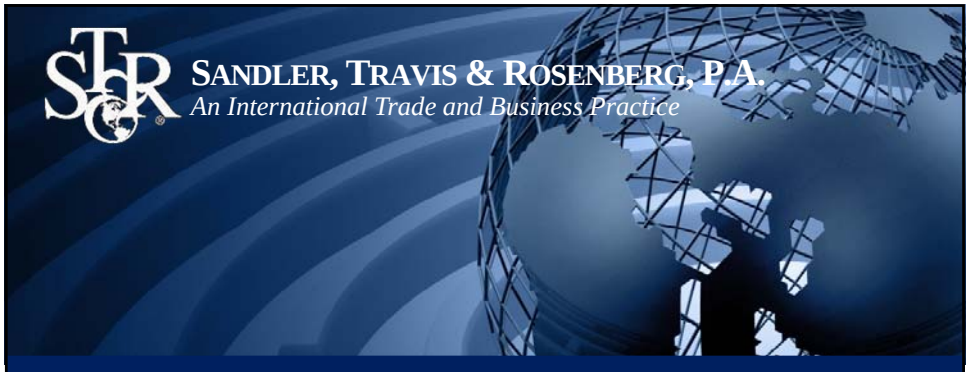

FDA'S Implementation of FSMA:
THE 2012 UPDATE

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International Trade Association of Greater Chicago
Chicago, Illinois July 11, 2012

The Food Safety Modernization Act

- Effective January 4, 2011
- Most significant change to U.S. food supply regulations since 1938
- Creates a comprehensive risk-based approach to food safety
- 50 FDA guidances and/or regulations to be published over approximately 36 months

FSMA = Paradigm Shift

Before FSMA…

- Event-based response
- Reactive
- "Gatekeeper". Partnered w/ OGAs to enforce laws.
- Addressed problems only after they arose

After FSMA…

- Risk-based, approach
- Proactive: Inspections, verifications
- FDA has new enforcement authority and tools
- Regulations intended to prevent food safety incidents

Prevention is the key!

What is a “Food” under FSMA?

Agenda

I. FSMA Overview
II. FSMA Implementation Update
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V. Import Alerts & HACCP Plans
VI. What to expect in 2012 and Beyond
VII. Question & Answer

Implementation Schedule

UPON ENACTMENT (JANUARY 2011)	
101	Inspection of records
107	Authority to collect fees (Implemented/Under enforcement discretion)
201	Targeting of inspections resources
206	Mandatory recall authority
303	Authority to require import certificates
306	Inspection of foreign food facilities
309	Identification of smuggled food

Implementation Schedule

JULY 2011	
102	New requirements for registration (Deadline 12/31/12)
113	New Dietary Ingredients (Guidance published 07/03/11)
207	Interim final rule on administrative detention of food
304	Prior Notice of imported food shipments
OCTOBER 2011	
204	Traceability Pilot Projects (launched 09/07/12)
JANUARY 2012	
105	Draft Standards for Fresh Produce (Delayed)
105	Guidelines for Fresh Produce (Delayed)
106	Guidelines re: Intentional Adulteration (Delayed)
204	High Risk Food: Recordkeeping & Pilots (Partial)

Implementation Schedule

JULY 2012	
103	**Hazard Analysis and Risk-based controls**
106	**Standards re: Intentional Adulteration**
302	**Voluntary Qualified Importer Program (VQIP)**
307	**Third Party Accreditation Process**
JAN 2013	
202	**Program for Accreditation of Laboratories**
204	**Draft traceability standard**
301	**Foreign Supplier Verification Program (FSVP)**
305	**Plan to expand foreign government capacity**
307	**Recognition of accreditation bodies**
307	**Accreditation of third parties**

