

FDA FOOD SAFETY MODERNIZATION ACT

SECTION-BY-SECTION ANALYSIS

Final Version of S. 510, as Passed by the Senate on November 30, 2010

As Passed again by the Senate on December 19, 2010 as H.R. 2751

As Passed by the House on December 21, 2010 as H.R. 2751

Last Updated: December 21, 2010

Title I – General Food Provisions

Section 101 – Inspection of Records

This section expands FDA’s records inspection authority provided initially in the Bioterrorism Act of 2002, which gave the agency records inspection authority when it “has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death.” The expansion grants FDA authority to access and copy all records related to not just the article of food, but, also those related to, any “other article of food” that “the Secretary reasonably believes is likely to be affected in a similar manner.” These related articles would likely include food produced on the same manufacturing line. [See also Sections 103 and 301 for additional records access authority.]

Section 102 – Registration of Food Facilities

Pursuant to current law, registration is required of every manufacturer, processor, packer, or holder of food for consumption in the United States. This bill expands this requirement by mandating that each of these entities re-register every two years, with “abbreviated registration renewal” for those registrants reporting no changes. FDA is provided the authority to adjust food registration categories.

Notably, the bill gives FDA the authority to suspend the registration of any facility if FDA determines that food manufactured, processed, packed or held by that facility “has a reasonable probability of causing serious adverse health consequences or death” – an authority analogous to the withdrawal of inspection by the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA). Informal hearings to challenge a suspension determination are permitted. Issuance of an order to suspend registration and to hold an informal hearing are assigned to the FDA Commissioner and cannot be further delegated. Following such hearings,

the Commissioner can either vacate the order or require the submission of a corrective action plan before lifting the suspension. The FDA will have 14 days to review a facility's corrective action plan for reinstatement of its registration. Any facility with a suspended registration will be prohibited from importing or otherwise introducing food into interstate commerce.

For a facility that merely packs, receives or holds food, the standard for suspension of registration is narrowed to those circumstances where the facility "knew or should have known" that the food posed a reasonable probability of causing serious adverse health consequences or death.

This section also clarifies the term "retail food establishment," as used in FDA's regulations (21 CFR § 1.227(b)(11)), as including: (A) the sale of food directly to consumers at a roadside stand or farmers' market at a location other than where the food was manufactured or processed; (B) the sale and distribution of such food through a community supported agricultural program; and (C) the sale and distribution of such food at any other direct sales platform as determined by FDA.

Section 103 – Hazard Analysis and Risk-Based Preventive Controls

Each registered facility will be required to conduct a hazard evaluation to identify "known or reasonably foreseeable hazards," including "biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, and unapproved food and color additives," and "hazards that occur naturally or may be unintentionally introduced." Each registered facility is then required to implement preventive controls (including at critical control points, if any) to provide assurances that the identified hazards would be significantly minimized or prevented, and that the food will not be adulterated or contain an undeclared allergen. Each registered facility will also be required to analyze hazards that "may be intentionally introduced, including by acts of terrorism," and assure that any intentional hazards are addressed consistent with Section 420.

Preventive controls expressly include the following controls:

- Sanitation
- Training
- Environmental controls
- Allergen controls
- Recall contingency plan
- Good Manufacturing Practices
- Supplier verification activities

Each facility will be required to monitor the controls; establish corrective actions; maintain records of monitoring, instances of nonconformance, and corrective actions taken to ensure that if the controls are not properly implemented or are found to be ineffective, the likelihood of reoccurrence is reduced and all affected food is evaluated and prevented from

entering commerce if it cannot be ensured that it is not adulterated; and verify that the plan is working, including through the use of environmental and product testing programs.

The results of the hazard evaluation and identification of preventive controls will be required to be reduced to writing and made available to FDA during an inspection (along with documentation that the plan is being implemented, including monitoring, instances of nonconformance material to food safety, results of testing and other appropriate means of verification, corrective actions, and efficacy of preventive controls and corrective actions). Verification activities include the use of environmental and product testing and other appropriate means.

A hazard re-evaluation will be required at least every three years or when a significant change is made in the activities conducted at a facility. The re-evaluation must be completed before the change in activities begins. FDA also can require a reanalysis to respond to new hazards or developments in scientific understanding or results of risk assessments from the Department of Homeland Security.

