



# Ready to Eat: An Introduction to the Preventative Controls for Human Food Rule

The webinar will begin promptly at 11:00am Pacific / 12:00pm Mountain.



United States Department of Agriculture  
National Institute of Food and Agriculture



# Ready to Eat: An Introduction to the Preventative Controls for Human Food Rule

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# Webinar Tips



**Close all other programs running on your computer**



**Check your sound – problems with clarity, speed, etc. switch to the phone**

Call-in number provided in the welcome email

Mute computer sound when using phone



**Type in questions for speakers into question box**

For help with sound or other technical issues, use the chat box



**Handouts are available to download on your computer**





# Overview

- FSMA and PCHF
- Exemptions and Requirements
- Farm vs. Facility
- Fundamentals of PCHF
  - Hazard Analysis
  - Preventive Controls
  - Supply Chain Program
  - Recall Plan
  - Updated GMPs



# What is Preventive Controls for Human Food (PCHF)?

## Food Safety Modernization Act (FSMA)

- Signed into law 2011
- Composed of seven rules
  1. Produce Safety Rule
  2. [Preventive Controls for Human Food](#)
  3. Preventive Controls for Animal Food
  4. Foreign Supplier Verification Programs
  5. Accreditation of Third-Party Auditors/Certification Bodies
  6. Sanitary Transportation of Human and Animal Food
  7. Prevention of Intentional Contamination/Adulteration
- Prevent food safety hazards across the entire food system



# PCHF – Are You In or Out?

- Applies if you manufacture, process, pack or hold human food for consumption in the U.S.
- Compliance Dates:
  - Large businesses - September 19, 2016
  - Small businesses (<500 FT employees) – Sept 18, 2017
  - Very small businesses (avg <\$1m per year in annual sales) – Sept 18, 2018
    - Includes market value of food manufactured, processed, packed or held without sale
    - Adjusted yearly for inflation





# PCHF Exemptions and Modified Requirements

- Qualified Facilities – businesses with average annual sales of less than \$500,000
  - At least half the sales to consumers, local retailers, restaurants or Indian reservation
    - Must be within the same state or within 275 miles
- Very small businesses averaging less than \$1,000,000 (adjusted for inflation)
  - Includes both sales of human food plus the market value of human food that is manufactured, processed, packed, or held without sale (e.g. held for a fee)
  - Avg. per year during the 3-year period preceding the current calendar year.



# Qualified Exemption Requirements

- 1. Required** to notify FDA about its status and attest that it is either:
  - Addressing identified hazards through preventive controls and monitoring the preventive controls; or
  - Complying with applicable non-Federal food safety regulations, **and** notifying consumers of the **name and complete business address of the facility** where food was manufactured or processed.
  - Must submit these notifications to FDA and register facility

**An otherwise Qualified Facility that does NOT notify FDA is subject to the requirements for Hazard Analysis and Preventive Controls.**





# Qualified Exemption Requirements

2. **Must** follow conditions and practices for processing safe food under sanitary conditions (GMPs):
- Personnel
  - Plant and grounds
  - Sanitary operations
  - Sanitary facilities and controls
  - Equipment and utensils
  - Processes and controls
  - Warehousing and distribution
  - Holding and distribution of human food by-products for use as animal food, and
  - Defect action levels



# Farm vs. Facility

- **A farm is exempt** from FDA's food facility registration requirement.
  - Does not have to register with FDA
  - Not subject to the preventive controls requirements.
  - "In general, on-farm packing or holding of produce would fall under produce safety rule."

## **Very strict definition of what encompasses a farm!**

- Two kinds of farming operations:
  1. Primary production farm
  2. Secondary activities farm



# What is a Primary Production Farm?

- An operation under one management in one general, but not necessarily continuous, location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities

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 under the same management; or
  - The manufacturing/processing falls into limited categories.



A photograph showing several glass jars filled with jam, stacked on top of each other. In the foreground, there is a pile of fresh produce including walnuts, orange slices, and carrots. The background is blurred, suggesting an outdoor setting.

