

TITLE III--PROTECTING SAFETY AND SECURITY OF FOOD AND DRUG SUPPLY

Subtitle A--Protection of Food Supply

SEC. 301. <<NOTE: 21 USC 341 note.>> FOOD SAFETY AND SECURITY STRATEGY.

**Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188)**

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Subtitle A--Protection of Food Supply

SEC. 301. <<NOTE: 21 USC 341 note.>> FOOD SAFETY AND SECURITY STRATEGY.

(a) In General.--The President's Council on Food Safety (as established by Executive Order No. 13100) shall, in consultation with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. Such strategy shall address threat assessments; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

(b) Authorization of Appropriations.--For the purpose of implementing the strategy developed under subsection (a), there are authorized to be appropriated \$750,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 302. PROTECTION AGAINST ADULTERATION OF FOOD.

(a) Increasing Inspections for Detection of Adulteration of Food.--Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following subsection:

“(h)(1) The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.”.

(b) Improvements to Information Management Systems.--Section 801(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)

of this section, is amended by adding at the end the following paragraph:

“(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this Act.”.

(c) Linkages With Appropriate Public Entities.--Section 801(h) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b) of this section, is amended by adding at the end the following paragraph:

“(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages with the States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))).”.

(d) Testing for Rapid Detection of Adulteration of Food.--Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a) of this section, is amended by adding at the end the following:

“(i)(1) For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies--

“(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

“(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

“(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

“(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

“(4) <<NOTE: Reports.>> The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).”.

(e) <<NOTE: Deadline.>> Assessment of Threat of Intentional Adulteration of Food.--The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall ensure that, not later than six months after the date of the enactment of this Act--

(1) the assessment that (as of such date of enactment) is being conducted on the threat of the intentional adulteration of food is completed; and

(2) <<NOTE: Reports.>> a report describing the findings of the assessment is submitted to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Health, Education, Labor, and Pensions of the Senate.

(f) Authorization of Appropriations.--For the purpose of carrying out this section and the amendments made by this section, there are authorized to be appropriated \$100,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006, in addition to other authorizations of appropriations that are available for such purpose.

### SEC. 303. ADMINISTRATIVE DETENTION.

(a) Expanded Authority.--Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended by adding at the end the following subsection:

``(h) Administrative Detention of Foods.--

``(1) Detention authority.--

``(A) In general.--An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

``(B) Secretary's approval.--An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

``(2) Period of detention.--An article of food may be detained under paragraph (1) for a reasonable period, not to

exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302. <<NOTE: Regulation.>> The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

((3) Security of detained article.--An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 801(b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

((4) Appeal of detention order.--

((A) In general.--With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

((B) Effect of instituting court action.--The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 302 regarding the article of food involved."

(b) Prohibited Act.--Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

“(bb) The transfer of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order to identify the article as detained.”.

(c) Temporary Holds at Ports of Entry.--Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 302(d) of this Act, <<NOTE: 21 USC 381.>> is amended by adding at the end the following:

“(j)(1) If an officer or qualified employee of the Food and Drug Administration has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and such officer or qualified employee is unable to inspect, examine, or investigate such article upon the article being offered for import at a port of entry into the United States, the officer or qualified employee shall request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate.

“(2) The Secretary shall request the Secretary of Treasury to remove an article held pursuant to paragraph (1) to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held.

“(3) An officer or qualified employee of the Food and Drug Administration may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

“(4) With respect to an article of food for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located that the request has been made, and as applicable, that such article is being held under this subsection.”.

#### SEC. 304. DEBARMENT FOR REPEATED OR SERIOUS FOOD IMPORT VIOLATIONS.

(a) Debarment Authority.--

(1) Permissive debarment.--Section 306(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)(1)) is amended--

(A) in subparagraph (A), by striking “or” after the comma at the end;

(B) in subparagraph (B), by striking the period at the end and inserting `` , or"; and

(C) by adding at the end the following subparagraph:

``(C) a person from importing an article of food or offering such an article for import into the United States.".

