

Food Safety in the Supply Chain

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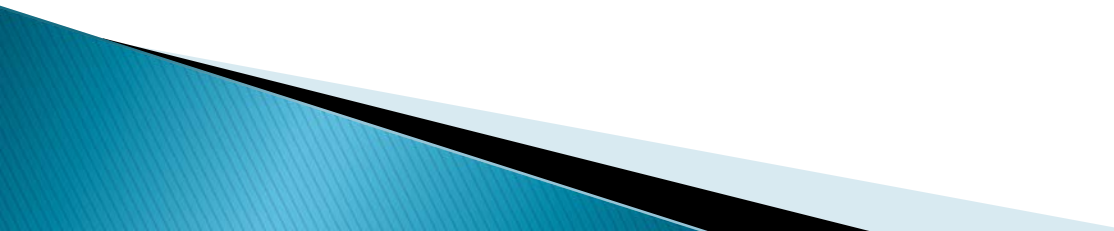
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Focus on Prevention

**FDA Food Safety
Modernization Act**

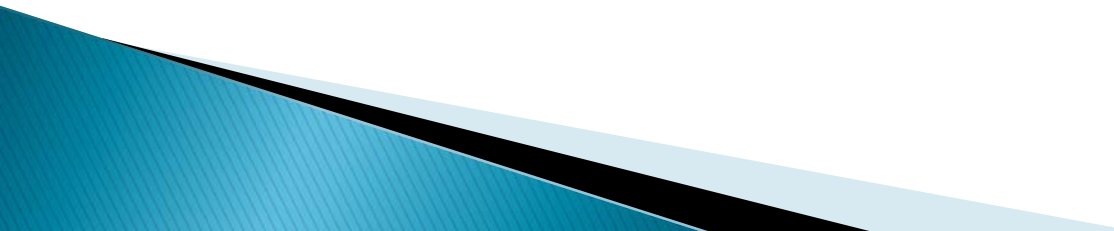
The Public Health Imperative

- ▶ Foodborne illness is a significant burden
 - About 48 million (1 in 6 Americans) get sick each year
 - 128,000 are hospitalized
 - 3,000 die
 - ▶ Immune-compromised individuals more susceptible
 - Infants and children, pregnant women, older individuals, those on chemotherapy
 - ▶ Foodborne illness is not just a stomach ache—it can cause life-long chronic disease
 - Arthritis, kidney failure
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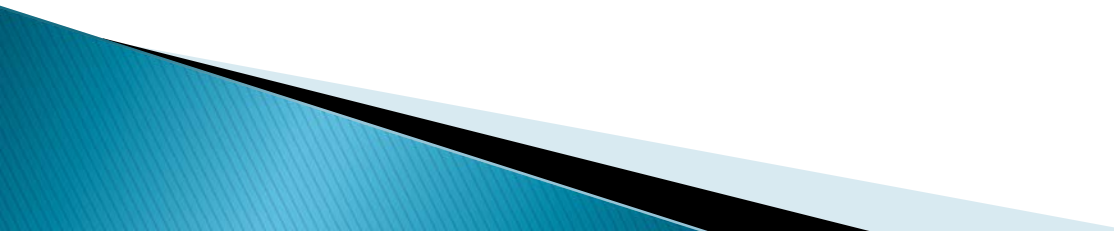
Why is the law needed?

- ▶ Globalization
 - 15 percent of U.S. food supply is imported
- ▶ Food supply more high-tech and complex
 - More foods in the marketplace
 - New hazards in foods not previously seen
- ▶ Shifting demographics
 - Growing population (about 30%) of individuals are especially “at risk” for foodborne illness

