

The Process of Environmental Monitoring





Product Testing
VS
Environmental Monitoring
for Food Safety
VS
Process Control Monitoring

Product Testing Issues

- Statistically you can't prove a negative unless you test 100%

Sampling Probability
Probability of Missing Sporadic Contamination by Product Sampling

Number of Samples Tested	% Contamination in Lot			
	10%	2%	1%	0.5%
3	73%	94%	97%	99%
10	35%	82%	90%	95%
60	<0.5%	30%	55%	74%
120	<0.5%	8.5%	30%	55%
180	<0.5%	2.6%	16%	41%
240	<0.5%	0.8%	9%	30%

- Contamination events are generally not “normally” distributed.
- Only highly contaminated lots can be identified by testing product.
- This is the reason that Pillsbury developed the HACCP concept.

Product Testing Issues

- A positive result gives no information about the cause of contamination. Without a known source corrective action is not possible.
- A positive result produces a record that the company has “produced adulterated product”
- Can be required by a customer and add cost.
- Is only required by FSIS in very limited situations.
- Industry typically tests for process validation purposes only.

When to Test Product

- As verification of other systems such as HACCP
- Customer requirement (specification)
- Export requirements
- Whenever you have doubts
 - Environmental sample positives
 - Previous product positives



Eliminate *Listeria* from RTE

The “*Listeria* Equation”



Process Control Monitoring

- Can identify issues before product can become contaminated.
- Provides data on point sources of potential contamination permitting facility, process or sanitation practice improvements.

Silliker/NAMI Compositing Study

When testing product, give consideration to:

- Combining 5 X 25 g samples into one 125 g composite worked for USDA cultural method and BAX PCR
- Composite sampling not recommended using ELISA method
- Composites containing 15 X 25 g (375 g) not recommended for any *Listeria* method
- Details: www.meatpoultryfoundation.org
Research Topics, *Listeria monocytogenes*

FSIS Requirements and Resources

- 3 Alternatives - {per 9 CFR430.4(b)(1-3)}

FSIS Compliance Guideline:

<http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling-Lm-RTE-Guideline.pdf?MOD=AJPERES>

An Effective *Listeria* spp. Sampling Program Will Yield Occasional Positive Samples



- The ultimate goal is a *Listeria* negative environment, but this is difficult to maintain over the long term.
- The sampling plan should be designed to detect *Listeria*, if it is present.
- Positives enable corrections that can protect consumers
 - Should positives be celebrated?

Routine Environmental Monitoring is Intended to Verify Control of *Listeria* by the HACCP plan, SSOPs and GMPs

HACCP Plan

- Sanitation
- Good Manufacturing Practices
- Employee Training
- Plant Layout
- Equipment Design
- Traffic Patterns
- Lot/line Separation

HOW TO GET STARTED

to FIND it



Basic Needs

- In-depth knowledge of the facility and the uniqueness of its processes
- Blueprint
- Flow chart / equipment list
- Resources and budget
- Personnel training and commitment
- Outcome based goal

