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H. R. 5904

To amend the Federal Food, Drug, and Cosmetic Act to establish new procedures and requirements to improve the safety of food, whether produced and distributed domestically or imported into the United States, by providing for improved information technology to identify high-risk imports and for enhanced capacity in the United States and in foreign governments to identify and address food safety issues on a scientific basis, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 24, 2008

Mr. COSTA (for himself, Mr. PUTNAM, Mr. CARDOZA, Mr. NUNES, and Mr. FARR) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

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

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

2 (a) SHORT TITLE.—This Act may be cited as the
 3 “Safe Food Enforcement, Assessment, Standards and
 4 Targeting Act of 2008” or as the “Safe FEAST Act of
 5 2008”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings and purposes.
- Sec. 3. Inspection of records during food-related emergencies.
- Sec. 4. Hazard analysis and risk-based preventive controls.
- Sec. 5. Mandatory foreign supplier safety assurance program.
- Sec. 6. Certification of certain imports by competent authority of exporting country.
- Sec. 7. Voluntary qualified importer program.
- Sec. 8. Recognition of qualified laboratories for analyses of imported foods.
- Sec. 9. Standards for the safety of fruits and vegetables.
- Sec. 10. Targeting of inspection resources for domestic facilities and points of entry.
- Sec. 11. Recognition of third party certification programs.
- Sec. 12. Fees relating to food.
- Sec. 13. Biennial registration renewal.
- Sec. 14. Mandatory recall authority.
- Sec. 15. Building capacity of foreign governments.
- Sec. 16. Domestic capacity building and annual report on food safety programs.
- Sec. 17. Authorization of appropriations.

8 **SEC. 2. FINDINGS AND PURPOSES.**

9 (a) FINDINGS.—Congress finds that—

- 10 (1) American consumers have a vital interest in
- 11 a safe, affordable, and wholesome food supply;
- 12 (2) maintenance of a safe food supply requires
- 13 scientifically based food safety standards;
- 14 (3) food production and distribution is increas-
- 15 ingly global;

1 (4) ensuring the safety of the food supply, re-
2 gardless of the source of the food, is a responsibility
3 shared by food producers, processors, and retailers
4 and by Federal, State, and local agencies;

5 (5) assurance of the safety of food is best
6 achieved by the adoption of appropriate food produc-
7 tion and processing practices and procedures;

8 (6) enhanced cooperation among regulatory
9 agencies worldwide is critical to maintenance of a
10 safe food supply;

11 (7) food producers, processors, and retailers
12 have a vital role in ensuring the safety of the food
13 supply;

14 (8) food producers, processors, and retailers are
15 best situated to ensure the implementation of
16 science-based food safety standards worldwide;

17 (9) in order to provide appropriate oversight,
18 regulatory agencies with responsibility for food safe-
19 ty must have access to adequate scientific resources,
20 modern information technology systems, modern and
21 efficient laboratories, and adequate inspectional ca-
22 pacity;

23 (10) ensuring the adequacy of resources for
24 regulatory agencies is a public responsibility; and

1 (11) efficient and effective enforcement of food
2 safety requirements for imported foods necessitates
3 a risk-based systems approach.

4 **SEC. 3. INSPECTION OF RECORDS DURING FOOD-RELATED**
5 **EMERGENCIES.**

6 (a) IN GENERAL.—Section 414 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 350c) is amended—
8 (1) by redesignating subsections (b), (c), and
9 (d) as subsections (c), (d), and (e), respectively; and
10 (2) by inserting after subsection (a) the fol-
11 lowing:

12 “(b) RECORDS INSPECTIONS DURING FOOD-RE-
13 LATED EMERGENCIES.—If the Secretary has a reasonable
14 belief that an article of food presents a threat of serious
15 adverse health consequences or death to humans or ani-
16 mals, during a food-related emergency, the Secretary—

17 “(1) may have access to and copy all records
18 relating to such article of food in the same manner
19 and for the same purpose as described in subsection
20 (a); and

21 “(2) shall, from each person (excluding farms
22 and restaurants) who manufactures, processes,
23 packs, distributes, receives, holds, or imports an ar-
24 ticle of food related to the article of food referred to
25 under paragraph (1) (such as an article of food pro-

1 **“SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVEN-**
2 **TIVE CONTROLS.**

3 “(a) IN GENERAL.—Each owner, operator, or agent
4 in charge of a facility, as defined in subsection (k)(1),
5 shall, in accordance with this section—

6 “(1) evaluate the hazards that could affect
7 products from such facility;

8 “(2) identify and implement risk-based preven-
9 tive controls to keep such hazards from occurring or
10 to significantly minimize their occurrence and pro-
11 vide reasonable assurances that a product is not
12 adulterated;

13 “(3) monitor the performance of those controls;

14 “(4) maintain records of this monitoring as a
15 matter of routine practice; and

16 “(5) provide for inspection of the facility at
17 such frequency, but not less often than biennially, as
18 the Secretary may specify, with an increase in the
19 periodicity of such inspections based on facilities
20 identified as having an increased risk.

21 “(b) HAZARD ANALYSIS.—The owner, operator, or
22 agent in charge of a facility shall identify and evaluate
23 known or reasonably foreseeable biological, chemical, and
24 physical hazards that may be associated with the facility.

25 “(c) PREVENTIVE CONTROLS.—

1 “(1) IMPLEMENTATION.—The owner, operator,
2 or agent in charge of a facility shall identify and im-
3 plement reasonably appropriate preventive controls
4 so that—

5 “(A) risks identified in the hazard analysis
6 conducted under subsection (b) will not affect
7 the food manufactured, processed or packed by
8 such facility;

9 “(B) the food will not be adulterated under
10 section 402; and

11 “(C) the food will not present a threat of
12 serious adverse health consequences or death to
13 humans or animals.

14 “(2) CONTROLS.—Preventive controls include,
15 at a minimum, the following practices that improve
16 the safety of the food:

17 “(A) Sanitation procedures for food con-
18 tact surfaces and utensils and food-contact sur-
19 faces of equipment.

20 “(B) Supervisor, manager, and employee
21 hygiene training.