Within 18 months, FDA is directed to promulgate regulations establishing minimum standards for the effective implementation of this section and will have to review existing domestic and international standards (such as the Pasteurized Milk Ordinance) to ensure consistency with such standards, as appropriate. The regulations must provide sufficient flexibility to small businesses, comply with the Paperwork Reduction Act, and not require any facility to hire a third party to identify, implement, or audit preventive controls. FDA will not have the authority to apply specific controls or practices or specific technologies to an individual facility. FDA will be required to coordinate with the Secretary of Homeland Security when promulgating regulations for intentionally introduced hazards.

Within 9 months, FDA is directed to issue a proposed rule clarifying the low-risk on-farm manufacturing, processing, packing, or holding activities involving low-risk food categories for small and very small businesses that would be exempt from or subject to modified requirements under the preventive controls and inspection frequency requirements. Such facilities would still be subject to registration. FDA will need to conduct a science-based risk analysis of such activities involving specific food categories to determine which constitute a low risk. FDA will be required to issue a final rule within 9 months of the close of the comment period for the proposed rule.

FDA would be required to issue a Small Entity Compliance Guide within 180 days of enactment.

The preventive controls requirements would take effect within 18 months of enactment for large firms.

FDA is directed to define, by regulation, “small business” and “very small business” after conducting a study. The effective date for small businesses and very small businesses will be 6 months and 18 months, respectively, from the date of completion of this regulation.

Limitations on Scope: The bill excludes: (a) at FDA’s discretion, warehouses where the food does not come into direct contact with the environment; the storage of raw agricultural

commodities other than fruits and vegetables intended for further processing or distribution; and pet food manufacturers; (b) those facilities subject to the companion section on the safety of fruits and vegetables; (c) facilities subject to other FDA HACCP or analogous regulatory programs (seafood, juice and low acid canned foods); (d) dietary supplements; and (e) alcohol-related facilities.

Limited Exemption: The bill provides an exemption from preventive controls for qualifying very small businesses with limited size and limited scope of distribution. However, the facility is still subject to the registration requirement.

- The limited size is for annual sales (3 year average) of less than \$500,000.
- The limited scope of distribution is either intrastate or within a 275 mile radius (includes Canadian or Mexican imports).
- A majority of the distribution must be directly to consumers or directly to restaurants or retail food establishments (i.e., not through distributors).
- The product label (if it has one) must include the name/place of the business, or if there is no label, this information must be provided in a written placard or by some other suitable means.
- To qualify, the facility must submit to FDA either: (a) documentation that it is applying preventive controls; or (b) documentation that it is in compliance with state, local or other non-Federal requirements.
- The exemption can be withdrawn by FDA, on a qualifying facility basis, if the food is directly linked to a foodborne illness outbreak.

Within 180 days, FDA will be required to update the Seafood HACCP guidance document.

There is no limitation on the agency to revise, issue, or enforce product or category specific regulations such as existing HACCP programs.

Failure to comply with this section is a prohibited act.

Section 104 – Performance Standards

This section of the bill will require FDA to periodically, not less frequently than every two years, review and evaluate “the most significant food-borne contaminants” and, when appropriate, FDA would then issue contaminant specific “science-based guidance documents, including guidance documents regarding action levels, and regulations” to help prevent adulteration. The bill provides that such guidance documents shall apply to products or product classes; shall, where appropriate, differentiate between food for human consumption and food intended for animal consumption; and shall not be facility-specific. In conducting this review, FDA is directed to consider toxicological and epidemiological studies and analyses, current

Good Manufacturing Practices regulations issued by the agency, and recommendations by relevant advisory committees, including the agency's Food Advisory Committee, to determine the most significant foodborne contaminants.

Section 105 – Standards for Produce Safety

Within a year of the bill's enactment, FDA, in consultation with USDA, state departments of agriculture, and the Secretary of Homeland Security, will be required to publish a proposed rule establishing science-based standards for the safe production and harvesting of those types of fruits and vegetables (including mixes or categories of fruits and vegetables) for which FDA has determined that such standards would "minimize the risk of serious adverse health consequences or death." FDA is instructed to prioritize regulations for fruits and vegetables that have been associated with foodborne illness outbreaks.

FDA will be required to give flexibility to different types of entities including farms that sell directly to consumers, as well as consider conservation practices and organic production requirements.

FDA has the discretion to exempt or modify the requirements for small and very small businesses that produce and harvest low-risk fruits and vegetables. The regulations also must provide flexibility to small businesses and comply with the Paperwork Reduction Act. FDA must also acknowledge differences in risk and minimize the number of separate standards that apply to separate foods. FDA may not require a facility to hire a consultant or third party. Within 180 days after the regulations are promulgated, FDA would be required to issue a Small Entity Compliance Guide.