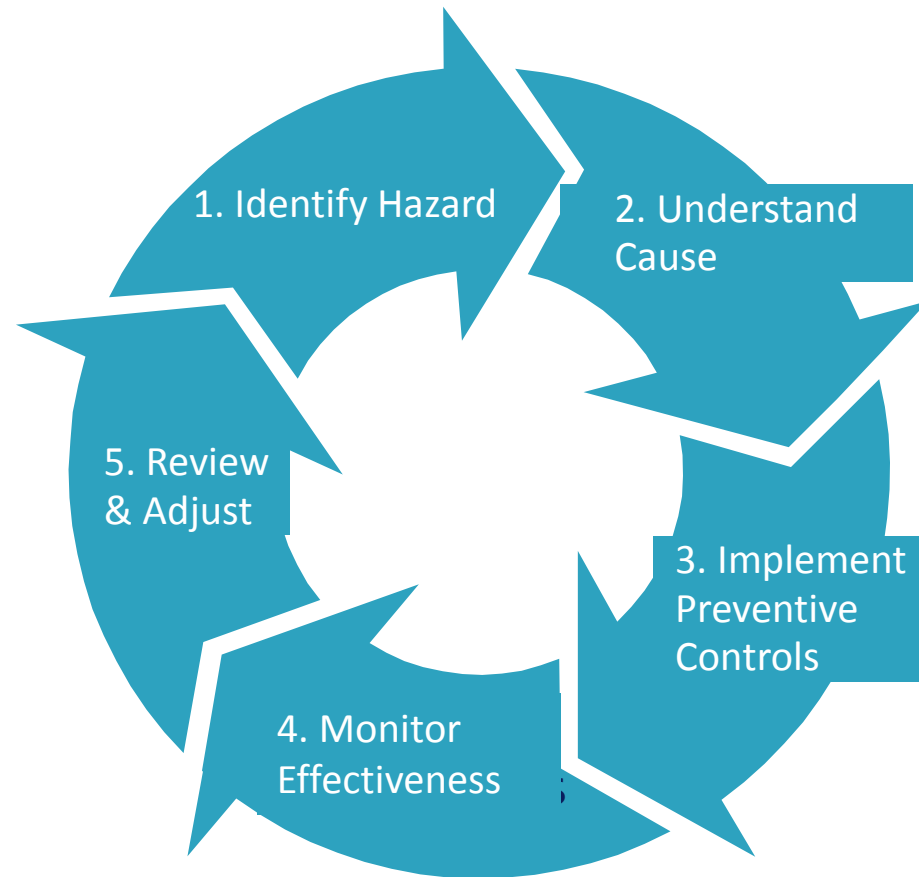
What's so historic about the law?

- ▶ Involves creation of a new food safety system
 - ▶ Broad prevention mandate and accountability
 - ▶ New system of import oversight
 - ▶ Emphasizes partnerships
 - ▶ Emphasizes farm-to-table responsibility
 - ▶ Developed through broad coalition
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Prevention: The cornerstone

- ▶ Comprehensive preventive controls for food and feed facilities
 - Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
 - Strengthens accountability for prevention
 - ▶ Produce safety standards
 - ▶ Intentional adulteration standards
 - ▶ Transportation
 - ▶ Import regulations
- 


General Approach to Preventive Controls



Prevention Standards Mandates

Sec. 103. Hazard analysis and risk-based preventive controls

Requires human and animal food facilities to:

- 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.
- 

Modified Requirements for Qualified Facilities (Part 117)

Facility is exempt if:

- ▶ Defined as very small business;

OR

- ▶ The facility has a limited annual monetary value of sales

Modified Requirements for Qualified Facilities (Part 117)

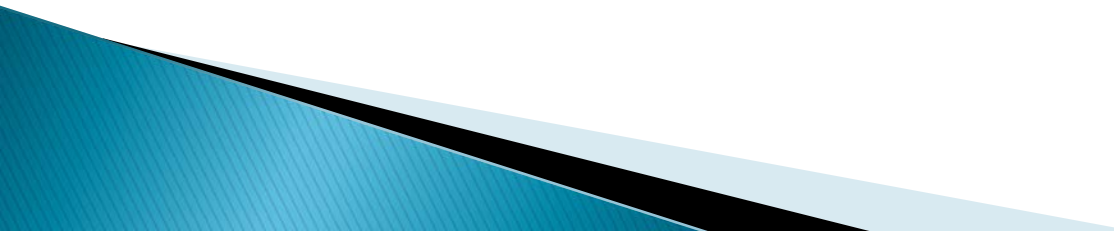
Limited annual monetary value of sales is defined as:

- ▶ During the last 3 years, sales were less than \$500,000;

AND

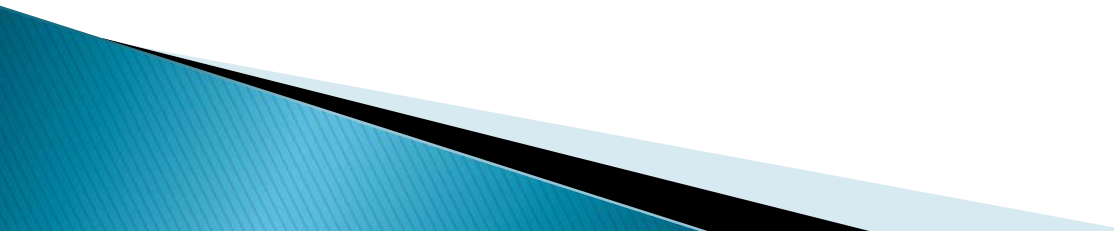
- ▶ Sales to "Qualified End Users" exceed sales to others

