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Introduction to Preventative Controls for Human Food for Very Small Value-Added Food Processors

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WASHINGTON STATE UNIVERSITY EXTENSION

University of Idaho Extension

Overview

- FSMA and PCHF
- Exemptions and Requirements
- Fundamentals of PCHF
  - Overview of a Food Safety Plan
  - Hazard Analysis
  - Preventive Controls
  - Supply Chain Program
  - Recall Plan
  - Updated GMPs
  - Employee training

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**

Enforcement and Compliance

- Mandated inspection frequency - The FSMA establishes a mandated inspection of food facilities.
  - All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter.
- Records access - FDA will have access to records, including industry food safety plans and implementation of their plans.
- Testing by accredited laboratories - The FSMA requires certain food testing to be carried out by accredited laboratories.
- Mandatory recall - Provides FDA with authority to issue a mandatory recall.

Enforcement and Compliance

- Expanded administrative detention - FDA can detain products that are potentially in violation of the law.
- Suspension of registration - FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death.
- Enhanced product tracing abilities - Enhance ability to track and trace both domestic and imported foods.
- Additional Recordkeeping for High Risk Foods - Establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that are designated as high-risk foods.

Enforcement and Compliance

- Importer accountability - Importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe.
- Third Party Certification - Qualified third parties can certify that foreign food facilities comply with U.S. food safety standards, to facilitate the entry of imports.
- Certification for high risk foods - FDA has the authority to require that high-risk imported foods be accompanied by a credible third party certification or other assurance of compliance as a condition of entry into the U.S.
- Voluntary qualified importer program - FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers.
- Authority to deny entry - FDA can refuse entry into the U.S. of food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.

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 $1 million
  - Average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users exceeds the average annual monetary value of the food sold by such facility

  AND
  - The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.
  - Avg. per year during the 3-year period preceding the current calendar year.

  Qualified End User:

  At least half the sales to consumers, local retailers, restaurants or Indian reservation
    - Must be within the same state or within 275 miles
    - 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)

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

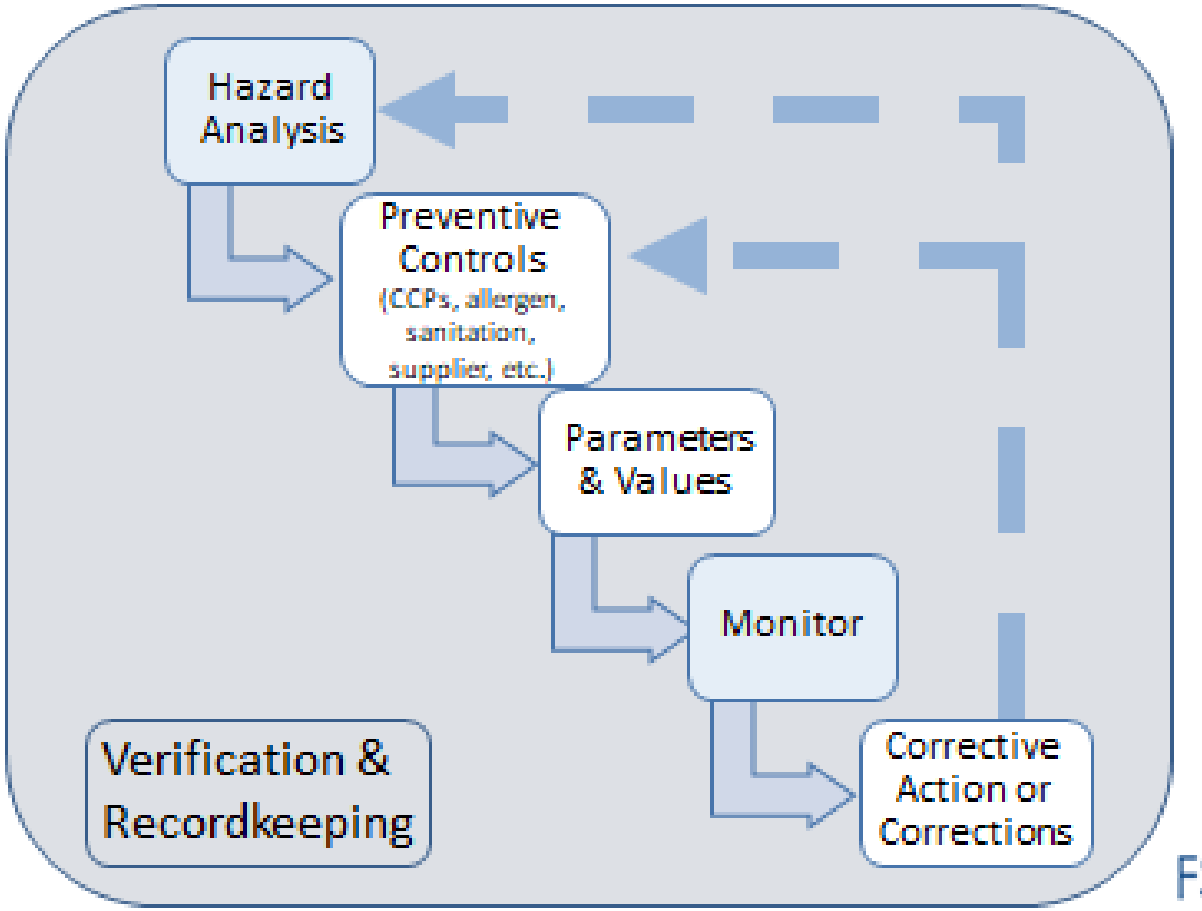
An otherwise Qualified Facility that does NOT notify FDA is subject to the requirements for Hazard Analysis and Preventive Controls.

