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WORKSHOP AGENDA

- Overview
- What is HACCP?
- GMPs
- Contents of a Food Safety Plan
- Hazard Analysis
- Preventive Controls
- Modified Requirements/Attestations for Qualified Processors
- Next Steps



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INTRODUCTION – OVERVIEW, HACCP, INTRO TO PREVENTIVE CONTROLS & GMP

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IF YOU DON'T KNOW WHERE YOU'RE GOING, YOU NEED A "ROADMAP" TO TAKE YOU THERE

Food Safety Management is your roadmap

- Strategy
- Decisions
- Guide for food safety



Image: John Bell, 1999

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WHAT ARE THE BENEFITS TO A FOOD SAFETY PROGRAM?

- Safe food product
- Regulatory requirements
- React quickly to issues
- Minimize potential for recalls
- Process oriented – increase efficiency, productivity
- Better of product for quality/yield
- Buyer's requirements
- Liability
- Consumer satisfaction and adverse publicity



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WHO COVERS WHAT?

USDA

- Meat
- Poultry
- Egg Products
 - Out of shell products and egg quality

FDA

- All other food products
- Dietary supplements
- Seafood
- Juice
- Bottled water
- Infant formulas



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Food Safety

HACCP




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HACCP

Risk Assessment = Evaluation + **Risk Management = Control**



- * Hazard Analysis
- * Critical Control Points
- * Critical Limits
- * Monitoring
- * Corrective Action
- * Recordkeeping
- * Verification/validation



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PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF)

Generally, domestic and foreign food facilities that are required to register with section 415 of the Food, Drug, & Cosmetic Act must comply with the requirements for **risk-based preventive controls** mandated by the **FDA Food Safety Modernization Act (FSMA)** as well as the modernized Current Good Manufacturing Practices (CGMPs) of this rule (unless an exemption applies).





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PREVENTIVE CONTROLS FOR HUMAN FOOD

Risk Assessment = Evaluation + **Risk Management = Control**

- * Hazard Analysis
- * Process controls
- * Allergen controls
- * Sanitation controls
- * Supplier controls



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HACCP VS PCHF: WHAT'S DIFFERENT?

Food Safety Plan Type	Hazard Control	Monitoring
HACCP	"Critical Control Point (CCP)"	Critical limits
PCHF	<ul style="list-style-type: none"> • Process Preventive Control • Sanitation Preventive Control • Allergen Preventive Control • Supply Chain Preventive Control 	Parameters and values


Both use a **science-based** approach to mitigate food safety risks!

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COMPONENTS OF PREVENTIVE CONTROLS FOR HUMAN FOOD

Facilities that need to comply must:

- Conduct a hazard analysis to identify known and reasonably foreseeable hazards
- Biological, chemical, physical
- Identify hazards that need preventive controls
- Monitor and verify preventive controls
- Corrective actions when necessary
- Keep records
- Training, monitoring, verifying, and corrective actions
- **These tasks are performed using a food safety plan**



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PCHF AND YOUR FOOD SAFETY PLAN

Preventive Controls for Human Food introduces the concept of a **food safety plan**

A food safety plan:

- Is a set of written documents
- Is based on food safety principles
- Incorporates hazard analysis, preventive controls, supply-chain programs and a recall plan
- Delineates the procedures to be followed for monitoring corrective actions and verification



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BUT FIRST...

Employee Training & Good Manufacturing Practices (GMP's)



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EMPLOYEE TRAINING

• Under PCHF, all food processors are required to train employees

- Training in food safety as it applies to product and process
- Training in employee hygiene
- Training as it applies to the job
- This responsibility falls on the supervisor



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EMPLOYEE TRAINING

Encourage your employees to report problems

- Problems will arise within your operation
- Employees become sick
- Sanitation/processing criteria not being reached
- Identify issues **before** your product leaves your facility



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GMP'S :WHAT ARE THEY?

GMP's are the support for your food management

- Operating procedures related to food safety
- Support the development of a safe food product
- Includes aspects such as
 - Employee hygiene
 - Plant and grounds condition
 - Sanitary facilities and controls
 - Equipment and utensils
 - Sanitary Operations



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GMPS AND 21 CFR 117

Under the Preventive Controls for Human Food rule, all food processors must implement and follow current GMP's

- 21 CFR 117 Subpart B (GMP regulation)
- While we are not able to cover all current GMP's in this training course, we will briefly overview some of the main ones



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GMP'S: PERSONNEL - HYGIENE

Employee hygiene is required for all employees who manufacture, process, pack, or hold food. Employees are expected to:

- Be excluded from handling food when sick
- Cover any cuts, lesions, and sores
- Maintain adequate personal cleanliness
- Wash hands before handling food or returning to workstations
- Restrain hair in hairnets and beard nets
- Remove unsecured jewelry



For more information on Personnel, please refer to §117.10

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GMP'S: PERSONNEL - HYGIENE

What are some of the things this employee is doing correctly?



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GMP'S: PLANT/GROUNDS

Plant and grounds should be kept in a condition that will protect against the contamination of food, which includes:

- Maintaining the outside of your plant to avoid attracting pests
 - Cutting grass, removing vines/shrubs that could serve as homes for pests, etc.
- Properly draining areas inside and outside your plant
- Implementing waste disposal practices
- Ensuring floors, walls, and ceilings can be cleaned and don't pose risk to food contact surfaces
 - They should not drip water onto any food contact surfaces
- Providing adequate lighting and ventilation
- Covering openings (such as windows) with screens to prevent pest entry



For more information on Plant and Grounds, please refer to §117.20

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GMP'S: SANITARY FACILITIES AND CONTROLS

Each plant must be equipped with adequate sanitary facilities including:

- Safe, potable water
- Adequate plumbing, including backflow protection
- Proper sewage and rubbish disposal
- Proper handwashing and toilet facilities



For more information about Sanitary Facilities and Controls, please refer to §117.37

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GMP'S: SANITARY FACILITIES AND CONTROLS



What is wrong with this picture?

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GMP'S: EQUIPMENT AND UTENSILS

Equipment and utensils should be designed in a way to make them easy to maintain and clean

- Food-contact surfaces must:
 - Be corrosion resistant and made of non-toxic materials
 - Have smooth seams
 - Be maintained to avoid contamination and allergen cross-contact



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GMP'S: EQUIPMENT AND UTENSILS

- Freezers and cold storage compartments must be fitted with a thermometer to show temperature
- Instruments for measuring properties that control microorganism growth (temperature, pH, water activity, etc.) must be accurate and maintained
- For more information on Equipment and Utensils, please refer to §117.40



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GMP'S: SANITARY OPERATIONS

Your facility must be maintained in a clean and sanitary condition. This includes:

- Proper storage and labeling of:
 - Toxic materials
 - Sanitizing chemicals
 - Materials needed for plant/equipment maintenance
- Establishment of pest control practices
- Sanitation of both food-contact surfaces and non food-contact surfaces
 - As needed to protect against allergen cross-contact and contamination of food
- Proper storage of clean portable equipment and utensils



For more information on Sanitary Operations, refer to §117.35

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CLEANING AND SANITIZING

- Cleaning is the physical removal of soil and debris from a surface with potable water and cleaner.
- Sanitizing is the reduction or elimination of microorganisms to a safe level with heat or chemicals.



Surfaces must be cleaned before they can be sanitized!

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GMP'S: SANITARY OPERATIONS

Cleaning and sanitation procedures should include:

- **Why** is it being done?
- **When** is it being done?
- **What** is the procedure?
- **Who** is performing the procedure?
- **How** the procedure being done?
- **Where** is the procedure performed?

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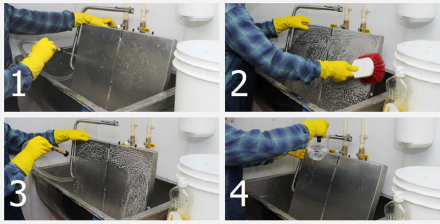
STEPS TO EFFECTIVE CLEANING/SANITIZING

- Remove extraneous food/soil
- Pre-rinse
- Apply cleaner
- Loosen soil and rinse with water
- Inspect
- Apply sanitizer
 - **Apply sanitizer only after effective clean**
 - Use only approved sanitizers in approved concentrations
 - Know sanitizer concentration
 - Breakdown equipment as much as possible



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CLEANING AND SANITIZING



UMaine and Penn State - Extension, Sanitation.

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GMP'S: WRAP-UP

Ensure GMPs are in place. Ways to do this include:

- Training employees on proper GMP's
- **Include importance** - Not just "because I told you to"
- Post reminders around your facility
 - Handwashing reminders
 - Post proper attire reminders in locker rooms or other employee spaces
- Have periodic check-ins or reminder sessions



Ultimately, GMP's are the required building block for all food safety management- without good GMP's, you don't have good food safety practices

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QUESTIONS?

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INTRODUCTION TO A FOOD SAFETY PLAN

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COMPONENTS OF A FOOD SAFETY PLAN

- Recall plan
- Product/process description and flow diagram*
- Hazard analysis
- Preventive controls implemented
- Record keeping

*Not required, but highly recommended

Selected Sections of a Food Safety Plan
Teaching Example: Small Scale Operation

Food Safety Plan
for
Chocolate Chip Cookie

Revised by: _____ Date: _____
Approved by: _____ Date: _____

The intention of this document is to identify hazards and control measures for the production of chocolate chip cookies. This document is not intended to be a substitute for a HACCP plan. It is intended to be a guide for the development of a HACCP plan. The HACCP plan should be developed by a qualified person and should be reviewed and updated as necessary. This document is intended to be used as a guide for the development of a HACCP plan. It is not intended to be a substitute for a HACCP plan. The HACCP plan should be developed by a qualified person and should be reviewed and updated as necessary.

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FOOD SAFETY PLAN: RECALL PLAN

While it will hopefully never be used, an effective recall plan can be the difference between quickly recovering bad product and losing your business

An effective recall plan:

- Includes the names, duties, and contact information of everyone involved in the recall process
- Alerts stores and consumers that a recall is occurring
- Swiftly recovers as much product as possible
- Disposes of product



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IMPORTANCE OF RECALL - PREPARATION/MAJOR CAUSES

Importance:

- Prevent unnecessary consumer illness/death
- Minimize negative publicity
- Minimize civil/criminal actions

Causes for Recalls:

- Undeclared ingredients i.e. allergens
- Pathogenic microorganisms i.e. cross contamination or faulty process
- Foreign objects
- Chemical contamination
- Packaging defects
- Labeling errors



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FOOD SAFETY PLAN: PRODUCT/PROCESS DESCRIPTION

The best place to start your food safety plan is with a product and process description

Product Name(s)	Chocolate Chip Cookie
Product Description, including Important Food Safety Characteristics	All-natural, preservative free, shelf stable fresh baked chocolate chip cookie.
Ingredients	Flour, chocolate chips, butter, white sugar, brown sugar, egg, salt, baking soda, vanilla
Allergens	Wheat, Milk, Egg
Packaging Used	Plastic trays, wrapped with plastic wrap and inserted into cardboard boxes
Intended Use	Ready to eat product
Intended Consumers	General public
Shelf Life	2 months
Labeling Instructions	Ready to eat
Storage and Distribution	Store in cool, dry place.

