

Overview/review of FSMA's  
Preventive Controls Rule:  
*What is my **food hub's** status and  
what does it mean?*

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

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# **USDA NIFA Food Safety Outreach Program team**

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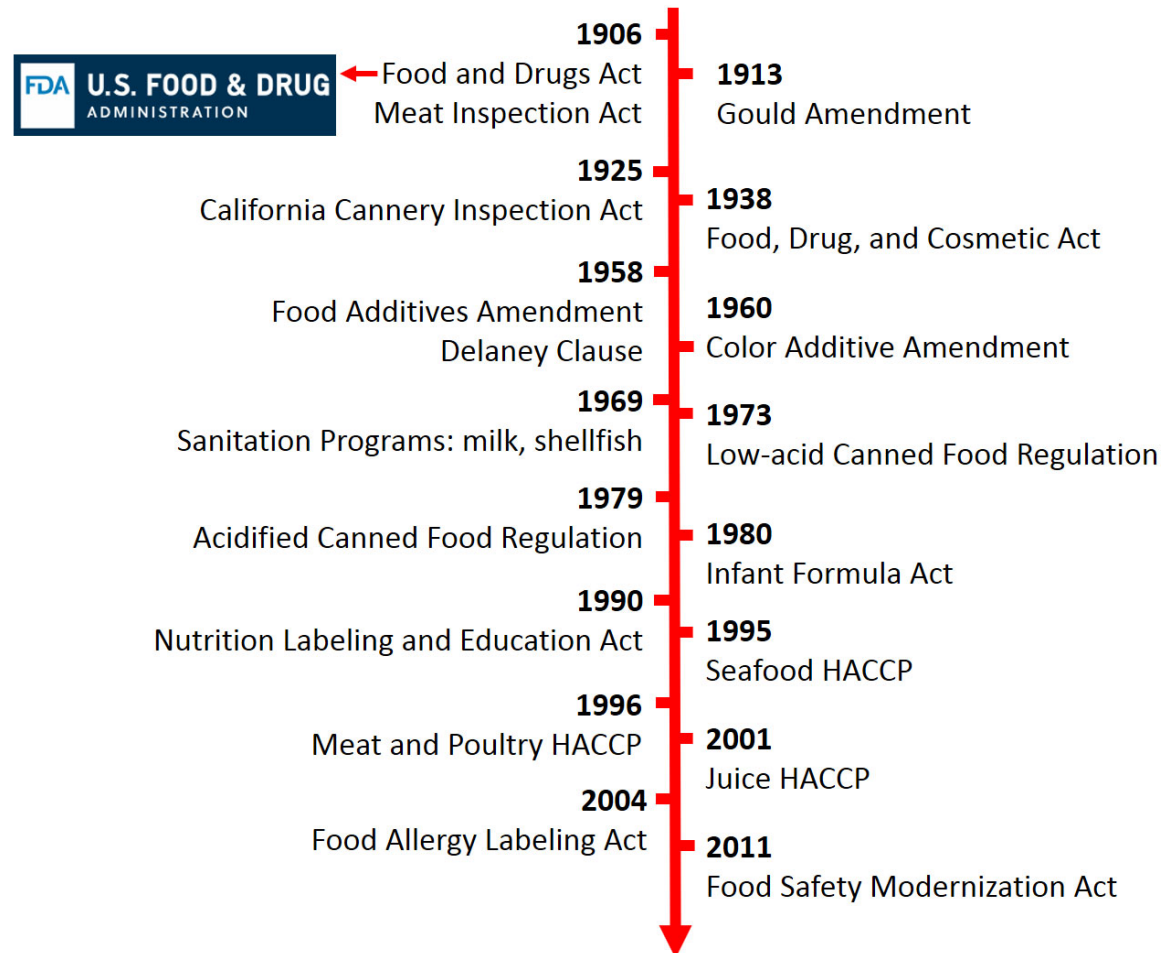
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# Food Safety Modernization Act

- 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?