# Secondary Activities Farm

- An operation not located on a primary production farm
  - Is devoted to farming activities (e.g. harvesting, packing and/or holding RACs).
- The primary production farms(s) must own or jointly own a majority interest in the secondary activities farm.



# Manufacturing/Processing within the Farm Definition

- Drying/dehydrating RACs to create a distinct commodity (e.g., drying grapes to produce raisins)
- Treatment to manipulate the ripening of RACs (e.g. treating produce with ethylene gas)
- Packaging and labeling RACs



# Manufacturing/Processing NOT within the Farm Definition

## 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)

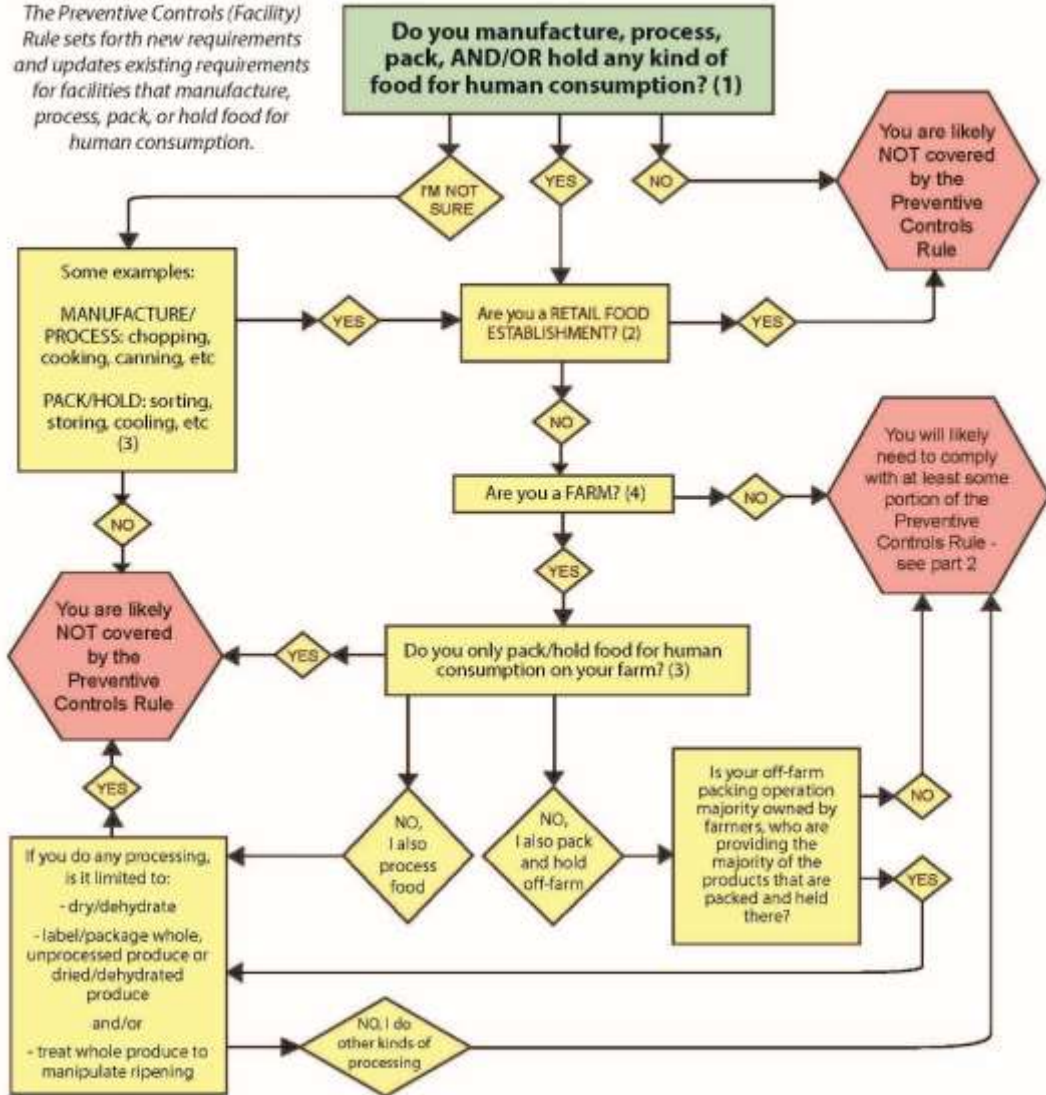
**If you do these activities, you are covered under the rule!**



