Environmental Monitoring Programs for Food Processing Plants

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Our Mission: To contribute to global health and safety by providing our customers with high-quality laboratory and advisory services while creating opportunities for our employees and generating sustainable shareholder value.
Allergens a Continuing Problem
### Primary Reports

<table>
<thead>
<tr>
<th></th>
<th>Year 1 – 229</th>
<th>Year 2 – 225</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella</td>
<td>38%</td>
<td>38%</td>
</tr>
<tr>
<td>Allergens</td>
<td>35%</td>
<td>33%</td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td>14%</td>
<td>18%</td>
</tr>
</tbody>
</table>

**Top 4 Foods Reported with Salmonella**

- Spices/seasoning
- Raw produce
- Animal feed/pet food
- Nuts and seeds

“RFR has helped FDA better target its inspection and sampling activities”
Allergens

Allergen cross contamination

- Shared harvesting sacks
- Shared transportation vehicles
- Shared processing equipment
- Allergenic carriers/flow aides
- Mislaveling
Salmonella as an Environmental Contaminant

- Due to fecal shedding, prevalence is widespread in livestock production and processing areas including immediate vicinity ➔ importance of site location monitoring

- Contaminated water is a frequent vehicle for cross-contamination of fresh produce ➔ importance of monitoring irrigation and process water

- Commonly associated with feral animals including rodents, birds, reptiles, and insects ➔ importance of pest control monitoring programs

- Able to survive many weeks in a dry environment ➔ importance of environmental monitoring
Why Test for Pathogens & Allergens?

- Brand protection and liability reduction
- Regulatory expectation
- Validate effectiveness of critical control point interventions such as heating, cooling, cleaning, etc.
- Validate effectiveness of environmental control programs
- Validate purchase specifications by you or your customers
- Outbreak investigations
Why do Environmental Monitoring?

- Regulatory perspective
- Customer expectations
- YOUR EXPECTATIONS

“Environmental monitoring is an essential component for microbial control. . .”

“. . .environmental monitoring is not a control measure, but rather an assessment tool . . .”
Public Law 111–353 111th Congress
An Act To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

SHORT TITLE.—This Act may be cited as the “FDA Food Safety Modernization Act”
SEC. 418. HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

“(4) the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means”

“(C) An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.”
Cost of Not Testing

• Potential for injuring or killing your customer

• Intrinsic and extrinsic costs associated with recalls

• Facility closure and loss of business

• Damaged brand reputation

• No liability protection – in fact liability increases due to lack of prudence
Environmental Monitoring Program

- Baseline sanitation program to identify, clean, and sanitize potential harborage sites
- Environmental testing program to assess SSOP effectiveness
- Evaluation of results and root cause analysis when positive environmental samples are found
- Corrective actions taken based on root cause analysis
Environmental Monitoring Program

What are the Goals?

• Find pathogens and allergens in the environment before they contaminate product
• Assess effectiveness of cleaning, sanitation, and employee hygiene practices

Where to Test?

• Use zone approach
• Direct product contact surfaces
• Non-product contact surfaces
**What Are You Trying to Control?**

*Salmonella* is the target organism for environmental monitoring of product-contact and non-product contact surfaces in a **low-moisture** food manufacturing facility.

*Listeria monocytogenes* is the target organism for environmental monitoring of product-contact and non-product contact surfaces in a **high-moisture** food manufacturing facility.

**Allergens – U.S. list**
- Milk
- Eggs
- Fish (e.g., bass, flounder, cod)
- Crustacean shellfish (e.g., crab, lobster, shrimp)
- Tree nuts (e.g., almonds, walnuts, pecans)
- Peanuts
- Wheat
- Soybeans
The focus of an environmental monitoring program should be on the Primary Microbial Control Area. *This area is* defined as the area subsequent to the lethality step up to the packaging step. For processes that do not have a *Salmonella* or *Listeria* lethality step, the entire processing area is considered the Primary Microbial Control Area.
Where to Test?

- Sampling priorities should be based on zone approach.
- Monitoring for *Salmonella* or *Listeria* should focus on non-product contact surfaces in the post-lethality area.
- Monitoring for allergens should occur where ever potential for cross contamination is possible.
- Product contact surfaces should be routinely monitored for indicator organisms.
- A rotation schedule should be developed to ensure all areas of facility are periodically sampled.
- Compositing or pooling of samples is not recommended.
What Samples?