22 “(C) An environmental monitoring pro-
23 gram to verify the effectiveness of pathogen
24 controls.

1 “(D) An allergen control program to en-
2 sure that products do not contain allergens that
3 are not declared on the label.

4 “(E) A recall contingency plan.

5 “(F) Good manufacturing practices.

6 “(d) MONITORING OF EFFECTIVENESS.—The owner,
7 operator, or agent in charge of a facility shall monitor the
8 effectiveness of the preventive controls implemented under
9 subsection (c) to provide reasonable assurances that none
10 of the outcomes set forth in subsection (c)(1) shall occur.

11 “(e) CORRECTIVE ACTIONS.—The owner, operator,
12 or agent in charge of a facility shall establish procedures
13 that a facility will implement if the preventive controls im-
14 plemented under subsection (c) are found to be ineffective
15 through effectiveness monitoring under subsection (d) or
16 if an adulteration or recall situation warrants such action.

17 “(f) VERIFICATION.—The owner, operator, or agent
18 in charge of a facility shall verify that—

19 “(1) the preventive controls implemented under
20 subsection (c) are adequate to control the hazards
21 found under subsection (b);

22 “(2) the owner, operator, or agent is conducting
23 monitoring in accordance with subsection (d);

1 “(3) the owner, operator, or agent is making
2 appropriate decisions about corrective actions taken
3 under subsection (e); and

4 “(4) there is documented, periodic revalidation
5 of the plan under subsection (h) to ensure that the
6 plan is still relevant to the raw materials as well as
7 to conditions and processes in the facility.

8 “(g) RISK ASSESSMENT AND PREVENTIVE CONTROL
9 IMPLEMENTATION PLAN.—Each owner, operator, or
10 agent in charge of a facility shall prepare a written plan
11 that documents and describes the procedures used by the
12 facility to comply with the requirements of this section,
13 including analyzing the hazards under subsection (b) and
14 identifying the preventive controls adopted to address
15 those hazards under subsection (c). Such written plan, to-
16 gether with documentation that the plan is being imple-
17 mented, shall be made promptly available to a duly author-
18 ized representative of the Secretary upon oral or written
19 request for the purpose of verifying compliance with this
20 requirement.

21 “(h) REQUIREMENT TO REANALYZE.—Each owner,
22 operator, or agent in charge of a facility shall conduct a
23 reanalysis under subsection (b), at a minimum, biennially,
24 or whenever a significant change is made in the activities
25 conducted at a facility operated by such owner, operator,

1 or agent if the change creates a reasonable potential for
2 a new hazard or a significant increase in a previously iden-
3 tified hazard. Such reanalysis shall take into account any
4 new scientific or technological advances and any additional
5 preventive controls needed to address the hazard identi-
6 fied, if any, and shall be implemented before any change
7 in activities at the facility is commenced. Such owner, op-
8 erator, or agent shall revise the written plan required
9 under subsection (g) if such a significant change is made
10 or document the basis for the conclusion that no additional
11 or revised preventive controls are needed.

12 “(i) EXCEPTION FOR FOOD FACILITIES IN COMPLI-
13 ANCE WITH APPLICABLE HACCP OR OTHER REGU-
14 LATORY STANDARDS.—This section shall not apply to an
15 owner, operator, or agent in charge of a facility that proc-
16 esses a food if such facility is subject to the standards
17 for a Hazard Analysis Critical Control Points Program or
18 other regulatory program of the Food and Drug Adminis-
19 tration relating to that food.

20 “(j) EXCEPTION FOR FACILITIES IN COMPLIANCE
21 WITH SECTION 419.—This section shall not apply to an
22 owner, operator, or agent in charge of a facility that is
23 subject to section 419.

24 “(k) DEFINITIONS.—For purposes of this section:

1 “(1) FACILITY.—The term ‘facility’ means a
2 domestic or a foreign facility that is required to reg-
3 ister under section 415, but does include a ware-
4 house that—

5 “(A) holds food packaged for sale to con-
6 sumers or packed in cases for commercial dis-
7 tribution; and

8 “(B) does not process food or otherwise ex-
9 pose food to the environment in a way as to
10 dramatically increase the likelihood for contami-
11 nation, not including processing incidental to
12 the handling of fruits and vegetables that may
13 be held in the warehouse and regulated under
14 section 419.

15 “(2) REASONABLY APPROPRIATE SCIENCE-
16 BASED PREVENTIVE CONTROLS.—The term ‘reason-
17 ably appropriate science-based preventive controls’
18 means those procedures, practices, and processes
19 that a person knowledgeable about the processing
20 and packing of food and science-based food safety
21 practices would have employed to address the haz-
22 ards identified during the hazard analysis under
23 subsection (b) at the time of such analysis. Such
24 term does not include those controls that result in
25 a food that is not commercially viable.”.

1 (b) GUIDANCE DOCUMENT.—Not later than 1 year
2 after the date of enactment of this Act, the Secretary shall
3 issue a guidance document related to the preparation of
4 a hazard analysis and preventive control plan required
5 under section 418 of the Federal Food, Drug, and Cos-
6 metic Act, as added by subsection (a).

7 (c) REGULATIONS.—

8 (1) IN GENERAL.—The Secretary of Health and
9 Human Services shall promulgate regulations to es-
10 tablish minimum standards for the effective imple-
11 mentation of section 418 of the Federal Food, Drug,
12 and Cosmetic Act, as added by subsection (a).

13 (2) CONTENT.—The regulations promulgated
14 under paragraph (1) shall—

15 (A) be consistent with the principles con-
16 tained in internationally recognized hazard
17 analysis and preventive control standards; and

18 (B) provide sufficient flexibility to be appli-
19 cable in all situations, including in the oper-
20 ations of small businesses.

21 (3) REVIEW.—In promulgating the regulations
22 under paragraph (1), the Secretary shall review reg-
23 ulatory hazard analysis and preventive control pro-
24 grams in existence on the date of enactment of this
25 Act to ensure that the program under such section

1 418 is consistent with applicable internationally rec-
2 ognized standards in existence on such date.

