

Food Safety Modernization Act

Operational Considerations

- ### FSMA
- Signed into Law January 4, 2011
 - Most significant regulatory change since “the Act” was updated in 1938.
 - Need has been discussed for some time i.e. update of cGMPs
 - Change is driven by outrage.
 - Don’t mess with our Kids and Pets.

- ### Key Areas of Focus
- Preventative Controls
 - HACCP Based
 - Inspections, Compliance and Response
 - Defined Frequency based on risk
 - Records Access
 - Detention
 - Imported Food Safety
 - Importer Responsibility
 - Agency Collaboration
 - USDA/FDA, States

January 2012

- Produce Safety Standards
- High Risk Foods List
- Foreign Supplier Verification Guide/Regs
- Food Protection Plan NPR (Comments 12/20)

July 2012

- Food Safety Plan Regs
- Food Safety Plan Minimum Standards
- Food Defense Regs
- Food Trace Pilot Study Results
- Farm Related Activities Final Regs
- Voluntary Qualified Importer Program

January 2013

- Food Safety Plans for Small Entities
- Recordkeeping for High Risk Foods NPR
- Enforcement of Supplier Verification Regs

Other Key Dates

- Biennial based Registration - Oct – Dec 2012
- Produce Standard Final Regs – April 2013
- Small Entity CPG Recordkeeping – July 2013
- Food Safety Plan very small entities – Jan 2014
- Electronic Registration – Jan 2016
- Performance Standards - ?
- Product Tracing System - ?



Imports Sections 301-307

Also including Section 107 – Fees!!! \$\$\$\$\$\$\$\$\$\$

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Section 107 - Fees

- "(A)to cover reinspection-related costs;
- "(B)who does not comply with a recall order to cover food recall activities including technical assistance, follow-up effectiveness checks, and public notifications,
- "(C)each importer participating in the voluntary qualified importer program to cover the administrative costs of such program for such year; and
- "(D)importer subject to a reinspection to cover reinspection-related costs..."

2011 fees - \$224 per hour with no foreign travel
2011 fees - \$325 per hour with foreign travel

Was to go into effect October 1 but this section has been re-opened for public comment with no fees to be assessed prior to January 1, 2012

Section 301
Foreign Supplier Verification program

- Foreign supplier verification (guidance/regulation 1 year – effective 2 years) :
- Levels the playing field
- Potential exacerbation of port delays



Section 303
Import Certification Authority

- Import certification authority for FDA:
 - Authorizes HHS to require imported food certificates
 - Definition of high risk foods required
- Who is the importer?




Section 304 & 305
Prior notice/ Building capacity of foreign governments with respect to food safety

- Potential alteration to supply chain economics, logistics



Sections 306 and 307
Inspection of foreign facilities
Accreditation of 3rd party auditors

- Inspection of foreign food facilities (immediate)
- 3rd party audits (no time line):
 - voluntary vs. required
 - penalties for auditors
 - domestic vs. foreign
 - regulatory vs. customer



Electronic Inspection Tools

- POC (proof of concept) taking place
- Uses electronic tablet with camera and video
- Electronic database
- PHOTOGRAPH Policies!!



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Impact of Food Safety Modernization Act on Operations


by
John Lin



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Administrative Detention:

FDA can order administrative detention if there is reason to believe that an article of food is adulterated or misbranded




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Reason to believe:

To be determined on a case by case basis

- Class I recall
- Class II recall
- Insanitary processing environment



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Preventive Control: Food and Animal Feed


- Hazard Analysis
- Preventive Controls
- Corrective Actions
- Verification
- Recordkeeping and Record Access



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Inspections:

- **High-Risk Facilities:**
At least once in the first 5-year period and at least once every 3 years thereafter
- **Non High-Risk Facilities:**
At least once in the first 7-year period and at least once every 5 years thereafter



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High-Risk Facilities:

- Types of food
- Compliance history of the facility
- Effectiveness of hazard analysis and preventive control
- Third-party audits




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Facility Registration:

- FSMA requires food facilities to register with FDA biennially.

Suspension of Registration:

- Facility that is responsible for the cause
- Facility that packed, received, or held such food and that knew, or had reason to know, such reasonable probability



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What should the food industries do:

- Be Proactive
- Focus on Training and Education
- Enhance Sanitation and Pest Control Programs
- Execute Preventive Controls
- Verify supply chains
- Control Risks



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Impact of FSMA on Operations.

- Partnership in reaching the common goal
- Communication is the key
- More effective food safety system
- More consumer confidence