My food hub is eligible for a Qualified Exemption: *What do I need to do to be in compliance with FSMA Preventive Controls for Human Food Rule?*

USDA NIFA Food Safety Outreach Program : Dec 2018

UCDAVIS FOOD SCIENCE AND TECHNOLOGY

University of California Sustainable Agriculture Research and Education Program

University of California Agriculture and Natural Resources

UCDAVIS AGRICULTURAL SUSTAINABILITY INSTITUTE

USDA NIFA Food Safety Outreach Program team

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

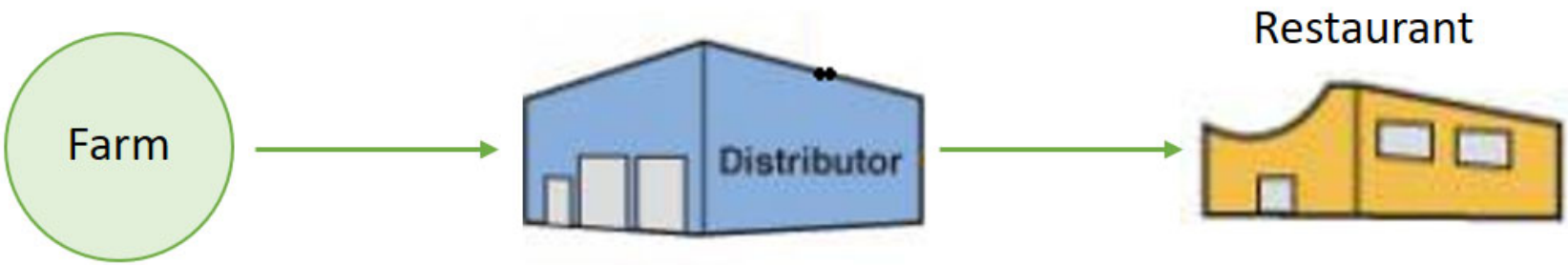
Dr. Erin DiCaprio, Assistant Cooperative Extension Specialist in Community Food Safety in the Department of Food Science and Technology at UC Davis

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

Regulation cannot be one size fits all

- No food facility is exempt from the responsibility to produce safe food
- However, different scales and types of supply chains pose varying levels of risk to public health
- One of the parts of this risk-based, scale-sensitive approach was a provision that set forth modified requirements for very small businesses



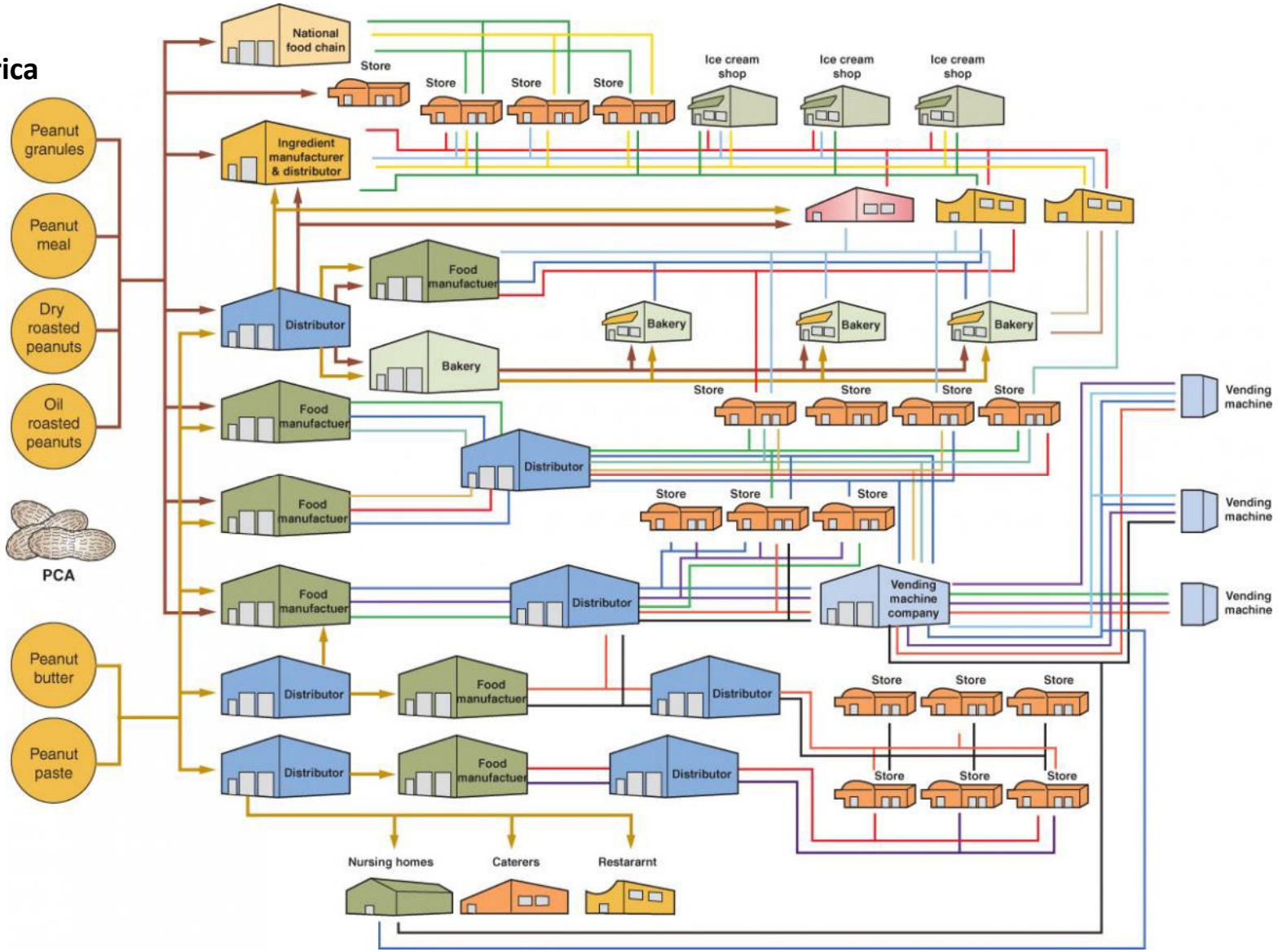
2008-2009 Outbreak
Peanut Corporation of America