Qualified Exemption Requirements

2. ***Must*** follow conditions and practices for processing safe food under sanitary conditions (cGMPs):
   - 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

Overview of Requirements for PCHF

Preventive Controls Include More Than HACCP



FSPCA

If you identify a hazard then you must have preventive controls in place and a food safety plan!

Scope of the Food Safety Plan

- Specific to a facility
  - Preventive controls specific to a product and process
- Products may be grouped if hazards and controls are managed generally the same
- Define and address:
  - Specific product(s) and process(es)
  - Part of the food chain to be studied
  - Biological, chemical (including radiological) and physical hazards

Contents of a 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*

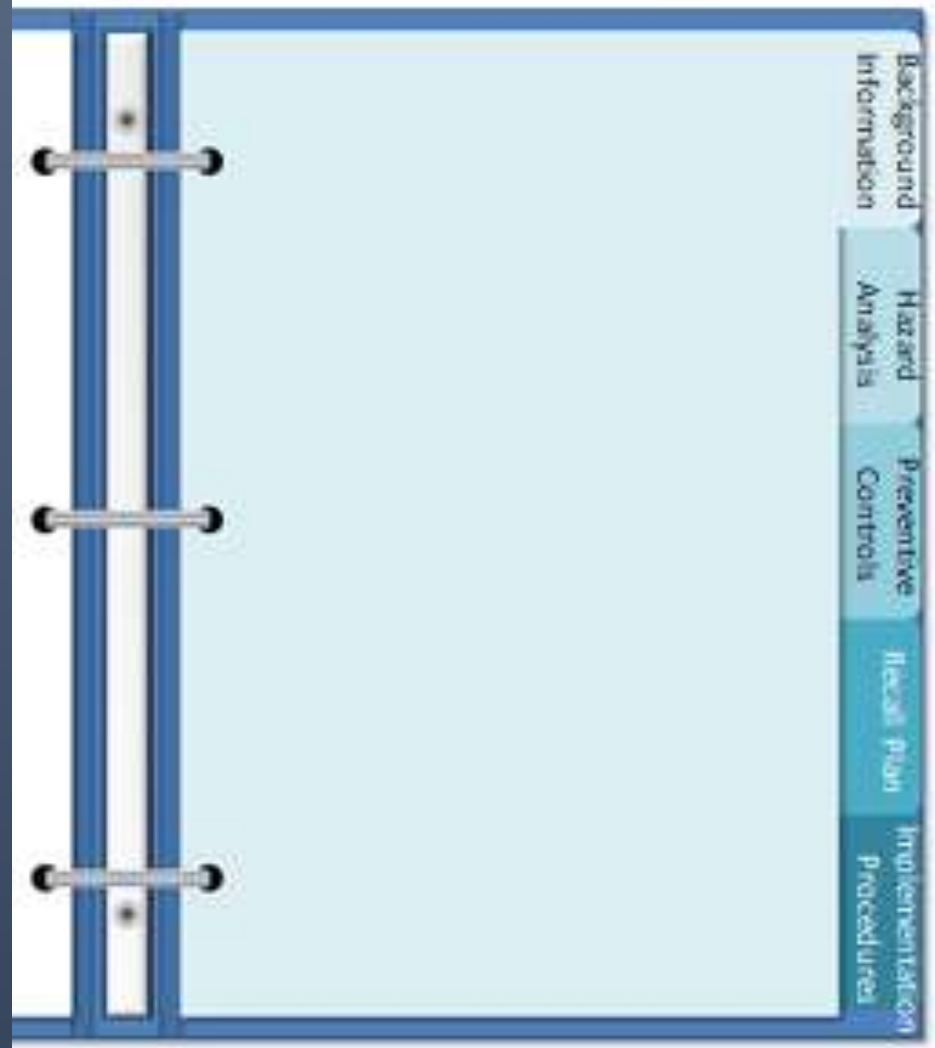
Useful

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

* Required when a hazard requiring a preventive control is identified

FSPCA

Main Organizational Sections



1. Background information - optional
2. Hazard analysis
3. Preventive controls
4. Recall plan
5. Implementation procedures