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FOOD SAFETY PLAN: PROCESS FLOW DIAGRAM

Your process flow diagram is a visual walk-through of all the processes

- Start with receiving your ingredients
- End with storage of final products/shipping

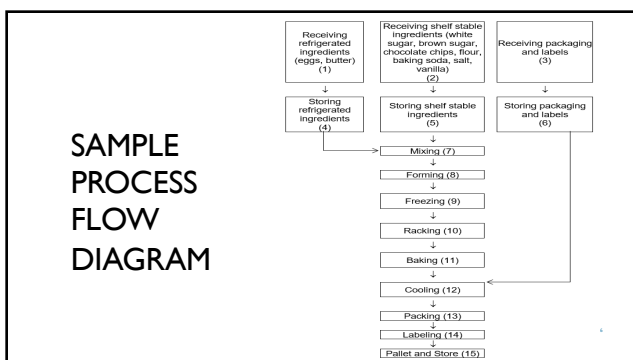
There is no mandatory format for process flow diagrams, they can be made in a variety of ways

Chocolate Chip Cookie Example:

Racking (11): Dough rounds are placed on metal trays in 4 rows of 5. 10 metal trays are placed on each rack before baking.

Baking (12): Full racks are placed on rotating platforms (3 rotations per minute) in walk in ovens and cooked for ≥ 13 minutes at ≥ 350°F, before being removed. Oven temperature is taken using a thermometer and monitored on an exterior temperature display.

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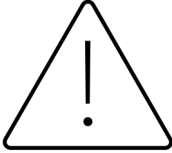


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FOOD SAFETY PLAN: HAZARD ANALYSIS

Your hazard analysis is the basis of your food safety plan - in your hazard analysis you should inspect each processing step to determine if it:

- Introduces a potential food safety hazard
- Controls a potential food safety hazard
- Or enhanced a potential food safety hazard
 - Does it increase the likelihood of a hazard occurring?



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SAMPLE OF "SIMPLE" HAZARD ANALYSIS

(1) Ingredient/processing step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any other food safety hazards occur as a result of this step?	(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 CCP, Allergen, sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
					Yes	No
1) Receiving refrigerated ingredients (eggs, butter)	Biological	Vegetative pathogens such as <i>Salmonella</i>	While pasteurization minimizes the likelihood of <i>Salmonella</i> , USDA recommends the product be used in cooked foods. Experience has shown <i>Salmonella</i> occasionally occurs in this ingredient.	Process Control- subsequent cook step		X
	Chemical	Allergen- Egg, milk	Egg and milk are allergens that must be labeled to inform consumers. Allergen cross-contact is not an issue- all products contain egg and milk.	Allergen Control- allergen labeling at other steps		X
	Physical	None				

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PREVENTIVE CONTROLS

Preventive controls means 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 understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis."



Translation: Preventive controls are science-based procedures you implement to reduce or remove hazards that are found in your food product or process.


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FOOD SAFETY PLAN: RECORD KEEPING

Keeping records of food safety activities performed is important- they're the proof you're doing what you say you are.

What kind of record format should you use?

- There is no required format for how you keep records
- However general requirements for records include
 - Keeping original copies (true or electronic)
 - No erasures if written records are kept
 - Recording of actual values or observations
 - Permanent records (ink or non-editable online)
 - Adequate detail



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INFORMATION IN A RECORD


- Name of record
- Name/location of facility
- Date and time (if applicable) of activity
- Actual measurement or observation
- Product name
- Signature/initials of record keeper
- Signature/initials of record review (and date of review)

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FOOD SAFETY PLAN: RECORD KEEPING

Computerized records are allowed, but should be:

- Equivalent to paper records with hand-written signatures
- Limited to authorized individuals
 - Password protected
- Traceable to older versions
- Reviewed by a trained individual



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PRODUCT ID: Chocolate Chip Cookies PAGE 18 of 18
 PLANT NAME: Cookies Mania ISSUE DATE: 03/03/2015
 ADDRESS: 11 Cookies Land Boulevard, Sweetsville MA 04313 SUPERSEDES: 03/03/2015 Name/location of facility

Sample Record Keeping Log: Metal Detection-Visual Log Name of record

Hazard: Metal Inclusion

Parameters, values or critical limits:
 All mixing bowls and blades are visually inspected for signs of damage.

Procedure: Mixing bowls and blades are properly cleaned and sanitized, following sanitary operation protocols. Once cleaned and sanitized, mixing bowls and blades are inspected for any signs of damage which could lead to metal in foods (grooves, gashes, missing pieces, etc.)

Corrective action:
 Hold all product produced since the previous satisfactory check until it can be run through a metal detector. If it cannot be run through a metal detector, all product produced since the previous satisfactory equipment check.

Accual observation

Date	Date/Time	Product	Batch number	Signs of damage present: mixing bowls (Yes/No)	Signs of damage present: mixer blades (Yes/No)	Production Employee (initials)
				Product damage and touch		

Signature of record keeper

Signature of record review

Verification/Reviewer Signature: Date of Reviewer:

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FOOD SAFETY MANAGEMENT: NEXT STEPS FOR YOUR OPERATION

Determine applicable governing body

- FDA or USDA
- May have other regulatory requirements if making certain foods: i.e. acidified shell-stable food, juice, dairy, meat and poultry, or seafood

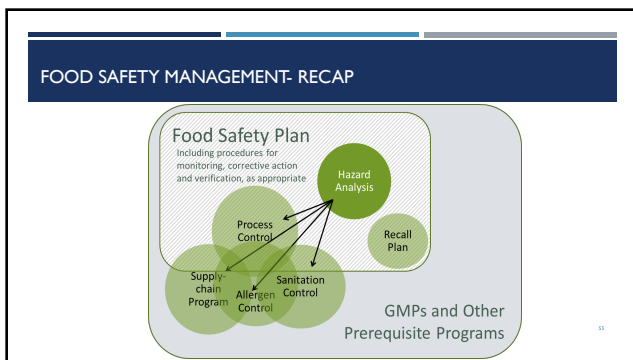
Determine Preventive Controls Requirements

- Even if you are partially exempt, you need to file an attestation form with the FDA proving exemption
- Ensure GMP's are implemented and followed
 - Best way to do so is through good employee training
- Develop a recall plan for your operation
 - Can be helpful to perform mock recall to test efficiency

FDA FOOD SAFETY MODERNIZATION ACT

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QUESTIONS?

