FDA's New Food Safety Law To-Do List

Key Implementation Dates in the FDA Food Safety Modernization Act

Date of Enactment: Jan. 4, 2011

This document was created by the editorial staff of *Food Chemical News* with assistance from the consulting firm of *FDAimports.com*. *Note: Not all of the items on this list are jobs for the FDA. However, in instances where the law assigns a task to the Secretary of Health and Human Services, we have substituted FDA, which is the organization most likely to be given the task.

IN EFFECT NOW

Access to Records

FDA now has authority to demand access to and copies of all records at a food-related company in relation to any article of food that is believed to cause serious health consequences or death to humans or animals. The new law applies to all persons who manufacture, process, pack, distribute, receive, hold or import the article of food. Farms and restaurants are excluded. The FDA officer or designated official requesting the information must present appropriate credentials and a written notice at reasonable times and within reasonable limits. (Inspections of Records: Section 101)

Post-Harvest Processing Report

Should FDA seek to issue any guidance or regulation in relation to the National Shellfish Sanitation Program's Model Ordinance or the agency's Seafood Hazard Analysis Critical Control Points Program to require the post-harvest processing of raw oysters, 90 days in advance the FDA must prepare and submit to the Senate Health Education Labor and Pensions Committee and the House Committee on Energy and Commerce a report that includes: an assessment of how post-harvest processing or other equivalent controls feasibly might be implemented in the fastest, safest and most economical manner; the projected public health benefits of any proposed post-harvest processing; the projected costs of compliance with such measures; the impact of the measures on the sales, cost and availability of raw oysters; criteria for ensuring the standards will apply to imported shellfish; an evaluation of alternative measures; and the extent to which FDA has consulted with other regulatory agencies. The report must be made available to the public. (Requirement for Guidance Relating to Post Harvest Processing of Raw Oysters: Section 114)

Port Shopping

Until the FDA promulgates a final rule in relation to amendments made to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, it is to notify the Department of Homeland Security in all instances where it refuses to admit food into the U.S. so that DHS, acting through the Department of Customs and Border Protection, can better prevent food refused admittance into the U.S. at one port of entry from entering at other ports. (Port Shopping: Section 115)

Increase the Frequency of Inspections

FDA is to increase the frequency of inspections of "all facilities." The agency should inspect domestic, high-risk facilities not less than once in the five-year period following the date of enactment and not less than once every three years thereafter. Facilities not considered to be high risk should be visited not less than once in the seven-year period following enactment and every five years thereafter. FDA is instructed to inspect no less than 600 foreign facilities during the one-year period. In each of the five years following the one year period, HHS shall inspect "not fewer than twice the number of foreign facilities inspected… during the previous year." (Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities and Ports of Entry; Annual Report: Section 201)

Mandatory Recall

If FDA determines, based on information collected from its Reportable Food Registry, that there is reasonable probability that an article of food (other than infant formula) is adulterated or misbranded and the article might cause serious adverse health consequences or death to humans or animals, the agency is to provide the responsible party with an opportunity to cease distribution and recall the article. If the responsible party refuses or fails to comply, FDA may order an immediate cease of distribution and notification of all persons involved in manufacturing, processing, packing, transporting, distributing, receiving, holding, importing and/or selling of the food. (Mandatory Recall Authority: Section 206)

Environmental Cleanup Assistance

The Environmental Protection Agency, in coordination with FDA, the Department of Homeland Security and the United States Department of Agriculture, is to assist state, local and tribal governments in preparing for, assessing, decontaminating and recovering from an agriculture or food emergency. The EPA is to develop and disseminate specific standards and protocols to undertake cleanup, clearance and recovery. At least annually EPA is to administer evaluate and identify weaknesses in decontamination and disposal plans. Plans are to be reviewed no less than biennially. (Decontamination and Disposal Standards and Plans: Section 208)

Foreign Food Facility Inspections

FDA is given permission to enter into arrangements with foreign governments and instructed to direct resources to the inspection of foreign facilities, suppliers and food types, especially those that present high risk to the safety and security of the U.S. food supply. Food is to be refused admission into the U.S. from foreign factories, warehouses and other establishments in instances where the owner, operator or an agent in charge or the government of the foreign country refuses to permit entry by U.S. inspectors. It shall be deemed a refusal if the inspection is not permitted within 24 hours of the request or such other time period as agreed upon by FDA and the foreign entity. (Voluntary Qualified Importer Program: Section 306)

