Preventive Control for Human Food - Food Safety Plan –

Presented by Dr. Jang Ho Kim, Food Safety Specialist, University of Idaho Extension

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United States Department of Agriculture
National Institute of Food and Agriculture

Oregon State University

Cooperative Extension Service
University of Alaska Fairbanks

University of Idaho Extension

Washington State University Extension

Food Safety Modernization Act

- The Food Safety Modernization Act (FSMA) was signed into law Jan 2011.
- 7 different rules of FSMA covers a specific part of domestic food production, processing, and transportation of human and animal food in order to protect the US food supply during all points of the supply and distribution chain.

- **Preventive Controls for Human Food**
- Produce Safety
- Foreign Supplier Verification Programs
- International Adulteration
- Preventive Controls for Animal Food
- Sanitary Transportation
- Accredited Third Party Certification

Preventive Controls for Human Food Rule

- If you make “processed food” then your operation is covered under **21 CFR Part 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food** (FDA Preventive Controls for Human Food Rule).
- The regulation requires that food safety activities must be completed by a **“Preventive Controls Qualified Individual (PCQI)”** unless your facility is exempted or qualified exempted **(Decision Trees).**

Preventive Controls for Human Food Rule

- **PCQI:** A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Exemptions and Modified Requirements

- Exempt or qualified exempt facilities
- Foods subject to low-acid canned food regulations
- Foods subject to HACCP (seafood and juice)
- Dietary supplements (Dietary Supplement Safety Act, 2010)
- Alcoholic beverages
- Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods (jams/jellies/preserves from acid fruit, milling grains, extracting oils from grains and fruits/vegetables)
- cf. *Cottage Food regulation*

Preventive Controls for Human Food

- The covered food facility MUST:
  1) have and implement a written **Food Safety Plan** that identified FOOD SAFETY HAZARDS that require a preventive controls, and
  2) implement preventive controls to significantly reduce or prevent the identified hazard.
- The Food Safety Plan include ***(1) Hazard Analysis, (2) Preventive Control, (3) Risk-Based Supply Chain Program***, and ***(4) Recall Plan*** as well as **Good Manufacturing Practices (GMP)** and other prerequisite programs.

Preventive Controls for Human Food

- Hazard Analysis and Risk-Based Preventive Controls
  - Hazard: Any biological, chemical, or physical agent (object or material) that could cause illness or injury (cf. economic fraud, spoilage, insect parts, hair etc.)
- Updated Good Manufacturing Practices
- Facilities that manufacture, process, pack or hold human food
- Facilities required to register with FDA under sec. 415 of the FD&C Act.
- Some ***exemptions*** and ***modified requirements*** apply.

Preliminary Steps

1. Assemble the food safety team - PCQI, QA, QC, processing supervisor, manager, consultant (team approach).
2. Describe product and distribution – product name. food safety characteristics, ingredients, packaging, shelf-life, storage and distribution
3. Describe intended use and consumer of the food
4. Develop a flow diagram and describe the process

