The Food Safety Modernization Act (FSMA)

An overview of final and proposed rules from the Food and Drug Administration

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Why focus on food safety?

The Centers for Disease Control and Prevention estimates that 1 in 6 Americans, representing about 48 million people, get sick from foodborne illnesses each year — resulting in an estimated 128,000 hospitalizations and 3,000 deaths annually.¹

Three major events prompted legislation: the 2006 E. coli outbreak linked to spinach; the 2007 melamine contamination of pet food from China; and the 2008-09 salmonella outbreak whereby the Peanut Corporation of America knowingly sold tainted peanut butter.

“By the end of 2016, we will begin overseeing [FSMA] implementation, and we will do that in large part through legally mandated FSMA inspections of food facilities. Those inspections will happen.” — Michael Taylor, FDA Deputy Commissioner for Foods and Veterinary Medicine ²

Timeline

The FDA is operating under a court order to complete the rules on a specified timetable.

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Note: According to the FDA, “FSMA requires the FDA to issue regulations in seven areas.”

1Source: http://www.cdc.gov/foodborneburden/
3Source: http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm

Key requirements in each of the final and prospective FSMA rules

<table>
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<tr>
<th>Who is impacted</th>
<th>Preventive Controls for Human Food</th>
<th>What FSMA requires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities that hold or store raw agricultural commodities, pack food or manufacture/process food off-site, or operations meeting the definition of “farm” are exempt.</td>
<td>Develop and implement written food safety plan with preventive controls around process sanitation and allergens to:</td>
<td>Identify and evaluate potential food safety hazards</td>
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<td></td>
<td></td>
<td>Specify and conduct preventive steps or controls</td>
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<td>Specify and conduct procedures to monitor controls and procedures to verify efficacy of controls</td>
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<td>Train qualified employees on good manufacturing practices</td>
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<td></td>
<td></td>
<td>Document actions to correct problems that arise</td>
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<td></td>
<td></td>
<td>Maintain routine maintenance of monitoring records</td>
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<td>Foreign Supplier Verification Program (FSVP)</td>
<td>All US food importers (retailers and wholesalers), defined as “the person in the US who has purchased an article of food that is being offered for import into the US.”</td>
<td>Perform supplier verification showing that imported food is produced in compliance with FDA food regulations. The FDA may refuse imported food admission if the foreign facility does not meet requirements or the country refuses to allow FDA inspection.</td>
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<td>Document each food product offered for importation into the US and provide when filing entry with U.S. Customs and Border Protection</td>
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<td></td>
<td>Identify and evaluate hazards for each food</td>
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<td></td>
<td>Establish an FSVP for each food imported into the US</td>
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<td>Maintain compliance records for foreign suppliers</td>
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<td>Periodically reassess FSVP</td>
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<td>Import only from approved foreign suppliers (temporary exception allowed)</td>
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<td>Depending on the hazard analysis results, importers select appropriate verification activities; highest risk defaults to annual on-site inspection</td>
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<tr>
<td>Produce Safety</td>
<td>Raw agricultural commodities (RACs) (fruits and vegetables frequently consumed raw). Exemptions and modified requirements apply to food that is rarely consumed raw and to operations meeting the definition of “farm.”</td>
<td>For the first time, required to apply science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption to:</td>
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<td></td>
<td></td>
<td>Meet criteria for microbial water quality</td>
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<td></td>
<td>Test untreated surface water and groundwater</td>
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<td>Meet microbial standards for biological soil (i.e., raw manure and stabilized compost)</td>
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<td>Meet requirements for worker training, health, and hygiene</td>
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<td>Identify and not harvest produce likely contaminated by domestic and wild animals</td>
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<td></td>
<td>Prevent equipment, tools, buildings and inadequate sanitation from contaminating produce</td>
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<td>Additional requirements apply for sprouts</td>
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<th>Who is impacted</th>
<th>Preventive Controls for Animal Food</th>
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<tr>
<td>Facilities that manufacture, process, pack or hold domestic or imported animal food. Operations meeting the definition of “farm” are exempt.</td>
<td>Implement written food safety plan with preventive controls and hazard analysis to:</td>
<td>Identify and evaluate potential animal food safety hazards, e.g., supply chain risks, nutrient imbalances</td>
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<td>Document actions to correct problems that arise</td>
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<tr>
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<td></td>
<td>Document a recall plan</td>
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<td></td>
<td>Maintain routine maintenance of monitoring records</td>
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<tr>
<td>Sanitary Transportation of Human and Animal Food</td>
<td>Shippers, loaders, carriers by motor vehicle or rail vehicle, or receivers engaged in transportation. Also applies to animal food and some USDA-regulated foods excluded from FDA preventative controls (meat, poultry and egg products). Exclusions include those having annual sales less than $500,000, fully packaged shelf-stable foods, live food animals and transportation activities performed by farms.</td>
<td>Implement sanitary transportation practices to:</td>
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<td></td>
<td>Determine whether food is adulterated due to improper transport based on FSMA criteria and definitions</td>
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<td>Design and maintain vehicles and transportation equipment to prevent contamination</td>
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<td>Train carrier personnel on sanitary transportation practices</td>
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<td>Perform pre-transport sanitization, cleaning (e.g., cleaning of transport equipment, preloads)</td>
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<td>Specify and conduct procedures to prevent contamination (e.g., adequate temperature controls, separation of food from non-food items in the same load)</td>
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<td>Retain and provide relevant records for a required period not to exceed 12 months</td>
</tr>
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Who is impacted | Preventive Controls | What FSMA requires |
<table>
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<tr>
<td>Domestic and foreign facilities that manufacture, process, pack, or hold food, Farms or other food facilities not covered by regulation under section 415 of the FDC Act are exempt.</td>
<td>Intentional Adulteration (final rule expected March 2016)</td>
<td>Implement written food defense plan that addresses significant vulnerabilities in a food operation to:</td>
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<td>Protect most vulnerable food system activities (bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, mixing)</td>
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<td>Identify and implement actionable steps and mitigation strategies</td>
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<td>Implement monitoring strategies and corrective actions</td>
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<td>Specify and conduct verification activities</td>
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<td>Train personnel and supervisors in food defense awareness</td>
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Note: Third-party accreditation rule describes a voluntary program for the accreditation of third-party certification bodies to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. Given applicability, this update does not highlight requirements.
Why focus on food safety?

