



FSMA 101 for Organic Food Processors

Hosted by the CCOF Foundation
September 14 + 15, 2021



National Institute of Food and Agriculture
U.S. DEPARTMENT OF AGRICULTURE

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Acknowledgements & Disclaimers

- This webinar series is supported by Food Safety Outreach Program Grant 2020-70020-33025 from the USDA National Institute of Food and Agriculture.
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- This webinar is not legal advice. For specific information on how the FSMA Produce Safety Rule might impact your operation, please contact an attorney.



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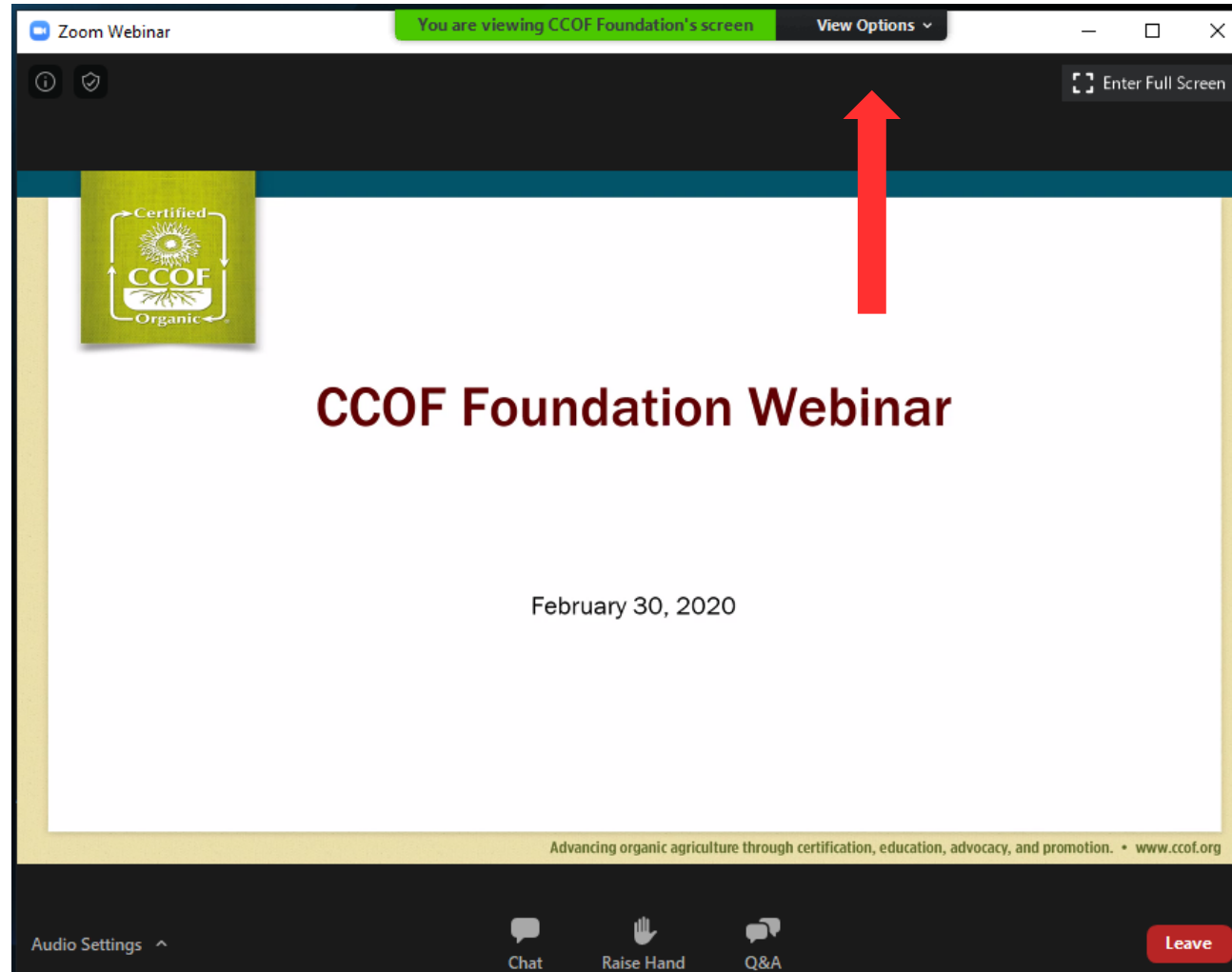
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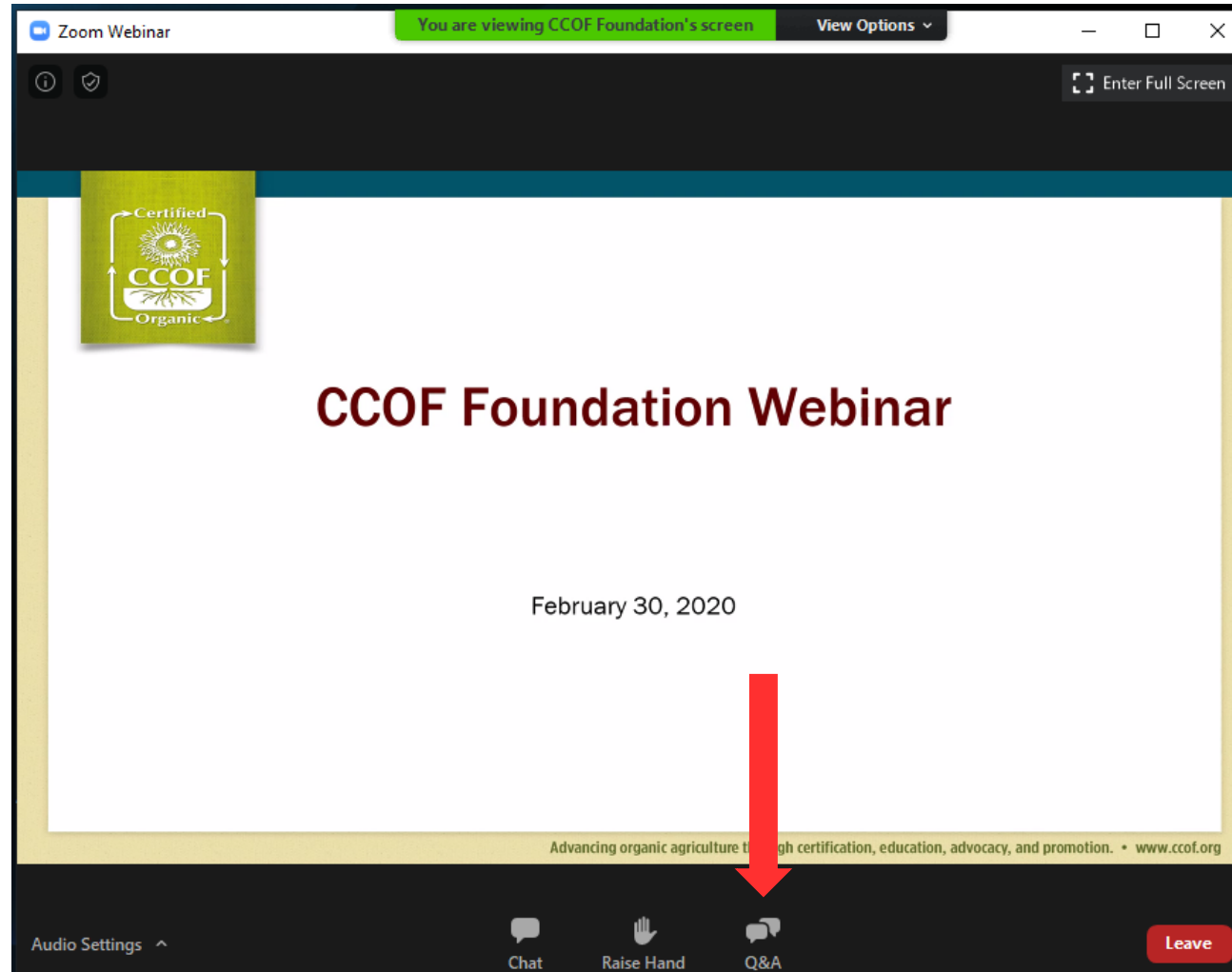
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All questions (1)

