

FDA Food Safety Modernization Act (Public Law 111-353)

Import Provisions

TITLE III--IMPROVING THE SAFETY OF IMPORTED FOOD

SEC. 301. FOREIGN SUPPLIER VERIFICATION PROGRAM.

(a) In General- Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

“SEC. 805. FOREIGN SUPPLIER VERIFICATION PROGRAM.

“(a) In General-

“(1) VERIFICATION REQUIREMENT- Except as provided under subsections (e) and (f), each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer or agent of an importer is--

“(A) produced in compliance with the requirements of section 418 or section 419, as appropriate; and

“(B) is not adulterated under section 402 or misbranded under section 403(w).

“(2) IMPORTER DEFINED- For purposes of this section, the term ‘importer’ means, with respect to an article of food--

“(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or

“(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

“(b) Guidance- Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall issue guidance to assist importers in developing foreign supplier verification programs.

“(c) Regulations-

“(1) IN GENERAL- Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (a).

“(2) REQUIREMENTS- The regulations promulgated under paragraph (1)--

“(A) shall require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier to the importer produces the imported food in compliance with--

“(i) processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under section 418 or section 419 (taking into consideration variances granted under section 419), as appropriate; and

“(ii) section 402 and section 403(w).

“(B) shall include such other requirements as the Secretary deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

“(3) CONSIDERATIONS- In promulgating regulations under this subsection, the Secretary shall, as appropriate, take into account differences among importers and types of imported foods, including based on the level of risk posed by the imported food.

“(4) ACTIVITIES- Verification activities under a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

“(d) Record Maintenance and Access- Records of an importer related to a foreign supplier verification program shall be maintained for a period of not less than 2 years and shall be made available promptly to a duly authorized representative of the Secretary upon request.

“(e) Exemption of Seafood, Juice, and Low-acid Canned Food Facilities in Compliance With HACCP- This section shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, 1 of the following standards and regulations with respect to such facility:

“(1) The Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

“(2) The Juice Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

“(3) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the Food and Drug Administration (or any successor standards).

The exemption under paragraph (3) shall apply only with respect to microbiological hazards that are regulated under the standards for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers under part 113 of chapter 21, Code of Federal Regulations (or any successor regulations).

“(f) Additional Exemptions- The Secretary, by notice published in the Federal Register, shall establish an exemption from the requirements of this section for articles of food imported in small quantities for research and evaluation purposes or for personal consumption, provided that such foods are not intended for retail sale and are not sold or distributed to the public.

“(g) Publication of List of Participants- The Secretary shall publish and maintain on the Internet Web site of the Food and Drug Administration a current list that includes the name of, location of, and other information deemed necessary by the Secretary about, importers participating under this section.”.

(b) Prohibited Act- Section 301 (21 U.S.C. 331), as amended by section 211, is amended by adding at the end the following:

“(zz) The importation or offering for importation of a food if the importer (as defined in section 805) does not have in place a foreign supplier verification program in compliance with such section 805.”.

(c) Imports- Section 801(a) (21 U.S.C. 381(a)) is amended by adding ‘or the importer (as defined in section 805) is in violation of such section 805’ after ‘or in violation of section 505’.

(d) Effective Date- The amendments made by this section shall take effect 2 years after the date of enactment of this Act.

SEC. 302. VOLUNTARY QUALIFIED IMPORTER PROGRAM.

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 301, is amended by adding at the end the following:

“SEC. 806. VOLUNTARY QUALIFIED IMPORTER PROGRAM.

“(a) In General- Beginning not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall--

“(1) establish a program, in consultation with the Secretary of Homeland Security--

“(A) to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program; and

“(B) consistent with section 808, establish a process for the issuance of a facility certification to accompany food offered for importation by importers who have voluntarily agreed to participate in such program; and

“(2) issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with, such program.

“(b) Voluntary Participation- An importer may request the Secretary to provide for the expedited review and importation of designated foods in accordance with the program established by the Secretary under subsection (a).

“(c) Notice of Intent To Participate- An importer that intends to participate in the program under this section in a fiscal year shall submit a notice and application to the Secretary of such intent at the time and in a manner established by the Secretary.

