

Summary of the FDA Food Safety Modernization Act

January 4, 2011

The following is a summary of changes to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.) contained in the Food and Drug Administration (FDA or the Agency) Food Safety Modernization Act (the Act). The Act imposes a number of mandates on individuals and entities that manufacture, process, pack, transport, distribute, receive, or hold articles of food. It broadens the FDA's authority to regulate food facilities and would establish new requirements for those facilities. It provides FDA with mandatory recall authority (Section 206); requires food companies to enhance due diligence on imported foods (Section 301), provide food testing results to FDA (Section 202), enact Hazard Analysis and Critical Control Point (HACCP) programs (Section 103), and supplement food tracking recordkeeping; and provides employees at food industry employers with whistle-blower protection (Section 402). It exempts some farms and small business from some of the new regulatory requirements, and imposes fees on a limited number of FDA services/functions such as recalls, re-inspections, and export certifications (Section 207).

Title I – Improving Capacity to Prevent Food Safety Problems

Section 101 – Inspections of records

- Expands the authority of the Secretary of Health and Human Services (HHS)/FDA to inspect all records (excluding those of farms and restaurants) relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of adulterated food, or a related article of food if the Secretary believes that there is a reasonable probability that that food will cause serious adverse health consequences or death to humans or animals.

Section 102 – Registration of food facilities

- Creates a biennial registration requirement and provides the Secretary with the authority to create an abbreviated registration renewal process for registration that has not had any changes since the last renewal.
- Subject to due process protections, authorizes the Secretary to suspend the registration of a food facility if the food manufactured, processed, packed, or held by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.
- Allows the Secretary to reinstate suspended firms if appropriate.
- Requires the Secretary to promulgate regulations that describe the standards for making a determination to suspend a registration.
- Facilities will be subject to these requirements the earlier of—
 - (A) the date on which the Secretary issues the above regulations or
 - (B) 180 days after the date of enactment of the FDA Food Safety Modernization Act.
- Requires FDA to publish a small-entity compliance guide on new standards.

Section 103 – Hazard analysis and risk-based preventive controls

- Requires each food facility to (1) evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility; (2) identify and implement preventive controls; (3) monitor the performance of those controls; (4) establish procedures for corrective actions should preventive controls fail; and (5) maintain records of such monitoring.
- Exempts facilities that are in compliance with certain existing food-specific standards. (e.g., HACCP rules for seafood, juice, and low-acid canned food facilities).
- Requires the Secretary to promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting such implementation.
- Prohibits the operation of a food facility if it is not in compliance with this section.
- Exempts qualified facilities from compliance with this section. Qualified facilities are those who sell less than \$500,000 a year in food and sell directly to consumers or to restaurants and retail food establishments located in the same state as, or within 275 miles of, the qualified facility.
- Delays implementation of this section for small businesses.
- Requires FDA to publish a small-entity compliance guide on the new standards.

Section 104 – Performance standards

- Directs the Secretary to (1) determine the most significant food borne contaminants at least every two years; and (2) issue contaminant-specific and science-based guidance documents, action levels, or regulations.
- Does not allow performance standards to be facility-specific.

Section 105 – Standards for produce safety

- Sets forth provisions related to produce safety, including requiring the Secretary to (1) establish science-based

minimum standards for raw agricultural commodities; and (2) publish updated good agricultural practices and guidance for fresh produce.

- Allows the Secretary to modify or exempt low risk commodities from the new standards.
- Exempts farms from compliance with this section if they meet two criteria: (1) they sell, over a three-year average, more food directly to consumers or to restaurants and retail food establishments located in the same state as, or within 275 miles of, the farm than to all other buyers; and (2) they sell less than \$500,000 worth of food per year on average.
- Requires FDA to publish a small-entity compliance guide on the new standards.

Section 106 – *Protection against intentional adulteration*

- Requires the Secretary, in coordination with the Department of Homeland Security (DHS) and the Secretary of Agriculture, to conduct vulnerability assessments of the food system, and promulgate regulations to protect against the intentional adulteration of food.
- Requires the regulations to specify science-based mitigation strategies or measures to prepare and protect the food supply chain at points that are at high risk of intentional contamination.
- Does not apply to farms as defined in 21 C.F.R. § 1.227, except those that produce milk.
- Allows the Secretary, in consultation with DHS, to limit distribution of guidance documents and reports in the interest of national security.

Section 107 – *Authority to collect fees*

- Directs the Secretary to assess and collect fees related to (1) food facility re-inspection; (2) food recalls; (3) the voluntary qualified importer program; and (4) importer re-inspection.
- Applies export certification fees to food.