***Salmonella* Typhimurium**

- 714 individuals sickened
- 9 deaths
- From 46 states

Complex supply chain

- Multiple products
- Poor traceability
- Thousands of consumers



PCHF requirements for a qualified facility

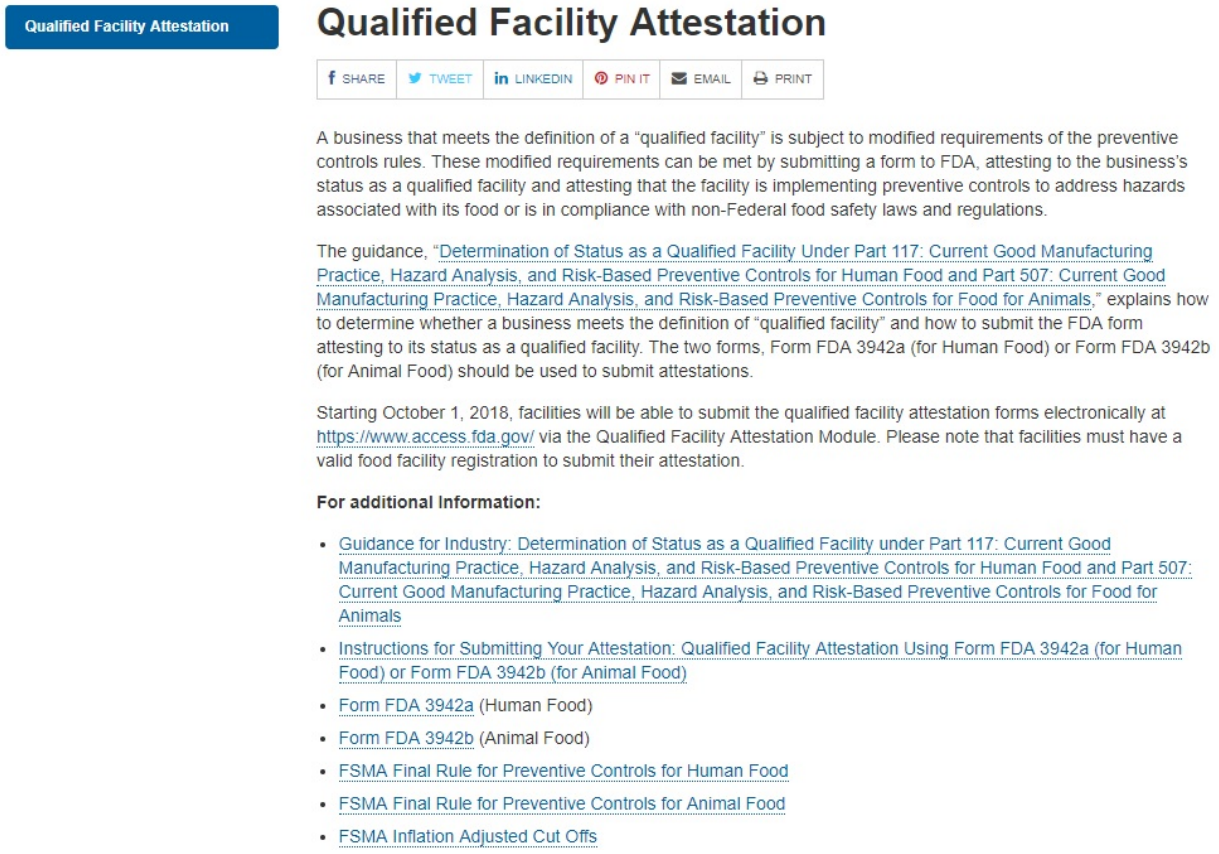
- Subject to modified requirements in 21 CFR Part 117.201 of the Preventive Controls for Human Food Rule
- These modified requirements require the business to submit a form to FDA, attesting to its status as a qualified facility

