



NECAFS

The Northeast Center to
Advance Food Safety



**FDA FOOD SAFETY
MODERNIZATION ACT**



Introduction to Preventive Controls

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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**



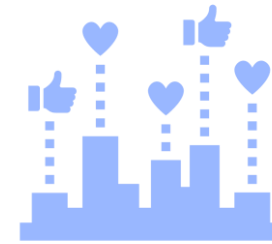
Understand
**Preventative
Controls**



**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**





FSMA

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

Food Safety Regulation and Processing

Food Safety

HACCP



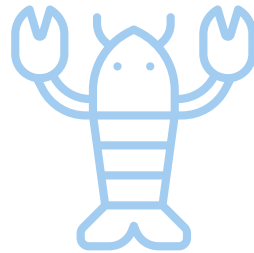
**Meat &
poultry**

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

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

Biological Hazards

➔

Chemical Hazards

➔

Physical Hazards

➔



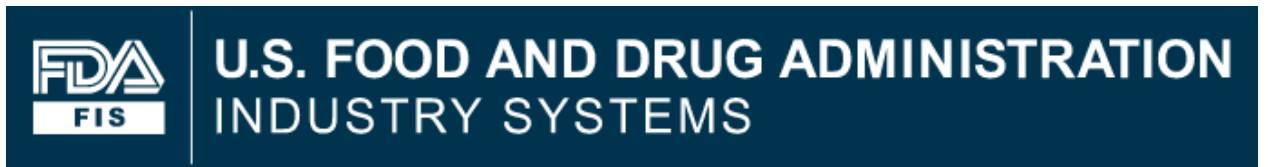
Hazard Analysis	Prepared Frozen Omelet		PAGE X of Y
PLANT NAME	Joe's Famous Breakfasts Facility	ISSUE DATE	mm/dd/yy
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(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving refrigerated ingredients – liquid 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.



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



FDA FOOD SAFETY
MODERNIZATION ACT

- 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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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>