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Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)

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Summary

Congress passed comprehensive food safety legislation in December 2010 (FDA Food Safety Modernization Act, or FSMA, P.L. 111-353), representing the largest expansion and overhaul of U.S. food safety authorities since the 1930s. FSMA greatly expanded food safety oversight authority at the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services (HHS). Among its many provisions, FSMA expanded FDA's authority to conduct a mandatory recall of contaminated food products; enhanced surveillance systems to investigate foodborne illness outbreaks; established new preventive controls and food safety plans at some food processing facilities and farms; enhanced FDA's traceability capacity within the nation's food distribution channels; increased inspection frequencies of high-risk food facilities (both domestic and foreign facilities); and expanded FDA's authority and oversight capabilities with regard to foreign companies that supply food imports to the United States.

Under FSMA, FDA is responsible for more than 50 regulations, guidelines, and studies. This included seven "foundational" rules required to fully implement FSMA covering:

(1) **Preventive Controls for Human Food:** Requires that food facilities have safety plans that set forth how they will identify and minimize hazards.

(2) **Preventive Controls for Animal Food:** Establishes Current Good Manufacturing Practices and preventive controls for food for animals.

(3) **Produce Safety:** Establishes science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms.

(4) **Foreign Supplier Verification Program:** Importers will be required to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of U.S. food producers.

(5) **Third Party Certification:** Establishes a program for the accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities producing food for humans or animals.

(6) **Sanitary Transportation:** Requires those who transport food to use sanitary practices to ensure the safety of food.

(7) **Intentional Adulteration:** Requires domestic and foreign facilities to address vulnerable processes in their operations to prevent acts intended to cause large-scale public harm.

These regulations were to have been proposed or, in some cases, finalized within one to two years of enactment (roughly January 2012 and January 2013); other rules were to have been submitted within 18 months of enactment (roughly mid-2012). However, many of these regulations did not become final until 2015, and regulations for two rules have yet to be finalized. Other FDA actions under FSMA also have been delayed. Several factors have contributed to delays in FSMA implementing, including the Office of Management and Budget's (OMB's) review process, extensions in the public comment and response period for many of FDA's proposed rules and the agency's re-proposal of key provisions of some major regulations, and also, according to FDA, limited agency resources and the lack of availability of discretionary appropriations. Delays in FDA's rulemaking process resulted in many FSMA regulations being released according to a court-ordered schedule under a federal lawsuit brought by the Center for Food Safety.

This report documents the scheduled timeline for action on selected FSMA provisions, as specified in the enacted law, and FDA-reported actions taken to date, based on available FDA press releases and publicly available progress reports.

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Congress passed comprehensive food safety legislation in December 2010 (FDA Food Safety Modernization Act, or FSMA, P.L. 111-353), which was signed into law on January 4, 2011. FSMA represented the largest expansion and overhaul of U.S. food safety authorities since the 1930s. FSMA greatly expanded food safety oversight authority at the Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services (HHS), but did not alter oversight authorities within other federal agencies responsible for food safety, such as the U.S. Department of Agriculture.

Under FSMA, FDA is responsible for more than 50 regulations, guidelines, and studies. These included several "foundational" rules required to fully implement FSMA covering preventive controls for human food and for animal food, produce safety, sanitary transportation, intentional adulteration, and development of a Foreign Supplier Verification Program along with a program for the accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities producing food for humans or animals. Most of these regulations become final in 2015 and 2016. This report documents the scheduled timeline for action on selected FSMA provisions, as specified in the enacted law, and FDA-reported actions taken to date.

Overview of FSMA Provisions

FSMA focused on FDA-regulated foods and amended FDA's existing structure and authorities, in particular the Federal Food, Drug, and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.). Among its many provisions, FSMA expanded FDA's authority to conduct a mandatory recall of contaminated food products; enhanced surveillance systems to investigate foodborne illness outbreaks; established new preventive controls and food safety plans at some food processing facilities and farms; enhanced FDA's traceability capacity within the nation's food distribution channels; increased inspection frequencies of high-risk food facilities (both domestic and foreign facilities); and expanded FDA's authority and oversight capabilities regarding foreign companies that supply food imports to the United States. FSMA does not directly address meat and poultry products under the jurisdiction of USDA.

When the law was enacted, FDA has identified five key elements of FSMA:[1]

- **Preventive controls**—FSMA provides FDA with a legislative mandate to require comprehensive, prevention-based controls across the food supply. As examples, the act requires mandatory preventive controls for food facilities and mandatory produce safety standards, and also gives FDA the authority to prevent intentional contamination.
- **Inspection and Compliance**—FSMA provides FDA with the ability to conduct oversight and ensure compliance with new requirements and to respond when problems emerge. Examples include establishing a mandated inspection frequency (based on risk);[2] giving FDA access to industry records and food safety plans; and requiring certain testing to be conducted by accredited labs.

[1] See, for example, FDA, "Questions and Answers on the Food Safety Modernization Act," "The New FDA Food Safety Modernization Act (FSMA)," and "Background on the FDA Food Safety Modernization Act (FSMA)."

[2] FSMA specified that all "high-risk" domestic facilities must be inspected within five years of enactment. High-risk facilities will be identified based on "known safety risks of the facilities" according to "known safety risks of the food manufactured, processed, packed, or held at the facility, ... compliance history of a facility, including ... food recalls, outbreaks of foodborne illness, and violations of food safety standards" and "the rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls" among other factors stated in the law (P.L. 111-353, §201).

- **Response**—FSMA provides FDA with the ability to respond to problems when they emerge. Examples include giving FDA mandatory recall authority for all food products; expanding FDA's authority to administratively detain products that are in violation of the law; giving FDA the authority to suspend a facility's registration, effectively prohibiting the company from selling any products within the United States;[3] establishing pilot projects so FDA can enhance its product tracing capabilities; and requiring additional recordkeeping by facilities that "manufacture, process, pack or hold" foods designated as "high-risk."
- **Imported Food Safety**—FSMA provides FDA with the ability to help ensure that food imports meet U.S. food safety standards. Examples include requiring importers to verify that their foreign suppliers have adequate preventive controls; establishing a third-party verification system; requiring certification by a credible third party for high-risk foods as a condition for entry into the United States; establishing a voluntary qualified importer program for expedited review and entry from participating importers; and giving FDA the right to refuse entry into the United States of food from a foreign facility if FDA is denied access to the facility or the country where the facility is located.
- **Enhanced Partnerships**—FSMA provides FDA with the authority to improve training of state, local, territorial, and tribal food safety officials. Examples include requiring FDA to develop and implement strategies to enhance the food safety capacities of state and local agencies through multi-year grants, as well as strategies to enhance the capacities of foreign governments and their industries; and giving FDA the authority to rely on inspections of other federal, state, and local agencies in meeting its increased inspection mandate for domestic facilities.

FSMA authorized additional appropriations and staff for FDA's future food safety activities. The Congressional Budget Office (CBO) estimated that implementing the newly enacted law could increase net federal spending subject to appropriations by $1.4 billion over a five-year period (FY2011-FY2015).[4] FSMA authorizes an increase in FDA staff, to reach 5,000 in FY2014.