Eligibility to be a qualified facility

1. "Very Small Business"
   - Less than $1 million in annual sales of human food, OR
2. Less than $500,000 in annual gross sales (adjusted for inflation) over a previous three-year period AND sells the majority of the food directly to a "qualified end-user"
   - "Qualified end-user": i.e., a consumer, or a restaurant or retail food establishment (e.g., a grocery store) that is located in the same state as the facility or not more than 275 miles from the facility)

FDA qualified facility attestation website

https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/qualifiedfacilityattestation/default.htm



Qualified Facility Attestation

Qualified Facility Attestation

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

A business that meets the definition of a "qualified facility" is subject to modified requirements of the preventive controls rules. These modified requirements can be met by submitting a form to FDA, attesting to the business's status as a qualified facility and attesting that the facility is implementing preventive controls to address hazards associated with its food or is in compliance with non-Federal food safety laws and regulations.

The guidance, "Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals," explains how to determine whether a business meets the definition of "qualified facility" and how to submit the FDA form attesting to its status as a qualified facility. The two forms, Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food) should be used to submit attestations.

Starting October 1, 2018, facilities will be able to submit the qualified facility attestation forms electronically at https://www.access.fda.gov/ via the Qualified Facility Attestation Module. Please note that facilities must have a valid food facility registration to submit their attestation.

For additional Information:

- Guidance for Industry: Determination of Status as a Qualified Facility under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals
- Instructions for Submitting Your Attestation: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)
- Form FDA 3942a (Human Food)
- Form FDA 3942b (Animal Food)
- FSMA Final Rule for Preventive Controls for Human Food
- FSMA Final Rule for Preventive Controls for Animal Food
- FSMA Inflation Adjusted Cut Offs

Will the FDA determine if my facility is a qualified facility?

NO

- You are responsible for determining whether your business meets the definition of a qualified facility
- Subject to verification by FDA

Calculation to determine qualified facility status

- How often do I need to do this calculation?
  - Each year
  - No later than July 1 of each calendar year (21 CFR 117.201(c)(1))

Calculation to determine qualified facility status

- Include ALL human food
- Regardless of whether the human food is subject to the PCHF Rule
  - Foods subject to HACCP regulations
    - juice, seafood
  - Food subject to other regulations
    - low acid canned foods, dietary supplements
  - Raw Agricultural Commodities (RACs)
    - produce, grains, milk, eggs
  - USDA regulated products
    - meat, poultry

How do I calculate my average annual sales?

- Determine which three years to include in the average
- Determine annual sales and market value of food manufactured, processed, packed, or held without sale for each of the three years
- Adjust annual sales and market value for each year for inflation
- Calculate the inflation-adjusted average annual sales and market value

What years do I use in my calculation?

- Average is based on the 3-year period preceding the applicable calendar year
- The applicable calendar year is the current year
- If the current year is 2019, the three preceding calendar years would be 2016, 2017 and 2018

What if I do not have 3 years of financial records for my calculation?

- The compliance date for you to keep records to support your status as a qualified facility is January 1, 2016
  - The compliance date for you to begin complying with the modified requirements for a qualified facility is September 17, 2018.
  - FDA intends to accept records for the preceding 2 calendar years as adequate to support status as a qualified facility.
- If you begin operations between January 1, 2017, and September 17, 2018, your applicable financial records would not cover even 2 calendar years by September 17, 2018
  - FDA intends to accept records for the preceding one or two years as adequate to support your status as a qualified facility until you have been in operation long enough to provide three years of records.
- If you begin operations after January 1, 2018, you can rely on a projected estimate of revenue (or market value) at the time you begin operations.
  - FDA intends to evaluate the credibility of the projected revenue (or market value) based on such factors as your number of employees

How do I determine annual sales of human food?

