

FDA Required Action Under the FSMA

Activity Involved	What FDA is Required to Do	Deadline	Industries Most Likely Impacted	Citation
Registering Food Facilities	Promulgate regulations establishing the procedure for suspending the registration of facilities whose food has a reasonable probability of causing serious health risks	No deadline, but facilities will be subject to this subsection's requirements on the earlier of the date on which regulations are promulgated or 180 days after the date of enactment of the FSMA (July 3, 2011)	Registered facilities that manufacture, process, pack, receive, or hold food	21 U.S.C. § 350d(b)
Registering Food Facilities	Issue a small entity compliance policy guide to help "small entities" comply with regulations regarding registration suspension	Within 180 days after the issuance of regulations under 21 U.S.C. § 350d(b)	Small entities that manufacture, process, pack, receive, or hold food	21 U.S.C. § 350d Note
Registering Food Facilities	Amend the definition of the term "retail food establishment" in 21 C.F.R. §1.227(b)(1) to include food sold directly to consumers, through a community supported agriculture program, or via other forms of direct sale	No deadline	Local harvesters, food cooperatives, and community supported agriculture programs.	21 U.S.C. § 350d Note
Hazard Analysis and Preventive Control	Issue a guidance document outlining requirements to obtain an exemption from conducting a hazard analysis if the facility is a very small business or has limited annual sales	1 year after the date of enactment of this section (January 4, 2012)	Very small businesses	21 U.S.C. § 350g(l)(1)-(2)
Hazard Analysis and Preventive Control	Conduct study of the food processing sector to facilitate rulemaking establishing science-based minimum standards for hazard analyses and preventive controls and submit to Congress a report describing the results	18 months after the date of enactment of the FSMA (July 4, 2012)	Food processors	21 U.S.C. § 350g(l)(5)

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Hazard Analysis and Preventive Control	Promulgate regulations establishing science-based minimum standards for hazard analyses and preventive controls	18 months after the date of enactment of the FSMA (July 4, 2012)	All involved in the food supply-chain	21 U.S.C. § 350g(n)
Hazard Analysis and Preventive Control	Issue a guidance document to help owners, operators, or agents in charge of a facility identify and evaluate hazards associated with the facility	No deadline	Owners, operators, and agents of facilities	21 U.S.C. § 350g Note
Hazard Analysis and Preventive Control	Publish a notice of proposed rulemaking (NPRM) with the Secretary of Health and Human Services regarding regulating on-farm packing or holding of food that is not grown, raised, or consumed on the farm and on-farm manufacturing or processing of foods and adopt a final rule. In the interim, conduct a science-based risk analysis of the types of on-farm packing, holding, manufacturing, and processing	NPRM published by 9 months after the date of enactment of the FSMA (October 4, 2011); final rule adopted by 9 months after the close of the comment period	Farms	21 U.S.C. § 350d Note
Hazard Analysis and Preventive Control	Issue a small entity compliance policy guide to help "small entities" comply with hazard analysis and preventive control requirements	180 days after the issuance of the regulations promulgated under 21 U.S.C. § 418(n)	Small entities	21 U.S.C. § 350g Note
Hazard Analysis and Preventive Control	Update the Fish and Fisheries Products Hazards and Control Guidance to take into account advances in technology	180 days after the enactment of the FSMA (July 3, 2011)	Fish processing and handling facilities	21 U.S.C. § 342 Note
Product Safety	Research most significant foodborne contaminants and issue contaminant-specific and science-based guidance documents regarding action levels and regulation	At least every 2 years	Any entity involved with a food that has been identified as prone to foodborne contamination	21 U.S.C. § 2201(a)-(b)

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Product Safety	Issue NPRM to establish science-based minimum standards for safe fruit and vegetable harvest and processing	NPRM issued by 1 year after the enactment of the FSMA (January 4, 2012); final rule adopted by 1 year after the close of the comment period	Fruit and vegetable farmers , importers, and processors	21 U.S.C. § 419(a)-(b)
Product Safety	Update the good agricultural practices and guidance for the safe production and harvesting of fruits and vegetables	1 year after the date of enactment of the FSMA (January 4, 2012)	Fruit and vegetable farmers , importers, and processors	21 U.S.C. § 350h(e)
Product Safety	In consultation with the Secretary of Homeland Security, promulgate rules to protect against the intentional adulteration of food	18 months after the date of enactment of the FSMA (July 4, 2012)	Imported foods, bulk items, any food that is vulnerable or poses a threat	21 U.S.C. § 350i(b)
Product Safety	Issue a guidance document related to protection against the intentional adulteration of food	1 year after the date of enactment of the FSMA (January 4, 2012)	Imported foods, bulk items, any food that is vulnerable or poses a threat	21 U.S.C. § 350i Note
Fees	Publish fees regarding inspection of facilities in a Federal Register notice	Not later than 60 days before the start of each fiscal year (November 2 of the prior year)	All subject to inspections	21 U.S.C. § 379j-31(b)
Fees	Propose a set of guidelines considering the burden of fee amounts on "small businesses"	180 days after the enactment of the FSMA (July 3, 2011)	Small businesses	21 U.S.C. § 379j-31(b)(2)(B)(iii)

