under section 415(b)(5) of the Federal Food, Drug, and Cosmetic Act (as added by this section), the Secretary shall issue a small entity compliance policy guide setting forth in plain language the requirements of such regulations to assist small entities in complying with registration requirements and other activities required under such section.

(3) IMPORTED FOOD.—Section 801(l) (21 U.S.C. 381(l)) is amended by inserting "(or for which a registration has been suspended under such section)" after "section 415".

(c) CLARIFICATION OF INTENT.— 21 USC 350d note.

(1) RETAIL FOOD ESTABLISHMENT.—The Secretary shall amend the definition of the term "retail food establishment" in section in 1.227(b)(11) of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include—

(A) the sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed;

(B) the sale and distribution of such food through a community supported agriculture program; and

(C) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary.

(2) DEFINITIONS.—For purposes of paragraph (1)—

(A) the term "community supported agriculture program" has the same meaning given the term "community supported agriculture (CSA) program" in section 249.2 of title 7, Code of Federal Regulations (or any successor regulation); and

(B) the term "consumer" does not include a business.

(d) CONFORMING AMENDMENTS.—

(1) Section 301(d) (21 U.S.C. 331(d)) is amended by inserting "415," after "404,".

(2) Section 415(d), as redesignated by subsection (b), is amended by adding at the end before the period "for a facility to be registered, except with respect to the reinstatement of a registration that is suspended under subsection (b)". 21 USC 350d.

SEC. 103. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS. 21 USC 350g.

"(a) IN GENERAL.—The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

"(b) HAZARD ANALYSIS.—The owner, operator, or agent in charge of a facility shall—

"(1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—

"(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and

"(B) hazards that occur naturally, or may be unintentionally introduced; and

"(2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and

"(3) develop a written analysis of the hazards.

"(c) PREVENTIVE CONTROLS.—The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

"(1) hazards identified in the hazard analysis conducted under subsection (b)(1) will be significantly minimized or prevented;

"(2) any hazards identified in the hazard analysis conducted under subsection (b)(2) will be significantly minimized or prevented and addressed, consistent with section 420, as applicable; and

"(3) the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 or misbranded under section 403(w).

"(d) MONITORING OF EFFECTIVENESS.—The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (c) to provide assurances that the outcomes described in subsection (c) shall be achieved.

Procedures.

"(e) CORRECTIVE ACTIONS.—The owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under subsection (c) are not properly implemented or are found to be ineffective—

"(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;

"(2) all affected food is evaluated for safety; and

"(3) all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 or misbranded under section 403(w).

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

"(1) the preventive controls implemented under subsection (c) are adequate to control the hazards identified under subsection (b);

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

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

"(4) the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means; and

"(5) there is documented, periodic reanalysis of the plan under subsection (i) to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats.

"(g) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under subsection (c), instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under subsection (f)(4), instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions. Time period.

"(h) WRITTEN PLAN AND DOCUMENTATION.—The owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards under subsection (b) and identifying the preventive controls adopted under subsection (c) to address those hazards. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

"(i) REQUIREMENT TO REANALYZE.—The owner, operator, or agent in charge of a facility shall conduct a reanalysis under subsection (b) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. Such reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities at the facility is operative. Such owner, operator, or agent shall revise the written plan required under subsection (h) if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. The Secretary may require a reanalysis under this section to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment. Deadline.

"(j) EXEMPTION FOR SEAFOOD, JUICE, AND LOW-ACID CANNED FOOD FACILITIES SUBJECT TO HACCP.—

"(1) IN GENERAL.—This section shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, 1 of the following standards and regulations with respect to such facility:

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

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

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

"(2) APPLICABILITY.—The exemption under paragraph (1)(C) shall apply only with respect to microbiological hazards that are regulated under the standards for Thermally Processed

Low-Acid Foods Packaged in Hermetically Sealed Containers under part 113 of chapter 21, Code of Federal Regulations (or any successor regulations).

"(k) EXCEPTION FOR ACTIVITIES OF FACILITIES SUBJECT TO SECTION 419.—This section shall not apply to activities of a facility that are subject to section 419.

"(l) MODIFIED REQUIREMENTS FOR QUALIFIED FACILITIES.—

"(1) QUALIFIED FACILITIES.—

"(A) IN GENERAL.—A facility is a qualified facility for purposes of this subsection if the facility meets the conditions under subparagraph (B) or (C).