Product Description

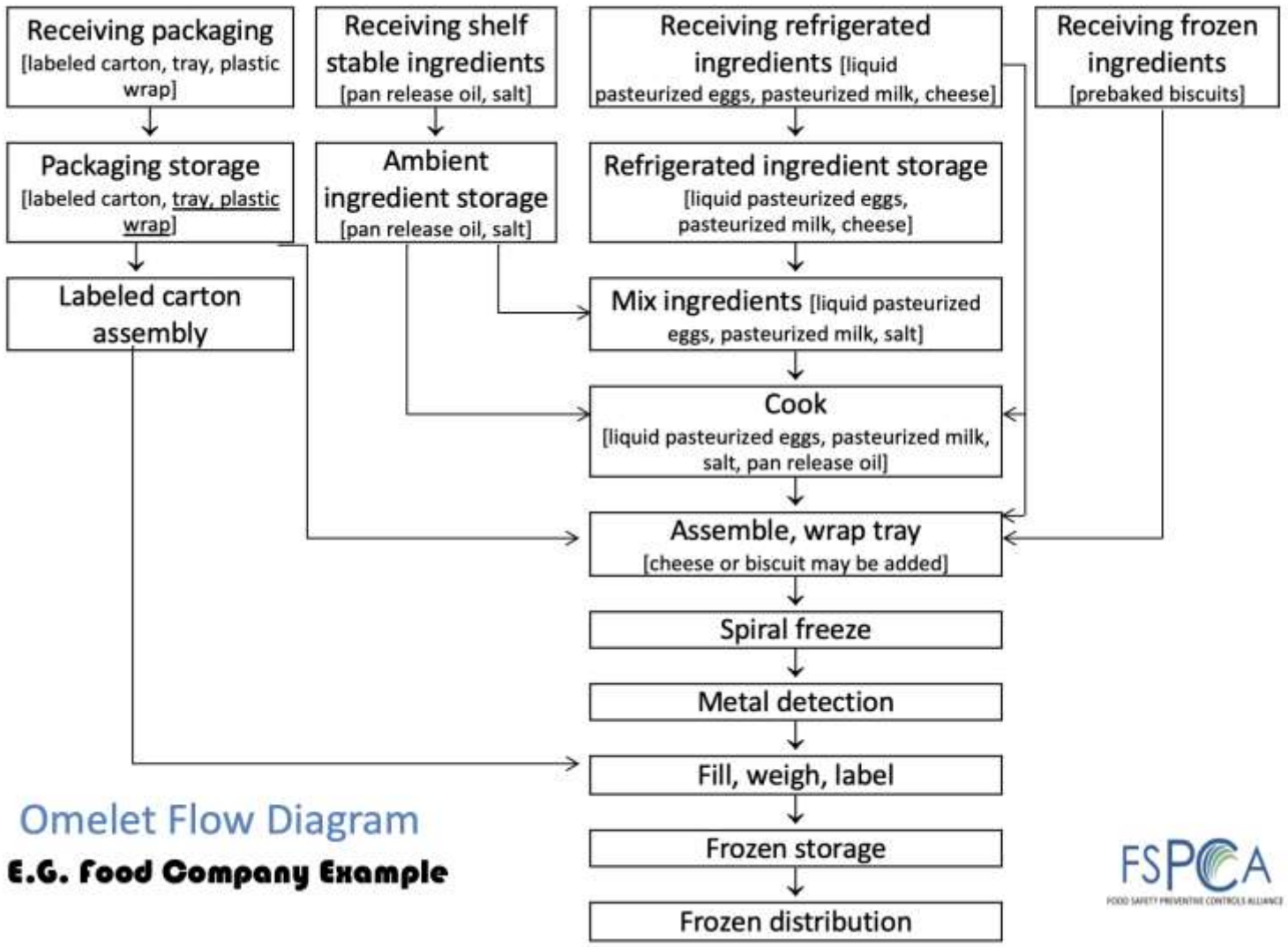
PRODUCT(S) Omelet – Plain, Cheese and Cheese Biscuit		**PAGE 4 of 38**
PLANT NAME: E.G. Food Company	**ISSUE DATE**	2/13/2016
ADDRESS: 360 Culinary Circle, Mytown, USA	**SUPERSEDES**	09/20/2015

Product Description, Distribution, Consumers and Intended Use

Product Name(s)	**Omelet – Plain, Cheese and Cheese Biscuit**
Product Description, including Important Food Safety Characteristics	Frozen, cooked egg omelet, with or without cheese filling and a wheat biscuit bun pH 7.1 - 7.9, water activity >0.98, no preservatives
Ingredients	Plain: Eggs, milk, pan release oil, salt Cheese: Eggs, milk, cheese, pan release oil, salt Cheese Biscuit: Eggs, milk, cheese, biscuit, pan release oil, salt
Packaging Used	Paperboard trays wrapped with plastic wrap and inserted in a corrugated case.
Intended Use	The product is considered ready-to-eat, but is typically heated to hot holding temperatures (135°F (57°C)) or above for palatability. Heating is typically conducted using microwaves or convection oven. End user may thaw at refrigeration temperatures overnight to reduce cooking time. End users may also add toppings or fillings. Sold for foodservice applications. *Potential abuse:* Some establishments may hold thawed product for longer than the recommended 24 hours.
Intended Consumers	General public
Shelf Life	1 year frozen
Labeling Instructions	Keep frozen or thaw under refrigeration (<41°F (5°C)) for <24 hours before cooking.
Storage and Distribution	Frozen
Approved:* Signature: F.S. Leader Print name: F.S. Leader	**Date:** April 11, 2015

*Signature may just be on plan, or may be on each page.

