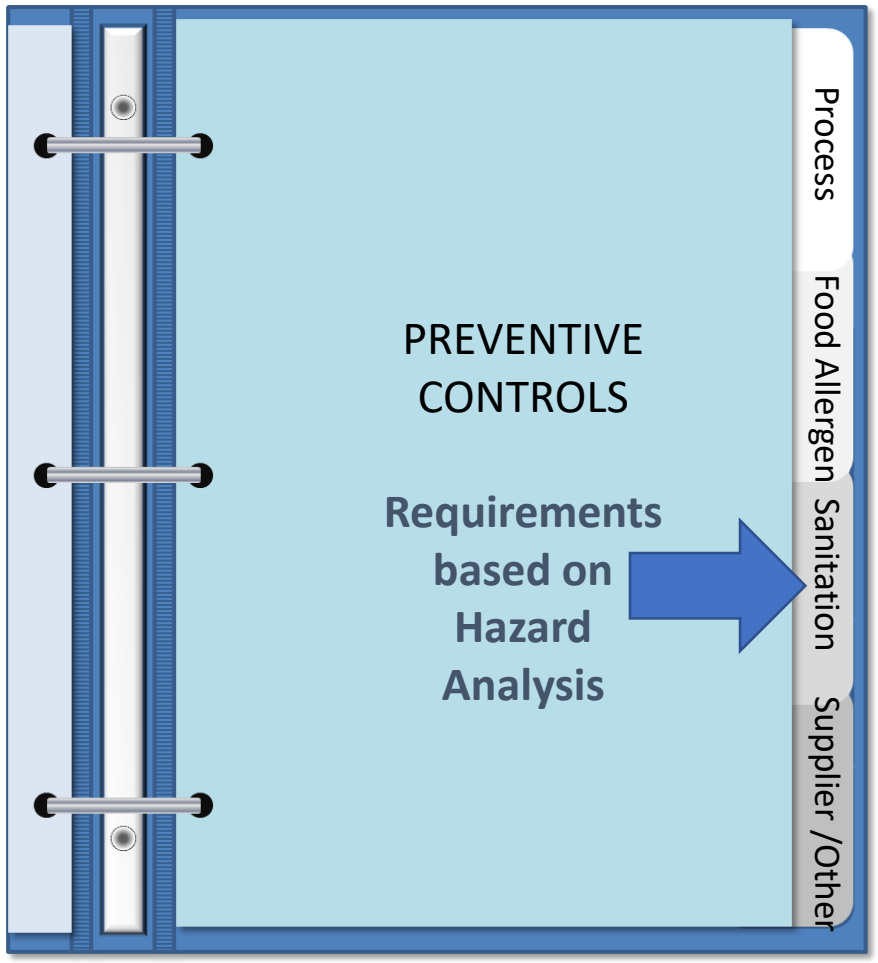
Sanitation Controls

Sanitation Preventive Controls Objectives

- Major food safety hazards controlled by sanitation practices
- That sanitation preventive controls are identified through hazard analysis
- Sanitation preventive controls management components required in a Food Safety Plan
  - Monitoring
  - Corrections
  - Verification



Hazards and Conditions Relevant to Sanitation Preventive Controls

- 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

- 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

- RTE food, exposed to the food
- Processed on the same lines as a unique allergen-containing food

Cross-contact

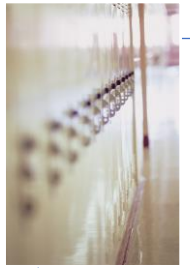
Cross-contamination

Hygienic Zoning

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

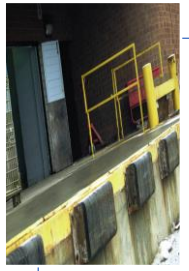
Non-manufacturing areas

- 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

Cleaning and Sanitizing Procedures

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

Documenting Sanitation Preventive Controls

- 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

Form Name: Sanitation Preventive Controls

Location		
Purpose		
Frequency		
Who		
Procedure		
Monitoring		
Corrections		
Records		
Verification		Date

Assemble, Wrap Table Sanitation

Purpose: Cleaning and sanitizing of the assembly and wrapping table is important to remove potential allergens and reduce microbial cross-contamination or recontamination with environmental pathogens that may impact product safety.

Frequency:

Cleaning: At lunch break, after production, at the end of daily production.