Food Import Certification Requirement

FDA can require, as a condition of granting admission to an article of food for import, that an entity provide a certification that the complies with applicable requirements of the law. Such certification may be provided in the form of shipment-specific certificates or a listing of certified facilities that manufacture, process, pack or hold food. FDA is to consider known safety risks associated with the food and risks associated with the country. (Authority to Require Import Certifications for Food: Section 303)

Permission to Grow FDA's Field Staff

The law authorizes FDA to increase its food-related field staff to: 4,000 in FY 2011; 4,200 in FY2012; 4,600 in FY2013; and 5,000 in FY2014. It calls for an increase of 150 employees by fiscal year 2011 to provide additional detection of and response to food defense threats, and to detect, track and remove smuggled food. (Funding for Food Safety: Section 401)

Whistleblower Protections

Companies in the business of manufacturing, processing, packing, transporting, distributing, receiving, holding or importing food are prohibited from taking punitive actions against employees for providing to the company or enforcement authorities information about or refusing to participate in actions related to violations of this new law. (Employee Protections: Section 402)

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Other Key Changes to Be Implemented in Chronological Order

2011

Feb. 1 2011 (and each year on this date) – FDA is to submit an extensive report to Congress on its efforts to coordinate and cooperate with other agencies in relation to food safety inspections. The reports are to be made available to the public. (Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities and Ports of Entry; Annual Report: Section 201)

April 4, 2011 (90 days from enactment) -- FDA must modify its website to include a consumer-friendly search engine that provides relevant information regarding each article of food that has been subject to recall. (Mandatory Recall Authority: Section 206)

April 4, 2011 (90 days from enactment) – The Government Accountability Office is to submit a report to Congress that identifies state and local agencies with the authority to require mandatory food recalls. The report is to evaluate mechanisms available to compensate for instances when a recall was ordered in error. If the GAO determines such a mechanism does not exist, within 90 days of its review, the USDA is required to conduct a study of the feasibility of implementing a farmer indemnification program to provide for losses sustained as a result of a mandatory recalls made in error. (Mandatory Recall Authority: Section 206)

May 4, 2011 (120 days from enactment) – FDA is to issue an interim final rule that amends 21 CFR (subpart K of part 1) to allow for the agency to hold food for a short period of time when it believes it is adulterated or misbranded. Regardless of whether FDA issues the interim final rule, the amendment itself will be effective by July 3 (180 days from enactment). (Administrative Detention of Food: Section 207)

July 3, 2011 (180 days from enactment) – Food facilities, as defined in the Public Health Security and Bioterrorism and Response Act of 2002, must register with the FDA and renew their registration biennially. The facility's registration may be suspended if the agency has reasonable probability that food from the facility will cause serious adverse health consequences or death to humans or animals. The registration requirement can be implemented sooner if FDA is able to promulgate regulations. (Registration of Food Facilities: Section 102)

July 3, 2011 (180 days from enactment) – FDA is to coordinate with the Department of Homeland Security to develop and implement a strategy to better identify smuggled food and prevent its entry into the U.S. (Smuggled Food: Section 309)

July 3, 2011 (180 days from enactment) – FDA is to conduct a study in relation to the exemption for small businesses from the requirements for hazard analysis and risk-based preventive control plans. The study, which is to involve the USDA, is to include the information necessary to define the terms "small business" and "very small business" in relation to the exemption. (Hazard Analysis and Risk-Based Preventive Controls Section 103)

July 3, 2011 (180 days from enactment) – FDA must issue a "small entity compliance guide" that sets forth, in plain language, the requirements for a hazard analysis plan. (Hazard Analysis and Risk-Based Preventive Controls Section 103)

July 3, 2011 (180 days from enactment) – FDA must update the Fish and Fisheries Product Hazards and Control Guidance to take into account advances in technology. (Hazard Analysis and Risk-Based Preventive Controls: Section 103)

July 3, 2011 (180 days from reenactment) FDA must publish in the *Federal Register* a proposed set of guidelines for determining the burden of re-inspection fee amounts on small businesses. (Authority to Collect Fees: Section 107)

July 3, 2011 (180 days from enactment) – The Department of Homeland Security, in coordination with FDA and USDA, is to submit to the relevant committees of Congress and make publicly available on the Internet a report on the activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council. (Food and Agriculture Coordinating Councils: Section 109)

July 3, 2011 (180 days from enactment) – FDA is to publish guidance clarifying when a dietary supplement ingredient is a new dietary ingredient and the manufacturer or distributor of the ingredient or supplement must provide information to the agency. (New Dietary Ingredients: Section 113)

