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

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

Food Safety Management is your roadmap

- Strategy
- Decisions
- Guide for food safety

IF YOU DON’T KNOW WHERE YOU’RE GOING, YOU NEED A “ROADMAP” TO TAKE YOU THERE
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

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

Food Safety

HACCP

Meat & poultry
9 CFR 304

Juice
21 CFR 101/102

Seafood
21 CFR 123

Low Acid
21 CFR 113

Preventive Controls
* Dairy – also PMO
* Acidified – also comply with 21 CFR 114
HACCP

Risk Assessment = Evaluation + Risk Management = Control

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

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).

PREVENTIVE CONTROLS FOR HUMAN FOOD

Risk Assessment = Evaluation + Risk Management = Control

* Hazard Analysis
* Process controls
* Allergen controls
* Sanitation controls
* Supplier controls
HACCP VS PCHF: WHAT’S DIFFERENT?

<table>
<thead>
<tr>
<th>Food Safety Plan Type</th>
<th>Hazard Control</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>HACCP</td>
<td>&quot;Critical Control Point (CCP)&quot;</td>
<td>Critical limits</td>
</tr>
</tbody>
</table>
| PCHF                  | • 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!

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

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
BUT FIRST…

Employee Training &
Good Manufacturing Practices (GMP’s)

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

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
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

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

GMPS: 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
GMP’s: Personnel - Hygiene

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

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

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
GMP’S: SANITARY FACILITIES AND CONTROLS

What is wrong with this picture?

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

- 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
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

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!

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?
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

CLEANING AND SANITIZING

GMP’S: WRAP-UP

Ensure GMPs are in place. Ways to do this include:
- Training employees on proper GMPs
- 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, GMPs are the required building block for all food safety management; without good GMPs, you don’t have good food safety practices.
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

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

IMPORTANCE OF RECALL - PREPARATION/MAJOR CAUSES

Importance:
- Prevent unnecessary consumer illness/death
- Minimize negative publicity
- Minimize environmental 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
**FOOD SAFETY PLAN: PRODUCT/PROCESS DESCRIPTION**

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

<table>
<thead>
<tr>
<th>Product Name(s)</th>
<th>Chocolate Chip Cookie</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Description, including prepared food table</strong></td>
<td>Almond, preservative free, shelf stable fresh baked chocolate chip cookies</td>
</tr>
<tr>
<td><strong>Ingredients</strong></td>
<td>Flour, chocolate chips, butter, white sugar, brown sugar, egg, salt, baking soda, vanilla</td>
</tr>
<tr>
<td><strong>Allergens</strong></td>
<td>Wheat, milk, egg</td>
</tr>
<tr>
<td><strong>Packaging Used</strong></td>
<td>Plastic bags, wrapped with plastic wrap and inserted into cardboard boxes</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>Ready to eat at retail</td>
</tr>
<tr>
<td><strong>Intended Consumers</strong></td>
<td>General public</td>
</tr>
<tr>
<td><strong>Shelf Life</strong></td>
<td>2 months</td>
</tr>
<tr>
<td><strong>Labeling instructions</strong></td>
<td>Read as is</td>
</tr>
<tr>
<td><strong>Storage and Distribution</strong></td>
<td>Store in cool, dry place</td>
</tr>
</tbody>
</table>

**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/distribution

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.

**SAMPLE PROCESS FLOW DIAGRAM**

[Diagram showing process flow with steps labeled 1 to 8]
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?

SAMPLE OF “SIMPLE” HAZARD ANALYSIS

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.
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

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)

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
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 shelf-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
  - Can be helpful to perform mock recall to test efficiency

Records must be accurate and complete in order to be valid

FOOD SAFETY MANAGEMENT: RECAP

Food Safety Plan
- Including procedures for monitoring, corrective actions and verification, as appropriate
- Process Controls
- Sanitation Control
- Hazard Analysis
- Recall Plan
- GMPs and Other Prerequisite Programs

Taken from FSPC A Preventive Controls for Human Food Course
HAZARD ANALYSIS

REMINDER: FOOD SAFETY VS. FOOD QUALITY

Food Safety focuses on hazards that pose a risk to human health, including:
- Biological
- Chemical
- Physical

Food Quality focuses on quality factors that are desirable in a food product, including:
- Consistent product appearance
- Coloration
- Maintain aroma & flavor (avoid rancidity/off-odors)

A hazard analysis focuses on food safety concerns.
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

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

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
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 role in the step, include it!
- Helps ensure it's not forgotten later

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

Determine if a documented Preventive Control is required
- 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

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?
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

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, metallic 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-contamination

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

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

- [ ] Receiving ingredients (raw, bulk)
- [ ] Processing steps
- [ ] Sanitation
- [ ] Allergen
- [ ] Supply-Chain Controls

If yes, what corrective action is needed to ensure compliance with all legal requirements.
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.

