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The Northeast Center to  
Advance Food Safety



FDA FOOD SAFETY  
MODERNIZATION ACT



# Introduction to Preventive Controls

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<https://umass.app.box.com/s/rdvykbb25kbu49wb563420sfi23lzq3x>



# 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**



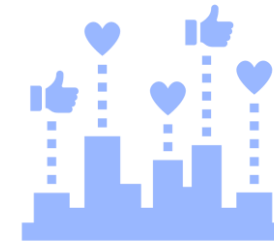
Understand  
**Preventative  
Controls**



**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**





# FSMA

## Exemption-Qualified Facility, Registration, Fees, Mandatory Recall and FDA Authority for Detention of Food

Accredited  
3<sup>rd</sup> 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

# Food Safety Regulation and Processing

## Food Safety

### HACCP



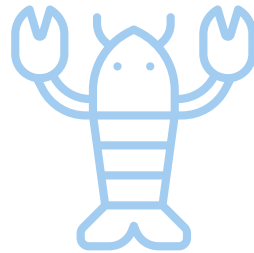
**Meat &  
poultry**

**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





# 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

| <b>Hazard Analysis</b>                   |  | PRODUCT: Prepared Frozen Omelet  |    |   |   | PAGE X of Y  |          |
|--|--|--|----|---|---|--|----------|
| PLANT NAME                               |  | Joe's Famous Breakfasts Facility   |    |   | ISSUE DATE  |  | mm/dd/yy |
| ADDRESS                                  |  | 1000 Main St, Amherst MA USA   |    |   | SUPERSEDES  |  | mm/dd/yy |
| (1)<br>Ingredient/<br>Processing<br>Step | (2)<br>Identify <u>potential</u><br>food safety<br>hazards<br>introduced,<br>controlled or<br>enhanced at this<br>step | (3)<br>Do any <u>potential</u><br>food safety<br>hazards require a<br>preventive<br>control? |    | (4)<br>Justify your<br>decision for<br>column 3 | (5)<br>What preventive control<br>measure(s) can be applied<br>to significantly minimize<br>or prevent the food safety<br>hazard?<br><br><i>Process including CCPs,<br/>Allergen, Sanitation, Supply-<br/>chain, other preventive<br/>control</i> | (6)<br>Is the<br>preventive<br>control<br>applied at<br>this step? |          |
|  |  | Yes  | No |   |   | Yes  | No       |
| B  |  |  |    |   |   |  |          |
| C  |  |  |    |   |   |  |          |
| P  |  |  |    |   |   |  |          |

Biological Hazards

Chemical Hazards

Physical Hazards



|                        |                                  |            |             |
|------------------------|----------------------------------|------------|-------------|
| <b>Hazard Analysis</b> | Prepared Frozen Omelet           |            | PAGE X of Y |
| PLANT NAME             | Joe's Famous Breakfasts Facility | ISSUE DATE | mm/dd/yy    |
| ADDRESS                | 1000 Main St, Amherst MA USA     | SUPERSEDES | mm/dd/yy    |

| (1) Ingredient/<br>Processing Step                                      | (2)<br>Identify <u>potential</u><br>food safety hazards<br>introduced,<br>controlled or<br>enhanced at this step | (3)<br>Do any<br><u>potential</u> food<br>safety hazards<br>require a<br>preventive<br>control? |    | (4)<br>Justify your decision for column 3 | (5)<br>What preventive control measure(s)<br>can be applied to significantly<br>minimize or prevent the food safety<br>hazard?<br><i>Process including CCPs, Allergen,<br/>Sanitation, Supply-chain, other preventive<br/>control</i> | (6)<br>Is the<br>preventive<br>control applied<br>at this step? |    |
|---|--|---|----|---|---|---|----|
|   |  | Yes   | No |   |   | Yes   | No |
| Receiving<br>refrigerated<br>ingredients –<br>liquid<br>pasteurized egg | B  | [Redacted]  | X  | [Redacted]                                | [Redacted]  |   | X  |
|   | C  | [Redacted]  | X  | [Redacted]                                | [Redacted]  |   | X  |
|   | P  | [Redacted]  |    | X   |   |   |    |



## Modified Requirements

- 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.



**U.S. FOOD AND DRUG ADMINISTRATION**  
**INDUSTRY SYSTEMS**

# 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

22<http://www.fpsa.org/wp-content/uploads/CFR-110-vs-117.pdf>



# 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



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- 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

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## NECAFS

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Advance Food Safety



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



# Further References:

- FSPCA Preventive Controls for Human Foods Participant Manual, First Edition 2016.
- **FSMA Final Rule for Preventive Controls for Human Food.** *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.* <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>
- FDA Current Good Manufacturing Practice (CGMP) Regulations. <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>