“(d) Eligibility- Eligibility shall be limited to an importer offering food for importation from a facility that has a certification described in subsection (a). In reviewing the applications and making determinations on such applications, the Secretary shall consider the risk of the food to be imported based on factors, such as the following:

“(1) The known safety risks of the food to be imported.

“(2) The compliance history of foreign suppliers used by the importer, as appropriate.

“(3) The capability of the regulatory system of the country of export to ensure compliance with United States food safety standards for a designated food.

“(4) The compliance of the importer with the requirements of section 805.

“(5) The recordkeeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer.

“(6) The potential risk for intentional adulteration of the food.

“(7) Any other factor that the Secretary determines appropriate.

“(e) Review and Revocation- Any importer qualified by the Secretary in accordance with the eligibility criteria set forth in this section shall be reevaluated not less often than once every 3 years and the Secretary shall promptly revoke the qualified importer status of any importer found not to be in compliance with such criteria.

“(f) False Statements- Any statement or representation made by an importer to the Secretary shall be subject to section 1001 of title 18, United States Code.

“(g) Definition- For purposes of this section, the term ‘importer’ means the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.”.

SEC. 303. AUTHORITY TO REQUIRE IMPORT CERTIFICATIONS FOR FOOD.

(a) In General- Section 801(a) (21 U.S.C. 381(a)) is amended by inserting after the third sentence the following: “With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this Act, then such article shall be refused admission.”.

(b) Addition of Certification Requirement- Section 801 (21 U.S.C. 381) is amended by adding at the end the following new subsection:

“(q) Certifications Concerning Imported Foods-

“(1) IN GENERAL- The Secretary may require, as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity described in paragraph (3) provide a certification, or such other assurances as the Secretary determines appropriate, that the article of food complies with applicable requirements of this Act. Such certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in such other form as the Secretary may specify.

“(2) FACTORS TO BE CONSIDERED IN REQUIRING CERTIFICATION- The Secretary shall base the determination that an article of food is required to have a certification described in paragraph (1) on the risk of the food, including--

“(A) known safety risks associated with the food;

“(B) known food safety risks associated with the country, territory, or region of origin of the food;

“(C) a finding by the Secretary, supported by scientific, risk-based evidence, that--

“(i) the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act; and

“(ii) the certification would assist the Secretary in determining whether to refuse or admit the article of food under subsection (a); and

“(D) information submitted to the Secretary in accordance with the process established in paragraph (7).

“(3) CERTIFYING ENTITIES- For purposes of paragraph (1), entities that shall provide the certification or assurances described in such paragraph are--

“(A) an agency or a representative of the government of the country from which the article of food at issue originated, as designated by the Secretary; or

“(B) such other persons or entities accredited pursuant to section 808 to provide such certification or assurance.

“(4) RENEWAL AND REFUSAL OF CERTIFICATIONS- The Secretary may--

“(A) require that any certification or other assurance provided by an entity specified in paragraph (2) be renewed by such entity at such times as the Secretary determines appropriate; and

“(B) refuse to accept any certification or assurance if the Secretary determines that such certification or assurance is not valid or reliable.

“(5) ELECTRONIC SUBMISSION- The Secretary shall provide for the electronic submission of certifications under this subsection.

“(6) FALSE STATEMENTS- Any statement or representation made by an entity described in paragraph (2) to the Secretary shall be subject to section 1001 of title 18, United States Code.

“(7) ASSESSMENT OF FOOD SAFETY PROGRAMS, SYSTEMS, AND STANDARDS- If the Secretary determines that the food safety programs, systems, and standards in a foreign region, country, or territory are inadequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act, the Secretary shall, to the extent practicable, identify such inadequacies and establish a process by which the foreign region, country, or territory may inform the Secretary of improvements made to such food safety program, system, or standard and demonstrate that those controls are adequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act.”.

(c) Conforming Technical Amendment- Section 801(b) (21 U.S.C. 381(b)) is amended in the second sentence by striking “with respect to an article included within the provision of the fourth sentence of subsection (a)” and inserting “with respect to an article described in subsection (a) relating to the requirements of sections 760 or 761,”.

(d) No Limit on Authority- Nothing in the amendments made by this section shall limit the authority of the Secretary to conduct inspections of imported food or to take such other steps as the Secretary deems appropriate to determine the admissibility of imported food.

