

# Welcome

## OnTrak with FSMA: A Webinar Series

Hosted By:



Presentation by:



*Today's Presentation:*

# Your “Get Ready” Checklist for Produce Safety Compliance



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# Overview

- FSMA Rules Review
- What is a Farm?
- Who does the rule apply to?
- Rule Requirements
- Training Options and Details
- Compliance Dates
- Get Ready Checklist



# 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

# FDA's Definition of a Farm



# Key Points

- Primary and Secondary Farms are required to comply
- 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



# Who is 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



# FSVP and the Produce Safety Rule

- Foreign Supplier Verification Programs (FSVP) require the US based Importer to Verify that foreign farms meet the same level of public health protection as US Farms.
  - Same exemptions apply based on size
- Responsibility is with the US Importer
- Compliance dates are 6 months after Produce Safety Compliance dates

# Standards for Produce Safety

## Focus on identified routes of microbial contamination

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



# Main Requirements

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



# 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





# 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”



# Agricultural Water

- FDA Issued a Proposed Rule to delay enforcement and obtain comments
- September 17, 2017
- [https://www.federalregister.gov/documents/2017/09/13/2017-19434/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-extension?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](https://www.federalregister.gov/documents/2017/09/13/2017-19434/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption-extension?source=govdelivery&utm_medium=email&utm_source=govdelivery)
- Comments closed Nov 13, 2017