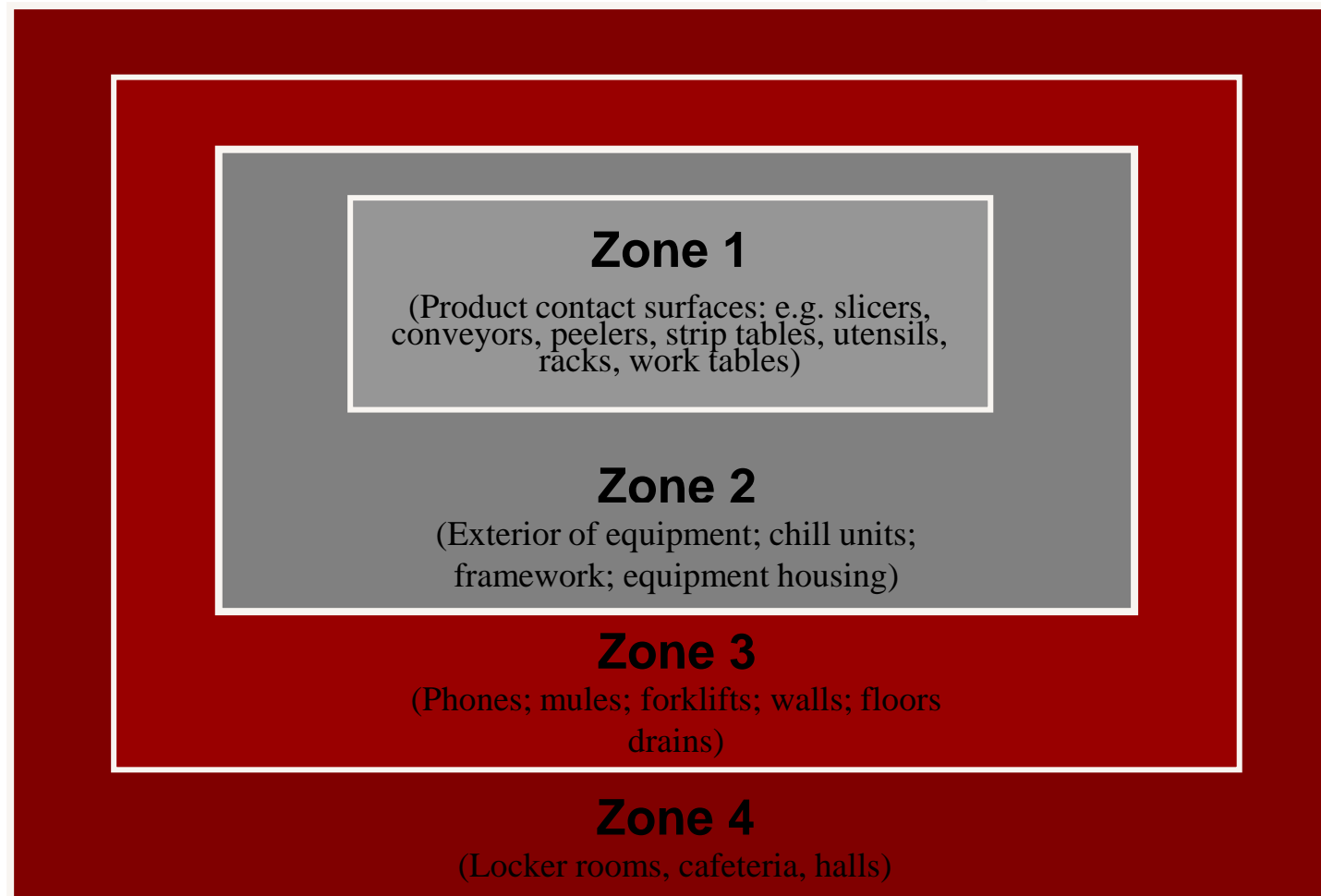
WHERE AND WHAT TO SAMPLE



Sample Site Selection

- Environmental sampling provides process control data.
- Sample product contact and non-contact sites.
 - Is there cross over from ventilation, transient carts and equipment, traffic patterns?
- Use the Sanitary Zone System.
- Maximize cost/benefit ratio.
- Sampling locations are unique to the facility and to the processing line.
 - What is a “line”?

Sanitary Zones

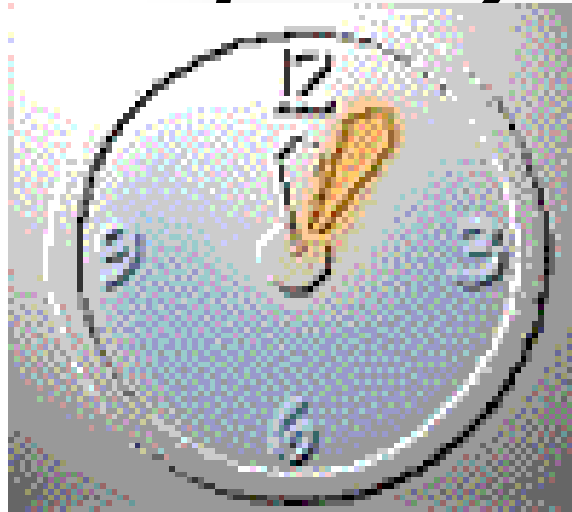


Examples of niches and other sources of *Listeria* in RTE operations

- Hollow rollers on conveyors
- Conveyor belting with fabric
- In-feed mechanism to slicer
- Worn hydraulic seals for scale on slicer
- Casing removal system for linked product
- Rubber seals on doors to brine chill
- Hand tools (e.g., for opening rejected packages)
- Spiral freezers

