The Food Safety Modernization Act of 2011 (FSMA), the first major overhaul of food safety legislation in more than 70 years, gives FDA the new job of building a modern, prevention oriented food safety system suited for today’s globalized food supply. With new mandates and authorities come greater responsibilities, and many in the food industry are now wondering where to begin to accomplish all that FSMA requires. AIB has put together this guide to help our readers better understand the basis of FSMA’s 41 applicable sections, the key dates, and the various FDA and industry responsibilities (where applicable). Specific items that industry can be doing now to prepare for FSMA implementation are indicated in red.

**Sec. 101. Inspections of records.**
If there is reasonable belief that a food will cause serious adverse health consequences or death to humans or animals (SAHCODHA), the FDA has the right to inspect all records relating to manufacture, processing, packing, distribution, receipt, holding, or importation of that food. Includes all products that are suspect and all products that were likely to be affected in a similar manner. Inspect records related to suspect products. 
Update company procedure for handling regulatory inspections to allow for sharing of records. Ensure good documentation and recordkeeping practices. 
Effective January 4, 2011

**Sec. 102. Registration of food facilities.**
Food plants under FDA rule must re-register between October 1 and December 31 in even numbered years. FDA has the right to suspend registration (close the plant). Suspend facility registrations (close the plant) if re-registrations are not current. Suspend facility registrations if there is a reasonable belief the food will cause SAHCODHA. Re-register between October 1 and December 31 in every even numbered years: 2014, 2016, 2018, etc. Keep registration current with facility updates between these mandatory re-registration periods. First re-registration period: October - December 2012

**Sec. 103. Hazard analysis and risk-based preventive controls.**
Each facility must have a hazard analysis program that assures food is not adulterated or misbranded. The program must include identified controls that are monitored. Associated records must be maintained. Hazards include those that may be intentionally introduced, including by acts of terrorism. Must publish rule with expectations regarding hazards and controls. Must maintain a hazard analysis and preventive controls program. Establish a strong HACCP Program and Vulnerability Assessment-based Food Defense Program as the foundation for the new requirements. Preventive Controls Rule scheduled for publication on July 4, 2012. Delayed. Fish and Fishery Products Hazards and Controls Guidance (4th Edition) published November 2011.

**Sec. 104. Performance standards.**
FDA must generate a report every two years on relevant health data related to food. Generate report. Generate guidance documents based on reports. Adhere to guidance documents that result from these reports. Reports to be generated at least every two years, beginning no later than January 2013.

**Sec. 105. Standards for produce safety.**
### Sec. 106. Protection against intentional adulteration.
FDA must conduct a vulnerability assessment of the food system and determine science-based mitigation strategies.

*Conduct a vulnerability assessment. Publish a rule around mitigation strategies.*

Establish a Food Defense Program as a foundation for any future mitigation strategies to be published.


### Sec. 107. Authority to collect fees.
FDA has the authority to collect fees for reinspection.

*Pay fees when requested by FDA*

Determine when fee collection will be implemented. Collect fees.

Pay fees when requested by FDA


### Sec. 108. National agriculture and food defense strategy.
FDA must publish the National Agriculture and Food Defense Strategy. Must revise the strategy at least every 4 years. For national security reasons, there will be limited distribution.

*Publish the Strategy.*

Establish a Food Defense Program as a foundation for any future mitigation strategies to be published.


### Sec. 109. Food and Agriculture Coordinating Councils.
A report is to be generated about how the following agencies can best coordinate efforts to reduce disease outbreaks, food contamination, and to respond to natural disasters affecting food: Homeland Security, Health and Human Services, Department of Agriculture.

*Publish biennial reports.*

Adhere to regulation and guidance generated as a result of these reports.

Due January 4, 2013.

### Sec. 110. Building domestic capacity.
FDA to generate a report on food safety and food security that includes needs for further regulations, prompt distribution of information related to preventive strategies, communication systems for specific threats, laboratory networks, outreach and education for state and local governments, and resource requirements.

*Publish regulation.*

Ensure a transportation policy is established. The policy will be used as a foundation for the specifics of the regulation once published.


