Introduction to Preventive Controls

Amanda Kinchla – UMass Extension Specialist
Christina Wormald – UMass Extension – Masters Student

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Agenda

• Objectives
• Overview of Preventive Controls
  • FSMA
  • Preventive Controls Rule
  • Food Safety Plan
  • Hazard Analysis
• Legal Implications
• Modified Requirements/Attestations
• Recommendations
• Resources
Introduction to PC Webinar Objectives

Gain insight on FSMA

Understand Preventative Controls

Begin to develop understanding of GMPs and their relevance in food safety initiatives

Discuss the importance of Record Keeping and Legal Implications

Become familiar with resources for preventative controls

Briefly discuss modified requirements and attestation
Exemption-Qualified Facility, Registration, Fees, Mandatory Recall and FDA Authority for Detention of Food

Accredited 3rd Party Certification Rule 21 CFR Subpart M

Preventative Controls Human Food Rule and GMP 21 CFR 117

Produce Safety Standard Rule 21 CFR 112

Preventative Controls Animal Food 21 CFR 507

Foreign Supplier Verification Program Rule 21 CFR Subpart L

Intentional Adulteration (Food Defense) 21 CFR 121.1

Sanitary Transport Human & Animal Food 21 CFR Subpart O

FSMA
Food Safety Regulation and Processing

Food Safety

HACCP

Meat & poultry
9 CFR 304

Juice
21CFR 101/102

Seafood
21CFR 123

Low Acid
21CFR 113 AND Preventive Controls

Preventative Controls
*Dairy – also PMO
*Acidified – also comply with 21CFR 113
Preventive Controls: What are they?

- Preventive Controls are procedures you implement to reduce or remove hazards that are found in your food product at your facility
- There are four categories:
  - Process Preventive Control
  - Allergen Preventive Control
  - Sanitation Preventive Control
  - Supply chain Preventive Control
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
Hazard Analysis

The first step of creating a FSP is conducting a hazard analysis:

1. List Ingredient/processing steps
2. Identify potential food safety hazards
3. Determine if hazard requires a PC
4. Justify Decision
5. Identify preventive controls for significant hazard
6. Double check preventive control has been implemented
Potential Preventive Controls Examples

**Biological Hazards**
- Process controls that kill pathogens
  - E.g. Cooking
- Process controls that prevent growth; e.g.
  - Time/temperature controls
  - Checking formulation
- Supply-chain programs for sensitive ingredients used without a kill step
- Sanitation Controls that prevent recontamination

**Chemical Hazards**
- Supply-chain programs
- Allergen Labeling
- Sanitation controls to prevent allergen cross-contact

**Physical Hazards**
- Process Controls such as
  - Filtering, metal detection, X-ray devices
## Hazard Analysis Example

<table>
<thead>
<tr>
<th>Ingredient/Processing Step</th>
<th>Identify potential food safety hazards introduced, controlled or enhanced at this step</th>
<th>Do any potential food safety hazards require a preventive control?</th>
<th>Justify your decision for column 3</th>
<th>What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? (Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control)</th>
<th>Is the preventive control applied at this step?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biological Hazards</strong></td>
<td>B</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Chemical Hazards</strong></td>
<td>C</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td><strong>Physical Hazards</strong></td>
<td>P</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>(1) Ingredient/Processing Step</td>
<td>(2) Identify potential food safety hazards introduced, controlled or enhanced at this step</td>
<td>(3) Do any potential food safety hazards require a preventive control?</td>
<td>(4) Justify your decision for column 3</td>
<td>(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?</td>
<td>(6) Is the preventive control applied at this step?</td>
</tr>
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<td>---------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Receiving refrigerated ingredients – liquid pasteurized egg</td>
<td>B</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>P</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Receiving refrigerated ingredients – liquid pasteurized egg**

- **Ingredient**
  - B
  - C
  - P

- **Processing Step**
  - Liquid pasteurized egg

- **Potential Food Safety Hazards**
  - Vegetative pathogens such as **Salmonella**
  - **Allergen** – egg

- **Preventive Control Measures**
  - **Process Control**
    - Subsequent cook step
  - **Allergen Control**
    - Allergen labeling at other steps

- **Preventive Control Applied**
  - Yes

**FSPCA – Hazard Analysis and Preventive Controls Determination for Human Food**
• Read this article to check if you fall under the qualified individual category:
  • *Guidance for Industry: Determination of Status as a Qualified Facility*
• Where to find attestation forms online – FDA Website
• Having a food safety plan is relevant! You want to assure that risks in the facility are being addressed properly.
GMPs

- Current Good Manufacturing Practices 21 CFR Part 117
- Personnel
- Plant and grounds
- Sanitary operations
- Sanitary facilities and control
- Equipment and utensils
- Processes and controls
- Warehousing and distribution
- Holding/distribution of human byproducts for animal use
- Natural or unavoidable defects that present no health hazard

Legal & Financial Implications - Recalls

• Recalls are actions taken to remove an adulterated, misbranded, or violative product from the market.

• If there is a hazard in your facility or with your product, you MUST have a recall plan!
  
  ✓ Your liability
  ✓ Your customers
  ✓ Your reputation
  ✓ The local food system
Record Keeping

• Records used to document that food safety hazards have been controlled by preventive controls

• Accurate record keeping provides documentation that food safety hazards are being controlled.

• Information required:
  • Standard information required
  • Signature or initials of the person reviewing the record, and date of the review
  • Cost and risk considerations
Recommendations: Where Do I Start?

- Implement/Develop/Maintain GMPs
- Set up a documentation system for critical control points in your operating procedures (SOPs)
- Develop written ingredient and packaging material specifications developed for all suppliers, and verification of compliance with those suppliers.
- Sanitation Controls – recommended cleaning products to be used during manufacturing
- Audit – will provide recommendations for improvement*
Key Points for Preventive Controls

• **FSMA** - “Directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation.”

• Preventive controls fall under FSMA

• Should have plan by January 2020 if you’re a qualified facility

• If your product falls under the modified qualifications, understand and file for attestation
Key Points for Preventive Controls

• Key core components of FSP/Preventive Controls
  • Hazard Analysis
  • Preventive Controls*
  • Monitoring
  • Corrective Actions
  • Verifications and Associated Records

• Developing a food safety plan will help you and your staff understand the risks and significantly reduce food-related incidents.
Personnel

• Consultants and auditors
• Process authorities and subject matter experts
• University specialists
• Government agencies
• Trade associations
• Suppliers, buyers, laboratory analysts
Trusted Internet Sites and FDA Guidance

- FSPCA, FDA Website, Trade Association Websites, USDA Website

- In Development: *Food Safety Preventive Controls for Human Food Hazards and Controls Guidance*
- Seafood HACCP Hazards and Controls Guidance
- Juice HACCP Hazards and Controls Guidance
Helpful Reminders

• Don’t be alone in making your food safety plan!
• Say what you do, do what you say
• Hazards are okay!
• Your safety plan is dynamic
• Make a commitment to ensure food safety
Introduction to Preventive Controls

Amanda Kinchla – UMass Extension Specialist
Kinchla@umass.edu

Christina Wormald – UMass Extension Independent Contractor
Cwormald@umass.edu

Jill Fitzsimmons – Resource Economist
Jfitzsim@umass.edu

Louisa Bachman – Summer Scholar
lbachman@umass.edu

This content was supported in acknowledgement of the USDA Food Safety Outreach Program grant #015331-00002
Further References:

