



# Welcome

## OnTrak with FSMA: A Webinar Series

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*Today's Presentation:*

# FSMA Finalizes Produce Safety Rule: What's Now Required



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# Overview



- FSMA Rules Review
- Am I a Farm or Not?
- Key Points and Definitions
- How do I know if the Rule applies to me?
- Exemptions
- Main Requirements of the Rule

# Food Safety Modernization Act (FSMA)



# The Seven Pillars of Prevention

- Preventive controls for human food
- Preventive controls for animal food
- Produce safety
- Foreign supplier verification
- Third party auditor
- Intentional Adulteration
- Sanitary Transport



# FSMA Status Summary - “The 7 Pillars”

Proposed Rule	Final Deadline	Published
PC- Human Food-Final	September 17, 2015	✓
PC- Animal Food-Final	September 17, 2015	✓
Produce Safety	October 31, 2015	✓
FSVP	October 31, 2015	✓
Third Party Accreditation	October 31, 2015	✓
Sanitary Transport	March 31, 2016	
Food Defense	May 31, 2016	

# Am I a Farm or Not?



## Key Points

- A farm is exempt from FDA's food facility registration requirement
- Facilities that do not have to register with FDA are not subject to the *Preventive Controls* requirements
  - No food safety plan or cGMPs
  - Depending on certain factors, farms may be subject to the Produce Safety rule
- *Preventive Controls Human Food and Produce Rule* revises the farm definition to reflect modern farming practices
  - Primary Production Farm
  - Secondary Activities Farm





# Primary Production Farm: Definition

- An operation under one management in one general, but not necessarily contiguous, location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
  - The definition has been expanded to include operations that just grow crops and operations that just harvest crops



## A Primary Production Farm Can...

- Pack or hold RACs (regardless of who grew or raised them)
- Manufacture/process, pack, or hold processed foods so long as:
  - all such food is consumed on that farm or another farm under the same management; or
  - the manufacturing/processing falls into limited categories



## Secondary Activities Farm: Definition

- An operation not located on a primary production farm that is devoted to harvesting, packing, and/or holding RACs.
- The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm.
- The definition also allows certain, limited additional manufacturing/processing, packing, and holding
  - Same as those for a primary production farm



## Activities Not Under Farm Definition

- Manufacturing/ processing that goes beyond what falls within the farm definition. As examples:
  - Pitting dried plums, chopping herbs
  - Making snack chips or flours from legumes
  - Roasting peanuts, tree nuts, or seeds (e.g., pumpkin, sunflower, or flax seeds)
- FDA expects to issue guidance on activities that fall within the farm definition and activities that do not in the near future



# Does the Produce Rule Apply to Me?



# Produce Rule: FDA Implementation

14

- Expected to prevent 1.57M illnesses, save \$400M
- Science- and Risk-based (based on practices)
  - Focus on microbial contamination
  - Excludes certain produce rarely consumed raw (RCR)
    - **CONTROVERSIAL!**
      - **Cashews, peanuts, pecans RCR=EXEMPT**
      - **Pistachios, almonds not deemed RCR=COVERED**
      - **Kale was out now covered by Final Rule**
  - Excludes produce to be further commercially processed (documentation required)
- **Flexible compliance, based on business size**
  - Very small farms given 4 years to comply
  - Small businesses – 3 years to comply
  - All farms – 2 years, with certain aspects of the water quality standards given an additional 2 years.



# Who Would be Covered?

- Farms that grow, harvest, pack or hold most produce in raw or natural state (raw agricultural commodities)
- Primary Production and Secondary Activities Farms
- Domestic and imported produce
- Farms with annual sales > \$25,000 per year



# Standards for Produce Safety

## Focus on identified routes of microbial contamination

- Domesticated and wild animals
- Equipment, tools, buildings and sanitation
- Worker health and hygiene
- Agricultural water
- Growing, harvesting, packing and holding activities
- Biological soil amendments of animal origin
- Specific requirements for sprouts



## Exemptions

- Produce that is not a raw agricultural commodity
- Produce rarely consumed raw (as per the US FDA item list)
- Produce for commercial processing
- Food grains
- Produce used for personal or on-farm consumption
- Farms with a three year average value of produce sales of less than \$25,000 USD.