FDA is directed to define, by regulation, "small business" and "very small business." The effective date for small businesses and very small businesses would be 1 year and 2 years, respectively, from the date of completion of this regulation.

During the proposed rulemaking comment period, FDA will be required to conduct at least three public meetings in diverse geographical areas. A final rule will be required within a year of the closing of the comment period on the proposal.

The regulations must permit states and foreign governments to seek variances from the requirements and provide for coordination of education and enforcement activities with states and local governments. FDA may also coordinate with USDA to ensure compliance.

Also within a year of the bill's enactment, FDA is directed to publish guidance updating good agricultural practices. FDA will be required to hold at least 3 public meeting to conduct education and outreach regarding the guidance.

Violation of the requirements under this section is a prohibited act.

Limitation on Scope: This section does not apply to facilities subject to the companion section on preventive controls or to persons who grow food for their own personal consumption.

Limited Exemption: The bill provides an exemption from mandatory produce standards for qualifying very small farms with limited size and limited scope of distribution.

- The limited size is for annual sales (3 year average) of less than \$500,000.
- The limited scope of distribution is either intrastate or within a 275 mile radius (includes Canadian or Mexican imports).
- A majority of the distribution must be directly to qualified end-users – directly to consumers or directly to restaurants or retail food establishments (i.e., not through distributors).
- The product label (if it has one) must include the name/place of business, or if no label, this information must be provided in a written placard or by some other suitable means.
- The exemption can be withdrawn by FDA, on a facility basis, if the food is directly linked to a foodborne illness outbreak.

There is be no limitation on the agency to revise, issue, or enforce product or category specific regulations such as existing HACCP programs.

Section 106 – Protection Against Intentional Adulteration

This section requires FDA, in consultation with USDA and the Department of Homeland Security (DHS), to promulgate regulations within 18 months to protect food against intentional adulteration. ^{1/} These regulations would apply only to food in bulk or batch form prior to being packaged for the final consumer for which FDA has identified clear vulnerabilities and that there is a high risk that intentional adulteration could cause serious adverse health consequences or death. To make these determinations, FDA will be required to conduct vulnerability assessments of the food system, consider risks and costs, and determine the types of science-based strategies necessary for protection. The regulations are to specify how facilities should assess whether to implement mitigation measures to protect against intentional adulteration and the measures that should be implemented. Within a year of enactment, FDA will be required to issue guidance documents related to protection against intentional adulteration of food.

Section 107 – Authority to Collect Fees

The bill authorizes FDA to collect certain fees from companies within the food industry, including fees from the following: (1) domestic facilities to cover reinspection-related costs, (2) domestic facilities to cover recall-related activities performed by FDA if the facility refuses to conduct a mandatory recall order, (3) importers to cover administrative costs of participating in the voluntary qualified importer program, and (4) importers to cover reinspection-related costs. Additionally, FDA would be authorized to assess fees for export certificates for foods.

^{1/} This section would not apply to foods produced on farms, except for milk.

Unlike other FDA fee-related statutes that are oriented to premarket review activities, this provision would tailor fees either to compliance activities, particularly reinspections for domestic and imported products, or to voluntary activities. Thus, fees would only be assessed against companies that need a reinspection by FDA, that have refused to conduct a mandatory recall, or that are voluntarily participating in the qualified importer program or are voluntarily requesting export certificates from the agency. The bill would cap total annual recall-related fees at \$20 million and reinspection-related fees at another \$25 million, for a total of \$45 million. ^{2/}

FDA would not be authorized to collect fees in any fiscal year where the total appropriated funding for FDA's food safety activities (excluding any fees) does not exceed that for fiscal year 2009, adjusted annually for inflation. This is often referred to as the "trigger" provision because it triggers the agency's ability to collect fees. This protects FDA's food safety-related appropriated base funding, especially during a period of level or declining budgets.

FDA's authority to collect fees continues indefinitely.

Section 108 – National Agriculture and Food Defense Strategy

Within a year of enactment, the Department of Health and Human Services (HHS) and USDA, in consultation with DHS, will be required to submit to Congress a National Agriculture and Food Defense Strategy, which is to include a coordinated research agenda and a description of the process for meeting the following goals: (1) enhancing the preparedness of the agriculture and food system, (2) improving agriculture and food system detection capabilities, (3) ensuring an efficient response to agriculture and food emergencies, and (4) securing agriculture and food production after an emergency. Every four years, a revised plan is to be submitted to Congress. The three agencies will also be required to develop metrics to measure progress and report on the progress measured.