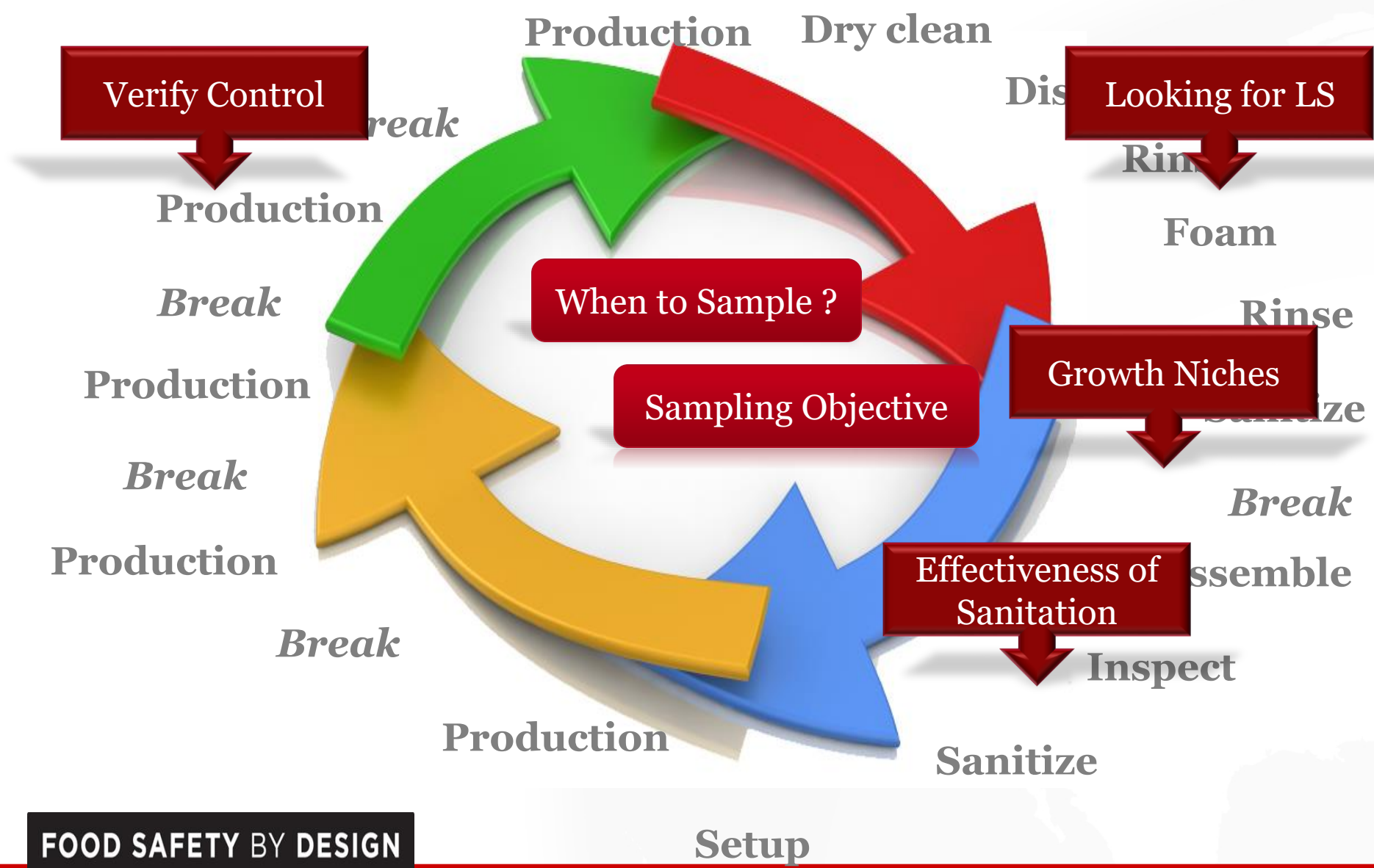
WHEN TO SAMPLE

Frequency

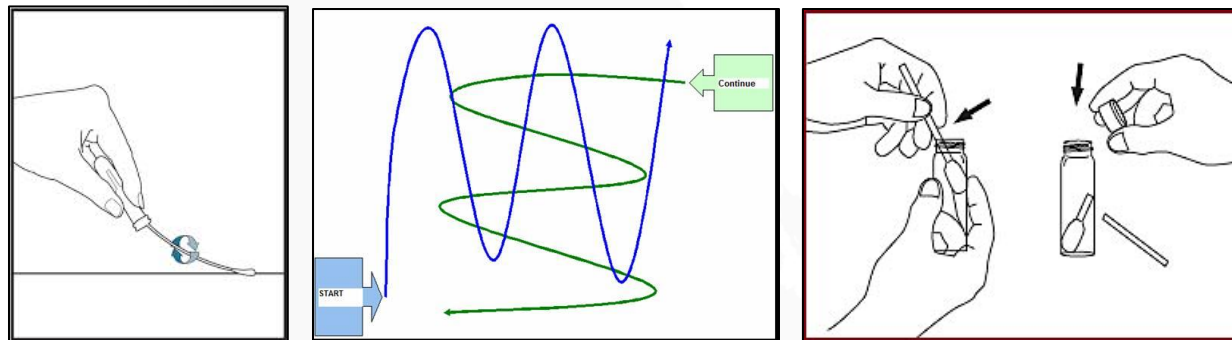


Sampling: When and Frequency

- Time of day:
 - Pre-op
 - Post-op
 - Operational
 - First shift / second shift
- Weekly
- Number of samples per line
- History and trends should influence “when and frequency”