SEC. 304. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

(a) In General- Section 801(m)(1) (21 U.S.C. 381(m)(1)) is amended by inserting “any country to which the article has been refused entry;” after “the country from which the article is shipped;”.

(b) Regulations- Not later than 120 days after the date of enactment of this Act, the Secretary shall issue an interim final rule amending subpart I of part 1 of title 21, Code of Federal Regulations, to implement the amendment made by this section.

(c) Effective Date- The amendment made by this section shall take effect 180 days after the date of enactment of this Act.

SEC. 305. BUILDING CAPACITY OF FOREIGN GOVERNMENTS WITH RESPECT TO FOOD SAFETY.

(a) In General- The Secretary shall, not later than 2 years of the date of enactment of this Act, develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States.

(b) Consultation- In developing the plan under subsection (a), the Secretary shall consult with the Secretary of Agriculture, Secretary of State, Secretary of the Treasury, the Secretary of Homeland Security, the United States Trade Representative, and the Secretary of Commerce, representatives of the food industry, appropriate foreign government officials, nongovernmental organizations that represent the interests of consumers, and other stakeholders.

(c) Plan- The plan developed under subsection (a) shall include, as appropriate, the following:

(1) Recommendations for bilateral and multilateral arrangements and agreements, including provisions to provide for responsibility of exporting countries to ensure the safety of food.

(2) Provisions for secure electronic data sharing.

(3) Provisions for mutual recognition of inspection reports.

(4) Training of foreign governments and food producers on United States requirements for safe food.

(5) Recommendations on whether and how to harmonize requirements under the Codex Alimentarius.

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

(d) Rule of Construction- Nothing in this section shall be construed to affect the regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994 (Public Law 103-417).

SEC. 306. INSPECTION OF FOREIGN FOOD FACILITIES.

(a) In General- Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 302, is amended by inserting at the end the following:

“SEC. 807. INSPECTION OF FOREIGN FOOD FACILITIES.

“(a) Inspection- The Secretary--

“(1) may enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under section 415; and

“(2) shall direct resources to inspections of foreign facilities, suppliers, and food types, especially such facilities, suppliers, and food types that present a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States.

“(b) Effect of Inability To Inspect- Notwithstanding any other provision of law, food shall be refused admission into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon

request, to inspect such factory, warehouse, or other establishment. For purposes of this subsection, such an owner, operator, or agent in charge shall be considered to have refused an inspection if such owner, operator, or agent in charge does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after such request is submitted, or after such other time period, as agreed upon by the Secretary and the foreign factory, warehouse, or other establishment.”.

(b) Inspection by the Secretary of Commerce-

(1) IN GENERAL- The Secretary of Commerce, in coordination with the Secretary of Health and Human Services, may send 1 or more inspectors to a country or facility of an exporter from which seafood imported into the United States originates. The inspectors shall assess practices and processes used in connection with the farming, cultivation, harvesting, preparation for market, or transportation of such seafood and may provide technical assistance related to such activities.

(2) INSPECTION REPORT-

(A) IN GENERAL- The Secretary of Health and Human Services, in coordination with the Secretary of Commerce, shall--

(i) prepare an inspection report for each inspection conducted under paragraph (1);

(ii) provide the report to the country or exporter that is the subject of the report; and

(iii) provide a 30-day period during which the country or exporter may provide a rebuttal or other comments on the findings of the report to the Secretary of Health and Human Services.

(B) DISTRIBUTION AND USE OF REPORT- The Secretary of Health and Human Services shall consider the inspection reports described in subparagraph (A) in distributing inspection resources under section 421 of the Federal Food, Drug, and Cosmetic Act, as added by section 201.

SEC. 307. ACCREDITATION OF THIRD-PARTY AUDITORS.

Chapter VIII (21 U.S.C. 381 et seq.), as amended by section 306, is amended by adding at the end the following:

“SEC. 808. ACCREDITATION OF THIRD-PARTY AUDITORS.

“(a) Definitions- In this section:

“(1) AUDIT AGENT- The term ‘audit agent’ means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party auditor.

“(2) ACCREDITATION BODY- The term ‘accreditation body’ means an authority that performs accreditation of third-party auditors.