My questions (1)

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Today's Lead Trainer



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FSMA 101 for Organic Food Processors



Agenda

- Introduction to food safety and regulation of processed food
- Food Safety Modernization Act
- Low- and high-risk food categories
- Exemptions and Partial Exemptions to the Preventive Controls for Human Food Rule
- Requirements of the Preventive Controls for Human Food Rule

Poll #1

- What does the business you are affiliated with process?
 - Jams, jellies, and/or preserves
 - Pickles
 - Baked goods
 - Dried fruit, vegetables, or herbs
 - Canned fruit
 - Canned vegetables
 - Fermented fruits or vegetables
 - Sauces (ex. Hot sauce, tomato sauce)
 - Other
 - Not applicable

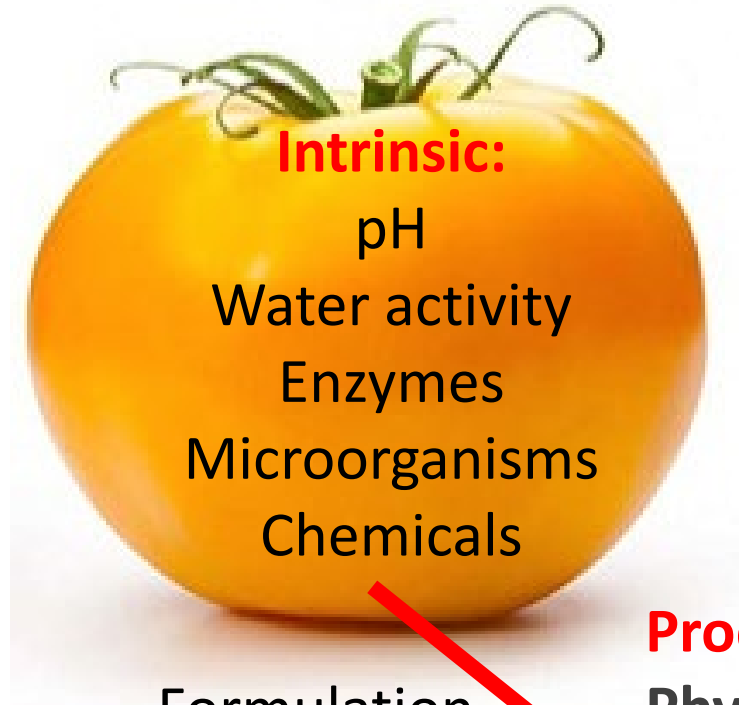
Poll #2

- What FSMA compliance category does the business you are affiliated with fall under?
 - Qualified Facility under the Preventive Controls Rule
 - Fully Subject Facility under the Preventive Controls Rule
 - Farm Mixed-Type Facility under the Produce Safety Rule
 - I'm not sure
 - Not applicable

Types of Hazards in Foods



Factors impacting food safety and shelf life (quality)



Intrinsic:

pH

Water activity

Enzymes

Microorganisms

Chemicals

Interplay of:

- 1) Intrinsic factors
- 2) Processing
- 3) Extrinsic factors
 - 1) Packaging
 - 2) Storage

Formulation

Processing:

Physical: *heat (most often), non-thermal*

Chemical: *acid, preservatives, fermentation*

Extrinsic:

Packaging: *atmosphere, relative humidity, physical protection*

Storage Conditions: *temperature, atmosphere, relative humidity*

Food safety regulatory oversight of different foods

USDA

Food Safety Inspection Service (FSIS)



Meats



Poultry

Amenable
Species

US Food and Drug Administration (FDA)



Oil/Oil seeds



Tree nuts, Fruits,
Vegetables



Seafood



Cereals and
Grains



Dairy

Additives
and
preservatives



Legumes



Juices

+ Everything
Else



California

Processed Food Regulatory Bodies and Program Oversight at a Glance

LOCAL: County Environmental Health Department

- Cottage Food Operations
- Restaurants
- Temporary Permits for Farmer's Markets
- Retail Food Establishments

STATE: CA Department of Public Health Food and Drug Branch

- Processed Food Registration
- Organic Processed Food Registration (if applicable)
- Cannery License
- Enforcement of federal regulations

