Principles For Pathogen Cross-Contamination Prevention (Zoning Preventive Control) and Zoning Verification Activities – Environmental Monitoring

Larry Cohen
Kraft Foods
Food Safety & Micro
Principal Scientist
May 18, 2011
Association and Company Participation:

- GMA – Preventive Controls and Records Working Group. 25 companies and 54 members.
- AFFI – Current Good Manufacturing Practices (CGMPs) Coalition Working Groups – >60 companies and trade associations
Guiding Principles For Building a Food Safety Plan

—Directional and not prescriptive.
—Focused on goals and outcomes as opposed to tasks.
—Practical to develop and maintain.
—Based on industry leading practices.
—Allow for diversity of approaches to achieve public health objective.
—Appropriate for large and small businesses and domestic and international operations.
Key Points to Food Safety Plans

1. Public health will benefit from a focus on science based risk management.

2. Food safety plans are most robust if based in risk assessment. Risk assessment process is critical.

3. Rules and regulations should be goal oriented - multiple approaches can result in the same level of food safety.

4. Not all Preventive controls are critical control points (CCPs) and shall be identified as pre-requisites (PPs).

5. Preventive Controls need to be tailored to each situation, plant design, product, equipment, process and employees.

6. CGMP’s topics include environmental pathogen monitoring; sanitation, allergen control; temperature monitoring/control and employee training. Use as a supplement to existing GMP requirements prescribed by FDA and USDA.
Product Design is the Foundation to Food Safety

Key Objectives:
1. **Product and packaging** that delivers safety during intended shelf life and consumer use.
2. Controllable **processes** that ensure elimination or reduction of hazards to acceptable levels and an environment that prevents recontamination.
3. Science based approach is necessary.
Product, Package, & Process Design

Risk Assessment Considerations
- Consumer/Customer
- Consumer Behavior
- Product Use
- Consumer Preparation and Storage
- Package Integrity
- Manufacturing conditions
- Transportation and Storage

Shelf life
- Manufacturing Equipment and Hygienic Design
- Cleaning/Sanitation Method and Frequency
- Facility Structure
- Traffic Flow
- Plant Zoning
Hazard Analysis

• Creating a Food Safety Plan requires the assessment of each individual product and process.

• Hazard Identification
  – Chemical, biological, & physical potential hazards:
    • In raw materials
    • In packaging materials
    • During processing
    • Environment
    • Equipment
  – Design Hazards Out
    • Most effective method is to eliminate hazards – if feasible

• Once identified, appropriate preventive controls will be determined for each hazard that is likely to occur.
Verification Activities Should be Science And Risk Based

• Knowledge & history of products and process determine level of verification activities

• Dry Mix (without kill step) → More stringent Raw Material verification
• Wet Environment or Raw/RTE Interface → More stringent Environmental verification
• Absence of History, On-going Issues, New Process → More stringent Finished Product verification
Zoning Preventive Controls

- Zoning programs may be applied to facilities manufacturing or handling food products to reduce the potential for pathogen contamination of materials and products from the environment or other materials.
- The definition of zoning is “the division of areas of the facility based upon the barriers, cleaning procedures, employee practices and control of movement of people, equipment and materials necessary to protect products from potential hazards originating from the manufacturing environment and its surroundings”.
- A risk assessment is critical to understanding where and how hygienic zoning programs and related controls should be employed. Zoning principles may be evaluated at steps throughout the process including the receipt, storage, processing and packaging of food.
- Zoning programs should focus on ensuring that appropriate controls exist to protect product, raw materials and packaging during their movement from one area to another in a facility and to protect the processing environment where exposed product and materials might become contaminated from higher risk plant areas.
- Zoning preventive controls focus on the interfaces and movements between areas where the microbial profile changes such as between cooked and raw product. The importance of zoning programs will vary based on the product type, design of the manufacturing process and process flow. In raw facilities where there is no targeted microbial reduction step, the need for zoning is minimal.
Elements of a Zoning Preventive Program

• Conduct and document a risk assessment to identify areas within the facility where potential sources of pathogen contamination exist and where exposed product must be protected from contamination.

• Based on the outcome of the risk assessment, identify and implement controls to address risks.

• Review and validate the program at a predetermined frequency.
Protocol for Conducting a Zoning Assessment

• Level of in-process/finished product sensitivity.

• Based on product characteristics such as Aw, pH, formulation, finished products can be ranked based on the following criteria.
  – Pathogens may grow
  – Pathogens cannot grow, but may survive
  – Pathogens cannot grow, and may only have limited survival
Protocol for Conducting a Zoning Assessment

• Risk assessment should include product handling during production, amount of exposure to the environment after the kill step, and other processing factors that may reduce or increase potential cross-contamination.