# 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
- Specific 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



# Growing, Harvesting, Packing, & 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



# 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

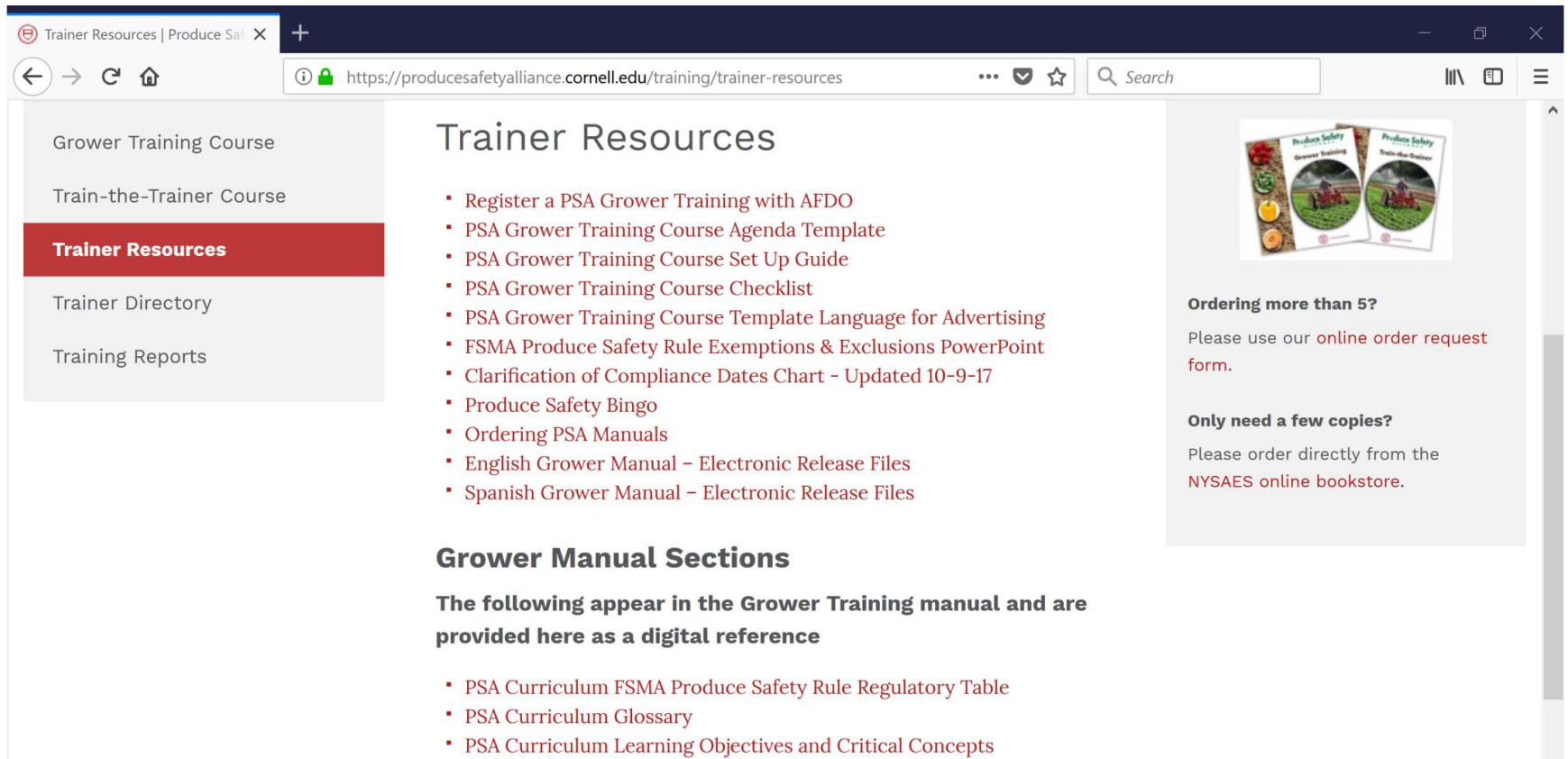




# Training

The screenshot shows a web browser window displaying the Cornell CALS website. The address bar shows the URL <https://producesafetyalliance.cornell.edu/training>. The page header features the Cornell CALS logo (College of Agriculture and Life Sciences) and a search bar with a 'go' button. Below the header, the main navigation menu includes 'Training', 'News', 'Resources', 'Food Safety Modernization Act', 'The Alliance', 'Committees', and 'Contact Us'. The 'Training' menu is expanded, showing options: 'Grower Training Course', 'Train-the-Trainer Course', 'Trainer Resources', 'Trainer Directory', and 'Training Reports'. The main content area features a banner image of fresh produce (peaches, bell peppers, and cucumbers) with the text 'Produce Safety ALLIANCE' and 'PSA Training Courses'. Below the banner, the breadcrumb 'Home / Training' is visible, followed by the heading 'Produce Safety Alliance Training Courses' and the introductory text: 'The Produce Safety Alliance (PSA) has been tasked with developing the standardized national produce safety training'.

# Training Resources



Trainer Resources | Produce Saf X

https://producesafetyalliance.cornell.edu/training/trainer-resources

Trainer Resources

- Register a PSA Grower Training with AFDO
- PSA Grower Training Course Agenda Template
- PSA Grower Training Course Set Up Guide
- PSA Grower Training Course Checklist
- PSA Grower Training Course Template Language for Advertising
- FSMA Produce Safety Rule Exemptions & Exclusions PowerPoint
- Clarification of Compliance Dates Chart - Updated 10-9-17
- Produce Safety Bingo
- Ordering PSA Manuals
- English Grower Manual – Electronic Release Files
- Spanish Grower Manual – Electronic Release Files

**Grower Manual Sections**

The following appear in the Grower Training manual and are provided here as a digital reference

- PSA Curriculum FSMA Produce Safety Rule Regulatory Table
- PSA Curriculum Glossary
- PSA Curriculum Learning Objectives and Critical Concepts

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# Modules in PSA Training

1. Introduction to Produce Safety
2. Worker Health, Hygiene and Training
3. Soil Amendments
4. Wildlife, Domesticated Animals & Land Use
5. Part I Production Water  
Part II Post Harvest Water
6. Postharvest Handling and Sanitation
7. How to develop a Farm Food Safety Plan

# 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 Exemptions

- 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



# Records

- 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



**24** hours 

*Time allotted for records requested by the FDA*

**2** years 

*Retention period for required records under FSMA*

# Compliance Dates as of Sept. 2017

Provision in Produce Rule	Compliance Date
Produce General Provisions	January 26, 2018
Ag Water Provisions (Subpart E)	January 26, 2022*
Sprouts (Subpart M)	January 26, 2017

*\*Per Sept 17, 2017 Federal Register Proposed Rule*



# Get Ready Checklist

1. Am I a Farm?
2. Am I importing produce?
3. Grower training through Produce Safety Alliance
4. Training for food workers handling produce
5. Produce Safety Plan
6. Records
7. Communication with Supply Chain

# Thank You! – Questions??

*For more information...*

- <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>
- <https://producesafetyalliance.cornell.edu/>
- <http://repositrak.com/>
- <http://www.fmi.org/>