July 3, 2011 (180 days from enactment and biennially thereafter) – FDA is to submit to relevant congressional committees and make publicly available on the Internet a report on the progress of creating a national food emergency response laboratory network. Among other jobs, this network is to provide "ongoing surveillance, rapid detection and surge capacity for large-scale, food-related emergencies, including intentional adulteration of the food supply," while coordinating the capacities of state, local and tribal food laboratories. (Laboratory Accreditation for Analyses of Foods: Section 202)

July 3, 2011 (180 days from enactment) -- FDA is to enter into one or more memoranda of understanding or cooperative agreements with USDA to establish a competitive grant program with the National Institute for Food and Agriculture to provide food safety training and technical assistance to owners and operators of farms, small food processors and small fruit/vegetable merchant wholesalers. Appropriations are authorized for fiscal years 2011 through 2015. (Improving the Training of State, Local, Territorial and Tribal Food Safety Officials: Section 209)

July 3, 2011 (180 days from enactment) -- FDA is to establish a working group to make recommendations regarding the designation of at least five Integrated Food Safety Centers of Excellence. These Centers shall be headquartered at selected state health departments and should partner with one or more institutions of higher education. The Centers are to providing training for epidemiological and environmental investigations of foodborne illness, establish fellowship and scholarships to train future epidemiological and food safety leaders and to address critical workforce shortages, etc. (Enhancing Food Safety: Section 210)

July 3, 2011 (180 days from enactment) – FDA is to implement a strategy to better identify smuggled food and prevent its entry into the U.S. Not later than 10 days after the agency identifies a smuggled food item that would cause serious adverse health consequences, it is to notify the Department of Homeland Security. (Smuggled Food: Section 309)

Oct. 1, 2011 (270 days from enactment) -- FDA is to establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of contaminated food to prevent or mitigate a foodborne illness. FDA is to conduct one or more pilot projects with the processed food sector and one or more with processors or distributors of fruits and vegetables that are raw agricultural commodities. The projects must include at least three different types of food that have been subject to significant outbreaks during the previous five-year period. A report is due to Congress on July 4, 2012 (18 months from enactment). (Enhancing Tracking and Tracing of Food and Recordkeeping Requirements: Section 204)

Oct. 4, 2011 (nine months from enactment) – FDA must issue proposed rulemaking

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governing the safety of food packed or held by a farm when it is not grown, raised, or consumed on such farm or another farm under the same ownership. Final rules are due with nine months of the close of the comment period for the proposed rulemaking (roughly May 2012). (Hazard Analysis and Risk-based Preventive Controls: Section 103)

Oct. 1, 2011 -- FDA shall submit to Congress a report on the basis for the selection of foreign countries in which the agency establishes offices and the progress made by these offices with respect to assisting the governments of other countries in providing safe articles of food and other products regulated by FDA for export to the U.S. FDA is directed to consult with the Department of State, Department of Homeland Security and the U.S. Trade Representative. (Foreign Offices of the Food and Drug Administration: Section 308)

2012

Jan. 4, 2012 (one year from enactment) – FDA must issue a guidance document regarding the exemption for very small businesses from new requirements for hazard analysis and risk-based preventive control plans. (Hazard Analysis and Risk-based Preventive Controls: Section 103)

Jan. 4, 2012 (one year from enactment) -- FDA must publish updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce. It is to consult with the USDA, state agriculture departments, farmer representatives and various other entities. FDA is to hold no less than three public meetings in geographically diverse areas. (Standards for Produce Safety: Section 105)

Jan. 4, 2012 (one year from enactment) – FDA, in coordination with USDA's National Organic Program and the Department of Homeland Security, is to publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of fruits and vegetables. During the comment period, at least three public meetings must be held in geographically diverse areas. A final regulation is due within one year of the close of the comment period (approximately March 2013). (Standards for Produce Safety: Section 105)

Jan. 4, 2012 (one year from enactment) -- FDA must issue guidance documents related to protection against the intentional adulteration of food, including mitigation strategies. These documents must include a model assessment, examples of mitigation strategies or measures, and specify situations in which these measures are appropriate. (Protection Against Intentional Adulteration: Section 106)

Jan. 4, 2012 (one year from enactment) -- FDA and USDA, in coordination with the Department of Homeland Security, shall prepare and transmit to the relevant committees of Congress and make available on the Internet the "National Agriculture and Food Defense Strategy." The strategy is to include a coordinated research agenda for use by the different agencies. (National Agriculture and Food Defense Strategy: Section 108)