During the regulatory development phase of FSMA, seven "foundational" rules were identified as required to fully implement FSMA (see listing in text box below).[5] These regulations were to have been proposed or, in some cases, finalized within one to two years of enactment (roughly January 2012 and January 2013); other rules were to have been submitted within 18 months of enactment (roughly mid-2012). However, many of these regulations did not become final until 2015, and regulations for two rules—Intentional Adulteration (FSMA §106) and Sanitary Transportation of Human and Animal Food proposal (FSMA §111)—are scheduled to be finalized in 2016. Some other FDA actions under FSMA have been delayed. **Table 1** documents the scheduled timeline for action on selected FSMA provisions, as specified in the law, and FDA-reported actions taken to date, based on available FDA press releases and publicly available progress reports. For more information about each of these provisions, see Appendix B in CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*.

[3] If a facility's food is found to have a "reasonable probability of causing serious adverse health consequences or death." FDA exercised this authority for the first time in November 2012 when it suspended the registration of Sunland Inc., a peanut butter processor, because of concerns linking the plant to a *Salmonella* outbreak.

[4] CBO, cost estimate, "S. 510, Food Safety Modernization Act, as reported by the Senate Committee on Health, Education, Labor, and Pensions on December 18, 2009, Incorporating a Manager's Amendment Released on August 12, 2010," August 12, 2010.

[5] See, for example, FDA, "Frequently Asked Questions on FSMA."

Seven "Foundational" Rules Required to Fully Implement FSMA

(1) **Preventive Controls for Human Food:** Requires that food facilities have safety plans that set forth how they will identify and minimize hazards (FSMA §103).

(2) **Preventive Controls for Animal Food:** Establishes Current Good Manufacturing Practices and preventive controls for food for animals (FSMA §103).

(3) **Produce Safety:** Establishes science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms (FSMA §105(a)).

(4) **Foreign Supplier Verification Program:** Importers will be required to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of U.S. food producers (FSMA §301(a)).

(5) **Third Party Certification:** Establishes a program for the accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities producing food for humans or animals (FSMA §307).

(6) **Sanitary Transportation:** Requires those who transport food to use sanitary practices to ensure the safety of food (FSMA §111).

(7) **Intentional Adulteration:** Requires domestic and foreign facilities to address vulnerable processes in their operations to prevent acts intended to cause large-scale public harm (FSMA §106(b)).

Delays in FSMA's Implementation Schedule

FDA began to release proposed rules for some of the foundational regulations that constitute the food safety framework under FSMA in 2013. However, there were continued delays in the agency's release of other FSMA rules, industry guidance, and reports, well beyond the dates required under the law. These delays were exacerbated by FDA's decision to extend the public comment and response period for most FSMA proposed regulations as well as the agency's decision to re-propose key provisions of some regulations. Other factors also contributed to delays in FSMA implementation, including oftentimes a lengthy review process by the Office of Management and Budget's (OMB) and—according to FDA—limited agency resources and the lack of availability of discretionary appropriations. Delays in FDA's rulemaking process resulted in many FSMA regulations being released according to a court-ordered schedule under a federal lawsuit brought by the Center for Food Safety.

Delayed Publication of FDA's Proposed Rules

Publication of FDA proposed regulation often took place well after FSMA's mandated rulemaking schedule. Most of the law's key regulations were not proposed until 2013, with some proposals being delayed until later that same year. For example, proposed rules regarding Preventive Controls for Human Food (FSMA §103) and Produce Safety Standards (FSMA §105) were both released in January 2013. Two other related rules regarding imported foods—Foreign Supplier Verification Program (FSMA §301) and Standards for Third-Party Auditors (FSMA §307)—were not released until July 2013. Proposed requirements for Preventive Controls for Food for Animals (FSMA §103) were not released until October 2013, followed by proposed requirements for Intentional Adulteration (FSMA §106) in December 2013. FDA's Sanitary Transportation of Human and Animal Food proposal (FSMA §111) was released in February 2014.

For some proposed rules, press reports indicated that several proposals were held up, often for many months, by OMB's review process.[6] It was also reported that OMB made changes to several proposed rules while in review.[7]

Extensions in Public Comment and Response Period

Some FSMA proposed rules were granted multiple extensions for public comment and review. For example, FDA's first two proposed foundational rules—Preventive Controls for Human Food (FSMA §103) and Produce Safety Standards (FSMA §105)—were released in January 2013 but later granted a series of extensions, eventually closing on November 15, 2013. These extensions were requested by a wide range of stakeholders, given the complexity of the regulations as well as FDA's delayed release of other related FSMA rules that some groups argued needed to be considered together as a full regulatory package.

FDA's Decision to Re-Propose Certain Key Provisions

Further delay in FDA's implementation of FSMA is attributable to FDA's announcement that would re-propose key provisions in some of its proposed regulations. In the agency's December 2013 announcement, it acknowledged that "significant changes will be needed in key provisions of the two proposed rules affecting small and large farmers," namely regulations implementing Preventive Controls for Human Food (FSMA §103) and also Produce Safety Standards (FSMA §105).[8] Provisions that FDA plans to change "include water quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities, and procedures for withdrawing the qualified exemption for certain farms."[9] Some stakeholders expect further changes to other provisions in these proposed rules.[10] In March 2014, FDA announced it would also re-propose regulations implementing a second preventive controls regulation, namely the Preventive Controls for Food for Animals (FSMA §103).[11]

FDA had suggested that they would likely publish the re-proposed sections of these rules at or very near to the same time. The agency also indicated that it will accept "additional comments only on those sections of the proposed rules that have been revised," recognizing the "court order regarding the timelines for finalizing these rules."[12] In September 2014, FDA re-proposed certain aspects of four major proposed rules, including preventative controls for both human food and animal food (FSMA §103(a) and (c)), produce safety (FSMA §105(a)), and the Foreign Supplier Verification Program (FSMA §301(a)).

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[6] See, for example, D. ElBoghdady, "Food-Safety Rules in Limbo at Office of Management and Budget," *Washington Post*, May 2, 2012; and M. Patoka, "Three Food Safety Rules Grow Moldy at OIRA as Import-Related Outbreaks Continue," *Food Safety News*, June 26, 2013.

[7] See, for example, J. Murphy, "HHS Documents Reveal OMB Edits of Original FSMA Preventive Controls Proposal," *Food Chemical News*, March 22, 2013; J. Murphy, "OMB Removed Mandatory Onsite Audits from FSVP Proposal, Internal Documents Show," *Food Chemical News*, October 25, 2013.

[8] FDA, "Statement from FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers," December 19, 2013.

[9] Ibid.

[10] See, for example, D. Flynn, "Letter from the Editor: Produce Growers Get Early Christmas Present," *Food Safety News*, December 22, 2013.

[11] FDA, "Update on Proposed Rules Under the FDA Food Safety Modernization Act," March 19, 2014.