Section 108 – *National agriculture and food defense strategy*

- Requires the Secretary and the Secretary of Agriculture to prepare and submit to the relevant congressional committees and make public the National Agriculture and Food Defense Strategy, which shall include (1) an implementation plan; (2) a coordinated research agenda; and (3) a process to achieve, and evaluate progress toward goals – preparedness, detection, emergency response, and recovery.
- Allows the Secretary, in consultation with DHS, to limit distribution of guidance documents and reports in the interest of national security.

Section 109 – *Food and Agriculture Coordinating Councils*

- Directs the Secretary of Homeland Security (DHS), in coordination with the Secretary of HHS and the Secretary of Agriculture, to report annually on the activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council.

Section 110 – *Building domestic capacity*

- Requires the HHS Secretary, in coordination with DHS and USDA, to submit to Congress (1) a comprehensive report that identifies programs and practices intended to promote the safety and security of the food supply chain and to prevent outbreaks of food-borne illness and other food-related hazards; and (2) biennial reports on food safety programs and practices.
- Requires the HHS Secretary, the Secretary of Agriculture, and the Secretary of Homeland Security to submit to Congress, biennially, a joint food safety and food defense research plan.
- Requires the Secretary, acting through the Commissioner of Food and Drugs, to examine the need for a unique identification number for each food facility registered with the Secretary.

Section 111 – *Sanitary transportation of food*

- Requires the HHS Secretary to promulgate regulations on sanitary transportation practices for the transportation of food.
- Requires FDA to conduct a study on the transportation of food, including the unique needs of rural and frontier areas.

Section 112 – *Food allergy and anaphylaxis management*

- Requires the Secretary to develop guidelines for developing plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs, to be implemented on a voluntary basis.
- Sets forth issues for such guidelines to address, including (1) parental obligation to provide documentation of their child's food allergy; (2) the creation of an individual plan for food allergy management; (3) communication strategies between schools or childhood education programs and providers of emergency medical services; (4) strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms and common school or early childhood education program areas, such as cafeterias; (5) food allergy management training for personnel; and (6) the creation of a plan in each individual plan for food allergy management in extracurricular programs.
- Allows the Secretary to award nonrenewable two-year matching grants of no more than \$50,000 to assist local educational agencies in implementing such food allergy and anaphylaxis management guidelines.

Section 113 – *New dietary ingredients*

- Requires the Secretary to notify the Drug Enforcement Administration (DEA) if a new dietary ingredient (NDI) notification is inadequate to establish its safety because it contains an anabolic steroid or an analogue of an anabolic steroid.
- Requires the Secretary to publish guidance that clarifies when a dietary supplement ingredient is an NDI, when information should be provided to the Secretary on the ingredient and its safety, and appropriate methods for establishing the identity of an NDI.

Section 114 – *Requirement for guidance relating to post-harvest processing of raw oysters*

- Requires the Secretary to submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Energy and Commerce a report on the proposed post-harvest processing of raw oysters prior to issuing any guidance, regulation, or suggested amendment to the National Shellfish Sanitation Program's Model Ordinance or the Seafood Hazard Analysis Critical Control Points Program.

Section 115 – *Port shopping*

- Until the Secretary promulgates a final rule that implements the amendments in section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Secretary is required to notify DHS of all instances in which the admission of a food into the United States is refused.

Section 116 – *Alcohol-related facilities*

- In general, with some exceptions, this Act and the amendments made by it, do not apply to facilities that receive and distribute alcoholic beverages.

Title II – Improving Capacity to Detect and Respond to Food Safety Problems**Section 201** – *Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report*

- Requires the Secretary to (1) allocate resources to food inspection based on a facility's risk profiles; (2) increase the frequency of inspection of all facilities to once every seven years and subsequently every five years thereafter for low in state domestic facilities, and every five years and subsequently every three years thereafter for high-risk domestic facilities, and to inspect at least 600 foreign facilities in the first year, and at least 1,200 the second year and subsequently every five years thereafter; and (3) report to the appropriate congressional committees annually on food facility and food import inspections.
- Permits the Secretary of HHS, the Secretary of Commerce, the Secretary of DHS, the Chairman of the Federal Trade Commission, and the heads of other appropriate agencies to enter into agreements necessary and appropriate to improve seafood safety.

Section 202 – *Laboratory accreditation for analyses of foods*

- Requires the Secretary to, within two years of this Act's enactment, (1) establish a program for the testing of food by accredited laboratories; (2) establish a publicly available registry of accreditation bodies; (3) develop model standards that an accreditation body shall require U.S. and foreign laboratories to meet; and (4) periodically reevaluate accreditation bodies and revoke recognition of any not in compliance with this section.

