



# ***Preventive Controls for Human Food***

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**Center for Dairy Research** *“Solution Based Research Backed by Experience, Passion and Tradition”*



# Preventive Controls Definition

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

# Preventive Controls May Include:

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- Process preventive controls
- Food allergen preventive controls
- Sanitation preventive controls
- Supply-chain program
- Recall plan
- Other preventive controls

# Potential Preventive Control Examples

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## Biological hazards

- Process controls that kill pathogens
  - E.g., cooking
- Process controls that prevent growth; e.g.,
  - Time/temperature controls
  - Checking formulation
- Supply-chain programs for sensitive ingredients used without a kill step
- Sanitation controls that prevent recontamination

## Chemical hazards

- Supply-chain programs
- Allergen labeling
- Sanitation controls to prevent allergen cross-contact

## Physical hazards

- Process controls such as
  - Filtering, metal detection, X-ray devices

# Other Preventive Control Considerations

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- Does it actually control the identified hazard?
- Can you monitor the control?
- Does it have an effect on other preventive controls?
- How much process variability exists where the control is applied?
- How severe are the consequences if the control fails?
- Is the control specifically applied to eliminate or reduce the level of a hazard?
- Does the control enhance other controls?

# Purpose of Monitoring Process Controls

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- To track the operation of the process and enable the identification of trends toward a critical limit that may trigger process adjustments
- To identify when there is a loss of control or when a “deviation” from a critical limit occurs
- To provide written documentation that can be used to verify that the process is under control

# Pulling It All Together

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- Hazard analysis process identifies hazards requiring a preventive control
  - Process preventive controls
  - Food allergen preventive controls
  - Sanitation preventive controls
  - Supply-chain program
  - Other preventive controls

# What Might Be Monitored?

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Depends on process, examples include:

- Temperature
- Time
- Volume / weight
- Line speed
- Flow rate
- Bed depth
- Acid addition
- pH
- Water activity
- Chemical concentration
- Appearance
- Process performance
- Many others

# How is Monitoring Conducted?

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Depends on the nature of the control. Examples include:

- Calibrated thermometer
- Calibrated pH meter
- Calibrated chart recorder
- In-line analyzer
- “Real time” laboratory analysis
- Visual checks

# Corrective Actions and Corrections

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- Key discussion points
  - The definition of corrective action and corrections
  - Procedures for corrective actions
  - Record-keeping requirements for corrective actions

# Definitions

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## Corrective action

- Procedures that must be taken if preventive controls are not properly implemented.
  - from 21 CFR 117.150(a)(1)

## Correction

- An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).
  - 21 CFR 117.3

# Corrective Actions

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- Must be taken when process preventive controls are not properly implemented, resulting in a deviation
  - E.g., there is a deviation from a critical limit
- Unsafe product may have been produced
- Appropriate to the nature of the hazard and preventive control

# Corrective Action Procedures

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- Written procedures must describe steps to taken to:
  1. Identify and correct a problem with implementation
  2. Reduce likelihood of occurrence
  3. Evaluate affected food for safety
  4. Prevent affected food from entering commerce if you cannot ensure the food is not adulterated

# Corrective Action Examples

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## Process Examples

- Immediate adjustment of process
- Employees stop line when deviation occurs
- Apply alternate process
- Repair equipment
- Retrain employees
- Evaluate operation

## Product Examples

- Hold product
- Evaluate product
- Determine product disposition
  - Release, rework or destroy product

# Unanticipated Problems Include:

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- Preventive control not properly implemented and a corrective action procedure has not been established
- One or more preventive controls are ineffective
- Review of records finds:
  - the records incomplete,
  - the activities did not follow the Food Safety Plan, or
  - corrective action decisions were not appropriate

# Unanticipated Problems

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- Required corrective action includes:
  1. Standard corrective action procedures
    - Identify and correct an implementation problem
    - Reduce the likelihood of occurrence
    - Evaluate all implicated product for safety
    - Prevent adulterated or misbranded product from entering commerce
  2. Reanalyze the Food Safety Plan
    - See Chapter 13 Verification and Validation Procedures

# Corrective Actions Required Records

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1. Actions taken to identify and correct the problem,
2. Actions taken, when necessary, to reduce the likelihood that the problem will recur
3. Safety evaluation for all affected food
4. Records demonstrate that food that is potentially injurious to health did not enter commerce

# Process Preventive Controls Summary

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- Procedures must be documented for the process-related hazards requiring a preventive control identified through the hazard analysis process.
  - These controls are usually CCPs.
  - Specific controls depend on the nature of the hazard and the nature of the preventive control.