(2) Amendment regarding debarment grounds.--Section 306(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is amended--

(A) in paragraph (2), in the matter preceding subparagraph (A), by inserting ``subparagraph (A) or (B) of" before ``paragraph (1)";

(B) by redesignating paragraph (3) as paragraph (4); and

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

``(3) Persons subject to permissive debarment; food importation.--A person is subject to debarment under paragraph (1)(C) if--

``(A) the person has been convicted of a felony for conduct relating to the importation into the United States of any food; or

``(B) the person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.".

(b) Conforming Amendments.--Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is amended--

(1) in subsection (a), in the heading for the subsection, by striking ``Mandatory Debarment.--" and inserting ``Mandatory Debarment; Certain Drug Applications.--";

(2) in subsection (b)--

(A) in the heading for the subsection, by striking ``Permissive Debarment.--" and inserting ``Permissive Debarment; Certain Drug Applications; Food Imports.--"; and

(B) in paragraph (2), in the heading for the paragraph, by striking ``permissive debarment.--" and inserting ``permissive debarment; certain drug applications.--";

(3) in subsection (c)(2)(A)(iii), by striking ``subsection (b)(2)" and inserting ``paragraph (2) or (3) of subsection (b)";

(4) in subsection (d)(3)--

(A) in subparagraph (A)(i), by striking ``or

(b)(2)(A)" and inserting `` or paragraph (2)(A) or (3) of subsection (b)";

(B) in subparagraph (A)(ii)(II), by inserting ``in applicable cases," before ``sufficient audits";

(C) in subparagraph (B), in each of clauses (i) and (ii), by inserting ``or subsection (b)(3)" after ``subsection (b)(2)(B)"; and

(D) in subparagraph (B)(ii), by inserting before the period the following: ``or the food importation process, as the case may be".

(c) Effective Dates.--Section 306(l)(2) of the Federal Food, Drug, and Cosmetic Act <<NOTE: 21 USC 335a.>> (21 U.S.C. 335a(l)(2)) is amended--

(1) in the first sentence--

(A) by striking ``and" after ``subsection (b)(2),"; and

(B) by inserting ``, and subsection (b)(3)(A)" after ``subsection (b)(2)(B)"; and

(2) in the second sentence, by inserting ``, subsection (b)(3)(B)," after ``subsection (b)(2)(B)".

(d) Prohibited Act.--Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 303(b) of this Act, is amended by adding at the end the following:

``(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 306(b)(3)."

(e) Importation by Debarred Persons.--Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 303(c) of this Act, <<NOTE: 21 USC 381.>> is amended by adding at the end the following subsection:

``(k)(1) If an article of food is being imported or offered for import into the United States, and the importer, owner, or consignee of the article is a person who has been debarred under section 306(b)(3), such article shall be held at the port of entry for the article, and may not be delivered to such person. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

``(2) An article of food held under paragraph (1) may be delivered to a person who is not a debarred person under section 306(b)(3) if such

person affirmatively establishes, at the expense of the person, that the article complies with the requirements of this Act, as determined by the Secretary."

## SEC. 305. REGISTRATION OF FOOD FACILITIES.

(a) In General.--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. 415. <<NOTE: 21 USC 350d.>> REGISTRATION OF FOOD FACILITIES.

#### (a) Registration.--

(1) <<NOTE: Regulations.>> In general.--The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. To be registered--

(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and

(B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.

(2) Registration.--An entity (referred to in this section as the `registrant') shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business and, when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, packed, or held at such facility. <<NOTE: Notification.>> The registrant shall notify the Secretary in a timely manner of changes to such information.

(3) <<NOTE: Notification.>> Procedure.--Upon receipt of a completed registration described in paragraph (1), the Secretary shall notify the registrant of the receipt of such registration and assign a registration number to each registered facility.