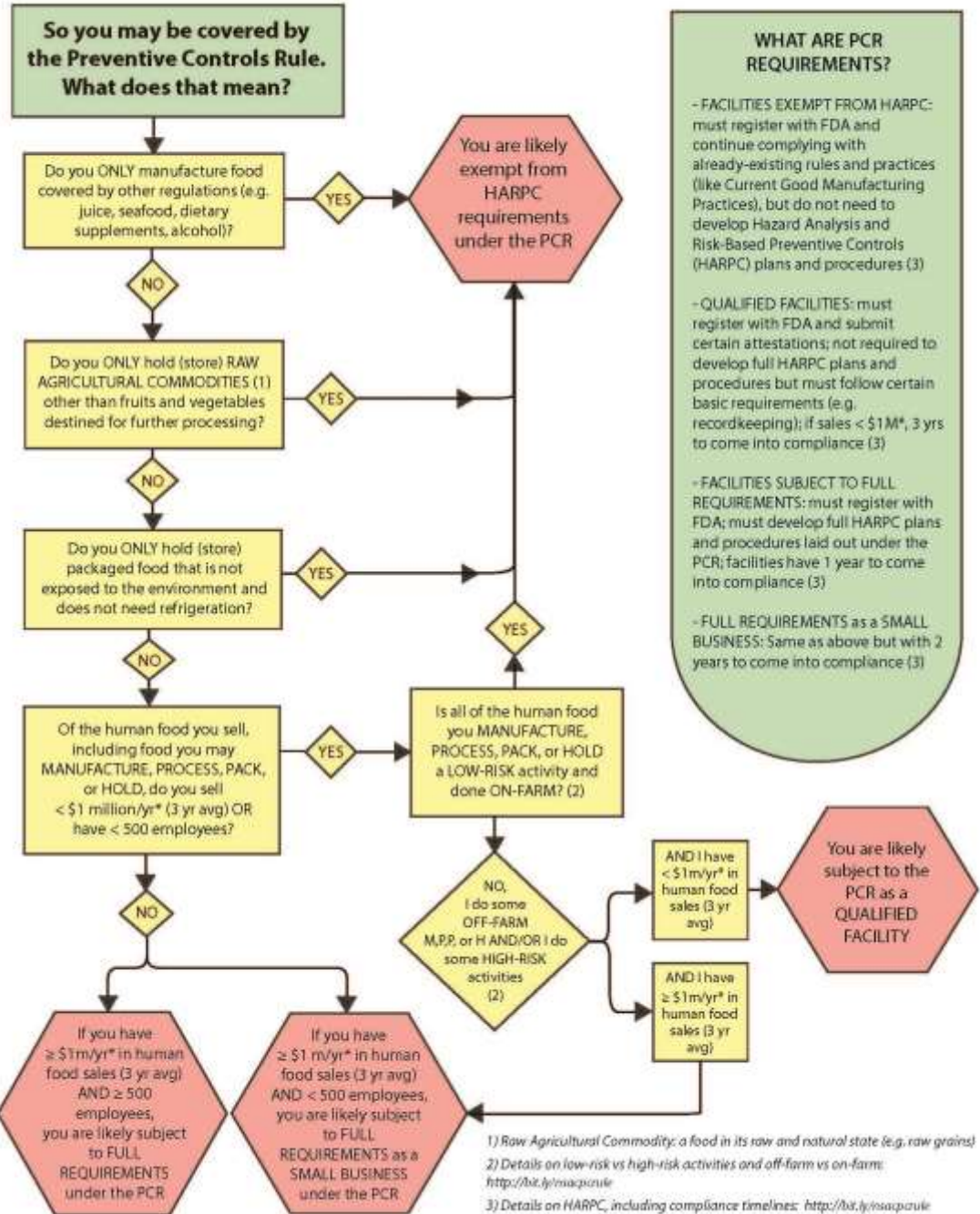
# Am I Affected by the FSMA

## Preventive Controls (Facility) Rule?

The Preventive Controls (Facility) Rule sets forth new requirements and updates existing requirements for facilities that manufacture, process, pack, or hold food for human consumption.