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HAZARD ANALYSIS

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REMINDER: FOOD SAFETY VS. FOOD QUALITY

<p>Food Safety: Focuses on hazards that pose a risk to human health, including:</p> <ul style="list-style-type: none">• Biological• Chemical• Physical	<p>Food Quality: Focuses on quality factors that are desirable in a food product, including:</p> <ul style="list-style-type: none">• Consistent product size/texture• Coloration• Maintain aroma & flavor (avoid rancidity/off-odors)
---	--

A hazard analysis focuses on food **safety** concerns

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STEPS FOR CONDUCTING A HAZARD ANALYSIS

1. List ingredient/processing steps
2. Identify potential food safety hazards introduced, controlled, or enhanced at these steps
3. Determine if hazard requires a preventive control
4. Justify decision
5. Identify preventive controls for significant hazard
6. Determine if preventive control is applied at that step

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HAZARD ANALYSIS STEP 1: LIST INGREDIENTS/PROCESSING STEPS

Listing your ingredients and processing steps needs to be the first thing done:

- It's like making a grocery list - once you have everything in front of you, you can plan accordingly
- No grocery list = forgotten items
- No ingredient/processing list = **forgotten steps and possible food safety risks missed**

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HAZARD ANALYSIS STEP 2: IDENTIFY POTENTIAL FOOD SAFETY HAZARDS INTRODUCED, CONTROLLED, OR ENHANCED AT THIS STEP

Identify potential hazards at each step

- Look at historical data
- Recalls for similar products
- Scientific literature
- Resources from this class
- FDA guidance document



Ask for help

- Extension
- Regulatory (state and federal)
- Food safety consultants

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HAZARD ANALYSIS STEP 2: IDENTIFY POTENTIAL FOOD SAFETY HAZARDS INTRODUCED, CONTROLLED, OR ENHANCED AT THIS STEP

Is the hazard introduced, controlled, or enhanced?

- Introduced
 - Ex) new ingredient
- Controlled
 - Ex) processing steps or storage conditions
- Enhanced
 - Ex) ingredient additions or processing steps

If the hazard plays any roll in the step, include it!


- Helps ensure it's not forgotten later

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HAZARD ANALYSIS STEP 3: DETERMINE IF HAZARD REQUIRES A PREVENTIVE CONTROL

Determine if hazard requires a documented Preventive Control

- Hazard analysis is plant, process, and product dependent
- Utilize resources to determine the potential hazards at any step
 - Historical data
 - Validated studies
 - Guidance documents
- Identified hazards require a preventive control



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HAZARD ANALYSIS STEP 3: DETERMINE IF HAZARD REQUIRES A PREVENTIVE CONTROL


When identifying hazards, consider:

- The severity of potential illness or injury AND
- Likelihood of occurrence

If both are low or unlikely, the hazard may not require a preventive control

Example:

- Issue: Pesticide residue on produce
- Justification: **What could be a possible justification?**



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HAZARD ANALYSIS STEP 4: JUSTIFY YOUR DECISION

Justifying your decision provides:

- Information to auditors/inspectors
- A reminder regarding your thought process

If you determine the potential hazard requires a preventive control, justify why

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HAZARD ANALYSIS STEP 5: IDENTIFY PREVENTIVE CONTROLS FOR SIGNIFICANT HAZARD

There are 4 types of preventive controls:

- 1. Process Controls** - Processing steps taken to control a hazard within your product
 - Examples: cooking, metal detecting
- 2. Allergen Controls**: Controls to alert consumer to allergens within your product, and control allergen cross contact
 - Examples: allergen labeling and sanitation to prevent cross-contact
- 3. Sanitation Controls**: Sanitation steps performed specifically for the control of a hazard identified at a specific processing step
 - Examples: monitoring for environmental pathogens, sanitation to eliminate cross-contamination
- 4. Supply-Chain Controls**: Controls applied by your supplier, removing the need for you to apply the control- must be documented
 - Example: supplier pasteurizing milk before you receive it

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HAZARD ANALYSIS STEP 6: IDENTIFY IF THE PREVENTIVE CONTROL IS APPLIED AT THIS STEP

(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? <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
1) Receiving refrigerated ingredients (eggs, butter)	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, milk	X		Egg and milk are allergens that must be labeled to inform consumers. Allergen cross-contact is not an issue- all products contain egg and milk.	Allergen Control- allergen labeling at other steps		X
P None							


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HAZARD ANALYSIS STEP 6: IDENTIFY IF THE PREVENTIVE CONTROL IS APPLIED AT THIS STEP

Helps ensure preventive controls are applied when needed

- This can be a yes or no answer
- Even if it's no, this step is an important reminder that
 - The hazard plays a role in this step **and**
 - That a preventive control needs to be applied at a subsequent step in the process
- In the previous example (receiving refrigerated ingredients)
 - *Salmonella* is first introduced as a biological hazard through receipt of eggs
 - While it's not controlled at receipt, making note that it exists will remind you that it needs to be controlled at a later step



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HAZARD ANALYSIS STEP 1: LIST INGREDIENTS/PROCESSING STEPS


(1) Ingredient/ Processing Step	



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HAZARD ANALYSIS STEP 2: IDENTIFY POTENTIAL FOOD SAFETY HAZARDS INTRODUCED, CONTROLLED, OR ENHANCED AT THIS STEP

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step
11) Baking	



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HAZARD ANALYSIS STEP 3: DETERMINE IF HAZARD REQUIRES A PREVENTIVE CONTROL

(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? Yes No	
11) Baking	B Survival of vegetative pathogens, such as <i>Salmonella</i>	X	
	C None		
	P None		

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HAZARD ANALYSIS STEP 4: JUSTIFY YOUR DECISION

(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? Yes No	(4) Justify your decision for column 3
11) Baking	B Survival of vegetative pathogens, such as <i>Salmonella</i>	X	
	C None		
	P None		

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HAZARD ANALYSIS STEP 5: IDENTIFY PREVENTIVE CONTROLS FOR SIGNIFICANT HAZARD

