Aggressive Sampling During Verification Monitoring and Seek and Destroy

Swab With a Purpose







For the People, Animals & Climate of Tomorrow

Aggressive Sampling

• Aggressive:

- Meaning: "Pursuing one's aims and interests forcefully, sometimes unduly so."
- Swab with a purpose of *"intention"*.
 - Know why you are swabbing a specific surface.
 - Swab within the definition of the site with **NO** constraints
 - Swab like you mean it ("Tear" the sponge).
 - How do you swab surfaces that you cannot physically access?
- Avoid *"unintentional consequences"*.
 - Swab within the rules. Never put the plant in regulatory or business risk.
 - Never swab a surface if you are NOT prepared to deal with an answer you don't want.



Verification Monitoring

• Swabbing Zones:

- Z1: Product contact surfaces
- Z2: Adjacent to product contact surfaces
- Z3: Exposed product processing areas
- Z4: Non-production areas
- Typically, sampling is:

Random

- **Random** No swabbing *intent*
- Static "Operations know <u>when</u> you are going to sample"
- Fixed "Follow the <u>same</u> sampling approach"

Sampling Maturity





VM "Positive" Finding

- A positive finding on a surface is an unexpected result.
- Program maturity:
 - Developing: The usual first course of action is to challenge the result as a "one off" and focus efforts on remediation so that there is no disruption to Operations.
 - Mature: Seek and destroy activity is focused on the determination of the root cause (contamination source) and transfer vectors.
 Corrective actions implemented that are effective and sustainable.

"In a mature state, a positive finding represents a program failure". (Dr J Butts)



Credit to Jim Mino Hormel



Example of VM (Transfer Point) Findings



Transfer point findings: Remediation through intensified cleaning without "Seek and Destroy" activity to determine the source and transfer vectors is just plain old *firefighting*.



Seek and Destroy (S&D) Reference Paper

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General Interest

Seek and Destroy Process: *Listeria monocytogenes* Process Controls in the Ready-to-Eat Meat and Poultry Industry

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"S&D is an investigative technique that includes an aggressive, systematic approach to identifying harborage sites and niche locations where microbes survive (or persist) despite cleaning and sanitation measures".

"The present article was prepared to provide formal support for the use of the S&D process and its associated environmental sampling protocols as a scientifically valid approach to control L. monocytogenes contamination in RTE foods".



Seek and Destroy – Key Attributes BEFORE Starting One

- Treat the affected production line like a "crime scene":
 - Upon notification of a positive finding: Do **NOT** rush to "nuke" the area.
 - Observe the last hour of production and the transition to sanitation.
 - Talk to front line employees.
- Form the team and remember that Seek and Destroy is a TEAM sport:
 - The plant manager and function leaders must participate. S&D is **NOT** just a QA task.
 - Gather relevant data and make it visual to provide context so that ALL stakeholders can participate.
 - Use the Listeria Control equation (control factors) to brainstorm hypotheses and develop sampling plans that will either prove/disprove each one.
- Brainstorm on "what has changed" (contributing factors) in the plant:
 - Event related: construction activity, operational inefficiencies, "work arounds" etc.
 - Systemic: Recent deviations in daily and non-daily sanitation procedures, product and process changes, people turnover etc.



Seek and Destroy – Key Attributes BEFORE Starting One

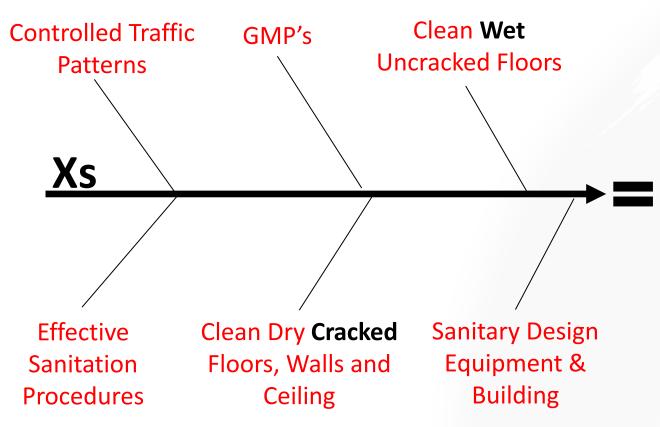
- The "Mission":
 - SEEK: Deploy aggressive sampling with INTENT (hypotheses testing and sampling) to find the source where Listeria is harboring and how (transfer vectors) Listeria moves from the source to where VM sampling found it (transfer point).
 - DESTROY: Implement corrective actions that are effective (killed it in its "home") and sustainable ("won't come back").