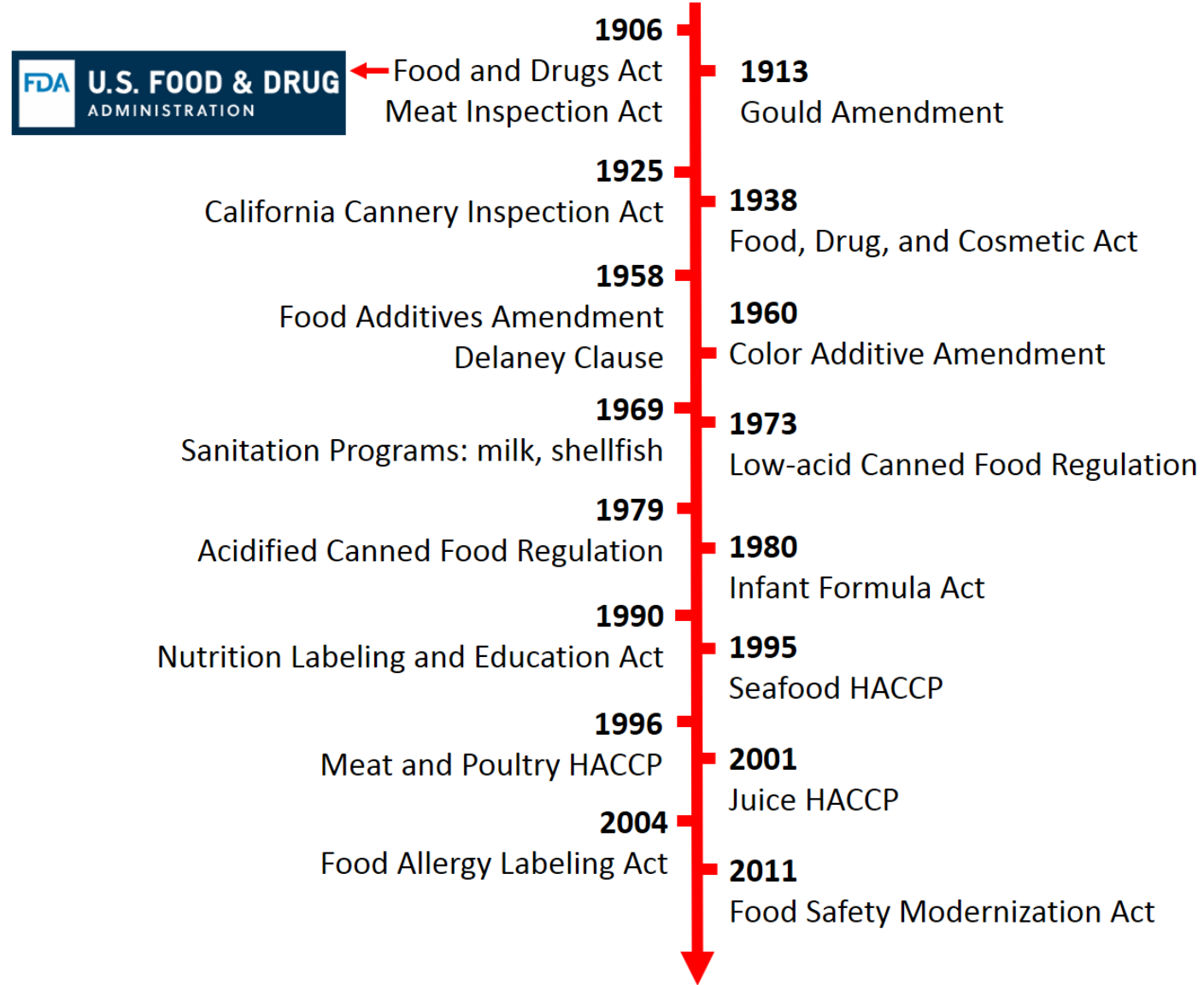
FEDERAL: Food and Drug Administration

- HACCP (juice and seafood)
- Food Safety Modernization Act (FSMA)
- Acidified Food Regulations
- Low Acid Canned Food Regulations
- Labeling Requirements

**USDA: National
Organic Program**

What is the 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



Food Safety Modernization Act

21 CFR Part 117

7 Foundational Rules:

Accredited Third-Party Certification

Foreign Supplier Verification Programs

Mitigation Strategies to Protect Food Against Intentional Adulteration

Sanitary Transportation of Human and Animal Food

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

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Preventive Controls Rule

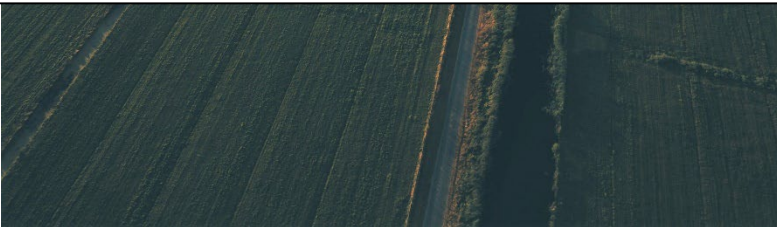
Produce Safety Rule

What types of business are covered by the rules?



Produce Safety Rule

- Farms that grow, harvest, pack, or hold fresh produce
 - Some types of low risk processing allowable
- Some growers may be eligible for an exemption or excluded



Preventive Controls Rule

- Facilities that manufacture, process, pack, or hold human food
 - Not farms or retail food establishments
- Some exemptions and modified requirements apply



Low-Risk Foods

- Honey
- Nut mixes
- Popcorn
- Fruit-based jams and jellies
- Dried or dehydrated whole vegetables and fruits

FOOD SAFETY RISK (examples)

Medium Risk

- Oils
- Canned tomatoes
- Canned fruits
- Traditionally fermented foods
- Some types of refrigerated foods

Highest-Risk Foods

- Canned salsa
- Hot sauces
- Vinegar pickled vegetables
- Canned vegetables
- Relishes
- Low-acid refrigerated foods

Fewest Regulations

- Cottage Food Law

NUMBER OF APPLICABLE REGULATIONS

- Processed Food Registration Permit *
- Organic Processed Food Registration Permit *
- FDA Labeling Regulations

Many Regulations

- Cannery License *
- Preventive Controls Rule
- Acidified Food Regulation
- Low Acid Canned Food Regulation

Lowest Cost

COST

Highest Cost

*CA specific requirements

An example of a low risk food: Apple Jelly

Recipe

- 4 cups apple juice
- 2 tablespoons lemon juice, if needed or desired
- 3 cups sugar

Recipe Source: National Center for Home Food Preservation

Added sugar
decreases a_w



pH: 3.5

a_w : 0.65

An example of a higher risk food: Pumpkin Butter

Recipe

- 7 quarts pumpkin puree
- 2 tsps. ground cloves
- ½ tsp. allspice
- 4 cups sugar

Recipe source: <http://www.yourown.org/pumpkinbutter.php>

Significantly less added sugar than jelly/preserves

NO ADDED ACID!