3 (d) PROHIBITED ACTS.—Section 301 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
5 ed by adding at the end the following:

6 “(oo) The operation of a facility that processes or
7 packs food for sale in the United States if the person who
8 operates such facility has not conducted the hazard anal-
9 ysis required under section 418(b), implemented reason-
10 ably appropriate science-based preventive controls under
11 section 418(c) in accordance with 418(g), failed to conduct
12 a reanalysis as required under section 418(h), or failed
13 to have a plan documenting compliance with section 418.”.

14 (e) EFFECTIVE DATE.—

15 (1) GENERAL RULE.—The amendments made
16 by this section shall take effect 1 year after the date
17 of enactment of this Act.

18 (2) EXCEPTIONS.—Notwithstanding paragraph

19 (1)—

20 (A) the amendments made by this section
21 shall apply to a small business (as defined in
22 the small business size regulations of the Small
23 Business Administration, as specified in part
24 121 of title 13, Code of Federal Regulations)

1 after the date that is 2 years after the date of
2 enactment of this Act; and

3 (B) the amendments made by this section
4 shall apply to a very small business (as defined
5 in such regulations) after the date that is 3
6 years after the date of enactment of this Act.

7 **SEC. 5. MANDATORY FOREIGN SUPPLIER SAFETY ASSUR-**
8 **ANCE PROGRAM.**

9 (a) IN GENERAL.—Chapter VIII of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
11 is amended by adding at the end the following:

12 **“SEC. 805. MANDATORY FOREIGN SUPPLIER SAFETY AS-**
13 **SURANCE PROGRAM.**

14 “(a) FOREIGN SUPPLIER SAFETY ASSURANCE PRO-
15 GRAM.—

16 “(1) IN GENERAL.—Each U.S. importer of
17 record shall adopt and document a foreign supplier
18 safety assurance program to assure that food im-
19 ported into the United States—

20 “(A) is in compliance with the require-
21 ments of section 418;

22 “(B) is not adulterated under section 402;
23 and

24 “(C) does not pose a threat of serious ad-
25 verse health consequences or death.

1 “(2) TREATMENT OF CERTAIN CUSTOMS BRO-
2 KERS.—For purposes of this section, an ‘importer of
3 record’ shall not include a person holding a valid li-
4 cense under section 1641 of title 19, United States
5 Code (commonly referred to as a ‘customs broker’),
6 if the customs broker has executed a written agree-
7 ment with another person who has agreed to comply
8 with the requirements of this section with regard to
9 food imported or offered for import by the customs
10 broker.

11 “(b) REQUIREMENTS.—

12 “(1) IN GENERAL.—A foreign supplier safety
13 assurance program shall include such risk-based
14 processes and procedures as the U.S. importer of
15 record determines to be necessary and appropriate
16 to reasonably ensure that food imported into the
17 United States by the importer of record complies
18 with U.S. food safety requirements in accordance
19 with section 418 and is not adulterated within the
20 meaning of section 402.

21 “(2) COMPONENTS OF A FOREIGN SUPPLIER
22 SAFETY ASSURANCE PROGRAM.—In establishing a
23 foreign supplier safety assurance program, a U.S.
24 importer of record shall verify, with respect to each
25 foreign supplier from which it obtains food, that the

1 foreign supplier has an effective safety assurance
2 program. Such verification may include certification
3 by a recognized third party certification program
4 (under section 421), but such certification from the
5 approved third party certification program shall not
6 serve as the sole means that may be accepted by the
7 Secretary of verification of adherence to a foreign
8 supplier safety assurance program. An effective safe-
9 ty assurance program shall include, at a minimum,
10 an evaluation of hazards in accordance with section
11 418 and the implementation of reasonable and ap-
12 propriate preventive controls.

13 “(c) GUIDANCE.—Within 270 days of the date of the
14 enactment of this section, the Secretary shall issue guid-
15 ance to assist U.S. importers of record in developing for-
16 eign supplier safety assurance programs.

17 “(d) RECORD ACCESS.—Records of a U.S. importer
18 of record related to a foreign supplier safety assurance
19 program shall, for a period of not less than 2 years, be
20 made available promptly to the Secretary upon written or
21 oral request.”.

22 (b) PROHIBITED ACTS.—Section 301 of such Act (21
23 U.S.C. 331), as amended by section 4(d), is further
24 amended by adding at the end the following:

1 “(pp) The importation or offering for importation of
2 a food if the importer of record does not have in place
3 a foreign supplier safety assurance program in compliance
4 with section 805.”.

5 (c) IMPORTS.—Section 801(a) of such Act (21 U.S.C.
6 381(a)) is amended by inserting “or section 805” after
7 “or in violation of section 505”.

8 **SEC. 6. CERTIFICATION OF CERTAIN IMPORTS BY COM-**
9 **PETENT AUTHORITY OF EXPORTING COUN-**
10 **TRY.**

11 (a) IN GENERAL.—Whenever the Secretary of Health
12 and Human Services (in this section referred to as the
13 “Secretary”) determines to enter into a memorandum of
14 understanding or equivalent agreement with the regu-
15 latory authorities of another country with responsibility
16 for food safety, the Secretary shall include in such memo-
17 randum of understanding or equivalent agreement a provi-
18 sion to provide for the certification of certain foods offered
19 for import into the United States by a competent regu-
20 latory authority in the country of export.

21 (b) CERTIFICATION.—Such certification provision
22 shall provide that, upon reasonable notice given by the
23 Secretary, and as a condition of permitting the importa-
24 tion of food from a specific foreign country or from a spe-
25 cific facility within a foreign country, a competent regu-

1 latory authority in the exporting country agrees to certify
2 that each specific shipment of food or food from a specific
3 facility offered for importation into the United States has
4 been produced, packaged, and held under conditions that
5 meet United States food safety standards. Nothing in this
6 section shall limit the Secretary's ability to conduct ran-
7 dom checks of imported food or to take such other steps
8 as the Secretary deems necessary to assure the safety of
9 imported food.

