Environmental Monitoring for Pathogen Control Verification

Warren E. Stone, MBA
Grocery Manufacturers Association
Safe Food California
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Introduction

- Most foodborne disease outbreaks are the cause of two microbial contamination issues:
  - Product is underprocessed
  - Product has been contaminated in the environment
    - Either after a lethality step or
    - There is no lethality step

Today’s goals

- Very briefly review proposed regulatory requirements for environmental monitoring programs (EMPs)
- To provide information to help them design an effective EMP to verify other pathogen control procedures are effective
- To use the EMP to detect potential changes in sanitary conditions in the processing environment
- Explore extensive investigative sampling when a potential harborage is identified, and when to escalate sampling/environmental analysis and potentially finished product sampling
- Review corrective action, mitigation and documentation recommendations
- Using these techniques over time with data analysis and corrective actions will drive prevention of insanitary conditions and greatly reduce the likelihood of contamination

Environmental Monitoring & FSMA Preventive Controls

- As part of the hazard evaluation, FDA proposed to require an evaluation of environmental pathogens whenever a RTE food is exposed to the environment prior to packaging and the food does not receive subsequent lethality treatment (21 CFR 117.130(c)(ii))
- FDA proposes to require environmental monitoring as a verification activity if contamination of a RTE food with an environmental pathogen is a significant hazard
- Environmental monitoring procedures would need to:
  - Identify the locations and sites for routine environmental monitoring;
  - The timing and frequency of monitoring; and
  - Address the presence of an environmental pathogen or appropriate indicate organism detected through environmental monitoring

Elements of an effective pathogen monitoring plan in a facility

- Should include raw materials, factory environment, production lines, and finished products
- Should be designed to assure that effective source detection strategies (e.g., seek and destroy) are performed
- Should have a documentation system that allows for trend analysis of the data
- The results obtained must be reviewed regularly so that appropriate, timely action can be taken
- Should allow for dynamic adaptation depending upon results and their evaluation
Components of a successful EMP

1. Risk Evaluation
2. Monitoring for Pathogens
3. Sampling Program
4. Sampling Methods
5. Sample Handling
6. Testing Methods
7. Evaluation of Results
8. Documentation

However...

- An EMP is NOT a control program in itself
- Verification program to ensure all other food safety programs are effective
  - Sanitary facility design
  - Sanitary equipment design
  - Hygienic zoning
  - Traffic patterns
  - Separation of RTE and non-RTE areas
  - Good manufacturing practices
  - SSOPs
  - Employee hygiene training

Should we have an environmental monitoring program (EMP)?

- The EMP may not be needed in all manufacturing situations
  - Such a determination should be the outcome of a thorough, comprehensive and robust risk evaluation
  - The risk evaluation may determine the comprehensiveness of the EMP
- In the post-FSMA world, regulatory requirements should also be taken into consideration

Seek and Destroy!

- An effective EMP program is a “seek and destroy” mission
- Positive results are viewed as an opportunity to correct and improve factory sanitary conditions
- Objective is to find potential niches of pathogenic growth and implement corrective action plans and mitigation steps to eliminate them
- The objective is not to generate clean, consistently negative results
  - If all current sampling sites yield negative results, go look somewhere else

As one prominent FDA official has said many, many times...

If you’re not on your hands and knees crawling under equipment when looking for sites and doing swabs, your not looking in the right place
Risk evaluation

- Could pathogens survive and/or multiply in the food between production and consumption? (RTE?)
- Would the process allow for post-process (post lethality) contamination?
- Does the factory infrastructure allow for adequate separation between raw and RTE products?
- Does the design of the equipment minimize harborage sites?
- Does the design of the processing environment minimize harborage sites?

Risk evaluation (cont)

- Are there sensitive raw materials/ingredients that could contain the pertinent pathogen?
- Is the product intended for consumption by a high-risk group?
- For refrigerated/frozen products, consider the risk of temperature abuse. Is the cold chain well controlled?
- Is there anything that the consumer or final customer may do that could change the risk?
  - Cooking
  - Temperature abuse

Monitoring program - general

- Considering the outcome of the risk evaluation, the monitoring plan should be proportional to the risk of environmental post-process contamination and growth/survival of the pertinent pathogen in the food.
- The objective of the EMP is to detect & eliminate potential growth niches before pathogens can contaminate product contact surfaces or product, and...
- To monitor effectiveness of control programs (such as GMP, sanitation, hygienic zoning, etc.)
- The sampling program will typically focus on surfaces in the processing area and may include food contact surfaces.

