

# Food Safety Modernization Act (FSMA)

Michigan Dairy Industry Conference



*Michigan Department of Agriculture & Rural Development*

Tim Slawinski  
Emerging Issues Specialist

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# FSMA Update

- Signed into Law January 4, 2011
- 41 Sections
- Focus on **Prevention**
- Ensure the US Food Supply is Safe





# Preventive Focus

Food Safety Incident



Unacceptable Condition



Breakdown or Lack of Preventive Plan



# FSMA 7 Proposed Rules

- Preventive Controls for human food
- Preventive Controls for animal food
- Produce Safety
- Foreign Supplier Verification
- Third Party Auditor
- Intentional Adulteration
- Sanitary Transportation





# General Timeline

Proposed  
Rules  
2013

Comment  
Periods  
2013/2014

Final Rules  
2015/2016

Compliance  
Dates  
2016 - 2019



# Preventive Controls

- **Who's Covered:**
  - Manufacture/Process, Pack or Hold Food
- **Who's Not Covered:**
  - Restaurants, Retail, Farms, Non-Profit, Transport Vehicles, USDA Facilities, Municipal Water, Fishing vessels and Private Residence.
- **Exemptions:**
  - Juice, Seafood, Low Acid Canned Food, Alcoholic Beverages, Dietary Supplements, Low-Risk On-Farm, Businesses with less than \$1M in Annual Sales



# Compliance Dates

- Large Businesses: >500 employees
  - 1 Year After Final Rule
- Small Businesses: <500 employees
  - 2 Years After Final Rule
- Very Small Businesses: <\$1M Annual Sales
  - 3 Years After Final Rule

**Estimated** Final  
Rule Effective:  
10/30/2015

Large Businesses  
10/30/2016

Small Businesses  
10/30/2017

Very Small  
Businesses  
10/30/2018



# Preventive Controls

- What's Required?
  - Food Safety Plan
    - Hazard Analysis
    - Preventive Controls
    - Monitoring
    - Corrective Action
    - Verification







# Hazard Analysis

- Identify Hazards
  - Biological, Chemical, Physical
  - Natural, unintentionally introduced and intentionally introduced for economic gain
- Hazard Evaluation:
  - Severity of illness
  - Probability it will occur
- Result = list of “Significant Hazards”



# Preventive Controls

- Minimize or Prevent Significant Hazards
  - Process Controls
  - Allergen Controls
  - Sanitation Controls
  - Supplier Controls
  - Recall Plan
  - Other Controls





# Preventive Controls

- Monitoring:
  - Written Procedures
  - Adequate Frequency
- Corrective Action:
  - Steps to be taken to:
    - Identify and correct the problem
    - Evaluate food
    - Prevent adulterated food from entering commerce





# Preventive Controls

- **Verification:**
  - Validation (Proof that it works)
  - Verification Activities:
    - Calibration
    - Product Testing
    - Environmental Monitoring
    - Records Review





# Preventive Controls

## Qualified Individual:

- Successfully completed training on risk-based preventive controls
  - Preparation of the food safety plan
  - Validation of the preventive controls
  - Review of records
  - Reanalysis of the food safety plan



# Produce Safety

- Who's Covered?
  - Produce that is typically eaten raw.
- What's Covered?
  - Agricultural Water
  - Biological Soil Amendments of Animal Origin
  - Equipment, Tools and Buildings
  - Animals in the Growing Area
  - Health and Hygiene





# Foreign Supplier Verification Program (FSVP)

- Who's Covered?
  - All Importers of Food into the US
- What's Required?
  - Perform a Compliance Status Review
  - Assess Supplier's Food Safety Plans
  - Supplier Verification Activities





# Third Party Auditor Accreditation

- Applies to 3<sup>rd</sup> Party Auditors of foreign facilities that will perform certifications
- How will certifications be used?
  - FDA can require based on risk
  - Voluntary Qualified Importer Program







# Intentional Adulteration

- Who's Covered?
  - Facilities that manufacture or pack human food
  - Over \$10M in annual sales required.
- What's Covered?
  - Acts intended to cause massive public health harm
- What's Required?
  - Food Defense Plan
    - Focused Mitigation Strategies





# Sanitary Transportation

- Who's Covered?
  - Shippers, Carriers and Receivers of Food
- What's Required?
  - Responsibilities for each party involved:
    - Shippers - Product requirements, pre-load inspections
    - Carriers – Sanitary conditions, temp control, previous cargo and cleaning info
    - Receivers - Hand washing facilities for vehicle operators, prevent adulteration during unloading



## Resources

- FDA FSMA Proposed Rules page
  - <http://www.fda.gov/FSMA>
  - Page Contents:
    - Fact Sheets on proposed rules
    - Full text of proposed rules
    - Links to submit comment to Federal Register



# Questions?

Tim Slawinski

MDARD

(517) 420-5364

[slawinski@michigan.gov](mailto:slawinski@michigan.gov)