[12] FDA, "Statement from FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers," December 19, 2013.

Congress pushed FDA to consider rewriting these proposed regulations. Several Members of Congress have submitted a series of letters to FDA requesting that the agency release a second set of proposed rules and solicit public comment before going final. Within Congress, two letters were sent to FDA on November 22, 2013, including a House-Senate letter from Senators Shaheen and Blunt and Representatives Courtney and Gibson, and a letter from members of the House Organic Caucus, each expressing concerns about the proposed requirements in FDA's produce rule, among other concerns. A third letter was sent to FDA on November 13, 2013, by Senators Tester and Hagan expressing concerns about the effects of the proposed rules on small farms and facilities.[13] Another letter was sent on November 15, 2013, from Members from Vermont (Senators Leahy and Sanders, and Representative Welch), urging FDA to re-propose these rules.[14] A wide range of stakeholders have also expressed similar concerns and are supporting FDA's reexamination of some of its proposed regulations.[15]

Other congressional actions taken regarding FSMA include the addition of a provision in the enacted 2014 farm bill (P.L. 113-79, §12311) requiring FDA to provide Congress with a scientific and economic analysis of FSMA, including an analysis of how the law affects farm businesses of all sizes, prior to implementing final regulations under the law.[16] Recent appropriations bills also have addressed certain aspects of FDA's implementation of regulations under FSMA. As part of the enacted FY2014 appropriations, Congress directed FDA to implement a "comprehensive training program" for federal and state inspectors and commended FDA for its decision to revise its proposed rules affecting farmers.[17] As part of the enacted FY2015 and FY2016 Agriculture appropriations, both the House and Senate Appropriations Committees made a number of recommendations in their respective bills regarding FDA's ongoing efforts to develop FSMA-related regulations and guidance.[18] Both committees have addressed FSMA's re-proposal of certain key regulations regarding food safety preventive controls for both human and animal food, and standards for produce, and have also expressed a range of concerns as FDA has developed regulations under FSMA, including concerns about extensive delays in FDA's rulemaking and implementation of FSMA.

Budgetary and Staff Resources

Limited resources and the availability of discretionary appropriations might also have affected FDA's rollout and full implementation of FSMA.[19] Although the law authorized appropriations, it did not provide the actual funding needed for FDA to perform these activities. When the law was being debated in Congress, CBO had estimated that implementing the law could increase net federal spending subject to appropriation by about $1.4 billion over a five-year period (FY2011-

[13] Links to three of these congressional letters are provided at the National Sustainable Agriculture Coalition (NSAC) website (http://sustainableagriculture.net/blog/congress-fsma-letters/).

[14] "Vermont Lawmakers Urge Re-Write of FSMA Rules," *Food Chemical News*, November 29, 2013.

[15] Public comments are in FDA's rulemaking docket. Also see comments posted by the National Association of State Departments of Agriculture; United Fresh Produce Association; and the National Sustainable Agriculture Coalition.

[16] For farm bill information, see CRS Report R43076, *The 2014 Farm Bill (P.L. 113-79): Summary and Side-by-Side.*

[17] P.L. 113-76. Explanatory Statement Regarding the House Amendment to the Senate Amendment on H.R. 3547.

[18] For more information, see CRS Report R44309, *FY2016 Appropriations: Selected Federal Food Safety Agencies*, and also CRS Report R43669, *Agriculture and Related Agencies: FY2015 Appropriations.*

[19] See annual FDA Budget Explanatory Notes for Committee on Appropriations, various years, http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/default.htm. Also see letter from Leslie Kux, FDA's Assistant Commissioner for Policy, to U.S. District Court judges regarding a food labeling policy, January 6, 2014.

FY2015).[20] The Obama Administration has repeatedly requested that additional user fees be implemented to cover some of these costs, which Congress has not approved. Increases in appropriated funding for FDA's Food Program have not matched the Administration's additional requested user fees. Staff levels at FDA also have remained below levels authorized in FSMA, with an estimated 3,700 FDA staff working on food-related activities in FY2014.[21] As part of the agency's implementation of FSMA, FDA has conducted stakeholder outreach, hosted public meetings, and released web videos and other written materials and presentations.[22]

During the past six years (FY2011-FY2016), enacted budgetary changes for food safety and FSMA implementation (as reported by congressional appropriators) have totaled nearly $300 million.[23] This amount includes the enacted FY2016 Agriculture appropriation for FDA food safety activities, which provided for a $104.5 million increase in budget authority to "assist the FDA in preparation for the implementation of FSMA prior to the effective dates of the seven foundational proposed rules."[24] Previously, FDA reported that an additional $400 million to $450 million per year above the FY2012 base is needed to fully implement FSMA.[25] Available FDA funding for FSMA implementation and other food safety activities has been lower than what FDA has said it needs to fully implement the law.

Lawsuit and Court-Order Deadlines for Final Rules

In August 2012, the Center for Food Safety (CFS)[26] filed suit in federal court against FDA and OMB, citing the government's failure to implement seven food safety regulations required by FSMA (see box below).[27] CFS argues that, by not meeting statutory deadlines for rulemaking, FDA is breaking the law and needs to protect the public.

FDA filed a motion to dismiss the complaint against the agency in November 2012,[28] which was denied by the court in April 2013.[29] As part of a June 2013 agreement, FDA was ordered to complete the regulations as follows: by November 30, 2013, publish all remaining proposed regulations; by March 31, 2014, close any comment period on these proposed regulations; and by June 30, 2015, finalize all regulations.[30]

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[20] CBO, cost estimate, "S. 510, Food Safety Modernization Act, as Reported by the Senate Committee on Health, Education, Labor, and Pensions on December 18, 2009," August 12, 2010.

[21] FSMA, P.L. 111-353, §401. By fiscal year, staff level increases were authorized at a total of not fewer than 4,000 staff members (FY2011); 4,200 staff (FY2012); 4,600 staff (FY2013); and 5,000 staff (FY2014).

[22] For information, see FDA's FSMA website, http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359450.htm.

[23] For more information on FDA's budget for the agency's food safety activities and FSMA implementation, CRS Report R44309, *FY2016 Appropriations: Selected Federal Food Safety Agencies*.

[24] H.Rept. 114-205, S.Rept. 114-82.

[25] FDA, *Building Domestic Capacity to Implement the FDA Food Safety Modernization Act (FSMA)*, May 2013.

[26] The Center for Food Safety is a national nonprofit public interest and environmental advocacy organization that has been tracking FDA's implementation of FSMA, as have other public health organizations, such as the Center for Science in the Public Interest (CSPI).

[27] Center for Food Safety, et al. v. Margaret E. Hamburg, M.D., et al., Case No. 12 CV 4529 (N.D. Cal. 2012), August 29, 2012. The original complaint is at http://www.centerforfoodsafety.org/issues/308/food-safety/legal-actions. Other information on the case is available at CFS' website (http://www.centerforfoodsafety.org).

[28] FDA's motion to dismiss is at http://www.foodsafetynews.com/files/2012/12/FDA-motion-to-dismiss.pdf.