Section 109 – Food and Agriculture Coordinating Councils

Within 180 days of enactment, the bill will require DHS, in consultation with USDA and HHS, to submit a report to Congress on the activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council.

Section 110 – Building Domestic Capacity

Within two years of enactment, FDA, in coordination with USDA and DHS, will be required to submit a report to Congress identifying its food safety programs and practices. This will include descriptions of the following: analysis of the need for additional regulations or guidance, outreach to food industry sectors, systems for distributing information and technical assistance to industry, communication systems to disseminate information concerning specific threats, surveillance systems to detect foodborne illness outbreaks, and resources needed to implement the plan. This report also should include information on risk-based activities, the capacity for laboratory analyses, information technology, and recommendations for enhanced

^{2/} Fees for recalls and reinspections could surpass these caps if a facility becomes subject to either a recall or reinspection after the relevant cap has been reached.

surveillance, outbreak response and traceability involving fruits and vegetables. Thereafter, FDA would be required to submit a report on a biennial basis reviewing previous food safety programs and practices and identifying future ones. In addition, on a biennial basis, FDA will be required to submit a food safety and food defense research plan to Congress. FDA will also be required to evaluate the effectiveness of its programs and report to Congress on this evaluation within one year of enactment.

Within one year of enactment, FDA will be required to conduct a study on the need for and challenges associated with requiring unique facility identification numbers for each registered food facility and import broker. FDA will be required to submit a report regarding the results of the study within 15 months of enactment.

Section 111 – Sanitary Transportation of Food

Within 18 months of enactment, the bill will require FDA to promulgate regulations regarding the sanitary transportation of food, as required by pre-existing section 416(b) of the Act.

Section 112 – Food Allergy and Anaphylaxis Management

The bill directs the Secretary of Health and Human Services, in consultation with the Secretary of Education, to develop voluntary food allergy management guidance to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs. In addition, the bill will provide for non-renewable food allergy management incentive grants for up to two years to assist local education agencies with adoption and implementation of the voluntary food allergy management guidelines.

Section 113 – New Dietary Ingredients

Within 6 months, the bill will require FDA to issue guidance regarding new dietary ingredient notifications, including clarification of what a new dietary ingredient is, when a notification to FDA is required, the evidence needed to support safety, and the methods for establishing the identity of a new dietary ingredient. FDA will also be required to notify the Drug Enforcement Administration whenever the agency has concerns that a new dietary ingredient may be an anabolic steroid or analogue of such.

Section 114 – Requirement for Guidance Relating to Post-Harvest Processing of Raw Oysters

Whenever FDA is planning to issue any guidance, regulation or related action relating to the post-harvest processing of raw oysters, the agency will be required to notify Congress with a detailed report at least 90 days prior to taking such planned action. Such a report would not be required if FDA issues a guidance that is adopted as a consensus agreement between federal and state regulators and the oyster industry, acting through the Interstate Shellfish Sanitation Conference.

Section 115 – Port Shopping

FDA will be directed to coordinate with the Department of Homeland Security on any food refused admission into the United States in order to prevent port shopping by the importer.

Section 116 – Alcohol-Related Facilities

In general, many of the bill’s provisions would not apply to alcohol facilities required to register with FDA under Section 415 because they are engaged in the manufacturing, processing, packing or holding of alcoholic beverages. Specifically, facilities that are required to obtain a permit or register with the Department of the Treasury under the Federal Alcohol Administration Act and are required to register with the FDA, are exempted from most provisions of the new law, except for sections 102 (Registration), 206 (Mandatory Recall), 207 (Administrative Detention), 302 (Voluntary Qualified Importer Program), 304 (Prior Notice of Imported Food Shipments), 402 (Employees Protections), 403 (Jurisdiction; Authorities) and 404 (Compliance with International Agreements).

This exemption would not apply to facilities engaged in activities involving non-alcohol food, unless the food is received and distributed in prepackaged form and constitutes not more than 5% of overall sales of the facility

Title II – Detection and Surveillance

Section 201 – Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Points of Entry; Annual Report

The bill requires FDA to allocate inspection resources according to the risk profiles of facilities, which would take into account the type of food, the facility’s history of recalls and violations, the rigor of the facility’s hazard analysis and risk-based preventive controls, whether the food is imported and certified, and other criteria as deemed appropriate. Domestic facilities designated as *high risk* would be inspected not less than once during the first five years after enactment, and not less than once every three years for each succeeding year. Domestic facilities determined not to be high risk would be inspected not less than once during the first seven years after enactment, and not less than once every five years for each succeeding year. In meeting this domestic inspection frequency, FDA may rely on inspections conducted by other Federal, State or local agencies.