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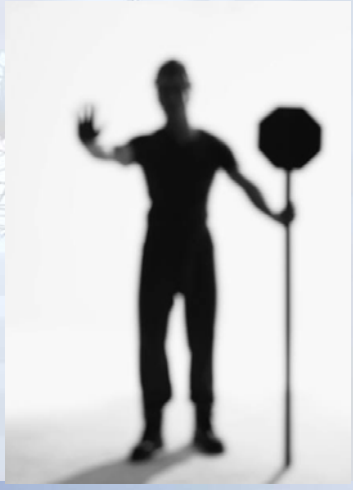
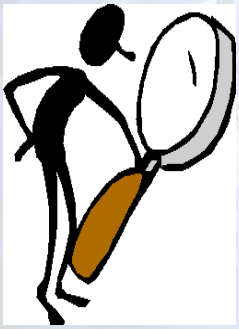
Food facility registration

- Under BTA: registration required for all foreign food facilities + US Agent
- Under **FSMA 102**:
  - bi-annual registration (Beginning Oct/Dec 2012)
  - FSMA - new authority to suspend registration

Registration goes from passive database to active enforcement tool!



Inspection of Foreign Facilities

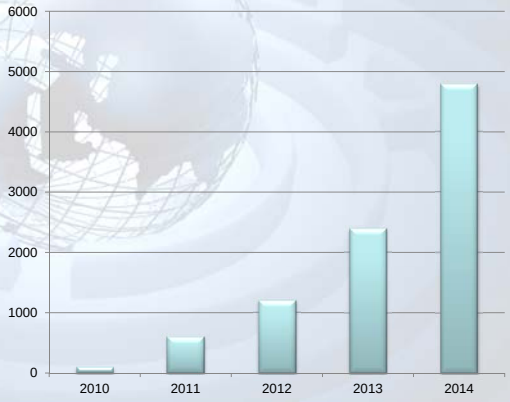


- **Under FSMA 306**:
  - Secretary MAY enter into arrangements…to facilitate inspections pursuant FSMA 102
- **Under FSMA 102:**
  - registration of facilities
  - suspension of registration
- **Under FSMA 306:**

Request for inspection shall be considered refused if factory, warehouse, etc. does not respond to inspection request during the 24 hours after such request is made.

➢ ***Consequence: Entries may be refused.***

Inspections Frequency



Total Inspections:	106	600	1200	2400	4800

User Fees

Under **FSMA 107**:

- FDA has authority to collect fees
- Was to begin Oct. 1, 2011, but postponed to Jan. 1, 2012
- US Registered Agent shall be responsible registered facility's fees
- FDA will charge hourly fees for its employees' time spent on:

1. Re-inspection of Imported Foods
2. Re-inspection of Food Facilities
3. Recalls
   - Domestic: US$ 224/hour
   - Foreign: US$ 325/hour

Imported Food Certification

Under **FSMA 303**:

- FDA will determine which foods require certification
  - Based on country/region risk
  - Based on food safety risk
- Imports w/ safety standards will not be allowed in after 2013 without certification
- Who certifies?
  - Gov't or accredited body of exporting country
- Falsification of certification is a "prohibited act"

HAZARD ANALYSIS & RISK-BASED PREVENTIVE CONTROLS

Under **FSMA 103** facilities must:

- Evaluate hazards & implement preventive controls
- Monitor performance & verify effectiveness of preventive controls
- Maintain records & written plan on hazards and preventive controls
- July 2012:
  - general requirements take effect
  - FDA to establish science-based standards for conducting hazard analysis & implementing preventive controls
  - FDA initiates study of food processing industry
- ***Modified requirements for "qualified facilities" (US only)***

HAZARD ANALYSIS & RISK-BASED PREVENTIVE CONTROLS

FDA Response to Peanut &Tree Nut Processors Association:
(June 18, 2012)

*"This responds to your letter of May 29, 2012, concerning FDA's plans regarding the preventive controls and foreign supplier verification provisions in sections 103 and 301 of the Food Safety Modernization Act (FSMA). Your letter was prompted by the approaching statutory effective date of **July 3, 2012**, for the preventive controls provision."*

*"FDA is committed to full and timely implementation of FSMA and **will be issuing proposed rules to implement sections 103 and 301**. Those rules, when final, will contain provisions that clarify industry's responsibilities and will foster compliance with FSMA's new requirements in an orderly and effective manner. FDA will expect to enforce compliance with these new FSMA requirements in timeframes that will be described in the final rules."*

