

**Legislative Agriculture Chairs 2018  
Summit  
State Ag and Rural Leaders**

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**FDA FOOD SAFETY**  
MODERNIZATION ACT



**THE FUTURE IS NOW**



# Current Landscape for Food Safety Modernization Act

- Much has changed with FSMA since 2016 presentation to SARL by Mike Taylor
- Foundational regulations finalized May 2016
- Implementation now underway
- Collaboration with federal and state partners
- Work with state associations (NASDA, ASTHO, AFDO)
- Collaborative agreement program (CAP) with states funded for produce safety implementation Sept. 2016

# FSMA Compliance Dates

- Initial compliance dates
  - Preventive controls for human food-Sept. 2016
  - Preventive controls for animal food-Sept. 2016
  - Produce safety rule (sprouts only)-Jan. 2017
  - *Produce safety rule (non sprouts)-Jan. 2018*
  - Sanitary transportation- April 2017
  - Foreign supplier verification program – May 2017
  - Third party accreditation-June 2017 (website)
  - *Intentional adulteration- July 2019*

# FSMA Implementation

- Flexibility built into rules
- Educate before & while we regulate
- Committed to assist producers to “get it right”
  - Continued engagement as they implement
- Alliance training for all the rules
- Initial inspections designed to be “educational” in nature
  - Unless egregious conditions or violations found
- *High rates of compliance are crucial for success*
- Committed to domestic and import parity

# Central Wisconsin – Vegetables Oct 2017



# Northern Alabama – Cotton Ginning Oct 2017



# Hawaii – Produce Safety Aug 2017







# FSMA “Fixes”

- Working to resolve unanticipated issues due to nuances of the law or regulations
  - Differential treatment of “like” activities
  - Decrease under-appreciated burdens
  - Examples:
    - Packinghouses/holding facilities
    - Secondary activities farms
    - Coloring of raw agricultural commodities
    - Cotton ginning
    - Certain processing of human food by-products for animal feed
  - Issued enforcement discretion guidance on Jan 4
    - While regulatory solutions put in place

# The Produce Safety Rule

**Science-based standards associated with known routes of contamination of produce:**

- **Agricultural Water**
- **Biological Soil Amendments**
- **Domesticated and Wild Animals**
- **Worker Training and Health and Hygiene**
- **Equipment, Tools, and Buildings**

# Produce Safety Compliance Dates by Farm Size

- Jan 2018 – large farms (>\$500k 3-year annual sales)
- Jan 2019 – small farms (\$250-499k)
- Jan 2020 – very small farms (\$25-249k)



# Exemptions

## *Full Exemptions*

- Farms with annual sales <\$25,000
- Farms that grow for personal or on-farm consumption
- Fruits and vegetables rarely consumed raw
- Food grains

## *Qualified Exemption*

- Small or very small farms where
  - >50% of food sales is produce sold directly to consumers or to restaurants/retail establishments in the same state or within 275 miles of farm
- Estimated 47% of covered farms fit this exemption

# Next Steps for Implementation of Produce Safety Rule

- Biological soil amendments
- Agricultural water
  - Microbial quality standards:  
too complex to understand and  
costly to implement
  - Examine ways to simplify  
standards while still protecting  
public health
  - Proposed earliest compliance  
date for water: January 2022





**Produce Safety**  
ALLIANCE

**FEB. 27-28, 2018**  
**WATER SUMMIT**

**RADISSON HOTEL – CINCINNATI  
RIVERFRONT**

# **Next Steps for Implementation of Product Safety Rule (cont.)**

- **Produce inspections – postponed until 2019**
- **Interim actions in 2018:**
  - **Guidance publication**
  - **On-Farm Readiness Reviews**
  - **Development of farm inventories by states**
  - **Training:**
    - **Domestic and foreign growers**
    - **Inspection workforce**
  - **Cooperative Agreement Program**





# **State Produce Implementation Cooperative Agreement Program (CAP)**

- **Year 1: \$21.8 million to 42 states**
- **Year 2: \$30.9 million to 43 states**
- **Resources to:**
  - **hire staff**
  - **education, outreach and technical assistance**
  - **Inventory**
  - **Inspectional activities**
- **Working with NASDA to bring additional states onboard**
- **FDA will have to conduct activities where states elect not to**

# Produce Safety Network

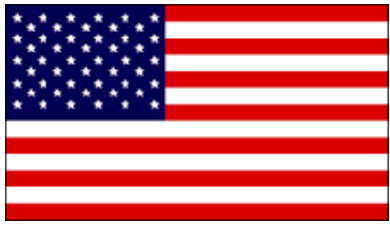
- **FDA produce experts in each region of the country**
  - **Staff from the Office of Regulatory Affairs and the Center for Food Safety and Applied Nutrition**
- **Outreach, education, and technical assistance**
- **Inspections and outbreak response**
- **Technical Assistance Network for regulators**



# Dairy Issues

- Exports to China
- Ultra-Filtered Milk
- Automated Milking Systems

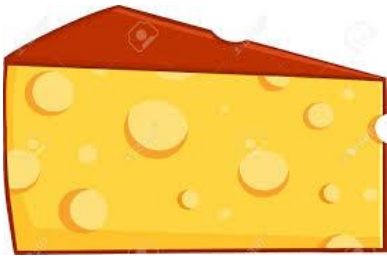




# Dairy Export Certification



- Last April, FDA and China signed an MOU to provide U.S. exporters access to the Chinese market for dairy, seafood and infant formula.
- These commodities require registration when exporting to China.
- China requires exporters to meet Chinese food safety standards.
- FDA does not inspect against another authority's standards.
- Agreement allows 3<sup>rd</sup> parties designated by China to determine if standards are being met; determination provided to FDA.
- FDA, as the competent food safety authority, maintains and provides the list of U.S. dairy products manufacturers and processors eligible to export to China.
- List updated and supplied to China quarterly.



# Ultra-Filtered Milk

- **Recent changes in export market resulted in oversupply and lower prices for ultra-filtered (UF) milk.**
- **U.S. dairy suppliers sought new domestic market opportunities.**
- **Use of UF milk authorized for non-standardized cheeses; but not cheeses which have standard of identity.**
- **Suppliers asked FDA to use “regulatory discretion” to allow use in standardized cheese without the need to declare on labels.**
- **After review, request granted in Aug 2017 for both use and labeling while regulation is being finalized.**

# Automated Milking Systems



- Increasing use – especially on larger dairy farms
- At present AMS don't fully conform to PMO standards
- Farms at risk of losing Grade A status due to “unsanitary” equipment
- In 2017, FDA took actions to ensure no shipper would lose Grade A status based on use of AMS alone
- Actions expire after 2019 NCIMS
  - Allows time for states, FDA and manufacturers to reach consensus
- Internal FDA workgroup focused on AMS; guidance to address questions from states and manufacturers
- Work underway with 3-A Sanitary Standards, Inc. involving manufacturers to develop sanitary standards for AMS that would resolve PMO non-conformity