### Sec. 111. Sanitary transportation of food.
FDA to create regulation for sanitary transportation practices. Regulation may include: sanitation, limitations on use of vehicles, recordkeeping; and not compatible material list.

*Publish regulation.*


### Sec. 112. Food allergy and anaphylaxis management.
FDA shall publish guidelines for handling food allergies for schools and early childhood education programs. School-based food allergy management grants may be issued.

*Publish guidelines.*

Educational agencies should adhere to the allergy management guidelines.


### Sec. 113. New dietary ingredients.
New dietary supplements that contain anabolic steroids will be reported to the Drug Enforcement Administration.

*Manufacturers of dietary ingredients must adhere to Guidance for Industry: New Dietary Ingredient Notifications and Related Issues (published July 2011).*

**Sec. 114. Requirement for guidance relating to post harvest processing of raw oysters.**

Prior to any changes to Seafood HACCP regulations, the FDA shall issue a report on the post harvest processing of raw oysters.

Publish a report. Update Seafood HACCP Regulations accordingly.

Seafood processors must adhere to updates to the Seafood Hazards and Controls Guide. Processors of raw oysters must adhere to regulations once published.

**Fish and Fishery Products Hazards and Controls Guidance (4th Edition) published November 2011. The report on oysters has not been published.**

**Sec. 115. Port shopping.**

FDA must notify homeland security of any refused entries in order to prevent port shopping.

Communicate with homeland security.

**Effective January 4, 2011.**

**Sec. 116. Alcohol-related facilities.**

Exceptions to FSMA are outlined for alcohol related facilities.

Alcohol related facilities shall become familiar with components of FSMA that do not apply.

**Effective January 4, 2011.**

**Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report.**

FDA shall identify high-risk and non-high risk facilities. FDA to inspect all domestic high-risk facilities by 2016 and at least every 3 years thereafter. FDA to inspect all domestic non-high risk facilities by 2018 and at least every 5 years thereafter. FDA is to inspect at least 600 foreign facilities by 2012 and to double the number of foreign facilities inspected every 5 years.

Increase inspections. Define high risk and non-high risk.

In preparation for increased frequencies for FDA inspections, review company established regulatory inspection procedure with responsible personnel. Understand “new” definition of high risk.


**Sec. 202. Laboratory accreditation for analyses of foods.**

FDA is implementing an accreditation program for laboratories conducting testing on their behalf.

Develop and implement a lab accreditation program.

**Due January 4, 2013**

**Sec. 203. Integrated consortium of laboratory networks.**

A laboratory network will be established between the following US agencies: Health and Human Services, Department of Agriculture, Department of Commerce, and EPA.

Develop laboratory network.

**Effective January 4, 2011.**

Conduct pilot trace projects in conjunction with IFT.

**Sec. 204. Enhancing tracking and tracing of food and recordkeeping.**

FDA to conduct pilot projects for improved traceability.

Ensure robust Traceability Program is in effect for ingredients, processing aides, and food contact packing. Make any updates to the program, such as additional recordkeeping requirements for high risk foods, once regulation is published.


**Sec. 205. Surveillance.**

FDA to work with other government agencies and laboratories to improve monitoring for and responding to food borne outbreaks.

Enhance monitoring and information sharing systems related to food borne outbreaks.

**Effective January 4, 2012. Improved recall search engine on FDA website April 2011.**
**Sec. 206. Mandatory recall authority.**

If a responsible party does not voluntarily recall a food that is in violation of the law, the FDA may cease distribution of the product, notify all persons to whom the product has been distributed.

**Sec. 207. Administrative detention of food.**

The threshold for the FDA to detain product has been lowered. The new standard is that if there is reason to believe that the food is adulterated or misbranded, the FDA may detain the product.

**Sec. 208. Decontamination and disposal standards and plans.**

The following agencies shall work together to develop plans to respond to agriculture or food emergencies: Environmental Protection Agency, Health and Human Services, Homeland Security, Department of Agriculture.

**Sec. 209. Improving the training of state, local, territorial, and tribal food safety officials.**

FDA shall establish training standards and administer training for state and local food safety officials.