10 (c) NOTIFICATION AND DETENTION.—Whenever the
11 Secretary has entered into a memorandum of agreement
12 that includes a certification requirement, the Secretary
13 shall notify the Secretary of Homeland Security. The Sec-
14 retary of Homeland Security shall deny entry to any food
15 offered for import for which a certification under this sec-
16 tion has been required if such certification has not been
17 provided in a manner deemed timely and appropriate by
18 the Secretary.

19 (d) REGISTRY OF CERTIFIED FACILITIES.—The Sec-
20 retary shall maintain a registry of facilities with respect
21 to which certification has been made under this section.

22 **SEC. 7. VOLUNTARY QUALIFIED IMPORTER PROGRAM.**

23 Chapter VIII of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 381 et seq.), as amended by section

1 5(a), is further amended by adding at the end the fol-
2 lowing:

3 **“SEC. 806. VOLUNTARY QUALIFIED IMPORTER PROGRAM.**

4 “(a) IN GENERAL.—Beginning not later than 1 year
5 after the date of enactment of this section, the Secretary
6 shall establish a program, in consultation with the Sec-
7 retary of Agriculture and Secretary of Homeland Security,
8 to provide for the expedited review and importation of food
9 products offered for importation by U.S. importers of
10 record who have voluntarily agreed to participate in such
11 program. In establishing such a program, the Secretary
12 shall ensure that the program does not impose redundant
13 requirements on persons who participate in existing border
14 security programs. In determining eligibility to participate
15 in such a program, the Secretary shall consider, among
16 other relevant information, the following:

17 “(1) Nature and risk-profile of the food or in-
18 gredient to be imported.

19 “(2) Compliance history of the foreign supplier.

20 “(3) Capability of the regulatory system of the
21 country of export to ensure compliance with United
22 States food safety standards, including hazard anal-
23 ysis and preventive control measures in accordance
24 with section 418.

1 governmental organizations and shall establish a registry
2 of laboratories that have been so recognized.

3 (b) CRITERIA.—The Secretary of Health and Human
4 Services shall require, as a condition of inclusion in the
5 registry provided for under subsection (a), that entities
6 providing laboratory analyses establish to the satisfaction
7 of the agency or organization that is providing the recogni-
8 tion that—

9 (1) appropriate sampling and analytical proce-
10 dures are followed and reports of analyses are cer-
11 tified as true and accurate;

12 (2) internal quality systems are established and
13 maintained;

14 (3) procedures exist to evaluate and respond
15 promptly to complaints regarding analyses and other
16 activities for which the laboratory is recognized; and

17 (4) individuals who conduct the analyses are
18 qualified by training and experience to do so.

19 (c) REVIEW OF RECOGNITION.—Any agency or orga-
20 nization that maintains a program under which labora-
21 tories are recognized as qualified to conduct analyses in
22 accordance with the criteria set forth in this section shall
23 conduct periodic assessments of the qualifications of the
24 laboratories that have been recognized by it and shall
25 promptly revoke the recognition of any laboratory found

1 not to be in compliance with the agency's or organization's
2 standards. The agency or organization shall also promptly
3 notify the Secretary of Health and Human Services of any
4 change in the status of a previously recognized laboratory
5 and the Secretary shall promptly revise the registry main-
6 tained under subsection (a).

7 (d) ALTERNATIVE LABORATORIES.—Nothing in this
8 section shall prevent a person from using an alternative
9 laboratory, such as a university or food company labora-
10 tory, so long as such person submits—

11 (1) to the Secretary evidence to establish the
12 qualifications of the laboratory and a reference to
13 the validated test method (or methods) used; and

14 (2) to the Food and Drug Administration all
15 testing results and data.

16 **SEC. 9. STANDARDS FOR THE SAFETY OF FRUITS AND**
17 **VEGETABLES.**

18 (a) IN GENERAL.—Chapter IV of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.), as
20 amended by section 4(a), is amended by adding at the end
21 the following:

1 **“SEC. 419. STANDARDS FOR THE SAFETY OF FRUITS AND**
2 **VEGETABLES.**

3 “(a) DEFINITION.—For purposes of this section, the
4 term ‘fruits and vegetables’ shall mean raw agricultural
5 products as defined in section 201(r).

6 “(b) IN GENERAL.—Not later than 1 year after en-
7 actment of this section, the Secretary, in consultation with
8 the Secretary of Agriculture and representatives of State
9 departments of agriculture, shall publish a notice of pro-
10 posed rulemaking to establish regulations for the safe pro-
11 duction, harvesting, and packaging of those types of fruits
12 and vegetables for which the Secretary has determined
13 that such regulations are necessary to minimize the risk
14 of serious adverse health consequences.

15 “(c) FINAL REGULATION.—Not later than 1 year
16 after the close of the comment period on the notice of pro-
17 posed rulemaking under subsection (a), the Secretary shall
18 adopt a final regulation covering those types of fruits and
19 vegetables for which the Secretary has determined that
20 such regulations are necessary to minimize the risk of seri-
21 ous adverse health consequences. The final regulation
22 shall provide a reasonable period of time for implementa-
23 tion, taking into account the needs of small businesses for
24 additional time to comply. The final regulation shall pro-
25 vide for coordination of education and enforcement activi-
26 ties by the Secretary of Agriculture, appropriate State and

1 local agencies, and appropriate agencies of foreign govern-
2 ments.

3 “(d) COOPERATION.—The Secretary shall work with
4 State and local public health officials in carrying out this
5 section. The Secretary shall coordinate activities with the
6 Secretary of Agriculture related to on-farm requirements
7 for growers including the development of food safety
8 standards and enforcement mechanisms that will address
9 regulations adopted under subsection (c).