The inspection of imported food also would be prioritized according to risk profile, which would take account of the type of food, the origin, the history of the importer, the rigor of the foreign supplier verification of the importer (under in Section 301 of the bill), whether the importer participates in the Voluntary Qualified Importer Program (under Section 302 of the bill), and whether the food is imported and certified. The inspection frequency of foreign inspections will proceed under a different formula: in the first year following enactment, FDA will be required to inspect no less than 600 foreign facilities; FDA will then be required to double the number of foreign inspections each year for the next five years. Under this formula, in 2015 FDA will be expected to inspect 9,600 foreign facilities.

FDA will be authorized to enter into interagency agreements to improve seafood safety, and will be directed to improve coordination with the Departments of Agriculture and Homeland Security to target food inspection resources. FDA will also be required to submit an annual report to Congress regarding inspection frequency and cost.

Section 202 – Laboratory Accreditation for Analyses of Foods

Within two years of enactment, the bill will require FDA to provide for the recognition of accreditation bodies that accredit laboratories – including independent private laboratories and laboratories operated by a Federal agency – and to establish a publicly available registry of recognized accreditation bodies. As a condition of inclusion on this registry, accreditation bodies will have to require that laboratories meet certain model standards developed by FDA. Foreign laboratories that meet the domestic standards will be eligible for accreditation. FDA will be required to reevaluate periodically all recognized accreditation bodies every five years and to revoke recognition if warranted. FDA is directed to work to increase the number of accredited laboratories.

Within 30 months of enactment, either federal laboratories or laboratories accredited by an accreditation body on FDA’s registry will be required to be used for all food testing in support of admission of an imported food, as required by an Import Alert, as required by specific testing regulations when applied to address an identified or suspected food safety problem, or as otherwise deemed appropriate by FDA to address an identified or suspected food safety problem. In these circumstances, the test results will be required to be reported directly to FDA. If the testing of food by a state-run laboratory results in a state recall of a particular food, FDA will be required to review the sampling and testing results to determine the need for a national recall. Also, FDA could waive the required use of an accredited laboratory if new methodologies have been developed and validated and are necessary to protect the public health during a foodborne illness outbreak but a laboratory has not yet been accredited to use them.

Within 180 days of enactment, the bill will require FDA, in coordination with other agencies, to submit to Congress a report on the progress of implementing a national food emergency response laboratory network (as called for in an earlier Presidential Directive).

Section 203 – Integrated Consortium of Laboratory Networks

The bill would require DHS, in consultation with HHS, USDA, and EPA, to maintain an agreement through which laboratory network members could do the following: (1) agree on common laboratory methods to facilitate the sharing of information, (2) identify the means by which the members could work cooperatively, and (3) engage in ongoing dialogue and build relationships to support integrated responses during emergencies.

Section 204 – Enhancing Tracking and Tracing of Food and Recordkeeping

Within nine months of enactment, FDA will be required to conduct pilot projects, in cooperation with the applicable food sector, to explore methods to improve the tracking and tracing of food. The bill will require separate pilot projects for: (a) packaged food; and (b) fruits and vegetables that are raw agricultural commodities. After completion of the pilot projects,

FDA will be required to establish within the agency a product tracing system to receive information to track and trace food. FDA will be required to ensure that the parameters of such system are supported by the results of the pilot projects. FDA will be required to conduct additional data gathering to assess the cost and benefits associated with adoption of product tracing technologies, the feasibility of such technologies for different food sectors, and whether such technologies are compatible with the statutory requirements for this section. FDA will also be required to evaluate domestic and international product tracing practices in commercial use, consider international efforts, and consult with a diverse and broad range of experts and stakeholders.

Within two years of enactment, FDA will be required to issue a proposed rule to establish additional recordkeeping requirements for product tracing but such requirements would apply only to high-risk foods. FDA would have to consider certain factors when determining whether a food is high-risk for purposes of product tracing, including the history of outbreaks attributed to the food and the likelihood of contamination and steps taken during manufacturing to reduce the likelihood of contamination.

The new recordkeeping requirements cannot prescribe the use of specific technologies, cannot require the creation of duplicate records, cannot require a facility to change business systems, cannot require the full pedigree of the food, and cannot require product tracing to the case level.

The new requirements will not apply to certain farm sales of food, fishing vessels, or commingled raw agricultural commodities, and FDA will not be permitted to impose any limitations on the commingling of food. A “commingled raw agricultural commodity” is defined as any commodity that is combined or mixed after harvesting but before processing, but would not include certain types of fruits and vegetables as determined by FDA. The term “processing” would mean operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization. Grocery stores would be required to maintain records documenting the farm that was the source of the food.