Product

Food-Contact Surfaces

Environmental

- Non-contact surfaces
- Environmental parameters
- Air??
Selecting sample methods

- Don’t make it harder then it has to be
- Sample for the type of product (raw/processed) in the room
- Select appropriate equipment recognized by industry to perform sampling
Why Are You Sampling? How Will You Use Results?

• Trending of results (i.e., LOOK AT THE DATA)
• Establishment of effective alert and action limits
• Investigation and evaluation of trends as well as excursions from alert and action limits
• Corrective actions to be implemented in response to environmental monitoring excursions
Biofilms
Develop Written EMP Plan

- Identify sampling sites
  - use facility grid
  - random rotation among grids
  - routine selective sampling of high risk sites
- Frequency of sampling
- Number of samples
- Sampling procedure
- Test method
- Corrective actions
Concept Areas
"Zones" or "strata"

Controlled areas

Critical areas
Establishment of monitoring locations should be based on previous studies during dynamic conditions

- “gridding” or “mapping” study to determine worst case locations/most meaningful locations

Should also establish baseline flora
- will aid in investigations
• Zone 1 Direct Product Contact Surfaces

• Zone 2 Non-Product Contact Surfaces Close to Zone 1 Surfaces

• Zone 3 Non-Product Contact Surfaces in Open Processing Area

• Zone 4 Support Facilities Not in Open Processing Area
Surfaces where cooked/finished product is exposed to the environment before final package closure

- Tables
- Conveyor belts
- Buckets
- Fillers
- Hoppers
- Utensils
- Employee hands and gloves
Zone 1 - weekly

- Items and surfaces directly over or in close proximity to direct food contact surfaces such as lights fixtures and piping, compressed air lines, and water filters

- Program Validation – Necessary if only using indicator organisms in the routine program. Validation includes periodic testing for pathogens of concern.

- Product Disposition – All product produced on the line tested should be held until final results are received when testing any Zone 1 sites for pathogens
Zone 2 - weekly

- Equipment frames
- Drip shields and pans
- Control panels and buttons
- Overhead fixtures and piping not directly over or in close proximity to food contact surfaces
- Computer screens
- Maintenance tools
Zone 3 - weekly

- Floors
- Walls
- Ceilings
- Drains
- Hoses
- Cleaning equipment including brooms and brushes
- Air handling units
- Condensate drip pans
Zone 3

- Carts
- Pallets
- Forklifts
- Trash cans
- Foot baths
- Sink area including soap and towel dispensers
Zone 4 - monthly

- Bathrooms
- Locker rooms
- Cafeteria and break rooms
- Office rooms
- Hallways
- Warehouse
- Loading docks
- Maintenance shop
- Storage areas
High Risk Areas for *Salmonella*

- Aspirator line
- Dust collection system
- Filter sock
- Air conveyance system, e.g., rotary air lock, cyclone, air locks, duct work, pneumatic conveyance system
- Inside disassembled pump
- Inside air duct
- Exposed insulation
- Eroded flooring
- Space between walls
High Risk Areas for *Salmonella*

- Poorly sealed wall/floor junction
- Leaky roof
- Leaky drain pipe
- Conveyor
- Bucket elevator
- Fork lift
- Employees
- Fans
- Cat walks
- Central or portable vacuums
High Risk Areas for *Salmonella*

- Maintenance tools
- Floor scrubber
- Floor squeegee
- Mop head
- Drain
- Insects, rodents, reptiles, amphibians, other pests
High Risk Areas for *Salmonella* - Outside

- Fire exits – used by construction crew
- Entrance to employee locker room
- Pathway to trash compactor
- Receiving dock
- Insect light traps
- Employee congregation area – smoking site
- Grounds where birds congregate – picnic tables, around tree landscaping
Hand Grading

Courtesy Roger Clarke
In Line Magnet

Courtesy Roger Clarke
Magnet Grid

Courtesy Roger Clarke
Tool Storage

Courtesy Roger Clarke
## Sampling Plans

<table>
<thead>
<tr>
<th>Step</th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Why are you sampling?</td>
<td><em>Because ...</em></td>
</tr>
<tr>
<td>2</td>
<td>What are you sampling for?</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>What are the capabilities of the analytical method?</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>How will you use the data?</td>
<td></td>
</tr>
</tbody>
</table>
Sampling Plans?

Where do you sample?