10 “(e) CRITERIA.—The regulations adopted under sub-
11 section (b) shall—

12 “(1) set forth those procedures, processes, and
13 practices as the Secretary determines to be reason-
14 ably necessary to minimize the introduction of
15 known or reasonably foreseeable biological, chemical,
16 and physical hazards into fruits and vegetables and
17 to provide reasonable assurance that the fruits and
18 vegetables are not adulterated under section 402;

19 “(2) permit States and foreign governments to
20 seek variances from the requirements of the regula-
21 tions, where the State or foreign government deter-
22 mines that the variance is necessary in light of local
23 growing conditions and that the procedures, proc-
24 esses, and practices to be followed under the vari-
25 ance are reasonably likely to ensure that the fruits

1 or vegetables are not adulterated within the meaning
2 of section 402 to the same extent as the require-
3 ments of the regulation adopted under subsection
4 (b);

5 “(3) require that any State or foreign govern-
6 ment seeking a variance under paragraph (2) shall
7 first notify the Secretary of the intended variance
8 and the basis for it, and the Secretary may grant
9 the variance after 90 days of such notification if
10 Secretary does not communicate objections or modi-
11 fications to the intended variance to the respective
12 State or foreign government prior to the conclusion
13 of the 90-day period; and

14 “(4) provide for publication of notices of re-
15 quests for variances under paragraph (2) at the time
16 they are received.

17 “(f) ENFORCEMENT.—The Secretary shall coordinate
18 enforcement under this section with appropriate State and
19 local agencies and with appropriate agencies of foreign
20 governments. In enforcing any standards for the safety of
21 fruits and vegetables, the Secretary shall, to the maximum
22 extent practicable, use the Department of Agriculture and
23 state agricultural agencies. Such enforcement may be in
24 the form of audit-based verification systems or other
25 methods of inspection.

1 “(g) GUIDANCE FOR GOOD AGRICULTURAL PRAC-
2 TICES.—Not later than 1 year after the date of the enact-
3 ment of this section, the Secretary shall publish updated
4 guidance, in coordination with the Secretary of Agri-
5 culture and representatives of State departments of agri-
6 culture, based on the most currently available scientific
7 evidence, for the safe production, harvesting, and pack-
8 aging of fruits and vegetables. The Secretary shall publish
9 subsequently updated guidance, as necessary.

10 “(h) SCOPE.—This section shall apply to the produc-
11 tion, harvesting, and packaging of fruits and vegetables
12 intended for human consumption, but not to—

13 “(1) activities involving the further processing
14 of fruits and vegetables which shall be subject to
15 section 418; or

16 “(2) those activities that occur in a retail food
17 establishment (as such term is defined in regulations
18 to carry out section 415(b)(1)).”.

19 (b) PROHIBITED.—Section 301 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 331), as amended by
21 sections 4(d) and 5(b), is further amended by adding at
22 the end the following:

23 “(qq) Production, harvesting, or packaging of fruits
24 or vegetables not in accordance with the regulations or a
25 variance issued under section 419(d)(2).”.

1 **SEC. 10. TARGETING OF INSPECTION RESOURCES FOR DO-**
2 **MESTIC FACILITIES AND POINTS OF ENTRY.**

3 Chapter IV of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 341 et seq.), as amended by sections 4(a)
5 and 9(a), is amended by adding at the end the following:

6 **“SEC. 420. TARGETING OF INSPECTION RESOURCES FOR**
7 **DOMESTIC FACILITIES AND POINTS OF**
8 **ENTRY.**

9 “(a) IDENTIFICATION AND INSPECTION OF FACILI-
10 TIES.—

11 “(1) IDENTIFICATION.—The Secretary shall al-
12 locate resources to inspect facilities according to the
13 risk profile of the facilities, which shall be based on
14 the following factors:

15 “(A) The risk profile of the food manufac-
16 tured, processed, packed, handled, prepared,
17 treated, distributed, or stored at the facility.

18 “(B) The facility’s history of food recalls,
19 outbreaks, and violations of food safety stand-
20 ards.

21 “(C) The rigor of the facility’s hazard
22 analysis and risk-based preventive controls.

23 “(D) Whether the facility has been cer-
24 tified to conform with United States food safety
25 standards by a recognized third party certifi-
26 cation program under section 421.

1 “(E) Any other criteria deemed necessary
2 and appropriate by the Secretary for purposes
3 of allocating inspection resources.

4 “(2) INSPECTIONS.—The Secretary shall con-
5 duct inspections of domestic facilities identified
6 under paragraph (1) as high-risk facilities not less
7 often than once a year.

8 “(b) IDENTIFICATION AND INSPECTION OF POINTS
9 OF ENTRY.—The Secretary shall inspect shipments of
10 food imported into the United States according to the risk
11 profile of the food shipment, which shall be based on the
12 following factors:

13 “(1) The risk profile of the food imported.

14 “(2) The risk profile of the origin of the food
15 imported.

16 “(3) The history of food recalls, outbreaks, and
17 violations of food safety standards of the food im-
18 porter.

19 “(4) The rigor of the foreign supplier
20 verification of the food importer under section 805.

21 “(5) Whether the food importer participates in
22 the Voluntary Qualified Importer Program under
23 section 806.

24 “(6) Whether the facility has been certified to
25 conform with United States food safety standards by

1 a recognized third party certification program under
2 section 421.

3 “(7) Any other criteria deemed necessary and
4 appropriate by the Secretary for purposes of allo-
5 cating inspection resources.

6 “(c) FACILITY.—For purposes of this section, the
7 term ‘facility’ has the meaning given that term in section
8 415.”.

9 **SEC. 11. RECOGNITION OF THIRD PARTY CERTIFICATION**
10 **PROGRAMS.**

11 Chapter IV of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 341 et seq.), as amended by sections 4(a),
13 9(a), and 10, is amended by adding at the end the fol-
14 lowing:

15 **“SEC. 421. RECOGNITION OF THIRD PARTY CERTIFICATION**
16 **PROGRAMS.**

17 “(a) IN GENERAL.—Beginning not later than 2 years
18 after the date of the enactment of this section, the Sec-
19 retary shall establish a process under which a third party
20 may apply to the Secretary for recognition of a third party
21 certification program it operates.

22 “(b) RECOGNITION OF PROGRAMS.—

23 “(1) IN GENERAL.—The Secretary may not rec-
24 ognize a third party with respect to its operation of

1 a third party certification program unless the fol-
2 lowing requirements are met:

3 “(A) The third party has demonstrated the
4 capacity and competence to operate a third
5 party certification program.

6 “(B) The processes and standards used by
7 the third party in the auditing and certification
8 of food processors and producers are sufficient
9 to verify compliance of such producers and
10 processors with federal food safety standards.