## Qualified Exemption

- To qualify, farms must have food sales averaging less than \$500,000 USD over three years, AND
- Sales to qualified end users must exceed sales to all others
- A qualified end user is the consumer or a restaurant/retailer in the same state or Indian reservation as the farm, or not located more than 275 miles away from the farm.
- Modified requirements need specific documentation to be maintained and disclosed

**EXEMPT**

# Main Requirements

- 1) Agricultural water
- 2) Biological soil amendments
- 3) Domesticated and wild animals
- 4) Growing, harvesting, packing, and holding
- 5) Worker training and health and hygiene
- 6) Equipment, tools and buildings
- 7) Sprouts



# Agricultural Water

- Water must be safe and sanitary
- Beginning of growing season, inspect water sources for hazards and prevent from being a source of contamination
  - “to the extent they are under your control”
- No detectable generic *E. coli* in 100 mL ag water
- Requirements if water is not safe



# Agricultural Water

## Testing Requirements

- No testing if water from public sources or treated according to rule
- Survey required for untreated surface water and untreated ground water
- Specific testing requirements in §112.46



# Biological Soil Amendments

- Requirement – evaluate status of untreated soil amendments
- Treatment processes outlined as acceptable are physical, chemical and biological
- Organisms of concern are *L. monocytogenes*, *Salmonella* species, *E. Coli* O157:H7



## Domesticated and Wild Animals

- Assess the growing areas for evidence of potential contamination as indicated by observation of animals, excreta or crop destruction.
- Evaluate if produce can be harvested without contamination and in accordance with the regulations.
- Standard is “known or reasonably foreseeable hazard”



# Growing, Harvesting, Packing, and Holding

- Segregation of produce that is covered by the regulations and not covered by the regulations
- Harvesting requirements to avoid contamination
- Dropped produce – does not include root crops or produce intentionally dropped to harvest
- Food packaging materials





# Worker Training & Health and Hygiene

- All workers who handle produce (including harvesting) or food contact surfaces must receive adequate training
- Prevent contamination from people
  - Ill workers and reporting illnesses to manager
- Hygiene requirements including hand washing
- Visitor policies



# Equipment, Tools and Buildings

- All contact equipment and equipment used to measure, regulate or record conditions to control or prevent the growth of organisms of public health significance
- Adequate design, construction, and workmanship to be cleaned and maintained
- Transport vehicles
- Toilet and handwashing facilities



# Sprouts

- Prevent introduction of known or reasonably foreseeable hazards into or onto seeds or beans used for sprouting
- Avoid contaminated lots of seeds
- Grow in fully enclosed building
- Clean and sanitize all food contact surfaces
- Written plan for testing spent water or sprouts



# Records



24 hours

*Time allotted for records requested by the FDA*



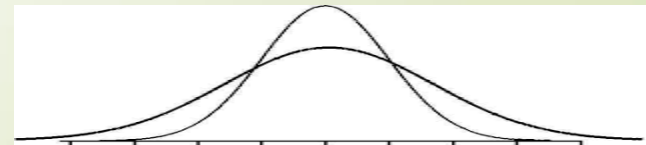
2 years

*Retention period for required records under FSMA*

- Should include the farm name, location, covered produce, growing areas, date and time, and be signed
- Accessible in 24 hours and maintained for 2 years
- Existing records are acceptable and may be supplemented if necessary to comply
- Offsite storage is acceptable if accessible in 24 hrs

## Variations

- The rule permits states, tribes, or foreign countries importing into the U.S. to submit a petition, along with supporting information, to FDA requesting a variance from one or more of the requirements of this rule if meeting requirements would be problematic in light of local growing conditions.
- The applicant must demonstrate that the variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s)



# Thank You! - Questions??

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