

Food Safety Modernization Act: Summary and Timeline

Section	Upon Enactment	180 Days	270 Days	1 Year	1.5 Years	2 Years	2.5 Years	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							
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.								
<ul style="list-style-type: none"> Facilities subject to new registration requirements 		X						Or upon FDA issuance of regulation, if before 180 days
<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.								

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<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			
<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
Sec. 104. Performance standards: Requires FDA to review foodborne contaminants and issue guidance or regulations as necessary to reduce risks.								As appropriate
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.								
<ul style="list-style-type: none"> FDA issue proposed rule 				X				
<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 effective date of regulation
<ul style="list-style-type: none"> FDA publish updated GAPs 				X				
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				
<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.								

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• FDA publish fees 60 days before each FY	X							
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			
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						
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							
Sec. 115. Port shopping: Requires FDA to provide notification to the Secretary of Homeland Security when refusing to admit food.	X							
Sec. 116. Alcohol-related facilities: Alcohol-related facilities are exempt from this Act.	X							

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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							
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							
Sec. 204. Enhancing tracking and tracing of food and recordkeeping: Requires FDA to pilot tracing systems, consider establishing a product tracing program, and expand recordkeeping requirements for high-risk foods.								
<ul style="list-style-type: none"> FDA conduct tracking and tracing pilots 		X						
<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				
<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							
<ul style="list-style-type: none"> Review of strategies 				X				

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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.		7/3/11						Issue rule within 120 days, Rule goes into effect 7/3/2011
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							
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							
<ul style="list-style-type: none"> FDA contracts and memorandum include provisions to ensure adequate training 	X							
<ul style="list-style-type: none"> FDA will establish grant program with National Institute for Food and Agriculture 		X						
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.								
<ul style="list-style-type: none"> Grants to states 	X							
<ul style="list-style-type: none"> FDA to designate 5 Centers of Excellence 				X				
Sec. 211. Improving the reportable food registry: Requires additional information to be submitted to the reportable food registry.					X			
Sec. 301. Foreign supplier verification program: Requires importers to perform risk-based foreign supplier verification to verify that imported food is produced in								

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compliance with applicable U.S. laws and is not adulterated or misbranded.								
• FDA publish guidance				X				
• FDA publish regulation				X				
• 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.								
• FDA publish guidance				X				
• 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							
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.		7/3/11						Regulation within 120 days Rule goes into effect 7/3/2011
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							
Sec. 307. Accreditation of third-party auditors: Requires FDA to establish a program to recognize accreditation bodies and third-party auditors.								
• FDA recognize accreditation bodies						X		
• FDA develop model standards					X			
• FDA issue regulations re: conflict of interest					X			
Sec. 308. Foreign offices of the Food and Drug								By October 1, 2011

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Administration: Requires a status report on the FDA foreign offices.								
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						
Sec. 401. Funding for food safety: Authorizes appropriation of funds to carry out activities in the Act.	X							
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							
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							
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							
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							