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# Process Preventive Controls Summary

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- For each process-related preventive control identified, the following must be recorded, as appropriate:
  - Parameters and values (e.g., valid critical limits) that must be met
  - Monitoring procedures, including what, how, frequency and who
  - Corrective actions that identify the implicated product, determine its disposition, correct the cause and determine that the preventive controls are working again
    - Corrections may be appropriate in some situations
  - Verification and records (discussed in subsequent chapters)

# Food Allergen Preventive Control

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## BIG 8 ALLERGENS



TREE NUTS



WHEAT



SHELLFISH



MILK



SOY



FISH



PEANUTS



EGGS

# FALCPA\* Required Food Allergen Labeling

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- Milk
- Egg
- Peanut
- Tree nuts (species specific)
- Fish (species specific)
- Crustacean shellfish (species specific)
- Wheat
- Soy

\* Food Allergen Labeling and Consumer Protection Act



Photo Sources: Microsoft Clip Art and KMJ Swanson (soybeans)

# Allergen Preventive Controls Requirements

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1. Preventing allergen cross-contact
    - Clean shared equipment – potential sanitation controls
    - Properly manage rework
    - Avoid in-process or post-process allergen cross-contact
  2. Accurate allergen labeling of finished food
    - Ensure labels are correct – potential supply-chain program
    - Ensure the correct label or package is used
- Human error can be involved – training is essential!

# Allergen Cross-contact Prevention Considerations

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- Equipment cleaning and sanitary design
- Scheduling
- Manufacturing and engineering controls
- Allergenic ingredient control
- Rework management
- Personnel practices
- Employee training relevant to the above

# Equipment Cleaning

## A Potential Preventive Control for Allergens

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- Thorough cleaning between products with different allergens is required to prevent cross-contact
- Validation of allergen cleaning procedures is not required but may be useful
- Optional – Dedicate tools, surfaces and other devices for specific allergens

# Verification of Allergen Cleaning

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- Visually clean
  - Minimum requirement
  - No residue, film or sheen
- Optional tests
  - Non-specific tests, e.g., ATP and protein
    - May not be sensitive enough to detect some allergens
  - Allergen test kits
    - Follow manufacturer's instructions!
  - Complex tests
    - Special situations

# Scheduling or Run Sequencing

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- Minimize changeovers
- Run dedicated or designated systems as much as possible
- Schedule appropriate sanitation activities
- Control allergen addition

# Manufacturing and Engineering Controls

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- Engineer the line to minimize mixing of allergenic products with non-allergenic products
- Use physical barriers to separate processing lines
- Minimize the reuse of water or oil

# Maintenance and Engineering

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- Sanitary design principles
- Monitor and reduce dust levels
- Minimize use of air compressors
- Maintain tools

# Allergenic Ingredient Control

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- Develop a master list of allergenic ingredients used in the facility
  - Letters of guarantee from suppliers on the presence or absence of allergenic ingredients
  - Accessibility of master list at receiving dock
  - Use common names of allergens
- Apply careful handling at receiving to avoid allergen cross-contact
- Identify allergens with icons

# Receipt of Incoming Goods

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- Review labels of incoming raw materials
- Include allergen check as a prerequisite program or in allergen preventive control for deliveries, depending on risk
- Color coding and pallet labeling useful
- Separate each type of tree nut, peanut, fish or crustacean shellfish species
- Consider separate area for each allergen
- Consider dedicated transportation vehicles for different allergens, depending on risk

# Storage of Incoming Goods

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- Separate allergenic ingredients from non-allergenic ingredients to prevent allergen cross-contact
  - Control traffic patterns also
- Use signage in areas used to store allergens
  - Maintain consistent allergen identifiers – color or image
- Store allergens in sealed, intact containers, as appropriate
- Do not store allergens above non-allergens on racks or pallets
- Store allergens with “like” allergens
- Have documented clean up procedures available

# Allergen Cross-contact Prevention During Processing

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- Requires segregation of unique allergenic material, e.g.:
  - Weigh powders containing unique allergens in a different area
  - Cover totes containing allergen-containing ingredients during transfer
  - Control ventilation over lines where protein powders are dumped
  - Consider dedicated tools and equipment
  - Proper use of containers that previously held food allergens

# Rework and Product on QA Hold

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- Store allergen-containing rework or open product on QA hold to avoid cross-contact
- Clearly mark rework or open QA-hold material for the presence of allergens

# Personnel Practices

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- Manage employee outer clothing to avoid allergen cross-contact
- Consider keeping personnel who handle unique allergens out of non-allergen areas
- Training is essential!