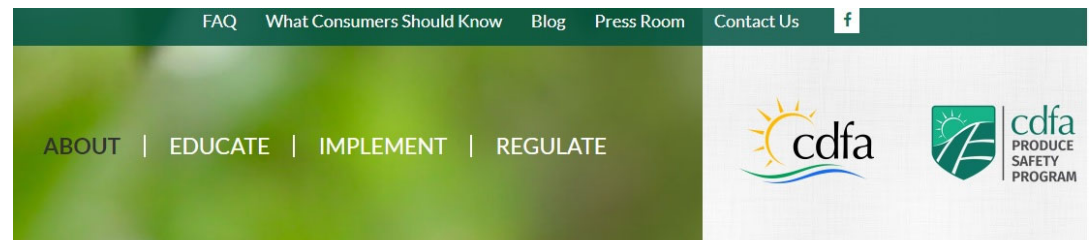
- Attend Produce Safety Alliance Grower Training Course
- Farm Food Safety Plan (not required, but suggested to manage and document adherence to the Regulation)
- On farm inspection (FDA)
  - In CA CDFA will inspect farms on behalf of FDA



## Produce Safety Alliance

Training   PSA Curriculum   Resources   News   Food Safety Modernization Act   The Alliance   Contact Us

<https://producesafetyalliance.cornell.edu/>



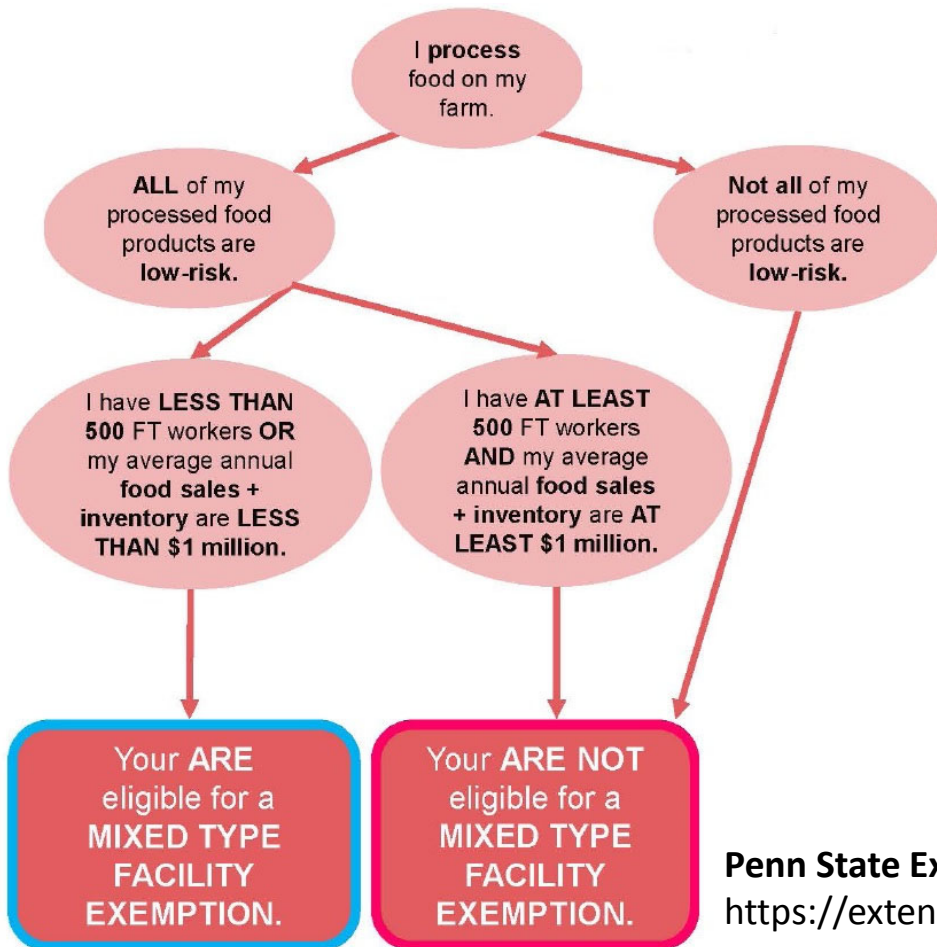
## ABOUT

The California Produce Safety Program is a unit operating under the California Department of Food and Agriculture's Inspection Services Division. It exists to help bring California produce farms into compliance with U.S. Food and Drug Administration's Produce Safety Rule.