## The FSMA Preventive Controls (Facility) Rule - Part 2



**WHAT ARE PCR REQUIREMENTS?**

- FACILITIES EXEMPT FROM HARPC: must register with FDA and continue complying with already-existing rules and practices (like Current Good Manufacturing Practices), but do not need to develop Hazard Analysis and Risk-Based Preventive Controls (HARPC) plans and procedures (3)
- QUALIFIED FACILITIES: must register with FDA and submit certain attestations; not required to develop full HARPC plans and procedures but must follow certain basic requirements (e.g. recordkeeping); if sales < \$1M\*, 3 yrs to come into compliance (3)
- FACILITIES SUBJECT TO FULL REQUIREMENTS: must register with FDA; must develop full HARPC plans and procedures laid out under the PCR; facilities have 1 year to come into compliance (3)
- FULL REQUIREMENTS as a SMALL BUSINESS: Same as above but with 2 years to come into compliance (3)

1) If you are manufacturing, processing, packing, or holding food for personal consumption on farm only, the Preventive Controls Rule does not apply.  
 2) Retail Food Establishment: grocery stores, farm stands, and restaurants that sell the majority of their food directly to consumers; details: <http://bit.ly/nsacpcrule>  
 3) Find definitions of manufacturing, processing, packing, and holding, along with examples of what "off-site" and "on-farm" mean, here: <http://bit.ly/nsacpcrule>  
 4) Find details on FDA's "farm" definition and on packaging, labeling, dehydrating, other on-farm activities that do and don't trigger the "facility" definition: <http://bit.ly/nsacpcrule>. Note also that FDA may be making changes to the rules to address operations that walk the line between a farm and a facility.

1) Raw Agricultural Commodity: a food in its raw and natural state (e.g. raw grains)  
 2) Details on low-risk vs high-risk activities and off-farm vs on-farm: <http://bit.ly/nsacpcrule>  
 3) Details on HARPC, including compliance timelines: <http://bit.ly/nsacpcrule>



# Overview of Requirements for PCHF



# Food Safety Plans

1. Have and implement a written food safety plan
  - Identify food safety hazards that require preventive control
2. Implement preventive controls to minimize or prevent hazards

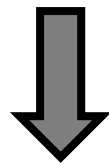
Plan must have:





# Hazard Analysis

1. Must identify and known or reasonably foreseeable hazard
2. Determine if those hazards require a preventive control





# Types of Hazards - Examples

## 1. Biological

- Bacteria
- Viruses
- Parasites
- Fungi

## 2. Chemical

- Allergens
- Chemical adulteration

## 3. Physical

- Glass
- Rubber
- Metal

# Preventive Controls

*If hazard analysis identifies a preventive control, must develop and implement a plan to significantly minimize or prevent the hazard.*

## Plan may include:

1. Process controls
2. Allergen controls
3. Sanitation controls
4. Other controls as needed/identified







# Process Controls - Examples

## Biological

- Cooking (correct temp to kill microorganisms)
- Refrigeration/freezing (to slow growth of organisms)
- pH (inhibit microbial growth)
- Water activity ( $a_w$ ) < 4.6

## Chemical

- Dedicating equipment
- Verifying labeling

## Physical

- Use of metal detectors



# Process Controls

## Must have:

- Parameters (min and max values)
  - ✓ Example: Product internal temperature must be within range of 160-165°F for a minimum of 30 seconds
- Monitoring
  - ✓ Example: Checking the product temperature on 10% of the products using a calibrated thermometer
- Corrective action
  - ✓ Example: If out of range, adjust equipment cooking temp and re-process
- Verification/Validation
  - ✓ Example: Verify corrective action worked. Validate process to ensure it is effective at killing pathogens
- Records
  - ✓ Example: Thermometer calibration records, re-processing records, product temp logs