# Allergen Labeling Considerations

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- Label accuracy
  - Accurate printing of allergen ingredients on the label
  - The right label on the package
- Supply-chain program
  - Ingredients
  - Labels

# Product Labeling and Packaging

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- Proper package labeling protects:
  - Consumers
    - Only way for them to know the allergen is in the product
  - Companies
    - Product recalls
    - Regulatory inquiry
    - Potential liability
- Preventive controls for food labels and packages are as important as other food allergen management techniques!

# Product Labeling Must Be Accurate

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- Ensure all allergens are identified in compliance with appropriate law:
  - Food Allergen Labeling and Consumer Protection Act provides requirements for FDA-regulated foods

# Considerations for Food Labels and Packages

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- Allergen labeling errors are a primary cause of food product recalls
- Consider controls that:
  - Ensure accurate printing
  - Ensure the right label or package is used for the product
  - Manage formula changes to ensure that the correct label is used during transition

# Allergen Label Design Control Examples

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Examples of procedures:

- Design and copy proofreading
- Written approval of label and package proofs
- Identity coding of printed labels and packages
- Lack of co-mingling when shipping labels and pre-printed packages

# “May Contain” Labeling

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- “May Contain” or similar labeling is NOT a substitute for appropriate GMPs
- Carefully consider label implications for ingredients with precautionary labels (e.g., “May Contain”)

# Allergen Preventive Controls for Labeling

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- Preferable continuous review of label or wrap material during a processing run
  - E.g., bar code scanner
- Colored striping on edges of packages stacked flat in packaging machines reduces line operator errors
- Especially important when labels are applied to product held in unlabeled inventory

# Allergen Control by Suppliers

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- Understand allergens handled by suppliers
  - See Chapter 12: Supply-chain Preventive Controls
- Use caution with ingredient substitution

# Allergen Training

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- Critical to implementation and execution of an Allergen Control Plan
- Applies to a variety of personnel
- Education and knowledge building
- Empower individual role and responsibility
- Reinforce commitment to food safety
- Highlight changes or new development

# Allergen Preventive Controls Summary

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- Undeclared allergens present a risk :
  - Consumer reactions can be severe
  - Major cause of food recalls
- Allergen preventive controls required to:
  - Prevent allergen cross-contact
  - Accurately label product
- Allergen management best practices exist to:
  - Protect the allergic consumer
  - Reduce a company's risk
  - Make food safer for all to enjoy

# Sanitation Preventive Control

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# Hazards and Conditions Relevant to Sanitation Preventive Controls

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- Environmental pathogens when RTE product is exposed to the environment prior to packaging
  - E.g., *Salmonella* and *L. monocytogenes*
- Pathogens transferred through cross-contamination
  - E.g., from insanitary objects or employees handling raw and processed product
- Food allergen cross-contact
  - Unintended milk, soy, egg, fish, crustacean shellfish, wheat, peanut or tree nut cross-contact

# GMPs That Support Cross-contamination and Cross-contact Prevention

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- Employee hygiene practices
- Employee food handling practices
- Plant design and layout
- Packaging material storage and handling
- General cleaning and sanitizing
- Physical separation of:
  - Raw and ready-to-eat products
  - Unique food allergens

# Sanitation Preventive Controls\*

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- Procedures, practices and processes for:
  - Cleanliness of food-contact surfaces
  - Prevention of allergen cross-contact and cross-contamination
    - From insanitary objects and personnel to food, food packaging material, other food contact surfaces
    - From raw product to processed products

\* When hazard analysis identifies a hazard requiring a preventive control

# Sanitation Considerations for:

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- Wet cleaning versus dry cleaning
- Personnel practices
- Hygienic zoning

# Hygienic Zoning

Differentiates facility hygiene requirements to minimize product cross-contamination, e.g.,



## Non-manufacturing areas

- Maintenance shop, offices, employee areas, waste disposal



## Transition areas

- Entry rooms, locker rooms that enter onto basic GMP areas, etc.