Examples of Compliance with Prevention Standards

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

Prevention Standards Mandates

Sec. 105. Standards for Produce Safety

- 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.
- 


Exemption for Direct Farm Marketing (Part 112)

Farms exempt if:

- ▶ During the last 3 years, sales were less than \$500,000 and
- ▶ Majority of product is distributed directly to consumers or farmers' markets and restaurants either intrastate or within a 275-mile radius

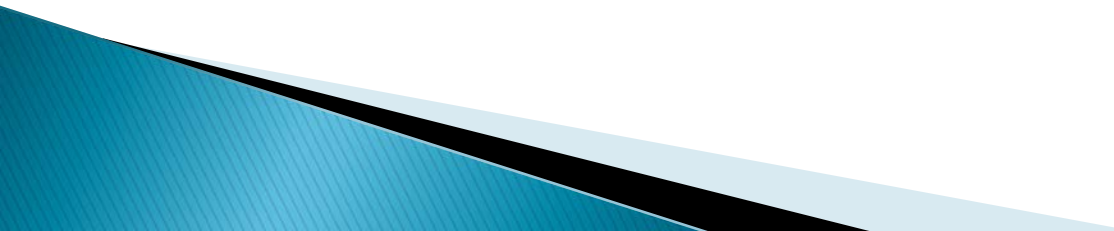
Intentional Contamination

Sec. 106. Protection against Intentional Adulteration

- 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
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Prevention Standards Mandates

Sec. 111. Sanitary Transportation of Food

- Addresses implementation of the Sanitary Food Transportation Act of 2005, which requires persons engaged in food transportation to use sanitary transportation practices to ensure that food is not transported under conditions that may render it adulterated.
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Prevention in Imports

Sec. 301 Foreign Supplier Verification Program (FSVP)

- ▶ Requires importers to conduct risk-based foreign supplier verification activities to verify that food imported into the United States is not adulterated and that it was produced in compliance with FDA's preventive controls requirements and produce safety standards

Sec. 307. Third Party Auditor Accreditation

- ▶ Can be used by importers for supplier verification under FSVP
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Food Safety Modernization Act (FSMA) Activities Signed into Law 2011

Seven (7) New Rules 2015 & 2016:

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Produce Safety
- Foreign Supply Verification Program
- Third Party Audit
- Sanitary Transport
- Intentional Adulteration



Who is Covered

by the *Preventive Controls for Human Food Regulation?*

- ▶ Facilities that manufacture, process, pack or hold human food (§ 117.1)
- ▶ In general, facilities required to register with FDA under sec. 415 of the FD&C Act
 - **Not farms or retail food establishments**
- ▶ Applies to domestic and imported food
- ▶ Some exemptions and modified requirements apply

Preventive Food Safety Systems

Food Safety Plan

Including procedures for monitoring, corrective action and verification, as appropriate