[29] The April 2013 court decision on the case is at http://www.centerforfoodsafety.org/files/57-sj-decision_76498.pdf.

[30] The June 2013 court order is available at http://www.centerforfoodsafety.org/files/fsma-remedy-order_52466.pdf.

Center for Food Safety Lawsuit Against FDA and OMB

In August 2012, the Center for Food Safety (CFS) filed suit in federal court against FDA and OMB, citing the government's failure to implement seven food safety regulations required by FSMA:

- final regulations due July 4, 2012, to "establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls" (FSMA §103(a));
- notice of proposed rulemaking due October 4, 2011 (with final rule due nine months after close of public comment period), regarding activities that constitute on-farm manufacturing, processing, packing, or holding of food (FSMA §103(c));
- notice of proposed rulemaking due January 4, 2012 (with final rule due nine months after close of public comment period), to establish science-based minimum standards for the safe production and harvesting of produce (FSMA §105(a)-(b));
- final regulations due July 4, 2012, regarding intentional adulteration of food (FSMA §106(b));
- regulations due July 4, 2012, to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices (FSMA §111);
- final regulations due January 4, 2012, regarding the supplier verification program for imported foods (FSMA §301(a)); and
- final regulations due July 4, 2012, regarding "model standards, including requirements for regulatory audit reports, and for each recognized accreditation body to ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors" (FSMA §307).

FDA filed a motion to dismiss the complaint against the agency in November 2012, which was denied by the court in April 2013. FDA was ordered to new deadlines to complete the regulations, under a June 2013 agreement.

In July 2013, FDA filed a motion to reconsider, asking the court to extend the implementation timeline for two FSMA-required rules. This motion was also denied in August 2013; however, CFS accepted extensions of the deadline for publication of these rules.

As part of FDA's July submission, the agency said it was prepared to meet court-imposed deadlines for several other major FSMA rules. In February 2014, FDA and CFS reached an agreement regarding the deadlines for publishing final rules implementing FSMA. Under the new agreement, FDA must issue regulations for many of the major rules between late 2015 and mid-2016.

Source: Center for Food Safety, et al. v. Margaret E. Hamburg, M.D., et al., Case No. 12 CV 4529 (N.D. Cal. 2012), August 29, 2012. The original complaint and decision is at http://www.centerforfoodsafety.org/issues/308/food-safety/legal-actions. Other information on the case is available at CFS's website (http://www.centerforfoodsafety.org).

In July 2013, FDA filed a motion to reconsider, asking the court to extend the implementation timeline for two FSMA-required rules: Sanitary Transport of Food and Feed (FSMA §111) and Intentional Contamination (FSMA §106).[31] This motion was also denied in August 2013.[32]

The Center for Food Safety accepted a 60-day extension of the deadline for publication of the sanitary transport proposed rule (until January 31, 2014), provided that the comment period end date not be extended beyond April 30, 2014, and that the final rule date remain June 30, 2015. The rule timeline for the intentional contamination proposal was not extended, although in November 2013 FDA was later granted a 20-day extension, until December 20, 2013, to publish the proposed rule on intentional contamination due to setbacks that were likely caused by the

[31] FDA's July 2013 motion to reconsider is at http://www.freeborn.com/assets/fda_motion_to_reconsider.pdf.

[32] The August 2013 court order is available at http://www.centerforfoodsafety.org/files/69—order—granting-in-part-denying-in-part-mot-recons_34619.pdf.

federal government shutdown in October 2013.[33] FDA was able to meet the deadline for the proposed intentional contamination rule and published the proposed sanitary transport rule in early February 2014.

Under a February 2014 agreement between FDA and the Center for Food Safety, the agency has agreed to a new court-ordered schedule requiring that final FSMA regulations for many of the major rules be issued between late 2015 and mid-2016 (**Figure 1**). This schedule further pushed back the implementation dates for final FSMA regulations beyond the dates originally mandated by Congress in the enacted law. As of late 2015, FDA has issued final rules for most of these foundational rules; however, some regulations and other additional FDA actions and guidance are still in the process of being developed.

Figure 1. FDA's Timetable to Develop Primary Regulations, Proposal and Final

Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	Jan 16, 2013	Aug 30, 2015
Preventive Controls (Animal Food)*	Oct 29, 2013	Aug 30, 2015
Produce Safety*	Jan 16, 2013	Oct 31, 2015
Foreign Supplier Verification Program*	Jul 29, 2013	Oct 31, 2015
Third Party Accreditation	Jul 29, 2013	Oct 31, 2015
Sanitary Transport	Feb 5, 2014	Mar 31, 2016
Intentional Adulteration	Dec 24, 2013	May 31, 2016

Source: FDA presentation materials to embassies and international stakeholders, June 23, 2015, http://www.fda.gov/downloads/InternationalPrograms/NewsEvents/UCM452962.pdf.

Note: * denotes supplemental proposals published September 2014.

Further extension beyond these dates, however, would require FDA to request an extension through a written agreement to the parties and also to notify the court, according to the agreement. If the parties do not agree to the extension, FDA might still be able to seek an extension through other avenues.[34]

Reportedly, an FDA official indicated in September 2014 that full implementation of FSMA would likely take another 10 years, the amount of time needed to "reasonably expect all the rules to be working."[35]

[33] The November 2013 decision is at http://www.centerforfoodsafety.org/files/15—order-denying-motion-for-stay-pending-appeal3b-expediting-appellate-briefing-schedule-in-part_71389.pdf.

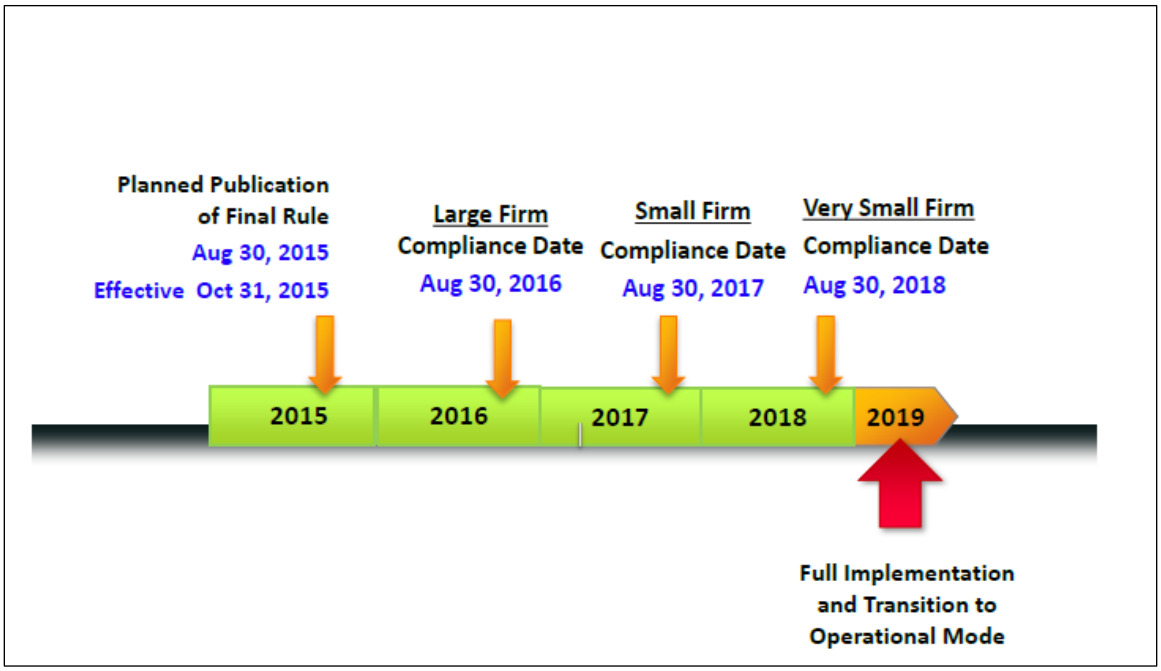
[34] "FDA, Center for Food Safety Agree to New Timeline for FSMA Rules," *Food Chemical News*, February 20, 2014.