## Basic GMP areas

- Raw, receiving and storage



## Primary pathogen control area – CONTROLLED ACCESS

- Cooked, pasteurized or RTE products exposed to the environment



## Sensitive/high hygiene area – RESTRICTED ACCESS

- Products for sensitive populations such as infants

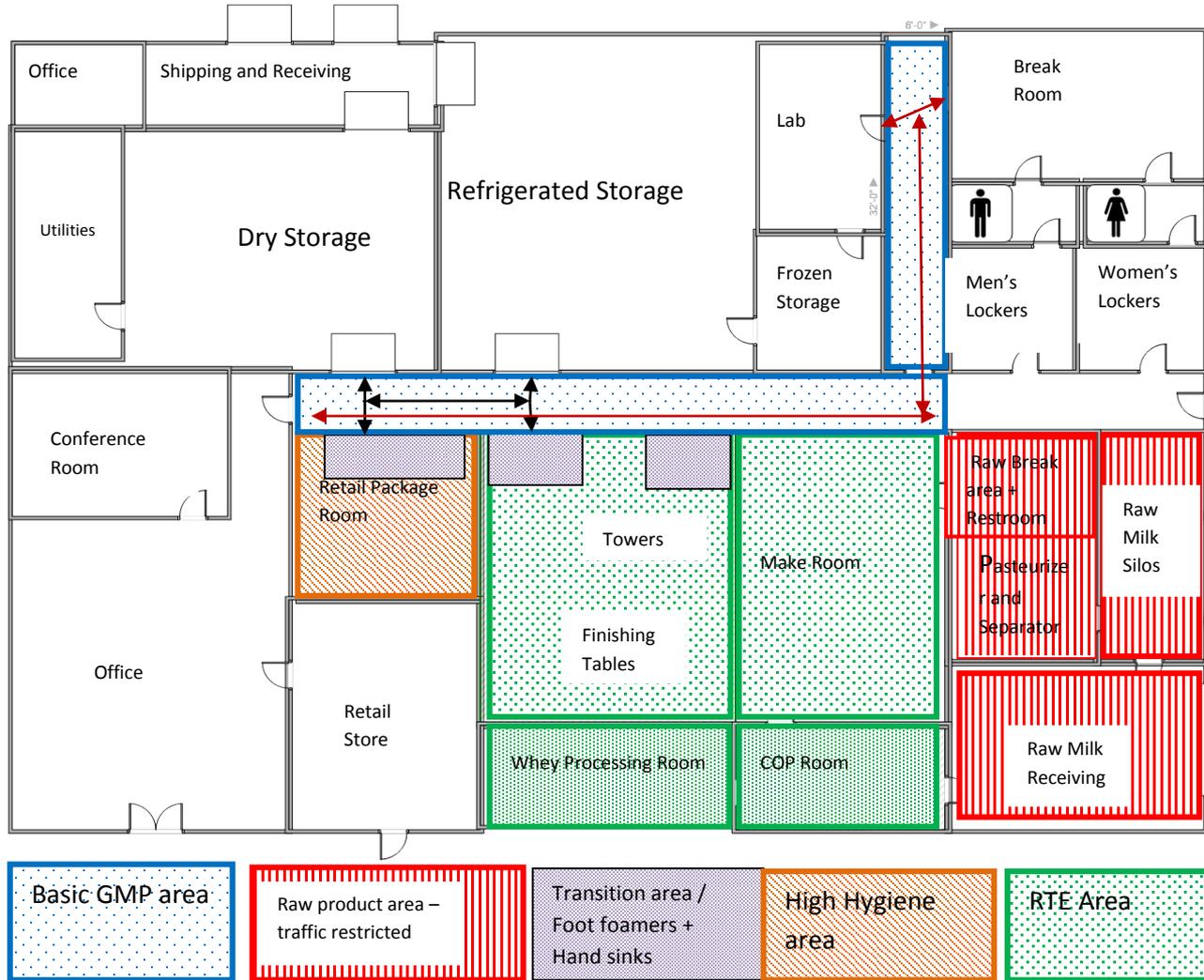
# Hygienic Zoning Considerations

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- Infrastructure
- Personnel, materials and other traffic flow
- Cross-over areas
- Room air
- Compressed air, if used in direct product contact
- Adjacent and support areas

# Example Hygienic Zoning Map

Cheese Plant Diagram



Basic GMP area

Raw product area –  
traffic restricted

Transition area /  
Foot foamers +  
Hand sinks

High Hygiene  
area

RTE Area

Foot Traffic

Fork lift Traffic

# Documenting Sanitation Preventive Controls

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- Document procedures, practices and processes to control identified hazards, including:
  - Cleanliness of food-contact surfaces
  - Prevention of allergen cross-contact and cross-contamination from:
    - Insanitary objects
    - Personnel to food, food packaging material, food-contact surfaces
    - Raw product to processed product
- Documentation required only for hazards a requiring preventive control

# Cleaning and Sanitizing Procedures

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- Should identify:
  - Purpose
  - Frequency
  - Who
  - Procedure
  - Monitoring
  - Corrections
  - Verification
  - Records
  - Other special considerations