Flow Diagram



Food Safety Plan

- Definition: A set of written documents that is based on food safety principles (adapted from 21 CFR 117.126).
  1. Hazard analysis
  2. Preventive controls: process controls, food allergen controls, sanitation controls and others

     - parameter, monitoring, corrective actions, verification, records
  3. Supply chain program
  4. Recall plan

Current Good Manufacturing Practices (cGMPs)

- The components and practices for safe food processing conditions:
  - Personnel (workers) – ***training requirement added***
  - Plant and grounds (building etc.)
  - Sanitary operations* (cleaning and sanitizing)
  - Sanitary facilities and controls
  - Equipment and utensils
  - Processes and controls* (Preventive Controls) – ***Allergen Control added***
  - Warehousing and distribution
  - ***Holding and distribution of human food by-products for use as animal food added***
  - Defect action levels

Food Safety Plan-Hazard Analysis

- Hazard - any biological, chemical, or physical hazard that is known to be, or has the potential to be, associated with the facility or the food
- Hazard Analysis
  - Determines how severity and frequency of hazards is and how often the hazard occurs in absence of preventive controls
  - Identify hazards requiring a preventive control
  - Focus resources on essential preventive controls
  - Identify operations that require improvement
  - Considers other factors

Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERSEDES	mm/dd/yy

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential 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? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							

E.G. Food Company Example

Hazard Analysis	PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit		PAGE X of Y
PLANT NAME	E.G. Food Company	ISSUE DATE	mm/dd/yy
ADDRESS	360 Culinary Circle, Mytown, 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? Yes	(3) No	(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? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
From flow diagram	B C P	Identify potential hazards that **may be** introduced or increase at this step	Decide if the hazards require a preventive control.		Provide a reason for "yes" or "no" in column 3 when a potential hazard is identified. Optional to justify a "None" in column 2.	For hazards requiring a preventive control ("Yes" in column 3), identify preventive controls (**process, food allergen, sanitation, supplier or other**) that are applied at this step or later	Indicate if the preventive control is applied at this step or later in the process	

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

PRODUCT(S) Omelet – Plain, Cheese and Cheese Biscuit						PAGE **9** of 36	
PLANT NAME: E.G. Food Company						ISSUE DATE	2/13/2016
ADDRESS: 360 Culinary Circle, Mytown, USA						SUPERSEDES	09/20/2015

(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? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Receiving packaging	B	None						
	C	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	X		Labeled cartons must declare allergens present in the product and print errors have occurred	Allergen Control – label review for allergen information	X	
	P	None						
Receiving shelf stable ingredients – salt	B	None						
	C	None						
	P	None						
Receiving shelf stable ingredients – pan release oil	B	None						
	C	Allergen – soy	X		Soy lecithin may contain soy allergen that must be labeled to inform consumers. Cross-contact is not an issue – all products contain soy.	Allergen Control – allergen labeling at subsequent step		X
	P	None						

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

PRODUCT(S) Omelet – Plain, Cheese and Cheese Biscuit		PAGE **9&10** of 36	
PLANT NAME: E.G. Food Company		ISSUE DATE	2/13/2016
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			Yes	No			Yes	No
Receiving refrigerated ingredients – liquid pasteurized eggs	B	Vegetative pathogens such as *Salmonella*	X		While pasteurization minimizes the likelihood of Salmonella USDA recommends the product be used in cooked foods. Experience has shown Salmonella occasionally occurs in this ingredient.	Process Control - subsequent cook step		X
	C	Allergen – egg	X		Egg is an allergen that must be labeled to inform consumers. Cross-contact is not an issue – all products contain egg.	Allergen Control – allergen labeling at subsequent step		X
	P	None						
Receiving refrigerated ingredients – pasteurized Grade A milk	B	Vegetative pathogens such as *Salmonella*	X		Raw milk has a history of association with *Salmonella.* Pasteurization by the supplier or our cook step can control the hazard.	Process Control - subsequent cook step		X
	C	Allergen – milk	X		Milk is an allergen that must be labeled to inform consumers. Cross-contact is not an issue – all products contain milk.	Allergen Control – allergen labeling at subsequent step		X
	P	None						

PRODUCT(S) Omelet – Plain, Cheese and Cheese Biscuit		PAGE **10** of 36
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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? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Receiving refrigerated ingredients – pasteurized process cheese	B	Vegetative and sporeforming pathogens such as *Salmonella*, pathogenic *E. coli*, *L. monocytogenes* and *C. botulinum*	X		Pathogens listed were identified as significant by ICMSF (2005) in process cheese. These hazards should have been controlled when the cheese was made.	Supplier Control – 3rd party supplier audit by a qualified auditor	X	
	C	Allergen – milk	X		Milk is an allergen that must be labeled to inform consumers. Cross-contact is not an issue – all products contain milk.	Allergen Control – allergen labeling at subsequent step		X
	P	None						