**Sec. 210. Enhancing food safety.**

FDA to make grants available to government and non-profit food safety training organizations. The grants will be used for conducting food safety inspections and investigations; conducting food safety training; build food safety capacity of laboratories. The FDA shall designate 5 Food Safety Centers of Excellence to act as resources for food safety officials.

**Sec. 211. Improving the Reportable Food Registry.**

Additional information is required to be submitted when reporting a Reportable Food. Grocery stores must post in a conspicuous location food on the Reportable Food Registry that they have sold.

**Sec. 301. Foreign supplier verification program.**

Importers must perform risk-based foreign supplier verification to ensure that the food complies with US Food Laws.

**Sec. 302. Voluntary qualified importer program.**

US importers will be allowed to apply for this voluntary program to expedite importation activities.
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<tr>
<td><strong>Sec. 303. Authority to require import certifications for food.</strong></td>
<td>The FDA has the authority to require foreign manufacturers to provide a certificate to accompany foods being exported to the US. The certificates would be provided by the government where the food is manufactured or by agencies that are accredited to issue such certificates. The certificate would provide assurance that the food was manufactured in compliance with the Food, Drug, and Cosmetic Act. Determine criteria for requiring import certifications. Authority granted January 4, 2011.</td>
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<tr>
<td><strong>Sec. 304. Prior notice of imported food shipments.</strong></td>
<td>Prior notice of imported food shipments will now need to include any country to which the food has been refused entry. Interim Final Rule: Information Required in Prior Notice of Imported Food published May 2011.</td>
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<td><strong>Sec. 305. Building capacity of foreign governments with respect to food safety.</strong></td>
<td>FDA to assist foreign governments with improving food safety in foreign countries.</td>
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<td><strong>Sec. 306. Inspection of foreign food facilities.</strong></td>
<td>FDA may inspect any foreign facility that is registered with the FDA. (FDA registration is required to export to the US.) Consider aiding foreign suppliers in understanding and preparing for FDA inspections. Determine if additional foreign suppliers are needed in the event that the facility refuses inspection or if the facility is seized. Effective January 4, 2011.</td>
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<td><strong>Sec. 307. Accreditation of third-party auditors.</strong></td>
<td>FDA to establish a program for accredited third party auditors to conduct audits on behalf of the FDA. Third party auditors may include foreign governments. Establish third-party auditor accreditation program. Due July 4, 2012. Overdue.</td>
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<td><strong>Sec. 308. Foreign offices of the Food and Drug Administration.</strong></td>
<td>FDA to establish offices in foreign countries. Report to Congress on FDA Foreign Offices published February 2012.</td>
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<td><strong>Sec. 309. Smuggled food.</strong></td>
<td>FDA to work with Department of Homeland Security to develop a strategy to improve detection of smuggled foods and public reporting of smuggled foods for which there is a reason to believe the food will cause serious adverse health consequences or death to humans or animals. Improve smuggled food program. Anti-smuggling strategy issued July 2011.</td>
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<td><strong>Sec. 401. Funding for food safety.</strong></td>
<td>FDA to increase number of field staff for food safety and food defense. Minimum staffing for 2011, 2012, 2013, and 2014 established. Increase staff.</td>
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<td><strong>Sec. 402. Employee protections.</strong></td>
<td>Employees cannot be fired or discriminated against for reporting violations of the Food, Drug, and Cosmetic Act. Report discrimination against “whistle-blowers” to the Department of Labor. Ensure Human Resource policies are in alignment with this new protection. Effective January 4, 2011.</td>
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<td><strong>Sec. 404. Compliance with international agreements.</strong></td>
<td>Nothing in the FSMA will be inconsistent with the World Trade Organization. Be mindful of impact of requirements for foreign suppliers on WTO treaties. Effective January 4, 2011.</td>
</tr>
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<td><strong>Sec. 405. Determination of budgetary effects.</strong></td>
<td>Budgetary effects of FSMA will be evaluated based on the “Budgetary Effects of PAYGO Legislation” Effective January 4, 2011.</td>
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