HAZARD ANALYSIS STEP 1: LIST INGREDIENTS/PROCESSING STEPS

HAZARD ANALYSIS STEP 2: IDENTIFY POTENTIAL FOOD SAFETY HAZARDS INTRODUCED, CONTROLLED, OR ENHANCED AT THIS STEP
### HAZARD ANALYSIS STEP 3: DETERMINE IF HAZARD REQUIRES A PREVENTIVE CONTROL

<table>
<thead>
<tr>
<th>Processing/Preparation Step</th>
<th>Hazard Identified:</th>
<th>Is the hazard eliminated by this step?</th>
<th>Preventive Control Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baking</td>
<td>Salmonella</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### HAZARD ANALYSIS STEP 4: JUSTIFY YOUR DECISION

<table>
<thead>
<tr>
<th>Processing/Preparation Step</th>
<th>Hazard Identified:</th>
<th>Justify your decision for column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baking</td>
<td>Salmonella</td>
<td>Preventive control is required to</td>
</tr>
</tbody>
</table>
HAZARD ANALYSIS STEP 6: IDENTIFY IF THE PREVENTIVE CONTROL IS APPLIED AT THIS STEP

<table>
<thead>
<tr>
<th>Preventive Control</th>
<th>Hazardous Pathogen</th>
<th>Is there a preventive control?</th>
<th>Preventive Control Applied at This Step?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>F</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>None</td>
</tr>
</tbody>
</table>

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

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
QUESTIONS?

PREVENTIVE CONTROLS

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
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?

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?
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)

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

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
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

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

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
**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 Taken to Restore Order to the Process:

1. Production was halted when the error was discovered.
2. The entire day's 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 run through a calibrated metal detector. One case did not pass the metal detectors 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 control.

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
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).

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).

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.
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?

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
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

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

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.
ALLERGEN PREVENTIVE CONTROLS: REQUIREMENTS

1. Allergen Labeling
   - Alert the consumer that the allergen is in the food product
   - Ensure labels accurately
   - State allergen and
   - Are on the correct product

2. Allergen Cross-Contact
   - Typically done when a facility makes multiple products with different allergens
   - Clean all shared equipment
   - Avoid in-processing and post-processing allergen cross-contact

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

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
SANITATION PREVENTIVE CONTROLS

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

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.

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.
HYGIENIC ZONING EXAMPLE

Blue: non-manufacturing area
Grey: hallway/transition area
White: basic GMP zones
Red: Primary pathogen control areas

SANITATION PREVENTIVE CONTROLS: DOCUMENTING

Sanitation Preventive Controls = Records for Sanitation
Document sanitation activities to control hazards including
- Cleaning and sanitizing of food-contact surfaces
- Prevention of allergen cross-contact and cross contamination
- Procedure
- Frequency

Two types
- Sanitation to avoid environmental pathogens
- Cleaning to avoid cross-contact

Look at your operation and determine your hygienic zoning will help reduce risk of food safety issues

SUPPLY CHAIN PREVENTIVE CONTROLS: ESTABLISHING A SUPPLY-CHAIN PROGRAM

Suppliers can apply controls to manage hazards in incoming ingredients
A supply chain preventive control requires
- Documentation from supplier
- Ongoing verification that the control(s) was applied

*For the purposes of this program, we won’t be diving into this topic, if you want more information on supply-chain programs, please refer to the resources included on your flash drive
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

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

QUESTIONS?
MODIFIED REQUIREMENTS FOR CERTAIN QUALIFIED PROCESSORS & ATTESTATIONS

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

Adapted from Erin DiCaprio – UC Davis Extension
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

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

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
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, packaging and holding activities conducted by small/very small businesses on farms for specific foods

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 $300,000 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

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
SUMMARY: STEP ONE

Find out if your facility falls under the Produce Rule or Preventive Controls for Human Foods

SUMMARY: STEP 2

If your product/facility falls under PC, understand where your facility falls under the modified requirements as explained by FSMA (number of employees/revenue)

SUMMARY: STEP 3

Access "Instructions for Submitting Qualified Facility Attestation" via the FDA website, and access, complete, and submit attestation forms through the FDA website.
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
- Allergens
- Sanitation
- Supply chain

GMP's are a regulatory requirement.

Employees must understand their role in 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).
FUTURE PROGRAM SUPPORT

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

PREVENTIVE CONTROLS PROGRAM TIMELINE

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