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			Yes	No			Yes	No
Receiving frozen ingredients – biscuits	B	None						
	C	Allergen - wheat	X		Wheat is an allergen that must be labeled to inform consumers. Cross-contact with other products must be controlled because some products produced on the same line do not contain wheat.	Allergen Control – allergen labeling at subsequent step Sanitation Control – at a subsequent step to prevent cross-contact		X
	P	None						
Storage – Pack-aging & dry ingredients [pan release oil, salt]	B	None						
	C	None						
	P	None						

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			Yes	No			Yes	No
Refrigerated ingredient storage [eggs, milk]	B	Vegetative pathogens such as Salmonella		X	Pathogen growth to levels that render the cook step ineffective is not likely to occur			
	C	None						
	P	None						
Frozen ingredient storage [biscuits]	B	None						
	C	None						
	P	None						
Labeled carton assembly	B	None						
	C	None						
	P	None						

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			Yes	No			Yes	No
Mix ingredients [eggs, milk, salt]	B	None						
	C	None						
	P	Metal	X		Mixer has metal-on-metal contact	Process Control – subsequent metal detection		X
Cook [eggs, milk, salt, pan release oil]	B	Survival of vegetative pathogens such as Salmonella	X		Thorough cooking is required to kill vegetative pathogens	Process Control – cooking to achieve a lethal temperature	X	
	C	None						
	P	None						

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			Yes	No			Yes	No
Assemble, wrap	B	Introduction of environmental pathogens such as *L. monocytogenes*	X		Recontamination may occur if sanitation controls are not in place	Sanitation Controls – prevent recontamination	X	
		Growth of vegetative pathogens such as *Salmonella* and *L. monocytogenes*		X	Time is too short for growth to be reasonably likely.			
	C	Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit	X		Biscuits could introduce wheat allergen to other products without control	Sanitation and Allergen Controls – prevent allergen cross-contact	X	
	P	None						

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

PRODUCT(S) Omelet – Plain, Cheese and Cheese Biscuit		PAGE **12** of 36
PLANT NAME: E.G. Food Company	ISSUE DATE	09/20/2015
ADDRESS: 360 Culinary Circle, Mytown, USA	SUPERSEDES	08/06/2015

(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? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Spiral freeze	B	Growth of vegetative pathogens such as *Salmonella* and *L. monocytogenes*		X	Time is too short for growth to be reasonably likely			
	C	None						
	P	None						
Metal detection	B	None						
	C	None						
	P	Metal	X		Metal-on-metal contact on the line may introduce metal fragments	Process Control – metal detection	X	

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PRODUCT(S) Omelet – Plain, Cheese and Cheese Biscuit							PAGE **12** of 36	
PLANT NAME: E.G. Food Company							ISSUE DATE	2/13/2016
ADDRESS: 360 Culinary Circle, Mytown, USA							SUPERSEDES	09/20/2015
(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? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Fill, weigh, label	B	None						
	C	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	X		All products contain egg, milk and soy allergens. The cheese biscuit also contains wheat	Allergen Control – correct labeled carton for product	X	
	P	None						
Frozen storage	B	None						
	C	None						
	P	None						
Frozen distribution	B	None						
	C	None						
	P	None						

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Potential Biological Hazards

- Microorganisms in foods may include:
  - Bacteria
  - Viruses
  - Protozoa
  - Yeasts
  - Molds
- Prions
- Some are pathogens, many are not!

Chemical Hazards

- Naturally occurring
  - Food allergens, mycotoxins, decomposition by-products
- Used in formulation
  - Food additives, color additives, preservatives
- Unintentionally or incidentally present
  - Cleaning and sanitizing chemicals, pesticides, industrial chemicals, heavy metals, drug residues, radiological hazards