HOW TO SAMPLE



Materials for Sampling

- Sponges or gauze pads; preferred for most samples from Zones 1-3. (can get pre-moistened sponges)
- Cotton tipped swabs - not normally used for routine sampling but can be useful when investigating a source involving hard reach sites (e.g., bolt hole, crevice)
- Disposable plastic gloves
- Sterile sample bags
- Marking pen and label stickers
- Sterile neutralizing solution (Neutralizing Buffer is preferred)

Routine Sampling

- Sample **LARGE** areas using sponge or gauze pad
- Place sample in sterile bag. (use good aseptic techniques)
- Label with date, time, and site (e.g., peeler line 3)
- Compositing is an option for routine samples with good history (*think: high maturity model*)

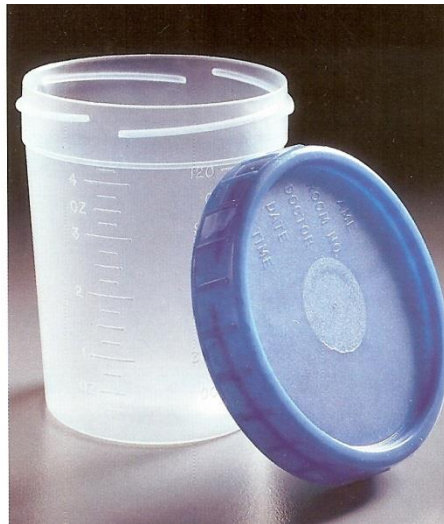


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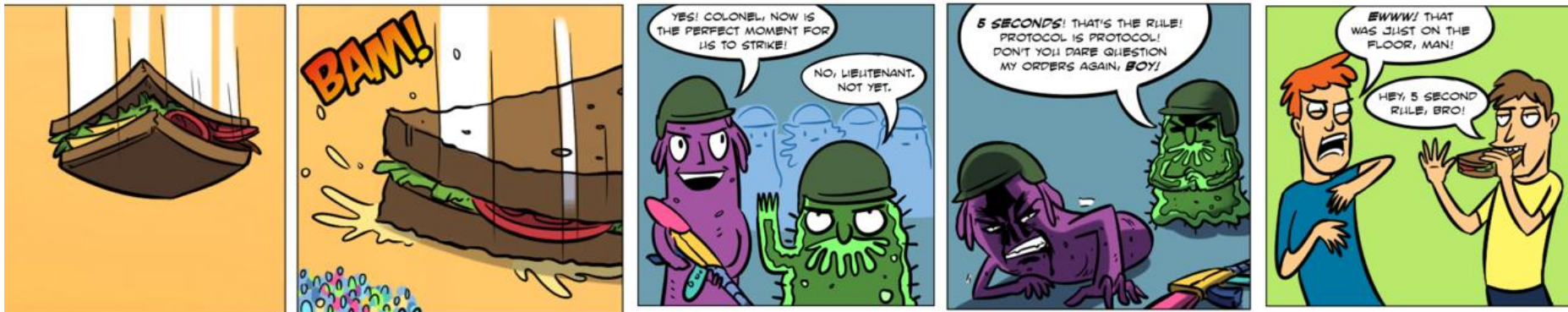


Brine Chill Solutions

- Collect in sterile bag or cup
- Label with date, time, location
- **FSIS compliance guide document can be useful**