[35] "Food Safety Law to Take a Decade to Implement, FDA Says," *CQ News*, September 9, 2014.

Expected Compliance Post Rulemaking

FDA's *Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA)* was released in May 2014 and describes "the next phase of FSMA implementation by outlining broadly the drivers of change in FDA's approach to food safety and the operational strategy for implementing that change, as mandated and empowered by FSMA."[36] Full implementation of the most FSMA regulations will be phased in, mostly to provide flexibility to farms and food businesses to comply with the new requirements, as provided for in the enacted law. Businesses that produce human and animal food are expected to comply with new preventive controls and become fully operational under the regulations by 2019 (**Figure 2**). Produce standards for produce farms become fully operational under the regulations by 2022 (**Figure 3**).

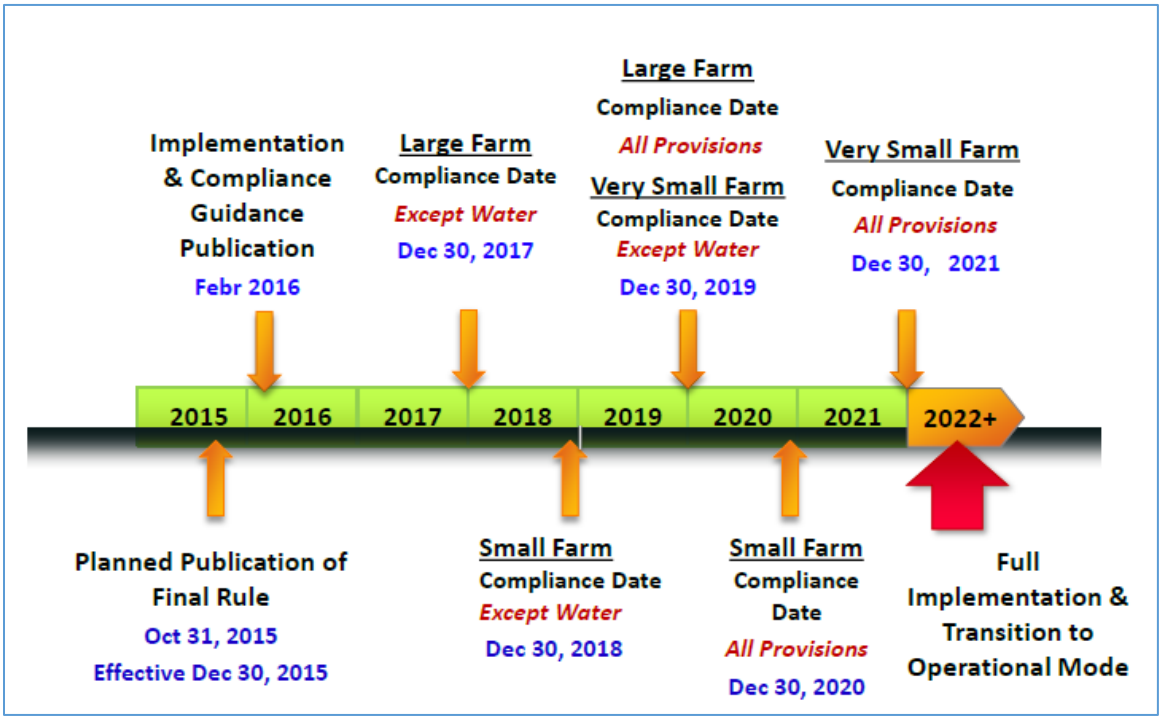
Figure 2. Proposed Preventive Controls Human and Animal Food Regulations, Implementation Timeline



Source: FDA presentation materials to embassies and international stakeholders, June 23, 2015, http://www.fda.gov/downloads/InternationalPrograms/NewsEvents/UCM452962.pdf.

[36] FDA, *Operational Strategy for Implementing the FDA Food Safety Modernization Act (FSMA): Protecting Public Health by Strategic Implementation of Prevention-Oriented Food Safety Standards*, May 2, 2014.

Figure 3. Proposed Produce Safety Rule, Implementation Timeline



Source: FDA presentation materials to embassies and international stakeholders, June 23, 2015, http://www.fda.gov/downloads/InternationalPrograms/NewsEvents/UCM452962.pdf.

Table 1. Food Safety Modernization Act (P.L. 111-353), Selected Provisions, Time/Schedule in Law, and Implementation Status

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Title I—Improving Capacity to Prevent Food Safety Problems					
Inspections of Records (§101)	Effective upon enactment of FSMA, the Department of Health and Human Service (HHS) may inspect records related to the "manufacture, processing, packing, distribution, receipt, holding, or importation" of certain foods of concern (as defined). Amends previous law which contained one standard (trigger) for records access, by creating two such standards.	x	x		In April 2014, FDA issued the following regarding FDA's access to records: • **Final Rule:** *Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements*. • **Guidance for Industry:** *FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act.* • **Guidance for Industry:** *What You Need to Know About Establishment and Maintenance of Records; Small Entity Compliance Guide*. In February 2012, FDA issued the following regarding FDA's access to records: • **Interim Final Rule:** *Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements* (Docket Number: FDA-2002-N-0153). • **Draft Guidance for Industry:** *FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act* (Docket Number: FDA-2011-D-0674). • **Guidance for Industry:** *Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food* (5th Edition) (Docket Number: FDA-2011-D-0598).

