AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute, to modernize Federal food safety efforts without placing unnecessary burdens on food producers, increasing food prices, or saddling taxpayers with additional debt.

IN THE SENATE OF THE UNITED STATES—111th Cong., 2d Sess.

S. 510

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT In the Nature of a Substitute intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Ensuring Greater Food Safety Act of 2010''.

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

SEC. 2. ENSURING FEDERAL AGENCIES EFFECTIVELY COMMUNICATE TO ENSURE GREATER FOOD SAFETY.

(a) IN GENERAL.—Notwithstanding any other provision of law, not later than 60 days after the date of enactment of this Act, the Secretary of Health and Human Services and the Secretary or Agriculture shall establish a plan to ensure effective information sharing regarding the regulation and inspection of food products and facilities, including violations, in which the Food and Drug Administration and the Department of Agriculture share joint, overlapping, or similar responsibility.

(b) JOINT REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services and the Secretary of Agriculture shall issue to Congress a joint report that summarizes the effectiveness, or lack of effectiveness, of the new information sharing arrangement established pursuant to subsection (a).

(c) GAO REPORT.—Not later than 1 year after the issuance of the report under subsection (b), the Comptroller General of the United States shall issue to Con-

gress a report concerning the determination and description of any inefficiencies or other challenges that remain regarding the sharing of information as required pursuant to subsection (a).

SEC. 3. STRATEGIC PLAN FOR HEALTH INFORMATION TECHNOLOGY.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a strategic plan on information technology that includes—

(1) an assessment of the information technology infrastructure, including systems for food safety data collection, access to data in external food safety databases, data mining capabilities, personnel, and personnel training programs, needed by the Food and Drug Administration to—

(A) comply with the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(B) achieve interoperability within the Center for Food Safety and Nutrition and be-

tween the Food and Drug Administration and the Department of Agriculture, U.S. Customs and Border Protection, and the Centers for Disease Control and Prevention;

(C) utilize electronic import and recall records; and

(D) communicate food safety and recall information to industry and the public;

(2) an assessment of the extent to which the current information technology assets of the Food and Drug Administration are sufficient to meet the needs assessments under paragraph (1);

(3) a plan for enhancing the information technology assets of the Food and Drug Administration toward meeting the needs assessments under paragraph (1); and

(4) an assessment of additional resources needed to so enhance the information technology assets of the Food and Drug Administration.

SEC. 4. EXPEDITING NEW FOOD SAFETY TECHNOLOGIES.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to Congress a plan for a

more expeditious process for approving new technologies used to ensure the safety of the food supply.

(b) CONTENT.—The report submitted under subsection (a) shall include a description of how the Food and Drug Administration plans to provide more effective risk-communication regarding new technologies described in such report that are approved by such Administration.

SEC. 5. LIMITED ACCESS TO RECORDS IN PUBLIC HEALTH EMERGENCIES.

(a) MAINTENANCE AND INSPECTION OF RECORDS.—Section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c) is amended—

(1) in subsection (a)—

(A) by inserting ''or a related article of food'' after ''such article'' each place the term appears;

(B) by inserting ''or a related article of food'' after ''whether the food''; and

(C) by adding at the end the following: ''In this subsection, the term 'related article of food' means an article of food that is related to the article of food the Secretary has reason to believe is adulterated, such as an article of food produced on the same manufacturing line as

the article of food believed to be adulterated.''; and

(2) by adding at the end the following:

''(e) FOOD-RELATED EMERGENCIES.—In the case of a food-related public health emergency declared by the Secretary under section 319 of the Public Health Service Act, the Secretary may take action as described in subsection (a) if the Secretary has a reasonable belief that such article of food—

''(1) presents a threat of serious adverse health consequences or death; and

''(2) is related to the emergency.''.

(b) FACTORY INSPECTION.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended in the second sentence by inserting '', and in the case of a food-related public health emergency declared by the Secretary under section 319 of the Public Health Service Act, the inspection shall extend to all records and other information described in section 414 if the Secretary has a reasonable belief that such article of food presents a threat of serious adverse health consequences or death and is related to the emergency, subject to the limitations established in section 414(d)'' before the period at the end.