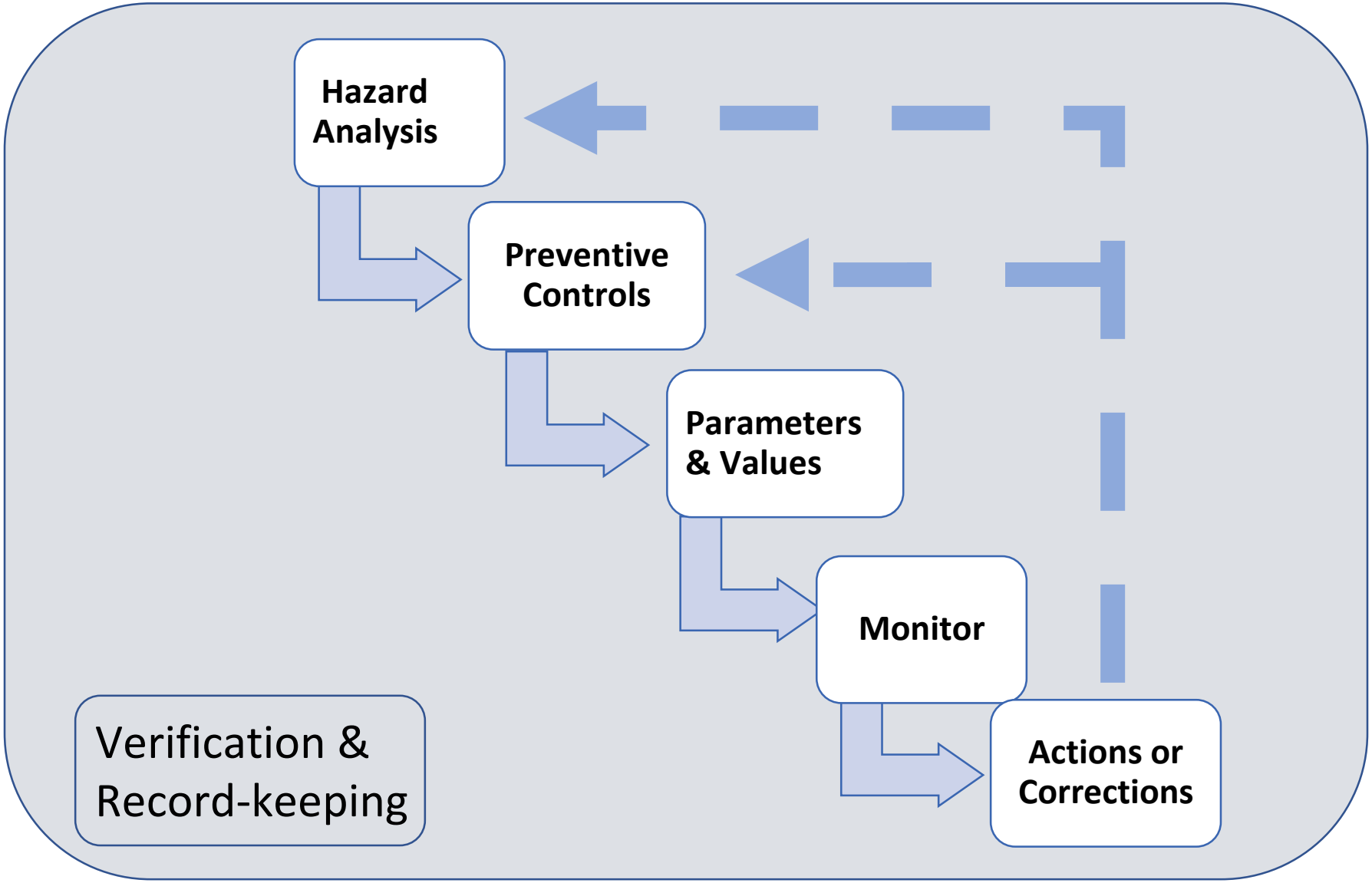
Food Allergy

- An adverse response by the body to foods containing allergenic proteins
- A very small amount of protein/allergen can trigger different symptoms in different individuals
- Food allergy symptoms are unpredictable and vary from mild reactions to death
- Major food allergens: milk, egg, peanut, tree nuts, fish, crustacean shellfish, wheat, and soy
- Labeling: Food containing allergens should be indicated

Food Safety Plan-Preventive Controls

- Measures (operations) required to ensure that hazards are significantly minimized or prevented.
- Include controls at critical control points (CCPs), if any, and controls other than those at CCPs that are appropriate for food safety
  - Process control
  - Food allergen controls
  - Sanitation controls
  - Supply-chain controls
  - Recall plan
- Not required when hazard is controlled by another entity later in the distribution chain

Food Safety Plan-Preventive Controls



Food Safety Plan-Preventive Controls

- Preventive Controls (21 CFR 117.3): "Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understand of safe food manufacturing, processing, packaging, or holding at the time of the analysis.

Food Safety Plan-Preventive Controls

- If the hazard analysis identifies a hazard that requires a preventive control, it is required to develop and implement a control to significantly reduce or prevent the hazard.
- And it includes:
  - Process controls such as cooking, metal detection, x-ray, time/ temperature controls
  - Food allergen preventive controls
  - Sanitation preventive controls
  - Supply-chain program
  - Recall plan

Food Safety Plan-Process Controls

- Procedures, practices, and processes to control parameters with **minimum or maximum values (Critical Limit)** during operations.
- The **critical limit** must be controlled to significantly minimize or prevent a hazard.
- The process control must be **monitor**ed based on what, how often, how, who.
- **Corrective action** must be taken if deviations occur (followed by verification and validation if necessary).

