IAFP’s Making Your Environmental Monitoring Plan Smarter

May 26, 2022

Moderator: Dr. Eric Wilhelmsen, CFS, SmartWashSolutions

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This webinar is being recorded and will be available to IAFP members within one week.
Today’s Moderator

Dr. Eric Wilhelmsen, CFS

- Senior Research Consultant for SmartWash Solutions
- more than 30 years of experience in the food industry
- special expertise and experience in risk assessment and management
- His research led to many patents and innovations
- M.S. in Food Science
- Ph.D. in Agricultural and Environmental Chemistry
Dr. Douglas L. Marshall

- Chief Scientific Officer with Eurofins Microbiology Laboratories
- His career focus is to improve the microbiological quality and safety of foods, with numerous publications and consultations in the area.
- He has received the Mississippi Chemical Corporation Award of Excellence for Outstanding Work and the International Association for Food Protection Educator and Harold Barnum Industry Awards.
- He is a Fellow of the Institute of Food Technologists.
Morgan Young

- Technical Sales of AEMTEK, Inc.
- Bachelor of Science in Animal Science from North Carolina State University
- Several years experience in foodborne pathogen research
- Extensive experience in environmental monitoring plan development and implementation.
Speaker

Dr. Florence Wu

• CEO of FREMONTA Corporation
• Fremonta focuses on research, development, manufacturing, and marketing innovative sampling technologies.
• Provides consultation in development of environmental monitoring plan, sanitation effectiveness testing, and food safety and food spoilage testing.
• M.S. in microbiology
• Ph.D. in mycology, University of Tennessee.
Today’s Topic: How to make your EMP smarter

• **Dr. Douglas L. Marshall**
  - Define environmental monitoring performance metrics that apply to your operation and utilize trend analysis in problem prevention.
  - Demonstrate examples of qualitative and quantitative deep dive data analysis that provides real actionable insight.

• **Morgan Young**
  - When, where, and how to do Zone 1 testing.
  - How to respond to organism recurrence as opposed to transient strains of pathogens.

• **Dr. Florence Wu**
  - Understanding when whole genome sequencing adds benefit to your EMP.
  - Examples of what to advise raw, ready to eat food manufacturers to include in EMP, and how to use the data generated to correct deficiencies.

• **Dr. Eric Wilhelmsen** – Open discussion
• Define environmental monitoring performance metrics that apply to your operation and utilize trend analysis in problem prevention.

• Demonstrate examples of qualitative and quantitative deep dive data analysis that provides real actionable insight.
Routine Monitoring Plan

• Focus on zones 2 & 3
• High number of identified sampling locations (>50)
• Randomly select 5-10 sample locations per week (increase sample numbers for larger, greater risk facilities)
• Number all locations for trending and investigation
• When a positive occurs
  ▪ Perform rigorous sanitation of the area
  ▪ Perform at least 3 samples of the exact same sampling area over 3 successive days (must have 3 negatives)
  ▪ Keep records of the corrective action
Which Pathogens are Important to Me?

All pathogens potentially can be found in ANY food or ingredient at ANY time!
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.

Allergen cross contact on product-contact surfaces.
Record Keeping

- Date and time of sampling
- Person collecting samples
- Sample locations
- Submission date to laboratory
- Results
- Action limits
- Corrective actions (if necessary)
Types of Data

- **Qualitative**
  - presence/absence of analyte on surface

- **Quantitative**
  - population size of target microbes or level of ATP on surface
## What Do the Numbers Mean

<table>
<thead>
<tr>
<th>Total <em>Enterobacteriaceae</em> Count (CFU/g)</th>
<th>Percent <em>Salmonella</em> Positive in 50 g</th>
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<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>
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<tr>
<td>&gt; 500</td>
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</table>

Dry milk processing environmental samples
## Establish Performance Targets

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

*Example only*
Recording of Data

- Number each location specifically
- Have defined targets for actions
- Record each result for each location
- Identify longer term action plans as necessary

<table>
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<tr>
<th>Location</th>
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<th>Jan 19</th>
<th>Jan 26</th>
<th>Feb 2</th>
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<td>13</td>
<td>13</td>
<td>38</td>
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</table>
Establish a Baseline and Trend Tracking

- Unacceptable level
- Early warning
- Target level
- Corrective action
Vectoring
Morgan Young’s Topics

- When, where, and how to do Zone 1 testing (what to do when Zone 1 is positive)
- How to respond to organism recurrence as opposed to transient strains of pathogens
Why Sample in Zone 1?