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Registration of Food Facilities (§102)	Among other provisions, food facilities shall be subject to biennial registration renewal (and HHS may suspend a facility's registration in certain cases) either once HHS issues interim final regulations or 180 days after enactment of FSMA. HHS shall issue a small entity compliance policy guide to assist small entities in complying with registration requirements (no later than 180 days after it issues regulations).	x	x		**Proposed Rule:** *Amendments to Registration of Food Facilities* (Docket Number: FDA-2002-N-0323, in April 2015) [FSMA amended Section 415 of the FDCA by requiring that certain additional information be included in registrations.] FDA's authority to suspend the registration of a food facility became effective on July 3, 2011. In November 2012, for the first time, FDA suspended the registration of a food facility, Sundland Inc., due to illness from *Salmonella* associated with its peanut products. **Guidance for Industry:** *Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories* (Docket Number: FDA-2012-D-0585, October 2012). **Guidance for Industry:** *What You Need To Know About Registration of Food Facilities; Small Entity Compliance Guide* (Docket Number: FDA-2012-D-1003, December 2012). **Guidance for Industry:** *Questions and Answers Regarding Food Facility Registration* (5th Edition) (Docket Number: FDA-2012-D-1002, December 2012). In April 2013, FDA issued draft guidance, which, when finalized, will replace *Compliance Policy Guide Section 110.300 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.*
Hazard Analysis and Risk-Based Preventive Controls (§103) **Provisions re. seafood, see (§114)	Among other provisions, HHS (coordinating with DHS) shall establish mandatory preventive controls for food facilities, except for "small business" and "very small business" as defined (§103(a)). Final regulations are due no later than 18 months after enactment. HHS shall also issue proposed regulations (within 9 months after enactment) and final regulations (within 9 months after the close of the public comment period on the proposed rule) regarding certain on-farm activities (§103(c)). HHS shall issue a small entity compliance guide, within 180 days of the rules (§103(d)). HHS, in consultation with USDA, shall issue a report on the food processing sector (within 18 months after enactment).	x	x	x	In May 2011, FDA opened a docket for information about preventive controls and other practices. In March 2012, FDA issued information on how FDA identifies a high-risk facility. **Final Rules:** • *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food* (Docket Number: FDA-2011-N-0920, September 2015) • *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals* (Docket Number: FDA-2011-N-0922, September 2015) **Final Rule:** *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Clarification of Compliance Date for Certain Food Establishments* (Docket Number: FDA-2011-N-0920, November 2015) **Proposed Rules:** • *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food* (Docket Number: FDA-2011-N-0920, January 2013) • *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive*

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
					*Controls for Food for Animals (*Docket Number: FDA-2011-N-09226; October 2013). In August 2012, FDA published a "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" to provide a science-based risk analysis of those activity/food combinations that could be considered low risk. In March 2013, FDA corrected technical errors to the proposed rule for Preventive Controls for Human Food. FDA also extended the comment period on the proposed rule numerous times until November 15, 2013. FDA has also conducted outreach and public meetings, and released web videos and written materials. **Proposed Supplemental Rules:** • *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (*Docket Number: FDA-2011-N-0920, September 2014) • *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals* (Docket Number: FDA-2011-N-0922, September 2014) Pending: HHS study on the food processing sector.
Performance Standards (§104)	HHS, in coordination with USDA, shall review and evaluate relevant health data and other relevant information, to determine the most significant foodborne contaminants, and shall issue contaminant-specific and science-based guidance documents (not less frequently than every two years).		x		Status of guidance documents unknown.
Standards for Produce Safety (§105)	Among other provisions, HHS shall establish mandatory science-based, minimum standards for the safe production and harvesting of fruits and vegetables, except for "small business" and "very small business" as defined. Proposed regulations shall be issued within one year after enactment, with final regulations following one year after the close of the public comment period on the proposed rule (§105(a)-(b)).	x	x		**Final Rule:** *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Docket Number: FDA-2011-N-0921, November 2015) **Proposed Rule:** *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Docket Number: FDA-2011-N-0921, January 2013). In March 2013, FDA corrected technical errors to the proposed rule. FDA also extended the comment period on the proposed rule numerous times until November 15, 2013. FDA also has conducted outreach and public meetings, and released web videos and written materials. In August 2013, FDA announced it would prepare an Environmental Impact Statement (EIS) to evaluate the potential environmental effects of the proposed rule for produce safety. **Proposed Supplemental Rule:** *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Docket Number: FDA-2011-N-0921, September 2014)

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Protection Against Intentional Adulteration (§106)	HHS, in coordination with the Department of Homeland Security (DHS) and in consultation with USDA, shall issue regulations to protect against the intentional adulteration of food (within 18 months of enactment). HHS, in consultation with DHS and USDA, shall issue guidance documents related to the intentional adulteration, including mitigation strategies (no later than one year after enactment).	x	x		**Proposed Rule:** Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (Docket Number: FDA-2013-N-14254, December 2013). Status of guidance documents unknown.
Fees (§107); Funding for Food Safety (§401)	Authorizes HHS to assess and collect fees for reinspection, recall, and importation activities (§107). HHS shall submit an annual report to include a description of fees assessed and collected each year and a description of the entities paying fees (no later than 120 days after each fiscal year). HHS shall increase its food safety field staff to the following levels: 4,000 staff (FY2011); 4,200 staff (FY2012); 4,600 staff (FY2013); and 5,000 staff (FY2014), with an increase of 150 field staff for food defense by FY2011 (§401).		x	x	**Guidance for Industry:** • *Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act* (Docket Number: FDA-2011-D-072135, September 2011). • *Guidance for Industry: Questions and Answers Regarding Food Facility Registration* (Docket Number: FDA-2012-D-1002; November 2014) In August of 2011, 2012, 2013, and 2014 FDA announced, respectively, the FY2012, FY2013, FY2014, and FY2015 fee schedule for certain domestic and foreign facility reinspection. FDA began collecting user fees for some activities in FY2012. Pending: HHS report on fees collected. HHS's Foods Program reports the following total full-time equivalents (FTEs) in recent years: about 3,600 FTEs (FY2011); about 3,500 FTEs (FY2012); and about 3,700 FTEs (FY2013).
National Agric. and Food Defense Strategy (§108)	Requires that HHS and USDA develop a "National Agriculture and Food Defense Strategy," in coordination with DHS (no later than one year after the enactment of FSMA), including an implementation plan and a coordinated research agenda. It shall be updated at least every four years.			x	In April 2015, HHS released its report to Congress, *National Agriculture and Food Defense Strategy*, on national agriculture and food defense strategy, implementation plan, and research plan. In April 2013, FDA published its *Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types*, documenting the results from 25 vulnerability assessments, conducted by FDA over several years on more than 50 products or processes, to determine if a potential "threshold" score for the implementation of mitigation strategies could be identified.
Food & Agric. Coordinating Councils (§109)	DHS, coordinating with HHS and USDA, shall submit an annual report on the activities of the Food and Agriculture government and sector coordinating councils (within 180 days of enactment).			x	Pending: DHS report on activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council.