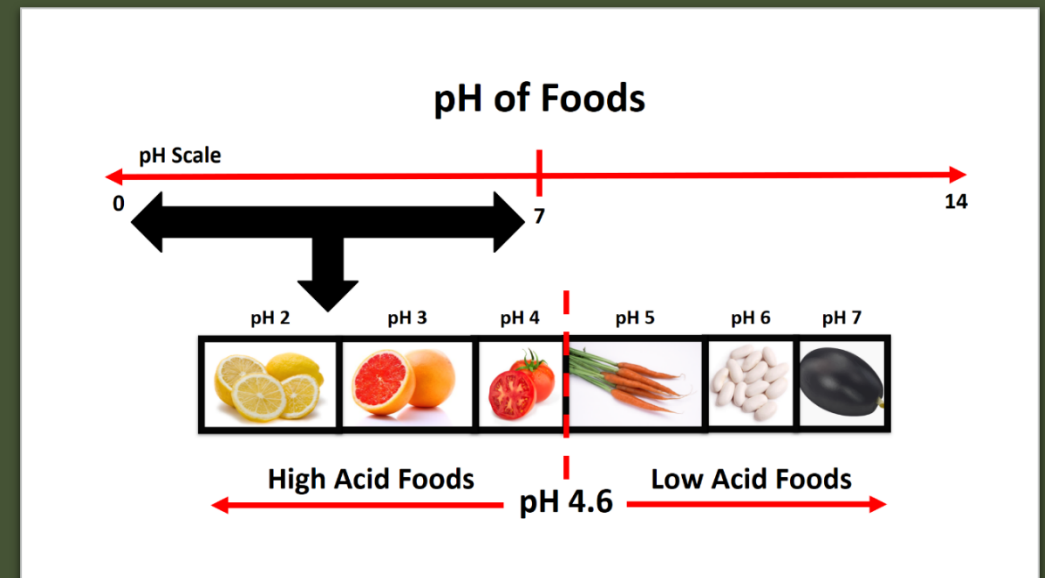
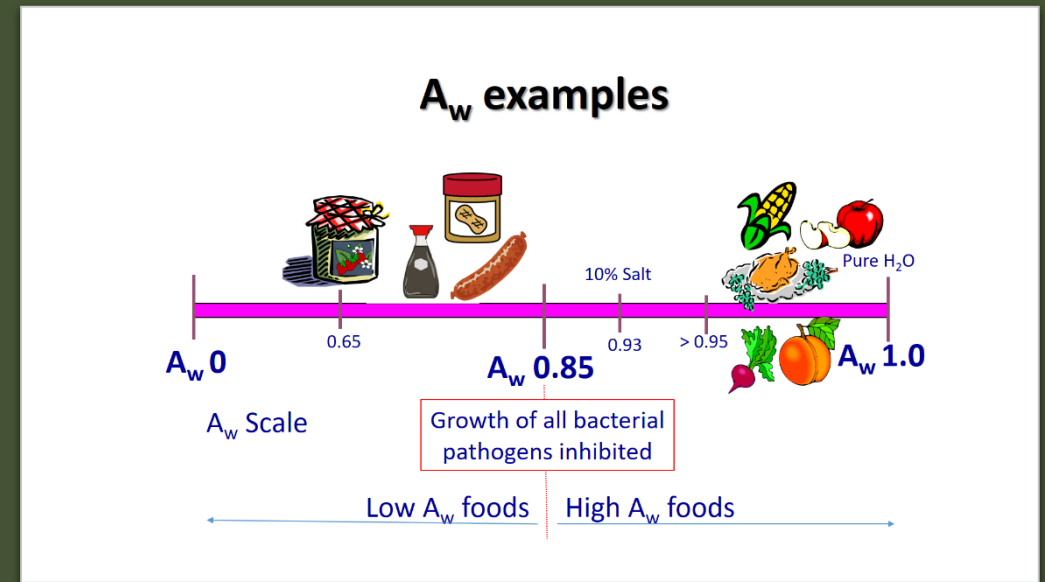
Pumpkin:
Low acid
Low sugar



pH: >4.6
 a_w : >0.85

Important to understand how food safety risks are minimized in a processed food

- Things you want to know about your product:
- pH (acidity level)
- Water activity (a_w)
- Formulation
 - Ingredients
 - Added preservatives
- Process
 - Time, temperature, viscosity, container size, etc.
- Many others





QUESTIONS?

The Produce Safety Rule

(Full exemption from the Preventive
Controls for Human Food Rule)

Types of processing allowed on primary or secondary production farm

1. Drying to create a distinct commodity without additional processing
2. Treatment to manipulate ripening
3. Packaging and labeling

On a farm, if only these activities take place, the Preventive Controls for Human Food Rule does not apply

FDA Guidance: Classification of Activities as Harvesting, Packing, Holding, or Processing for Farms and Facilities

<https://www.fda.gov/media/99911/download>

Community Alliance with Family Farmers: PC Rule Guide for Food Hubs and Values Based Buyers

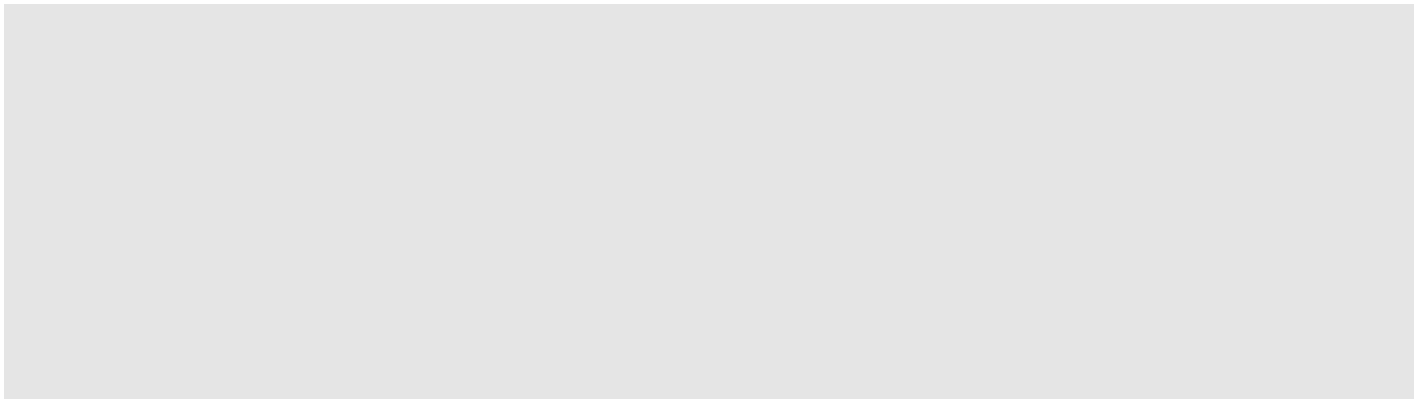
<https://www.caff.org/pc-rule-guide-for-food-hubs-and-values-based-buyers/>