SEC. 6. REGISTRATION OF FOOD FACILITIES.

Section 415(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(a)) is amended—

(1) in paragraph (2), by inserting ''(or any successor regulation)'' after ''Federal Regulations'';

(2) by redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively; and

(3) by inserting after paragraph (2) the following:

''(3) BIENNIAL REREGISTRATION.—

''(A) IN GENERAL.—On a biennial basis, a registrant that has registered under paragraph (1) shall submit to the Secretary a reregistration containing the information described in paragraph (2).

''(B) EXPEDITED REREGISTRATION.—The Secretary may provide for an expedited reregistration process in the case of a registrant for which the information described in paragraph (2) has not changed since the preceding registration or reregistration.''.

SEC. 7. CLARIFYING FDA AUTHORITY TO REQUIRE PREVENTIVE CONTROLS.

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

"SEC. 418. PREVENTIVE CONTROLS.

''(a) DEFINITIONS.—In this section:

''(1) CRITICAL CONTROL POINT.—The term 'critical control point' means a point, step, or procedure in a food process at which control can be applied, and, as a result, an identified food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

''(2) CRITICAL LIMIT.—The term 'critical limit' means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

''(b) REGULATIONS BY SECRETARY.—The Secretary—

''(1) may by regulation require manufacturers, processors, and packers of food to implement science-based and risk-based processes to prevent, reduce, or eliminate specific hazards from high-risk foods; and

''(2) may issue guidance to assist the relevant industry with compliance with this section.

''(c) LIMITATION.—The Secretary shall not have the authority to place any specific requirements on food safety plans required pursuant to subsection (d)(1). The author-

ity of the Secretary under this section is limited to validating the existence of a food safety plan that meets the explicit statutory requirements provided in this section.

''(d) CONTENT.—

''(1) DETERMINATION.—The regulations under subsection (b) shall include a determination specifying the food facilities which shall be required to develop and maintain a written food safety plan. The determination shall include a careful examination of the effect on small businesses and shall include specific exemptions for firms that will be adversely impacted by the requirements of this section.

''(2) REQUIREMENT.—The regulations under subsection (b) shall require that a required food safety plan—

''(A) list the food safety hazards which the plan is intended to address;

''(B) list the critical control points for each of the identified food safety hazards;

''(C) list the critical limits that must be met at each of the critical control points;

''(D) list the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

"(E) include any corrective action plans that have been developed to be followed in response to deviations from critical limits at critical control points to either prevent the food from entering commerce, or for correcting the deviation;

"(F) list the verification procedures, and frequency thereof, that the manufacturer, processor, packer will use to ensure the plan is adequate to control identified food safety hazards and that the plan is being effectively implemented;

"(G) provide for a recordkeeping system that documents the acceptance and implementation of the plan, including calibration of instruments, monitoring of the critical control points, and corrective actions;

"(H) establish a schedule for periodic reassessment of the adequacy of the plan which shall be at least annually and whenever any changes occur that could affect the hazard analysis or alter the food safety plan; and

"(I) be modified immediately whenever a reassessment or ongoing verification reveals

that the plan is no longer adequate to fully meet the requirements of this section.

''(3) DESCRIPTION.—The regulations under subsection (b) shall describe, as the Secretary determines necessary, any evidence that shall be required to accompany food imported or offered for import into the United States to verify that the food was manufactured, processed, or packed under conditions that comply with this Act. Such evidence shall be of a similar nature and stringency to that which is required by the regulations for food manufactured, processed, or packed in the United States.

''(e) OFFICIAL REVIEW.—All records, food safety plans, and procedures required by this section shall be made available to the Secretary upon request for official review and copying at reasonable times. In conducting such a review, the authority of the Secretary shall be limited to validating the existence of the plan and the Secretary shall not have the authority to alter the plan or require specific items with the plan.

''(f) PUBLIC DISCLOSURE.—All food safety plans and records required by this section shall not be made available for public disclosure unless such plans and records are data and information previously disclosed to the public (as described in section 20.81 of title 21, Code of Federal

Regulations), or such plans and records relate to a food or ingredient that has been abandoned and such plans and records no longer represent a trade secret or confidential commercial or financial information (as described in section 20.61 of title 21, Code of Federal Regulations).