"(B) VERY SMALL BUSINESS.—A facility is a qualified facility under this subparagraph—

"(i) if the facility, including any subsidiary or affiliate of the facility, is, collectively, a very small business (as defined in the regulations promulgated under subsection (n)); and

"(ii) in the case where the facility is a subsidiary or affiliate of an entity, if such subsidiaries or affiliates, are, collectively, a very small business (as so defined).

Applicability.

"(C) LIMITED ANNUAL MONETARY VALUE OF SALES.—

"(i) IN GENERAL.—A facility is a qualified facility under this subparagraph if clause (ii) applies—

"(I) to the facility, including any subsidiary or affiliate of the facility, collectively; and

"(II) to the subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate.

"(ii) AVERAGE ANNUAL MONETARY VALUE.—This clause applies if—

"(I) during the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility (or the collective average annual monetary value of such food at any subsidiary or affiliate, as described in clause (i)) that is sold directly to qualified end-users during such period exceeded the average annual monetary value of the food manufactured, processed, packed, or held at such facility (or the collective average annual monetary value of such food at any subsidiary or affiliate, as so described) sold by such facility (or collectively by any such subsidiary or affiliate) to all other purchasers during such period; and

"(II) the average annual monetary value of all food sold by such facility (or the collective average annual monetary value of such food sold by any subsidiary or affiliate, as described in clause (i)) during such period was less than $500,000, adjusted for inflation.

"(2) EXEMPTION.—A qualified facility—

"(A) shall not be subject to the requirements under subsections (a) through (i) and subsection (n) in an applicable calendar year; and

"(B) shall submit to the Secretary—

"(i)(I) documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective; or

"(II) documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law; and

"(ii) documentation, as specified by the Secretary in a guidance document issued not later than 1 year after the date of enactment of this section, that the facility is a qualified facility under paragraph (1)(B) or (1)(C). Deadline.

"(3) WITHDRAWAL; RULE OF CONSTRUCTION.—

"(A) IN GENERAL.—In the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under this subsection, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility, the Secretary may withdraw the exemption provided to such facility under this subsection.

"(B) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to expand or limit the inspection authority of the Secretary.

"(4) DEFINITIONS.—In this subsection:

"(A) AFFILIATE.—The term 'affiliate' means any facility that controls, is controlled by, or is under common control with another facility.

"(B) QUALIFIED END-USER.—The term 'qualified end-user', with respect to a food, means—

"(i) the consumer of the food; or

"(ii) a restaurant or retail food establishment (as those terms are defined by the Secretary for purposes of section 415) that—

"(I) is located—

"(aa) in the same State as the qualified facility that sold the food to such restaurant or establishment; or

"(bb) not more than 275 miles from such facility; and

"(II) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

"(C) CONSUMER.—For purposes of subparagraph (B), the term 'consumer' does not include a business.

"(D) SUBSIDIARY.—The term 'subsidiary' means any company which is owned or controlled directly or indirectly by another company.

"(5) STUDY.—

"(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Agriculture, shall conduct a study of the food processing sector regulated by the Secretary to determine—

"(i) the distribution of food production by type and size of operation, including monetary value of food sold;

"(ii) the proportion of food produced by each type and size of operation;

"(iii) the number and types of food facilities co-located on farms, including the number and proportion by commodity and by manufacturing or processing activity;

"(iv) the incidence of foodborne illness originating from each size and type of operation and the type of food facilities for which no reported or known hazard exists; and

"(v) the effect on foodborne illness risk associated with commingling, processing, transporting, and storing food and raw agricultural commodities, including differences in risk based on the scale and duration of such activities.

"(B) SIZE.—The results of the study conducted under subparagraph (A) shall include the information necessary to enable the Secretary to define the terms 'small business' and 'very small business', for purposes of promulgating the regulation under subsection (n). In defining such terms, the Secretary shall include consideration of harvestable acres, income, the number of employees, and the volume of food harvested.

"(C) SUBMISSION OF REPORT.—Not later than 18 months after the date of enactment the FDA Food Safety Modernization Act, the Secretary shall submit to Congress a report that describes the results of the study conducted under subparagraph (A).

"(6) NO PREEMPTION.—Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production of food. Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law.