Sanitizing: Before operations begin, at lunch break, after production, and at the end of daily production.

Who: Sanitation team member

Procedure:

Note: Blue cleaning tools are to be used ONLY for cleaning after a run to reduce the potential for unintentional allergen transfer.

Cleaning

1. Remove unused packaging material to an area at the end of the shift to prevent it from getting wet. Cover it during the lunch clean up.
2. Remove gross soil with a squeegee.
3. Wipe table surface with a clean cloth dipped in ABC cleaning solution (Y oz. per gallon).
4. Rinse table with clean water. Detergent remaining on the surface can inactivate the sanitizer.

Sanitizing

1. Spray table surface with 200 ppm quaternary ammonium compounds solution, ensuring that entire surface is covered.
2. Allow table to air dry, about 5 minutes. Contact time required per label – 1 minute.

Monitoring (at frequency indicated above)**:**

Inspect table for residual soil and cleanliness. Record on Daily Sanitation sheet.

Use test strip to measure the quat concentration BEFORE application. Record on Daily Sanitation sheet

Corrections:

1. If residual soil is observed on the table, reclean and sanitize.
2. If quat is not at the proper concentration, make a new solution.

Records: Daily Sanitation Sheet

Verification: Supervisor reviews and signs Daily Sanitation Sheet within 7 working days

Sanitation Monitoring

- 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

Daily Sanitation Control Record

DATE:						
Sanitation Area and Goal	Pre-Op Time:	Start Time:	Lunch Break Time:	Post-Op Time:	Comments and Corrections	Operator Initials
Condition & Cleanliness of Food Contact Surfaces • Equipment cleaned and sanitized (S/U)* • Sanitizer type and strength: *Quaternary ammonium compound, 200 ppm* Omelet line (ppm)+ Dish room dip tank (ppm)+						
Prevention of Cross-Contact • Cleaning after Cheese Omelet Biscuit (S/U/NA)&						
Condition & Cleanliness of Non-food Contact Surfaces • Floors and wall splash zones cleaned and sanitized (S/U) • Sanitizer type and strength: *Quaternary ammonium compound, 400-600 ppm* Floors and wall splash zones (ppm)+						
* S = Satisfactory, U = Unsatisfactory + Enter ppm measured per test strip & NA = not applicable because Cheese Omelet Biscuit run after other products						
Verification signature:				Date:		