Jan. 4, 2012 (one year from enactment) -- FDA is to conduct a study regarding the need for and challenges related to developing a program of unique identification numbers for each registered food facility and each broker that imports food into the U.S. The study is to evaluate the costs of creating such a system. By April 4, 2012 (15 months after enactment), FDA is to submit a report to Congress describing its findings. (Building Domestic Capacity: Section 110)

Jan. 4, 2012 (one year from enactment) – The Department of Health and Human Services is to conduct an evaluation of each program it administers to determine their effectiveness and submit a report to Congress. (Building Domestic Capacity: Section 110)

Jan. 4, 2012 (one year from enactment) – FDA, in consultation with the Department of Education, is to develop guidelines for managing the risk of food allergy and anaphylaxis in schools and early childhood education programs. (Food Allergy and Anaphylaxis Management: Section 112)

Jan. 4, 2012 (one year from enactment) -- FDA shall designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary. A new proposal for recordkeeping requirements is due two years from the enactment date (on Jan. 4, 2013). (Enhancing Tracking and Tracing of Food and Recordkeeping: Section 204)

Jan. 4, 2012 (one year from enactment) – FDA is to complete a review of state and local capacities and needs for enhancement, which may include a survey with respect to staffing levels and expertise available, lab capacity and information systems. (Surveillance: Section 205)

Jan 4. 2012 (one year from enactment) – FDA, through the Centers for Disease Control and Prevention, shall designate 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. (Enhancing Food Safety: Section 210)

Jan. 4, 2012 (one year from enactment) – FDA is to develop and publish a list of acceptable conspicuous locations and manners from which grocery stores shall be required to publish a one page summary about recalled food items. The summary language will come from the FDA website and must be displayed for 14 days. The requirement to publish the one page summary goes into effect on July 4, 2012. (Improving the Reportable Food Registry: Section 211)

Jan. 4, 2012 (one year from enactment) – FDA is to promulgate regulations to provide for the content of a foreign supplier verification program. The program of each importer must be adequate to provide assurances that the imported food is in compliance with certain processes and procedures, including reasonably appropriate risk-based preventive controls. Verification activities may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan and periodically testing and sampling shipments. By the same date FDA is to issue guidance to assist importers in developing foreign supplier verification programs. Records in relation to the foreign supplier verification program are to be maintained for not less than two years and be made available promptly to an authorized representative of the Secretary upon request. (Foreign Supplier Verification Program: Section 301)

July 4, 2012 (18 months from enactment) – FDA is to submit a report to Congress on the findings of its traceability pilot projects. (Enhancing Tracking and Tracing of Food and Recordkeeping: Section 204)

July 4, 2012 (18 months from date of enactment) – FDA must promulgate regulations related to new requirements that owners, operators and agents in charge of food-related facilities evaluate hazards that could affect food manufactured, processes, packed, or held, identifying and implementing preventive controls. Standards are to be "science-based and provide sufficient flexibility to be practicable for all sizes and types of facilities." FDA is to define small and very small businesses for exemption purposes. (Hazard Analysis and Risk-Based Preventive Controls: Section 103)

July 4, 2012 (18 months from enactment) -- FDA may begin to require a responsible party to submit consumer-oriented information regarding a reportable food that includes a description of the food, affected product identification codes, contact information, and any other information deemed necessary. A one-page summary must be published on FDA's website that can be easily

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printed by a grocery story for consumer notification. Grocery stores with 15 or more physical locations will have 24 hours from the creation of this page to display the information prominently. The information must be displayed for 14 days. (Improving the Reportable Food Registry: Section 211)

July 4, 2012 (18 months from enactment) -- FDA is to establish a program in consultation with the Department of Homeland Security to provide for the expedited review and importation of food for importers who have voluntarily agreed to participate. A guidance document is due by the same date. An importer that intends to participate in the program in a fiscal year is required to submit a notice and filled out application. Qualified importers shall be reevaluated not less often than once every three years.(Voluntary Qualified Importer Program: Section 302)

July 4, 2012 (18 months from enactment) -- FDA is to promulgate regulations to implement its new third-party auditing accreditation system for foreign governments and inspection agencies. The regulations are to include requirements that the third-party audits are "unannounced" and spell out the timing and public disclosure requirements as well as the fees to be paid. (Accreditation of Third-Party Auditors: Section 307)