Process Controls – Critical Limit

- The maximum or minimum value, or combination of values, to which any biological, chemical or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

Product	Hazard	Critical Control Point	Critical Limit Example
Ready-to-eat cooked and refrigerated product	*Listeria monocytogenes* survival	Cooking	≥160°F (71°C) internal product temperature for ≥1.5 min
Dried product	Pathogen growth	Drying oven	Drying schedule – Oven temperature ≥200°F (93.3°C) Time ≥120 minutes Air flow rate ≥2 ft^3/min Product thickness ≤0.5 inches (to achieve a_w ≤0.85)
Acidified product	*Clostridium botulinum* in pickled foods	Acidification	Batch schedule – Product weight < 100 lb Soak time ≥8 hr Acetic acid concentration ≥3.5%, volume ≥50 gal (to achieve maximum pH of 4.6)

PRODUCT: PAGE 1 of X
PLANT NAME: ISSUE DATE mm/dd/yy
ADDRESS: SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

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E.G. Food Company Example

Hazard Analysis Form

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit						PAGE X of Z	
PLANT NAME: E.G. Food Company					ISSUE DATE	mm/dd/yy	
ADDRESS: 360 Culinary Circle, Mytown, USA					SUPERSEDES	mm/dd/yy	
(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require 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? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Cook [eggs, milk, salt, pan release oil]	B **Survival of vegetative pathogens such as *Salmonella***	X		Thorough cooking is required to kill vegetative pathogens	Process Control – Cooking to achieve a lethal temperature	**X**	

Process Control Form

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit							PAGE Y of Z	
PLANT NAME: E.G. Food Company						ISSUE DATE	mm/dd/yy	
ADDRESS: 360 Culinary Circle, Mytown, USA						SUPERSEDES	mm/dd/yy	
Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Survival of vegetative pathogens such as *Salmonella*								

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E.G. Food Company Example

PRODUCT: Omelet - Plain
PLANT NAME: E.G. Food Company
ADDRESS: 360 Culinary Circle, Mytown, USA

PAGE 1 of X
ISSUE DATE mm/dd/yy
SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Vegetative pathogens such as *Salmonella*	Omelet temperature is ≥158°F (70°C) instantaneous before transfer to assembly table							

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Food Safety Plan-Process Controls

- **Monitoring**: the procedure designed to provide to make sure preventive controls are consistently working correctly.
- Track the operation of the process and identify trends toward a critical limit that may cause process adjustments.
- Identify when there is a loss of control (deviation) from a critical limit occurs.
- To provide written documentation that can be used to verify that the process is under control (record Keeping).
- Temperature, time, pH, chemical concentration, etc.

E.G. Food Company Example

PRODUCT: Omelet - Plain — PAGE 1 of X

PLANT NAME: E.G. Food Company — ISSUE DATE mm/dd/yy

ADDRESS: 360 Culinary Circle, Mytown, USA — SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Vegetative pathogens such as *Salmonella*	Omelet temperature is ≥158°F (70°C) instantaneous before transfer to assembly table	Omelet temperature is ≥158°F (70°C)	Infrared surface thermometer	Each cook station, 4 times per shift, about every 2-3 hours	QA technician, or designee			

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E.G. Food Company Example

PRODUCT Omelet - Frozen		PAGE 27 of 34
PLANT NAME: E.G. Food Company	ISSUE DATE	09/20/2015
ADDRESS: 360 Culinary Circle, Mytown, USA	SUPERSEDES	08/06/2015

Cook Log

Hazard: Vegetative pathogens such as *Salmonella*

Parameters, values or critical limits: Omelet temperature is ≥158°F (70°C) instantaneous before transfer to assembly table.

Who, How, Frequency: QA technician or designee, checks an omelet temperature each cook station 4 times/shift (every 2-3 hr) using an infrared surface thermometer.