(4) <<NOTE: Records.>> List.--The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section. Such list and any registration documents submitted pursuant to this subsection shall not be subject to disclosure under

section 552 of title 5, United States Code. Information derived from such list or registration documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that it discloses the identity or location of a specific registered person.

“(b) Facility.--For purposes of this section:

“(1) The term ‘facility’ includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).

“(2) The term ‘domestic facility’ means a facility located in any of the States or Territories.

“(3)(A) The term ‘foreign facility’ means a facility that manufactures, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States.

“(B) A food may not be considered to have undergone further processing or packaging for purposes of subparagraph (A) solely on the basis that labeling was added or that any similar activity of a de minimis nature was carried out with respect to the food.

“(c) Rule of Construction.--Nothing in this section shall be construed to authorize the Secretary to require an application, review, or licensing process.”.

(b) Prohibited Acts.--Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 304(d) of this Act, is amended by adding at the end the following:

“(dd) The failure to register in accordance with section 415.”.

(c) Importation; Failure to Register.--Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 304(e) of this Act, <<NOTE: 21 USC 381.>> is amended by adding at the end the following subsection:

“(l)(1) If an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 415, such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so

registered. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be."

(d) <<NOTE: 21 USC 350d note.>> Electronic Filing.--For the purpose of reducing paperwork and reporting burdens, the Secretary of Health and Human Services may provide for, and encourage the use of, electronic methods of submitting to the Secretary registrations required pursuant to this section. In providing for the electronic submission of such registrations, the Secretary shall ensure adequate authentication protocols are used to enable identification of the registrant and validation of the data as appropriate.

(e) <<NOTE: Deadline.>> Rulemaking; Effective Date.--Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed and final regulations for the requirement of registration under section 415 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section). Such requirement of registration takes effect--

- (1) upon the effective date of such final regulations; or
- (2) upon the expiration of such 18-month period if the final regulations have not been made effective as of the expiration of such period, subject to compliance with the final regulations when the final regulations are made effective.

## SEC. 306. MAINTENANCE AND INSPECTION OF RECORDS FOR FOODS.

(a) In General.--Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by section 305 of this Act, is amended by inserting before section 415 the following section:

### ``SEC. 414. <<NOTE: 21 USC 350c.>> MAINTENANCE AND INSPECTION OF RECORDS.

``(a) Records Inspection.--If the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to

and copy all records relating to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. <<NOTE: Applicability.>> The requirement under the preceding sentence applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.

“(b) Regulations Concerning Recordkeeping.--The Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Secretary shall take into account the size of a business in promulgating regulations under this section.

“(c) Protection of Sensitive Information.--The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.

“(d) Limitations.--This section shall not be construed--

“(1) to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of this Act;

“(2) to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);

“(3) to have any legal effect on section 552 of title 5, United States Code, or section 1905 of title 18, United States Code; or

“(4) to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).”.

(b) Factory Inspection.--Section 704(a) of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 374(a)) is amended--

(1) in paragraph (1), by inserting after the first sentence the following new sentence: ``In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d)."; and

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking ``second sentence" and inserting ``third sentence".

(c) Prohibited Act.--Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended--

(1) in paragraph (e)--

(A) by striking ``by section 412, 504, or 703" and inserting ``by section 412, 414, 504, 703, or 704(a)"; and

(B) by striking ``under section 412" and inserting ``under section 412, 414(b)"; and

(2) in paragraph (j), by inserting ``414," after ``412,".

(d) <<NOTE: Deadline. 21 USC 350c note.>> Expedited Rulemaking.-- Not later than 18 months after the date of the enactment of this Act, the Secretary shall promulgate proposed and final regulations establishing recordkeeping requirements under subsection 414(b) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

## SEC. 307. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.

(a) In General.--Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 305(c) of this Act, is amended by adding at the end the following subsection:

``(m)(1) <<NOTE: Regulations.>> In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the

anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food.

