FSMA Implementation – What Do I Need to Know and What Do I Need to Do?

Hilary Thesmar, PhD, RD, CFS
FMI
Intro to Federal Agencies with oversight of food safety

<table>
<thead>
<tr>
<th>FDA</th>
<th>USDA</th>
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<tbody>
<tr>
<td>• Everything else including</td>
<td>• Meat</td>
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<tr>
<td>• Shell eggs</td>
<td>• Poultry</td>
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<tr>
<td>• All other fish</td>
<td>• Egg Products</td>
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<td>• Catfish</td>
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Food Safety Modernization Act

- Signed January 4, 2011
- P.L. 111-353
- Most expansive changes to FD&C Act since 1938
  - New enforcement authorities
  - New program activities
  - Increased inspections
SUPPLY CHAIN CONFERENCE

Why?
Federal Regulatory Process

Legislative
- Congress passes laws directing agencies to regulate on specific issues (e.g. FSMA statutory mandate)

Regulatory
1. Pre-rulemaking activities: Agencies may open docket or publish advanced notice of proposed rulemaking requesting information needed to develop final rule
2. Proposed Rule published in Federal Register; begins notice and comment period (typically 60 days but can be longer and is often extended)
3. Preparation of final rule
   1. FDA must consider comments received in drafting final rule
   2. The Office of Management and Budget reviews proposed and final rules prior to publication if “economically significant”
   3. Final Rule: Published in Federal Register and carries the force of law

Process can take years to complete
Regulatory Process

- FSMA Bill was 89 Pages
- FDA has published well over 2000 pages of regulations in the Federal Register
FSMA at a Glance

**PREVENT**
- Records Inspection
- Registration of Facilities
- Preventive Controls
- Performance Standards
- Food Defense
- Sanitary Transportation
- Allergy Management
- Port Shopping

**DETECT & RESPOND**
- Inspection Resources
- Laboratory Accreditation
- Integrated Lab Networks
- Surveillance
- Mandatory Recall
- Admin. Detention of Food
- Training of Officials
- Improving RFR

**IMPORTS**
- Foreign Supplier Verification
- Voluntary Qualified Importer Program
- Import Certification
- Prior Notice
- Capacity of Foreign Gov.
- Inspection of Foreign Facility
- 3rd Party Auditor Accreditation
- Smuggled Food

**MISCELLANEOUS**
- Funding
- Employee Protections
- Jurisdictions/Authorities
- International Agreements
- Budgetary Effects
## Review of the 7 Major Rules

<table>
<thead>
<tr>
<th>Seven Major FSMA Regulations</th>
<th>Publication Date or Expected Date</th>
<th>Expected Compliance Deadline**</th>
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<tbody>
<tr>
<td>1. Preventive Controls – Human food</td>
<td>September 17, 2015</td>
<td>September 17, 2016</td>
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<tr>
<td>2. Preventive Controls – Animal food</td>
<td>September 17, 2015</td>
<td>September 17, 2016 cGMP September 19, 2017 PC</td>
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<td>3. Produce Safety</td>
<td>November 27, 2015</td>
<td>Jan 26, 2018</td>
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<td>5. Accreditation of Third Party Auditors</td>
<td>November 27, 2015</td>
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<tr>
<td>6. Sanitary Transportation</td>
<td>April 6, 2016</td>
<td>April 6, 2017</td>
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<tr>
<td>7. Food Defense</td>
<td>May 27, 2016</td>
<td>July 26, 2019</td>
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** Compliance deadlines depend on several variables so check the rules for details.
Preventive Controls for Human Food and Preventive Controls for Animal Food
Who has to comply?

• Facilities that manufacture, process, pack or hold food for humans or animals
• Facility Registration Requirement
• What do you have to do?
  – Hazard Analysis
  – Preventive Control Food Safety Plan
Food Safety Plan
Including procedures for monitoring, corrective action and verification, as appropriate

GMPs and Other Prerequisite Programs
Foreign Supplier Verification Programs
The **US owner or consignee** of an article of food that is being offered for import into the US. If there is no US owner or consignee of an article of food at the time of US entry, the importer is the US agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.
What is required?

- Supplier approval program
- Hazard analysis
- Evaluation of supplier’s performance and the risk posed by the food
- Verification Activities
- Corrective actions, as needed
- Reevaluate and reassess hazards periodically
- Recordkeeping
Are you the Importer?

- Importer Identification
- FSVP Importer must be identified at entry
  - Customs and Border Patrol Importer must identify the FSVP importer on the customs forms
  - FSVP Importers must have a Unique Facility Identifier (such as a DUNS number)
FSVP Records for Compliance

- Hazard analysis
- Foreign supplier performance evaluation
- Procedures for approving foreign suppliers
- Foreign supplier approval
- Procedures to assure use of only approved foreign suppliers
- Determination of verification methods and frequency
- Performance of verification activities
- Any necessary corrective actions
- Reevaluations of your FSVP either for cause or routinely every 3 years
SANITARY TRANSPORTATION
Sanitary Transportation Resource

Global Cold Chain Alliance Guide and Checklists

http://www.gcca.org/resources/sanitary-transportation-food-compliance-resources/
Waivers

• Final Rule on Sanitary Transport Waivers
  – April 6, 2017
  – Three waivers for businesses whose transportation operations are subject to separate State-Federal controls
  – One is for retail establishments and for direct to consumer transportation
    • Retail stores are exempt from being receivers
    • Direct to consumer delivery is exempt from being carriers
Training

Preventive Controls for Human Food

Preventive Controls for Animal Food

Foreign Supplier Verification Programs

Sanitary Transportation Carrier Training
Cross Functional Teams

- Senior Management
- IT
- Operations
- Logistics
- Food Safety

- Food Safety
- HR
- Procurement
Recordkeeping

• In general, keep records for 2 year and have records available to FDA in 24 hours
• Paper is going to be a challenge
• Document management systems
  – Maintaining records
  – Reminders for expired certificates, audits, etc
Overwhelmed?

- https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm
Effort Matters
Questions?