"Can an effective "destroy" plan be implemented if the "Seek" activities have not determine the contamination source and transfer vectors?"



Use the Listeria Control Equation to Develop the Seek and Destroy Plan

"Spreaders": Control factors that allow Listeria to move from where it is harboring to where it is detected (transfer point) through the movement of product, equipment and people during Production.



"Shedders": Growth niche (harborage) that allows Listeria to grow in spite of daily sanitation and sheds during production.

Y A positive Listeria finding is the result of a failure in one or more of the factors that control Listeria. Control can be reestablished through a "Seek and destroy" problem solving process:

- Seek: <u>Where</u> is the growth niche and <u>what</u> transfer vector(s) move the organism from its harborage site to where the positive finding was detected (transfer point).
- 2. Destroy: <u>Eliminate</u> the growth niche by designing out the risk or implement procedures to manage the risk. <u>Implement</u> preventive measures and monitor the effectiveness through "targeted" sampling.

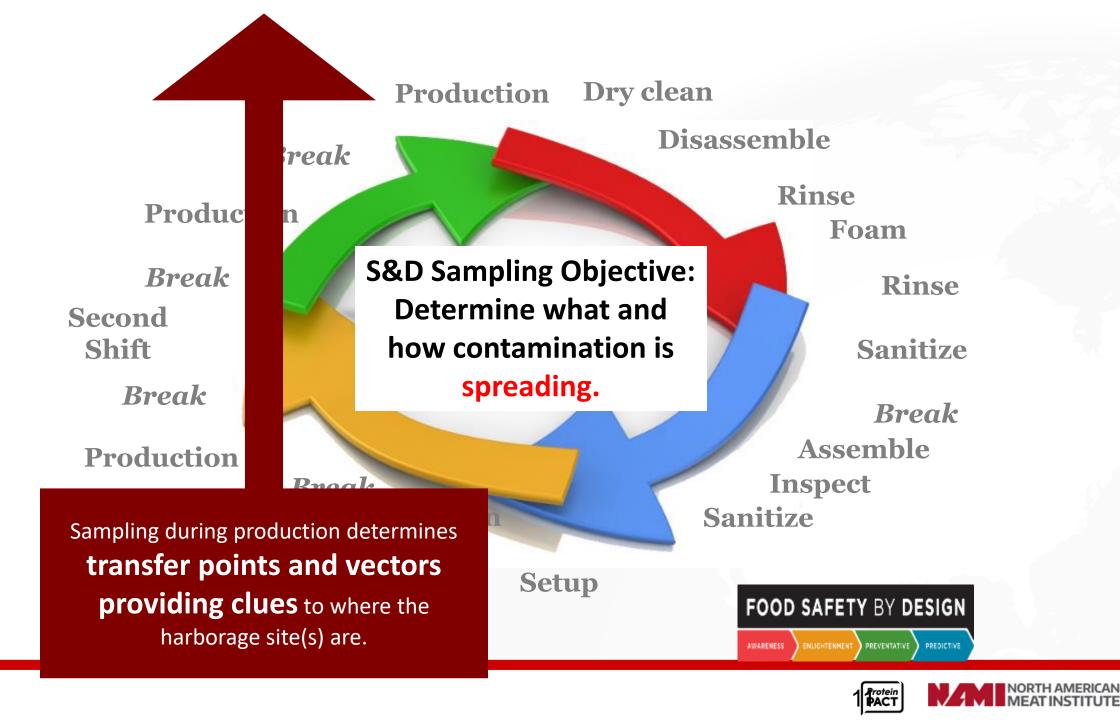


Change Sampling Strategies during S&D

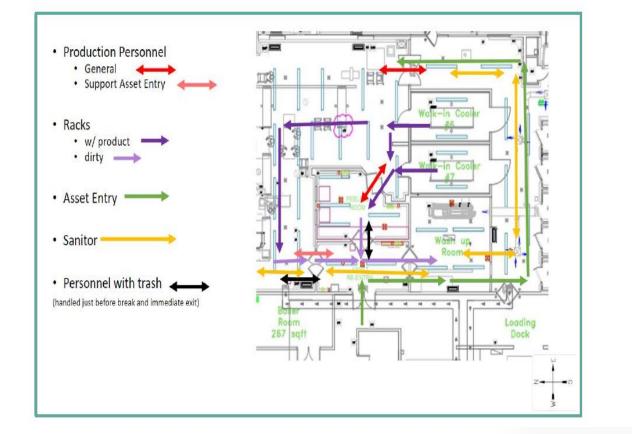
- **Biased**, not Random "Where to sample"
 - Focus on sampling sites that support your hypotheses of where the contamination source is coming from.
 - Use a "targeted" approach ie there is a specific reason why the site is "on the list" (INTENT).
- **Dynamic**, not Static "When to sample"
 - Sampling during Sanitation is required to identify equipment harborage.
 - Include the entire production window in your sampling plan.
- Variable, not Fixed "How to sample"
 - Consider other sampling approaches beyond "one site one sample":
 - Time Series sampling: Catching Listeria in motion.
 - Rinsate sampling: Sampling method to detect for equipment harborage.

VM sampling methods will not be effective during Seek and Destroy activities. Seek and Destroy is <u>NOT</u> Listeria Battleship.