"(7) NOTIFICATION TO CONSUMERS.—

"(A) IN GENERAL.—A qualified facility that is exempt from the requirements under subsections (a) through (i) and subsection (n) and does not prepare documentation under paragraph (2)(B)(i)(I) shall—

"(i) with respect to a food for which a food packaging label is required by the Secretary under any other provision of this Act, include prominently and conspicuously on such label the name and business address of the facility where the food was manufactured or processed; or

"(ii) with respect to a food for which a food packaging label is not required by the Secretary under any other provisions of this Act, prominently and conspicuously display, at the point of purchase, the name and business address of the facility where the

food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice.

"(B) NO ADDITIONAL LABEL.—Subparagraph (A) does not provide authority to the Secretary to require a label that is in addition to any label required under any other provision of this Act.

"(m) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—The Secretary may, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment.

"(n) REGULATIONS.—

"(1) IN GENERAL.—Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act, the Secretary shall promulgate regulations— Deadline.

"(A) to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under this section; and

"(B) to define, for purposes of this section, the terms 'small business' and 'very small business', taking into consideration the study described in subsection (l)(5).

"(2) COORDINATION.—In promulgating the regulations under paragraph (1)(A), with regard to hazards that may be intentionally introduced, including by acts of terrorism, the Secretary shall coordinate with the Secretary of Homeland Security, as appropriate.

"(3) CONTENT.—The regulations promulgated under paragraph (1)(A) shall—

"(A) provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm;

"(B) comply with chapter 35 of title 44, United States Code (commonly known as the 'Paperwork Reduction Act'), with special attention to minimizing the burden (as defined in section 3502(2) of such Act) on the facility, and collection of information (as defined in section 3502(3) of such Act), associated with such regulations;

"(C) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and

"(D) not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventative controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party.

"(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to provide the Secretary with the authority to prescribe specific technologies, practices, or critical controls for an individual facility.

"(5) REVIEW.—In promulgating the regulations under paragraph (1)(A), the Secretary shall review regulatory hazard analysis and preventive control programs in existence on the date of enactment of the FDA Food Safety Modernization Act, including the Grade 'A' Pasteurized Milk Ordinance to ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence on such date.

"(o) DEFINITIONS.—For purposes of 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 is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

"(2) FACILITY.—The term 'facility' means a domestic facility or a foreign facility that is required to register under section 415.

"(3) PREVENTIVE CONTROLS.—The term 'preventive controls' means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis conducted under subsection (b) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. Those procedures, practices, and processes may include the following:

"(A) Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment.

"(B) Supervisor, manager, and employee hygiene training.

"(C) An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.

"(D) A food allergen control program.

"(E) A recall plan.

"(F) Current Good Manufacturing Practices (cGMPs) under part 110 of title 21, Code of Federal Regulations (or any successor regulations).

"(G) Supplier verification activities that relate to the safety of food.".

21 USC 350g note.

(b) GUIDANCE DOCUMENT.—The Secretary shall issue a guidance document related to the regulations promulgated under subsection (b)(1) with respect to the hazard analysis and preventive controls under section 418 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

21 USC 350d note.

(c) RULEMAKING.—

(1) PROPOSED RULEMAKING.—

Deadline. Federal Register, publication. Notice.

(A) IN GENERAL.—Not later than 9 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall publish a notice of proposed rulemaking in the Federal Register to promulgate regulations with respect to—

(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed

on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act; and

(ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415.

(B) CLARIFICATION.—The rulemaking described under subparagraph (A) shall enhance the implementation of such section 415 and clarify the activities that are included as part of the definition of the term "facility" under such section 415. Nothing in this Act authorizes the Secretary to modify the definition of the term "facility" under such section.

(C) SCIENCE-BASED RISK ANALYSIS.—In promulgating regulations under subparagraph (A), the Secretary shall conduct a science-based risk analysis of—

(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and

(ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.

(D) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—

(i) IN GENERAL.—In promulgating the regulations under subparagraph (A), the Secretary shall consider the results of the science-based risk analysis conducted under subparagraph (C), and shall exempt certain facilities from the requirements in section 418 of the Federal Food, Drug, and Cosmetic Act (as added by this section), including hazard analysis and preventive controls, and the mandatory inspection frequency in section 421 of such Act (as added by section 201), or modify the requirements in such sections 418 or 421, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific foods the Secretary determines to be low risk.