# Sanitation Monitoring

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- Definition – Monitor
  - To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.
    - 21 CFR 117.3 Definitions
- Monitoring critical elements of the sanitation process
- Monitoring implementation for other controls, as relevant, such as hygienic zoning

# Actions to Correct Sanitation Deficiencies

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- Depend on situation and could include:
  - Re-clean
  - Re-sanitize
  - Re-train

# Sanitation Verification

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- Activities that demonstrate that sanitation procedures are operating as intended
- Methods used can vary significantly depending on the food, the facility, and relevance in the food safety system
- Potential examples
  - Measuring chemical concentrations
  - ATP swabs, contact plates, microbial count swabs
  - Environmental monitoring for environmental pathogens
  - Record review

# Environmental Monitoring

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- If applicable, required to verify the effectiveness of preventive controls for environmental pathogens
  - E.g., facilities where ready-to-eat product is exposed to the environment
- Must be tailored to each facility
- A useful program diligently *tries to find* the organism and addresses issues identified!
- See Appendix 6 for more information

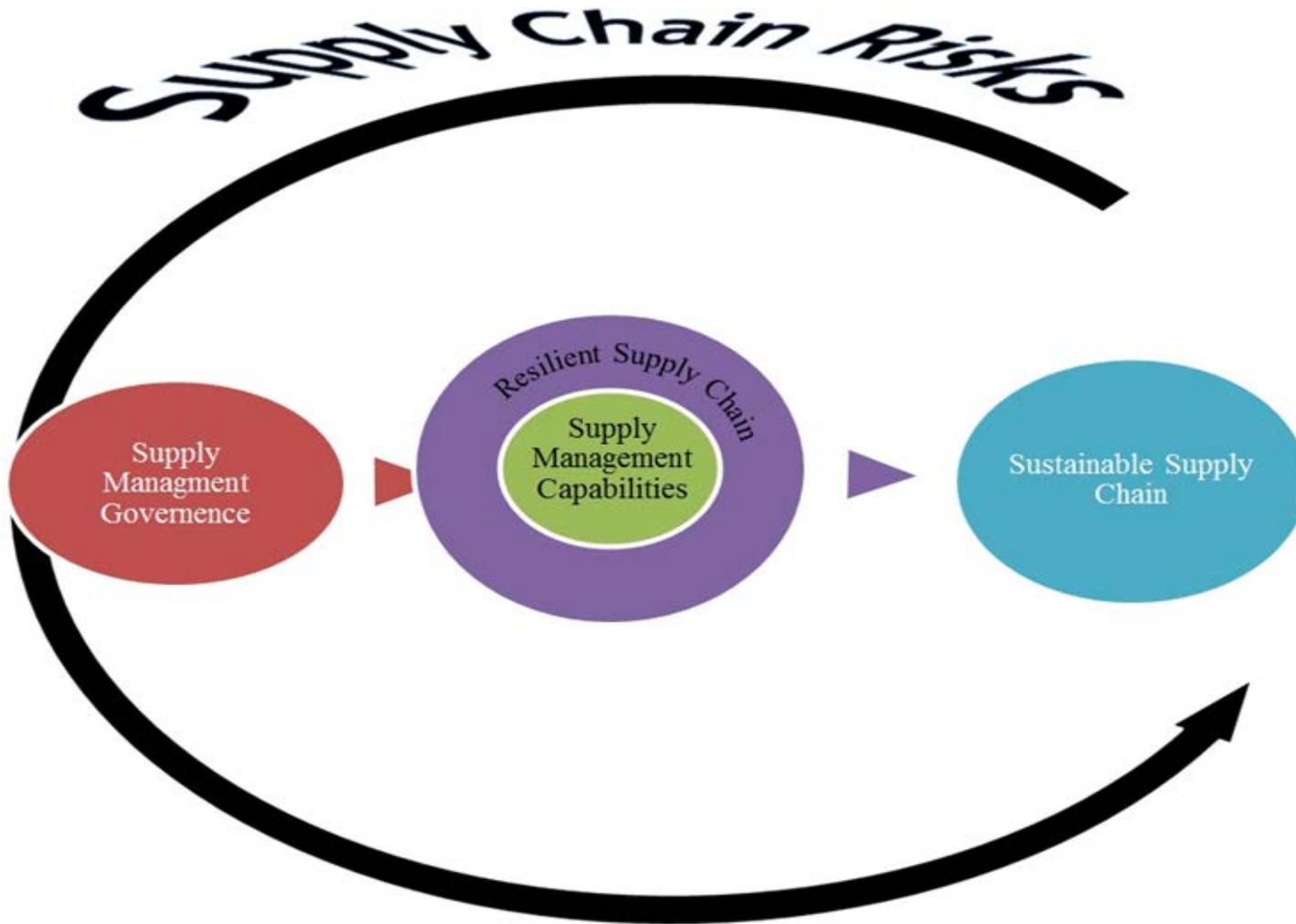
# Sanitation Preventive Controls Summary