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Fees	Submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, describing the fees assessed and collected and the entities and types of businesses paying the fees	120 days after each fiscal year for which fees are assessed (May 2 in a non-leap year, May 1 in a leap year)	All businesses	21 U.S.C. § 379j-31(f)
Monitoring	Develop and give to Congress the National Agriculture and Food Defense Strategy	1 year after the date of enactment of the FSMA (January 4, 2012) and update it once every 4 years thereafter		21 U.S.C. § 2202
Building Domestic Capacity	Draft and submit to Congress a comprehensive report identifying ways to promote the safety and supply chain security of food and prevent illness	2 years after the date of enactment of the FSMA (January 4, 2013)		21 U.S.C. § 2204(a)
Tracing and Tracking	Study programs that require a unique identification number for each food facility registered and each broker that imports food. Submit report on the study to Congress	Complete study by 1 year after the enactment of the FSMA (January 4, 2012); submit report to Congress 15 months after the date of enactment of the FSMA (April 4, 2012)	Importers and registered facilities	21 U.S.C. § 2204(i)
Transportation	Promulgate rules regarding the sanitary transportation of food	18 months after the date of enactment of the FSMA (July 4, 2012)	Transporters	21 U.S.C. § 350e Note

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Food Allergy	Develop voluntary food allergy and anaphylaxis management guidelines for schools and early childcare facilities. Note that any federal grants given to local education agencies may be conditioned on the implementation of the food allergy and anaphylaxis management guidelines, even though they otherwise are voluntary.	1 year after the date of enactment of the FSMA (January 4, 2012)	School food suppliers	21 U.S.C. § 2205(b)
Dietary Supplements	Issue guidelines clarifying when a dietary supplement ingredient is a new dietary ingredient requiring the manufacturer and distributor to provide required information	180 days after the enactment of the FSMA (July 3, 2011)	Producers of dietary supplements	21 U.S.C. § 350b Note
Food Testing	Establish a program for the testing of food by accredited laboratories and increase capacity for food testing	2 years after the date of enactment of the FSMA (January 4, 2013)	All food manufacturers	21 U.S.C. § 350k(a)
Food Testing	Conduct food testing by accredited laboratories	30 months after the date of enactment of the FSMA (July 4, 2013)	All food producers	21 U.S.C. § 350k(b)
Food Testing	Report to Congress and make publicly available a report on the progress in implementing a national food emergency response laboratory network	180 days after the date of enactment of the FSMA and biennially thereafter (July 3, 2011)		21 U.S.C. § 2221(b)
Tracing and Tracking	Establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate foodborne illness outbreaks	270 days after the date of enactment of the FSMA (October 1, 2011)	All in the food-supply chain	21 U.S.C. § 2223(a)(1)-(2)

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Tracing and Tracking	Report to Congress on the findings of pilot projects with recommendations for improving the tracking and tracing of food	18 months after the date of enactment of the FSMA (July 4, 2012)	All in the food-supply chain	21 U.S.C. § 2223(a)(3)
Tracing and Tracking	Publish a NPRM to establish record keeping requirements for facilities that manufacture, process, pack or hold "high risk" foods	2 years of the date of enactment of the FSMA (January 4, 2013)	All in the food-supply chain with high-risk foods	21 U.S.C. § 2223(d)(1)
Tracing and Tracking	Designate high-risk foods requiring additional recordkeeping	1 year after the date of enactment of the FSMA (January 4, 2012)	All involved with high-risk foods	21 U.S.C. § 2223(d)(2)
Tracing and Tracking	Issue a small entity compliance guide to help small entities, including farms and small businesses, to comply with recordkeeping requirements	180 days after promulgation of final rule establishing recordkeeping requirements	All involved with high-risk foods	21 U.S.C. § 2223(h)
Tracing and Tracking	Rules promulgated under 21 U.S.C. § 2223(d) will apply to "small businesses"	Beginning on the date that is 1 year after the effective date of the final regulations	Small businesses	21 U.S.C. § 2223(i)(1)
Tracing and Tracking	Rules promulgated under 21 U.S.C. § 2223(d) will apply to "very small businesses"	Beginning on the date that is 2 years after the effective date of the final regulations	Very small businesses	21 U.S.C. § 2223(i)(2)
Food Safety and Defense Capacity	Complete a review of state and local food safety and defense capacities and needs for enhancement	1 year after the date of enactment of the FSMA (January 4, 2012)	State and local governments	21 U.S.C. § 2224(c)(2)