11 “(C) The third party must conform to re-
12 quirements established by the Secretary, includ-
13 ing periodic reevaluation by the Secretary. In
14 establishing such requirements, the Secretary
15 shall consider existing standards and proce-
16 dures established by national and international
17 accreditation organizations.

18 “(2) APPLICATION OF ACCREDITATION.—In ap-
19 proving third parties with respect to third party ac-
20 creditation programs under this section, the Sec-
21 retary may take into account the accreditation of
22 such entities and programs by national and inter-
23 national accreditation organizations.

1 “(3) REGISTRY.—The Secretary shall maintain
2 a registry of recognized third party certification pro-
3 grams.

4 “(c) THIRD PARTY CERTIFICATION PROGRAM DE-
5 FINED.—In this section:

6 “(1) The term ‘third party certification pro-
7 gram’ means an independent auditing and certifi-
8 cation program—

9 “(A) that evaluates the food safety man-
10 agement systems and practices of food pro-
11 ducers and processors using recognized auditing
12 standards; and

13 “(B) that only certifies such producers or
14 processors that it determines are in compliance
15 with such standards.

16 “(2) The term ‘recognized third party certifi-
17 cation program’ means a third party certification
18 program, and the entity operating which, is recog-
19 nized under this section.

20 “(d) CONSTRUCTION.—Nothing in the section should
21 be construed to limit the ability of the Secretary or a des-
22 ignated agent of the Secretary to conduct random checks
23 of imported food or audit facilities as the Secretary deems
24 necessary to ensure compliance with federal food safety
25 standards.

1 “(e) TERMINATION OF RECOGNITION.—The Sec-
2 retary may terminate the recognition of a third party with
3 respect to its operation of a third party accreditation pro-
4 gram under this section—

5 “(1) following an investigation and finding by
6 the Secretary that the third party or program is no
7 longer in compliance with requirements for recogni-
8 tion under this section; or

9 “(2) following the party’s refusal to allow
10 United States officials to conduct such audits as
11 may be necessary to ensure continued compliance of
12 the entity and program with the applicable require-
13 ments of this section.”.

14 **SEC. 12. FEES RELATING TO FOOD.**

15 (a) IN GENERAL.—Chapter VII of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
17 ed—

18 (1) by redesignating sections 741 and 742 as
19 sections 744 and 745, respectively; and

20 (2) by adding at the end of subchapter C the
21 following:

1 **“PART 3—FEES RELATING TO FOOD**

2 **“SEC. 741. AUTHORITY TO COLLECT AND USE REIMBURS-**
3 **ABLE FEES FOR VOLUNTARY QUALIFIED IM-**
4 **PORTER PROGRAM.**

5 “(a) FEES FOR VOLUNTARY QUALIFIED IMPORTER
6 PROGRAM.—For fiscal year 2009 and each subsequent fis-
7 cal year, the Secretary shall, in accordance with this sec-
8 tion, assess and collect fees from each importer required
9 to register under section 415 which participates in the vol-
10 untary qualified importer program under section 806 in
11 such year, to reimburse the Food and Drug Administra-
12 tion for the administrative costs of that importer’s partici-
13 pation in such program for such year.

14 “(b) ESTABLISHMENT OF FEES.—

15 “(1) IN GENERAL.—Subject to subsection (c),
16 the Secretary shall establish a fee schedule for reim-
17 bursable expenses to be collected under this section
18 for each fiscal year specified in section (a), based on
19 the methodology described in paragraph (2). The
20 Secretary shall publish such fee schedule for a fiscal
21 year in a Federal Register notice not later than 60
22 days before the beginning of each fiscal year.

23 “(2) FEE METHODOLOGY AND FEE SCHED-
24 ULE.—

25 “(A) FEE METHODOLOGY.—Fees amounts
26 established for collection shall be based on 100

1 percent of the Secretary's actual costs of the
2 activities for each importer participating in the
3 voluntary qualified importer program, as de-
4 scribed in subsection (a), for such fiscal year.

5 “(B) FEE SCHEDULE.—The Secretary
6 shall establish in each such fiscal year a fee
7 schedule to include all reimbursable expenses,
8 including an hourly rate for salaries and ex-
9 penses for government personnel carrying out of
10 such activities, as well as a rate to cover indi-
11 rect costs necessary for the efficient conduct of
12 such activities. The Secretary's publication of
13 the fee schedule under paragraph (1) shall be
14 accompanied by a written explanation of the
15 methodology for determining each fee on the fee
16 schedule.

17 “(C) OTHER CONSIDERATIONS.—In estab-
18 lishing the fee schedule for a fiscal year, the
19 Secretary shall also consider the need to ac-
20 count for any adjustment of fees under para-
21 graph (3) and such other factors as the Sec-
22 retary determines appropriate.

23 “(3) ADJUSTMENT OF FEES.—The Secretary
24 may provide for the waiver or reduction of fees
25 under this subsection based on financial hardship or

1 other circumstances as determined appropriate by
2 the Secretary.

3 “(4) COMPLIANCE WITH INTERNATIONAL
4 AGREEMENTS.—Nothing in this section shall be con-
5 strued to authorize the assessment of any fee incon-
6 sistent with the agreement establishing the World
7 Trade Organization or any other treaty or inter-
8 national agreement to which the United States is a
9 party.

10 “(c) CREDITING AND AVAILABILITY OF FEES.—Fees
11 collected for each fiscal year under this section shall be
12 credited to a fund, hereby established in the Treasury of
13 the United States and to be known as the ‘Food and Drug
14 Administration Food User Fee Account’, and shall be
15 available in accordance with appropriations Acts until ex-
16 pended, without fiscal year limitation. Such fees shall be
17 made available solely to carry out the activities by the Cen-
18 ter for Food Safety and Applied Nutrition and related ac-
19 tivities of the Office of Regulatory Affairs related to the
20 voluntary qualified importer program.

21 “(d) COLLECTION OF FEES.—

22 “(1) IN GENERAL.—The Secretary shall specify
23 in the Federal Register notice described in sub-
24 section (b)(1) the time and manner in which fees as-
25 sessed under this section shall be collected, but in no

1 case shall a facility be required to pay a reimburs-
2 able fee less than 60 days after the date of receipt
3 of a notice from the Secretary assessing such fee.