<https://www.cdfa.ca.gov/producesafety/about.html>

# FSMA Preventive Controls for Human Food Mixed Type Facility Exemption



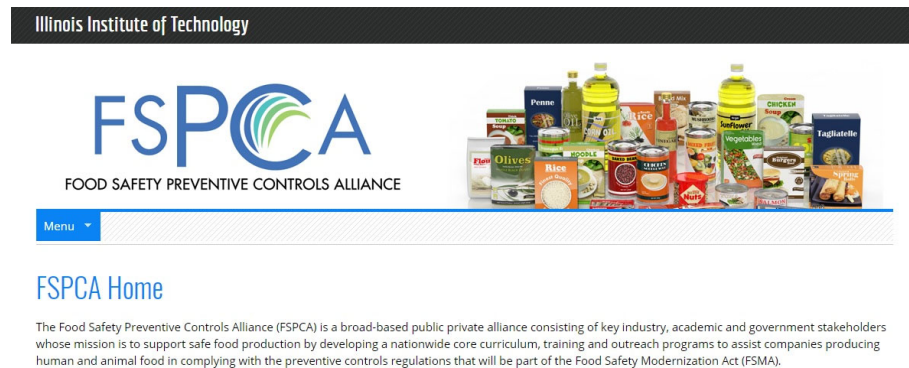
- Applicable to individuals that also process foods
- Examples of low risk processing activities:
  - Chopping, coring, cutting, peeling, pitting, shredding, slicing fruits and vegetables that have a pH < 4.2
  - Drying/dehydrating cut fruits and vegetables with a pH < 4.2
  - Freezing fruits and vegetables with pH < 4.2
  - Others: NSAC (<http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-FACILITIES-FINAL-.pdf>)

**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. 9<sup>th</sup> 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



The screenshot shows the top portion of the FSPCA website. At the top left, the text "Illinois Institute of Technology" is displayed in white on a dark grey background. Below this is the FSPCA logo, which consists of the letters "FSPCA" in a blue, sans-serif font, with a stylized green and blue circular graphic to the right. Underneath the logo, the full name "FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE" is written in a smaller, blue, sans-serif font. To the right of the logo is a photograph of various food products, including cans of soups, boxes of pasta, and bottles of oil. Below the logo and image is a blue navigation bar with the word "Menu" and a small downward-pointing arrow. Underneath the navigation bar, the text "FSPCA Home" is written in blue. At the bottom of the screenshot, a small paragraph of text describes the FSPCA as a broad-based public private alliance.

