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FDA Food Safety Modernization Act
What you should know about its impact on imported foods

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Agenda

- Basic provisions of the FSMA we will cover:
  - Preventive Controls
  - Foreign Supplier Verification
  - Voluntary Qualified Importer Program
  - Required Import Certifications
  - Building Capacity of Foreign Governments
  - Increased Foreign Inspections by FDA
  - Tracking & Tracing
  - Facility Registration
  - Changes to prior notice for food imports
  - Enhanced FDA Enforcement Powers:
    - Recalls
    - Suspension of Facility Registration
    - Administrative Detention
- FDA's priorities and resources
- WTO Obligations

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Introduction

- FSMA responds to food safety concerns from the American public, prompted by highly publicized foodborne illness outbreaks:
  - E. coli in spinach
  - Salmonela in peanut butter
  - Salmonela in Eggs
- According to new CDC statistics, there are 3,000 deaths, 128,000 hospitalizations and 48 million illnesses annually in the U.S. caused by foodborne pathogens.
- FSMA includes provisions long sought by consumer advocates, notably FDA's new authority to order food recalls.
- FSMA tends to impose U.S. food safety standards on the rest of the world.
- FSMA is extremely detailed.

Hazard Analysis and Risk Based Preventive Controls

- Every U.S. food processing facility must:
  - Develop a written evaluation of the hazards (microbiological, chemical, intentional, etc.) that could affect food handled at the facility.
  - Identify and implement preventive controls.
  - Monitor the effectiveness of those controls and maintain records of this monitoring.
  - Establish procedures for corrective action if preventive controls are not properly carried out or are found to be ineffective.
  - Verify the preventive controls are adequate and have periodic reanalysis.

Hazard Analysis and Risk Based Preventive Controls *continued*

- Facilities must prepare a written plan that documents these procedures.
- Facilities must maintain for at least 2 years records documenting their monitoring of the preventive controls, instances when corrective actions were implemented, etc.
- A facility's written plan + the recordkeeping documentation must be made available to authorized inspectors upon request.
- Exceptions: seafood, juice, low-acid canned food facilities subject to HACCP, and dietary supplement facilities in compliance with dietary supplement GMP rule + adverse event reporting.
- FDA to adopt regulations within 18 months.

Foreign Supplier Verification

- Represents a significant shift in U.S. law.
- Becomes effective in January 2013.
- Each U.S. food importer "shall perform risk-based foreign supplier verification activities" to verify the imported food is:
  - Produced in compliance with the new requirements of section 418 (hazard analysis and risk-based preventive controls); and
  - Not "adulterated" or "misbranded."
- FDA is required to issue guidance and regulations in this area by January 2012.

Foreign Supplier Verification *continued*

- The regulations issued in this area shall be aimed at providing the same level of public health protection as those issued under section 418 (hazard analysis and risk-based preventive controls for U.S. facilities).
- FDA can include additional requirements, as needed, to verify imported food is as safe as food produced and sold within the U.S.
- Importers must maintain records related to foreign supplier verification programs for at least 2 years and make those records available to inspectors.
- Exemption is carried over for foreign seafood, juice, and low-acid canned food facilities complying with HACCP.

Voluntary Qualified Importer Program

- Participating importers receive expedited review and importation of food shipments.
- FDA is directed to establish a process for issuing "facility certifications" to accompany food offered for import.
- To begin no later than 18 months after FSMA's adoption (i.e., by July 2012).
- FDA is directed to issue guidance (not rulemaking).

Voluntary Qualified Importer Program
continued

- Eligibility is limited to importers offering food from a certified facility.
- In reviewing applications, FDA must consider risk of the food based on factors such as:
  - Known (inherent) safety risks of the food
  - Compliance history of the foreign supplier
  - Capability of regulatory system of the country of export
  - The importer's compliance with foreign supplier verification program
  - Recordkeeping, testing, inspections, traceability, temperature controls, and sourcing practices of the importer
  - Potential risk of intentional contamination
  - Any other factor FDA deems appropriate

Voluntary Qualified Importer Program
continued

- FDA can revoke qualified importer status and must re-evaluate qualified importers at least once every 3 years.
- False statements from importers to FDA are punishable with fines, imprisonment, or both.
- In this context, “importer” means the person who brings food or causes food to be brought from a foreign country into the U.S.