Time Series Sampling – Developing a Microbe "Video"



Floor Cross-Contamination due to Foot Traffic (Revealed During Camera Review)

- The value of in plant surveillance cameras provides the ability to watch the movement of product, people and equipment over a period of time.
- Time series sampling enables what is not visible to be visible when done correctly.
- In order to "catch" Listeria in motion from the moment it first appears AND how it spreads in the processing environment, sampling plans must be developed at a frequency that captures ALL the movement that is in the investigation scope.



In addition to "mandated" Seek and Destroy swabbing, a more intensified sampling approach may be required to determine the contamination source and transfer vectors.

Time series sampling changes two important sampling variables:

- When to sample:
 - Determine the tact time (rhythm) of the process?
 - Does it make sense to sample based on time or object?
- What to sample:
 - What is already known based on previous positives?
 - What are the potential contamination sources?
 - What are the potential transfer vectors?

What is Your Area of Suspicion?



The sampling methodology is **formidable** and will require significant resources:

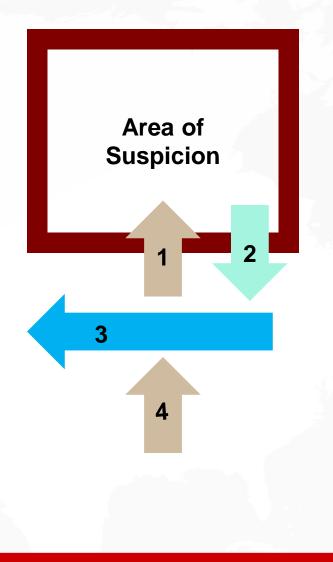
- Are there enough swabbing consumables to support the activity?
- Has the lab been informed that several hundred swabs will be coming their way?
- Are there a sufficient number of trained swabbers available to execute the activity?
- Have people been assigned to manage the logistics to ensure the chronology of the swabbing activity remains intact? Capture ALL the metadata of the sampling event.
- Take Listeria swabs AND TPC swabs together where possible. It is always good to have both qualitative and quantitative data.



Step 1: Determine whether sampling is based on time or unit.Step 2: If based on time, how many sites for each sampling "shot".Step 3: Determine the metadata to be collected.