Michael R. Taylor
Deputy Commissioner for Foods

WRITTEN SAFETY PLAN

- **FSMA 106**
- For facility site AND for specific food articles
- Site risks
- Control of food risks
- Systems monitoring

NOTE: Plan is basis for compliance. If you violate your plan you violate the law

STANDARDS FOR FRESH PRODUCE

- **FSMA 105**
- FDA will establish standards for safe production & harvesting
- Standards will apply to processed foods and raw fruits & vegetables and are intended to minimize risk of serious adverse health consequences
- Jan. 2012
  - Proposed rule to be published (delayed)
  - Updated Good Agricultural Practices (GAP) to be published (delayed)

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Foreign Supplier Verification

- **FSMA 301**
- Risk-based verification by importers
- Provide assurances of compliance w/ **FSMA 103** and **105**
- Recordkeeping
- Publication of Importer List on Web Site: Non-compliance is "Prohibited Act"
- **Exempted**: Juice, Seafood & LACF Facilities

Voluntary Qualified Importer Program

- **FSMA 301**
- "Expedited review and importation" (i.e. good clear customs more quickly!- perhaps)
- Issuance of a facility certification
- Eligibility for participation based on risk factors
- Re-evaluation: not less than once every three years
- Prompt revocation if not in compliance
- July 2012: Program to be established

Prior Notice

- **FSMA 304**, amending BTA Prior Notices Requirement
- **Effective**: June 2011
- (m) **Prior notice of imported food shipments** (1) In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; **any country to which the article has been refused entry;** and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food.

Third-Party Auditor Accreditation

- **FSMA 307**
- FDA will accredit 3rd parties or recognize accreditation bodies
- FDA/accreditation bodies: certify food articles and/or facilities
- Jan 2013: List of accreditation bodies will be posted on FDA list
- June 2012:
  - FDA develops model standards
  - FDA issues regulations re: conflict of interest

MANDATING FOOD RECALLS

- **FSMA 206**
- FDA has mandatory food-recall authority
- Where an article is "adulterated or misbranded and exposure to such article will cause serious adverse consequences to consumer"
- Effective Jan. 2011

CONSEQUENCES OF NON- COMPLIANCE

- New Authority
- New Triggers
- What is at Stake?
- Suspension of Registration
- New Crimes
- Expanded Penalties

Enforcement of FSMA

1. Shut down food facility via suspension of registration
2. Issue civil penalties in the $10,000's or $100,000's
3. Initiate court action for seizure or injunction
4. Issue Import Alert which results in refused entry
5. Prosecute for "Smuggled Food" (knowing false statement)

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FDA Import Alerts

- **Violative History**: of foods, manufacturers/shippers, growers, geographic area, countries of origin, importers, combination of issues
- **Detention Without Physical Exam (DWPE):** based on evidence from field offices or foreign inspections; foreign govt, state or agency
- **Removal from DWPE:** by submitting petition to FDA.
- **Petition require evidence of**:
  1. Successful identification of source of contamination
  2. Successful implementation of adequate Corrective Action Plan (CAP)
  3. **Implementation of a new HACCP Plan incorporating CAP**
  4. Evidence of entry of a minimum of five (5) non-violative shipments (including laboratory analysis)
  5. Assurance cause of violation has been corrected

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Foreign Government Capacity Building

- **FSMA 305**
- Effective Jan. 2013
- Bilateral/multilateral food safety agreements
- Secure electronic data sharing

- Mutual recognition of inspection reports
- Training of foreign governments and producers
- Harmonization of *Codex Alimentarius*
- Multilateral acceptance of laboratory methods and testing and detection techniques

3-Steps Process for Compliance

1. **Understand** which provisions of the FSMA affects your business directly and when compliance is required
2. **Begin training** your staff to understand new FDA requirements
3. **Work** with experienced FDA and customs counsel to:
   - Understand impact of new regulations
   - Plan for timely compliance
   - Train your staff
   - Comply fully with portions of FSMA that apply to your business

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Questions?

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