



# Food Safety Modernization Act

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## Public Health Reality

- Foodborne Illness Annual Impact
  - 48 million cases (one in six)
  - 128,000 hospitalizations
  - 3,000 deaths
  - \$77.7B (lost productivity, medical costs, pain, etc.)



## Public Health Perception

- Half are confident in the safety of U.S. food supply<sup>1</sup>
- 61% think imported food is less safe than domestic foods due to lack of U.S. government regulation<sup>1</sup>
- 79% believe stronger U.S. food safety policies are needed<sup>2</sup>

1: International Food Information Council Health and Food Survey (2011)

2: Supermarket News (2011)



# Food Safety Modernization Act (FSMA)



Signed into law January 4, 2011.

It signaled a paradigm shift of federal regulators from response to prevention.



# FSMA: Focus Areas

Inspection, Compliance and Response

Prevention

Imports

Enhanced Partnerships



# FSMA: Inspection, Compliance & Response

## Mandated inspection frequency

- Considering new ways to inspect

## New tools

- Mandatory recall
- Expanded records access
- Expanded administrative detention
- Suspension of registration
- Enhanced product tracing
- Third party laboratory testing



## FSMA: Prevention

### Sec. 103: Hazard Analysis And Risk-based Preventive Controls

Human and animal food facilities must\*:

- Evaluate hazards that could affect food safety;
- Identify and implement preventive controls to prevent hazards;
- Monitor controls and maintain monitoring records; and
- Conduct verification activities

*\*Exemptions Exist*



## FSMA: Prevention

### Sec. 103. Hazard Analysis And Risk-based Preventive Controls

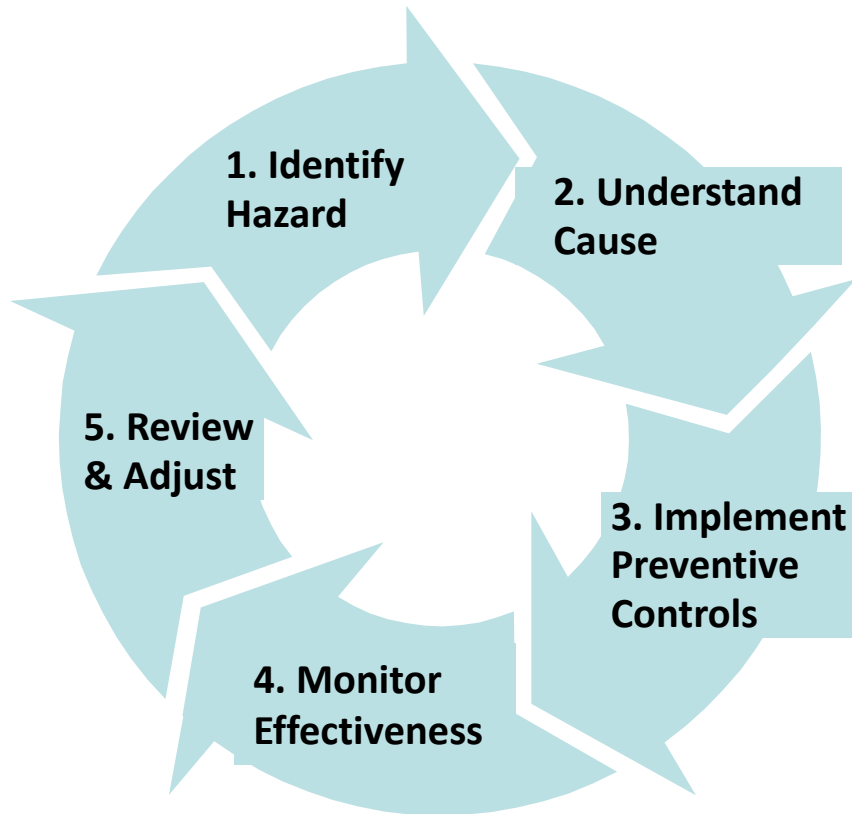
Human and animal food facilities are exempt if:

- Defined as very small business; or
- The facility has a limited annual monetary value of sales
  - During the last 3 years, sales were less than \$500,000; and
  - Sales to "Qualified End Users" exceeds sales to others
- Manufacturing process already covered by HACCP





# FSMA: Prevention



- Good Manufacturing Practices (GMPs)
- Sanitation
- Training for supervisors and employees
- Environmental controls and monitoring
- Food allergen controls
- Recall contingency plan
- Supplier verification activities



# FSMA: Prevention

## Sec. 105. Standards for Produce Safety

The Agency must:

- Establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables\*.
- Applies to raw agricultural commodities for which FDA determines that such standards minimize the risk of serious adverse health consequences or death.

*\*Exemptions Exist*



# FSMA: Prevention

## Sec. 105. Standards for Produce Safety

Farms are exempt if:

- During the last three years, sales < \$500,000 and
- Majority of product is distributed directly to consumers or farmers' markets and restaurants either intrastate or within a 275-mile radius



## FSMA: Prevention

### **Sec. 106. Protection against intentional contamination**

- Issue final rule and guidance to protect against the intentional adulteration of food
- Conduct vulnerability assessments of the food supply and determine mitigation strategies

### **Sec. 108 Prepare a National Agriculture and Food Defense Strategy with USDA and DHS (Enhancing Partnerships)**



# FSMA: Prevention

## Sec. 111: Sanitary Transportation of Food

Persons engaged in food transportation must use sanitary transportation practices to ensure that food is not transported under conditions that may render it adulterated.



## FSMA: Imports

FDA-regulated products originate from more than 150 countries, 130,000 importers, and 300,000 foreign facilities.

20 percent of fresh vegetables

50 percent of fresh fruits

80 percent of the seafood & active pharmaceutical ingredients

Ports of Los Angeles and Long Beach

32% of all U.S. Port volume (40% of all imports from Asia)



# FSMA: Imports

## Guiding Concepts

- Globalization has made reliance on port-of-entry inspection too costly and infeasible.
- FDA must work with and rely on foreign governments/industry to build their food safety capacity (Enhancing Partnerships)
- Capacity building helps to prevent problems before products reach the U.S. port of entry.



## FSMA: Imports

### **Sec. 201. Targeting of inspection resources**

- Increased inspection of foreign as well as domestic facilities

### **Sec. 301. Foreign supplier verification program**

- Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S. requirements.





## **FSMA: Imports**

### **Sec. 302. Voluntary qualified importer program**

- Allows for expedited review and entry; facility certification required

### **Sec. 303. Certification for high-risk food imports**

- FDA has discretionary authority to require assurances of compliance for high-risk foods



## FSMA: Imports

### **Sec.304. Prior notice of imported food shipments**

- Requires information on prior refusals to be added to prior notice submission

### **Sec. 305. Capacity building**

- FDA mandate to work with foreign governments to build food safety capacity (Enhanced Partnerships)



## FSMA: Imports

### **Sec. 306. Inspection of foreign food facilities**

- Can deny entry if FDA access for inspection is denied

### **Sec. 307. Accreditation of third-party auditors**

- Program for accredited third parties to perform regulatory and compliance audits to certify that imported food meets U.S. requirements. Used as part of the Voluntary Qualified Importer Program.



## FSMA: Imports

### **Sec. 308. Foreign Offices of the Food and Drug Administration.**

- Establish offices in foreign countries to provide assistance on food safety measures for food exported to the U.S.

### **Sec. 309. Smuggled Food**

- In coordination with DHS, better identify and prevent entry of smuggled food (Enhanced Partnerships)



# FSMA: Imports

## Sec. 404 Compliance with International Agreements

- FSMA must be consistent with our agreement with the World Trade Organization (WTO) and any other treaty or international agreement.



# FSMA: Implementation

Three-year process with items are prioritized based on public health protection

Implementation progress at <http://www.fda.gov/fsma>