FDA will be able to provide additional exemptions or modifications for specific types of food or facilities if the agency determines that such requirements are not necessary to protect the public health.

During an active investigation of a foodborne illness outbreak, FDA will be able to request that a farm identify potential immediate recipients of the food that is the subject of the investigation.

Within two years of enactment, FDA will be required to publish a proposed regulation covering the recordkeeping requirements associated with product tracing of “high risk” foods, to be followed by public meetings to obtain input from different regions of the country. Such proposed requirements will, among other things: (1) be required to be science based; (2) ensure that the public health benefits outweigh the costs of compliance; (3) be scale appropriate; (4) minimize the number of different requirements for facilities that handle more than one type

of food; and (5) ensure that FDA has procedures in place to protect trade secret or other confidential information.

Within one year of enactment, the GAO will be required to submit a report to Congress evaluating the benefits and risks of limiting product tracing requirements to high-risk foods and of limiting the participation of restaurants.

Small businesses will have an additional year to comply with any final regulations and very small businesses will have an additional two years to comply. FDA also will be required to issue a Small Entity Compliance Guide.

The new traceability requirement will also apply to imported products.

Failure to comply with any recordkeeping requirements is a prohibited act.

Section 205 – Surveillance

This section will require HHS, through the Centers for Disease Control (CDC), to enhance foodborne illness surveillance systems to improve the collection, analysis, reporting and usefulness of data on foodborne illness by, among other activities, coordinating with federal, state, and local surveillance systems; increasing participation in national networks of public health; facilitating the sharing of findings among governmental agencies on a timely basis; and developing improved epidemiological tools. This section will also require FDA to develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies. In addition, the bill will establish a working group of experts and stakeholders to recommend recommendations on improving foodborne illness surveillance. The bill authorizes appropriations of \$24 million to carry out this provision.

Section 206 – Mandatory Recall Authority

The bill grants FDA mandatory recall authority if a company refuses to voluntarily recall a product for which “there is a reasonable probability” that the food is adulterated or contains an undeclared food allergen and consumption of the food will cause “serious adverse health consequences or death.” This is the same standard as applies to a Class I recall. In addition to notifying the public through a press release, FDA must also “consult the policies of the Department of Agriculture regarding providing to the public a list of retail consignees receiving products involved in a Class I recall and shall consider providing such a list to the public.”

The bill’s mandatory recall provision also mandates that failure to comply with a recall order would trigger a civil money penalty of no more than \$50,000 per individual and \$250,000 per other entities, not to exceed \$500,000 for all related violations. It would also constitute a prohibited act for which criminal penalties are provided under existing law.

Mandatory recall authority may only be delegated to the Commissioner of the FDA.

FDA will be required to establish an incident command operation that would operate within 24 hours of the initiation of a Class I recall, regardless of whether the recall was mandated or was conducted voluntarily.

To assist consumers in learning about recalled food products, FDA will be required to publish on its website a picture of food subject to a mandatory recall. In addition, within 90 days of enactment, the agency will be required to establish a web search engine to allow consumer access to information that is the subject of a mandatory recall.

FDA will be required to submit an annual report to Congress identifying when the agency has used its mandatory recall authority. In addition, GAO will be directed to report to Congress on mechanisms available to compensate parties for wrongly ordered recalls. Within 90 days of the report, USDA will be directed to conduct a study on the ability to implement a farmer restitution program.

Section 207 – Administrative Detention of Food

Effective 180 days after enactment, the bill broadens the authority granted under the Bioterrorism Act of 2002 and provides FDA with administrative detention authority whenever the agency “has reason to believe” that a food “is adulterated or misbranded.”

Section 208 – Decontamination and Disposal Standards and Plans

The bill will require the EPA to provide support for and technical assistance to state and local governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency. To do this, the EPA will develop and disseminate specific standards, including model plans, concerning clean up, clearance, and recovery activities following the decontamination and disposal of specific threat agents and foreign animal diseases. Exercises to identify weaknesses in the plans are to be conducted at least annually, with modifications to the plan made at least every two years.

Section 209 – Improving the Training of State, Local, Territorial, and Tribal Food Safety Officials

This section requires FDA to set standards and administer training and educational programs for state, local, territorial, and tribal officials to conduct food safety examinations and investigations. FDA is authorized to use such employees to conduct inspections and investigations.