- Routinely (FDA recommendation)
- Investigational
- Root cause analysis
- New line
- Construction or other major events
- Positive for pathogen in food sample
- Positives for pathogen in Zones 2, 3 or 4
- Troubling trends
WHEN TO SAMPLE IN ZONE 1?

**Pre-op**
- Less likely to yield positive results
- Will identify sanitation weaknesses
- Easier to interpret

**During operation**
- More likely to yield positive results
- Will provide information on spread of target pathogen during processing
- Positive sample site may not be the site where the pathogen survives
- Will require pre-op follow up sampling to identify pathogen source/niche

**Post sanitation**
- To evaluate sanitation effectiveness

Note: FDA recommends testing 3-4 hours after start of production
How to Sample in Zone 1

- Make a game plan
- Involve other teams in plan.
- Test and hold procedure
  - Will require involvement from operation, materials teams, schedulers, and warehouse teams.
- Follow proper aseptic sampling technique.
- Documentation, documentation, documentation!
Responding to Pathogen Positives in Zone 1

If detected on FCS, conduct comprehensive investigation (i.e., expanded root cause analysis)

Observation and sampling:
- Hold and test product for the production day(s)
- Examine equipment that tested positive and surrounding area
  - Disassemble equipment
- Intensify sampling and testing for minimum 3 consecutive days
- Test upstream and around positive testing location (Vector analysis)
- Interview and observe sanitation, maintenance, production personnel

Document Review
- Check maintenance records for major equipment
- Review/modify HACCP or Food Safety Plan
- Review/modify production, maintenance, sanitation procedures
Finding the Pathogen with Microbiological Testing

- Vector swabbing – 360 degrees
- 10-15 samples around positive location
- Overhead, under, inside
- Belts, drains, cracks
- Drip, joints
- Break down equipment
- Rollers, hollow joints
- Air outlets, hoses
- Movable equipment in area
  - Carts, waste, re-work, fork-lift
- Sample at least 3 days consecutively after vector swabbing
RECURRING POSITIVE RESULTS

• Detecting the organisms in several sampling locations during same sampling period could indicate:
  ➤ Routine sanitation procedures are inadequate
  ➤ Potential harborages
• Increased risk of cross contamination from Zone 2 to Zone 1 or food
• May indicate presence of a resident strain
  ➤ Instances where organisms have persisted in facilities for over 10 years.
**Organism Recurrence**

- **Transient Strain:**
  A microorganism that is found in passing during routine analysis. After repeated sampling, the specific strain is not found repeatedly.

- **Resident Strain:**
  A microorganism that has taken up residence in a manufacturing environment. This organism may have formed a biofilm, making it extremely difficult to clean. The strain has been found repeatedly in a processing environment.

Note: The strain may not be found in consecutive sampling, it may be found repeatedly over a period of time.
When Corrective Actions Don’t Work

- After repeatedly cleaning and sampling
  - Hot spots continue to test positive
  - Equipment cannot be cleaned properly
  - Production line continues to test positive erratically
- Segregate line or equipment until solution is found
- Consider taking out of service
Example of Finding a Resident Strain

Situation:
- Presumptive positive found on a floor in the mechanic's shop. Sample taken to confirmation to determine specific strain.

Vector swabbing:
- Hit on the wall adjacent to the positive floor sample.
- More vector swabbing due to the second positive.
- Another hit, this time in the handwashing sink.
- Consistent hits in the sink after vector swabbing and follow up swabbing on days after the intensified sanitation.
Corrective Actions:

• Reviewed sanitation documents and practices.
• Disassembled sink for intensified cleaning.
• Found potential harborage points behind sink where welds were not sanitary.