FSPCA

Hazard Analysis

1. Must identify any known or reasonably foreseeable hazard
   - Example – If you know your product is a risk for *Listeria*, you must control for *Listeria*.
2. Determine if those hazards require a preventive control

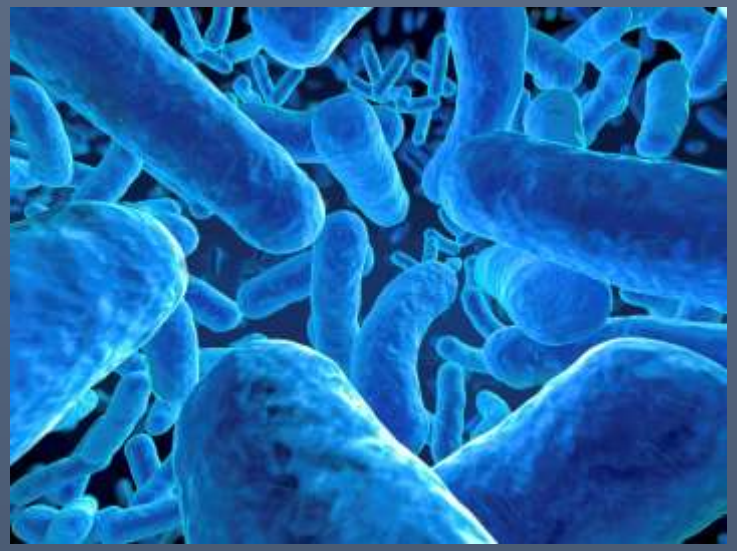
A hazard analysis is the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore must be addressed in a food safety plan.

What is a hazard?

- *Hazard* – Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

- *Known or reasonably foreseeable hazard* – A biological, chemical, or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Types of Hazards - Examples



1. Biological
   - Bacteria
   - Viruses
   - Parasites
   - Fungi
2. Chemical
   - Allergens
   - Chemicals (e.g. lead, arsenic, pesticides, residues)
   - Radiological
3. Physical
   - Glass
   - Rubber
   - Metal
   - Plastic
   - Stones

Hazard Evaluation Considerations

- Formulation of the food
- Condition, function and design of facility and equipment
- Raw materials and ingredients
- Transportation practices
- Processing procedures, including rework
- Packaging and labeling activities
- Storage and distribution
- Intended or reasonably foreseeable use
- Sanitation including employee hygiene
- Others relevant factors

Evaluating Likelihood of Occurrence

- Requires consideration of factors including:
  - Data from past foodborne illness outbreaks
  - Recall data from similar products
  - Information in the scientific literature
  - Historical information in the establishment
  - Regulatory guidance
  - Trade association information
  - University extension documents

Preventive Controls

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

Preventive controls may include:

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

Process Controls - Examples

Biological

- Process controls that kill pathogens
  - Cooking (correct temp to kill microorganisms)
- Process controls that prevent growth
  - Refrigeration/freezing (to slow growth of organisms)
  - pH (inhibit microbial growth)
  - Water activity (a_w) <4.6
- Supply chain programs
- Sanitation controls

Chemical

- Supply chain programs
- Sanitation controls
- Dedicating equipment
- Allergen labeling
- Ingredient testing

Physical

- Process controls
  - Use of metal detectors, x-rays, filters

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

Big 8 Allergens – Must Be Labelled

Milk

Soy

Tree nuts

Shellfish

Fish

Eggs

Peanuts

Wheat

These 8 cause ~90% of all allergic reactions!

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 used 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

Resources for Preparing Food Safety Plans

- Personnel
  - Consultants
  - Auditors
  - Employees
  - Process authorities
  - Suppliers
- Reliable Internet Sources
  - FDA website
  - FSPCA website
  - Other government agency sites
- Publications
  - Peer-reviewed literature
  - FDA publications & guidance documents
  - Trade association publications
- Extension

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 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
- 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!

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/

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