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- Hazard analysis identifies hazards requiring a preventive control such as:
  - Environmental pathogens when RTE food is exposed to the environment prior to packaging
  - Pathogens transferred through cross-contamination
  - Allergens transferred through allergen cross-contact
- Sanitation preventive controls focus on:
  - Cleanliness of food-contact surfaces
  - Prevention of cross-contamination and allergen cross-contact
- Sanitation preventive controls describe:
  - Monitoring activities and frequency
  - Corrections to make when requirements are not met and corrective actions that apply for allergens and environmental pathogens
  - Verification activities appropriate to the facility

# Supply Chain Preventive Control

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# Link to Hazard Analysis

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- The hazard analysis identifies hazards requiring a supply-chain-applied control
- An ingredient may not have a hazard requiring a preventive control; e.g., vinegar
- A hazard requiring a preventive control that is associated with an ingredient or raw material may not require a supply-chain program; e.g.,
  - Pathogens that will receive a validated kill step in your facility

# Who Controls The Hazard?

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- Manufacturer, processor
- Raise the animal
- Grow the food



- Manufacturer, processor



- Manufacturer, processor or preparer

# Supply-chain Program **Not** Required:

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1. When no hazards requiring a supply-chain-applied control exist  
OR
2. When you (the receiving facility) control the hazard  
OR
3. When a Customer or downstream entity provides written assurance that they control the hazard

# Supply-Chain Program Exclusions

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- An importer in compliance with the foreign supplier verification program for the ingredient
- Food supplied for research or evaluation use

# Supply-chain Program General Requirements

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Use approved suppliers



Determine supplier verification activities



Conduct supplier verification activities



Document supplier verification activities



When applicable, verify a supply-chain-applied control applied by an entity other than your supplier

# Using Approved Suppliers

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- Applies to hazards requiring a supply-chain-applied control
- Approval required *before* receiving the ingredient
  - Temporary exception may be possible with justification
- Written procedures for receiving
- Receiving records required

# Receiving Procedure Example

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## **Receiving Procedure for Ingredients Requiring Supply-chain-applied Control**

**Purpose:** Ensure that all ingredients requiring a supply-chain-applied control are received from approved suppliers with appropriate preventive controls in place.

**Frequency:** Each delivery

**Who:** Receiving clerk

### **Procedure:**

1. Verify that each load of Pasteurized Process Cheese was produced by Cheesy Co. located in Cowtown, USA by checking the bill of lading and manufacturer name on the cases received.
2. Document on receiving sheet

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# Appropriate Supplier Verification Activities

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Conduct one or more of the following verification activities *before* using and periodically thereafter:

- Onsite audit
- Sampling and testing
  - By the supplier or the receiving facility
- Review supplier's food safety records for the ingredient
- Other if applicable

# Considerations for Appropriate Verification

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- What does the hazard analysis suggest about the nature of the hazard?
- Are preventive controls applied by the supplier or the supplier's supplier?
- What are the supplier's procedures, processes and practices related to safety for the ingredient or raw material?
- Has FDA issued warning letters or import alerts related to the supplier's compliance?
- Do your historical test or audit results for the supplier indicate a trend – positive or negative?
- Have the supplier's corrective actions to past issues been appropriate and timely?
- Are the supplier's storage or transportation practices appropriate?