“(3) THIRD-PARTY AUDITOR- The term ‘third-party auditor’ means a foreign government, agency of a foreign government, foreign cooperative, or any other third party, as the Secretary determines appropriate in accordance with the model standards described in subsection (b)(2), that is eligible to be considered for accreditation to conduct food safety audits to certify that eligible entities meet the applicable requirements of this section. A third-party auditor may be a single individual. A third-party auditor may employ or use audit agents to help conduct consultative and regulatory audits.

“(4) ACCREDITED THIRD-PARTY AUDITOR- The term ‘accredited third-party auditor’ means a third-party auditor accredited by an accreditation body to conduct audits of eligible entities to certify that such eligible entities meet the applicable requirements of this section. An accredited third-party auditor may be an individual who conducts food safety audits to certify that eligible entities meet the applicable requirements of this section.

“(5) CONSULTATIVE AUDIT- The term ‘consultative audit’ means an audit of an eligible entity--

“(A) to determine whether such entity is in compliance with the provisions of this Act and with applicable industry standards and practices; and

“(B) the results of which are for internal purposes only.

“(6) ELIGIBLE ENTITY- The term ‘eligible entity’ means a foreign entity, including a foreign facility registered under section 415, in the food import supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

“(7) REGULATORY AUDIT- The term ‘regulatory audit’ means an audit of an eligible entity--

“(A) to determine whether such entity is in compliance with the provisions of this Act; and

“(B) the results of which determine--

“(i) whether an article of food manufactured, processed, packed, or held by such entity is eligible to receive a food certification under section 801(q); or

“(ii) whether a facility is eligible to receive a facility certification under section 806(a) for purposes of participating in the program under section 806.

“(b) Accreditation System-

“(1) ACCREDITATION BODIES-

“(A) RECOGNITION OF ACCREDITATION BODIES-

“(i) IN GENERAL- Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet the applicable requirements of this section.

“(ii) DIRECT ACCREDITATION- If, by the date that is 2 years after the date of establishment of the system described in clause (i), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.

“(B) NOTIFICATION- Each accreditation body recognized by the Secretary shall submit to the Secretary a list of all accredited third-party auditors accredited by such body and the audit agents of such auditors.

“(C) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY- The Secretary shall promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section.

“(D) REINSTATEMENT- The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary determines, based on evidence presented by such accreditation

body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

“(2) MODEL ACCREDITATION STANDARDS- Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall develop model standards, including requirements for regulatory audit reports, and each recognized accreditation body shall ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors under this section. In developing the model standards, the Secretary shall look to standards in place on the date of the enactment of this section for guidance, to avoid unnecessary duplication of efforts and costs.

“(c) Third-party Auditors-

“(1) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR-

“(A) FOREIGN GOVERNMENTS- Prior to accrediting a foreign government or an agency of a foreign government as an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of food safety programs, systems, and standards of the government or agency of the government as the Secretary deems necessary, including requirements under the model standards developed under subsection (b)(2), to determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or foods certified by such government or agency meet the requirements of this Act with respect to food manufactured, processed, packed, or held for import into the United States.

“(B) FOREIGN COOPERATIVES AND OTHER THIRD PARTIES- Prior to accrediting a foreign cooperative that aggregates the products of growers or processors, or any other third party to be an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of the training and qualifications of audit agents used by that cooperative or party and conduct such reviews of internal systems and such other investigation of the cooperative or party as the Secretary deems necessary, including requirements under the model standards developed under subsection (b)(2), to determine that each eligible entity certified by the cooperative or party has systems and standards in use to ensure that such entity or food meets the requirements of this Act.

“(2) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES OR FOODS-

“(A) IN GENERAL- An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) may not accredit a third-party auditor unless such third-party auditor agrees to issue a written and, as appropriate, electronic food certification, described in section 801(q), or facility certification under section 806(a), as appropriate, to accompany each food shipment for import into the United States from an eligible entity, subject to requirements set forth by the Secretary. Such written or electronic certification may be included with other documentation regarding such food shipment. The Secretary shall consider certifications under section 801(q) and participation in the voluntary qualified importer program described in section 806 when targeting inspection resources under section 421.