“(2)(A) Regulations under paragraph (1) shall require that a notice under such paragraph be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration. Nothing in the preceding sentence may be construed as a limitation on the obligation of the Secretary to receive, review, and appropriately respond to any notice under paragraph (1).

“(B)(i) If an article of food is being imported or offered for import into the United States and a notice under paragraph (1) is not provided in advance in accordance with the requirements under paragraph (1), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such notice is submitted to the Secretary, and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1). Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

“(ii) In carrying out clause (i) with respect to an article of food, the Secretary shall determine whether there is in the possession of the Secretary any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

“(3)(A) This subsection may not be construed as limiting the authority of the Secretary to obtain information under any other provision of this Act.

“(B) This subsection may not be construed as authorizing the Secretary to impose any requirements with respect to a food to the

extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)."

(b) Prohibited Act.--Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 305(b) of this Act, <<NOTE: 21 USC 331.>> is amended by adding at the end the following:

``(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m)."

(c) <<NOTE: 21 USC 351 note.>> Rulemaking; Effective Date.--

(1) <<NOTE: Deadline.>> In general.--Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed and final regulations for the requirement of providing notice in accordance with section 801(m) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section). Such requirement of notification takes effect--

(A) upon the effective date of such final regulations; or

(B) upon the expiration of such 18-month period if the final regulations have not been made effective as of the expiration of such period, subject to compliance with the final regulations when the final regulations are made effective.

(2) Default; minimum period of advance notice.--If under paragraph (1) the requirement for providing notice in accordance with section 801(m) of the Federal Food, Drug, and Cosmetic Act takes effect without final regulations having been made effective, then for purposes of such requirement, the specified period of time that the notice is required to be made in advance of the time of the importation of the article of food involved or the offering of the food for import shall be not fewer than eight hours and not more than five days, which shall remain in effect until the final regulations are made effective.

## SEC. 308. AUTHORITY TO MARK ARTICLES REFUSED ADMISSION INTO UNITED STATES.

(a) In General.--Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended by section 307(a) of this Act, is amended by adding at the end the following:

``(n)(1) If a food has been refused admission under subsection (a), other than such a food that is required to be destroyed, the Secretary

may require the owner or consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: 'UNITED STATES: REFUSED ENTRY'.

“(2) All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.

“(3) A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with this Act.”.

(b) Misbranded Foods.--Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

“(v) If--

“(1) it fails to bear a label required by the Secretary under section 801(n)(1) (relating to food refused admission into the United States);

“(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

“(3) upon or after notifying the owner or consignee involved that the label is required under section 801, the Secretary informs the owner or consignee that the food presents such a threat.”.

(c) <<NOTE: 21 USC 381 note.>> Rule of Construction.--With respect to articles of food that are imported or offered for import into the United States, nothing in this section shall be construed to limit the authority of the Secretary of Health and Human Services or the Secretary of the Treasury to require the marking of refused articles of food under any other provision of law.

#### SEC. 309. PROHIBITION AGAINST PORT SHOPPING.

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

“(h) If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 801(a), unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this Act, as determined by the Secretary.”.

#### SEC. 310. NOTICES TO STATES REGARDING IMPORTED FOOD.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

391 et seq.) is amended by adding at the end the following section:

``SEC. 908. <<NOTE: 21 USC 398.>> NOTICES TO STATES REGARDING IMPORTED FOOD.

``(a) In General.--If the Secretary has credible evidence or information indicating that a shipment of imported food or portion thereof presents a threat of serious adverse health consequences or death to humans or animals, the Secretary shall provide notice regarding such threat to the States in which the food is held or will be held, and to the States in which the manufacturer, packer, or distributor of the food is located, to the extent that the Secretary has knowledge of which States are so involved. In providing notice to a State, the Secretary shall request the State to take such action as the State considers appropriate, if any, to protect the public health regarding the food involved.

