

Food Safety Modernization Act: Implementation Scorecard

Section	Deadline/Effective Date							Status	Additional Information	
	Jan 2011	July 2011	Sept 2011	Jan 2012	July 2012	Jan 2013	July 2013			Other
Sec. 101. Inspections of records: Expands FDA access, upon request, to all records relating to an article of food and all records relating any food that is likely to be affected in a similar manner, when there is a probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.	X								Authority given to FDA upon enactment	
Sec. 102. Registration of food facilities: Requires biennial facility registration renewal on even numbered years, gives the Secretary authority to suspend registration if there is a reasonable probability of serious adverse health consequences or death, and gives the Secretary authority to reorganize food categories.									Such facilities must initially register between October and December of 2012	Biennial Registration of Food Facilities: New Requirements and New Penalties
<ul style="list-style-type: none"> Facilities subject to new registration requirements 		X							Authority given to FDA on July 3, 2011	
<ul style="list-style-type: none"> FDA may require electronic submission 								5 years		
Sec. 103. Hazard analysis and risk-based preventive controls: Requires registered facilities to evaluate hazards, implement preventive controls, monitor the performance and verify the effectiveness of preventive controls, and maintain records, including a written plan, on hazards and preventive controls. Modified requirements will apply to qualified facilities.									WAITING FOR PROPOSED RULE	FSMA and Preventive Controls: Implications for Industry

Section	Deadline/Effective Date								Status	Additional Information
	Jan 2011	July 2011	Sept 2011	Jan 2012	July 2012	Jan 2013	July 2013	Other		
<ul style="list-style-type: none"> FDA to establish science-based standards for conducting a hazard analysis, implementing preventive controls, and documenting implementation of preventive controls and to define “small” and “very small” businesses” 					X					The Tester Amendment: Who’s In and Who’s Out?
<ul style="list-style-type: none"> FDA study of food processing sector 					X					
<ul style="list-style-type: none"> FDA publish NPRM on activities that constitute on-farm packing, holding, manufacturing and processing 			X							
<ul style="list-style-type: none"> FDA publish Final Rule on activities that constitute on-farm packing, holding, manufacturing and processing 								9 months after comment period		
<p>Sec. 104. Performance standards: Requires FDA to review foodborne contaminants and issue guidance or regulations as necessary to reduce risks.</p>								As appropriate		FSMA Implementation: Prioritizing Partnerships and Risk
<p>Sec. 105. Standards for produce safety: Establishes science-based minimum standards for the safe production and harvesting of produce. Modified requirements and exemptions will apply to qualified facilities.</p>										Farm or Registered Facility; Listeria Outbreak Highlights Need for Clarity
<ul style="list-style-type: none"> FDA issue proposed rule 				X					WAITING FOR PROPOSED RULE	
<ul style="list-style-type: none"> FDA issue final rule 								1 year after comment period Small + 1 year from effective date of regulation Very small + 2 years from		

Section	Deadline/Effective Date								Status	Additional Information
	Jan 2011	July 2011	Sept 2011	Jan 2012	July 2012	Jan 2013	July 2013	Other		
								effective date of regulation		
<ul style="list-style-type: none"> FDA publish updated GAPs 				X					WAITING FOR UPDATE	
Sec. 106. Protection against intentional adulteration: Requires development of guidance and regulations to protect against intentional adulteration.										
<ul style="list-style-type: none"> FDA issue guidance 				X					WAITING FOR UPDATE	
<ul style="list-style-type: none"> FDA issue regulation 					X					
Sec. 107. Authority to collect fees: Gives the Secretary authority to collect fees for reinspection, recalls, and voluntary qualified importer program.	X							FDA to publish fees 60 days before each FY	Authority given to FDA upon enactment	New User Fees: What will the Food Safety Modernization Act cost you?
Sec. 108. National agriculture and food defense strategy: Requires FDA, United States Department of Agriculture (USDA), and the Department of Homeland Security (DHS) to develop a national agriculture and food defense strategy.				X						
Sec. 109. Food and Agriculture Coordinating Councils: Requires creation of food and agriculture coordination councils, comprised of representatives from DHS, HHS, and USDA, to improve coordination and communication.		X						First report at 180 days; Reports due once a year thereafter		
Sec. 110. Building domestic capacity: Requires FDA to identify programs and practices to provide food safety and security.						X				
Sec. 111. Sanitary transportation of food: Requires FDA to develop new regulations for the safe transportation of food.					X					
Sec. 112. Food allergy and anaphylaxis management: Requires FDA to develop voluntary guidelines for food allergy risk management plans in schools and early education facilities.					X					