(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? Yes 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? <i>Process including CCPs, Allergen, Sanitation, Single-chains, other preventive control</i>
11) Baking	B Survival of vegetative pathogens, such as <i>Salmonella</i>	X	Thorough cooking is required to all vegetative pathogens	
	C None			
	P None			

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HAZARD ANALYSIS STEP 6: IDENTIFY IF THE PREVENTIVE CONTROL IS APPLIED AT THIS STEP

(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? <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
11) Baking	B Survival of vegetative pathogens, such as Salmonella	X		Thorough cooking is required to kill vegetative pathogens	Process Control-time/temperature to achieve a lethal temperature (see validation study)		
	C None						
	P None						



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HAZARD ANALYSIS: NEXT STEPS FOR YOUR PRODUCT

- While performing a hazard analysis can be daunting, it is critical for ensuring the safety of your product.
- Here are some things to consider when conducting a hazard analysis for your product:
 - Don't rush
 - Assemble a team
 - Make a flow diagram
 - Describe your product and process
 - Use resources



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HAZARD ANALYSIS: WRAP-UP

A good food safety plan relies on the hazard analysis

- If you don't identify your hazards, you can't control them
- A thorough hazard analysis allows you to keep your product safe



Just like food safety management is the roadmap of your operation, your hazard analysis is the roadmap for your food safety plan

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QUESTIONS?

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PREVENTIVE CONTROLS

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PREVENTIVE CONTROLS: WHAT ARE THEY?

- Remember: 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
 - Allergen
 - Sanitation
 - Supply chain



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CONTROLS IN YOUR OPERATION

Let's discuss:

1. What is a potential control in our chocolate chip cookie example?
2. What is one food safety control you already do?
3. What records do you keep for this control? Why?

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PROCESS PREVENTIVE CONTROLS

"Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods.

Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

- Parameters associated with the control of the hazard; and
- 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."

Taken from (21 CFR 117.135(c)(1))

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PROCESS PREVENTIVE CONTROLS

"Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods.

Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

- Parameters associated with the control of the hazard; and
- 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."

Taken from (21 CFR 117.135(c)(1))

What does this mean?




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PROCESS PREVENTIVE CONTROLS

Examples of process preventive controls

- Lowering pH (Image 1: pH probe)
- Reducing water activity (Image 2: water activity meter)
- Application of thermal treatment (Image 3: thermometer)




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REQUIREMENTS FOR PROCESS PREVENTIVE CONTROLS

Process preventive controls require:

1. Establishing minimum/maximum values (critical limits)
2. Monitoring procedures
3. Corrective action procedures
4. Process validation
5. Process verification



*Records are required for each of these steps

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PROCESS PREVENTIVE CONTROLS STEP 1: ESTABLISHMENT OF CRITICAL LIMITS

Critical limits

- The maximum/minimum value a preventive control must reach to minimize or prevent the targeted hazard from taking place
- **Critical limit not reached = unsafe food product**

Your records should show that critical limits were met for every batch

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PROCESS PREVENTIVE CONTROLS STEP 2: MONITORING

How do you ensure your critical limits are met? **Monitoring**

Elements of monitoring

- **What** to monitor
- **How** to monitor
- **How often** (frequency) to monitor
- **Who** will monitor



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PROCESS PREVENTIVE CONTROLS STEP 3: CORRECTIVE ACTIONS

What do you do if something goes wrong?

Be prepared – have an idea of what you would do **beforehand**:

- Reprocess?
- Product Hold?
- Destroy?



CORRECTIVE ACTIONS

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PROCESS PREVENTIVE CONTROLS STEP 3: CORRECTIVE ACTIONS

Record keeping for correction actions includes:

- Product identification
- Details of the deviation from the parameter
- Root cause for the deviation
- Actions taken to prevent this from reoccurring
- Disposition of implicated product
- Corrective action verification



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CORRECTIVE ACTION EXAMPLE	
Corrective Action Form	
Date of record:	September 6, 2019
Date and time of deviation:	1:42PM
Description of Deviation: Paddle mixer was observed to have a nick in the blade at the post-production sanitation inspection. The issue was observed by the cleaning and sanitation operator.	
Actions Take to Restore Order to the Process:	
<ol style="list-style-type: none"> 1. Production was halted when the error was discovered. 2. The entire days production was segregated based on production lot. 3. All implicated product was sent to over to XYZ Productions for use of their metal detector unit. 4. Maintenance inspected the unit to ensure that the blade alignment is not too close to the bowl to reduce metal on metal contact. 	
Person (name & signature) who took action:	C.C. Ahoy
Amount of product involved in deviation:	15 pallets (512 cases)
Evaluation of product involved with deviation:	Every case was sent through a calibrated metal detector. One case did not pass the metal detection inspection, was further investigated and destroyed.
Final disposition of product:	Implicated product was disposed. All other product was distributed into market.
Reviewed by (Name & Signature): C.C. Ahoy	Date Reviewed: 09/11/19

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PROCESS PREVENTIVE CONTROLS STEP 4: VALIDATION

"Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards."
- 21 CFR 117.3

Translation: Does my food safety plan control the hazards I identified?

*Note: This should be done upfront, before a food safety plan is implemented.

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PROCESS PREVENTIVE CONTROLS STEP 4: VALIDATION


Validation is the scientific evidence that your process preventive controls will control what you say they will

Ways to validate controls can include:

- Using scientific literature
- Expert opinion/recommendations
- In-plant tests
- Using mathematical models

Validation should take place

- Before implementing a food safety plan (if possible)
- When a change in your process occurs
- When reanalysis indicates a need



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VALIDATION IS SCIENCE-BASED!

The extension specialist provided Cookie Processor A's PCQI with a published study by Lathrop et al., (2014) on survival of Salmonella during baking of peanut butter cookies. The published study showed that peanut butter cookie dough made with peanut butter inoculated with high levels of Salmonella (28 g portions of dough, water activity (aw) of 0.82) and baked at 350°F (177°C) for 15 minutes had no detectable Salmonella. Cookies baked for 13 minutes showed at least a 5.2 log reduction in Salmonella. In that published study, the cookie temperature at the end of 15 minutes was 229°F (109°C).