WHAT TO TEST FOR

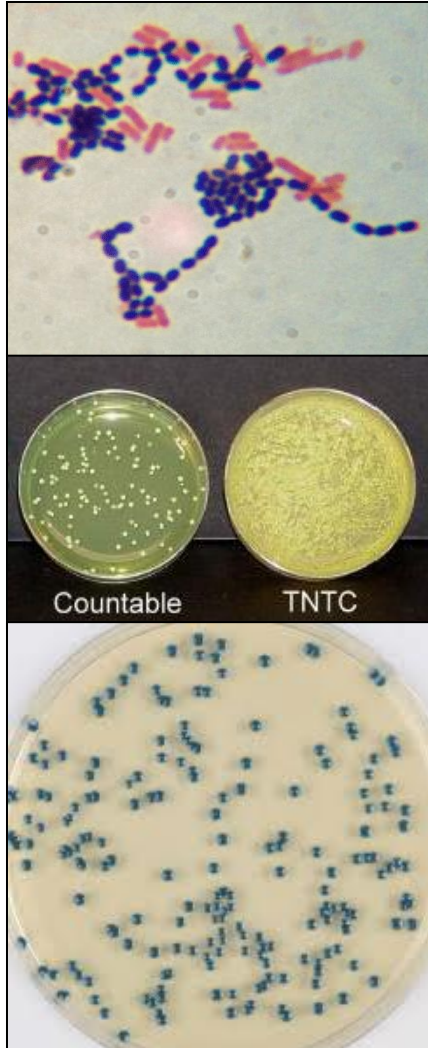


Methods for Environmental Monitoring



- General idea is to find areas that could possibly support the growth of Lm
- **The elements of food, water and sufficient time for growth are required**
- If program is too generic - baseline readings will be high, could miss niches
- If program too specific - could also miss niches – analyzing for *L. monocytogenes*

Environmental Methods - Too Generic



- Very Generic Indicator Groups - Not Adequate Alone
 - ATP Bioluminescence
 - Aerobic Plate Count
 - Psychrotrophic Aerobic Plate Count
 - Total Staphylococci
 - Total Gram Positives

Analysis for *Listeria*

- For species or for *Listeria monocytogenes*?

Do Not
Test the Environment
for Lm!

Evolution of Listeria Control

Associated with Swabbing

Awareness	Enlightenment	Preventive	Predictive
<p>No coherent strategy or management of the environmental program, no site selection strategy routine sites do not target potential niches.</p> <p>Swabbing is performed less than weekly, performed by an employee trained in swabbing but not trained in sanitary design.</p>	<p>The environmental program consists of regular and an expanded set of sampling sites on product contact surfaces and environmental sites.</p> <p>There a very few zone 4 sampling sites.</p> <p>Sampling is restricted to the written program.</p> <p>No "free" sites are available to the swabbing designee to sample.</p>	<p>The environmental program is structured around the objective of aggressive sampling.</p> <p>Sampling occurs randomly throughout the entire production window.</p> <p>Swabbing designees are not restricted by sampling area and encouraged to apply pressure when sampling.</p> <p>Investigational swabbing is encouraged targeting indicator sites and the effectiveness of interventions, hurdles and barriers.</p>	<p>Aggressive early warning sampling is the objective in a mature program.</p> <p>Potential growth niches are constantly sought out, identified, and incorporated into sampling program.</p> <p>Sampling situations presenting contamination risk identified outside of normal program is a routine practice.</p>

ROUTINE MONITORING EXAMPLE

Zone 1 Monitoring Sites



- Typically a limited number of product contact sites
- On an average line, choose around 5 zone 1 sites per line – these same sites sampled routinely
- May be composited if “under control”

Zone 2 Monitoring Sites

- Many more to choose from
- Recommendation is to make a list of all possible sites – sample on a rotating basis
- Allow technicians to collect from “creative sites” (make sure Zone 1 not accidentally sampled)