Within 180 days of enactment, FDA will be required to enter into memoranda of understanding with USDA to establish a competitive grant program to provide training and education to farms, small processors and small fruit and vegetable wholesalers.

FDA will also be authorized to make grants to states and localities for a variety of food safety-related functions.

Section 210 – Enhancing Food Safety (Grant Provision)

FDA will be authorized to make grants to states and localities, as well as to nonprofit food safety training entities that partner with an institution of higher education, to understand inspection and investigations and to undergo training.

CDC will be required to establish five Integrated Food Safety Centers of Excellence to serve as resources for federal, state, and local public health officials to respond to foodborne illness outbreaks. The Centers would be headquartered at selected state health departments. Within two years of enactment, the Secretary will be required to submit a report to Congress regarding the effectiveness of these Centers.

Section 211 – Improving the Reportable Food Registry

FDA will be authorized to require a responsible party to submit consumer-oriented information regarding a reportable food to the Reportable Food Registry, including a description of the food, the affected product identification codes, and contact information for the responsible party. FDA will be required to prepare this information as a standardized one-page summary to be published on the FDA website.

If a grocery store that is part of a chain of 15 or more stores sold such food, then the store will need to prominently display the summary within 24 hours for 14 days. FDA will be required to develop a list of acceptable locations, from which grocery stores can choose one, to provide the notification. These will include: posting near the register; posting near the location of the reportable food; and providing targeted recall information to consumers at purchase. The knowing and willful failure of a grocery store to comply with this requirement is a prohibited act, thereby invoking the Act's enforcement provisions.

Title III – Specific Provisions for Imported Food

Section 301 – Foreign Supplier Verification Program

This section requires each importer (defined as the owner of the food at the time of entry into the United States) to verify that its imported food is produced in accordance with U.S. requirements (including the new preventive controls and produce standards discussed in Sections 103 and 105 of the bill), is not adulterated, and does not contain an undeclared allergen. Within one year of enactment, the bill requires FDA to issue guidance on the development of foreign supplier verification programs and promulgate regulations regarding the content of these programs. Regulations will establish the process for verification by a United States importer for each relevant foreign supplier. Related records will be required to be maintained for two years and made available to FDA upon request. FDA will be required to publish a list on the Internet of the name and location of importers participating in this program. An exemption will be provided for importers of seafood, juice, and low-acid canned foods required to comply with HACCP-based regulations. FDA will also be required to publish a notice in the Federal Register exempting research samples and food for personal consumption from the foreign supplier verification requirement. This provision takes effect two years from enactment.

Section 302 – Voluntary Qualified Importer Program

Within a year of enactment, the bill requires FDA to establish, in consultation with DHS, a program for expedited review and importation of products from importers voluntarily participating in a qualified importer program. Importers that wish to participate will be required to provide notice and an application to FDA. Eligibility for the program will require a third party certification and turn on factors such as the following: the nature of the food; risk of intentional adulteration of the food; compliance history of the foreign supplier; exporting country's capability for ensuring compliance with U.S. standards; compliance with the foreign supplier verification program; and recordkeeping, testing, facility inspections and audits, traceability, temperature controls, and sourcing practices of the importer. FDA will be permitted to allow the expedited review and importation by importers of certain foods or from certain countries based on these criteria. FDA will be required to reevaluate importers qualified under this program every three years. Any false statement or representation by an importer will be subject to criminal liability under the Federal Criminal Code, 18 U.S.C. § 1001.

Section 303 – Authority to Require Import Certifications for Food

This section authorizes FDA to require third party certifications, or such other assurances as deemed appropriate, for specific types or sources of imported food based on public health considerations, including risks associated with the food or its place of origin, or a finding by FDA that the food safety system of the country of origin is inadequate. If FDA does determine that the food safety system of a foreign region, country or territory is inadequate, FDA will be required to identify the inadequacies and establish a process for the foreign government to inform the agency of improvements to its program.

If certification is required, then the imported food may be refused admission unless accompanied by a certification (from a competent regulatory authority in the country of export or other accredited entity) or other assurance that the food meets all applicable requirements of the Federal Food, Drug, and Cosmetic Act. These certifications or assurances can be provided in the form of shipment-specific certificates, a listing of certified entities, or in another form specified by FDA. FDA can require that certifications be renewed as deemed appropriate and refuse to accept certifications it deems no longer valid. The requirement for such certification does not prevent the FDA from conducting random checks of the covered imports.

Section 304 – Prior Notice of Imported Food Shipments

Effective 180 days after enactment, the bill requires prior notice of an imported food to include the name of any country that refused entry to the food.