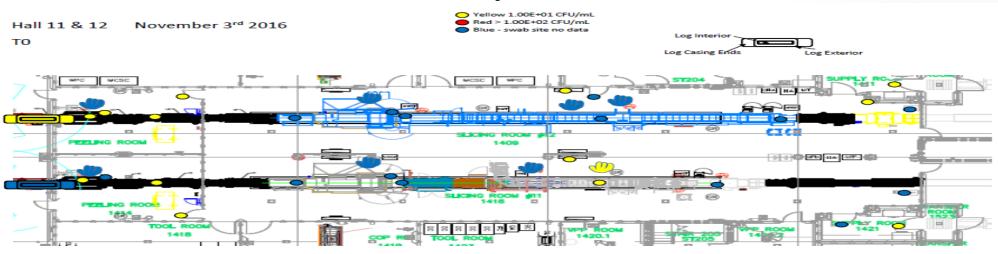
Note: It is ok to adapt "on the fly".

Sample	Time	Object	Direction	Comment
1	8:00 AM	Boot	Into cooler	Sam just came through boot washer
2	8:07 AM	Product Rack (21) wheels	Out of cooler	Rack was in position XY
3	8:15 AM	Boot	Adjacent to entry	John walking from rack wash
4	8:24 AM	Boot	Into cooler	Sam stayed in RTE



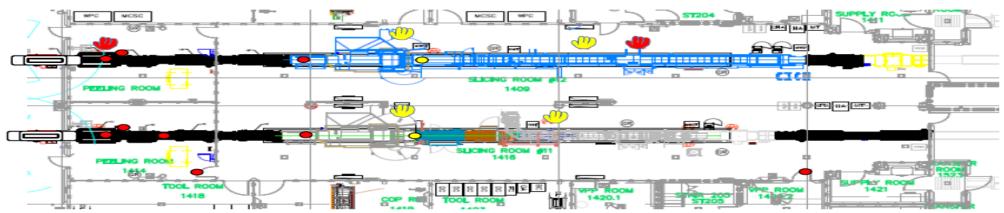


Time Series Example – Based on Time





Т6



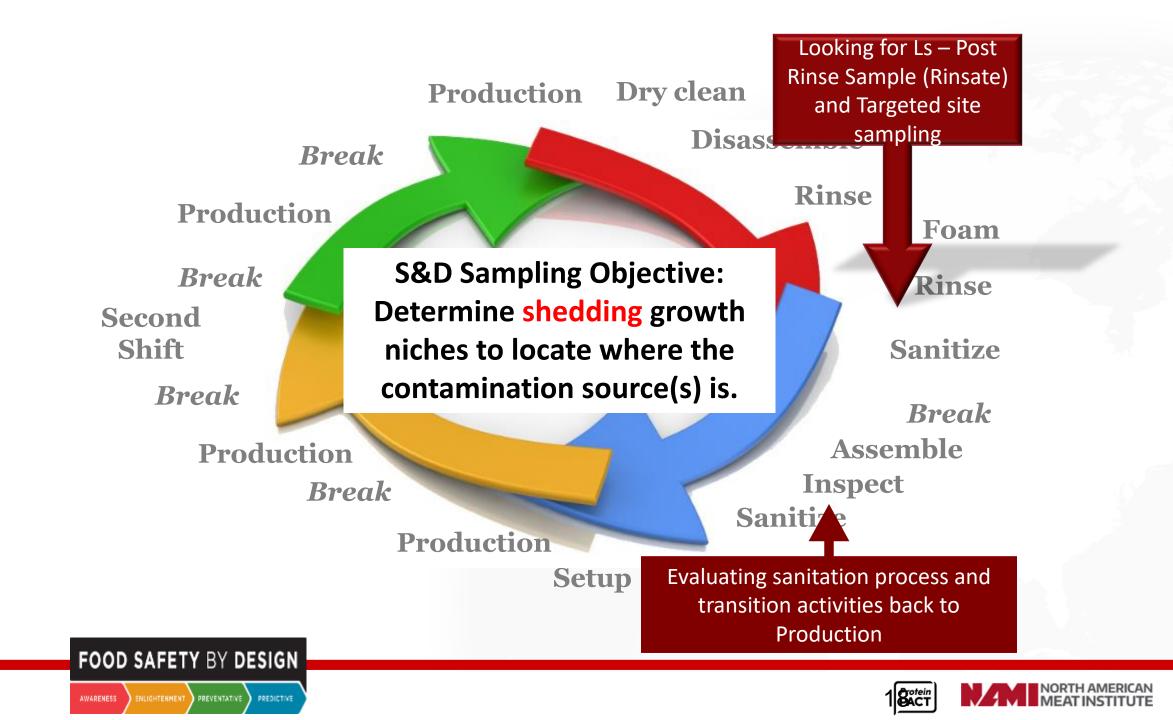
Determined the contamination source was upstream of the slicing line