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ESSENTIAL PROCESSING CONTROLS

The extension specialist identified the following processing parameters that need critical limits for food safety in Cookie Processor A's heat treatment:

- Convection oven temperature (°F) to achieve specified minimum product temperature;
- Baking time in oven (minutes); and
- Dough delivery process resulting in the specified cookie portion weight (g)



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ESTABLISH CRITICAL LIMITS

Based on the information obtained from the extension specialist, Cookie Processor A's PCQI established three critical limits to produce the cookies to ensure adequate lethality:

- The critical limit (minimum value) for the baking temperature is 350°F (177°C);
- The critical limit (minimum value) for the baking time is 13 minutes; and
- The critical limit (maximum value) for the cookie dough portion size is 28 g



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Bake Step Validation Study¹

The extension specialist provided Cookie Processor A's PCQI with a published study by Lathrop et al., (2014) on survival of Salmonella during baking of peanut butter cookies. The published study showed that peanut butter cookie dough made with peanut butter inoculated with high levels of Salmonella (28 g portions of dough, water activity (aw) of 0.82) and baked at 350°F (177°C) for 15 minutes had no detectable Salmonella. Cookies baked for 13 minutes showed at least a 5.2 log reduction in Salmonella. In that published study, the cookie temperature at the end of 15 minutes was 239°F (119°C).

The extension specialist identified the following processing parameters that need critical limits for food safety in Cookie Processor A's heat treatment:

- Convection oven temperature (°F) to achieve specified minimum product temperature;
- Baking time in oven (minutes); and
- Dough delivery process resulting in the specified cookie portion weight (g)


To determine critical limits for those processing parameters when baking cookies in batches in Cookie Processor A's convection oven, and demonstrate that these critical limits can be achieved in Cookie Processor A's convection oven, the extension specialist conducted in-house heat distribution tests on Cookie Processor A's ovens and heat penetration tests on the cookies using a fully loaded oven (each oven rack contained a full tray of cookies, deposited in 28 g portions using a dough depositor). These in-house heat distribution and heat penetration tests showed that all parts of each of Cookie Processor A's oven were at or above 350°F (177°C) when the ovens were set at that temperature and that the coldest cookie temperature was above 230°F (110°C) after 13 minutes. In addition, aw determinations by an outside laboratory on the cookie dough were equal to or greater than 0.82 using Cookie Processor A's recipes.

Based on the in-house tests, and the published study by Lathrop et al. (Lathrop, 2014), the extension specialist determined that the baking process of 350°F or greater for a minimum of 13 minutes (operating limit of 15 minutes) would provide adequate lethality for Salmonella for the recipe tested, so long as cookie dough portions did not exceed 28 g. The extension specialist informed Cookie Processor A that any subsequent change to the cookie recipe should be evaluated to determine whether it would impact these determinations.


Based on the information obtained from the extension specialist, Cookie Processor A's PCQI established three critical limits for the production of the cookies to ensure adequate lethality:

- The critical limit (minimum value) for the baking temperature is 350°F (177°C);
- The critical limit (minimum value) for the baking time is 13 minutes; and
- The critical limit (maximum value) for the cookie dough portion size is 28 g


¹Adapted from FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry Draft Guidance (Pages 156-161)



Science-based



Essential Processing Parameters



Established Critical Limits


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PROCESS PREVENTIVE CONTROLS STEP 5: VERIFICATION

“Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.”

- 21 CFR 117.3

What does this mean?



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PROCESS PREVENTIVE CONTROLS STEP 5: VERIFICATION

Verification activities take many forms, and can include:

- Record review
- Checking equipment calibration
- Product sampling and testing
- Visual inspection of labels for allergen information
- Environmental monitoring
- 3rd party audits

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VALIDATION AND VERIFICATION REVIEW

Validation

- How do I know my control will do what I say it will?
- **Required for process preventive controls**

Verification


- How do I know if my control is doing what I say it will?
- **Required for ALL preventive controls**

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PROCESS PREVENTIVE CONTROLS: SUMMARY


Process Preventive Controls

- Validated and verified procedures to protect against hazards in your product
- Must have
 - Documentation
 - Critical limits
 - Monitoring activities




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ALLERGEN PREVENTIVE CONTROLS

 **Remember:** There are 8 allergens that must be labeled:

1. Eggs	2. Milk	3. Peanuts
4. Soy	5. Wheat	6. Tree nuts
7. Fish	8. Crustacean shellfish	

 **If you have an allergen, you have a chemical hazard and therefore need a food safety plan and allergen preventive control**

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ALLERGEN PREVENTIVE CONTROLS: REQUIREMENTS

Allergen preventive controls are implemented as one of two things:

- Allergen Labeling**
 - Alert the consumer that the allergen is in the food product
 - Ensure labels accurately
 - State allergen **and**
 - Are on the correct product
- Allergen Cross-Contact**
 - Typically done when a facility make multiple products with different allergens
 - Clean all shared equipment
 - Avoid in-processing and post-processing allergen cross-contact

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ALLERGEN PREVENTIVE CONTROLS: PREVENT CROSS CONTACT

If you have multiple products with different allergens, have a plan in place to prevent cross-contact

- If you process multiple products in a day start with the product with:
 - The least allergens
 - No unique allergens
- Finish with the product with the most allergens/unique allergens
- This reduces risk of cross-contact

Zoning

- It may be helpful to have certain equipment or areas that are "allergen free" or contain only products with certain allergens

Two types

Allergen labeling	Allergen cross-contact
-------------------	------------------------

↓

Undeclared allergens are the most common cause for recall- check your labels

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SANITATION PREVENTIVE CONTROLS

Sanitation performed specifically for an identified hazard

- Sanitizing something is not the same as a sanitation preventive control

Sanitation controls are typically implemented to:

- Control the potential presence of environmental pathogens (such as *Listeria*) in your processing environment
- Reduce the risk of cross-contamination
- Raw material to cooked product
- For example, if the cookie dough was hand formed on a surface that also was used to package cooked product, you would want to implement a sanitation preventive control



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SANITATION PREVENTIVE CONTROLS

How would you know if a sanitation procedure was a preventive control or not?