What happens the processing activities covered by the Produce Safety Rule?

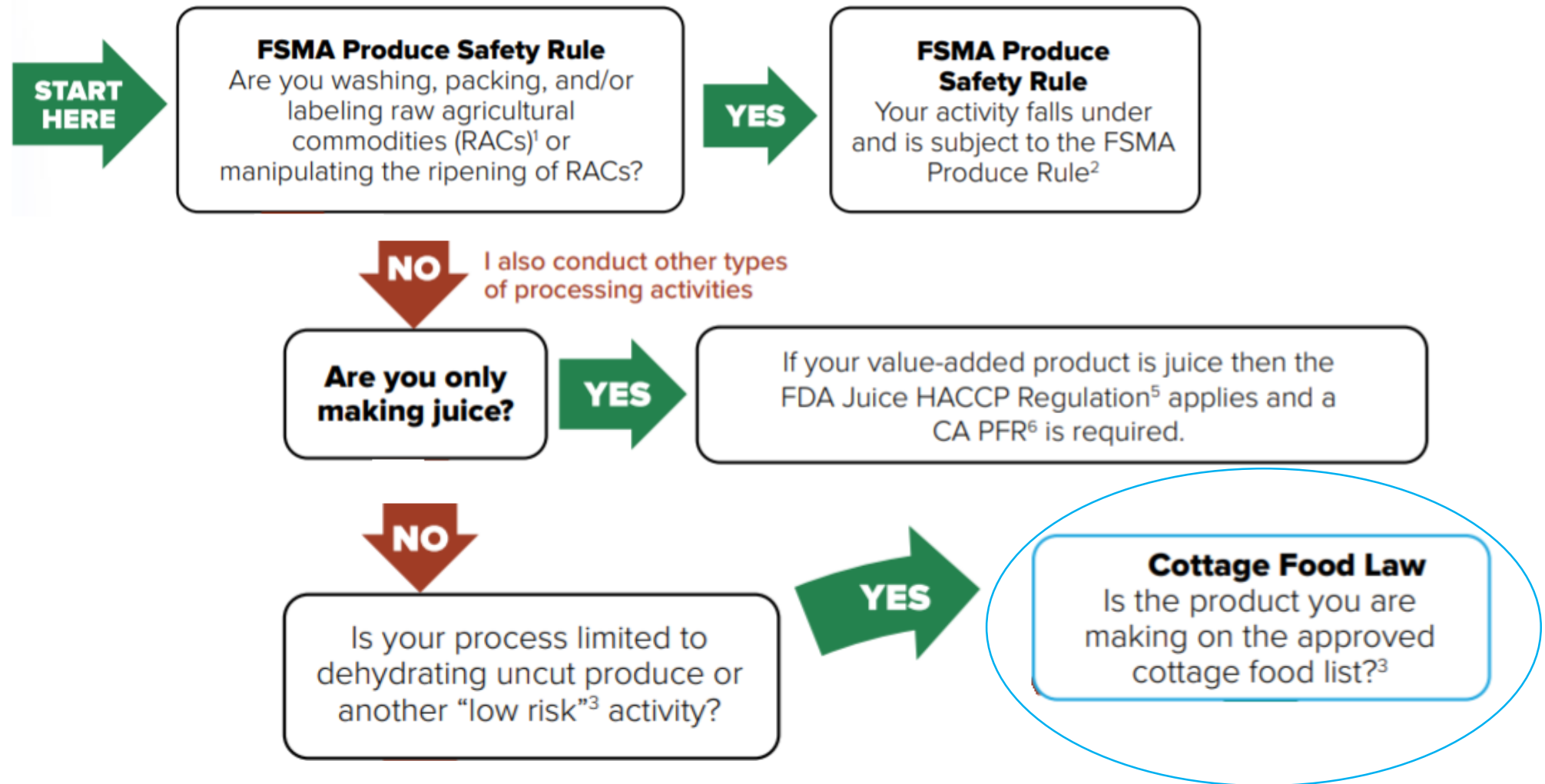
- Attend Produce Safety Alliance Grower's Training Course
- Farm Food Safety Plan (not required, but suggested to manage and document adherence to the Regulation)
- On farm inspection
 - In CA, CDFA will inspect farms on behalf of FDA



The Cottage Food Law



If the Produce Safety Rule does not apply how to determine if the full requirements of the Preventive Controls Rule do?



California Cottage Food Law

- Certain low risk foods can be produced in a home kitchen
- Gross less than \$50,000/year
- Types of permits
 - Class A
 - Sell directly to consumers
 - Class B
 - Sell through stores and restaurants
- Food Handler's Certificate Course
- County Environmental Health Dept.