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Building Domestic Capacity (§110)	HHS, in coordination with USDA and DHS, shall submit a comprehensive report to Congress identifying programs and practices intended to promote the safety and supply-chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities (no later than two years after the enactment). The report shall include a report on traceback and surveillance, a food safety and food defense research plan (biennial), and a study regarding "unique identification numbers" (one year after enactment).			x	In May 2013, FDA issued its report, *Building Domestic Capacity to Implement the FDA Food Safety Modernization Act (FSMA)*, a comprehensive report to Congress that identifies programs, practices, and resources needed to promote the safety of the U.S. food supply.
Sanitary Transport (§111)	HHS shall issue regulations requiring shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by HHS (due no later than 18 months after the enactment of FSMA). HHS shall also conduct a study of the transportation of food for consumption in the United States.	x		x	**Proposed Rule:** *Sanitary Transportation of Human and Animal Food* (Docket Number: FDA-2013-N-0013, January 2014). Pending: HHS study on food transportation.
Food Allergy & Anaphylaxis Management (§112)	HHS, in consultation with the Department of Education, shall develop guidelines (not later than one year after the date of enactment) to be used on a voluntary basis to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and children's education programs.		x		In December 2012, FDA opened a docket requesting data and information to determine whether the agency can safely establish threshold levels for major food allergens.
New Dietary Ingredients (§113)	HHS shall publish guidance clarifying when a dietary supplement ingredient is a new dietary ingredient, among other things (no later than 180 days after enactment).		x		**Draft Guidance for Industry:** *New Dietary Ingredient Notifications and Related Issues* (Docket Number: FDA-2011-D-0376, July 2011).

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Guidance, Raw Oysters (§114); Other Seafood (§103)	HHS shall prepare and submit a report on post-harvest processing of raw oysters regulation (within 90 days prior to the issuance of any guidance or regulation by FDA, as specified in FSMA §114). The Government Accountability Office (GAO) shall review and evaluate the report. HHS shall update the *Fish and Fisheries Products Hazards and Control Guidance* (within 180 days of enactment) (§103).		x	x	**Guidance for Industry:** *Fish and Fishery Products Hazards and Controls Guidance* (4th Edition) (Docket Number: FDA- 2011-D-0287, November 2011). Pending: HHS report on post-harvest processing of raw oysters regulation.
Title II—Improving Capacity to Detect and Respond to Food Safety Problems					
Targeting of Inspection Resources (§201)	Among other provisions, HHS shall identify high-risk facilities, increase the frequency of inspection of domestic and foreign facilities (according to specified timeframe), identify and conduct inspections at ports of entry (with DHS), and improve coordination and cooperation with USDA and DHS. HHS shall issue an annual report with information about food facilities (as outlined in FSMA).		x	x	HHS has sent Congress its first three annual reports, *Report on Food Facilities, Food Imports, and FDA Foreign Offices (*November 2013; August 2012; and April 2011). In March 2012, FDA issued information describing how the agency identifies a high-risk facility.
Recognition of Laboratory Accreditation for Analyses of Foods (§202)	Among other provisions, HHS shall establish a program for the testing of food by accredited laboratories (not later than two years after enactment of FSMA). Food testing shall be conducted by accredited labs within 30 months after enactment, unless otherwise exempted. HHS shall submit a progress report on implementing a national food emergency response laboratory network (within 180 days after enactment and biennially thereafter).		x	x	In September 2011 and in November 2013, FDA issued its *Biennial Report to Congress on the Food Emergency Response Network (FERN)*.
Integrated Consortium of Lab Networks (§203)	DHS (in coordination with HHS and EPA) shall maintain an agreement to establish an integrated consortium of laboratory networks. DHS shall submit a report on the progress of the integrated consortium on a biennial basis.			x	The Integrated Consortium of Laboratory Networks (ICLN) was established by a Memorandum of Agreement (MOA) signed in June 2005 (https://www.icln.org/). Pending: Report on the progress of the ICLN.

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Tracking and Tracing Food, Records (§204)	HHS, coordinating with USDA and state officials, shall establish pilot projects with industry to effectively and rapidly track and trace foods in an outbreak (within 270 days of enactment) (§204(a)). HHS, with USDA, shall establish a product tracing system. HHS shall publish a notice of proposed rulemaking within two years of enactment to establish additional recordkeeping for high-risk facilities (to be designated within one year of enactment), along with a list of high-risk foods (published at the time of the final rule) (§204(d)). Within a year of the effective date of the recordkeeping rule, GAO shall review and evaluate the pilot projects. HHS shall issue a small entity compliance policy guide, within 180 days of the rule. Small businesses will have one year and very small businesses will have two years to comply.	x	x	x	In September 2011, FDA announced that the Institute of Food Technologists (IFT) would carry out two new pilot projects. In March 2012, FDA announced the types of foods for product tracing pilots. In March 2013, FDA called for public comment on an IFT final report, *Pilot Projects for Improving Product Tracing along the Food Supply System*, which will be considered by FDA in the development of recommendations in a report to Congress (pending). In February 2014, FDA published its draft methodological approach to identify high-risk foods under Section 204(d)(2), *Requests for Information: Designation of High-Risk Foods for Tracing* (Docket Number: FDA-2014-N-0053; February 2014).
Surveillance (§205)	HHS, acting through the CDC, shall enhance foodborne illness surveillance systems, among other things (authorized appropriations of $24 million annually, FY2011-FY2015). HHS shall, within one year of enactment, conduct an assessment of state and local food safety and defense capacities. Reauthorizes food safety capacity grants at $19.5 million (FY2010), and such sums as necessary (FY2011-FY2015), subject to appropriations.			x	In September 2011, FDA awarded seven grants (totaling $7.3 million) to five land-grant universities (Auburn University, Iowa State University, North Carolina State University, University of California-Davis, and University of Tennessee-Knoxville) and two training institutes. In December 2011, FDA established the Food Safety Preventive Controls Alliance (FSPCA) to provide training and curriculum. In May 2012, FDA announced it had submitted to OMB for review a survey it intends to conduct of state and local agencies to assess state and local food safety capacity.

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Mandatory Recall Authority (§206)	Gives HHS expanded mandatory recall authority of foods under certain circumstances. Establishes reporting requirements: GAO review (no later than 90 days after enactment); USDA feasibility study (depending on GAO's findings); and annual Report to Congress by HHS (not later than two years after enactment).			x	In May 2015, FDA issued Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls (Docket Number: FDA-2015-D-0138) **Annual Reports:** • 2014 FDA published its *Annual Report to Congress on the Use of Mandatory Recall Authority (*February 2015) • 2013 FDA published its *Annual Report to Congress on the Use of Mandatory Recall Authority(*January 2014) Pending: Report on use of recall authority See also GAO's report, *FDA's Food Advisory and Recall Process Needs Strengthening* (GAO-12-589), July 2012.
Administrative Detention of Food (§207)	HHS shall issue an interim final rule (not later than 120 days after enactment of FSMA), effective 180 days after enactment of FSMA, on the administrative detention of foods that FDA believes are adulterated or misbranded.	x	x		**Final Rule:** *Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption* (Docket Number: FDA-2011-N-0197, February 2013). FDA issued an interim final rule in May 2011 on the criteria used to order administrative detention of food for human or animal consumption. **Guidance for Industry:** *What You Need to Know About Administrative Detention of Foods; Small Entity Compliance Guide* (Docket Number: FDA-2011-D-0643, March 2013).
Decontami-nation and Disposal Standards and Plans (§208)	EPA shall provide support and technical assistance to state, local, and tribal governments, and shall develop standards and model plans (coordinating with HHS, DHS, and USDA) regarding decontamination and disposal.		x		Status of EPA's model plans for decontamination and disposal is not known.
Training of State, Local, Territorial, and Tribal Officials, Grants (§209)	HHS shall establish standards and administer training of state, local, territorial, and tribal food safety officials, and enter into agreements with USDA within 180 days after enactment to establish a grant program ("National Food Safety Training, Education, Extension, Outreach and Technical Assistance Program"). Authorizes appropriations of such sums as necessary (FY2011-FY2015).		x		In July 2011, FDA and USDA entered into a MOU to collaborate on the establishment of a competitive grant program for food safety training, and other projects.