- Determine your annual sales using resources such as:
  - Tax Forms, e.g. Gross Receipts or Sales (Line 1A) from Internal Revenue Service (IRS) Form 1120;
  - Accounting documents, e.g. Total Sales or Revenues from an Income Statement; or
  - Invoices and bills of lading.
- Do not adjust the total sales for the year to include the cost of the sales – for example, you should not adjust total sales for the cost of labor

Do I subtract the sales from “qualified end users”?

- No
- The definition of very small business is based on average annual sales plus market value and is not adjusted for sales to a qualified end-user

How do I adjust annual sales plus market value of human food products for inflation?

- Use the U.S. Bureau of Economic Analysis' Implicit Price Deflators for Gross Domestic Product (GDP)
  - https://www.bea.gov/data/prices-inflation/gdp-price-deflator
  - Adjust using the 2011 Implicit Price Deflator as the baseline

$$\frac{\text{Annual sales + market value of food held} \times \text{2011 implicit price deflator index number}}{\text{Current year implicit price deflator number}} = \text{Inflation-adjusted sales plus market value}$$

How do I calculate the three-year average of the inflation-adjusted annual sales plus market value of human food?

$$\frac{\text{Annual Sales + Market Value Adjusted for Inflation (Previous Year 3)} + \text{Annual Sales + Market Value Adjusted for Inflation (Previous Year 2)} + \text{Annual Sales + Market Value Adjusted for Inflation (Previous Year 1)}}{3}$$

Records needed to show your food hub is an eligible qualified facility

- Records to support the attestations you make on Form FDA 3942a
- Records that you use for your calculations of annual sales
- Records of the actual calculations that you make
  - e.g., calculations of inflation-adjusted annual sales plus market value and the three-year average of inflation-adjusted annual sales plus market value

FDA form 3942a

Section 1 – FACILITY INFORMATION

Facility Registration Number

Facility Name

Facility Address

Address 1 *(Street address, P.O. box, etc.)*

Address 2 *(If applicable; apartment, suite, unit, building, floor, etc.)*

City | State/Province/Territory

Country | ZIP or Postal Code

Telephone Number *(Include area code)* | FAX Number *(Include area code)*

E-mail Address

Section 2 – TYPE OF NOTIFICATION

a. ☐ Initial Submission (21 CFR 117.201(c)(2)(i)) – Complete Sections 3, 4 and 5 only.

b. ☐ Biennial (Renewal) Submission (21 CFR 117.201(c)(2)(ii)) – Complete Sections 3, 4 and 5 only.

c. ☐ Status Change (21 CFR 117.201(c)(3)) – Complete Section 6 only.

FDA form 3942a

Section 3 – QUALIFICATION FOR MODIFIED REQUIREMENTS *(Fill out only if Section 6 does not apply.)*

Human food facilities may be exempt from the preventive controls regulations in 21 CFR part 117, primarily in subparts C and G, with associated requirements in subparts A, D, E, and F, under 21 CFR 117.5(a). Check the appropriate box to indicate the reason why your facility is a qualified facility.

When including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate:

- ☐ The above-named facility qualifies for the exemption as a "very small business" as defined in 21 CFR 117.3 because, during the preceding three calendar years, the facility (including any subsidiaries and affiliates) averaged less than $1,000,000, adjusted for inflation, per year, in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).
- ☐ The above-named facility qualifies for the exemption as a "qualified facility" as defined in 21 CFR 117.3 because:

  (1) during the preceding three calendar years, the average annual monetary value of the food manufactured, processed, packed, or held at the facility that was sold directly to qualified end-users (as defined in 21 CFR 117.3) exceeded the average annual monetary value of the food sold by the facility to all other purchasers; **and**

  (2) the average annual monetary value of all food sold during the preceding three calendar years was less than $500,000, adjusted for inflation.

FDA form 3942a

Section 4 – COMPLIANCE WITH 21 CFR 117.201 *(Fill out only if Section 6 does not apply.)*

Check the box to indicate how your facility is in compliance with 21 CFR 117.201(a)(2).

☐ I, as the owner, operator, or agent in charge of the above-named facility, (1) have identified the potential hazards associated with the food being produced, (2) am implementing preventive controls to address the hazards, **and** (3) am monitoring the performance of the preventive controls to ensure that such controls are effective. (21 CFR 117.201(a)(2)(i).) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(f).)