Section 305 – Building Capacity of Foreign Governments with Respect to Food Safety

The bill requires FDA, within two years of enactment, to develop a plan to expand the technical, scientific, and regulatory capacity of foreign countries exporting food to the United States. Reflecting consultation with other government agencies, the plan will include recommendations for bilateral or multilateral agreements, provisions for electronic data sharing, provisions for mutual recognition of inspection reports, training of foreign governments and

producers, recommendations for harmonization with Codex Alimentarius, and provisions for multilateral acceptance of laboratory methods and detection techniques.

Section 306 – Inspection of Foreign Food Facilities

The bill authorizes FDA to enter into agreements with foreign countries to facilitate the inspection of registered foreign facilities and require that inspection resources be directed to those facilities that present the highest risk. Department of Commerce (National Oceanic and Atmospheric Administration) will be authorized, in coordination with FDA, to send inspectors to foreign facilities and countries for seafood inspections. The importation of food from foreign facilities that refuse to permit, limit, or unduly delay United States inspections will be prohibited.

Section 307 – Accreditation of Third-Party Auditors

Within two years of enactment, FDA will be required to implement a system whereby (a) it recognizes accrediting bodies that operate in accordance with established standards, rather than carrying out that function itself (however, if FDA has not recognized an accreditation body in two years, FDA will be able to directly accredit third-party auditors); (b) the accreditation bodies will then evaluate and accredit third party auditors; and (c) the third party auditors will be authorized to certify that foreign facilities meet the requirements of the Act. FDA will issue model standards that accrediting bodies should ensure auditors meet. The program applies to imported foods only.

As a condition of accreditation, an auditor will be required to agree to issue a written and electronic certification to accompany each food shipment made for import from a certified facility. Such certificates will be considered by FDA when targeting inspection resources. Certification will be required to participate in the Voluntary Qualified Importer Program.

FDA will be authorized to monitor auditors, conduct its own inspections, and review inspection reports generated by auditors. The bill draws a distinction between consultative audits and regulatory audits, with this provision directed to regulatory audits. However, reports from the consultative audits will be accessible under Section 414 of the Act (which is tied to “a reasonable belief that an article of food [or similar article] presents a threat of serious adverse health consequences or death”).

The agency will also publish a public list of accreditation bodies and accredited third party auditors.

FDA will be required to issue regulations regarding conflicts of interest, including a requirement that audits be unannounced. In addition, false statements to auditors will be considered a criminal act. Auditors will be required to immediately notify FDA upon discovering “a condition that could cause or contribute to a serious risk to the public health.”

FDA may withdraw accreditation from an auditor if food from a facility it certifies is linked to a foodborne illness outbreak, if the auditor no longer meets requirements, or following a refusal to allow U.S. officials to conduct necessary audits.

To make the program revenue-neutral, FDA will establish a method by which auditors reimburse FDA for the work performed to establish and administer the accreditation system; no revenue surplus is to be generated.

Section 308 – Foreign Offices of the Food and Drug Administration

The bill requires FDA to establish an office in foreign countries selected by the agency to provide assistance to those countries with respect to the safety of food exported to the United States, including by directly conducting risk-based inspections. By October 1, 2011, FDA will be required to report to Congress on the basis for selecting the countries for foreign offices and the progress made in those offices.

Section 309 – Smuggled Food

In consultation with DHS, FDA will be required to develop and implement a strategy to better identify and prevent the entry of smuggled food. FDA will be required to publicly warn consumers of smuggled food that the agency reasonably believes would cause serious adverse health consequences or death.

Title IV – Miscellaneous Provisions

Section 401 – Funding for Food Safety

The bill authorizes appropriations for FDA's Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and related activities in the Office of Regulatory Affairs that would substantially increase the food safety budget for fiscal year 2011 through 2015. The bill also sets a goal that the field inspection staff for FDA's food safety programs should increase by more than 1,000 persons over a 5 year period, including an increase of 150 staff devoted to food defense.

Section 402 – Employee Protections

Whistleblowers will receive protection against retaliation or discrimination.

Section 403 – Jurisdiction; Authorities

The bill clarifies that amendments made by its enactment do not change the jurisdiction between FDA and USDA, DHS, or the Alcohol, Tobacco, Tax, and Trade Bureau.

Section 404 – Compliance with International Agreements

The bill states that it must not be construed in a manner inconsistent with the World Trade Organization (WTO) agreement or any other treaty.

Section 405 – Determination of Budgetary Effects

The bill provides that its budgetary impact shall be determined under the Statutory Pay-As-You-Go Act of 2010.