``(b) Rule of Construction.--Subsection (a) may not be construed as limiting the authority of the Secretary with respect to food under any other provision of this Act."

SEC. 311. GRANTS TO STATES FOR INSPECTIONS.

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as amended by section 310 of this Act, is amended by adding at the end the following section:

``SEC. 909. <<NOTE: 21 USC 399.>> GRANTS TO STATES FOR INSPECTIONS.

``(a) In General.--The Secretary is authorized to make grants to States, territories, and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) that undertake examinations, inspections, and investigations, and related activities under section 702. The funds provided under such grants shall only be available for the costs of conducting such examinations, inspections, investigations, and related activities.

``(b) Notices Regarding Adulterated Imported Food.--The Secretary may make grants to the States for the purpose of assisting the States with the costs of taking appropriate action to protect the public health in response to notification under section 908, including planning and otherwise preparing to take such action.

``(c) Authorization of Appropriations.--For the purpose of carrying out this section, there are authorized to be appropriated \$10,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006."

SEC. 312. SURVEILLANCE AND INFORMATION GRANTS AND AUTHORITIES.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317P the following:

``SEC. 317R. <<NOTE: 42 USC 247b-20.>> FOOD SAFETY GRANTS.

``(a) In General.--The Secretary may award grants to States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) to expand participation in networks to enhance Federal, State, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

``(b) Authorization of Appropriations.--For the purpose of carrying out this section, there are authorized to be appropriated \$19,500,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2006."

SEC. 313. <<NOTE: 7 USC 8319.>> SURVEILLANCE OF ZOOONOTIC DISEASES.

The Secretary of Health and Human Services, through the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, and the Secretary of Agriculture shall coordinate the surveillance of zoonotic diseases.

SEC. 314. AUTHORITY TO COMMISSION OTHER FEDERAL OFFICIALS TO CONDUCT INSPECTIONS.

Section 702(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372(a)) is amended--

(1) by striking ``(a)" and inserting ``(a)(1)";

(2) by striking ``In the case of food packed" and inserting the following:

``(3) In the case of food packed";

(3) by striking ``For the purposes of this subsection" and inserting the following:

``(4) For the purposes of this subsection,"; and

(4) by inserting after paragraph (1) (as designated by paragraph (1) of this section) the following paragraph:

``(2)(A) In addition to the authority established in paragraph (1),

the Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal department or agency, is authorized to conduct examinations and investigations for the purposes of this Act through the officers and employees of such other department or agency, subject to subparagraph (B). Such a memorandum shall include provisions to ensure adequate training of such officers and employees to conduct the examinations and investigations. The memorandum of understanding shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this section by the officers or employees of the other department or agency.

“(B) A memorandum of understanding under subparagraph (A) between the Secretary and another Federal department or agency is effective only in the case of examinations or inspections at facilities or other locations that are jointly regulated by the Secretary and such department or agency.

“(C) <<NOTE: Reports.>> For any fiscal year in which the Secretary and the head of another Federal department or agency carries out one or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the head of such department or agency shall with respect to their respective departments or agencies submit to the committees of jurisdiction (authorizing and appropriating) in the House of Representatives and the Senate a report that provides, for such year--

“(i) the number of officers or employees that carried out one or more programs, projects, or activities under such memorandum;

“(ii) the number of additional articles that were inspected or examined as a result of such memorandum; and

“(iii) the number of additional examinations or investigations that were carried out pursuant to such memorandum.”.

SEC. 315. <<NOTE: 21 USC 331 note.>> RULE OF CONSTRUCTION.

Nothing in this title, or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations.

Subtitle B--Protection of Drug Supply

SEC. 321. ANNUAL REGISTRATION OF FOREIGN MANUFACTURERS;  
SHIPPING

INFORMATION; DRUG AND DEVICE LISTING.