Hazard Analysis

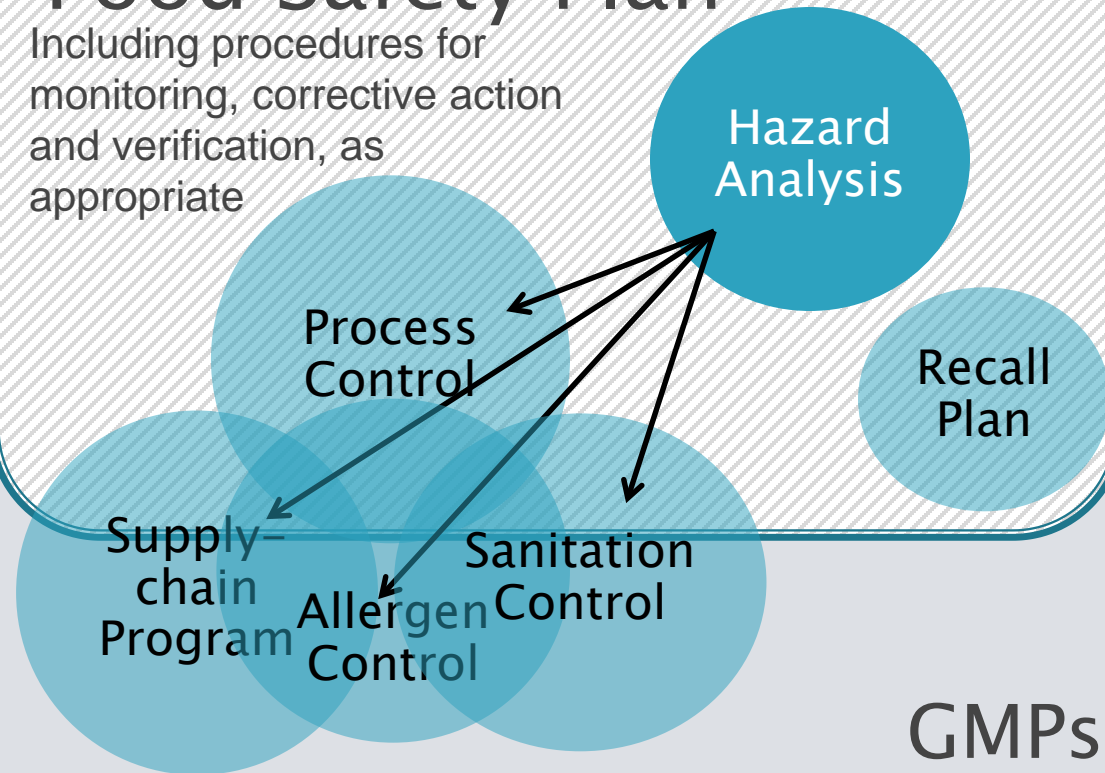
Recall Plan

Process Control

Supply-chain Program

Allergen Control
Sanitation Control

GMPs and Other
Prerequisite Programs



Key Implementation Principles

Training

- ▶ Emphasize Regulator & Industry Training
 - Alliance Courses with Industry
 - FSMA Chats
 - FSMA Rule Readiness
 - Regulator Specific Training & Mentoring
 - Technical Assistance Network

Key Implementation Principles

Training

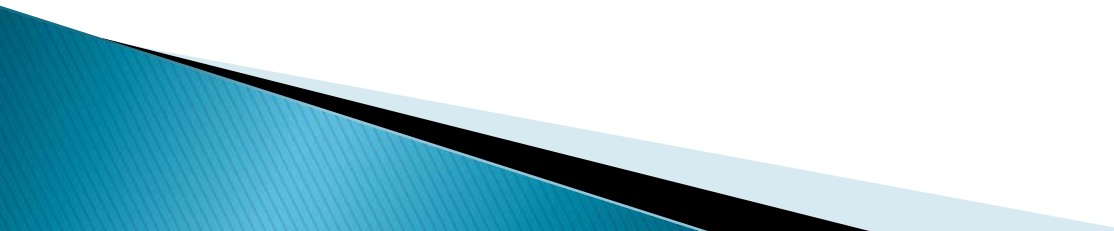


- ▶ Industry Training
 - PC Human Food
 - PC Animal Food
 - FSVP
 - Produce Safety

- ▶ Food Safety Staff (FSS)
 - FDA & State Training
 - Food Safety Preventive Controls Alliance
 - Modernized Human & Animal Food cGMP
 - Human Food PC Regulator

Key Implementation Principles

Inspections

- ▶ Gain industry compliance, reduce foodborne illness
 - ▶ Not a “one size fits all approach”
 - ▶ Systems-based inspections, not “observation focused”
 - ▶ Interactive, cooperative inspections
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Food Safety Modernization Act

First major Compliance dates are here

September 19, 2016 – cGMPs & PC Human Food

So what happens now?

WSDA/ FDA are focusing on providing support with:

- Education, Training and Technical Assistance
 - FSPCA PCHF Training Courses 2016 & 2017
 - Produce Safety Alliance Fall 2017