☐ The above-named facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law including relevant laws and regulations of foreign countries. This is based on my knowledge, as the owner, operator, or agent in charge of the above-named facility, of the facility's licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight. (21 CFR 117.201(a)(2)(ii).) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(f).)

FDA form 3942a

Section 5 – ATTESTATION STATEMENT*(Fill out only if Section 6 does not apply.)*

I attest that, to the best of my knowledge and belief, the information provided in this Qualified Facility Attestation is true, accurate and complete and that the above-named facility qualifies for the exemption requested. I understand that, as the owner, operator, or agent in charge of the above-named facility, I must maintain those records relied upon to support these attestations (21 CFR 117.201(f)) and make those records promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request (21 CFR 117.320). I also understand that under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Signature	Date

Printed Name and Title:

Please check one option below that best describes your relationship to the facility.

☐ Owner ☐ Operator ☐ Agent in Charge

When do I need to file with FDA?

- December 17, 2018
  - If your facility begins manufacturing, processing, packing, or holding food **before** September 17, 2018
- Before beginning operations
  - If your facility begins manufacturing, processing, packing, or holding food **after** September 17, 2018

Form FDA 3942a resubmissions

- Must re-submit Form FDA 3942a to FDA every 2 years
  - Beginning 2020
- During the food facility biennial registration renewal period beginning on October 1 and ending on December 31

When must I submit Form FDA 3942a to FDA if my facility's status changes from "qualified facility" to "not a qualified facility"?

- Submit Form FDA 3942a notifying FDA of that change in status by July 31 of the applicable calendar year

Do farms need to submit Form FDA 3942a?

NO

Do farm mixed-type facilities need to submit Form FDA 3942a?

- A farm mixed-type facility that meets the definition of “qualified facility” and wants to be considered as a “qualified facility” must submit Form FDA 3942a to FDA

Do food hubs need to submit Form FDA 3942a?

Submission of Form FDA 3942a is only required for businesses that are required to register with FDA as a food facility. Whether a food hub must submit Form FDA 3942a depends on whether the food hub is a food facility that is required to register with FDA or does not have to register, for example, because it meets the definition of “farm” in 21 CFR 1.227. Under the “farm” definition in 21 CFR 1.227, a business operation (such as a food hub) can be a “secondary activities farm” if it is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.

Qualified facilities are subject to 5 parts of the Preventive Controls for Human Food Rule

1. General provisions
2. Current Good Manufacturing Practices
3. Modified requirements that apply to a qualified facilities
4. Certain recordkeeping requirements
5. Withdrawal of modified requirements that apply to qualified facilities

1. General provisions

- Food facilities are prohibited through pre-existing law from selling adulterated food

Adulterated Food

- Food contains added poisonous or deleterious substance which may render the food injurious
- Food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious
- Food that omits a valuable constituent and substitutes for another ingredient (economic adulteration)
- Food that is contaminated with pathogens (microbial adulteration)

2. Current Good Manufacturing Practices

- Facilities will be required to follow updated cGMPs (subpart B)

https://instituteforfoodsafety.cornell.edu/trainings/good-manufacturing-practices-registration/

Components of Good Manufacturing Practices (GMPs)

- Programs required for processing safe food under sanitary conditions:
  - 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
  - Defect action levels

3. Documentation required for qualified facilities

- Under the modified requirements, qualified facilities must submit two types of documentation to FDA (in form 3942a):

1. A statement from the qualified facility certifying that it is a qualified facility
2. Either:
    1. Documentation showing that the facility has identified hazards, is implementing preventive controls, and is monitoring to ensure the effectiveness of the preventive controls; OR
    2. Documentation that the facility is complying with applicable non-Federal food safety law (e.g., state, local, or county)

4. Record keeping requirements

- A qualified facility must maintain records that support the documentation required
  - Examples: financial records, CDPH-FDB Processed Food Registration application/records, GAP audit records, hazard analysis, SOPs and associated monitoring documentation, etc.
- These records must:
  - Be accurate and legible
  - Be retained at the facility for at least two years after the date they were prepared
  - Records >6 months old can be stored offsite (must be retrievable in 24 hours)

5. FDA can revoke qualified facility status

- FDA can withdraw a qualified exemption under certain broad circumstances:

1. Foodborne illness outbreak linked to a qualified facility
2. Necessary to protect the public health and prevent or mitigate a foodborne illness outbreak
   - FDA discretion following an inspection
   - Based on conduct or conditions associated with the facility

QUESTIONS?