- Sets forth requirements for mandatory testing for specified reasons and, including that (1) testing be conducted by federal laboratories or accredited nonfederal laboratories; and (2) the results of such testing be sent directly to the Food and Drug Administration (FDA).
- Requires the Secretary to review state or local food recalls to evaluate the need for a national recall or other compliance and enforcement activities.
- Requires the Secretary to report to the relevant congressional committees on the progress in implementing a national food emergency response laboratory network.

Section 203 – *Integrated consortium of laboratory networks*

- Directs DHS to maintain an agreement through which relevant laboratory network members will (1) agree on common laboratory methods in order to facilitate the sharing of knowledge and information; (2) identify means by which each member could work cooperatively to optimize national laboratory preparedness and provide surge capacity during emergencies; and (3) engage in ongoing dialogue and build relationships that will support a more effective and integrated response during emergencies.
- Sets forth biennial reporting requirements.

Section 204 – *Enhancing tracking and tracing of food and recordkeeping*

- Requires the HHS Secretary to (1) improve tracking and tracing of processed foods and fruits and vegetables that are raw agricultural commodities in the event of a food-borne illness outbreak; and (2) establish standards for the type of information, format, and time frame for persons to submit records to aid the Secretary in such tracking and tracing.
- Requires the Secretary to establish a pilot project to explore and evaluate methods for rapidly and effectively tracking and tracing food.
- Requires the Secretary to designate and publish a list of high-risk foods and propose regulations for recordkeeping specific to high-risk foods.
- Generally excludes food that is produced and packaged on a farm from the requirements of this section, limits the requirements on food obtained from fishing vessels, and commingled raw agricultural, and other foods or facilities as the Secretary may exempt.
- Requires farms to respond to requests for information if the Secretary determines it is necessary to protect the public health and prevent or mitigate a food-borne illness outbreak.
- Requires the Secretary to issue a small-entity compliance guide.

Section 205 – *Surveillance*

- Requires the Secretary, acting through the Director of the Centers for Disease Control and Prevention (CDC), to enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses.

- Requires the Secretary to (1) develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies; and (2) complete a review of state and local capacities and needs for enhancement not later than one year after enactment of this Act.
- Reauthorizes appropriations for grants to states and Indian tribes 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.

Section 206 – *Mandatory recall authority*

- Authorizes the Secretary to (1) provide a responsible party (as defined under the reportable food registry law) with an opportunity to cease distribution and recall an adulterated or misbranded article of food, the use of or exposure to which will cause serious adverse health consequences or death to humans or animals; (2) order a responsible party to immediately cease distribution and provide notice to relevant persons if the responsible party does not voluntarily cease distribution of or recall such article of food; and (3) order a recall if the Secretary determines that removal of the article from commerce is necessary, but only after providing an opportunity for an informal hearing.
- Requires the responsible party subject to the order issued to include in its notice such information as is necessary for the warehouse-based third party logistics provider to identify the food.
- Allows the Secretary to limit the recall to the geographic area and markets affected.
- Prohibits the Secretary from initiating a mandatory recall or taking any other action under this section with respect to any alcoholic beverage until the Secretary has provided the Alcohol and Tobacco Tax and Trade Bureau with a reasonable opportunity to cease distribution and recall such article under the Alcohol and Tobacco Tax and Trade Bureau authority.
- Requires the Secretary to create an incident command operation or a similar operation within the Department of Health and Human Services that will begin operations no later than 24 hours after the initiation of a mandatory recall or the recall of an article of food.
- Requires the Secretary to submit an annual report to the Committee on Health, Education, Labor, and Pensions and the Committee on Energy and Commerce on the use of recall authority and any public health advisories issued.
- Makes refusal to obey a recall order a prohibited act under Section 301, and subject to civil penalties under Section 303.

Section 207 – *Administrative detention of food*

- Revises the standard for the administrative detention of food to allow such a detention if the FDA has “reason to believe” that such article is adulterated or misbranded.

Section 208 – *Decontamination and disposal standards and plans*

- Requires the Administration of the Environmental Protection Agency (EPA) to provide support for, and technical assistance to, state, local, and tribal governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency.

Section 209 – *Improving the training of state, local, territorial, and tribal food safety officials*

- Requires the Secretary to set standards and administer training and education programs for the employees of state, local, territorial, and tribal food safety officials relating to the regulatory responsibilities and policies established by this Act.
- Authorizes and encourages the Secretary to conduct examinations, testing, and investigations for the purposes of determining compliance with the food safety provisions of this Act.
- Requires the Secretary to establish a competitive grant program with the National Institute for Food and Agriculture to provide food safety training, education, extension, outreach, and technical assistance projects that will help improve public health by increasing the understanding and adoption of established food safety standards, guidance, and protocols.