''(g) IMPORTS.—

''(1) IN GENERAL.—The Secretary may establish additional or substitute methods and requirements to apply to foreign manufacturers, processors, and packers of food that are of similar stringency to the methods and requirements applicable to domestic manufacturers, processors, and packers of food. Such methods or requirements shall ensure that—

''(A) food imported or offered for import into the United States is manufactured, processed, and packed in accordance with this Act; and

''(B) food manufactured, processed, or packed in a foreign country is evaluated for compliance with this Act in a similar manner as food manufactured, processed, or packed in the United States.

''(2) COMPETENT THIRD PARTY.—An importer may contract with a competent third party to assist

with or perform any or all of the verification activities specified in this section.

''(h) EXCEPTIONS.—The regulations in this section shall not apply to—

''(1) harvesting food, without otherwise engaging in processing;

''(2) the operation of a retail establishment;

''(3) the manufacturing, processing, or packing of seafood or fresh juice; and

''(4) small producers that demonstrate in writing to the Secretary that complying with such regulations would adversely impact their operations.''.

SEC. 8. EXPORT CERTIFICATION FEES FOR FOODS AND ANIMAL FEED.

(a) AUTHORITY FOR EXPORT CERTIFICATIONS FOR FOOD, INCLUDING ANIMAL FEED.—Section 801(e)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)(A)) is amended—

(1) in the matter preceding clause (i), by striking ''a drug'' and inserting ''a food, drug'';

(2) in clause (i) by striking ''exported drug'' and inserting ''exported food, drug''; and

(3) in clause (ii) by striking ''the drug'' each place it appears and inserting ''the food, drug''.

(b) TREATMENT OF FEES.—Section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

(1) by amending subparagraph (B) to read as follows:

''(B) If the Secretary issues a written export certification within the 20 days prescribed by subparagraph (A), a fee for such certification may be charged but shall not exceed $175 for each certification.''; and

(2) by inserting after subparagraph (B) the following:

''(C) With respect to fees collected for a fiscal year pursuant to subparagraph (B), the following shall apply:

''(i) In the case of fees for certification of exported drugs, animal drugs, or devices, be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and be available in accordance with appropriations Acts until expended, without fiscal year limitation. To cover the cost of issuing such certifications, such sums as necessary may be transferred from such appropria-

tion account for salaries and expenses of the Food and Drug Administration without fiscal year limitation to such appropriation account for salaries and expenses with fiscal year limitation.

''(ii) In the case of fees for certification of exported foods, be credited to the Food and Drug Administration User Fee Account and be available in accordance with appropriations Acts until expended, without fiscal year limitation.''.

(c) CLARIFICATION OF CERTIFICATION.—Section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)), as amended by subsection (b), is amended by adding at the end the following:

''(D) For purposes of this paragraph, a certification by the Secretary shall be made on such basis, and in such form (which may include a publicly available listing) as the Secretary determines appropriate.''.

SEC. 9. LEVERAGING THIRD PARTY INSPECTIONS.

(a) IN GENERAL.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended by adding at the end the following:

''(h) ACCREDITATION OF ENTITIES THAT INSPECT DOMESTIC FACILITIES OR FOREIGN FACILITIES.—

''(1) DEFINITIONS.—In this subsection:

''(A) DOMESTIC FACILITY.—The term 'domestic facility' has the meaning given the term in section 415.

''(B) FOREIGN FACILITY.—The term 'foreign facility' has the meaning given the term in section 415.

''(2) VOLUNTARY USE OF ACCREDITED ENTITIES BY FACILITIES.—A domestic facility or foreign facility may employ an entity accredited under this subsection to inspect such facility to ensure compliance with this Act.

''(3) AUTHORIZATION.—

''(A) IN GENERAL.—Not later than 1 year after the date of enactment of the Ensuring Greater Food Safety Act of 2010, the Secretary, subject to subparagraph (B), shall accredit entities for the purpose of inspecting domestic facilities or foreign facilities to ensure compliance with this Act. Such entities may include State governments or foreign government entities.