Complete list on California Department of Public Health Food and Drug Branch website

<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/CottageFoodOperations.aspx>

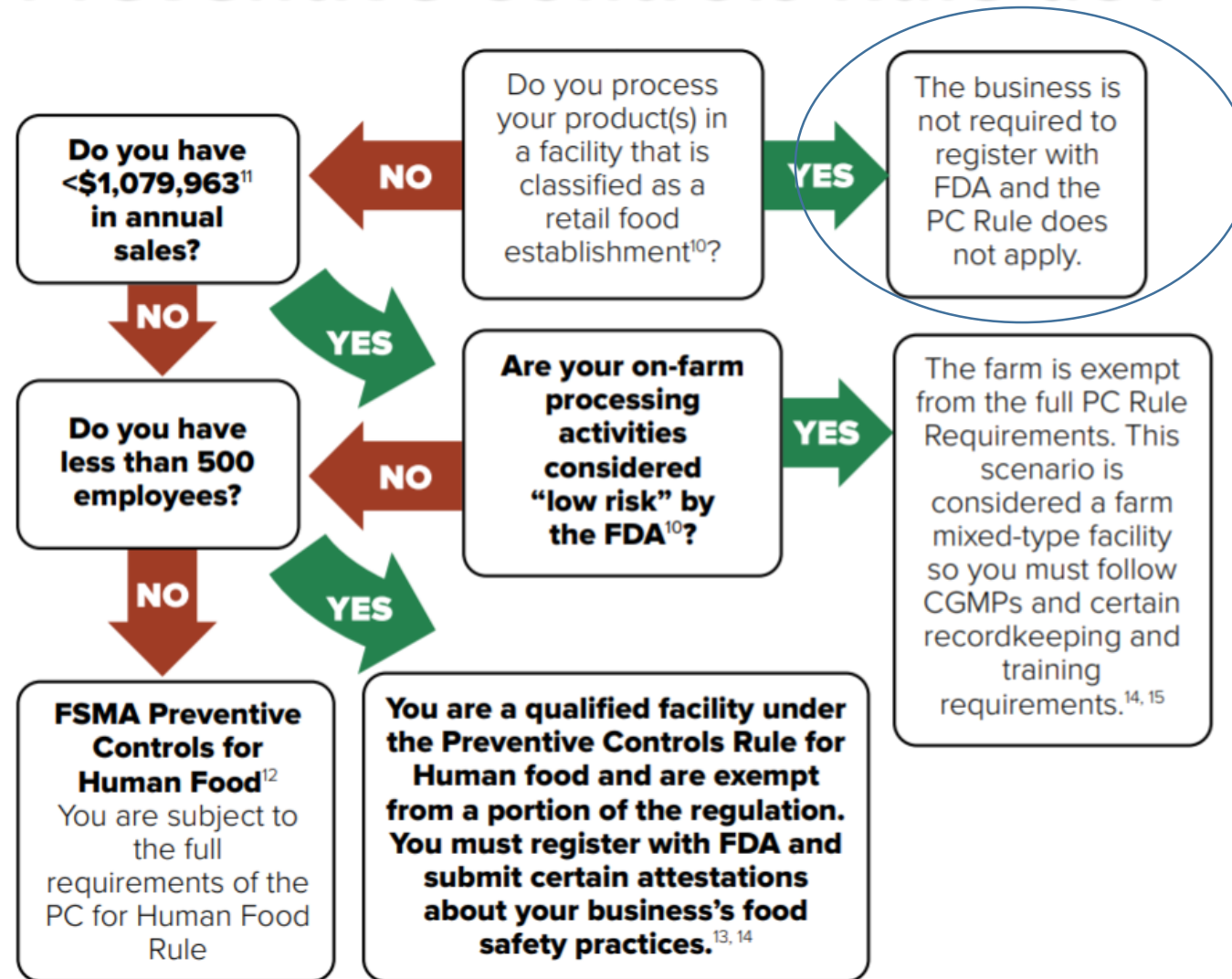
Some examples:

- Dried vegetables
- Dried fruit
- Jams, jellies, preserves (CFR 21 Part 150)
- Honey
- Fruit infused vinegars
- Low risk baked goods

Retail Food Establishments

(Full exemption from the Preventive
Controls for Human Food Rule)

If the Produce Safety Rule does not apply how to determine if the full requirements of the Preventive Controls Rule do?



Retail Food Establishment Exemption

Is your primary function to sell food directly to consumers? This means that 50.1% or more of the monetary value of sales of food products are made directly to individuals, not businesses. The retail food establishment exemption applies to roadside stands, farmers markets, and CSAs that hold and distribute food grown on and off the farm.

Yes, my operation satisfies the above condition.

You have a FSMA-defined "Retail Food Establishment." You have a Full Exemption from the PC Rule (so long as your activities stay within these limits).

Farm Mixed Type Facility

(Partial exemption from the Preventive
Controls for Human Food Rule)

Types of processing for a farm mixed-type facility exemption

A few from the list:

- Drying, freezing or cutting fruits and vegetables with pH <4.2
- Coating dried fruits and vegetable
- Jams, jellies, and preserves made from fruit with pH < 4.6
- Honey
- Some types of baked goods and candies
- Pasta

FDA Guidance: Classification of Activities as Harvesting, Packing, Holding, or Processing for Farms and Facilities

<https://www.fda.gov/media/99911/download>

Community Alliance with Family Farmers: PC Rule Guide for Food Hubs and Values Based Buyers

<https://www.caff.org/pc-rule-guide-for-food-hubs-and-values-based-buyers/>

FSMA Preventive Controls for Human Food Mixed Type Facility Exemption

What you have to do:

- Register with FDA
- Keep sales records
- Comply with Current Good Manufacturing Practices
- Comply with local and state food safety laws
- Do not have conduct a hazardous analysis or implement preventive controls

Partial exemption for on-farm low-risk processing activities: Is all the human food you manufacture, process, pack or hold: (a) done on-farm –AND– (b) using “low-risk processing activities” (See exhaustive list of activities that meet the definition of “low-risk” in the Appendix before answering.)

AND

Do you employ fewer than 500 full-time equivalent employees (i.e., you are a FSMA defined “small business”)? –OR– Do you gross less than \$1 M in average annual sales of all human food, based on an average of the three preceding years’ sales as adjusted for inflation* (i.e., you are a FSMA defined “very small business”)?

Yes, my operation satisfies the above conditions.

You are FSMA defined “Farm-Mixed Type Facility” with a **Partial Exemption**. Proceed.

Partial Exemption

- You must register with the FDA.
- You must keep sales records to support your exemption.
- You don’t have to comply with the HARPC provisions, including establishing a supply chain program. However, you must comply with updated CGMPs and personnel requirements and all existing local/state food safety laws.