(a) Annual Registration; Listing.--Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended--

(1) in subsection (i)(1)--

(A) by striking "Any establishment" and inserting "On or before December 31 of each year, any establishment"; and

(B) by striking "shall register" and all that follows and inserting the following: "shall, through electronic means in accordance with the criteria of the Secretary, register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such drug or device in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug or device to the United States for purposes of importation."; and

(2) in subsection (j)(1), in the first sentence, by striking "or (d)" and inserting "(d), or (i)".

(b) Importation; Statement Regarding Registration of Manufacturer.--

(1) In general.--Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 308(a) of this Act, is amended by adding at the end the following subsection:

"(o) If an article that is a drug or device is being imported or offered for import into the United States, and the importer, owner, or consignee of such article does not, at the time of offering the article for import, submit to the Secretary a statement that identifies the registration under section 510(i) of each establishment that with respect to such article is required under such section to register with the Secretary, the article may be refused admission. If the article is refused admission for failure to submit such a statement, the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such a statement is submitted to the Secretary. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be."

(2) Prohibited act.--Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended by section 307(b) of this Act, is

amended by adding at the end the following:

“(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o).”.

(c) <<NOTE: 21 USC 331 note.>> Effective Date.--The amendments made by this section take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act.

## SEC. 322. REQUIREMENT OF ADDITIONAL INFORMATION REGARDING IMPORT

### COMPONENTS INTENDED FOR USE IN EXPORT PRODUCTS.

(a) In General.--Section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)(3)) is amended to read as follows:

“(3)(A) Subject to subparagraph (B), no component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) if each of the following conditions is met:

“(i) The importer of such article of a drug or device or importer of such article of a food additive, color additive, or dietary supplement submits to the Secretary, at the time of initial importation, a statement in accordance with the following:

“(I) Such statement provides that such article is intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

“(II) The statement identifies the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to such importer of the article.

“(III) The statement is accompanied by such certificates of analysis as are necessary to identify such article, unless the article is a device or is an

article described in paragraph (4).

((ii) At the time of initial importation and before the delivery of such article to the importer or the initial owner or consignee, such owner or consignee executes a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

((iii) Such article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

((iv) <<NOTE: Records.>> The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary.

((v) <<NOTE: Reports.>> Upon request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of such article or portions thereof, and the manner in which such owner or consignee complied with the requirements of this subparagraph.

((B) Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under such subparagraph if the Secretary determines that there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

((C) This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under authority of subparagraph (A) meet each of the conditions established in such subparagraph for importation."

(b) Prohibited Act.--Section 301(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(w)) is amended to read as follows:

((w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802, or with section 351(h) of the

Public Health Service Act; or the failure to so export or to destroy such an article or portions thereof, or such a finished product."

(c) <<NOTE: 21 USC 331 note.>> Effective Date.--The amendments made by this section take effect upon the expiration of the 90-day period beginning on the date of the enactment of this Act.

Subtitle C--General Provisions Relating to Upgrade of Agricultural Security

SEC. 331. <<NOTE: 7 USC 8320.>> EXPANSION OF ANIMAL AND PLANT HEALTH

INSPECTION SERVICE ACTIVITIES.

(a) In General.--The Secretary of Agriculture (referred to in this section as the "Secretary") may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Animal and Plant Health Inspection Service to conduct activities to--

- (1) increase the inspection capacity of the Service at international points of origin;
- (2) improve surveillance at ports of entry and customs;
- (3) enhance methods of protecting against the introduction of plant and animal disease organisms by terrorists;
- (4) develop new and improve existing strategies and technologies for dealing with intentional outbreaks of plant and animal disease arising from acts of terrorism or from unintentional introduction, including--

(A) establishing cooperative agreements among Veterinary Services of the Animal and Plant Health Inspection Service, State animal health commissions and regulatory agencies for livestock and poultry health, and private veterinary practitioners to enhance the preparedness and ability of Veterinary Services and the commissions and agencies to respond to outbreaks of such animal diseases; and

(B) strengthening planning and coordination with State and local agencies, including--

- (i) State animal health commissions and regulatory agencies for livestock and poultry health; and
  - (ii) State agriculture departments; and
- (5) otherwise improve the capacity of the Service to protect against the threat of bioterrorism.