Corrective Action: Hold product back to the last good check and evaluate – rework, discard, or release. Determine root cause – retrain or correct as appropriate

Date:

Time	Cook Station	Cook name	Temperature (°F)	QA Tech (initials)

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Food Safety Plan-Process Controls

- **Corrective actions**
  - Procedures that must be taken if preventive controls are not properly implemented.
  - Identify and correct problems with implementation
  - Reduce likelihood of occurrence
  - Evaluate affected food for safety
  - Prevent affected food from entering commerce if you cannot ensure the food is not adulterated

Food Safety Plan-Process Controls

- **Corrective actions Examples**

Process Examples	Product Examples
• Immediate adjustment of process • Employees stop line when deviation occurs • Apply alternate process • Repair equipment • Retrain employees • Evaluate operation	• Hold product • Evaluate product • Determine product disposition - Release, rework or destroy product

E.G. Food Company Example

PRODUCT: Omelet - Plain — PAGE 1 of X

PLANT NAME: E.G. Food Company — ISSUE DATE mm/dd/yy

ADDRESS: 360 Culinary Circle, Mytown, USA — SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Vegetative pathogens such as *Salmonella*	Omelet temperature is ≥158°F (70°C) instantaneous	Omelet temperature is ≥158°F (70°C)	Infrared surface thermometer	Each cook station, 4 times per shift, about every 2-3 hours	QA technician or designee	Hold product back to the last good check and evaluate - rework, discard, or release. Determine root cause - retrain or correct as appropriate		

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

E.G. Food Company Example

Corrective Action Form PLANT NAME: E.G. Food Company ADDRESS: 360 Culinary Circle, Mytown, USA	PAGE 1 of X
Date of Record:	Code or Lot Number:
Date and Time of Problem:	
Description of Problem and Root Cause:	
Actions Taken to Restore Order to the Process:	
Person Taking Action (name and signature) :	
Amount of Product Involved in Problem:	
Evaluation of Product Involved with Problem:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date:

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Food Safety Plan-Process Controls

- **Verification**
  - Action to ensure that preventive controls are consistently implemented and effective to reduce hazards.

    Example:

    1) Scientific validating process for preventive controls to ensure that the preventive control is effectively reducing identified hazards.
    2) Calibrating (or checking accuracy) monitoring and verification devices (such as thermometer).
  - Verification also include reviewing records to ensure the monitoring and corrective action are correctly conducted.

E.G. Food Company Example

PRODUCT: Omelet – Plain, Cheese, Cheese Biscuit									PAGE 13 of 36
PLANT NAME: E.G. Food Company ADDRESS: 360 Culinary Circle, Mytown, USA							ISSUE DATE SUPERSEDES		mm/dd/yyyy mm/dd/yyyy
Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Vegetative pathogens such as *Salmonella*	Omelet surface temperature is ≥158°F (70°C) instantaneous before transfer to assembly table	Omelet surface temperature is ≥158°F (70°C)	Infrared surface thermometer	Each cook station, 4 times per shift, about every 2-3 hours	QA technician or designee	Hold product back to the last good check and evaluate – rework, discard, or release. Determine root cause – retrain or correct as appropriate.	Review of Cook Log, Corrective Action and Verification records within 7 working days Daily accuracy check for thermometer Annual calibration of thermometer	

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Food Safety Plan

- **Recordkeeping**: Documenting preventive controls, monitoring, and corrective actions
  - Monitoring records for preventive controls
  - Corrective action records
  - Verification records, when required
  - Supply-chain program and supporting documentation
  - Training records, as appropriate
  - Original, true copies or electronic
  - Contents: Actual values or observations, accurate, permanent, and legible document

PRODUCT: Omelet – Plain, Cheese, Cheese Biscuit PAGE 1 of X

PLANT NAME: E.G. Food Company ISSUE DATE mm/dd/yy

ADDRESS: 360 Culinary Circle, Mytown, USA SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Vegetative pathogens such as *Salmonella*	Omelet surface temperature is ≥158°F (70°C) instantaneous before transfer to assembly table	Omelet surface temperature is ≥158°F (70°C)	Infrared surface thermometer	Each cook station, 4 times per shift, about every 2-3 hours	QA technician or designee	Hold product back to the last good check and evaluate - rework, discard, or release. Determine root cause – retrain or correct as appropriate.	Review of Cook Log, Corrective Action and Verification records within 7 working days Daily accuracy check for thermometer Annual calibration of thermometer	Cook Log – cook temp by QA technician Corrective Action records Verification records, including Validation study

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Food Safety Plan-Food Allergen Controls

- Procedures, practices, and processes to control allergen cross-contact within a facility and procedures to ensure all food allergens are correctly labeled.
- Undeclared allergens present a risk:
  - Consumer reaction can be severe
  - Major cause of food recalls
- Allergen management practices ensuring to:
  - Protect allergic consumer and make food safer for all to enjoy
  - Reduce company ‘s risk

E.G. Food Company Example

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit PAGE 1 of X
PLANT NAME: E.G. Food Company ISSUE DATE mm/dd/yy
ADDRESS: 360 Culinary Circle, Mytown, USA SUPERSEDES mm/dd/yy

Product Line Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Crustacean Shellfish (market name)
Plain Omelet	1	X	X	X					
Cheese Omelet	1	X	X	X					
Cheese Omelet Biscuit	1	X	X	X	X Unique allergen				

Scheduling Implications:
Run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Omelet Biscuit at the end of the shift to reduce the potential for allergen cross-contact.