The Centers for Disease Control and Prevention estimates that 1 in 6 Americans, representing about 48 million people, get sick from foodborne illnesses each year — resulting in an estimated 128,000 hospitalizations and 3,000 deaths annually.¹

Foodborne illnesses represent a significant public health issue that can be largely prevented. The Centers for Disease Control and Prevention estimates that 1 in 6 Americans, representing about 48 million people, get sick from foodborne illnesses each year — resulting in an estimated 128,000 hospitalizations and 3,000 deaths annually.¹

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<td>Effective date</td>
<td>January 26, 2016</td>
<td>November 16, 2015</td>
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<td>60 days</td>
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* Compliance date is 18 months after the final rule issue date or 6 months after the preventive controls or produce safety regulations are enforceable for foreign suppliers, whichever is later.
** Final rule has not yet been issued.
*** "Small" and "very small" definitions may vary per rule. For example, "very small" is defined for human food import (FSVP) and human food preventive controls as an importer or company (as appropriate) with an annual sales ceiling of $2.5 million and is also defined for animal food import (FSVP) and animal food preventive controls as an importer or company (as appropriate) with an annual sales ceiling of $2.5 million.

Key requirements in each of the final and prospective FSMA rules

Who is impacted | What FSMA requires
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**Preventive Controls for Human Food** Facilities that manufacture, process, pack or hold domestic or imported animal food. Operations meeting the definition of "farm" are exempt. | Develop and implement written food safety plan with preventive controls around process sanitation and allergens to:
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**Sanitary Transportation of Human and Animal Food** Shipners, loaders, carriers by water vehicle or rail vehicle, or receivers engaged in transportation. Also applies to animal food and some USDA regulated foods excluded from FDA preventive controls (meat, poultry and egg products). Exclusions include those having annual sales less than $500,000, fully packaged shelf-stable foods, live food animals and transportation activities performed by farms. | Implement sanitary transportation practices to:
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**Intentional Adulteration (final rule expected March 2016)** Domestic and foreign facilities that manufacture or process, pack, or hold food, Farms or other food facilities not regulated by Water under section 415 of the F&OCA are exempt. | Implement written food defense plan that addresses significant vulnerabilities in a food operation to:
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