Authority to Require Import Certifications

- FDA may **require** that an agency or representative of a foreign government or an accredited third-party auditor certify that a food offered for import complies with the Food, Drug, and Cosmetic Act.
- In deciding to require such certification, FDA must consider:
  - Known food safety risks associated with the food
  - Known food safety risks associated with the country or territory
  - A finding, supported by evidence, that:
    - Food safety programs in the exporting country/territory are inadequate to ensure the food is as safe as U.S. produced version; and
    - The certification would assist FDA in determining whether to admit or refuse the food.

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Assessment of Foreign Food Safety Programs, Systems, Standards

- If FDA determines the food safety programs, systems, and standards of a foreign country/territory are inadequate to ensure safety (comparable to U.S. produced food), FDA must identify those inadequacies and establish a process for the foreign country/territory to inform FDA about improvements or demonstrate its food safety programs/standards are adequate.
- FDA must take such information received from foreign countries/territories into account in deciding whether to require import certifications.

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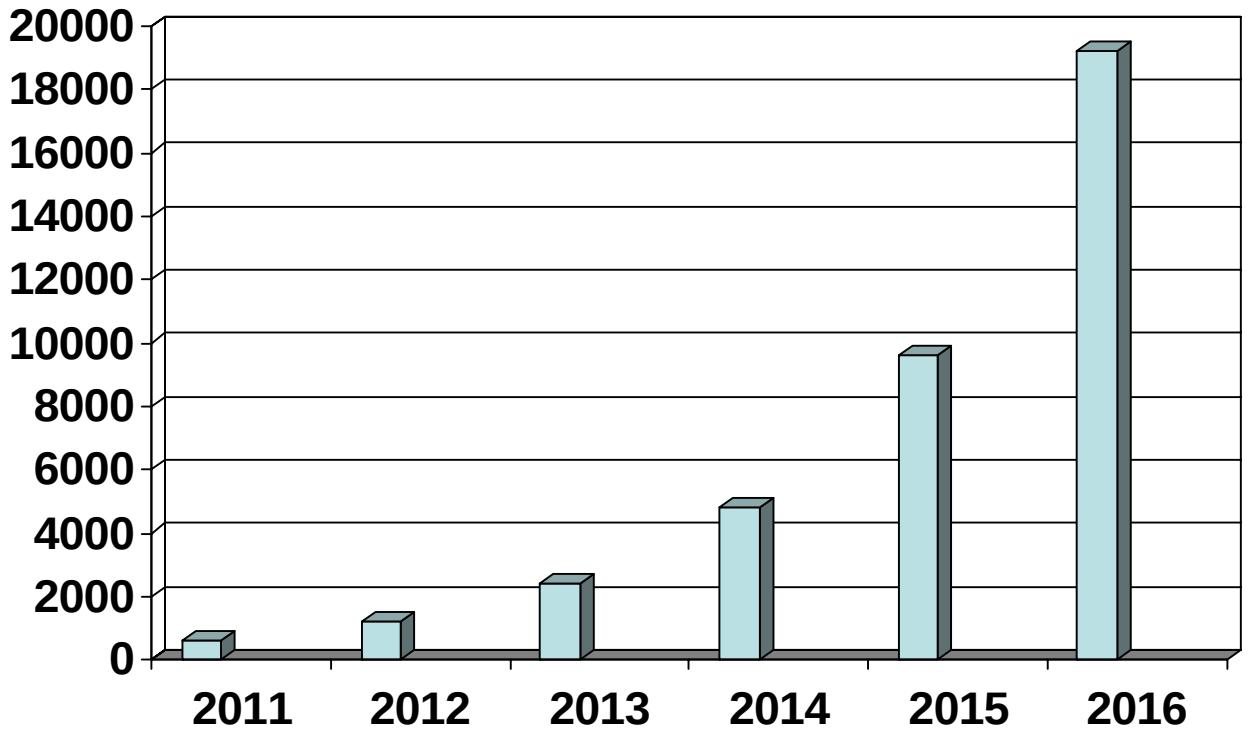
Building Food Safety Capacity of Foreign Governments

- Not later than January 2013, FDA must develop a plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their food industries, from which foods are exported to the U.S.
- This may include recommendations on whether and how to harmonize requirements under the standards developed by the Codex Alimentarius Commission.