Zone 3 Monitoring Sites



Zone 4 Monitoring Sites

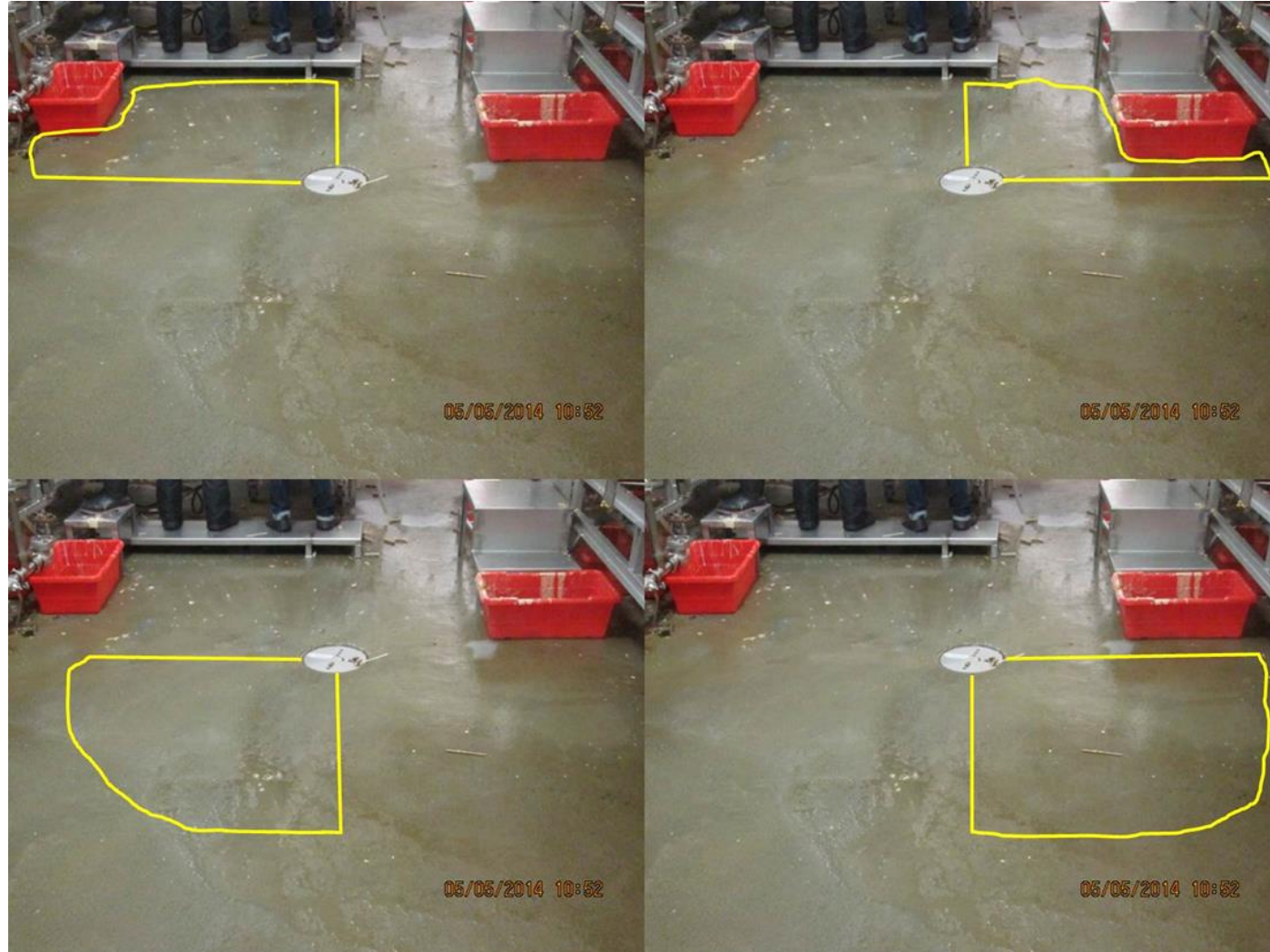


Boot scrubber center bar



Locker room

Quadrant Sampling





- *Positive samples in your routine monitoring program indicate that your pathogen control program is not working.*

Seek and Destroy (S&D)

The key to *Listeria* control in the food processing plant:

- Seek:
 - Aggressive environmental testing for *Listeria* and root cause analysis – **FIND IT!**
- Destroy:
 - Effective corrective actions that are sustainable – **FIX IT!**

Evolution of *Listeria* Control

Associated with Root Cause

Awareness	Enlightenment	Preventive	Predictive
<p>Positive findings are usually attributed to GMP or training issues with no formal process to determine root cause.</p> <p>Corrective actions are not initiated in a timely manner, not documented and with no investigational details.</p> <p>The focus is on achieving the 3 negatives that are required before returning to routine sampling.</p>	<p>There is little investigation outside the formal program.</p> <p>No reward system in place to acknowledge either effective and aggressive sampling or trouble shooting.</p> <p>Root cause analysis of positives is effective in determining a "true" cause in many but not all positive sampling events</p>	<p>A formal "seek and destroy" process utilizing a cross functional team is deployed for every positive finding.</p> <p>Getting to root cause and implementing effective corrective actions that are sustainable is the goal.</p> <p>When the root cause is not determined, plants are mandated to continue to test beyond quarantine requirements.</p> <p>Plants share their findings, S&D efforts and lesson learned across the plant network.</p>	<p>Seek and destroy deployment for root cause investigation leads to corrective actions that are shown not to be repeatable.</p> <p>Large scale investigative sampling events routinely conducted. Adoption of best practices resulting from investigation is recognized as a business priority.</p>