• Less stringent controls may be necessary to prevent contamination before a pathogen reduction step and more stringent controls maybe needed after the pathogen reduction step.

• Assessment should evaluate consumer use and behavior and the likelihood of product abuse.
Protocol for Conducting a Zoning Assessment

• During the risk assessment non-manufacturing areas of the facility such as refuse/recycling areas, restrooms / break rooms (when in manufacturing areas), roof accesses and emergency exits to and from processing should be considered.

• The risk assessment should evaluate the potential for pathogen contamination of the product and this information used to determine the appropriate level of control required to prevent microbial contamination of the product from sources such as environmental air, compressed air, personnel, the equipment and adjacent zones.
Classification of Different Areas

- **Non-manufacturing zone (still requires application of basic hygiene requirements):**
  - Areas where there is no open product.
  - May include non-production areas such as utility rooms, offices, cafeteria/break rooms, locker rooms, laboratory, etc.

- **Raw or limited process zone:**
  - Areas such as raw product receiving and storage, areas of product preparation that will be thermally or otherwise processed and that are known/have the potential to be contaminated and that may require controls to prevent contamination of high control zones.
  - These zones may have dedicated employees and are physically separated from controlled zones or high control zones.
Classification of Different Zones

– **Controlled zone:**
  • Product can be exposed to the environment and the operators.
  • Good hygiene practices are implemented and air requirements are met.
  • The controlled zone may also serve as transition from non-manufacturing or raw zone to high control zone.

– **High control zone:**
  • Product which supports growth of the pathogen of concern and can be exposed to the environment and/or the operators.
  • Depending on the product, additional good hygiene practices, such as captive footwear/clothing, may be required and more stringent equipment/building sanitary design requirements may be followed.
Plant Zoning Map Example

1st Level

- Boiler Rm
- #2 Oil Tk Rm
- Intake/Receiving Rm
- Ammonia Rm
- Air Comp. Rm
- Elect. Rm
- Water Soft. Heater
- Pit Tank
- #1 Warehouse
- Dry Blend Rm
- Ramp
- Sched. Warehouse
- #1 Hallway

2nd Level

- Lunch Rm
- Lobby
- Main Office
- QA Off.
- In. Clerk
- Conf. Rm
- SSE Off.
- #3 Bag Rm
- Ingredient Grinding Area
- Cook Rm
- Cooler

KEY

= Overhead Roll-up Doors
\( /= \) Exit/Service Doors
\( = \) Exit/Service Doors

Raw or Limited processing zone: Raw meat/ raw milk/ raw nuts receiving and storage of product that will be thermally processed.

High control zone: Product of high susceptibility can be exposed to the environment and/or the operators.

Controlled zone: Product of low to medium susceptibility can be exposed to the environment and the operators.

Non-manufacturing zone: There is no open product in this zone.

Additional notes:
- 1st Level: Main Entrance, Offices, #1 Hallway, #1 Warehouse, Dry Blend Rm, Ramp, #1 Warehouse, Intake/Receiving Rm
- 2nd Level: Lunch Rm, Lobby, Main Office, QA Off., In. Clerk, Conf. Rm, Eng. Off., SSE Off., #3 Bag Rm, Ingredient Grinding Area, Cook Rm, Cooler

Legend:
- Overhead Roll-up Doors
- Exit/Service Doors
- Exit/Service Doors

Additional zones:
- High control zone: Product of high susceptibility can be exposed to the environment and/or the operators.
- Controlled zone: Product of low to medium susceptibility can be exposed to the environment and the operators.
- Non-manufacturing zone: There is no open product in this zone.
Zone Control Measures

• **Control Measures:** Preventive controls should be applied as identified during the risk assessment.