Community Alliance with Family Farmers: PC Rule Guide

<https://www.caff.org/pc-rule-guide-for-food-hubs-and-values-based-buyers/>

Other exemptions to the Preventive Controls for Human Rule



(based on the type of food produced)

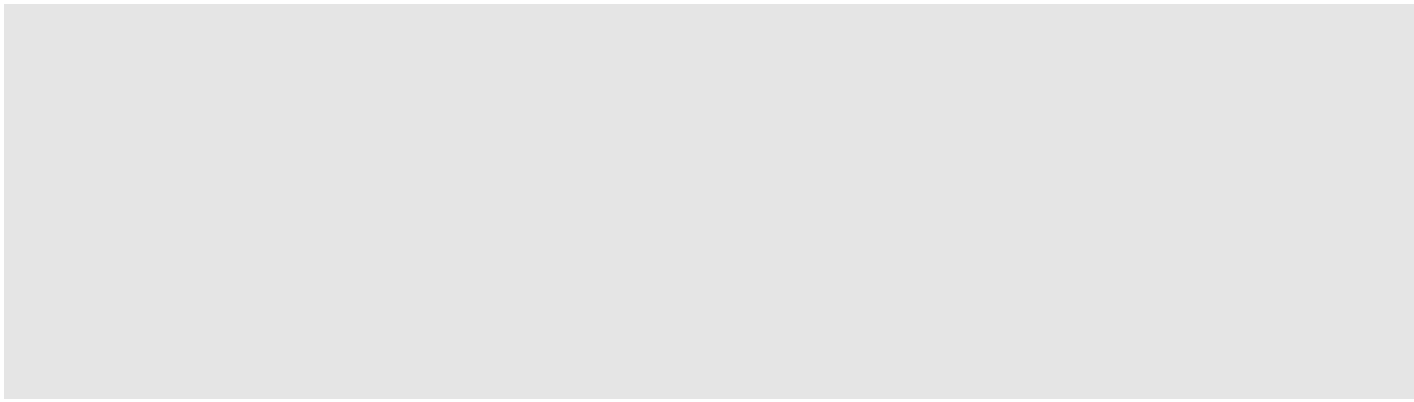




Exemptions to Preventive Controls for Human Food Rule

- 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
- Alcoholic beverages
- Facilities that only store unexposed packaged food
- Others previously discussed

State and local regulations



California state and local regulations still apply

- Cottage Food Law
 - Certain low risk foods
- Processed Food Registration
 - Required for food processing facilities
- Cannery License
 - Acidified low acid canned foods
 - Low acid canned foods

California Department of
Food and Drug Branch –
Food Safety Program

<https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram.aspx>

Google search: uc food
safety California regulations



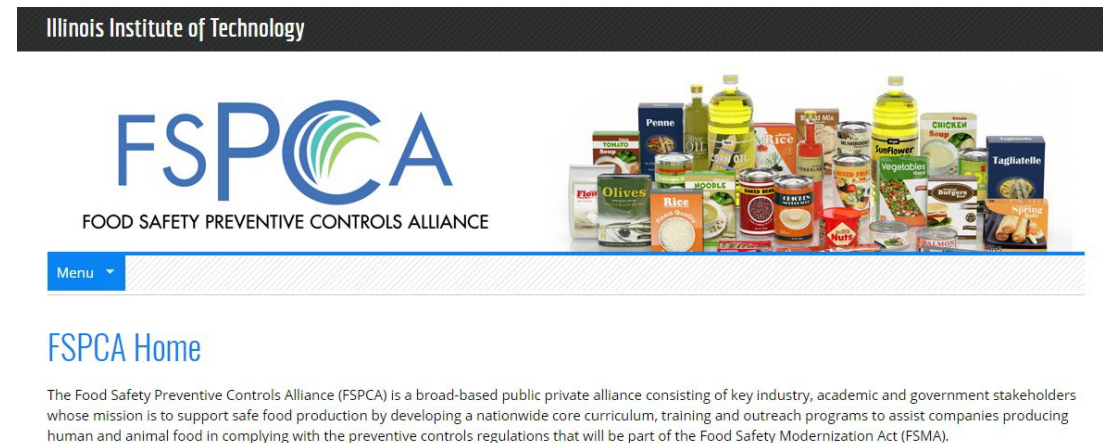
QUESTIONS?

Covered by the Preventive Controls for Human Food Rule?

- Determine if any exemptions exist or if the business is a “Qualified Facility”

If fully covered:

- 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
- Inspection



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

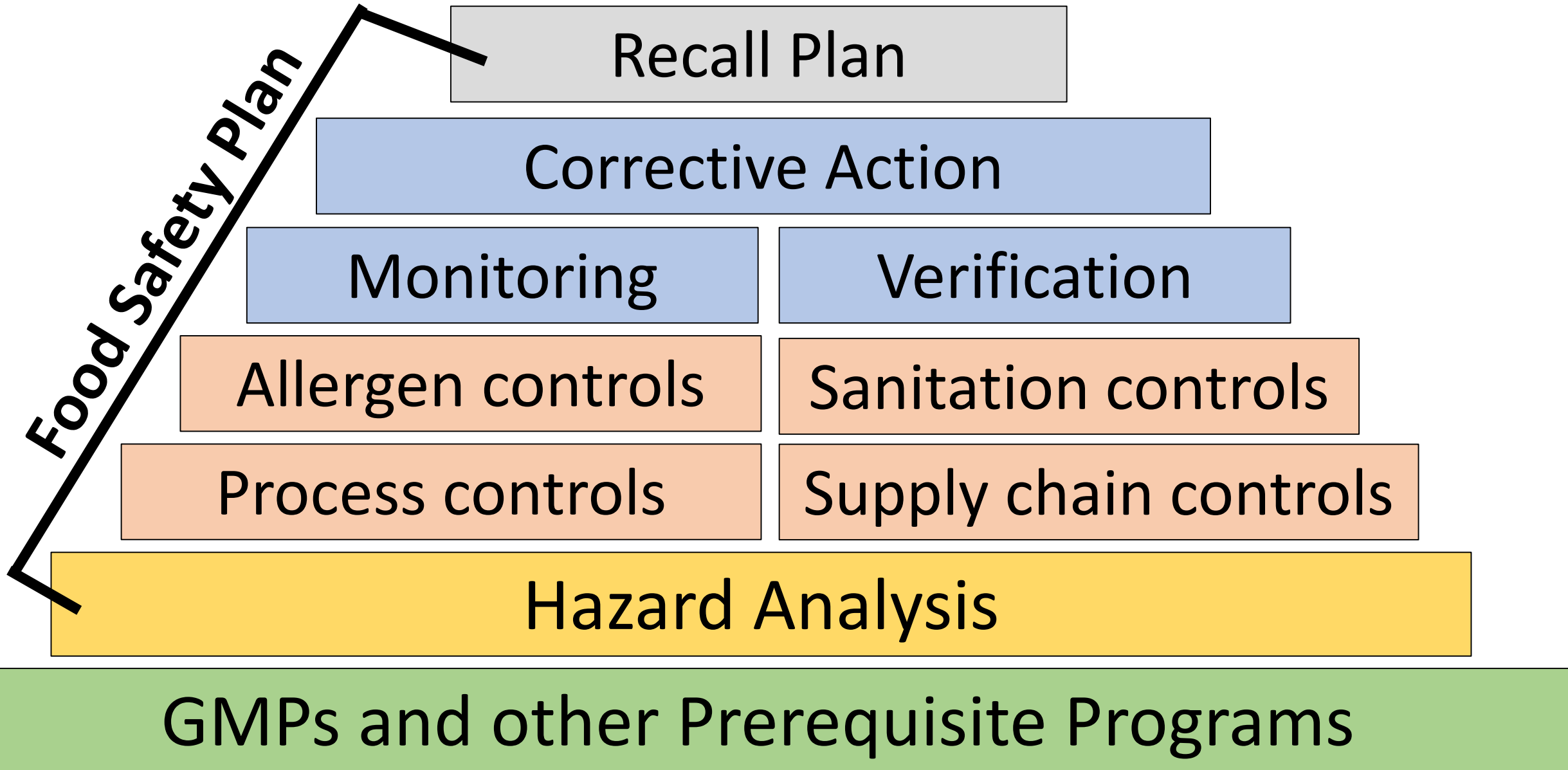
Exempt from hazard analysis and risk-based preventive controls when certain documentation is provided