4 “(2) COLLECTION OF UNPAID FEES.—In any
5 case where the Secretary does not receive payment
6 of a fee assessed under this section within 30 days
7 after it is due, such fee shall be treated as a claim
8 of the United States Government subject to provi-
9 sions of subchapter II of chapter 37 of title 31,
10 United States Code.

11 “(e) ANNUAL REPORT TO CONGRESS.—Not later
12 than 90 days after the end of each fiscal year for which
13 fees are assessed under this section, the Secretary shall
14 submit a report to the Committee on Health, Education,
15 Labor, and Pensions of the United States Senate and the
16 Committee on Energy and Commerce of the United States
17 House of Representatives, that includes a description of
18 fees assessed and collected for each such fiscal year and
19 a summary description of the entities paying such fees and
20 the types of business in which such entities engage.”.

21 (b) EXPORT CERTIFICATION FEES FOR FOODS AND
22 ANIMAL FEED.—

23 (1) AUTHORITY FOR EXPORT CERTIFICATIONS
24 FOR FOOD, INCLUDING ANIMAL FEED.—Section

1 801(e)(4)(A) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 381(e)(4)(A)) is amended—

3 (A) in the matter preceding clause (i), by
4 striking “a drug,” and inserting “a food, drug”;

5 (B) in clause (i), by striking “exported
6 drug,” and inserting “exported food, drug”;

7 and

8 (C) in clause (ii), by striking “the drug”
9 and “the drug,” and inserting “the food, drug”
10 and “the food, drug,” respectively.

11 (2) TREATMENT OF FEES.—Section 801(e)(4)
12 of such Act (21 U.S.C. 381(3)(4)) is amended—

13 (A) in subparagraph (B), by striking all
14 that follows the first sentence; and

15 (B) by adding at the end the following:

16 “(C)(i) In the case of fees collected for a fiscal year
17 pursuant to this paragraph for certification of exported
18 drugs, animal drugs, or devices, the fees shall be credited
19 to the appropriation account for salaries and expenses of
20 the Food and Drug Administration and be available in ac-
21 cordance with appropriations Acts until expended, without
22 fiscal year limitation. To cover the cost of issuing such
23 certifications, such sums as necessary may be transferred
24 from such appropriation account for salaries and expenses
25 of the Food and Drug Administration without fiscal year

1 limitation to such appropriation account for salaries and
2 expenses with fiscal year limitation.

3 “(ii) In the case of fees collected for a fiscal year pur-
4 suant to this paragraph for the certification of exported
5 foods, the fees shall be credited to the Food and Drug
6 Administration Food User Fee Account and be available
7 in accordance with appropriations Acts until expended,
8 without fiscal year limitation.”.

9 (3) CLARIFICATION OF CERTIFICATION.—Sec-
10 tion 801(e)(4) of such Act (21 U.S.C. 381(e)(4)), as
11 amended by paragraph (2), is further amended by
12 adding at the end the following:

13 “(D) For purposes of this paragraph, a certification
14 by the Secretary shall be made on such basis, and in such
15 form (including a publicly available listing) as the Sec-
16 retary determines appropriate.”.

17 **SEC. 13. BIENNIAL REGISTRATION RENEWAL.**

18 Section 415(a) of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 350d(a)) is amended—

20 (1) by redesignating paragraphs (3) and (4) as
21 paragraphs (4) and (5), respectively; and

22 (2) by inserting after paragraph (2) the fol-
23 lowing:

24 “(3) BIENNIAL REGISTRATION RENEWAL.—On
25 a biennial basis, a registrant that has submitted a

1 registration under paragraph (1) shall submit to the
2 Secretary a renewal registration containing the in-
3 formation described in paragraph (2). The Secretary
4 may provide for an abbreviated registration renewal
5 process for any registrant that has not had any
6 changes to such information since the registrant
7 submitted the preceding registration or registration
8 renewal for the facility involved.”.

9 **SEC. 14. MANDATORY RECALL AUTHORITY.**

10 (a) IN GENERAL.—Section 417 of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 350f) is amended by
12 adding at the end the following:

13 “(1) RECALL OF REPORTABLE FOOD.—

14 “(1) VOLUNTARY PROCEDURES.—If the Sec-
15 retary determines that there is a reasonable prob-
16 ability that the use of or exposure to an article of
17 food (other than infant formula) will cause serious
18 adverse health consequences, the Secretary shall pro-
19 vide the responsible party that produced or proc-
20 essed packed or held the reportable food with an op-
21 portunity to—

22 “(A) cease distribution of such article;

23 “(B) notify all persons—

24 “(i) producing, manufacturing, pack-
25 ing, processing, preparing, treating, pack-

1 aging, distributing, or holding such arti-
2 cles; or

3 “(ii) to which such article has been
4 distributed, transported, or sold, to imme-
5 diately cease distribution of such article;

6 “(C) recall such article;

7 “(D) provide, in consultation with the Sec-
8 retary and where deemed necessary, notice to
9 consumers to whom such article was, or may
10 have been, distributed; and

11 “(E) take any combination of the above
12 measures, as appropriate in the circumstances.

13 The Secretary may not delegate recall authority
14 under this subsection to any person other than the
15 Commissioner.

16 “(2) PRE-HEARING ORDER TO CEASE DISTRIBU-
17 TION AND GIVE NOTICE.—If the responsible party
18 refuses to or does not voluntarily cease distribution,
19 make notification, recall such article, or provide no-
20 tice to consumers as applicable, the Secretary may,
21 by order, require, as the Secretary deems necessary,
22 such person to—

23 “(A) immediately cease distribution of
24 such article;

25 “(B) immediately notify all persons—

1 “(i) producing, manufacturing, pack-
2 ing, processing, preparing, treating, pack-
3 aging, distributing, or holding such arti-
4 cles; or

5 “(ii) to which such article has been
6 distributed, transported, or sold, to imme-
7 diately cease distribution of such article; or

8 “(C) immediately take the actions specified
9 in both subparagraphs (A) and (B).