“(B) PURPOSE OF CERTIFICATION- The Secretary shall use certification provided by accredited third-party auditors to--

“(i) determine, in conjunction with any other assurances the Secretary may require under section 801(q), whether a food satisfies the requirements of such section; and

“(ii) determine whether a facility is eligible to be a facility from which food may be offered for import under the voluntary qualified importer program under section 806.

“(C) REQUIREMENTS FOR ISSUING CERTIFICATION-

“(i) IN GENERAL- An accredited third-party auditor shall issue a food certification under section 801(q) or a facility certification described under subparagraph (B) only after conducting a regulatory audit and such other activities that may be necessary to establish compliance with the requirements of such sections.

“(ii) PROVISION OF CERTIFICATION- Only an accredited third-party auditor or the Secretary may provide a facility certification under section 806(a). Only those parties described in 801(q)(3) or the Secretary may provide a food certification under 301(g).

“(3) AUDIT REPORT SUBMISSION REQUIREMENTS-

“(A) REQUIREMENTS IN GENERAL- As a condition of accreditation, not later than 45 days after conducting an audit, an accredited third-party auditor or audit agent of such auditor shall prepare, and, in the case of a regulatory audit, submit, the audit report for each audit conducted, in a form and manner designated by the Secretary, which shall include--

“(i) the identity of the persons at the audited eligible entity responsible for compliance with food safety requirements;

“(ii) the dates of the audit;

“(iii) the scope of the audit; and

“(iv) any other information required by the Secretary that relates to or may influence an assessment of compliance with this Act.

“(B) RECORDS- Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor to submit to the Secretary an onsite audit report and such other reports or documents required as part of the audit process, for any eligible entity certified by the third-party auditor or audit agent of such auditor. Such report may include documentation that the eligible entity is in compliance with any applicable registration requirements.

“(C) LIMITATION- The requirement under subparagraph (B) shall not include any report or other documents resulting from a consultative audit by the accredited third-party auditor, except that the Secretary may access the results of a consultative audit in accordance with section 414.

“(4) REQUIREMENTS OF ACCREDITED THIRD-PARTY AUDITORS AND AUDIT AGENTS OF SUCH AUDITORS-

“(A) RISKS TO PUBLIC HEALTH- If, at any time during an audit, an accredited third-party auditor or audit agent of such auditor discovers a condition that could cause or contribute to a serious risk to the public health, such auditor shall immediately notify the Secretary of--

“(i) the identification of the eligible entity subject to the audit; and

“(ii) such condition.

“(B) TYPES OF AUDITS- An accredited third-party auditor or audit agent of such auditor may perform consultative and regulatory audits of eligible entities.

“(C) LIMITATIONS-

“(i) IN GENERAL- An accredited third party auditor may not perform a regulatory audit of an eligible entity if such agent has performed a consultative audit or a regulatory audit of such eligible entity during the previous 13-month period.

“(ii) WAIVER- The Secretary may waive the application of clause (i) if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region.

“(5) CONFLICTS OF INTEREST-

“(A) THIRD-PARTY AUDITORS- An accredited third-party auditor shall--

“(i) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by such auditor;

“(ii) in carrying out audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of such auditor that has a financial conflict of interest regarding an eligible entity to be certified by such auditor; and

“(iii) annually make available to the Secretary disclosures of the extent to which such auditor and the officers and employees of such auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

“(B) AUDIT AGENTS- An audit agent shall--

“(i) not own or operate an eligible entity to be audited by such agent;

“(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that such agent does not have a financial conflict of interest regarding an eligible entity to be audited by such agent; and

“(iii) annually make available to the Secretary disclosures of the extent to which such agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

“(C) REGULATIONS- The Secretary shall promulgate regulations not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act to implement this section and to ensure that there are protections against conflicts of interest between an accredited third-party auditor and the eligible entity to be certified by such auditor or audited by such audit agent. Such regulations shall include--

“(i) requiring that audits performed under this section be unannounced;

“(ii) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

“(iii) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of such auditor and any person that owns or operates an eligible entity to be certified by such auditor, as described in subparagraphs (A) and (B).

“(6) WITHDRAWAL OF ACCREDITATION-

“(A) IN GENERAL- The Secretary shall withdraw accreditation from an accredited third-party auditor--

“(i) if food certified under section 801(q) or from a facility certified under paragraph (2)(B) by such third-party auditor is linked to an outbreak of foodborne illness that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

“(ii) following an evaluation and finding by the Secretary that the third-party auditor no longer meets the requirements for accreditation; or

“(iii) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to ensure continued compliance with the requirements set forth in this section.

