

# Food Safety Modernization Act (FSMA) Update

MCAFDO



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## Agenda

- “ Overview of FSMA focus and timelines
- “ Produce Safety Overview
- “ FSMA rules update
- “ Questions



## 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



# General Timeline

Proposed  
Rules  
2013

Comment  
Periods  
2013/2014

Final Rules  
2015/2016

Compliance  
Dates  
2016 - 2019



## **FSMA 7 Proposed Rules**

- “ Produce safety
- “ Preventive controls for human food
- “ Preventive controls for animal food
- “ Foreign supplier verification program
- “ Third party auditor
- “ Intentional adulteration
- “ Sanitary transportation





## 2<sup>nd</sup> Comment Period

” Revisions to 4 proposed rules released

- . Produce safety
- . Preventive controls for human food
- . Preventive controls for animal food
- . Foreign supplier verification program

” Comment period closes 12/15/14







## Produce Safety Update

- “ First time regulating at the farm level
- “ Similar in layout to the USDA Good Agricultural Practices Documents
- “ Will require the farmer to develop a Food Safety Plan
- “ Food Safety Plan will need to address all aspects of the farm’s activities





# 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





# Produce Safety Update

## ” Revisions to proposed rule released:

- . Farm Definition
  - ” Allows “others RACs”
- . Agricultural Water
  - ” Testing requirements modified
- . Soil Amendments
  - ” Deferring minimum-time intervals





## Details of Rule

- “ RAC’s grown on trees/bush vs. on ground
  - . Tomatoes, peppers, apples
  - . Cucumbers, carrots, cantelope
- “ No drops allowed for fresh consumption
- “ Drops may be used when they are subject to further processing, i.e. LACF, Acidified, Pasteurized
- “ Does not apply to nuts – fall does not damage edible crop due to durable shell



## Implementation of PS rule

- “ Produce Safety Alliance course for farmers
  - . Built off of current USDA GAPs model
  - . Course will be modified to meet specifics of rule when final,
- “ Train the Trainer Course is being rolled out now
  - “ Train the trainer curriculum will managed by the PSA
  - “ Coordination and certification will be managed by AFDO similar to Seafood HACCP model.



## Implementation of PS rule

- “ Educate before you regulate
- “ FDA will depend on state regulatory partners for implementation of rule at farm level
- “ National Association of State Departments of Agriculture has a grant from FDA
  - . Coordinate identification of the inventory of farms
  - . Development of a model agreement/contract for inspection of farms





# Preventive Controls (PC)

## ” Who’s Covered?

- Manufacture/Process, Pack or Hold Human Food

## ” What’s Covered?

- Food Safety Plan:
  - ” Hazard Analysis
  - ” Preventive Controls
  - ” Monitoring
  - ” Corrective Action
  - ” Verification





# Human Food PC Update

” Revisions to proposed rule released:

- . Definition Changes
- . Very Small Business = \$1M Annual Sales
- . Economically Motivated Adulteration
- . Supplier Verification
- . Produce Testing
- . Environmental Monitoring







## Animal Food PC

### ” Who’s Covered?

- . Manufacture/Process, Pack or Hold Animal Food

### ” What’s Covered?

- . Good Manufacturing Practices
- . Food Safety Plan:
  - ” Hazard Analysis
  - ” Preventive Controls
  - ” Monitoring
  - ” Corrective Action
  - ” Verification





# Animal Food PC Update

- ” Revisions to proposed rule released:
- . Very Small Business = \$2.5M Annual Sales
  - . More Flexible cGMPs
  - . By-Product doesn't need more controls
  - . Economically Motivated Adulteration
  - . Supplier Verification
  - . Produce Testing
  - . Environmental Monitoring





## Foreign Supplier Verification Program (FSVP)

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





## FSVP Update

- ” Revisions to proposed rule released:
- Hybrid of 2 options
  - More Comprehensive Hazard Analysis
  - Economically Motivated Adulteration





## 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?

- Manufacture/Process, Pack or Hold Human Food

## ” What’s Covered?

- Acts intended to cause massive public health harm
- Food Defense Plan:
  - ” Identify Actionable Process Steps
  - ” Develop focused Mitigation Strategies
  - ” Monitoring, Corrective Action and Verification





# Sanitary Transportation

## ” Who’s Covered?

- . Shippers, Carriers and Receivers of Food

## ” What’s Covered?

- . Clarity of Responsibility:

- ” Product requirements
- ” Inspections
- ” Temperature control,
- ” Previous cargo
- ” Cleaning







## 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?

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