Applicability.

(ii) LIMITATION.—The exemptions or modifications under clause (i) shall not include an exemption from the requirement to register under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act, if applicable, and shall apply only to small businesses and very small businesses, as defined in the regulation promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act (as added under subsection (a)).

(2) FINAL REGULATIONS.—Not later than 9 months after the close of the comment period for the proposed rulemaking under paragraph (1), the Secretary shall adopt final rules with respect to—

(A) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d), as amended by this Act;

(B) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of such section 415; and

(C) the requirements under sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act, as added by this Act, from which the Secretary may issue exemptions or modifications of the requirements for certain types of facilities.

Deadline.
21 USC 350g note.

(d) SMALL ENTITY COMPLIANCE POLICY GUIDE.—Not later than 180 days after the issuance of the regulations promulgated under subsection (n) of section 418 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)), the Secretary shall issue a small entity compliance policy guide setting forth in plain language the requirements of such section 418 and this section to assist small entities in complying with the hazard analysis and other activities required under such section 418 and this section.

(e) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418.".

21 USC 350g note.

(f) NO EFFECT ON HACCP AUTHORITIES.—Nothing in the amendments made by this section limits the authority of the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce Hazard Analysis Critical Control programs and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

Applicability.
21 USC 350g note.

(g) DIETARY SUPPLEMENTS.—Nothing in the amendments made by this section shall apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of sections 402(g)(2) and 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2), 379aa–1).

21 USC 342 note.
Deadline.

(h) UPDATING GUIDANCE RELATING TO FISH AND FISHERIES PRODUCTS HAZARDS AND CONTROLS.—The Secretary shall, not later than 180 days after the date of enactment of this Act, update the Fish and Fisheries Products Hazards and Control Guidance to take into account advances in technology that have occurred since the previous publication of such Guidance by the Secretary.

21 USC 350g.

(i) EFFECTIVE DATES.—

(1) GENERAL RULE.—The amendments made by this section shall take effect 18 months after the date of enactment of this Act.

Applicability.
Effective dates.

(2) FLEXIBILITY FOR SMALL BUSINESSES.—Notwithstanding paragraph (1)—

(A) the amendments made by this section shall apply to a small business (as defined in the regulations promulgated under section 418(n) of the Federal Food, Drug, and Cosmetic Act (as added by this section)) beginning on the

date that is 6 months after the effective date of such regulations; and

(B) the amendments made by this section shall apply to a very small business (as defined in such regulations) beginning on the date that is 18 months after the effective date of such regulations.

SEC. 104. PERFORMANCE STANDARDS. 21 USC 2201.

(a) IN GENERAL.—The Secretary shall, in coordination with the Secretary of Agriculture, not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, current Good Manufacturing Practices issued by the Secretary relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee, to determine the most significant foodborne contaminants. Deadline.

(b) GUIDANCE DOCUMENTS AND REGULATIONS.—Based on the review and evaluation conducted under subsection (a), and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 402 of the Federal Food, Drug, or Cosmetic Act (21 U.S.C. 342) or to prevent the spread by food of communicable disease under section 361 of the Public Health Service Act (42 U.S.C. 264), the Secretary shall issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations. Such guidance, including guidance regarding action levels, or regulations—

(1) shall apply to products or product classes; Applicability.

(2) shall, where appropriate, differentiate between food for human consumption and food intended for consumption by animals other than humans; and

(3) shall not be written to be facility-specific.

(c) NO DUPLICATION OF EFFORTS.—The Secretary shall coordinate with the Secretary of Agriculture to avoid issuing duplicative guidance on the same contaminants.

(d) REVIEW.—The Secretary shall periodically review and revise, as appropriate, the guidance documents, including guidance documents regarding action levels, or regulations promulgated under this section.

SEC. 105. STANDARDS FOR PRODUCE SAFETY.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by section 103, is amended by adding at the end the following:

"SEC. 419. STANDARDS FOR PRODUCE SAFETY. 21 USC 350h.

"(a) PROPOSED RULEMAKING.—

"(1) IN GENERAL.—

"(A) RULEMAKING.—Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990), and in consultation with the Secretary of Homeland Security, shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits Deadline. Publication. Notice.