sec-
22 retary of Agriculture, the Director of the Centers for
23 Disease Control and Prevention, and the Adminis-
24 trator of the Environmental Protection Agency, shall
25 establish guidelines for a sampling system under

1 which the Commissioner and the Secretary of Agri-
2 culture shall collect and analyze samples of fresh
3 produce, both minimally processed and unprocessed,
4 to assist the Commissioner in carrying out this Act
5 and the requirements of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 301 et seq.) that relate
7 to produce, and to assess more accurately the na-
8 ture, frequency of occurrence, and amounts of con-
9 taminants in the produce.

10 (2) MONITORING AND OTHER INFORMATION.—

11 In carrying out the sampling system, the Commis-
12 sioner of Food and Drugs and the Secretary of Agri-
13 culture shall provide for—

14 (A) statistically valid monitoring, including
15 the conduct of market-basket studies, on the
16 nature, frequency of occurrence, and amounts
17 of contaminants in produce available to con-
18 sumers; and

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

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

4 (A) a contaminant, or other substance,
5 that is commonly found on minimally processed
6 produce and, when present at low levels, accu-
7 rately indicates that the produce has been ap-
8 propriately processed, with adequate sanitation;
9 and

10 (B) a standard for the level of that sub-
11 stance that indicates that the produce has been
12 minimally processed as described in subpara-
13 graph (A).

14 **SEC. 202. PUBLIC EDUCATION SYSTEM.**

15 The Commissioner of Food and Drugs and the Sec-
16 retary of Agriculture, in cooperation with private and pub-
17 lic organizations, including the State cooperative extension
18 services and appropriate State entities, shall design and
19 implement a national public education program on food
20 safety relating to produce. In carrying out the program,
21 the Commissioner shall—

22 (1) provide information to the public regarding
23 Federal standards and good agricultural and manu-
24 facturing practice requirements relating to food safe-
25 ty and promote public awareness, understanding,

1 and acceptance of the standards and requirements;
2 and

3 (2) provide such other information or advice to
4 persons that work with the growing and minimal
5 processing of produce, the food service and retail in-
6 dustry, consumers, and other persons as the Com-
7 missioner determines will promote the purposes of
8 this Act.

9 **SEC. 203. RESEARCH.**

10 (a) IN GENERAL.—The Secretary of Agriculture, in
11 consultation with the Commissioner of Food and Drugs,
12 shall conduct research to assist in the implementation of
13 this Act and the requirements of the Federal Food, Drug,
14 and Cosmetic Act (21 U.S.C. 301 et seq.) that relate to
15 produce, including studies relating to—

16 (1) improving sanitation and food safety prac-
17 tices in the minimal processing of produce;

18 (2) developing improved techniques for the
19 monitoring of produce and inspection of produce;

20 (3) developing efficient, rapid, and sensitive
21 methods for determining and detecting the presence
22 of contaminants in produce;

23 (4) determining the sources of contamination of
24 produce, including contamination from growing, har-

1 vesting, and minimal processing produce and post-
2 processing contamination of produce;

3 (5) developing consumption data with respect to
4 produce (including minimally processed produce);
5 and

6 (6) mitigation strategies to aid produce proc-
7 essors and produce growers in deciding what actions
8 to take when contamination is found.

9 (b) CONTRACT AUTHORITY.—The Secretary of Agri-
10 culture is authorized to enter into contracts and agree-
11 ments with States, institutions of higher education, other
12 government agencies, and other persons to carry out the
13 activities described in this section.

14 **TITLE III—IMPORTED PRODUCE** 15 **AND OTHER PROVISIONS**

16 **SEC. 301. IMPORTED PRODUCE.**

17 (a) EQUIVALENCY PROCEDURES.—Not later than 1
18 year after the date of enactment of this Act, the Secretary,
19 in consultation with the Secretary of Agriculture, shall by
20 regulation establish procedures for equivalency with for-
21 eign countries that intend to export raw agricultural com-
22 modities and minimally processed produce to the United
23 States.

24 (b) CONTENT.—The Secretary, in consultation with
25 the Secretary of Agriculture, shall establish procedures to

1 require that imported raw agricultural commodities and
2 minimally processed produce meet the criteria established
3 in this Act (and the amendments made by this Act).

4 **SEC. 302. AUTHORIZATION OF APPROPRIATIONS.**

5 There are authorized to be appropriated such sums
6 as may be necessary to carry out this Act (and the amend-
7 ments made by this Act) for each fiscal year.

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