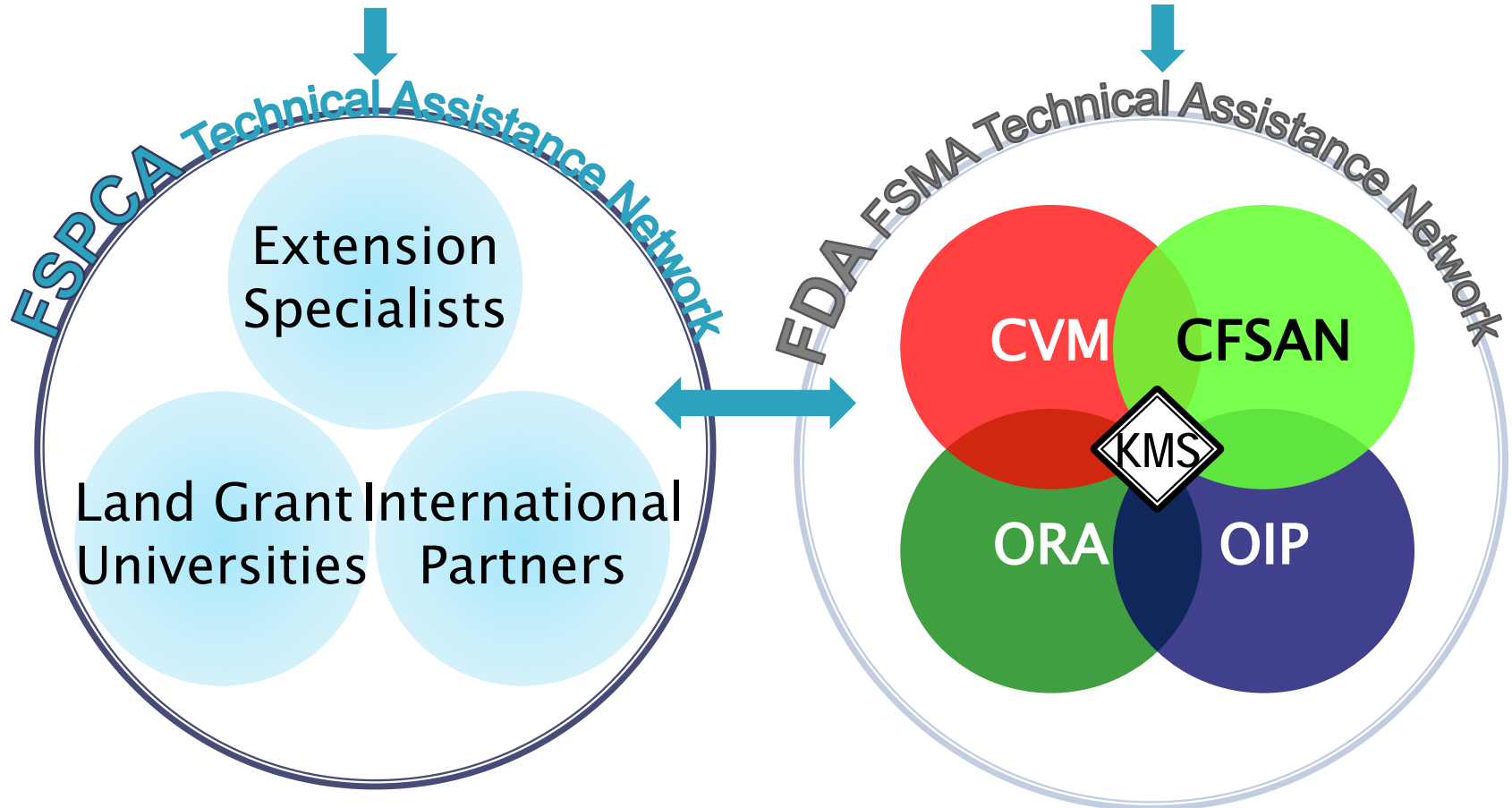
FSMA Technical Assistance Network

Technical Questions from Industry –
a Web form at:

www.iit.edu/ifsh/alliance

Interpretation Questions – a Web
form at:

www.fda.gov/FSMA



Food Safety Modernization Act

So what happens now?

WSDA is modernizing State Food/Feed regulations

- WAC 16-167 adopted Federal Food Rules updated 12/1/2017 through state rulemaking
- WAC 16-250 & 252 under revision
- Full review of 8 Food & Feed Laws for update and potential revision during 2018 legislative session

Food Safety Modernization Act

So what happens now?

WSDA is working with stakeholders on:

- 5 year FDA Produce Safety Cooperative Agreement for technical assistance, education and potential inspection program
- Monitoring impacts on marketing and export trade issues
 - e.g. Qualified Facilities & Produce Safety Exempt

Food Safety Modernization Act

So what happens now?

WSDA is working with stakeholders on:

- Training needs for Food Systems:
 - Sanitary Equipment Design
 - Food Safety & Food Hazards
 - Good Manufacturing Practices
 - Sanitation Procedures
 - Allergies
 - Recalls
 - Traceback
 - Many others.....

Food Safety Modernization Act

So what happens now?

WSDA is working with stakeholders on:

- WSDA is looking for ways to support technical assistance and educational programs for both industry and the regulatory communities as FSMA programs move forward

Thank
You

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