10 “(3) NOTIFICATION OF CONSUMERS BY SEC-
11 RETARY.—The Secretary may, as the Secretary
12 deems necessary, provide notice to consumers to
13 whom such article was, or may have been, distrib-
14 uted.

15 “(4) HEARING ON ORDER.—The Secretary shall
16 provide the responsible party subject to an order
17 under paragraph (2) with an opportunity for a hear-
18 ing, to be held as soon as possible but not later than
19 2 days after the date of the issuance of the order,
20 on the actions required by the order and on why the
21 article that is the subject of the order should not be
22 recalled.

23 “(5) POST-HEARING RECALL ORDER.—

24 “(A) AMENDMENT OF ORDER.—If, after
25 providing opportunity for a hearing under para-

1 graph (4), the Secretary determines that re-
2 moval of the product is necessary, the Sec-
3 retary, as the Secretary deems necessary,
4 may—

5 “(i) amend the order to require recall
6 of such article or other appropriate action;

7 “(ii) specify a timetable in which the
8 recall shall occur;

9 “(iii) require periodic reports to the
10 Secretary describing the progress of the re-
11 call; and

12 “(iv) provide notice to consumers to
13 whom such article was, or may have been,
14 distributed.

15 “(B) VACATING OF ORDER.—If, after such
16 a hearing, the Secretary determines that ade-
17 quate grounds do not exist to continue the ac-
18 tions required by the order, the Secretary shall
19 vacate or modify the order.

20 “(6) FAILURE TO COMPLY WITH RECALL
21 ORDER.—Any person who does not comply with a re-
22 call order under this subsection shall be liable to a
23 fine not to exceed \$10,000 for each day of such non-
24 compliance or to a term of imprisonment not exceed-
25 ing 6 months, or both.

1 “(7) REMEDIES NOT EXCLUSIVE.—The rem-
2 edies provided in this subsection shall be in addition
3 to and not exclusive of other remedies that may be
4 available.

5 “(8) COOPERATION.—The Secretary shall work
6 with the Secretary of Agriculture and State and
7 local public health officials in carrying out this sub-
8 section.”.

9 (b) PROHIBITED ACTS.—Section 301 of such Act (21
10 U.S.C. 331 et seq.), as amended by sections 4(d), 5(b),
11 and 9(b), is further amended by adding at the end the
12 following:

13 “(rr) The refusal or failure to follow an order under
14 section 417(l).”.

15 **SEC. 15. BUILDING CAPACITY OF FOREIGN GOVERNMENTS.**

16 (a) IN GENERAL.—The Secretary of Health and
17 Human Services (in this section referred to as the “Sec-
18 retary”) shall, within 2 years after the date of the enact-
19 ment of this Act, develop a comprehensive plan to expand
20 the technical, scientific, and regulatory capacity of foreign
21 governments, and their respective food industries, from
22 which foods are exported to the United States.

23 (b) CONSULTATION.—In developing the plan under
24 subsection (a), the Secretary shall consult with the Sec-
25 retary of Agriculture, the Secretary of State, the Secretary

1 of Treasury, and the Secretary of Commerce, and rep-
2 resentatives of the food industry and nongovernmental or-
3 ganizations that represent the interests of consumers, and
4 other stakeholders.

5 (c) PLAN.—The plan developed under subsection (a)
6 shall include, as appropriate, the following:

7 (1) Recommendations for bilateral and multilat-
8 eral agreements, including provisions to provide for
9 responsibility of exporting countries to ensure the
10 safety of food.

11 (2) Provisions for electronic data sharing.

12 (3) Provisions for reciprocal inspectional au-
13 thority.

14 (4) Training of foreign governments and ingre-
15 dient and food producers on United States require-
16 ments for safe food.

17 (5) Recommendations to harmonize require-
18 ments under the Codex Alimentarius.

19 (6) Provisions for the multilateral acceptance of
20 laboratory methods and detection techniques.

21 **SEC. 16. DOMESTIC CAPACITY BUILDING AND ANNUAL RE-**
22 **PORT ON FOOD SAFETY PROGRAMS.**

23 (a) IN GENERAL.—The Secretary of Health and
24 Human Services (in this section referred to as the “Sec-
25 retary”) shall, not later than December 31 of each year

1 following the first full year after the date of the enactment
2 of this Act, and annually thereafter, submit to the Con-
3 gress a report on the following:

4 (1) Progress in implementing the food protec-
5 tion plan and the import safety action plan issued in
6 November 2007.

7 (2) Progress in modernizing good manufac-
8 turing practice regulations for food.

9 (3) Progress in implementing the requirements
10 and programs required under this Act.

11 (4) Adequacy of resources available to the Sec-
12 retary to ensure the safety of the food supply.

13 (5) Adequacy of laboratory facilities available to
14 the Secretary to conduct analyses on food and
15 progress in the development of rapid detection tech-
16 nologies.

17 (6) Progress in modernizing the information
18 technology used by the Secretary for food safety re-
19 lated activities and progress in developing and imple-
20 menting modern information technology systems for
21 the review and processing of foods offered for impor-
22 tation into the United States.

23 (7) Food safety research projects conducted
24 during the previous year, including the extent to
25 which these projects have helped identify potential

1 food safety hazards and have provided appropriate
2 preventive control steps to address such hazards.

3 (8) Federal-State coordination on food safety
4 activities and proposals to improve the effectiveness
5 of such Federal-State partnerships, including with
6 respect to information sharing, conducting inspec-
7 tions, performing analysis and sampling, and con-
8 ducting education and outreach.

9 (9) Progress in increasing coordination between
10 relevant Federal, State, and local agencies respon-
11 sible for food safety.

12 (b) ANNUAL FOOD SAFETY IMPROVEMENT PLAN.—
13 In addition to the annual report to Congress under sub-
14 section (a), the Secretary shall submit a plan for improv-
15 ing food safety infrastructure. Such plan shall include
16 steps to address inadequacies as described in the annual
17 report.

18 **SEC. 17. AUTHORIZATION OF APPROPRIATIONS.**

19 There is authorized to be appropriated \$50,000,000
20 as necessary to carry out this Act.

○