Additional considerations:

- There is nothing more frustrating than a time series event that yields no significant results. <u>It is very</u> <u>important not to jump to time series as a "shotgun" approach to problem solving.</u> This tool must only be used when the team has narrowed down the probable "suscepts" and other swabbing methods have not narrowed down the field of potential contamination source(s).
- Don't be shocked when the swabbing activity yield lots of findings. Due to the repetitive nature of the sampling activity, if the team selected wisely, getting lots of positives must be celebrated.





Rinsate Sampling

- Created by Dr John Butts, first used at the Land O Frost Arkansas plant in 2003 and shared as part of the NAMI Advanced Listeria course.
- It is a practical method that allows surveillance of those surfaces that are either inaccessible or not practical to swab directly.
- Sampling is performed during sanitation, immediately after pre or post rinse steps (at the normal boosted hot water pressure and volume).
- Tested as a Z3 site for Ls. It is strongly recommended that when rinsate swabs are tested for listeria, duplicate swabs are also taken for TPC.

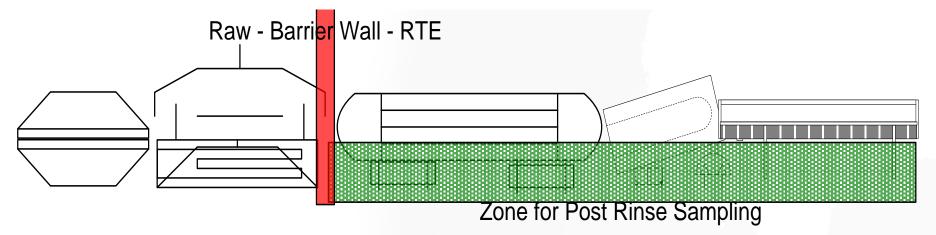


Rinsate Sample Sites



Enclosure Underside

Equipment wheels





Rinsate Sampling – "Leap of Faith"

- The sample collected is NOT rinse water. It is the weeping water residue that collects on the lower framework and equipment legs at the floor juncture AFTER post rinse water falls to the floor.
- A rinsate swab is an "indicator" sample site representing "many" equipment (internal and external) surfaces above and adjacent to the swab site.
- There are many uses including:
 - Harborage site "detector" during Seek & Destroy and VM.
 - Investigative sampling as a result of an EMP (listeria, coliform, EB, etc.) or spoilage finding (YM, Latic, etc.).
 - Annual EMP "swabathon": part of multi-day validation to verify program robustness.
 - Validation / Verification swabbing to help establish or support PEC / PIC cleaning frequency or for monitoring & managing known design growth niches (early warning & establishing predictive PEC / Maintenance PM's or repair frequencies).
 - Support Plant Zoning Risk Assessment.