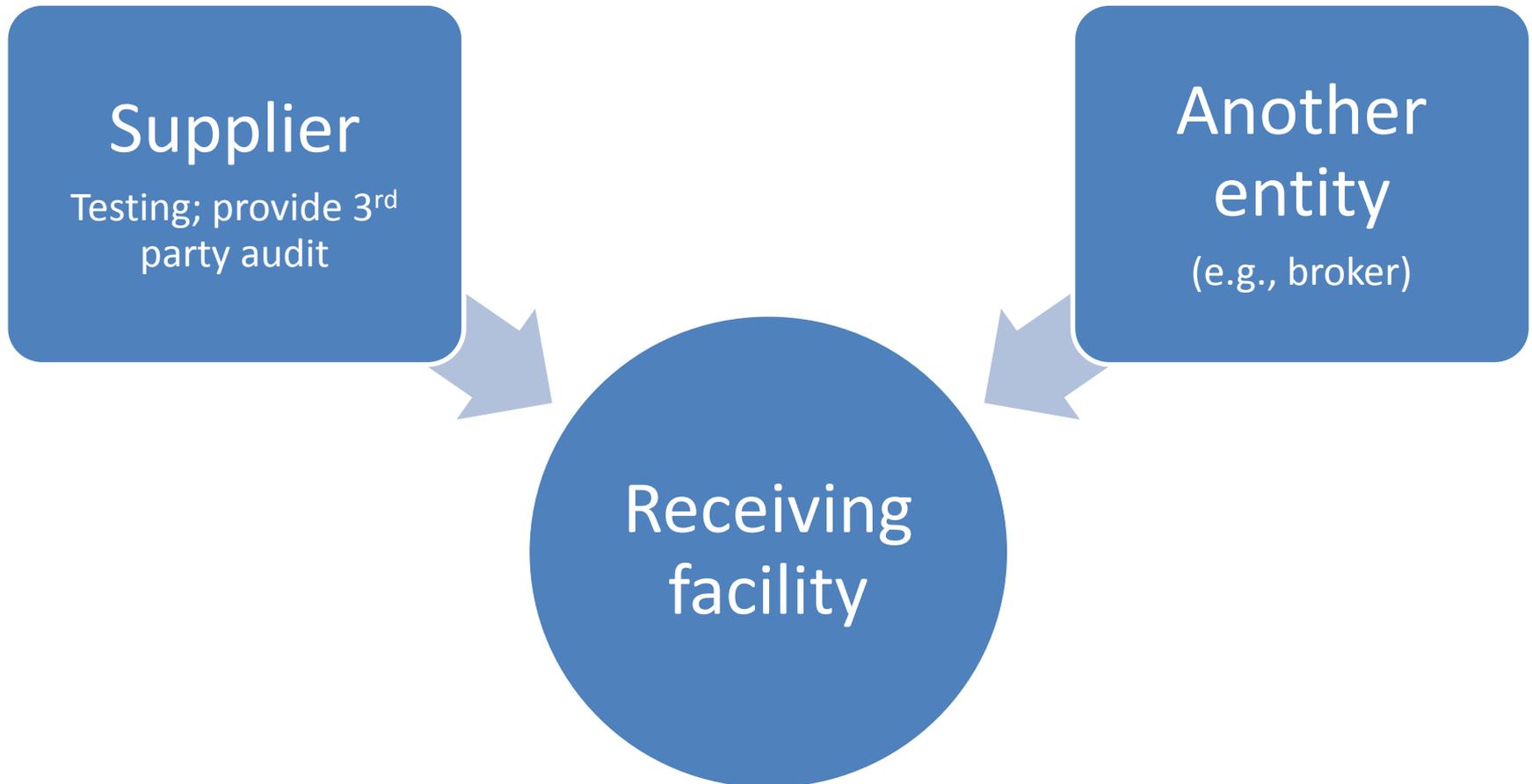
# Supplier Verification Activity Exceptions

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- Receiving facility does not need to conduct supplier verification for:
  - A very small business (qualified facility)
  - A farm that grows produce and is not covered under *Standards for Produce Safety* regulations
  - A shell egg producer that has <3,000 laying hens
- Must obtain written assurance that the supplier:
  - Retains its regulatory status
  - Complies with applicable food safety laws  
(see text for details)

# Who Can Perform Supplier Verification?

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Receiving facility must document review and assessment of documents provided by others

# Onsite Audit Requirements

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- For serious hazards requiring a supply-chain-applied control
  - Documented onsite audit *before* using the raw material
  - *At least annually* after the initial audit
- Exception
  - You document that other verification activities or less frequent auditing provides adequate assurance

# Onsite Audits – Who and What

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- Must use a qualified auditor
- Review supplier's written HACCP or other Food Safety Plan and implementation documents for hazard identified in your hazard analysis

# Sampling and Testing

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- May be conducted:
  - by the supplier
  - at an outside lab or
  - by the receiving facility
- Can communicate results in a COA
- Methods used must be fit for purpose
- Consult references on appropriate tests for different types of products
  - Indicator tests may be more useful than pathogen tests to assess effectiveness of overall controls,
    - e.g., coliforms in dairy products

# Other Verification Activities

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- Records reviews
- Requesting certificates of conformance
- Requesting continuing guarantees