Section	Deadline/Effective Date							Status	Additional Information	
	Jan 2011	July 2011	Sept 2011	Jan 2012	July 2012	Jan 2013	July 2013			Other
Sec. 113. New dietary ingredients: Requires FDA to issue guidance to define a new dietary ingredient and outline the evidence required to document the safety of a new dietary ingredient.		X							FDA issued guidance on July 3, 2011	Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues
Sec. 114. Requirement for guidance relating to post harvest processing of raw oysters: The Secretary must provide 90 days notification prior to issuing any guidance, regulation, or amendments to the National Shellfish Sanitation Program's Model Ordinance or Seafood HACCP that relates to the post harvest processing of oysters.	X								Requirement effective upon enactment	
Sec. 115. Port shopping: Requires FDA to provide notification to the Secretary of Homeland Security when refusing to admit food.	X								Requirement effective upon enactment	
Sec. 116. Alcohol-related facilities: Alcohol-related facilities are exempt from this Act.	X								Exemption effective upon enactment	
Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report: Requires that FDA inspectional resources be targeted based on risk and outlines inspection frequency requirements for domestic and foreign firms.	X								Requirement effective upon enactment	
Sec. 202. Laboratory accreditation for analyses of foods: Requires FDA to establish a program for accrediting food laboratories.										
<ul style="list-style-type: none"> FDA establish program for accredited labs 						X				
<ul style="list-style-type: none"> Food testing must be conducted by accredited labs when conducted by or on behalf of an owner, in response to testing requirements in the Act, or as required to address suspected or identified food safety problems 							X			
Sec. 203. Integrated consortium of laboratory networks: Requires FDA, USDA, and the Environmental Protection Agency (EPA) to form a consortium to identify common laboratory methods and provide surge capacity.	X								Requirement effective upon enactment	
Sec. 204. Enhancing tracking and tracing of food and									PILOTS	Product Tracking:

Section	Deadline/Effective Date								Status	Additional Information
	Jan 2011	July 2011	Sept 2011	Jan 2012	July 2012	Jan 2013	July 2013	Other		
recordkeeping: Requires FDA to pilot tracing systems, consider establishing a product tracing program, and expand recordkeeping requirements for high-risk foods.									UNDERWAY DUE FOR COMPLETION JULY 2012	Impact of FSMA
<ul style="list-style-type: none"> FDA conduct tracking and tracing pilots 		X							PILOTS UNDERWAY DUE FOR COMPLETION JULY	
<ul style="list-style-type: none"> FDA report to Congress on pilots, additional data 					X					
<ul style="list-style-type: none"> FDA publish list of high-risk food for recordkeeping provision 				X					WAITING FOR LIST TO BE PUBLISHED	
<ul style="list-style-type: none"> FDA establish product tracing system 								No specified deadline		
<ul style="list-style-type: none"> NPRM on recordkeeping 						X		Small + 1 year from final rule Very small +2 years from final rule		
Sec. 205. Surveillance: FDA and the Centers for Disease Controls and Prevention (CDC) shall enhance surveillance systems to improve collection, analysis and reporting.										
<ul style="list-style-type: none"> Coordinating and info sharing 	X								Requirement effective upon enactment	
<ul style="list-style-type: none"> Review of strategies 				X					NO PUBLISHED UPDATES	
Sec. 206. Mandatory recall authority: Provides FDA mandatory recall authority.	X									
Sec. 207. Administrative detention of food: Expands FDA administrative detention of food when there is a reasonable belief that the food is adulterated or misbranded.		X						Issue rule within 120 days	FDA issued interim final rule on May 4, 2011. in effect on July 3, 2011.	FDA Issues First New Rules under FSMA Prior Notice and Administrative Detention: What the New Rules

Section	Deadline/Effective Date								Status	Additional Information
	Jan 2011	July 2011	Sept 2011	Jan 2012	July 2012	Jan 2013	July 2013	Other		
										Mean
Sec. 208. Decontamination and disposal standards and plans: EPA, in conjunction with HHS, USDA, and DHS will develop standards and protocols to assist State, local and tribal governments with preparing for, assessing, decontaminating, and recovering from an agricultural or food emergency.	X								Requirement effective upon enactment	
Sec. 209. Improving the training of State, local, territorial, and tribal food safety officials: FDA will establish standards and administer training and education programs for State, local, territorial, and tribal food safety officials.										
<ul style="list-style-type: none"> FDA set standards and administer training on policies established by Act 	X								Requirement effective upon enactment	
<ul style="list-style-type: none"> FDA contracts and memorandum include provisions to ensure adequate training 	X								Requirement effective upon enactment	
<ul style="list-style-type: none"> FDA will establish grant program with National Institute for Food and Agriculture 		X							Requirement effective upon enactment	
Sec. 210. Enhancing food safety: Allows for FDA to provide multi-year grants to State, local, territorial, and tribal governments and establishes Centers of Excellence to serve as resources for public health professionals to respond to foodborne illness outbreaks.										FSMA Implementation: Prioritizing Partnerships and Risk
<ul style="list-style-type: none"> Grants to states 	X								Authority given to FDA upon enactment	
<ul style="list-style-type: none"> FDA to designate 5 Centers of Excellence 				X						
Sec. 211. Improving the reportable food registry: Requires					X					The RFR – What