Rinsate Sampling Example #1

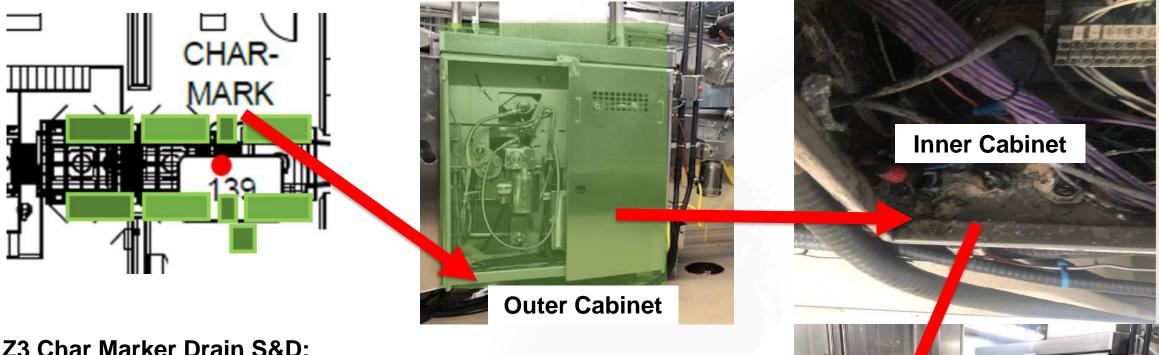


Lactics Investigation:

- Rinsate swab taken on the equipment foot of the jump conveyor.
- Opening of the enclosure panel revealed soil debris trapped between the cover and the gasket seal.



Rinsate Sampling Example #2



Z3 Char Marker Drain S&D:

- S&D involved extensive floor swabbing but no source determined.
- Rinsate swabbing deployed and source was found on the non operator side char marker electrical enclosure (inner cabinet).
- Short term: Sanitation room sequence was modified to minimize soil overspray to the non operator side.
- Long term: An equipment redesign repositioned the inner panel to the adjacent wall.





Destroy: You Found "Bio crud", Now What?



Developing state: The plant is focused on achieving negative results in order to resume regular production as soon as possible. No Continuous Improvement

Mature state: The plant is focused on source/transfer vector determination, implementing corrective actions that are effective and sustainable AND implementing preventive measures. **Drives plant FS risk out.**



Destroy: Effective/Sustainable Corrective Actions and Preventive Measures

- Use the "5 whys" to identify the root cause gaps in: equipment, procedure and culture that contributed to the failure.
 - What led to the incident and can it happen again?
 - What changes need to be made?
 - Is everyone "on the bus"?
- Determine and implement short and long term corrective actions.
 - Replace (design out) solutions <u>are better</u> than managing through procedures?
- Deploy preventative measures/controls if procedures are used.
 - What actions can be taken to "mistake proof" the control factors?
 - Develop "indicators sites" that will monitor the effectiveness of corrective actions implemented and will provide a failure alert BEFORE positives are detected by verification monitoring.

Positives during the developing phase of maturity provides an opportunity for continuous improvement in equipment/facility design and processes.



Seek and Destroy Maturity Model

Awareness	Enlightenment	Preventive	Predictive	
Not using the Listeria equation to develop a sampling approach to find root cause. Focus is on remediation.	to control but not having a process that	•	The cross functional S&D team meets routinely to drive continuous improvement through process control, sanitary design changes and investigational activity.	
Fire Fighting		Fire Prevention		
For Cause		Investigational ("No	ot For Cause")	

Complacency and Turnover



Process Control and Investigational Sampling May Yield "Positive" Findings



- Sampling is:
 - Process control swabbing is targeted towards indicator sites to monitor the effectiveness of the barriers/hurdles/interventions in place.
 - Investigational swabbing is used to assess the risks associated with process or infrastructure changes.
- "Good Positives" are celebrated (Pizza?) because control can be re-established BEFORE findings become known through verification monitoring and far away from food contact surfaces.

"Preventive S&D missions strengthen the robustness of the control program with the focus to eradicate persistent strains or mitigate their impact."



In Summary...

- Treat VM Like You are Playing "Listeria Battleship":
 - Sample aggressively to *truly* measure program effectiveness.
 - Install a "learn" mode to EMP and add "targeted" samples to weekly site selection.
- Use Seek and Destroy as the Continuous Improvement "Engine" to Design Out Findings:
 - Use alternative sampling methods to find contamination sources and transfer vectors.
 - Use time series sampling to "reveal listeria in motion" (how listeria spreads).
 - Use rinsate sampling as a "harborage detector" (Where listeria harbors and sheds).
 - Implement corrective actions that are effective and sustainable.
 - "Designing out" a problem is more effective than managing through procedures.
- Develop Process Control Measures to Add Program "Robustness":
 - Deploy investigative sampling to monitor and verify preventive measures that create barriers and hurdles to protect food contact surfaces.



Thanks!



