FSMA Implications for the Supply Chain
FSMA Implications for the Supply Chain

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Food Marketing Institute
Questions?

• What have you heard about FSMA?
• Has your company started planning for FSMA?
Intro to Federal Agencies with oversight of food safety

<table>
<thead>
<tr>
<th>USDA</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Meat</td>
<td>• Most foods</td>
</tr>
<tr>
<td>• Poultry</td>
<td>• Shell eggs</td>
</tr>
<tr>
<td>• Egg products (liquid eggs)</td>
<td>• All fish but catfish</td>
</tr>
<tr>
<td>• Catfish</td>
<td>• Food Labeling</td>
</tr>
</tbody>
</table>
Agency Rulemaking

- Procedure for Creating Rulemaking
  - Advanced Notice of Proposed Rulemaking (ANPR): “thinking about it”
  - Proposed Rule: “tentative conclusions...speak now or....”
  - Final Rule: “Comply or else”
Food Safety Modernization Act

• Modified the Food Drug and Cosmetic Act
  – New enforcement authorities
  – New program activities
  – Increased FDA inspection authority

• Signed January 4, 2011

• P.L. 111-353
FSMA Statute

1. Prevention - Improving capacity to prevent food safety problems
2. Detection - Improving capacity to detect and respond to food safety problems
3. Imports - Improving the safety of imported foods
**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
Question

Do you have FDA Registered Facilities?
Facility Registration

FSMA
Food Drug and Cosmetic Act §415
Facilities engaged in manufacturing, processing, packing, or holding food for consumption must register
Q4 each even number year
FDA Authority

- Facility Registration and Suspension of Registration
- Increased Inspections
  - Depends on appropriations
- Increased Records Access
- Mandatory Recall Authority
- Import Certification Authority
- Fees for Reinspection
- Administration Detention
Records and Records Access

• FSMA greatly expands FDA’s access to records, allowing FDA to review many food safety related records at any time

• Five main records-related changes or requirements:
  – Food Safety Plan records
  – Foreign Supplier Verification Program records
  – Food Defense Plan records
  – Sanitary transportation records
  – Expanded FDA access to records during an emergency (written request)

• Additional records expected...
  – High risk foods traceability
Question

Where are your food safety records?

Can you access them in 24 hours?
Some FSMA requirements are in effect, some are yet to come...
Timelines for final rules

<table>
<thead>
<tr>
<th>Seven Major FSMA Regulations</th>
<th>Court Ordered Deadlines for Final Regulations</th>
<th>Expected Compliance Deadline**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Preventive Controls – Human food *</td>
<td>August 30, 2015</td>
<td>August 30, 2016</td>
</tr>
<tr>
<td>2. Preventive Controls – Animal food*</td>
<td>August 30, 2015</td>
<td>August 30, 2016</td>
</tr>
<tr>
<td>6. Sanitary Transportation</td>
<td>March 31, 2016</td>
<td>March 31, 2017</td>
</tr>
</tbody>
</table>

* Published as supplemental proposed rules in September 2014
** Compliance deadlines are one year after final rule is published
Future FSMA Regulations

- High risk foods list
- Traceability
- Reportable Food Registry
  - Consumer notification of recalls
FSMA compliance by facility type

<table>
<thead>
<tr>
<th>Produce safety</th>
<th>Retailer with stores</th>
<th>Retailer: central kitchen, or off-site production</th>
<th>Retailer/wholesaler: DC, truck fleet</th>
<th>Retailer/wholesaler DC &amp; imports</th>
<th>Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Preventive Control Plan</td>
<td></td>
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<tr>
<td>Food Defense Plan</td>
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<tr>
<td>Sanitary transportation</td>
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<tr>
<td>Foreign supplier verification</td>
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Foreign Supplier Verification Program

- Importer required to verify food was produced in compliance with Preventive Controls or Produce Safety rules
- Food meets labeling requirements, allergen labeling
- Verification program requires auditing of food safety programs by third party
- Foreign supplier approvals (lists/database)
FSVP - Importer

2) IMPORTER DEFINED
For purposes of this section, the term ‘importer’ means, with respect to an article of food

(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or

(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

From 111th Congress Public Law 353, Section 301
Produce Safety

• Produce farms must meet minimal food safety requirements

• Small farms and direct sales to retail/restaurants are exempt
  – Labeling required at retail
Preventive Controls

• All FDA Registered Facilities must have a Hazard Analysis and Preventive Control - Food Safety Plan
  – Monitoring, corrective actions, verification, recordkeeping
  – Training for qualified individual
  – Supplier verification for manufacturers/processors with significant hazards
Food Defense Plan

• Preventing intentional contamination
• Written food defense plans
• Required for manufacturing/processing facilities and bulk liquid holding
Sanitary Transportation

- Prevent food safety issues during transport
- Applies to USDA and FDA food products
- Inter and intra-state
- Shippers, carriers and receivers
- Temperature control, preventing cross contamination, cleaning
- Records and contracts are key
FMI Resources

FMI Food Safety FSMA Resources

http://www.fmi.org/government-affairs/regulatory/food-safety---fsma-resources

• Preventive Controls plan for warehouses and distribution centers
• Generic recordkeeping forms for all retail specific documents

FMI Comments Filed

http://www.fmi.org/government-affairs/regulatory/recent-comments-filed
GMA Resources

Food and Product Safety

Food Safety Modernization Act

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