Overview/review of FSMA’s Preventive Controls Rule:
What is my \textit{food hub’s} status and what does it mean?

USDA NIFA Food Safety Outreach Program: Nov 2018
USDA NIFA Food Safety Outreach Program team

**Dr. Gail Feenstra**, Deputy Director of UC Sustainable Agriculture Research & Education Program (SAREP)

**Dr. Erin DiCaprio**, Assistant Cooperative Extension Specialist in Community Food Safety in the Department of Food Science and Technology at UC Davis

**Dr. Alda Pires**, Assistant Cooperative Extension Specialist in Urban Agriculture Food Safety in the Department of Population Health and Reproduction, School of Veterinary Medicine, UC Davis.

**Gwenaël Engelskirchen**, Sustainable Supply Chain Analyst, UC SAREP
Food Safety Modernization Act

- The Food Safety Modernization Act (FSMA) is the largest overhaul in U.S. food safety regulations in over 70 years.
- Shifted the focus to prevention of foodborne illness rather than reacting after an outbreak has occurred.
- The US Food and Drug Administration (FDA) has finalized seven major rules to implement FSMA.
7 Foundational Rules

1. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
2. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals
3. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
4. Sanitary Transportation of Human and Animal Food
5. Foreign Supplier Verification Programs
6. Accredited Third-Party Certification
7. Mitigation Strategies to Protect Food Against Intentional Adulteration
Foundational rules most likely to impact food hubs

• Current Good Manufacturing Practice and Hazard Analysis and Risk-Based **Preventive Controls for Human Food**

• Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (**Produce Safety Rule**)
Who is covered?
By the Produce Safety Rule

- Farms that grow, harvest, pack, or hold fresh produce
- Some growers may be eligible for an exemption or excluded based on:
  - Commodities grown (e.g., rarely consumed raw)
  - Processing activities that include a ‘kill step’
  - Average annual produce sales
  - Average annual food sales and sales to ‘qualified end users’
- Ultimately, all growers should understand and take action to reduce food safety risks on the farm
Who is covered?
By the Preventive Controls Rule for Human Food

• Facilities that manufacture, process, pack, or hold human food. In general, facilities required to register with FDA under section 415 of the Food, Drug, and Cosmetic Act
  • Not farms or retail food establishments
• Applies to domestic and imported food
• Some exemptions and modified requirements apply
FSMA Preventive Controls for Human Food Rule or Produce Safety Rule?

- The flow chart refers to the FSMA PSR Rule defined “secondary farm”
- Food hubs not located on farms may fall under the definition of secondary farm and therefore the PSR will apply
- If not located on a farm and does not meet ownership requirements PCHF will apply

Penn State Extension Flow Chart
https://extension.psu.edu/which-fsma-regulation-applies
What happens if my food hub is covered by the Produce Safety Rule?

- Attend Produce Safety Alliance Grower Training Course
- Farm Food Safety Plan (not required, but suggested to manage and document adherence to the Regulation)
- On farm inspection (FDA)
  - In CA CDFA will inspect farms on behalf of FDA

https://producesafetyalliance.cornell.edu/
https://www.cdfa.ca.gov/producesafety/about.html
FSMA Preventive Controls for Human Food Mixed Type Facility Exemption

• Applicable to individuals that also process foods
• Examples of low risk processing activities:
  • Chopping, coring, cutting, peeling, pitting, shredding, slicing fruits and vegetables that have a pH < 4.2
  • Drying dehydrating cut fruits and vegetables with a pH <4.2
  • Freezing fruits and vegetables with pH < 4.2
  • Others: NSAC

Penn State Extension Flow Chart
https://extension.psu.edu/fsma-preventive-controls-rule-exemptions
What if my food hub is covered under the Preventive Controls for Human Food Rule?