July 4, 2012 (18 months after enactment) -- The FDA, in consultation with the Department of Homeland Security and USDA, shall promulgate regulations to protect against the intentional adulteration of foods. The regulations shall specify how to assess whether mitigation strategies are required and "specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points, as appropriate." These regulations are only to apply to food for which there is a high risk of intentional contamination. This section exempts farms, except for those that produce milk. (Protection Against Intentional Adulteration: Section 106)

July 4, 2012 (18 months from enactment) -- FDA must issue regulations mandating the sanitary transportation of food. FDA must also conduct a study on the transportation of food for consumption in the U.S., including transportation by air. (Sanitary Transportation of Food: Section 111)

2013

January 4, 2013 (two years from enactment) – FDA is to deliver a comprehensive report to Congress that identifies programs and practices intended to promote the safety and supply chain security of food and to prevent outbreaks through preventive practices. This report and biennial reports thereafter are to address risk-related approaches, laboratory accreditation and IT-related needs. The report is to provide an analysis of FDA's performance during the preceding five years in relation to surveillance, outbreak response and traceability. (Building Domestic Capacity: Section 110)

Jan. 4, 2013 (two years from enactment) -- FDA shall establish a program for the testing of food by accredited laboratories. The agency is to create a publicly available registry of accreditation bodies and "model standards" that include: appropriate sampling and analytical procedures; commercially available techniques; internal quality systems; procedures to evaluate complaints regarding analyses; and qualifications for individuals. Foreign labs may be accredited. At least once every five years, FDA is to reevaluate the accreditation bodies and may accompany auditors working for the accreditation bodies. Six months later (July 4, 2013), food testing is to be conducted by federal or nonfederal labs that have been accredited. (Laboratory Accreditation for Analyses of Foods: Section 202)

Jan. 4, 2013 (two years from enactment) -- FDA is to publish a proposal to establish recordkeeping requirements for facilities that manufacture, process, pack or hold foods designated as high risk. FDA must set an appropriate effective date for additional requirements. The records may be required to be retained for not more than two years. By Jan. 4, 2012 (one year from enactment), FDA was to have designated high risk foods for which the additional recordkeeping requirements are appropriate and necessary. (Enhancing Tracking and Tracing of Food and Recordkeeping: Section 204)

Jan. 4, 2013 (two years from enactment and annually thereafter) -- FDA is to submit a report to the Senate Health Education Labor and Pension Committee and the House Energy and Commerce Committee on the use of its mandatory recall authority. (Mandatory Recall Authority: Section 206)

Jan. 4, 2013 (two years from enactment) -- FDA is to submit a report to Congress on the effectiveness of its five new Integrated Food Safety Centers of Excellence and provide legislative recommendations or describe additional resources required. (Enhancing Food Safety: Section 210).

Jan. 4, 2013 (two years from enactment) -- Importers must maintain foreign supplier verification programs as spelled out by FDA regulations. The program of each importer must be adequate to provide assurances that the imported food is in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as required of U.S. companies. (Foreign Supplier Verification Program: Section 301)

Jan. 4, 2013 (two years from enactment) – FDA shall develop a comprehensive plan to expand the technical, scientific and regulatory food safety capacity of foreign governments and the respective food industries from which foods are exported. FDA is to consult with USDA, the Department of State, the Department of Homeland Security, the U.S. Trade Representative and the Department of Commerce, as well as representatives of the food industry, appropriate foreign government officials, consumer groups and other stakeholders. The plan is to include: recommendations for bilateral and multilateral arrangements and agreements; provisions for secure electronic data sharing; mutual recognition of inspection reports; the training of foreign governments and producers on U.S. requirements for safe food; recommendations on whether or how to harmonize under Codex; provisions for the multilateral acceptance of lab methods; and detection techniques. (Building Capacity of Foreign Governments with Respect to Food Safety: Section 305)

January 4, 2013 (two years from enactment) -- FDA shall establish a system for the recognition of accreditation bodies that accredit third-party auditors, defined as a foreign government, the agency of a foreign government, a foreign cooperative or any other third party that FDA deems appropriate. If, two years after the date of establishment of this system, FDA has not identified and recognized an accreditation body to meet the requirements of this section, the agency itself may directly accredit third-party auditors. (Accreditation of Third-Party Auditors: Section 307)

By July 4, 2013 (30 months from enactment) -- Food testing is to be conducted by federal or nonfederal labs that have been accredited. Results are to be sent to the FDA. (Laboratory Accreditation for Analyses of Foods: Section 202)