“(B) ADDITIONAL BASIS FOR WITHDRAWAL OF ACCREDITATION- The Secretary may withdraw accreditation from an accredited third-party auditor in the case that such third-party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked, if the Secretary determines that there is good cause for the withdrawal.

“(C) EXCEPTION- The Secretary may waive the application of subparagraph (A)(i) if the Secretary--

“(i) conducts an investigation of the material facts related to the outbreak of human or animal illness; and

“(ii) reviews the steps or actions taken by the third party auditor to justify the certification and determines that the accredited third-party auditor satisfied the requirements under section 801(q) of certifying the food, or the requirements under paragraph (2)(B) of certifying the entity.

“(7) REACCREDITATION- The Secretary shall establish procedures to reinstate the accreditation of a third-party auditor for which accreditation has been withdrawn under paragraph (6)--

“(A) if the Secretary determines, based on evidence presented, that the third-party auditor satisfies the requirements of this section and adequate grounds for revocation no longer exist; and

“(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked--

“(i) if the third-party auditor becomes accredited not later than 1 year after revocation of accreditation under paragraph (6)(A), through direct accreditation under subsection (b)(1)(A)(ii) or by an accreditation body in good standing; or

“(ii) under such conditions as the Secretary may require for a third-party auditor under paragraph (6)(B).

“(8) NEUTRALIZING COSTS- The Secretary shall establish by regulation a reimbursement (user fee) program, similar to the method described in section 203(h) of the Agriculture Marketing Act of 1946, by which the Secretary assesses fees and requires accredited third-party auditors and audit agents to reimburse the Food and Drug Administration for the work performed to establish and administer the accreditation system under this section. The Secretary shall make operating this program revenue-neutral and shall not generate surplus revenue from such a reimbursement mechanism. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to remain available until expended.

“(d) Recertification of Eligible Entities- An eligible entity shall apply for annual recertification by an accredited third-party auditor if such entity--

“(1) intends to participate in voluntary qualified importer program under section 806; or

“(2) is required to provide to the Secretary a certification under section 801(q) for any food from such entity.

“(e) False Statements- Any statement or representation made--

“(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

“(2) by an accredited third-party auditor to the Secretary,

shall be subject to section 1001 of title 18, United States Code.

“(f) Monitoring- To ensure compliance with the requirements of this section, the Secretary shall--

“(1) periodically, or at least once every 4 years, reevaluate the accreditation bodies described in subsection (b)(1);

“(2) periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the review of regulatory audit reports by such auditors, the compliance history as available of eligible entities certified by such auditors, and any other measures deemed necessary by the Secretary;

“(3) at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present; and

“(4) take any other measures deemed necessary by the Secretary.

“(g) Publicly Available Registry- The Secretary shall establish a publicly available registry of accreditation bodies and of accredited third-party auditors, including the name of, contact information for, and other information deemed necessary by the Secretary about such bodies and auditors.

“(h) Limitations-

“(1) NO EFFECT ON SECTION 704 INSPECTIONS- The audits performed under this section shall not be considered inspections under section 704.

“(2) NO EFFECT ON INSPECTION AUTHORITY- Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this Act.”.

SEC. 308. FOREIGN OFFICES OF THE FOOD AND DRUG ADMINISTRATION.

(a) In General- The Secretary shall establish offices of the Food and Drug Administration in foreign countries selected by the Secretary, to provide assistance to the appropriate governmental entities of such countries with respect to measures to provide for the safety of articles of food and other products regulated by the Food and Drug Administration exported by such country to the United States, including by directly conducting risk-based inspections of such articles and supporting such inspections by such governmental entity.

(b) Consultation- In establishing the foreign offices described in subsection (a), the Secretary shall consult with the Secretary of State, the Secretary of Homeland Security, and the United States Trade Representative.

(c) Report- Not later than October 1, 2011, the Secretary shall submit to Congress a report on the basis for the selection by the Secretary of the foreign countries in which the Secretary established offices, the progress which such offices have made with respect to assisting the governments of such countries in providing for the safety of articles of food and other products regulated by the Food and Drug Administration exported to the United States, and the plans of the Secretary for establishing additional foreign offices of the Food and Drug Administration, as appropriate.