Illinois Institute of Technology

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

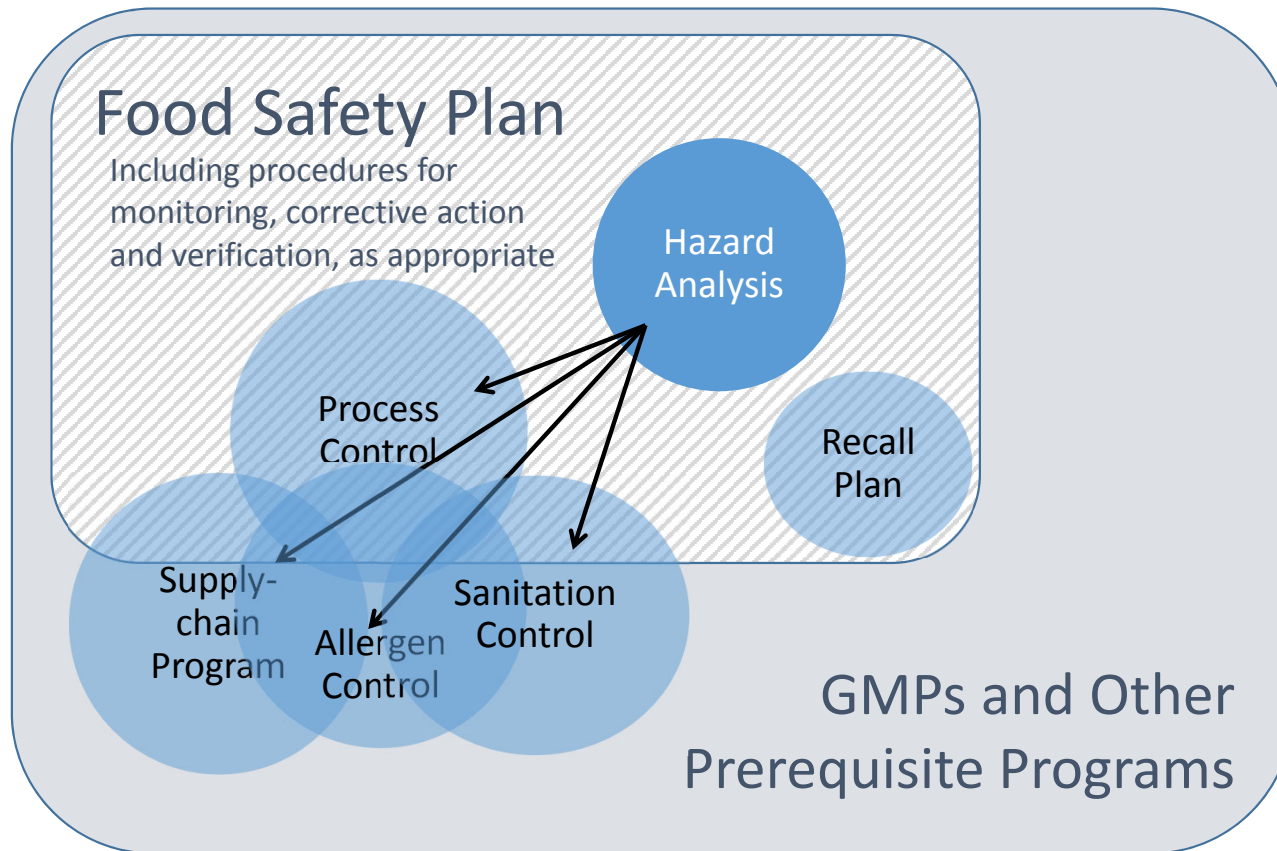
Menu ▾

[FSPCA Home](#)

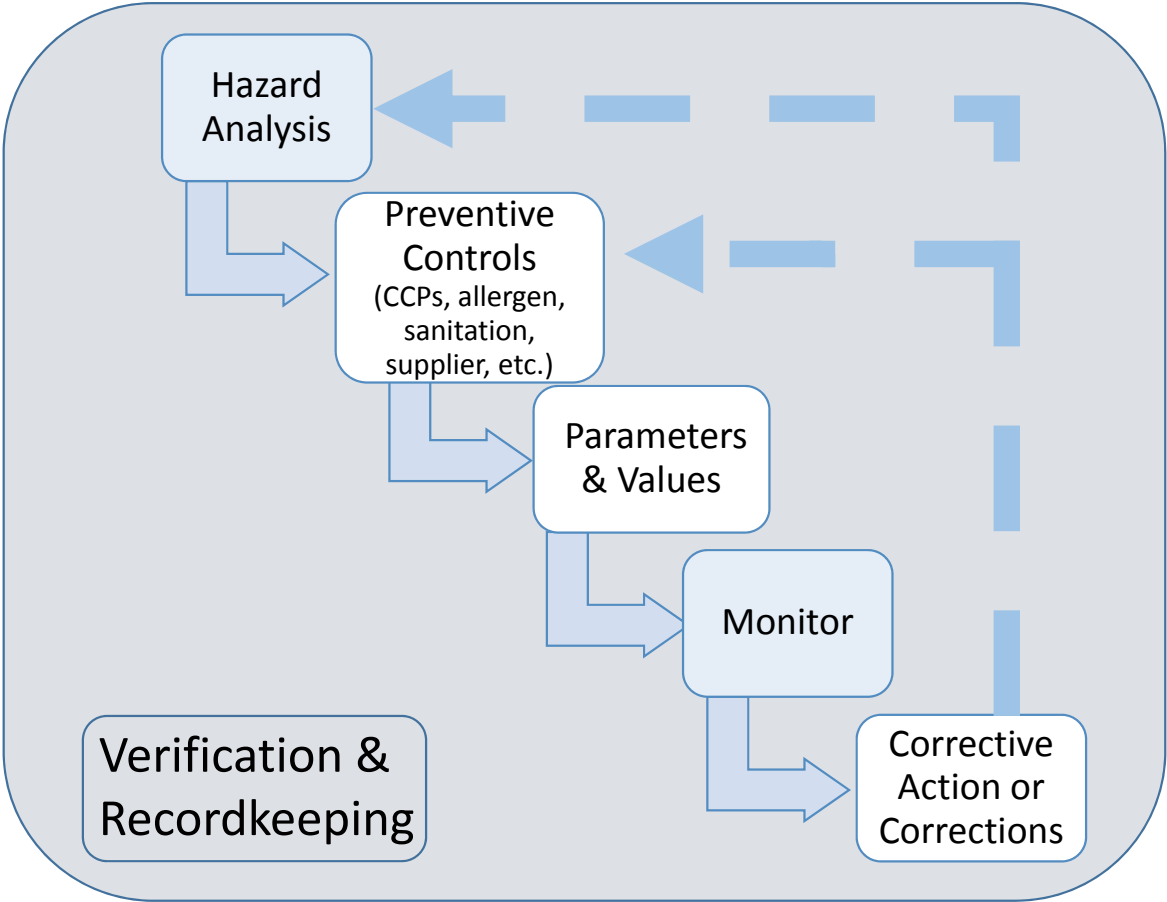
The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public private alliance consisting of key industry, academic and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training and outreach programs to assist companies producing human and animal food in complying with the preventive controls regulations that will be part of the Food Safety Modernization Act (FSMA).