Understand the Difference Between an Occupied Growth Niche and a Transfer Point

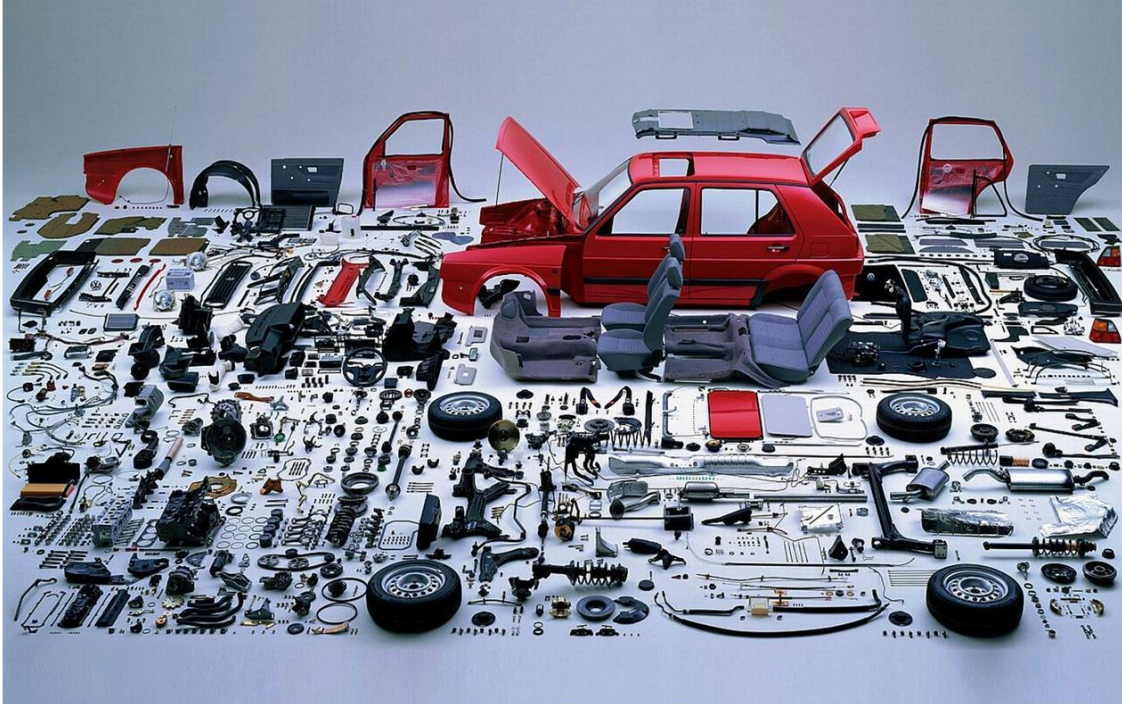
Many positive findings during verification monitoring are NOT occupied growth niches (sources of contamination). They are transfer points (a product handler's gloved hands, floor sample in high traffic pathway) that require Seek and Destroy effort to determine the root cause (contamination source) and transfer vectors involved.

Transfer points are not occupied growth niches because the organism is eliminated during daily cleaning and sanitizing processes.

Other Samplings

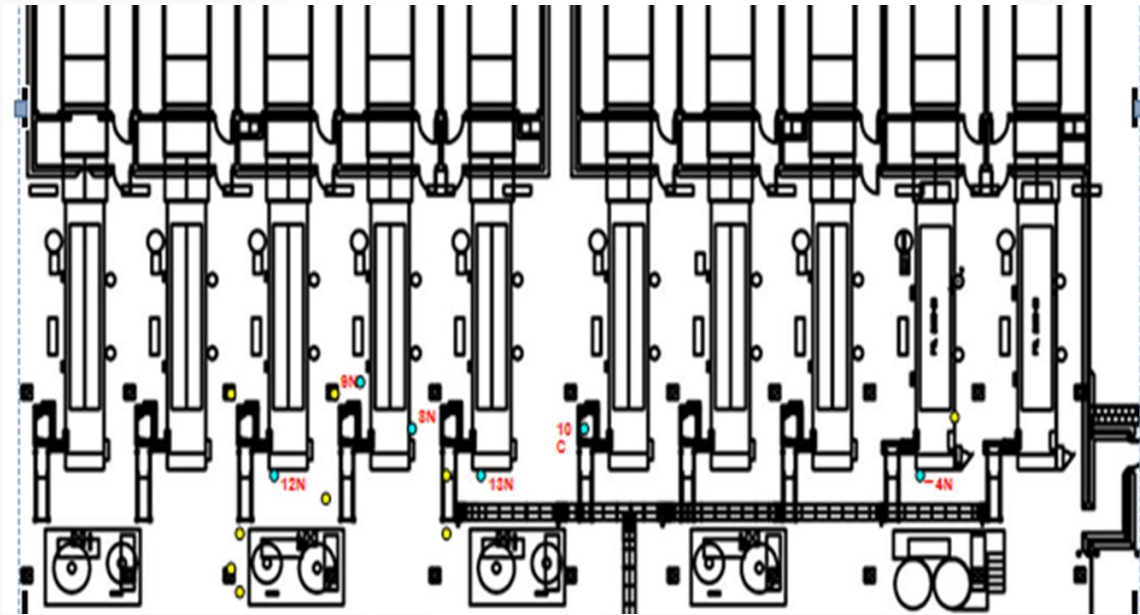
- Special Case Sampling
 - Construction: Disruptions to normal flow of people, product, packaging, equipment, air, water, waste, etc.
- Investigative Sampling (seek & destroy)
 - Usually more targeted and more intense
 - Example – Search and Destroy sampling of a slicer
- Intensive Sampling (seek & destroy “swabathon”)
 - Usually broad (line/area, not single piece of equipment) and very intense
 - In response to repetitive findings
 - Can be part of root cause analysis