Section	Deadline/Effective Date								Status	Additional Information
	Jan 2011	July 2011	Sept 2011	Jan 2012	July 2012	Jan 2013	July 2013	Other		
additional information to be submitted to the reportable food registry.										the Current Requirements and FSMA Changes Mean to You
Sec. 301. Foreign supplier verification program: Requires importers to perform risk-based foreign supplier verification to verify that imported food is produced in compliance with applicable U.S. laws and is not adulterated or misbranded.										Food Safety Modernization Act: What Does it Mean for Importers?
<ul style="list-style-type: none"> FDA publish guidance 				X					WAITING FOR GUIDANCE	
<ul style="list-style-type: none"> FDA publish regulation 				X					WAITING FOR REGULATION	
<ul style="list-style-type: none"> Effective date 						X				
Sec. 302. Voluntary qualified importer program: Establishes a program for expedited review of food offered by importers who have agreed to voluntarily participate in the program.										Food Safety Modernization Act: What Does it Mean for Importers?
<ul style="list-style-type: none"> FDA publish guidance 				X					WAITING FOR GUIDANCE	
<ul style="list-style-type: none"> FDA establish program 					X					
Sec. 303. Authority to require import certifications for food: Authorizes the Secretary to require imported food to have a certificate of compliance with applicable requirements.	X								Authority given to FDA upon enactment	FDA Import Strategy: Responding to New Challenges
Sec. 304. Prior notice of imported food shipments: Requires the manufacturer or shipper to notify FDA of any country to which the article has been refused entry.		X						Issue rule within 120 days	FDA issued interim final rule on May 4, 2011. Rule goes into effect July 3, 2011.	FDA Issues First New Rules under FSMA Prior Notice and Administrative Detention: What the New Rules Mean

Section	Deadline/Effective Date								Status	Additional Information
	Jan 2011	July 2011	Sept 2011	Jan 2012	July 2012	Jan 2013	July 2013	Other		
Sec. 305. Building capacity of foreign governments with respect to food safety: Requires FDA to develop a plan to expand technical, scientific and regulatory capacity of foreign governments and their respective food industries.						X				
Sec. 306. Inspection of foreign food facilities: Authorizes the Secretary enter into arrangements with foreign governments to facilitate inspections of foreign registered facilities, refuse admission of food from facilities refusing inspection, and permits the Department of Commerce to send inspectors to foreign seafood facilities.	X								CHECK THAT THIS IS EFFECITVE UPON ENACTMENT	Comparable Food Safety Systems and Menu Labeling: Updates on FDA Actions
Sec. 307. Accreditation of third-party auditors: Requires FDA to establish a program to recognize accreditation bodies and third-party auditors.										Will FDA Ever Use Third Party Auditors – And If So How?
<ul style="list-style-type: none"> FDA recognize accreditation bodies 						X				
<ul style="list-style-type: none"> FDA develop model standards 					X					
<ul style="list-style-type: none"> FDA issue regulations re: conflict of interest 					X					
Sec. 308. Foreign offices of the Food and Drug Administration: Requires a status report on the FDA foreign offices.								By October 1, 2011	FDA issued the first report to Congress on April 6, 2011.	
Sec. 309. Smuggled food: Requires FDA, in coordination with DHS, to develop and implement a strategy to better identify smuggled food and prevent entry of such food into the United States.		X							FDA issued joint anti-smuggling strategy on July 3, 2011.	Fact Sheet on the Anti-Smuggled Food Strategy
Sec. 401. Funding for food safety: Authorizes appropriation of funds to carry out activities in the Act.	X								Authority effective upon enactment	FY 2011 Appropriations: Food Safety Outlook The Food Safety Modernization Act: The Proof is in the

Section	Deadline/Effective Date								Status	Additional Information
	Jan 2011	July 2011	Sept 2011	Jan 2012	July 2012	Jan 2013	July 2013	Other		
										Budget
Sec. 402. Employee protections: No entity engaged in manufacture, processing, packing, transporting, distribution, receiving, holding, or importation of food may discharge or discriminate against a whistleblower.	X								Requirement effective upon enactment	
Sec. 403. Jurisdiction; authorities: This Act does not alter jurisdiction between the Department of Health and Human Services and the United States Department of Agriculture.	X								Requirement effective upon enactment	
Sec. 404. Compliance with international agreements: Nothing in this Act may be inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party	X								Requirement effective upon enactment	
Sec. 405. Determination of budgetary effects: Budgetary effects of this Act shall be determined by reference to the latest statement titled "Budgetary Effects of PAYGO Legislation."	X								Requirement effective upon enactment	