<https://www.ifsh.iit.edu/fspca>

# Preventive Food Safety Systems



# Key Requirements of the Preventive Controls for Human Food Rule



# 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

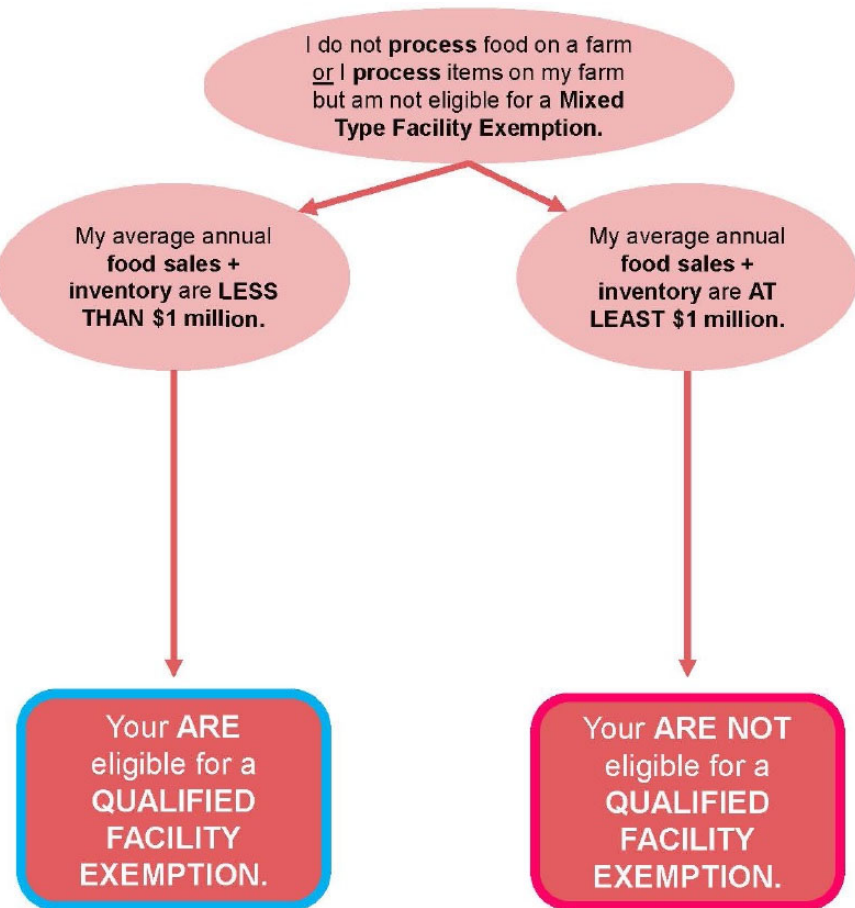
- Facilities that only store unexposed packaged food
- Certain storage facilities such as grain elevators and warehouses that only store raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing
- **Activities within the definition of “farm,” including 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. 12<sup>th</sup> webinar
- Comply with CGMPs
- Submit attestation to FDA that states they meet the criteria of a very small business (12/17/2018)



UNDERSTANDING FDA'S FSMA  
RULE FOR FOOD FACILITIES

<http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-FACILITIES-FINAL-.pdf>