Qualified Facility under the Preventive Controls for Human Food Rule?

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

- Comply with CGMPs
- Submit attestation to FDA that states they meet the criteria of a very small business

Preventive Food Safety Systems





QUESTIONS?

Case study: Strawberry jam producer

pH
3.00-3.40



pH
3.32-3.50

Case study: Strawberry jam producer



Cottage Food Law

- Under sales max

PC Rule

- >500 employees
- >1 million annual sales

Retail Food Establishment

- >50% direct to consumers

PC Rule Qualified Facility

- <500 employees
- <1 million annual sales

Farm Mixed-type facility

- On farm
- <500 employees
- <1 million annual sales

Useful resources

General

- UC Food safety website: <https://ucfoodsafety.ucdavis.edu/>
- FDA Guidance: Classification of Activities as Harvesting, Packing, Holding, Processing for Farms and Facilities: <https://www.fda.gov/media/99911/download>
- Community Alliance with Family Farmers: PC Rule Guide for Food Hubs and Values Based Buyers: <https://www.caff.org/pc-rule-guide-for-food-hubs-and-values-based-buyers/>
- Produce Safety Alliance website
- Food Safety Preventive Controls Alliance website: <https://www.ifsh.iit.edu/fspca>
- FDA Guidance: Qualified Facility Attestation <https://www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation>

California

- California Department of Public Health Food and Drug Branch Cottage Foods: <https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/CottageFoodOperations.aspx>
- California Department of Public Health Food and Drug Branch Food Safety Program: <https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram.aspx>
- UC Davis, CAFF flow chart for value-added food processing in California <https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/inline-files/287951.pdf>
- UC Davis, CAFF timeline for California Processed Food Registration <https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/inline-files/287953.pdf>
- UC Davis, CAFF timeline for California Cannery License <https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/inline-files/287956.pdf>

Poll #3

- What FSMA compliance category does the business you are affiliated with fall under?
 - Qualified Facility under the Preventive Controls Rule
 - Fully Subject Facility under the Preventive Controls Rule
 - Farm Mixed-Type Facility under the Produce Safety Rule
 - I'm not sure
 - Not applicable



QUESTIONS?

Poll #4

- What type of training opportunities would be of interest?
 - Produce Safety Rule Grower Training
 - Preventive Controls Qualified Individual Training
 - Meat HACCP training
 - Juice HACCP training
 - Food handler certificate training/Cottage Foods
 - Basic Good Manufacturing Practices
 - I'm not sure
 - Not applicable


Upcoming Events

Check the “FSMA 101 for Organic Processors” page for upcoming webinars:

<https://www.ccof.org/blog/fsma-101-organic-processors-webinar-series>

- **Webinar #2 – FSMA Preventive Controls Rule, Qualified Exemption**
 - Washington Webinar – October 12, 2021 – 10:00–11:30 a.m. Pacific Time
 - California Webinar – October 13, 2021 – 10:00–11:30 a.m. Pacific Time
- **Webinar #3 – FSMA Preventive Controls Rule, Fully Covered Category**
 - Washington Webinar – November 9, 2021 – 10:00–11:30 a.m. Pacific Time
 - California Webinar – November 10, 2021 – 10:00–11:30 a.m. Pacific Time
- **Webinar #4 – Current Good Manufacturing Practices (cGMPs)**
 - Washington Webinar – December 14, 2021 – 1:00–2:30 p.m. Pacific Time
 - California Webinar – December 15, 2021 – 10:00–11:30 a.m. Pacific Time

Opportunity for feedback on online training development

- Study to understand the barriers to food safety training
 - Goals:
 - Identify barriers to food safety training among small-scale food processors
 - Develop strategy to create more audience-targeted food safety training programs
 - Participants in interviews will receive \$75
 - Register for interview online:
 - https://purdue.ca1.qualtrics.com/jfe/form/SV_9nL7BTdp7U1h7pA
- 
- For More Information Contact: Zachary Berglund @ zberglun@purdue.edu
 - Purdue University IRB #: 2021-73; Primary Investigator: Dr. Betty Feng

CCOF YouTube Channel

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<https://www.youtube.com/channel/UCqFpRRg1JquOOzeFhKs0Gow>

Highlights

- FSMA Preventive Controls Rule Supplier Verification for Food Hubs & Farms
- FSMA Food Safety Updates for Produce Growers
- Organic Labeling and Marketing Strategies for Meat Producers
- Farm & Food Business Marketing Collaborations
- Sustainable Produce Packaging for Farms that Sell Directly to Consumers



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Meaghan Donovan

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