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Transparency	Modify the FDA's website to include a search engine that provides the public an easy method for finding food recall information	90 days after the enactment of the FSMA (April 4, 2011)	Public & any manufacturer of a recalled food	21 U.S.C. § 3501 Note
Annual Report to Congress	Submit a report to Congress on the use of recall authority	2 years after the date of enactment of the FSMA (January 4, 2013) and every 2 years thereafter	Producers subject to a recall or health advisory	21 U.S.C. § 3501-1(f)
Detention of Food	Issue an interim final rule amending regulations to reflect changes in FDA's authority to detain food	120 days after the date of enactment of the FSMA (May 4, 2011)		21 U.S.C. § 334 Note
Food Safety Training and Education	Enter into one or more memoranda of understanding or cooperative agreements with the Secretary of Agriculture to establish a competitive grant program within the National Institute for Food and Agriculture to provide food safety training, education, extension, outreach, and technical assistance to farm owners and operators, small food processors and small fruit and vegetable merchant wholesalers	180 days after the date of enactment of the FSMA (July 3, 2011)	Farm owners and operators, small food processors and small fruit and vegetable merchant wholesalers	21 U.S.C. § 399c(d)
Food Safety Integrated Centers of Excellence	Designate 5 Integrated Food Safety Centers of Excellence to serve as resources for federal, state, and local public health professionals to respond to foodborne illness outbreaks	1 year after the date of enactment of the FSMA (January 4, 2012)		42 U.S.C. § 280g-16(a)
Food Safety Integrated Centers of Excellence	Establish a working group to recommend designations of the Centers of the Excellence	180 days after the date of enactment of the FSMA (July 3, 2011)		42 U.S.C. § 280g-16(b)(2)

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Food Safety Integrated Centers of Excellence	Submit to Congress a report on the effectiveness of the Centers of Excellence and propose legislative recommendations for additional resources	2 years after the date of enactment of the FSMA (January 4, 2013)		42 U.S.C. § 280g-16(d)
Tracing and Tracking	May require a responsible party to submit product-identifying information regarding a reportable food, other than raw fruit and vegetable agricultural commodities	18 months after the date of enactment of the FSMA (July 4, 2012)	Any entity required to report	21 U.S.C. § 350f(f)
Tracing and Tracking	Develop and publish a list of acceptable customer notification methods grocery stores may use to post recall information	1 year after the date of enactment of the FSMA (January 4, 2012)	Grocery stores	21 U.S.C. § 350f(h)(2)
Importing	Issue guidance to assist importers in developing foreign supplier verification programs	1 year after the date of enactment of the FSMA (January 4, 2012)	Importers and their suppliers	21 U.S.C. § 384a(b)
Importing	Promulgate rules for the content of the foreign supplier verification program	1 year after the date of enactment of the FSMA (January 4, 2012)	Importers and their suppliers	21 U.S.C. § 384a(c)
Importing	Establish a program providing for expedited review and importation of goods whose importers have voluntarily agreed to participate in a voluntary qualified importer program	18 months after the date of enactment of the FSMA (July 4, 2012)	Importers and their suppliers	21 U.S.C. § 384b
Importing	Promulgate rules to require prior notice of any country to which an article of food has been refused entry before the article is allowed entry into the United States	120 days after the date of enactment of the FSMA (May 4, 2011)	Importers and their suppliers	21 U.S.C. § 381 Note

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Importing	Develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries, from which foods are exported to the United States	2 years after the date of enactment of the FSMA (January 4, 2013)	Importers and their suppliers	21 U.S.C. § 381 Note
Food Safety Auditing	Establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet requirements to perform food safety audits	2 years after the date of enactment of the FSMA (January 4, 2013)		21 U.S.C. § 384d(b)(1)(A)(i)
Food Safety Auditing	Develop model accreditation standards for accredited food safety auditors	18 months after the date of enactment of the FSMA (July 4, 2012)		21 U.S.C. § 384d(b)(2)
Food Safety Auditing	Reevaluate the accreditation bodies	Periodically, or at least once every 4 years		21 U.S.C. § 384d(f)
Food Smuggling	Develop and implement a strategy to better identify smuggled food and prevent entry of such food into the United States	180 days after the enactment of the FSMA (July 3, 2011)		21 U.S.C. § 2243