Complete Disassembly May Be Required

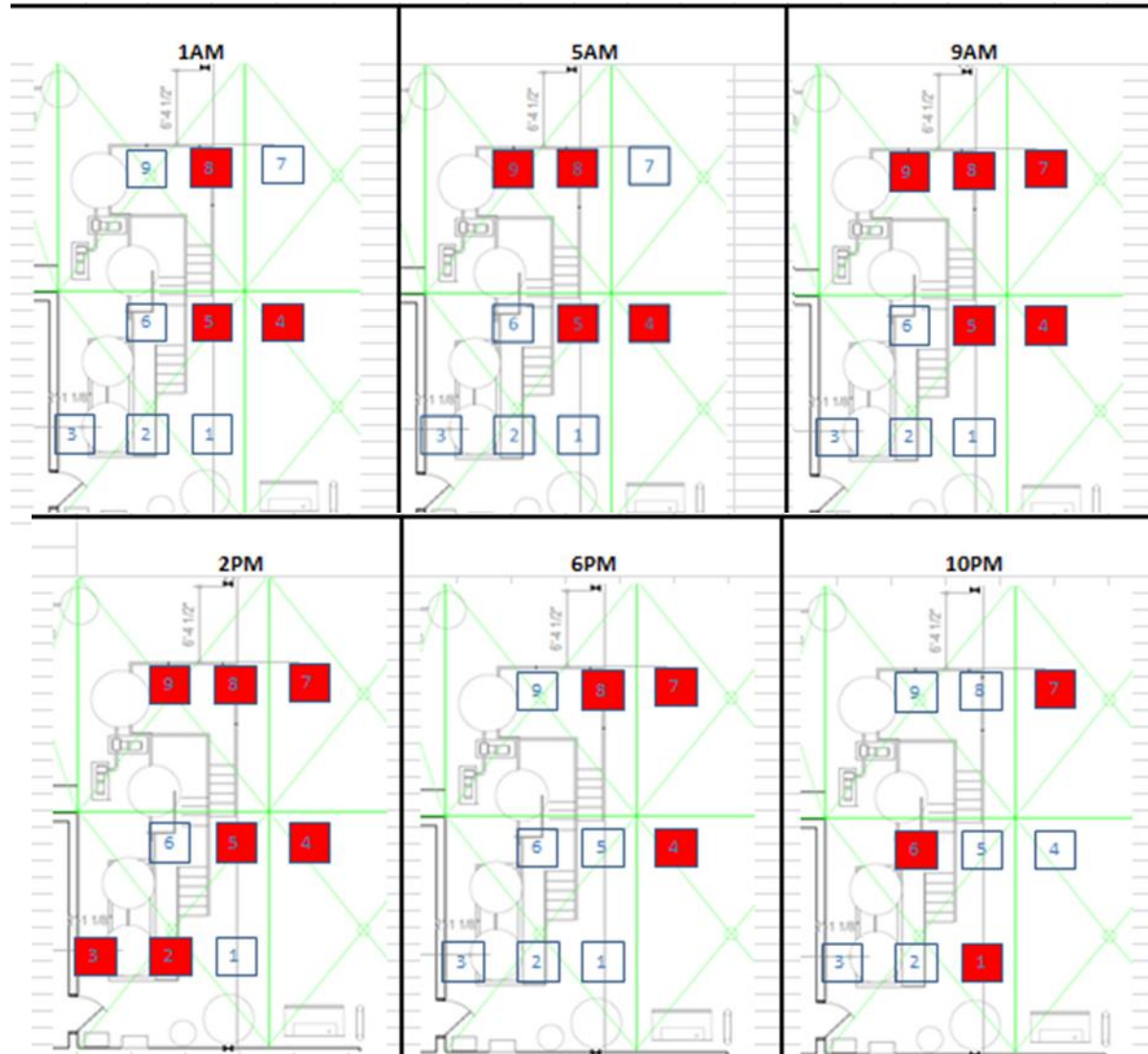


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Know Where You Are Really



Know When You Get There



Bottom Line

- Get the data and use it for continuous improvement!



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Thank You