# Food Allergen Controls

*Procedures, practices and processes to control allergen cross-contact and ensure proper labeling.*

- Monitoring
  - ✓ Example: Check that correct labels are applied, use of dedicated equipment, appropriate cleaning for allergen removal, supplier verification
- Corrective action
  - ✓ Example: Re-label product if wrong label is used. Destroy or divert contaminated product.
- Verification
  - ✓ Example: Verify corrective action worked (e.g. wrong labels removed and correct ones applied)
- Records
  - ✓ Example: Deviation remedied and corrective action applied





# Sanitation Controls

Procedure, practices, and processes to ensure facility is maintained in a sanitary manner to control hazards.

- Monitoring
  - ✓ Example: Regular swabbing protocol to detect *Listeria* spp.
- Corrective action
  - ✓ Example: Positive result → Hold product for microbial testing, re-cleaning and sanitizing of equipment.
- Verification
  - ✓ Example: Re-test for *Listeria* spp.
- Records
  - ✓ Example: Environmental monitoring records (areas swabbed, time, date), test results, corrective actions applied.

# Risk-based Supply Chain

*If a hazard is related to ingredients from a supplier, and you depend on supplier to control the hazard, you must have and implement a supply-chain program and perform verification.*





# Risk-based Supply Chain

- Must use approved suppliers
- Determine needed supplier verification activities
  - ✓ On-site audits
  - ✓ Sampling/testing of materials
  - ✓ Review supplier's records (e.g. testing, processing)
- Conduct supplier verification
- Document (examples)
  - ✓ Copies of records
  - ✓ Copies of laboratory test results
  - ✓ Sampling and testing dates/times/product type
  - ✓ Audit records



# Recall Plan

*If the hazard analysis identifies a hazard you must have a written recall plan!*





# Recall Plan

## *Must include:*

1. Procedures for conducting recall
2. Steps to perform recall
3. Assignment of responsibilities

## *Recall plan steps:*

1. Notification to regulators
2. Notifying receivers of recall
3. Disposition of affected food
4. Public notification
5. Verifying recall effectiveness



## Preventive Controls Qualified Individual

- Individual who has successfully completed training in the development and application of risk-based preventive controls
  - Training must be at least equivalent to that received under a standardized curriculum (e.g. FSPCA PCHF 2.5 day training)
- **or**-
  - Otherwise qualified through job experience to develop and apply a food safety system.

**Food safety plan must be prepared by (or overseen) by a “preventive controls qualified individual”!**





# Updated GMP Requirements

**1. Training** – Employees must be qualified to perform assigned duties and be trained in principles of food hygiene and safety

- Training records must be maintained

**2. Allergen cross-contact** – Must employ employee practices and procedures to control allergen cross-contact

**3. Food by-products used for animal food** – New provisions for holding and distribution



# Summary

- PCHF covers the manufacture, processing, packing or holding of human food
- Facilities should already be in compliance if not exempt
- Extension and your state ag department can help you determine if you are exempt or covered
  - Farms may be exempted from PCHF but covered under other regs (PSR)
- Even if qualified exempt, you must:
  1. Register with FDA
  2. Follow cGMPs
  3. Keep paperwork showing sales, etc.
  4. Label food with name and complete business address of the facility where produced/processed



# Summary

- If covered, you must have a PCQI to oversee the food safety plan
  - Best to take standardized training (FSPCA's PCHF)
- Many resources available; don't be afraid to reach out!





# For more information:

## *FDA Resources:*

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>

## *Extension Resources:*

- WSU- <https://foodprocessing.wsu.edu/extension/training/fsmapc/>
- UI- <https://www.uidaho.edu/extension/food-safety-for-produce-growers/food-safety-modernzation-act>
- PNW Food Safety - <https://pnwfoodsafety.wordpress.com/home/>



# Upcoming & Recorded Webinars

May 21: Food Safety from Field to Market: Harvest and Post-Harvest Sanitation Practices

May 28: Compost Happens: Managing Food Safety Risks in Biological Soil Amendments

**Register, view recorded webinars & learn more at:**

**[www.pnwfoodsafety.org](http://www.pnwfoodsafety.org)**