Monitoring in support of pathogen control

- Hygienic measures such as zoning, use of barriers, etc. are designed to prevent or reduce contamination. Pathogen monitoring can be used to verify the effectiveness of these hygienic practices.
- Therefore, microbiological monitoring the following is important:
  - production environment
  - production lines
  - finished product (under appropriate situations)

Monitoring the environment for pathogens

- What to monitor
- Sampling program
- Sampling methods and general guidance
- Sample handling
- Testing methods
- Analysis of results
- Documentation

What to monitor?

- Specific pathogen such as *Salmonella*
- Indicator organism
  - Prevention of *L. monocytogenes*, monitor for *Listeria* spp.
  - Note: FDA has indicated they are not aware of a suitable indicator organism for *Salmonella*.
  - *Enterobacteriaceae* is used by some GMA members in *Salmonella* management programs.
Where to monitor?

- In the production area, sampling locations include surfaces that are away from the product and surfaces closer to the product.
- Most sampling locations identified in the EMP will be from the production area.
  - Those sites are sampled more frequently than the sites outside the production area.

Examples of environmental sample sites

- Zone 2
  - Areas very near to the product contact surfaces where contamination could occur without much assistance
  - External parts of equipment that are near but not in direct contact with product:
    - Exterior of dryers, coolers, filling machines or mixers, super-sacks, conveyor belts and their supports
  - Parts of vacuum cleaners and other cleaning tools used to dry-clean the exterior of the line
  - Environment close to or near to the production line
    - Area under and around equipment where product is exposed
  - Others as defined by HACCP or other studies

Examples of environmental sample sites (cont.)

- Zone 4 (non-critical)
  - Remote areas where contamination of the high hygiene zones or products is unlikely
  - Entry ways into Zone 3 areas
  - Forklifts coming into Zone 3 areas
  - Raw material staging
  - Warehouses
Zone 1 sampling

- Proceed with caution!
- A positive zone 1 finding will implicate all the product that came in contact with that surface
- When sampling zone 1, consider taking mitigation steps to limit company exposure, particularly for lines running more than 24 hours without a break. For example ...
  - Additional cleaning at some interval
  - Holding finished product until test results are available
  - Cleaning equipment after swabbing
  - Re-sampling after cleaning
- All could help to possibly create a production break and/or limit product and market exposure should undesirable results be found in the samples

PCS (Zone 1) sampling as part of verification strategy

- Develop a policy on whether and when to test Product Contact Surfaces (PCS)
- Routine PCS testing can be used in verification activities
- May be useful for investigative purposes for positive pathogen findings in area
- Also, useful in qualification of new or used equipment

PCS samples

- Samples, residues or product samples associated with the production line.
- May include:
  - First product at start up from key processing locations
  - Residues taken from conveyer belts, intermediate storage bins
  - Residues taken from dismantled equipment before cleaning or maintenance
  - Swabs or sponge samples taken from product contact surfaces
- Frequency depends upon the control level of the factory and can be outlined in factory SOP

Sample frequency for environmental pathogen and hygiene monitoring

- Suggested emphasis on sampling zones:
  - Zone 2: 60 to 70%
  - Zone 3: 30 to 40%
  - Zone 4: 0 to 10%

<table>
<thead>
<tr>
<th>Zone</th>
<th>Control level</th>
<th>Minimum</th>
<th>Medium</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Once / week</td>
<td>Twice / week</td>
<td>Investigative</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Once / month</td>
<td>Once / week</td>
<td>Investigative</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Quarterly</td>
<td>Monthly</td>
<td>As needed</td>
<td></td>
</tr>
</tbody>
</table>

*GMA: CONTROL OF SALMONELLA IN LOW-MOISTURE FOODS

Examples of control levels for pathogen monitoring

- Minimum
  - Under normal circumstances, hygienic conditions under control
  - Emphasis on environmental samples
  - Finished product results may not be required for release purposes

- Medium
  - Abnormal situations occur, such as maintenance work or annual shutdown, which could lead to increased risk of contamination
  - New lines are started
  - Deviations of the hygienic status of the factory are observed in the environment of Zone 2 areas

- Maximum
  - Focused on finished product testing; increased environmental sampling regime
  - Applies to all lots of product produced on production lines of concern
  - Necessary if pertinent pathogen is found in a finished product, PCS sample, or Zone 2 sample

Sampling Methods and General Guidance

- Environmental samples should be taken with the intent of finding the target organism if it is present
- Do NOT avoid dirty areas
- Swabbing procedures are conducted aseptically, by trained personnel
- Sterile sponges are effective for sampling large areas
- Swabs may be used for small or difficult to access areas
- Some disassembly may be necessary for aggressive sampling
- Other methods such as sampling of sanitation procedure rinsates may also be utilized for difficult to reach areas
- A negative control sample should be included in each group
In low moisture processing plants, it is important that the collection of environmental samples does not introduce moisture into the processing areas.