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SANITATION PREVENTIVE CONTROLS: ENVIRONMENTAL MONITORING

Implemented when environmental pathogens are identified as a hazard

- Sampling and testing procedures to find target pathogen
- Often in facilities with ready-to-eat products
- Should be facility specific



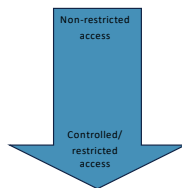
An effective program tries to find the food safety issue (pathogen and/or allergen) before it contaminates the food that enters commerce.

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SANITATION PREVENTIVE CONTROLS: HYGIENIC ZONING

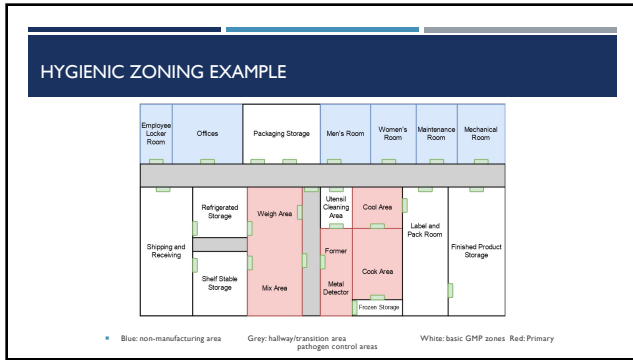
Different areas will require different levels of hygiene

- Non-manufacturing areas: offices, maintenance shop, employee areas
- Transition areas: entry rooms, hallways that lead into GMP areas
- Basic GMP areas: receiving, storage, shipping
- Primary pathogen control areas: processing floor, areas where hazards are controlled

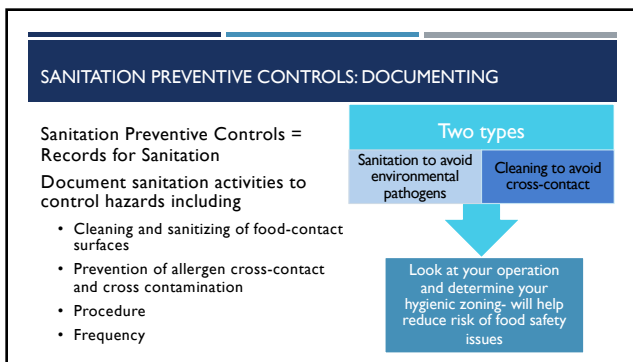


You can implement hygienic zoning regardless of whether you have sanitation preventive controls or not

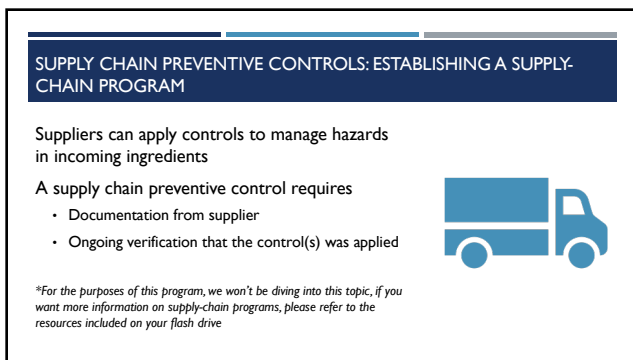
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NEXT STEPS: PREVENTIVE CONTROLS IN YOUR OPERATION

Considerations for existing controls:

- Ensure the control is effective
 - Science to support control- resources on flash drive
 - Validate control works in your operation
- Document the controls
- Examples
 - Label identification for allergen control
 - Measurement of temperature




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PREVENTIVE CONTROLS SUMMARY

Food safety focuses on hazards that pose a risk to human health: biological, chemical, and physical

- Preventive Controls ensure food safety
 - Process controls
 - Allergen controls
 - Sanitation controls
 - Supply chain controls
- Process controls need a science-based validation
- Food safety preventive strategies must be monitored
- Established record keeping procedures for monitoring activities
- Verification activities ensure the Food Safety Plan is being implemented as written



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QUESTIONS?

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MODIFIED REQUIREMENTS FOR CERTAIN QUALIFIED PROCESSORS & ATTESTATIONS

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FSMA


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

Accredited 3 rd 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 C
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WHO IS COVERED BY THE PREVENTIVE CONTROLS FOR HUMAN FOOD RULE?

- Facilities that manufacture, process, pack, or hold human food in general, facilities required to register with FDA under section 415 of the Food, Drug, and Cosmetic Act
 - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply



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Adapted from the FSMA 101 Check Sheet

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PC FOR HUMAN FOOD MIXED TYPE FACILITY EXEMPTION

- Applicable to individuals that also process foods
- Examples of low risk processing activities:
 - Chopping, coring, cutting, peeling, pitting, shredding, slicing fruits and vegetables that have a pH < 4.2
 - Drying/dehydrating cut fruits and vegetables with a pH < 4.2
 - Freezing fruits and vegetables with pH < 4.2
 - More

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WHAT IF MY FACILITY IS COVERED UNDER THE PREVENTIVE CONTROLS RULE?