When do you sample (how often)?
Sampling Plans

“statistical” vs. “risk based”

“stratified random”

Monitoring vs. investigative
Testing frequency should be based on:

- History and trends
- Features of the plant
- Type of product and volume
- Plant layout
- Product flow
Pharmaceutical industry Qualification Studies

Number of samples $= \sqrt{\text{area in meters}^2}$

Work area 40 feet by 60 feet $= 2400$ feet$^2$

$(12.2 \text{ by } 18.3 \text{ meters} = 223 \text{ meters}^2)$

$\sim 15 = \sqrt{223}$
Sample Sites and Frequency

Selection of sample sites and sampling frequency for non-product and product contact surfaces depends on establishment features such as plant layout, overhead structures, number of production lines/products, location of processing equipment, and product flow. A sampling protocol should include the sample sites, sample area size, sampling frequency and sample collection techniques. In general, samples sites should be selected randomly. However, some sites may be designated for sampling on a regular basis based on the hazard analysis. Sample size can be determined based on the nature of equipment or surfaces e.g. flat surfaces, inside of equipment, etc. The plan should also detail appropriate, progressive actions the establishment will take as positive samples are found.
Key Points for Sample Collection

- Don’t cross contaminate your sample with dirty hands, dirty attire, or dirty sample collection devices
- Send samples to the lab within 24 hours – ideal
- If unable to deliver within 24 hours consider dry sample collection using dry sponges/swabs
- When first starting, sample numerous sites and use large surface areas to gauge degree of contamination and identify potential problem areas
- Make an effort to find hard-to-clean areas
- Use results to educate employees
• Premoistened devices in sterile bags are recommended
• If sampling site with known presence of residual antimicrobials (sanitizer residue, antimicrobial ingredients) consider using dry devices
• When testing for allergens make sure your sample collection devices are free of allergenic proteins
When first starting, sample numerous sites and use large surface areas to gauge degree of contamination and identify potential problem areas.

Increase frequency when:

- Ingredient changes
- Leaky roof
- Drain backups
- Construction events
- Equipment installation
- Vermin/pest intrusion events
- Whenever *Salmonella* found
• Run processed products after thorough cleaning and sanitation routine and before running untreated products
• Use strict segregation to reduce cross-contamination risk
• Increase sampling frequency
• Consider end product testing
What Do the Numbers Mean?

<table>
<thead>
<tr>
<th>Total Enterobacteriaceae Count (CFU/g)</th>
<th>Percent <em>Salmonella</em> Positive in 50 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2</td>
<td>0.5</td>
</tr>
<tr>
<td>2 – 100</td>
<td>0.9</td>
</tr>
<tr>
<td>100 – 500</td>
<td>8.7</td>
</tr>
<tr>
<td>&gt; 500</td>
<td>9.0</td>
</tr>
</tbody>
</table>

Dry milk processing environmental samples example
### Establish Performance Targets

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Action Levels</th>
<th>Before Sanitation</th>
<th>After Sanitation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aerobic Plate Count</strong></td>
<td><strong>Target</strong></td>
<td>&lt; 100</td>
<td>&lt; 10</td>
</tr>
<tr>
<td></td>
<td><strong>Acceptable</strong></td>
<td>&lt; 500</td>
<td>&lt; 100</td>
</tr>
<tr>
<td></td>
<td><strong>Unacceptable</strong></td>
<td>&gt; 500</td>
<td>&gt; 100</td>
</tr>
<tr>
<td><strong>Coliforms</strong></td>
<td><strong>Target</strong></td>
<td>&lt; 10</td>
<td>&lt; 10</td>
</tr>
<tr>
<td></td>
<td><strong>Acceptable</strong></td>
<td>&lt; 100</td>
<td>&lt; 50</td>
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<td>&gt; 50</td>
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<td><strong>Enterobacteriaceae</strong></td>
<td><strong>Target</strong></td>
<td>&lt; 10</td>
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<td>&gt; 100</td>
<td>&gt; 50</td>
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</table>
Establish a Baseline and Trend Tracking

Unacceptable level

Target level

Early warning

Corrective action
Establish a Response Team

• QA/QC personnel
• Sanitation supervisor and crew
• Production supervisor and crew
• Maintenance supervisor and crew
Corrective Actions

• Break down and inspect equipment
• Thoroughly clean and sanitize all equipment, surfaces, and tools in area
• Re-swab equipment and surfaces where elevated indicator counts were detected
• Monitor area around hot site to find source
• Re-clean, re-sanitize, and re-swab as needed
• Goal to achieve at least 3 consecutive negatives at contamination site
Establish a Response Plan

• If pathogen found in zone 1, product is considered adulterated
• Determine product disposition if *Salmonella* found near zone 1
  - test and hold
  - reprocess if kill step used
  - destroy
  - divert
• Increase monitoring around contamination site to find and eliminate source