"(B) CRITERIA TO ACCREDIT ENTITIES AND CATEGORIES OF ACCREDITATION.—

"(i) IN GENERAL.—Not later than 180 days after the date of enactment of the Ensuring Greater Food Safety Act of 2010, the Secretary shall publish in the Federal Register criteria to accredit entities, including the requirements described in clause (iii), and the categories of accreditation.

"(ii) CONSULTATION.—In developing the criteria and categories described in clause (i), the Secretary shall consult with the Secretary of Agriculture, the Secretary of Commerce, and the heads of other agencies with experience in accrediting third parties to determine the accreditation categories and criteria that are most appropriate.

"(iii) REQUIREMENTS TO BECOME ACCREDITED.—In order for an entity to be accredited under this subsection, the entity shall, at a minimum, meet the following requirements:

''(I) Such entity may not be an employee of the Federal Government.

''(II) Such entity shall be an independent organization that is not owned or controlled by a manufacturer, supplier, or vendor of food regulated under this Act and that has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

''(III) Such entity shall be legally constituted and permitted to conduct the inspection activities for which it seeks accreditation.

''(IV) Such entity may not engage in the design, manufacture, promotion, or sale of food regulated under this Act.

''(V) The operations of such entity shall be in accordance with generally accepted professional and ethical business practices, and such entity shall agree in writing that, at a minimum, the entity will—

"(aa) certify that reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with this Act, and recommendations made during an inspection or at an inspection's closing meeting;

"(bb) limit work to that for which competence and capacity are available;

"(cc) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to the Secretary; and

"(dd) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited.

"(iv) CATEGORIES OF ACCREDITATION.—The categories of accreditation may include—

"(I) inspection of domestic facilities only;

"(II) inspection of foreign facilities only; or

"(III) inspection of both domestic facilities and foreign facilities.

"(C) ACTING ON REQUEST FOR ACCREDITATION.—

"(i) INFORMATION ON ADEQUACY.—Not later than 60 days after the date the Secretary receives a request from an entity to be accredited under this subsection, the Secretary shall inform the entity whether the request for accreditation is adequate for review.

"(ii) DETERMINATION.—Not later than 90 days after the date the Secretary informs an entity under clause (i), the Secretary shall make a determination with respect to the request.

"(D) CONTENT OF ACCREDITATION.—Any accreditation granted under this subsection

shall state that the entity is accredited to conduct inspections at domestic facilities, foreign facilities, or both, or such other categories as may be applicable.

''(E) EFFECT OF SUBSECTION.—Nothing in this subsection shall affect the authority of the Secretary under this Act to inspect any domestic facility or foreign facility.

''(4) REQUIREMENTS OF ACCREDITED ENTITIES.—

''(A) MAINTENANCE OF RECORDS.—

''(i) IN GENERAL.—An entity accredited under this subsection shall maintain records documenting—

''(I) the qualifications of the entity to inspect and the training and qualification of employees of the entity;

''(II) the procedures used by the entity for handling confidential information;

''(III) the compensation arrangements made by the entity; and

''(IV) the procedures used by the entity to identify and avoid conflicts of interest.

''(ii) ACCESS TO RECORDS.—Upon the request of an officer or employee designated by the Secretary, an entity accredited under this subsection shall permit the officer or employee, at all reasonable times, to have access to, copy, and verify the records described in clause (i).

''(iii) PRODUCTION OF RECORDS.—Not later than 15 days after the date an entity accredited under this subsection receives a written request from the Secretary for a copy of the records described in clause (i), the entity shall produce the copy at the place designated by the Secretary.

''(B) INSPECTION REPORTS.—

''(i) IN GENERAL.—In carrying out an inspection of a domestic facility or foreign facility to ensure compliance with this Act, an entity accredited under this subsection shall—

''(I) record in writing the entity's inspection observations;

''(II) present the observations to the facility's designated representative and describe each observation; and

''(III) prepare an inspection report (including for inspections for which there are no corrective actions needed) in a form and manner consistent with such reports prepared by employees and officials designated by the Secretary to conduct inspections.