Inspections of Foreign Food Facilities

FDA is directed to inspect (or arrange for inspection of) at least 600 foreign facilities in 2011, and the number then doubles each year for 5 years:



Inspections of Foreign Food Facilities
continued

- FDA must direct resources to inspections of foreign facilities that present a high risk (criteria to be developed).
- Food shall be refused entry into the U.S. if it comes from a facility that refuses to permit inspection by U.S. inspectors or other inspectors designated by FDA.
- The U.S. Department of Commerce may participate in inspections of facilities from which seafood imported into the U.S. originates and may provide technical assistance.
- Inspections can be expected to focus heavily on preventive controls and documentation.

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Tracking and Tracing

- FSMA directs FDA to establish "pilot projects" in coordination with the food industry to:
  - Explore and evaluate methods to identify recipients of food to prevent or mitigate a foodborne illness outbreak, and
  - Address credible threats of serious adverse health consequences as a result of food being adulterated (contaminated) or misbranded (e.g., containing an undelcared allergen).
- Pilot projects within 270 days (~ Sept. 2011)
- Report to Congress within 18 months on findings of pilot projects & recommendations.

Tracking and Tracing *continued*

- **For high risk foods**, FDA must publish a proposed rule within 2 years to establish additional (but unspecified) recordkeeping requirements beyond the “1-up, 1-down” records now required by the Bioterrorism Act.

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Facility Registration

- 2002 Bioterrorism Act requires registration of all food processing facilities.
  - Foreign facilities are required to register unless their food undergoes further processing by another foreign facility before it is exported to the United States.
- FSMA introduces 3 changes:
  - Facility registrations must be renewed every 2 years.
  - Registrations must state that FDA will be permitted to inspect.
  - FDA can suspend a registration, in which case food from the facility cannot be distributed or imported into the U.S.

Prior Notice

- 2002 Bioterrorism Act requires prior notice for all food imports, intended to facilitate inspection at port of entry.
- FSMA makes a minor change to the prior notice requirement for imported foods.
  - Reported information must now include the identity of any country to which the article has been refused entry.
- This becomes effective in 180 days (July 2011), and FDA is directed to amend the prior notice regulations in 120 days.

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Enhanced FDA Enforcement Powers

- Applies to all foods, not just imported foods:
  - Recall authority
  - Suspension of Facility Registration
  - Administrative detention of food

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What are FDA's Priorities?

- FSMA requires FDA to produce ~ 50 new rules, guidances, programs, and reports to Congress.
- Congressional Budget Office estimated cost of FSMA at $1.4 billion over first 4 years. Not clear FDA will get new funding.
- Expect FDA to focus on:
  - Produce Safety
  - Preventive Controls in Food Facilities
  - Preventing Intentional Contamination of Food
  - Imported Food Oversight
  - New Enforcement Tools
- Foreign Inspection Mandate will be Difficult to Fulfill. Expect creative approaches & partnering with foreign governments.
- Industry "user fees" may be revisited.

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Is FSMA Consistent with WTO Obligations?

- WTO Agreement on Sanitary & Phytosanitary Measures requires food regulation based on scientific principles, that does not arbitrarily or unjustifiably discriminate against food from other WTO members, and that does not operate as a disguised trade barrier.
- FSMA states that it shall be interpreted in a manner consistent with WTO agreements and other U.S. treaty obligations.
- FDA should avoid applying U.S. food safety law extra-territorially.

contact information

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