Actions to Correct Sanitation Deficiencies

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

Sanitation Verification

- 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

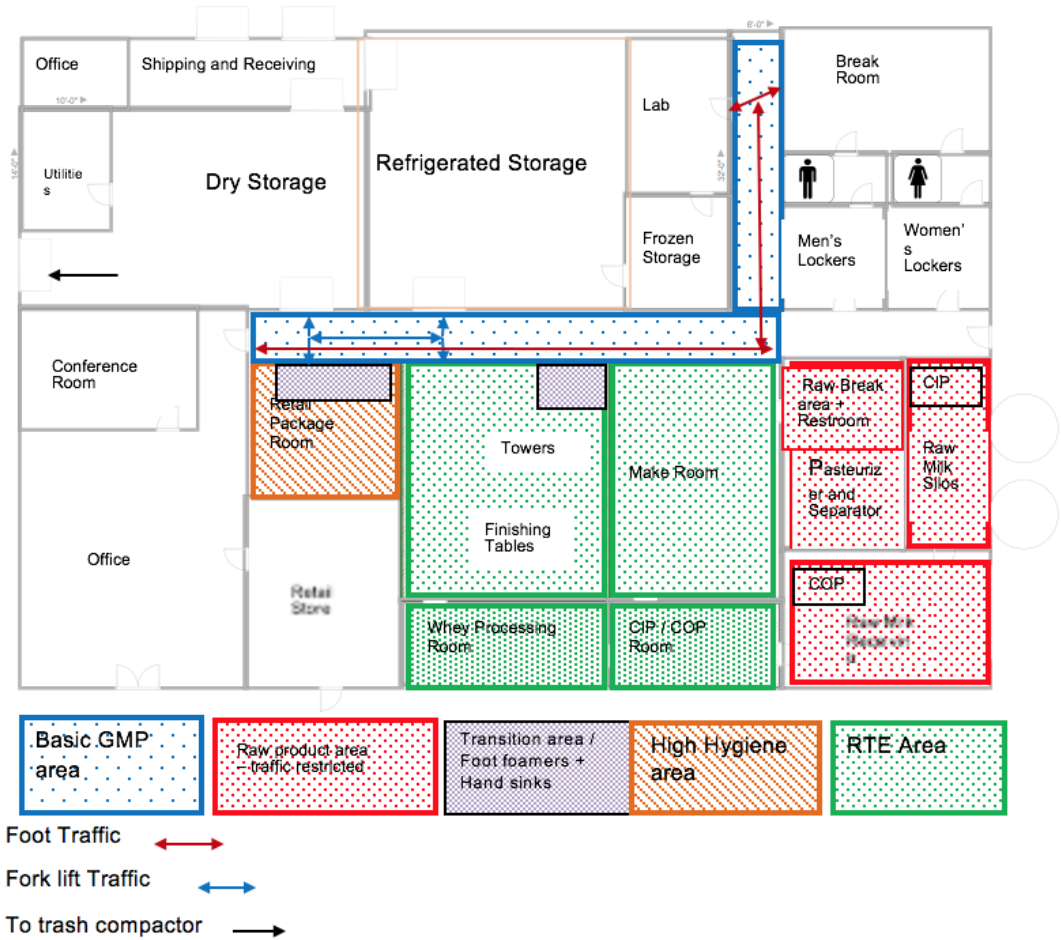
Sanitation Preventive Controls

NOTE: See Food Safety Plan in curriculum for an example of potential wording for cleaning and sanitation procedures to prevent allergen cross-contact from seafood containing product. Parameters can vary depending on the product, equipment, etc.

Hygienic Zoning/ Environmental Monitoring

Purpose: Hygienic zoning in the production facility is important to minimize potential of environmental pathogen cross-contamination. See diagram below.

Cheese Plant Diagram



Who: All employees are required to follow Hygienic Zoning protocols.

Procedure: Employees entering the described areas must follow the protocol for the area.

1. Raw product areas

   a. Traffic in these areas is limited to dedicated personnel. Dedicated personnel must wear a clean, gray uniform stored in lockers in Raw Area. Only employees working in this area wear gray uniforms. Employees in gray colored uniforms may not enter the common areas of the plant.
   b. Upon entering the area, employee changes into uniform and steel toe, slip resistant boots.
   c. Employee dons hairnet and beard net (where applicable) and red bump cap. Employee then washes hands and continues into the work area.
   d. Occasional employees may enter this area only if authorized. They must don Tyvek (disposable) suits and rubberized yellow shoe covers upon entrance to the area.
   e. Employee removes bump cap, discards hair covering and changes into street clothes and shoes OR removes Tyvek suit and shoe covers (if applicable) before leaving the raw area.
   f. Tools in this area are dedicated and must remain in the area.

2. RTE areas

   a. Employees working in RTE or High Hygiene (HH) areas change into a clean white uniforms each day and clean, dedicated slip resistant, steel toed footwear. Temporary employees use blue shoe covers.
   b. Employee dons hairnet and beard net (where applicable) prior to entering basic GMP, RTE or HH areas.
   c. Employees designated to work in the make room don green bump caps.
   d. Employees must wash hands in the gang sink located in the same hallway prior to entry into the plant.

3. High Hygiene area

   a. Employees entering the HH area must don a clean apron and arm guards upon entry to the HH area. They must wash their hands and wear gloves to handle product.
   b. Aprons and arm guards must be left in the HH area when employees go on break. At the end of the shift aprons must be placed in the soiled apron bins. Arm guards must be discarded.
   c. Gloves should be discarded as employee exits room, when non-food contact surface has been touched or if glove is torn and replaced with new prior to resuming packaging activities.
   d. Tools in this area are dedicated and must remain in the area. Tools must be cleaned and sanitized after use.

Monitoring: Supervisors visually observe the presence of properly garbed employees after start-up and after lunch break and at shift change as part of daily GMP Check. QA conducts monthly GMP audits as further verification.

Corrections: Employees are instructed to gown properly. Repeat offenders are subject to disciplinary action.

Records: Daily GMP Check. Monthly GMP audits.

Verification: Daily GMP record review within 7 working days. Monthly GMP Audits and Environmental monitoring.

Environmental Monitoring - Optional

- 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!
- Discussed in more detail later.

Build: Sanitation Controls