Chapter 11

SANITATION PREVENTIVE CONTROLS FOR HUMAN FOOD

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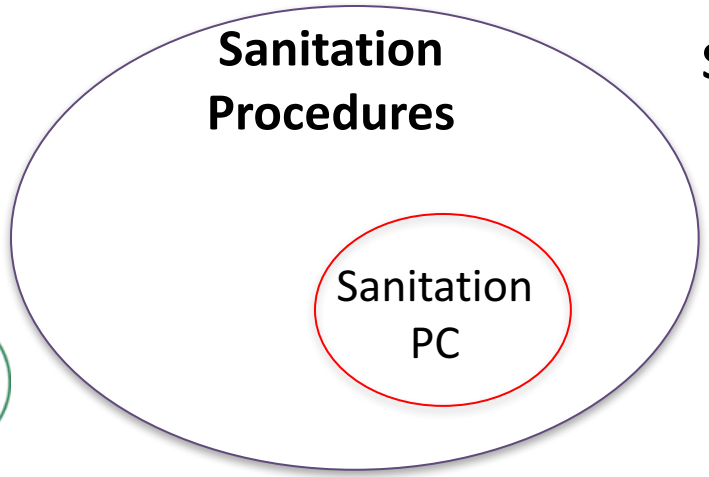
Review of Relevant Terms (Slide 11-1 a)

- **Allergen cross-contact**: unintentional incorporation of a food allergen into a food (21 CFR 117.3)
- **Cross-contamination**: unintentional transfer of a foodborne pathogen from a food anywhere it may occur naturally) or insanitary object to another food (where it may present a hazard)
- **Sanitation Preventive Control** is a subset of sanitation procedures managed through GMP



Review of Relevant Terms (cont'd) (Slide 11-1 b)

- **Sanitation**
  - Is the start, not the need, of food processing
  - Establishes the basic hygienic conditions needed to produce safe and wholesome food (including quality)
  - Sanitation practices are required by GMP (including, general cleaning, washing and sanitizing of equipment, walls, and floors)
  - Documentation is required ONLY for hazards requiring preventive controls

For Cleaning and Sanitation Basics, refer to Appendix 5.

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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

Read Participant Manual! *GMP related to cleaning and sanitation (21 CFR 117.35(d), (e), (f)) can be managed as prerequisite programs unless the hazard analysis identified hazards requiring a preventive control to address (1) cross-contamination or (2) allergen cross-contact.*

Difference Between General Controls and Preventive Controls (Slide 11-3 a)

- Preventive Controls: Those required to control hazards identified in the hazard analysis
  - Procedures, practices, and processes that must be **identified and performed** as designed on a continued basis to prevent the hazard.
  - Procedures, practices, and processes that must be **documented** in the Food Safety Plan.
- General Controls: Other controls that can be managed through routine GMP procedures

E.G. Food Company Example

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

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Assemble, wrap	B	Introduction of environmental pathogens such as *L. monocytogenes*	X		Recontamination may occur if sanitation control is not in place.	**Sanitation Controls** – prevent recontamination	X	
	C	Allergen cross-contact from other products handled at this step; e.g., Cheese Omelet Biscuit	X		Biscuits could introduce wheat allergen to other products without control	**Sanitation and Allergen Controls** – prevent cross-contact	X	

NOTE: *If there's a hazard requiring a preventive control, those preventive control procedures must be documented in the Food Safety Plan and performed on a continued basis.*

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Sanitation Considerations for: (cont'd) (Slide 11-6 a)

- *Primary focus of sanitation preventive controls* is cleanliness of:
  - Food-contact surfaces: to prevent cross-contamination
  - Non-food contact surfaces: also to prevent allergen cross-contact
- Wet cleaning is good for allergen control
- Dry cleaning is good for low-moisture foods
- Personnel must understand the reason for certain procedures
- Hygienic zoning is to minimize the transfer of hazards
  - Wet vs dry cleaning
  - Raw and RTE foods

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Hygienic Zoning (cont'd) (Slide 11-7 a)

- Hygienic zoning was developed for facilities where raw and RTE products are handled. Same concept is applicable to allergen control and wet vs. dry cleaning areas.
- Dedicated equipment in different areas, especially when it is difficult to clean (e.g., carts, forklifts)
- Color-coded uniforms (those in raw side, and those in RTE side)
- Linear flow through a facility (raw product does not enter cooked/ RTE product area)

Source: www. gettyimages.com

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Hygienic Zoning Considerations

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

Example Hygienic Zoning Map (cont'd) (Slide 11-0 top a)

- E.G. Food Company has a very open layout. It's not ideal but is a reality with small operations.
- Omelets are cooked by hand. When done, omelets are placed on a table between the cook area and the assemble/wrap station.

Question: *How do you minimize cross-contamination issues?*

Answer: *through hygienic zoning*

Actions to Correct Sanitation Deficiencies (cont'd) (Slide 11-13 a)

- **Correction**: Action to identify and correct a problem that occurred during food production without other actions associated with a corrective action procedure
  - Must be taken in a timely manner (otherwise, corrective action may be required)
  - Is adequate to correct the problem
  - Must be documented when appropriate
- Correction depends on the situation and could include:
  - If not visibly clean, re-clean
  - If sanitizer concentration is not correct, prepare correct sanitizing solution, check, and re-sanitize
  - If employees are making mistakes, re-train
- **Corrective Action**
  - Requires action to reduce the likelihood that the problem will recur
  - Requires evaluation of all affected food for safety, and
  - Requires prevention of affected food from entering commerce
  - Must be documented when appropriate unless corrections are made

Textbox

Actions to Correct Sanitation Deficiencies (cont'd) (Slide 11-13 a)

- Other corrections examples are in Appendix 3, pp. 22-24.

Textbox

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Assemble, Wrap Table Sanitation

E.G. Food Company Example

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 Cheese Omelet Biscuit production, at the end of daily production.

Sanitizing: Before operations begin, at lunch break, after Cheese Omelet Biscuit 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 cheese biscuit 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:

Corrective Action Report is not required when corrections are made.

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

Easy to read text is in Appendix 3

Definition of Verification (Slide 11-14 top a)

- Application of methods, procedures, tests and evaluations (random sampling & analysis) OTHER THAN monitoring to determine compliance with the Food Safety Plan.
  - Monitoring is done **while the product or the action is being made**, in real time.
  - Verification is done **after the product or the action is made**, off-line; checks the system.