• In depth details covered on Jan. 9th webinar
• At least one individual must attend the Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls Qualified Individual (PCQI) course
• Conduct a Hazard Analysis
• Develop a Food Safety Plan
• Register with FDA
• FDA inspection

https://www.ifsh.iit.edu/fspca
Preventive Food Safety Systems

Food Safety Plan
Including procedures for monitoring, corrective action and verification, as appropriate

- Hazard Analysis
- Process Control
- Supply-chain Program
- Allergen Control
- Sanitation Control
- Recall Plan

GMPs and Other Prerequisite Programs
Key Requirements of the Preventive Controls for Human Food Rule

- Hazard Analysis
- Preventive Controls (CCPs, allergen, sanitation, supplier, etc.)
- Parameters & Values
- Monitor
- Corrective Action or Corrections
- Verification & Recordkeeping
Key Requirements of the Preventive Controls for Human Food Rule: Food Safety Plan

**Required**
- Hazard analysis
- Preventive controls*
  - Process, food allergen, sanitation, supply-chain and other
  - Recall plan*
- Procedures for monitoring, corrective action and verification*

**Useful**
- Facility overview and Food Safety Team
- Product description
- Flow diagram
- Process description

* Required when a hazard requiring a preventive control is identified
Exemptions

• Foods subject to HACCP regulations (seafood and juice)
  • 21 CFR 123; 21 CFR 120

• Food subject to low-acid canned food regulations (only with respect to microbiological hazards)
  • 21 CFR 113

• Dietary supplements
  • 21 CFR 111

• Foods subject to produce safety requirements

• Alcoholic beverages
Exemptions

• Facilities that only store unexposed packaged food
• Certain storage facilities such as grain elevators and warehouses that only store raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing
• Activities within the definition of “farm,” including farm activities that are covered by the produce rule
  • Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods
Modified Requirements

• “Qualified” facilities (21 CFR 117.5(a))
  • Very small businesses (less than $1 million in total annual sales of human food plus the value of food held without sale)
  
  OR

  • Food sales averaging less than $500,000 per year during the last three years AND sales to qualified end-users must exceed sales to others

• Exempt from hazard analysis and risk-based preventive controls when certain documentation is provided
FSMA Preventive Controls for Human Food Qualified Facility Exemption

- PCHF Rule potentially applies to food hubs located off farm and where the “secondary farm” definition is not met
- If under $1,000,000 (adjusted for inflation) in annual sales than certain exemptions apply

Penn State Extension Flow Chart
https://extension.psu.edu/fsma-preventive-controls-rule-exemptions
What if my food hub is considered a Qualified Facility under the Preventive Controls for Human Food Rule?

• In depth details covered on Dec. 12th webinar
• Comply with CGMPs
• Submit attestation to FDA that states they meet the criteria of a very small business (12/17/2018)


Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food):
Guidance for Industry Draft Guidance

FSMA Preventive Controls for Human Food Compliance Dates

• Small businesses
  • A business employing less than 500 full-time employees
  • September 18, 2017

• Extended compliance dates:
  • *Facilities solely engaged in packing and/or holding activities on produce RACs*
    • Compliance Date: **January 28, 2019**
  • *Certain facilities that would qualify as secondary activities farms except for ownership*
    • Compliance Date: **January 28, 2019**
  • *Facilities that would qualify as farms if they did not color RACs*
    • Compliance Date: **January 28, 2019**
FSMA Preventive Controls for Human Food Compliance Dates

• **Very small businesses**
  • A business (including any subsidiaries and affiliates) that averages less than $1 million (adjusted for inflation) per year during the three-year period
  • **September 17, 2018**
  • Attestation form to FDA 12/17/2018

• Extended compliance dates:
  • *Facilities solely engaged in packing and/or holding activities on produce RACs*
    • Compliance Date: **January 27, 2020**
  • *Certain facilities that would qualify as secondary activities farms except for ownership*
    • Compliance Date: **January 27, 2020**
  • *Facilities that would qualify as farms if they did not color RACs*
    • Compliance Date: **January 27, 2020**
Case Study #1

• Food hub owned by farmer who is supplying produce and food hub is NOT located on the farm
Case Study #2

- Food hub located on primary production farm and food hub is drying/dehydrating fruits and vegetables
Farmer Owned Food Hub Located On Farm

- Holding of fresh produce ONLY
  - Covered by the Produce Safety Rule
- Dehydrating fruits and vegetables in addition to holding produce
  - Dehydrating apples
    - pH < 4.2
  - Dehydrating basil
    - pH > 4.2
  - Covered by the Preventive Controls for Human Food Rule

*Qualified Exemptions may still apply based on the specifics of the food hub*
QUESTIONS?