• Examples of Control Measures for Reducing Cross-Contamination.
  - Use of closed systems (e.g., milk pasteurization equipment, retort or aseptic systems).
  - Structural separation of the area by design (e.g., separate building, physical barriers, traffic controls or distance separation.
  - Restricted access to micro sensitive product areas (applies to employees not working in the area, visitors, etc.).
  - Use of a vestibule as entrance/exit with personnel hygiene and changing measures (e.g., hand washing/sanitizing station, footbath, additional garments).
Zone Control Measures

Examples of Control Measures Continued:

- Restrict people and equipment traffic flow between raw and other parts of the plant.
- Use of designated tools and equipment for micro sensitive product areas or adequate cleaning programs for tools used.
- Adequate filtration and pressure/flow of room air to protect product against relevant pathogens.
- Clean air systems (e.g., laminar flow units with HEPA air systems and air conditioning and humidity control systems).
- Use of enclosed filler supplied with filtered air and temperature and humidity controls.
- Prevention of entry/exit from outside directly into the production area.
Environmental Monitoring

- **Zoning Evaluation & Verification:** Zoning preventive control programs should be monitored and verified to assure effectiveness. Environmental monitoring is a common tool used to evaluate the effectiveness of the zoning preventive control (it is also used as a verification tool for other preventive controls such as sanitation and GMPs). It is not a control in itself.

  - A successful environmental monitoring program is one that rewards aggressive investigation and does not penalize the findings of positives. Positives are viewed as an opportunity to correct and improve manufacturing programs.

- **Requirements:** A comprehensive EM program – Reference CGMP’s for EM and Sanitation Practices:
  - detects conditions that may lead to the potential presence of pathogens in the processing environment including pathogen harborage areas; and
  - verifies the effectiveness of preventive controls for preventing microbial cross contamination.
Environmental Monitoring Program

Used as verification tool of zoning controls and applying
A 3-Stage Approach to Address Preventative & Corrective Actions

Sanitation / Environmental Practices
- Intensive Environmental swabbing
- Footwear / clothing
- Traffic patterns
- Sanitation
- Maintenance

Facility / Equipment Design
- Facility layout
- Floors
- Design for Sanitation

Personnel Training
- GMPs
- Maintenance
- Sanitation
- Behavior based food safety
- Outside Contractors
Sampling Criteria and Frequencies

• Monitoring sites may be categorized into three or four sampling areas based on proximity to process equipment.
• Example of product category and organism of concern includes: Low moisture products (Aw below 0.85) for *Salmonella*; and Processed refrigerated/frozen ready-to-eat products for *Listeria monocytogenes*.
• The number of samples and sampling frequency is determined by the product sensitivity, and other factors such as product exposure to the environment, design of the facility, design of the equipment, degree of separation between raw and RTE areas and historical information as assessed during the zoning risk assessment.
• Pathogen survival/growth studies and historical data may be used with a Food Safety Plan validation to modify the test plan or sampling frequencies.
Environmental Monitoring Sites

**Sampling Area #1**: Direct or indirect product contact surfaces with potential harborage and contamination build-up conditions. *Product conveyors, discharge chutes, pipe interior and storage hoppers to filling; filler hoppers, nozzles, product scrapers/utensils, etc.*
Environmental Sampling Sites

Sample Area #2 : Near product contact. Areas that are adjacent to product contact surfaces. *Equipment supports, frames outside of tunnels, enclosed filing cabinets or below filling equipment, control panels, weight scales, motor housings, catwalks, scrap carts, vacuum cleaners, used near contact surfaces, etc.*
Environmental Monitoring Sites

**Sampling Area #3**: Non-product contact areas within a room that are remote from product contact surfaces. *Drains, floors, ceilings, hand trucks, forklifts, equipment legs, tools, brooms, squeegees, floor scrubbers, floor debris, trash cans, traffic pathways into processing areas, wall/floor junctures, wash stations, ingredient storage areas, etc.*
Environmental Monitoring Sites

**Sampling Area #4:** Areas which are remote to product contact surfaces outside of the production room but could impact processing areas through movement of people, equipment, or materials. *Warehouses, bathrooms, cafeteria, plant entrance, hallways, offices, and refuse/recycle areas.*
Environmental Sampling Locations

- Sampling site locations and number of samples collected should be designed to aggressively identify potential harborage sites. The sampling plan should be dependent on the product produced, plant structure, equipment design, traffic patterns, and previous data and should be based on a zoning assessment.

- For raw, unprocessed products or raw processing areas (e.g., raw meat, poultry, fish, cocoa beans, and unpasteurized product, sampling should not be routinely required as it is assumed the area is contaminated. Focus sampling of interfaces between such processing areas and more sensitive, processing areas may be useful to verify zoning controls.