- At least one individual must attend the Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls Qualified Individual (PCQI) course
- Conduct a Hazard Analysis
- Develop a Food Safety Plan
- Register with FDA
- FDA inspection

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MODIFIED REQUIREMENTS

- Foods subject to HACCP regulations (seafood and juice)
 - 21 CFR 123; 21 CFR 120
- Food subject to low-acid canned food regulations (only with respect to microbiological hazards)
 - 21 CFR 113
- Dietary supplements
 - 21 CFR 111
- Foods subject to produce safety requirements
- Alcoholic beverages

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MODIFIED REQUIREMENTS CONTINUED

- Facilities that only store unexposed packaged food
- Certain storage facilities such as grain elevators and warehouses that only store raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing
- Activities within the definition of "farm," including farm activities that are covered by the produce rule**
- Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods




Adapted from FSIS/CD/Quality/CFR Chart Section 123

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MODIFIED REQUIREMENT FACILITIES

- "Qualified" facilities (21 CFR 117.5(a))
- Very small businesses (less than \$1 million in total annual sales of human food plus the value of food held without sale)
- Food sales averaging less than \$500,000 per year during the last three years AND sales to qualified end-users must exceed sales to others
- Exempt from hazard analysis and risk-based preventive controls when certain documentation is provided




FSIS State Exemption Flow Chart: <https://www.fsis.usda.gov/food-safety-inspection-service/compliance/qualified-facility-exemption>

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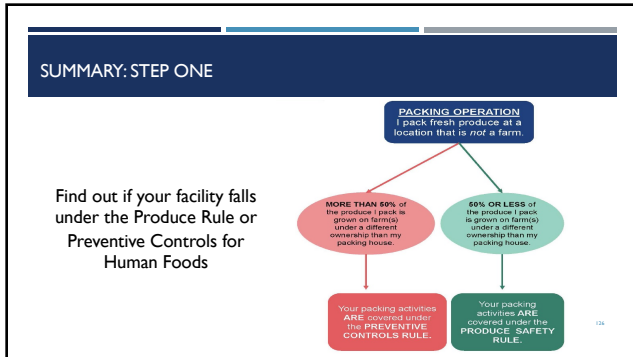
WHAT IF I AM CONSIDERED A MODIFIED REQUIREMENT FACILITY UNDER THE PC RULE?

- Comply with federal cGMPs
- Submit attestation to FDA that states they meet the criteria of a very small business
 - Link to FDA Attestations
 - Link to Coalition
- Recall plan

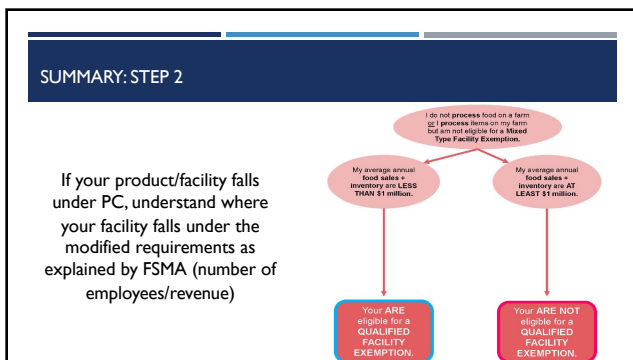


<https://www.sustainableagriculturecoalition.com/gmp-certified-manufacturing/>

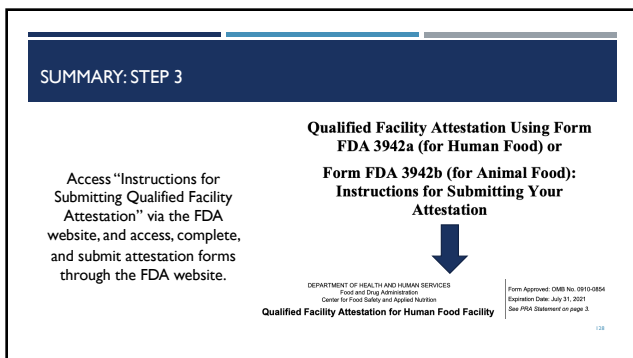
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SUMMARY: STEP 4

Comply with federal cGMPs

Subpart B—Current Good Manufacturing Practice

- \$117.10 Personnel.
- \$117.20 Plant and grounds.
- \$117.35 Sanitary operations.
- \$117.37 Sanitary facilities and controls.
- \$117.40 Equipment and utensils.
- \$117.80 Processes and controls.
- \$117.93 Warehousing and distribution.
- \$117.95 Holding and distribution of human food by-products for use as animal food.
- \$117.110 Defect action levels.

UPDATES TO THE CURRENT GOOD MANUFACTURING PRACTICES (CGMPs)

- Some provisions that used to be nonbinding, such as education and training, are now binding.
 - Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.
 - Such employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold food that is clean and safe. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility and the individual's assigned duties.
- The FDA's longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text.
- CGMPs also now include a provision for holding and distribution of human food by-products that are used for animal food.

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COURSE WRAP-UP


- A food safety hazard is any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury
- It is important to incorporate food safety planning into your product design and day-to-day operation.
- Establish monitoring procedures for food safety controls and food quality attributes to ensure the best product.
- Remember: 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
 - Allergen
 - Sanitation
 - Supply chain

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COURSE WRAP-UP

- GMP's are a regulatory requirement.
- Employees must understand their role in the ensuring that a safe food is produced. Training is a requirement.
- A Food Safety Plan is a set of written documents based on food safety principles, that includes:
 - Hazard analysis
 - Preventive controls
 - Monitoring
 - Record keeping
 - Verification
- There are exemptions, modified requirements, and attestations that food processors should consider and file as soon as possible (resources available on FDA website)

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FUTURE PROGRAM SUPPORT



Scholarships awarded to attend the PCQI Regulatory Compliance Course to those that participate in our Preventive Controls Practical Implementation Workshop.

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PREVENTIVE CONTROLS PROGRAM TIMELINE		
Training	Content	Milestone Timing
PCI	Introduction to Preventive Controls Webinar	August 20, August 27, September 10, September 16, October 6
PCII (you are here!)	Practical Implementation Workshop	September 24 @ 1pm, October 21 @ 9am, November 12 @ 2pm
PCIII	FSPCA Preventive Controls Qualified Individual Course	January 6, 7, 8 (8:30am – 5pm)
PCIV	Develop FSPs with different processors Virtual FSP Development Workshops with Others	February-April (TBD)

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PRACTICAL IMPLEMENTATION OF PREVENTIVE CONTROLS WORKSHOP

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