SEC. 309. SMUGGLED FOOD.

(a) In General- Not later than 180 days after the enactment of this Act, the Secretary shall, in coordination with the Secretary of Homeland Security, develop and implement a strategy to better identify smuggled food and prevent entry of such food into the United States.

(b) Notification to Homeland Security- Not later than 10 days after the Secretary identifies a smuggled food that the Secretary believes would cause serious adverse health consequences or death to humans or animals, the Secretary shall provide to the Secretary of Homeland Security a notification under section 417(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350f(k)) describing the smuggled food and, if available, the names of the individuals or entities that attempted to import such food into the United States.

(c) Public Notification- If the Secretary--

(1) identifies a smuggled food;

(2) reasonably believes exposure to the food would cause serious adverse health consequences or death to humans or animals; and

(3) reasonably believes that the food has entered domestic commerce and is likely to be consumed, the Secretary shall promptly issue a press release describing that food and shall use other emergency communication or recall networks, as appropriate, to warn consumers and vendors about the potential threat.

(d) Effect of Section- Nothing in this section shall affect the authority of the Secretary to issue public notifications under other circumstances.

(e) Definition- In this subsection, the term 'smuggled food' means any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead.

TITLE II--IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

SEC. 201. TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT.

- (a) Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry.--Chapter IV (21 U.S.C. 341 et seq.), as amended by section 106, is amended by adding at the end the following:
- "SEC. 421. (NOTE: 21 USC 350j). TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY; ANNUAL REPORT.
- "(a) Identification and Inspection of Facilities.--
- "(1) Identification.--The Secretary shall identify high-risk facilities and shall allocate resources to inspect facilities according to the known safety risks of the facilities, which shall be based on the following factors:
- "(A) The known safety risks of the food manufactured, processed, packed, or held at the facility.
- "(B) The compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards.
- "(C) The rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls.
- "(D) Whether the food manufactured, processed, packed, or held at the facility meets the criteria for priority under section 801(h)(1).
- "(E) Whether the food or the facility that manufactured, processed, packed, or held such food has received a certification as described in section 801(q) or 806, as appropriate.
- "(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.
- "(2) Inspections.--
- "(A) In general. <<NOTE: Effective date.>> --Beginning on the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall increase the frequency of inspection of all facilities.
- (b) "(B) Domestic high-risk facilities. <<NOTE: Deadlines.>> --The Secretary shall increase the frequency of inspection of domestic facilities identified under paragraph (1) as high-risk facilities such that each such facility is inspected--
- "(i) not less often than once in the 5-year period following the date of enactment of the FDA Food Safety Modernization Act; and
- "(ii) not less often than once every 3 years thereafter.
- "(C) Domestic non-high-risk facilities. <<NOTE: Deadlines.>> --The Secretary shall ensure that each domestic facility that is not identified under paragraph (1) as a high-risk facility is inspected--
- "(i) not less often than once in the 7-year period following the date of enactment of the FDA Food Safety Modernization Act; and
- "(ii) not less often than once every 5 years thereafter.
- "(D) <<NOTE: Time period.>> Foreign facilities.--
- "(i) Year 1.--In the 1-year period following the date of enactment of the FDA Food Safety

Modernization Act, the Secretary shall inspect not fewer than 600 foreign facilities.

"(ii) Subsequent years.--In each of the 5 years following the 1-year period described in clause (i), the Secretary shall inspect not fewer than twice the number of foreign facilities inspected by the Secretary during the previous year.

"(E) Reliance on federal, state, or local inspections.--In meeting the inspection requirements under this subsection for domestic facilities, the Secretary may rely on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memoranda of understanding, or other obligation.

"(b) Identification and Inspection at Ports of Entry.--The Secretary, in consultation with the Secretary of Homeland Security, shall allocate resources to inspect any article of food imported into the United States according to the known safety risks of the article of food, which shall be based on the following factors:

"(1) The known safety risks of the food imported.

"(2) The known safety risks of the countries or regions of origin and countries through which such article of food is transported.

"(3) The compliance history of the importer, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards.