''(ii) CONTENT OF REPORT.—An inspection report prepared under clause (i)(III) shall, at a minimum—

''(I) identify the person responsible for compliance with this Act at the inspected facility, the dates of the inspection, and the scope of the inspection;

''(II) describe in detail each observation identified by the entity accredited under this subsection;

''(III) identify other matters that relate to or may influence compliance with this Act; and

"(IV) describe any recommendations made by the entity accredited under this subsection to the inspected facility during the inspection or at the inspection's closing meeting.

"(iii) REPORT SENT TO THE SECRETARY.—Not later than 10 days after the last date of an inspection, the entity accredited under this subsection shall submit the inspection report prepared under clause (i)(III) to the Secretary and the designated representative of the inspected facility at the same time. The inspection report submitted to the Secretary shall be accompanied by all written inspection observations previously provided to the designated representative of the inspected facility.

"(iv) FALSE STATEMENTS.—Any statement or representation made by an employee or agent of a domestic facility or foreign facility to an entity accredited under this subsection shall be subject to section 1001 of title 18, United States Code.

"(v) IMMEDIATE NOTIFICATION.—If, at any time during an inspection by an entity accredited under this subsection, the entity discovers a condition that could cause or contribute to an unreasonable risk to the public health, the entity shall immediately notify the Secretary of the identity of the facility subject to inspection and such condition.

"(5) REQUIREMENTS OF THE SECRETARY.—

"(A) PUBLICATION OF LIST OF ACCREDITED ENTITIES ON INTERNET.—

"(i) IN GENERAL.—The Secretary shall publish on the Internet Web site of the Food and Drug Administration lists of entities that are accredited under this subsection in each category established under this subsection.

"(ii) UPDATING LISTS.—The lists described in clause (i) shall be updated to ensure that the identity of each entity accredited under this subsection, and the particular category for which the entity is accredited, is known to the public. The

lists shall be updated not later than 30 days after the date on which—

"(I) an entity is accredited under this subsection;

"(II) the accreditation of an entity under this subsection is suspended or withdrawn; or

"(III) the particular category for which an entity is accredited under this subsection is modified.

"(B) AUDITS; WITHDRAWAL; DEBARMENT.—

"(i) IN GENERAL.—To ensure that entities accredited under this subsection continue to meet the standards of accreditation, the Secretary shall—

"(I) audit the performance of such entities on a periodic basis through the review of inspection reports and inspections by the Secretary to evaluate the compliance status of a domestic facility or foreign facility and the performance of entities accredited under this subsection; and

"(II) take such additional measures as the Secretary determines to be appropriate.

"(ii) WITHDRAWAL.—

"(I) IN GENERAL.—The Secretary may withdraw accreditation of an entity accredited under this subsection, after providing notice and an opportunity for an informal hearing, if—

"(aa) such entity is substantially not in compliance with the standards of accreditation;

"(bb) such entity poses a threat to public health;

"(cc) such entity fails to act in a manner that is consistent with the purposes of this subsection; or

"(dd) the Secretary determines that there is a financial conflict of interest in the relationship between such entity and the owner or operator of a domestic facility or foreign facility

that the entity has inspected under this subsection.

''(II) SUSPENSION.—The Secretary may suspend accreditation of an entity during the pendency of the process under subclause (I).

''(iii) DEBARMENT.—If the Secretary determines that an entity accredited under this subsection has violated section 301(y), the Secretary—

''(I) shall withdraw such entity's accreditation under this subsection; and

''(II) may permanently debar a responsible person for such entity from being accredited and from carrying out inspection activities under this subsection.

''(6) FEES.—An entity accredited under this subsection may charge a domestic facility or foreign facility reasonable fees for inspection services.

''(7) SYMBOL INDICATING INSPECTION BY AN ACCREDITED ENTITY.—The Secretary may by regulation establish one or more tamper-resistant symbols indicating that an article of food was produced

in a domestic or foreign facility that passed an accredited third party inspection. Such a symbol may be affixed on the packaging of such an article.