# Actions Taken for Non-conformance

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- Non-conformance actions focus on:
  - Identification of the issue
  - Steps taken to mitigate the effects of the issue
  - Steps taken to correct the issue
  - Identification of the root cause of the issue
  - Steps taken to modify the system to prevent reoccurrence
- Document all root cause and corrective actions
  - Ensure that corrective actions are implemented
- Records of actions taken for non-conformance are **required**

# Supply-chain Program Review

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- Compare findings from verification and non-conformance activities to spec and contract requirements
- Key points to consider:
  - Do the supplier contract and specifications clearly convey your product safety requirements?
  - Have all product safety issues been corrected?
  - Have changes or innovation at the supplier level impacted food safety? Any changes within your company?
- Adjust the program as needed to enhance safety

# Change Control Process

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- Ensure supplier-initiated changes are communicated to the food safety team
- Ensure purchasing and others recognize resources required to manage supplier controls and verification
- Reanalysis of the Food Safety Plan may be needed

# Supply-chain Program Documentation

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- Written supply-chain program
- For import facilities, FSVP compliance documents
- Documentation of supplier approval
- Receiving procedures
- Receiving records
- Determination of appropriate supplier verification activities

*continues on subsequent slides*

# Onsite Audit Documentation

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- Must include
  - Supplier name and location
  - Audit procedures
  - Audit dates
  - Audit conclusions
  - Corrective actions taken in response to significant deficiencies identified
  - Documentation that the audit was conducted by a qualified auditor

# Sampling and Testing Documentation

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- Must include:
  - Identification of the raw material or other ingredient, including lot number, as appropriate, and number of samples tested
  - Test(s) conducted, including analytical method used
  - Date the test was conducted and date of the report
  - Results of the test
  - Corrective actions taken in response to detection of hazards
  - Identifying the laboratory conducting the test

# Additional Supply-chain Program Documents

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- Review of supplier's relevant food safety records
- Other supplier verification activity records
- Support for reduced audit timing or other verification in lieu of audit
- Qualified facility documents
- Small Farm documents
- Small shell egg producer documents
- Government inspections in lieu of onsite audit
- Supplier non-conformance documents
- Documents from entity other than the receiving facility
- Review and assessment of other documents

# Supply-chain Preventive Controls Summary

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- Hazard analysis identifies hazards requiring a supply-chain-applied control
- Key definitions include:
  - A “supplier” manufactures the food, grows the food or raises the animal
  - A “receiving facility” is a manufacturer/processor
  - A “customer” may or may not be subject to preventive controls regulation

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# Supply-chain Preventive Controls Summary

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- Supply-chain program must include:
  - Using approved suppliers
  - Determining, conducting and documenting supply-chain verification activities
- Supplier verification activities may include:
  - Onsite audits, sampling and testing, review of the supplier's relevant food safety records, other activities based on risk
  - An annual onsite supplier audit is required for serious hazards unless another approach can be justified
- Documentation is a key element of supply-chain control

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving packaging – Bags, corrugated boxes, labels	B none						
	C Allergen - milk	X		Milk is considered a major food allergen	Allergen control - for label review	X	
	P None						
Receiving - salt, calcium chloride, peppers	B Pathogens	X		Peppers may contain pathogens. Supplier has validated blanching/brining process to kill vegetative pathogens	Supply chain control - for pathogens in peppers in brine	X	X
	C None						
	P None						
Receiving – raw milk	B Pathogens	X		Raw milk may contain a variety of pathogens that must be subjected to a kill step	Process control - pasteurization		X
	C Drug Residues	X		Dairy farmers treat sick dairy cattle with various drugs and their residues sometimes find their way into the raw milk	Process control – antibiotic screening	X	
	P Metal from receiving equipment	X		Pumps and valving may shed metal into raw milk stream	Process control – metal detection		X
Receiving – rennet	B None						
	C None						
	P None						
Receiving – cultures	B Pathogens	X		Pathogens can grow during the production of starter cultures	Supply chain control - for pathogens in cultures		X
	C None						
	P None						

## *Hazard Analysis and Preventive Controls Determination Summary*

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- There are many types of food safety hazards
- The hazard analysis process:
  - Identifies known and reasonably foreseeable hazards (potential hazards)
  - Evaluates the likelihood and severity of potential hazards to identify those requiring a preventive control
  - Identifies process, allergen, sanitation, supply-chain or other preventive controls for potential hazards
- An effective hazard analysis reduces risk and focuses efforts
- A **written** hazard analysis is required for all products



# References

- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>
- <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm284406.htm>
- <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/default.htm>



# *Questions*