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Food Safety Grants, and Centers of Excellence (§210)	HHS shall establish a grant program to "enhance food safety," authorizing appropriations of such sums as necessary (FY2011-FY2015). HHS shall designate five Centers of Excellence (within one year after enactment); HHS shall submit a report on the effectiveness of the Centers of Excellence (within two years of enactment).		x	x	CDC has designated five Integrated Food Safety Centers of Excellence. After a competitive process, five state health departments and their affiliated university partners were selected and notified: Colorado, Florida, Minnesota, Oregon, and Tennessee. Pending: Report on the effectiveness of the Centers of Excellence.
Improving the Reportable Food Registry (§211)	HHS shall obtain information for reportable foods (except fruits and vegetables that are raw agricultural commodities) no later than 18 months after enactment. HHS shall prepare a one-page summary of each reportable food, to be publicly available. Within one year of enactment, HHS shall publish a list of "conspicuous locations" for posting such notifications.			x	No reported activity by FDA. FDA has a Reportable Food Registry (RFR) website (http://www.fda.gov/food/complianceenforcement/rfr/default.htm).
Title III—Improving the Safety of Imported Food					
Foreign Supplier Verification Program (§301)	HHS shall promulgate regulations to provide for the content of the foreign supplier verification (FSVP), within one year after enactment of FSMA, and shall issue guidance to assist importers in developing FSVPs. The program shall take effect two years after enactment.	x			**Final Rule:** *Accredited Third-Party Certification* (Docket Number: FDA-2011-N-0146, November 2015) **Proposed Rule:** *Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals* (Docket Number: FDA-2011-N-01438; July 2013). Under the proposed rule, U.S. importers would need to verify that their suppliers are meeting U.S. food safety requirements. FDA also has conducted outreach and public meetings, and released web videos and written materials. **Proposed Supplemental Rule:** *Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals* (Docket Number: FDA-2011-N-0143, September 2014). **Proposed Rule (Correction Notice):** *User Fee Program to Provide for Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications* (Docket Number: FDA-2011-N-0146, Correction Notice, July 2015).
Voluntary Qualified Importers (§302)	HHS, in consultation with DHS, shall establish a Voluntary Qualified Importer Program (VQIP) to provide for the expedited review and importation of food (beginning not later than 18 months after enactment of FSMA).		x		In June 2015, FDA issued Draft Guidance for Industry: FDA's Voluntary Qualified Importer Program (Docket Number: FDA-2011-N-0144)

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Authority, Import Certifications (§303)	HHS may require, as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity provide a certification concerning imported foods.				No reported activity by FDA.
Prior Notice, Food Imports (§304)	HHS shall issue an interim final rule regarding prior notice of imported foods (within 120 days of enactment of FSMA), which shall take effect 180 days after enactment of FSMA.	x	x		**Final Rule:** *Information Required in Prior Notice of Imported Food* (Docket Number: FDA-2011-N-0179, May 2013), establishing requirements for submitting prior notice of imported food, including food for animals. The final rule adopts FDA's interim final rule issued in May 2011. **Industry Guidance:** *Enforcement Policy Concerning Certain Prior Notice Requirements* (June 2011). *Draft Guidance for Industry: Prior Notice of Imported Food Questions and Answers* (Edition 3), March 2014.
Capacity Building, Foreign Govts. (§305)	HHS shall develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their food industries, which export foods to the United States (within two years of enactment).		x	x	In February 2013, FDA issued its "International Capacity-Building Plan," outlining goals, objectives, and key actions that will provide a strategic framework for the FDA in setting priorities and managing international food safety capacity-building programs. In May 2013, FDA released its report, *Building Domestic Capacity to Implement the FDA Food Safety and Modernization Act (FSMA)*, identifying programs and practices intended to promote the safety of the U.S. food supply.
Inspection of Foreign Food Facilities (§306)	HHS may enter into arrangements and agreements with foreign governments to facilitate inspections of registered foreign facilities and direct resources to inspections of foreign facilities, suppliers, and food types.				FDA has entered discussions with Australia, Belgium, Brazil, Canada, China, Costa Rica, Denmark, European Union (EU), Finland, France, Germany, Iceland, Ireland, Italy, Japan, Mexico, Netherlands, New Zealand, Norway, Philippines, Russia, Singapore, Spain, Sweden, Switzerland, Taiwan, and the United Kingdom. (See FDA's website, "Memoranda of Understanding and Other Cooperative Arrangements," available at http://www.fda.gov.)

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation	Guidance	Report	Available Information on Implementation Status
Accreditation of Third-Party Auditors (§307)	HHS shall develop model standards (within 18 months of enactment) and recognized accreditation bodies shall ensure third-party auditors and audit agents meet such standards to qualify third-party auditors as accredited auditors.	x			**Final Rule:** *Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals* (Docket Number: FDA-2011-N-0143, November 2015) **Proposed Rule:** *Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications* (Docket Number: FDA-2011-N-014610; July 2013) to establish a program for accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities and the foods they produce for both humans and animals. FDA also has conducted outreach and public meetings, and released web videos and written materials. **Amendment to Proposed Rule:** *User Fee Program to Provide for Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications* (Docket Number: FDA-2011-N-0146; July 2015). In July 2015, FDA issued Draft Guidance for Industry and Food and Drug Administration Staff: Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards (Docket Number: FDA-2011-N-0146).
Foreign Offices of FDA (§308)	HHS shall submit a congressional report regarding the selection of the foreign countries for established offices (no later than October 1, 2011).			x	In February 2012, FDA issued its *Report to Congress on the FDA Foreign Offices*.
Smuggled Food (§309)	HHS, coordinating with DHS, shall develop and implement a strategy to identify smuggled food and prevent its entry into the United States (not later than 180 days after enactment of FSMA)		x		In July 2011, HHS and DHS issued a joint anti-smuggling strategy to better identify and prevent entry of smuggled food into the United States.

Source: CRS, from language in the FDA Food Safety Modernization Act (FSMA, P.L. 111-353) and FDA actions to date, from FDA progress reports (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm255893.htm) and FSMA rules and guidance (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm).

Notes: For detailed information about each of these provisions, see Appendix B in CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*. Excludes some FSMA provisions, including provisions in Title 4 (Miscellaneous Provisions) and also FSMA Section 115 (Port Shopping) and Section 116 (Alcohol-Related Facilities), which mostly cover jurisdiction issues or address conforming language requirements.

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