Sample Handling
- Procedures should be in place to avoid cross-contamination during sampling and handling, as well as to protect sample integrity.
- After sampling, immediately return the samples to the lab and refrigerate until they are tested internally or shipped to an external testing laboratory.
- Freezing the environmental samples is not recommended.
- If using an outside lab, avoid Friday samples.

Testing Methods
- It is recommended that all environmental samples be tested for target organisms following current validated methods such as:
  - Method(s) described in the FDA Bacteriological Analytical Manual Online (BAM)
  - Association of Official Analytical Chemists (AOAC International)
  - International Organization for Standardization (ISO)
  - Or a similar scientifically validated method.

Documentation
- Document all EMP monitoring activities by date, zone, time, line and location (may include condition of location).
- Document all final product test results, by organism, date, time and line.
- Documentation should be maintained as per company policy but...
  - FSMA requires food safety records be kept for two years.

Corrective Actions - general
- Corrective actions should be taken any time the pertinent pathogen or indicator organism is identified in the processing facility.
- More later...

Investigations
- An investigation followed by corrective actions should be conducted on all positive test results.
- It is important to remember that several days have passed since the swabs were taken.
- The investigation should include:
  - A review of records: Processing, downtime, HACCP monitoring & verification, SSOP, GMPs, receiving, etc.
  - Direct observations of the positive site and surrounding areas.
- The size and extent of the investigation should be determined by the plant food safety team.
The investigation may include:

- A review of the location that tested positive, the area or zone and the equipment layout
  - Look at current and previous environmental sampling results (both positive and negative)
- Review cleaning and SSOP records for the implicated area
- Observe cleaning and sanitation procedures
- Observe employee hygiene/GMP practices
- Visually inspect equipment for cracks, bad welds, poor sanitary design, etc.
- Follow water use, water flows and waste streams
- Review conditions and practices for scenarios that could lead to the contamination of products or the plant environment ... inappropriate traffic patterns, back-up of floor drains and other scenarios

**Root Cause Analysis**

- If a root cause can be identified, complete corrective actions and/or preventive measures
- If a root cause cannot be identified, determine if additional investigative sampling is required or if the event is isolated

**Corrective Actions**

- Corrective actions (CA) should be taken any time the pertinent pathogen or indicator organism is identified in the processing facility
- Investigating and implementing corrective actions or preventive measures may detect and eliminate the condition that caused a positive finding
- Corrective actions should be initiated as rapidly as possible to eliminate the potential niche where the pathogen could grow
- Corrective actions should not be delayed pending final test results
  - E.g., confirming L. mono vs. L. spp.

**Examples of Corrective Actions**

- Immediate correction of deficient GMPs
- Conduct investigational sampling prior to cleaning
- Clean and sanitize using appropriate dry/controlled wet practices
- Resample area
- Change control level
Corrective Actions - Procedures

- Expanded disassembly of equipment
- Intensified or increased cleaning, procedural changes and/or employee training
- Equipment repair, modification or replacement.
- If the zone/equipment continues to be positive, the CA needs to be escalated. For example...
  - Equipment or structure may be heat treated (shrouded and steamed, baked, certain portions flamed)
  - If any of the swabs are positive pathogens or pathogen indicators, the CA needs to be escalated. For example...
    - Action(s) taken

Corrective Action - Documentation

Document all test results and corrective actions to close out the incident. The documentation demonstrates due diligence, serves as a reference should a similar incident surface, and provides information for continuous improvement.

SPECIAL CIRCUMSTANCES

- Under certain conditions, environmental monitoring may need to be intensified to verify pathogen control when a special event or circumstance occurs. Such circumstances or events may include...
  - Water leak events (roofs, fire sprinkler, etc.)
  - Construction events: equipment installation, major repair events
  - High number or large change in number of temporary workers
  - Major change in production system
  - Startup of different types of products in the facility
  - Drainage back ups
  - Breakdown in zoning practices
  - Non-RTE Ingredients found in RTE areas
  - Natural disasters

When a special circumstance or event occurs...