''(8) ELECTRONIC IMPORT CERTIFICATES.—If the standards, processes, and criteria to certify articles of food used by a foreign regulatory authority of an exporting country or an entity accredited under this subsection are sufficient to ensure compliance with this Act, the Secretary shall enter into agreements with such regulatory authority or such accredited entity to electronically certify each food shipment or class of shipments of designated food for compliance with this Act prior to shipment. Such agreements shall include provision of electronic certificates from such regulatory authority or such accredited entity to accompany each shipment. The Secretary shall provide criteria for such certificates to ensure a secure system that prevents counterfeiting of the certificates and takes into consideration possible transshipment of products as a way to avoid certification.

''(9) CONSIDERATION.—Notwithstanding any other provision of law, the Secretary shall consider inspections performed by accredited entities under this subsection, as well as other private food safety

contracts, when determining the overall inspection schedule of the Food and Drug Administration in order to focus on higher-risk facilities.''.

(b) PROHIBITED ACTS.—Section 301(y) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(y)) is amended—

(1) in paragraph (1), by inserting ''or an entity accredited under section 704(h)'' after ''523'';

(2) in paragraph (2)—

(A) by inserting ''or an entity accredited under section 704(h)'' after ''523''; and

(B) by inserting ''or entity'' after ''such person''; and

(3) in paragraph (3)—

(A) by inserting ''or an entity accredited under section 704(h)'' after ''523'';

(B) by inserting ''or entity'' after ''by such person''; and

(C) by inserting ''or entity'' after ''to such person''.

SEC. 10. ENTRY OF FOOD FROM FACILITIES INSPECTED BY AN ACCREDITED THIRD PARTY.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

''(p) ENTRY OF FOOD FROM FACILITIES INSPECTED BY AN ACCREDITED THIRD PARTY.—If an article of food is being imported or offered for import at a port of entry into the United States and such article of food is from a foreign facility at which an inspection by an entity accredited under section 704(h) was completed prior to the production of such article of food at such facility and—

''(1) the results of the inspection were no official action indicated, the Commissioner of Food and Drugs agrees with the results of the inspection, and such facility has a certificate described under section 704(h)(8), then the article of food shall be presumed to be admissible into the United States and shall not be detained or refused admission but shall receive permission for expedited entry into the United States;

''(2) the results of the inspection were voluntary action indicated and the Commissioner of Food and Drugs agrees with the results of the inspection, then the article of food shall be subject to increased random inspection at the border; or

''(3) the results of the inspection were official action indicated and the Commissioner of Food and Drugs agrees with the results of the inspection, then the article of food shall—

''(A) be—

''(i) held at the port of entry for the article without physical examination and refused admission if the inspection failure was due to a condition presenting a reasonable probability that the use of or exposure to the article of food will cause serious adverse health consequences or death; or

''(ii) placed on import alert if the inspection failure was due to a condition in which use of or exposure to the article of food may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote; and

''(B) be subject to other actions as provided under this Act.''.

SEC. 11. ACTIVITIES WITH OTHER GOVERNMENTS.

(a) MEETINGS AND AGREEMENTS.—

(1) IN GENERAL.—In carrying out the functions of the Office of International Programs of the Food and Drug Administration, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'')—

(A) shall regularly participate in meetings with representatives of foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements; and

(B) may enter into an agreement with a foreign entity to facilitate commerce in food between the United States and such entity—

(i) consistent with the requirements of this Act and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(ii) in which the Secretary shall encourage the mutual development and recognition of—

(I) good manufacturing practice regulations; and

(II) other regulations and testing protocols as the Secretary determines to be appropriate.

(2) JOINT INSPECTION.—An agreement entered into pursuant to paragraph (1)(B) may include joint inspection missions where an inspection team is composed of individuals from regulatory authorities of both countries.

(b) REDUCTION OF REGULATION BURDEN AND HARMONIZATION OF FOOD REGULATORY REQUIREMENTS.—The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of foreign governments to discuss methods and approaches to reduce the burden of regulation and harmonize food regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 12. COMPLIANCE WITH INTERNATIONAL AGREEMENTS.

Nothing in this Act (or an amendment made by this Act) shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.