Solution:

• Updated SSOP.
• Replaced sink.
• Sanitary welds.
Zone 1 testing is a critical component of a well rounded EMP
  ◆ With the right tools and practices, it can be successful and a low stress activity.
  ◆ Involve other departments in creating and implementing Zone 1 testing plans.
Pathogen Recurrence may happen in your processing environment.
  ◆ Observance of pathogen recurrence can mean there is something lacking in your sanitation or food safety plan. It can also point to unsanitary practices by other departments in your facility.
  ◆ With well thought-out corrective actions and amplified sampling, you can find the source and eliminate it.
• Reports of whole genome sequencing adding benefit to your EMP
• Examples of what to advise raw, ready to eat food manufacturers to include in EMP, and how to use the data generated to correct deficiencies.
What Whole Genome Sequencing Can Do
– An Example (Crowe et al., 2017)

- From 5/15 – 12/15/2014, 146 salmonellosis cases were identified in 24 states.
- During the outbreak, PulseNet identified 27 isolates from food samples and 1 isolate from a chicken cecal sample with the same PFGE patterns as that of the outbreak strain.
- Nearly all of the food isolates were from slaughtered chicken, but one was from a beef sample from a facility that processed both beef and chicken.
- CDC/FSIS conducted whole genome sequencing on 27 clinical isolates and 24 food isolates.
- The isolates formed seven main clades in the phylogenetic tree. These clades were genetically distinct from one another. Clade 7 is the largest clade.
Trace from clinical isolate -> chicken -> caterer -> producer
Link a Case of Sporadic Listeriosis to Consumption of Prepackaged Lettuce (Jackson et. al., 2016)

*Listeria monocytogenes*  
Packaged Lettuce
Connection of Lettuce Isolate and Patient Isolate
Transient or Resident?

- A plant had almost regular detections of *Listeria* in the same area of the plant.
- The sanitation crew and FSQA had literally torn apart that portion of the plant looking for potential harborages.
- Exhaustive cleaning did not break the pattern.
- WGS indicating that the repeatedly occurred organisms were not related.
- The search was on for a regular source of contamination.
- Ultimately, it was traced back to poor harvest practice of a minor ingredient.
- Totes were being set on the ground to make it easier to harvest.
- The entrained soil was the source of the contamination.
Examples

- What to advise raw, ready to eat food manufacturers to include in EMP, and
- how to use the data generated to correct deficiencies.
Where to look?

- Check items that move around and are more likely to test positive
  - Forklift wheels
  - Employee boots
  - Carts

- Check items that are expected to be positive sometimes because the organisms are brought into the plant
  - Drains
  - Cleaning brushes
  - Sanitation hoses that are dragged across the floor and not cleaned
Look furthermore

- Check places where pathogens are expected to arrive
  - Pallets
  - Cooling tubes
  - Breakroom

- Check the hard-to-clean places
  - Undersides of equipment
  - Drains
  - Pinch points where metal meets metal

- Real time observation of behavior and process
Critical Thinking for EMP

- Do NOT take “negative” as an answer
- Evaluate your sampling and testing process
- Select better microbial indicators that really help you to understand your environmental contamination risk
- Ask for expert opinion or external data review/audit
- Use analytics and historical data to improve your EMP
Use the data generated to correct deficiencies

- Dig deeper on what the data is telling you, the trend, the outliers, the “does not make sense”, “what is the story,” “what am I missing here,” etc.
- Use modern biotechnology tools (e.g., whole genome sequencing)
- Use data trending tools
- Use root cause analysis tools
Make EMP smarter by using smarter tools

**SmartSampler™**

**WIZARD**
One-click data trending simplifies thousands of data points to track results and generate insights.

**WAND**
An ergonomically designed handheld sampler for efficient sample collection and easy integration with the Wizard.

**VIAL**
Easily and safely send samples to the lab with the barcoded Vial.
Open Discussion

Please submit questions or share comments about how you have made your EMP smarter with the Q & A function and we will address the most relevant as time permits while addressing some planned questions.
A Challenge

How would you promote a shift to using more technology which adds cost to management?
Is it ever just a zone 4 detection?
Listeria are found along a forklift route. No path to zone 4 or outside. Intense sanitation efforts only yield a two-week reprieve. What do you suggest?
A plant consistently has twice the normal detection rate for Listeria. What would you suggest? Why?
Will each panelist suggest a first step or most important step to make an EMP smarter?
Contact Information

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Morgan Young  Morgan@aemtek.com
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**June 23**  
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