(b) Automated Recordkeeping System.--The Administrator of the Animal and Plant Health Inspection Service may implement a central automated recordkeeping system to provide for the reliable tracking of the status

of animal and plant shipments, including those shipments on hold at ports of entry and customs. The Secretary shall ensure that such a system shall be fully accessible to or fully integrated with the Food Safety Inspection Service.

(c) Authorization of Appropriations.--There is authorized to be appropriated to carry out this section, \$30,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 332. <<NOTE: 21 USC 679c.>> EXPANSION OF FOOD SAFETY INSPECTION SERVICE ACTIVITIES.

(a) In General.--The Secretary of Agriculture may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Food Safety Inspection Service to conduct activities to--

(1) enhance the ability of the Service to inspect and ensure the safety and wholesomeness of meat and poultry products;

(2) improve the capacity of the Service to inspect international meat and meat products, poultry and poultry products, and egg products at points of origin and at ports of entry;

(3) strengthen the ability of the Service to collaborate with relevant agencies within the Department of Agriculture and with other entities in the Federal Government, the States, and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) through the sharing of information and technology; and

(4) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

(b) Authorization of Appropriations.--There is authorized to be appropriated to carry out this section, \$15,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 333. <<NOTE: Appropriation authorization. State listing.>> BIOSECURITY UPGRADES AT THE DEPARTMENT OF AGRICULTURE.

There is authorized to be appropriated for fiscal year 2002, \$180,000,000 for the purpose of enabling the Agricultural Research Service to conduct building upgrades to modernize existing facilities, of which (1) \$100,000,000 shall be allocated for renovation, updating, and expansion of the Biosafety Level 3 laboratory and animal research facilities at the Plum Island Animal Disease Center (Greenport, New York), and of which (2) \$80,000,000 shall be allocated for the Agricultural Research Service/Animal and Plant Health Inspection Service

facility in Ames, Iowa. There are authorized to be appropriated such sums as may be necessary for fiscal years 2003 through 2006 for the purpose described in the preceding sentence, for the planning and design of an Agricultural Research Service biocontainment laboratory for poultry research in Athens, Georgia, and for the planning, updating, and renovation of the Arthropod-Borne Animal Disease Laboratory in Laramie, Wyoming.

SEC. 334. <<NOTE: 7 USC 3353.>> AGRICULTURAL BIOSECURITY.

(a) Security at Colleges and Universities.--

(1) Grants.--The Secretary of Agriculture (referred to in this section as the "Secretary") may award grants to covered entities to review security standards and practices at their facilities in order to protect against bioterrorist attacks.

(2) Covered entities.--Covered entities under this subsection are colleges or universities that--

(A) are colleges or universities as defined in section 1404 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3103); and

(B) have programs in food and agricultural sciences, as defined in such section.

(3) Limitation.--Each individual covered entity may be awarded one grant under paragraph (1), the amount of which shall not exceed \$50,000.

(4) Contract authority.--Colleges and universities receiving grants under paragraph (1) may use such grants to enter into contracts with independent private organizations with established and demonstrated security expertise to conduct the security reviews specified in such paragraph.

(b) Guidelines for Agricultural Biosecurity.--

(1) In general.--The Secretary may award grants to associations of food producers or consortia of such associations for the development and implementation of educational programs to improve biosecurity on farms in order to ensure the security of farm facilities against potential bioterrorist attacks.