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

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM499509.pdf>

# 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

Farmer Owned Food Hub  
Located Off Farm

Farmer/food hub owner supplies > 50% produce

Farmer/food hub owner supplies < 50% produce

Covered by the Produce Safety  
Rule

Covered by the Preventive  
Controls for Human Food Rule

Average Annual  
Sales < \$500,000

Average Annual  
Sales > \$500,000

Average Annual  
Sales + Inventory  
< \$1,000,000

Average Annual  
Sales + Inventory  
> \$1,000,000

> 50% Sales are  
direct to consumer

< 50% Sales are  
direct to consumer

NOT eligible for  
a QUALIFIED  
EXEMPTION

Eligible for a  
QUALIFIED  
EXEMPTION

NOT eligible for  
a QUALIFIED  
EXEMPTION

> 50% Sales are to  
restaurants/retail  
food establishments

< 50% Sales are to  
restaurants/retail  
food establishments

Eligible for a  
QUALIFIED  
EXEMPTION

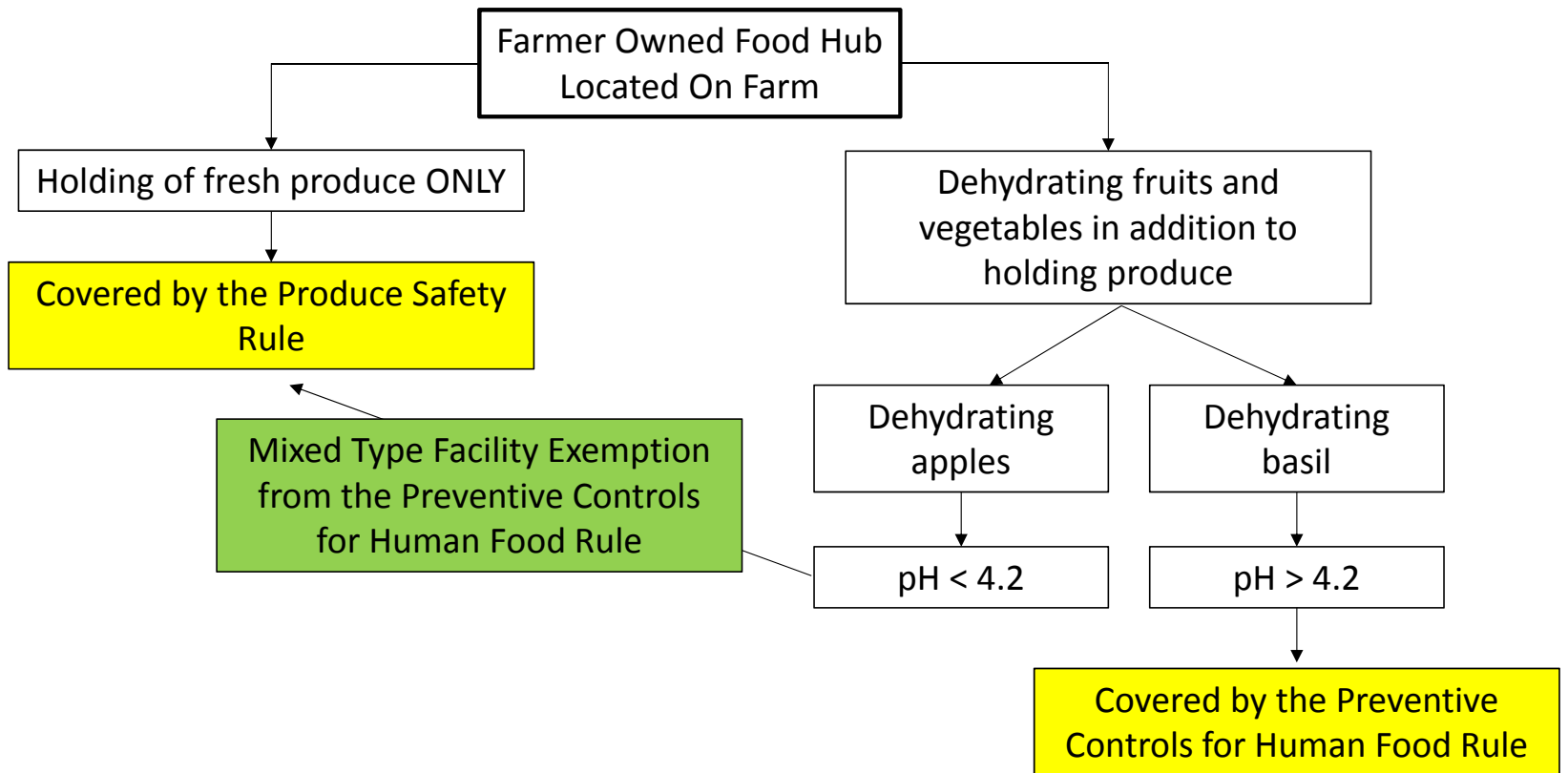
Food sales in same state  
or within 275 miles

Food sales NOT in same  
state or within 275 miles

## Case Study #2

- Food hub located on primary production farm and food hub is drying/dehydrating fruits and vegetables





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

QUESTIONS?