Allergen Cleaning Implications:
An allergen clean is required AFTER production of Cheese Omelet Biscuit because it contains a unique allergen – wheat.

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

E.G. Food Company Example

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit		PAGE 1 of X
PLANT NAME: E.G. Food Company	ISSUE DATE	mm/dd/yy
ADDRESS: 360 Culinary Circle, Mytown, USA	SUPERSEDES	mm/dd/yy

Run Order Monitoring Record

Hazard: Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit.

Run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Omelet Biscuit at the end of the shift to reduce the potential for allergen cross-contact. A full allergen clean is required AFTER production of Cheese Omelet Biscuit because it contains a unique allergen – wheat.

Product Name	Date	Start Time	End Time	Allergen Clean After run (Yes/No)	Initials for allergen clean
Verification Signature				Date:	

Allergen Label Check Monitoring Log Example

Form Title: Allergen Label Check Monitoring Log					
Firm Name:				**Firm Location:**	
Product Identification:					
Parameters: All finished product labels must declare the allergens present in the formula: *Product A: list allergens* *Product B: list allergens*					
Date	**Time**	**Lot Code**	**Lot Number**	**Proper Label Applied (Yes/No)**	**Line Operator (Initials)**
Verification Reviewer Signature:				**Date of Review:**	
Date issued: dd/mm/yy				Supersedes issue: dd/mm/yy	

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Food Safety Plan-Sanitation Controls

- Sanitation preventive controls focus on cleanliness of food-contact surfaces and prevention of cross-contamination and allergen cross-contact
  - Environmental pathogens when RTE food is exposed to the environment prior to packaging
  - Allergens transferred through allergen cross-contact
- Sanitation controls must record:
  - Monitoring activities and frequency
  - Corrections and corrective actions that apply for allergens and environmental pathogens
  - Verification activities

E.G. Food Company Example

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit — PAGE 31 of 36
PLANT NAME: E.G. Food Company — ISSUE DATE mm/dd/yyyy
ADDRESS: 360 Culinary Circle, Mytown, USA — SUPERSEDES mm/dd/yyyy

Daily Sanitation Control Record – Omelet Line

DATE:

Sanitation Area and Goal	Pre-Op Time:	Start Time:	Lunch Break Time:	Post-Op Time:	Comments and Corrections	Operator Initials
Condition & Cleanliness of Food Contact Surfaces • Equipment cleaned and sanitized (S/U)*						
• Sanitizer type and strength: *Quaternary ammonium compound, 200 ppm* Omelet line (ppm)+						
Dish room dip tank (ppm)+						
Prevention of Cross-Contact • Cleaning after Cheese Omelet Biscuit (S/U/NA)&						
Condition & Cleanliness of Non-food Contact Surfaces • Floors and wall splash zones cleaned and sanitized (S/U)						
• Sanitizer type and strength: *Quaternary ammonium compound, 400-600 ppm* Floors and wall splash zones (ppm)+						

* S = Satisfactory, U = Unsatisfactory
+ Enter ppm measured per test strip
& NA = not applicable because Cheese Omelet Biscuit run after other products

Verification signature: | Date:

Food Safety Plan-Supply Chain Program

- If a hazard related to ingredients identified and the supplier controls that hazard, a risk-based supply chain program must be implemented.
- **Supply chain program** MUST include:
  - Using approved suppliers
  - Determining appropriate supplier verification activities such as on-site audits, sampling and testing, review of supplier's food safety record, etc.
  - Conducting supplier verification activities
  - Documenting supplier verification activities

Food Safety Plan-Recall Plan

- If the hazard analysis identifies a hazard requiring a preventive control, the facility must have a written recall plan that describes the procedures to perform a recall of the product.
- The recall plan must include procedures to notify consignees, to notify the public when necessary, to conduct effectiveness checks and to appropriately dispose recalled product.
- Actions taken by a firm to remove a violative product from the market
- May be conducted on a firm's own initiative, by FDA or state request, or by FDA or state order
- Class I, II, or III recall depending on adverse health consequences severity.

View recorded webinars & learn more at:

www.pnwfoodsafety.org