- Sampling site locations should be changed on a periodic basis and the program should be designed for aggressive investigation. Sampling sites and frequencies maybe adapted to verify hygiene following specific events, such as start-up following a shutdown, or maintenance or other event that could affect the environment or equipment hygiene.
Program Approval, Review and Validation

- EM verification activities should be reviewed whenever the zoning preventive control program is updated and should be validated at a predetermined frequency in conjunction with zoning and sample site validations.
Testing Procedures and Testing Labs

- Test methods that are official or validated to be equivalent in specificity and sensitivity to official methods should be used.
- Qualitative methods (determine presence / absence) are typically used for pathogens of public health concerns.
- Quantitative methods (to enumerate the organisms) are typically used for organisms that may indicate conditions that may lead to presence of pathogens (e.g., Coliforms, Enterobactericea, etc.).
- Sampling of direct product contact areas (Sample Site #1) for pathogens may necessitate holding of potentially affected finished product.
- **Testing Laboratories:** should be evaluated for proficiency to perform the required testing.
Corrective Action and Verification

• If a sample organism is detected during routine monitoring, an investigation to identify the potential source is conducted and corrective actions implemented if appropriate.

• An appropriate action plan is designed and based on the positive finding.

• When indicators such as *coliform* and *Enterobactericea* are used, an action level is generally established and actions taken when the level is exceeded or the trend indicates a change in conditions.
Examples of Corrective Actions

• Conduct a preliminary investigation to determine potential cause or source for the contamination (e.g., water leaks, maintenance activity, and construction).

• Take actions to correct any deficiencies based on findings. These may include:
  – quarantine the suspect area and limit access to the area.
  – reinforce hygienic practices with appropriate employees (retrain if necessary).
Examples of Corrective Actions

– re-examine cleaning frequencies and revise, as appropriate.
– eliminate water and water collection points, if present.
– repair damaged floors/walls and other structural damage, as appropriate; and
– re-examine traffic patterns. Where necessary and feasible, limit traffic flows (both employees and mobile equipment) through the area, restrict fork truck movement, redirect high-risk traffic patterns from adjacent areas, etc.

• Consider investigational sampling of the suspect and surrounding areas (e.g. vector sampling) prior to cleaning.
• Thoroughly clean and sanitize the positive site and surrounding area using appropriate practices depending on the conditions in the environment.
• Re-sample the implicated area and other sites within the surrounding and traffic pattern areas.
• Increase sampling frequency until an appropriate number of consecutive negatives (e.g., typically three), resume the routine sampling frequency and rotation plan.
• Sample #4 remote positive sites do provide information about the non-production environment and impact of traffic flow from these areas. Positive findings may still prompt some additional actions.
Consecutive Positive Results

• Finding multiple and/or consecutive positives at the same sampling site may indicate a systemic issue where the primary source is a harborage site and where the organism may have become established/multiplying. Corrective actions outlined below may be followed for problem resolution.

• It is critical that a harborage site, be found and eliminated. This usually means taking more samples than those taken during routine monitoring in the affected and traffic flow areas.
Consecutive Positive Results

- Reinforce personnel training and hygienic practices and provide additional attention to sanitation procedures.
- Visually inspect areas for potential niches. Intensify cleaning activities around these areas.
- Visually inspect handling practices (production, sanitation, maintenance, material handling) and correct non-hygienic employee practices.
- Review equipment cleaning and preventive maintenance protocols and revise, if necessary.
- Examine processing equipment and consider equipment redesign, if necessary.
- Testing of product contact surfaces may be necessary or need to be intensified for Sample #2 consecutive positives. In some operations, enhanced monitoring may involve alternative sampling techniques. Line samples may be taken at various times and/or from various locations to help pinpoint potential contamination sites. Investigational samples often are analyzed individually, not as composites.
- Depending on the location of the positive, consider testing Sample #1 sites or the finished product. For example, we consider testing Sample #1 sites (i.e., product contact surfaces) as a response to multiple positives in Sample #2. Sample #1 sites may also be tested when a product tests positive, or products are implicated by epidemiologic investigations in an outbreak. When testing Sample #1 sites and using equipment for production, we retain potentially affected products pending investigation.
Special Circumstances

• **Special Circumstances:** Increased environmental control procedures and action steps should be considered in cases of new plant construction, new equipment installation or modification, and facility infrastructure damage (e.g., overhead leak, flooding, etc). Examples include:
  • reinforcing hygiene practices and traffic patterns with outside contractors;
  • setting-up temporary control barriers within the plant as applicable; and
  • increasing cleaning frequency of adjacent areas during construction, after equipment installation, and after major repairs are completed.
Plant Zoning & EM Programs

Pathogen Control Equation

Air, Water Controls & Traffic Patterns + GMPs + Dry, Uncracked, Clean Floors, Walls, Ceilings + Sanitary Design + Sanitation Procedures

= Plant Zoning Control and EM Verification Steady-State
Food safety is hard work
Each of us must
think with foresight
act with vigilance