(2) Limitation.--Each individual association eligible under paragraph (1) may be awarded one grant under such paragraph, the amount of which shall not exceed \$100,000. Each consortium eligible under paragraph (1) may be awarded one grant under such paragraph, the amount of which shall not exceed \$100,000 per association participating in the consortium.

(3) Contract authority.--Associations of food producers receiving grants under paragraph (1) may use such grants to

enter into contracts with independent private organizations with established and demonstrated expertise in biosecurity to assist in the development and implementation of educational programs to improve biosecurity specified in such paragraph.

(c) Authorization of Appropriations.--There are authorized to be appropriated to carry out this section such sums as may be necessary for each fiscal year.

SEC. 335. <<NOTE: 7 USC 3354.>> AGRICULTURAL BIOTERRORISM RESEARCH AND DEVELOPMENT.

(a) In General.--The Secretary of Agriculture (referred to in this section as the "Secretary") may utilize existing research authorities and research programs to protect the food supply of the United States by conducting and supporting research activities to--

(1) enhance the capability of the Secretary to respond in a timely manner to emerging or existing bioterrorist threats to the food and agricultural system of the United States;

(2) develop new and continue partnerships with institutions of higher education and other institutions to help form stable, long-term programs to enhance the biosecurity and food safety of the United States, including the coordination of the development, implementation, and enhancement of diverse capabilities for addressing threats to the nation's agricultural economy and food supply, with special emphasis on planning, training, outreach, and research activities related to vulnerability analyses, incident response, detection, and prevention technologies;

(3) strengthen coordination with the intelligence community to better identify research needs and evaluate materials or information acquired by the intelligence community relating to potential threats to United States agriculture;

(4) expand the involvement of the Secretary with international organizations dealing with plant and animal disease control;

(5) continue research to develop rapid detection field test kits to detect biological threats to plants and animals and to provide such test kits to State and local agencies preparing for or responding to bioterrorism;

(6) develop an agricultural bioterrorism early warning surveillance system through enhancing the capacity of and coordination between State veterinary diagnostic laboratories, Federal and State agricultural research facilities, and public health agencies; and

(7) otherwise improve the capacity of the Secretary to protect against the threat of bioterrorism.

(b) Authorization of Appropriations.--There is authorized to be appropriated to carry out this section, \$190,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

#### SEC. 336. ANIMAL ENTERPRISE TERRORISM PENALTIES.

(a) In General.--Section 43(a) of title 18, United States Code, is amended to read as follows:

``(a) Offense.--Whoever--

``(1) travels in interstate or foreign commerce, or uses or causes to be used the mail or any facility in interstate or foreign commerce for the purpose of causing physical disruption to the functioning of an animal enterprise; and

``(2) intentionally damages or causes the loss of any property (including animals or records) used by the animal enterprise, or conspires to do so,

shall be punished as provided for in subsection (b)."

(b) Penalties.--Section 43(b) of title 18, United States Code, is amended to read as follows:

``(b) Penalties.--

``(1) Economic damage.--Any person who, in the course of a violation of subsection (a), causes economic damage not exceeding \$10,000 to an animal enterprise shall be fined under this title or imprisoned not more than 6 months, or both.

``(2) Major economic damage.--Any person who, in the course of a violation of subsection (a), causes economic damage exceeding \$10,000 to an animal enterprise shall be fined under this title or imprisoned not more than 3 years, or both.

``(3) Serious bodily injury.--Any person who, in the course of a violation of subsection (a), causes serious bodily injury to another individual shall be fined under this title or imprisoned not more than 20 years, or both.

``(4) Death.--Any person who, in the course of a violation of subsection (a), causes the death of an individual shall be fined under this title and imprisoned for life or for any term of years."

(c) Restitution.--Section 43(c) of title 18, United States Code, is amended--

(1) in paragraph (1), by striking ``and" at the end;

(2) in paragraph (2), by striking the period at the end and inserting ``; and"; and

(3) by adding at the end the following:  
“(3) for any other economic damage resulting from the offense.”.