Section 210 – *Enhancing food safety*

- Expands the program for grants to states, territories, and Indian tribes for inspections to include grants to (1) undertake examinations, inspections, and investigations, and related food safety activities; (2) train to HHS standards for the examination, inspection, and investigation of food manufacturing, processing, packing, holding, distribution, and importation; (3) build the capacity of the laboratories for food safety; (4) build the infrastructure and capacity of the food safety programs; and (5) take appropriate action to protect the public health in response to a recall of food under the FFDCA.
- Establishes five Integrated Food Safety Centers of Excellence to serve as resources for federal, state, and local public health professionals to respond to foodborne illness outbreaks.

Section 211 – *Improving the reportable food registry*

- Allows the Secretary to require a responsible party to submit to the Secretary consumer-oriented information regarding a reportable food, except with respect to fruits and vegetables that are raw agricultural commodities.

Title III – *Improving the Safety of Imported Food*

Section 301 – *Foreign supplier verification program*

- Requires U.S. importers to perform risk-based foreign supplier verification activities to verify that imported food is produced in compliance with applicable requirements related to hazard analysis and standards for produce safety and is not adulterated or misbranded.

- Requires the Secretary to issue guidance to assist U.S. importers in developing foreign supplier verification programs.
- Allows the Secretary to create exemptions for articles of food imported in small quantities for research and evaluation purposes or for personal consumption, provided that such foods are not intended for retail sale and are not sold or distributed to the public.

Section 302 – *Voluntary qualified importer program*

- Requires the Secretary to (1) establish a program to provide for the expedited review and importation of food offered for importation by U.S. importers who have voluntarily agreed to participate in such program; (2) establish a process for the issuance of a facility certification to accompany food offered for importation by importers who have voluntarily agreed to participate in such programs; (3) and issue a guidance document related to participation and compliance with such program.

Section 303 – *Authority to require import certifications for food*

- Requires imported food that fails to meet requirements for a certification or other assurance of safety to be refused admission.
- Authorizes the Secretary to require that an entity provides a certification or other assurances that the article of food being imported into the United States complies with applicable FFDCA requirements.

Section 304 – *Prior notice of imported food shipments*

- Directs the Secretary to require, prior to importation of an article of food, notice of any country to which such article has been refused entry.

Section 305 – *Building capacity of foreign governments with respect to food safety*

- Directs the Secretary to develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and food industries from which foods are exported to the United States.

Section 306 – *Inspection of foreign food facilities*

- Authorizes the Secretary to enter into arrangements and agreements with foreign governments to facilitate the inspection of registered foreign facilities.
- Requires the Secretary to direct resources to inspections of foreign facilities, supplies, and food types, including facilities that import seafood into the United States.
- Requires food to be refused admission into the United States if permission to inspect the food facility is denied by the facility owner, operator, or agent or the foreign country.
- Requires the Secretary to prepare an inspection report for each inspection conducted.

Section 307 – *Accreditation of third-party auditors and audit agents*

- Sets forth provisions governing the establishment of a system to recognize bodies that accredit third-party

auditors and audit agents to certify that eligible entities meet applicable FFDCA requirements for importation of food into the United States.

Section 308 – *Foreign offices of the Food and Drug Administration*

- Requires the Secretary to establish offices of the Food and Drug Administration (FDA) in foreign countries to provide assistance to ensure the safety of articles of food and other products regulated by the FDA that are exported by such countries to the United States.

Section 309 – *Smuggled food*

- Requires the Secretary to (1) develop and implement a strategy to better identify and prevent the entry of smuggled food into the United States; and (2) notify the DHS Secretary not later than 10 days after identifying a smuggled food that would cause serious adverse health consequences or death to humans or animals.
- Requires a press release to warn consumers and vendors about a potential threat from smuggled food if certain requirements are met.

Title IV – *Miscellaneous Provisions*

Section 401 – *Funding for food safety*

- Authorizes appropriations for FY2010 – FY2014 for the activities of the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and related field activities in the Office of Regulatory Affairs of the FDA. Directs the HHS Secretary to increase the field staff of such centers and office.

Section 402 – *Employee protections*

- Establishes protections for employees of entities involved in the manufacturing, processing, packing, transporting, distribution, reception, holding, or importation of food who provide information relating to any violation of the FFDCA.

Section 403 – *Jurisdiction; authorities*

- Declares that nothing in the Act shall be construed to alter or limit the Act or the authority of several enumerated agencies and laws.

Section 404 – *Compliance with international agreements*

- Declares that nothing in this Act shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.

Section 405 – *Determination of budgetary effects*

- Explains that the budgetary effects of the Act, for the purpose of complying with the Statutory Pay-As-You-Go Act of 2010, shall be submitted for printing in the Congressional Record prior to the vote on passage.