- Consider increasing the intensity of the environmental monitoring program
  - selecting additional sampling sites
  - increasing the number of samples and/or
  - increasing the frequency of sampling
- Environmental monitoring should be initiated/intensified in the area where the events or activities occur (if the area is not already included under routine monitoring)
- Such an increase in EMP intensity would depend on a risk assessment

Monitoring the area for special circumstances:

- Consider taking additional samples within or adjacent to the activity site
- Samples can be taken while the activity is occurring, throughout the duration of the activity
- If any of the swabs are positive pathogens or pathogen indicators, the plant should determine, carry out and document appropriate corrective actions
- When the special circumstance is completed the food safety team may want to continue some monitoring to verify that the event has not created any long term issues
Special circumstance procedures: Baseline information

- All operations will experience both planned and unplanned production interruptions.
- Unfortunately, some special circumstances are unforeseen events that can impact food safety during processing and storage.
- In other instances, however, the special circumstance may be a planned event such as construction, major equipment overhauls, or major changes in production systems.
- When the interruptions are a planned event, food safety management should ensure that a microbial baseline of the appropriate area exists.
- If such a baseline does not exist, steps should be taken to establish that baseline before the special circumstance ensues.

SC – Establishing Baseline Data

- Baseline data should be collected:
  - Over a series of different production days.
  - At different times of the day.
  - Before the special circumstance.
- During or after the SC, EMP results can be compared against the baseline to detect if an unusually high amount of positives are occurring and apply corrective actions if necessary.

VERIFICATION & VALIDATION OF AN ENVIRONMENTAL MONITORING PROGRAM

V&V - Definitions

- Validation – a process that is used to ensure that control measures are effective:
  - Are you doing the right thing?
- Verification – a process that uses objective evidence to confirm that the specified requirements have been met:
  - Are you doing what you say you are doing?

EMP Validation

- Traditional validation is not feasible or appropriate.
- In the strictest sense/definition, validation would involve inoculating the environment with the target pathogen or suitable surrogate and demonstrating that the monitoring program is effective in identifying the presence of the organism and a corrective action can eliminate it.
- In the manufacturing environment, this is not a practical approach.

EMP Validation

- A more practical approach for validation of the EMP can include a combination of the following elements, based upon a risk assessment of the product and environment:
  - Methodology review.
  - Observation of practices, records review, and sampling results demonstrating established control measures are effective and properly implemented.
  - Do records show corrective actions effectively established control?
  - Other techniques such as use of an outside expert consultant or reliance on published materials can also be followed.
  - Does the monitoring program include the appropriate numbers of samples, site locations, and time of sampling? How were these determined?
- Put your best foot forward!
EMP - Verification

- A routine process involving review of all program elements; results, corrective actions and documentation.
- Includes visual observation of the program execution to ensure that all required steps are performed properly.
- Generally performed more frequently than validation.
- Generally performed less frequently than monitoring.
- Verification of the EMP may include activities specific to a line/area or to the overall program.

EMP Verification Activities - Examples

- Are documents/records and reported results (including required reviews/sign-offs) accurate and complete?
- Are there documents/records of appropriate response to findings and corrective actions?
- Are sampling tactics modified in response to:
  - Results/trends/repeat issues?
  - Special circumstances?
  - Changes to product, process, equipment and/or plant environment?
- Were corrective actions implemented and followed?
- Independent checks: Monitoring activities performed by someone other than the usual employee.
- Comparison of internal lab results against another lab.

Finished Product (FP) Testing

- Again, need to develop a policy on whether and when to test finished product samples.
- May be:
  - Required by customer (i.e., COA).
  - Required by inter-market shipment.
  - Used as part of an event investigation.
  - Company policy as part of Food Safety Plan/HACCP verification.
- Can you isolate “lots?”

Guidance for FP Testing

- Retesting advised for investigational purposes only (e.g., to determine level of contamination).
- Disposition of adulterated lot needs to be defined:
  - Outside third-party warehouses.
- If the product tests positive for pathogens and is in commerce, FDA Reportable Food Registry requirements may apply.

GMA Resources

- Equipment Design Checklist for Low Moisture Foods.
- Facility Design Checklist.
- Salmonella Control Guidance.
- Annex to Salmonella Guidance.

QUESTIONS???