"(4) The rigor and effectiveness of the activities conducted by the importer of such article of food to satisfy the requirements of the foreign supplier verification program under section 805.

"(5) Whether the food importer participates in the voluntary qualified importer program under section 806.

"(6) Whether the food meets the criteria for priority under section 801(h)(1).

"(7) Whether the food or the facility that manufactured, processed, packed, or held such food received a certification as described in section 801(q) or 806.

"(8) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

"(c) Interagency Agreements With Respect to Seafood.--

"(1) In general.--The Secretary of Health and Human Services, the Secretary of Commerce, the Secretary of Homeland Security, the Chairman of the Federal Trade Commission, and the heads of other appropriate agencies may enter into such agreements as may be necessary or appropriate to improve seafood safety.

"(2) Scope of agreements.--The agreements under paragraph (1) may include--

"(A) cooperative arrangements for examining and testing seafood imports that leverage the resources, capabilities, and authorities of each party to the agreement;

"(B) coordination of inspections of foreign facilities to increase the percentage of imported seafood and seafood facilities inspected;

"(C) standardization of data on seafood names, inspection records, and laboratory testing to improve interagency coordination;

"(D) coordination to detect and investigate violations under applicable Federal law;

"(E) a process, including the use or modification of existing processes, by which officers and employees of the National Oceanic and Atmospheric Administration may be duly designated by the Secretary to carry out seafood examinations and investigations under section 801 of this Act or section 203 of the Food Allergen Labeling and Consumer Protection Act of 2004;

"(F) the sharing of information concerning observed non-compliance with United States food

requirements domestically and in foreign nations and new regulatory decisions and policies that may affect the safety of food imported into the United States;

"(G) conducting joint training on subjects that affect and strengthen seafood inspection effectiveness by Federal authorities; and

"(H) outreach on Federal efforts to enhance seafood safety and compliance with Federal food safety requirements.

"(d) Coordination.--The Secretary shall improve coordination and cooperation with the Secretary of Agriculture and the Secretary of Homeland Security to target food inspection resources."(e) Facility. <<NOTE: Definition.>> --For purposes of this section, the term 'facility' means a domestic facility or a foreign facility that is required to register under section 415."

(b) Annual Report.--Section 1003 (21 U.S.C. 393) is amended by adding at the end the following:

"(h) Annual Report Regarding Food.--Not later than February 1 of each year, the Secretary shall submit to Congress a report, including efforts to coordinate and cooperate with other Federal agencies with responsibilities for food inspections, regarding--

"(1) information about food facilities including--

"(A) the appropriations used to inspect facilities registered pursuant to section 415 in the previous fiscal year;

"(B) the average cost of both a non-high-risk food facility inspection and a high-risk food facility inspection, if such a difference exists, in the previous fiscal year;

"(C) the number of domestic facilities and the number of foreign facilities registered pursuant to section 415 that the Secretary inspected in the previous fiscal year;

"(D) the number of domestic facilities and the number of foreign facilities registered pursuant to section 415 that were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such year;

"(E) the number of high-risk facilities identified pursuant to section 421 that the Secretary inspected in the previous fiscal year; and

"(F) the number of high-risk facilities identified pursuant to section 421 that were scheduled for inspection in the previous fiscal year and which the secretary did not inspect in such year.

"(2) information about food imports including--

"(A) the number of lines of food imported into the United States that the Secretary physically inspected or sampled in the previous fiscal year;

"(B) the number of lines of food imported into the United States that the Secretary did not physically inspect or sample in the previous fiscal year; and"(C) the average cost of physically inspecting or sampling a line of food subject to this Act that is imported or offered for import into the United States; and

"(3) information on the foreign offices of the Food and Drug Administration including--

"(A) the number of foreign offices established; and

"(B) the number of personnel permanently stationed in each foreign office.

"(i) Public Availability of Annual Food Reports. <<NOTE: Web posting.>> --The Secretary shall make the reports required under subsection (h) available to the public on the Internet Web site of the Food and Drug Administration."

(c) <<NOTE: 21 USC 350j note.>> Advisory Committee Consultation.--In allocating inspection resources as described in section 421 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), the Secretary may, as appropriate, consult with any relevant advisory committee within the Department of Health and Human Services.

