ENVIRONMENTAL MONITORING "BEST PRACTICES"

IAFP Webinar

June 2017

FOOD SAFETY BY DESIGN

AWARENESS ENLIGHTENMENT PREVENTATIVE PREDICTIVE

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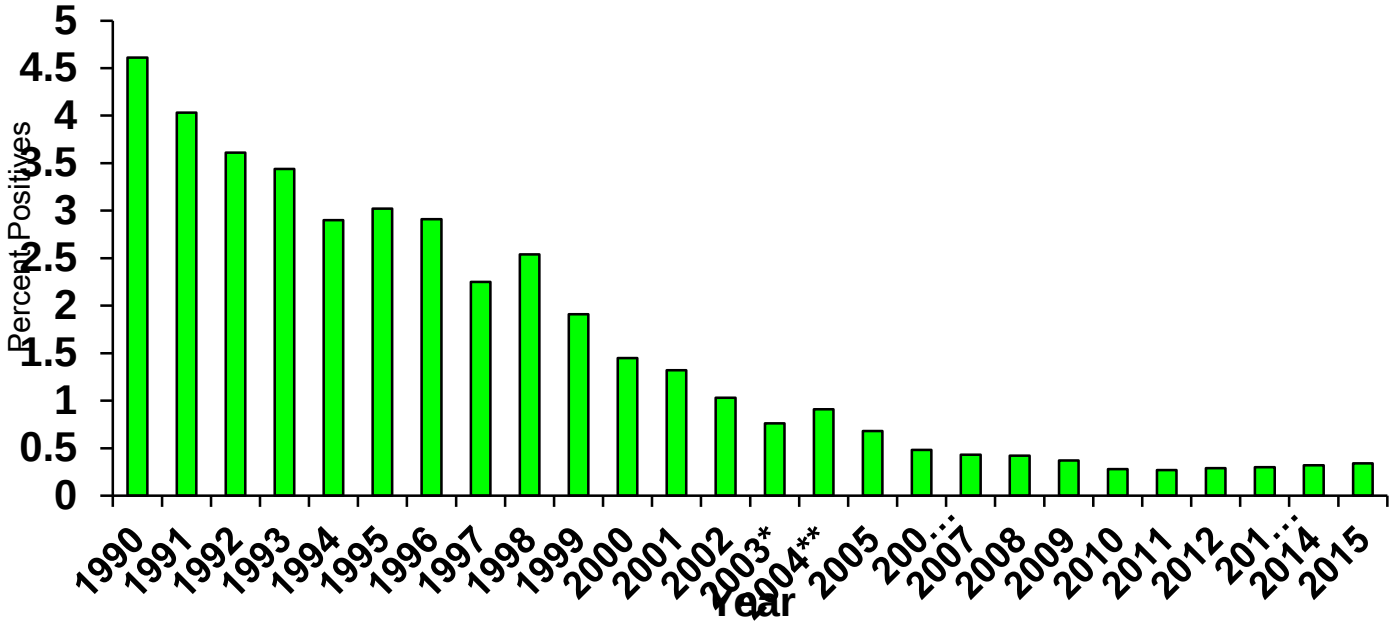
Great Tasting Lunchmeats™

Seek & Destroy Required

Learning Objectives

- Definitions
- The S&D Process
- “Find it” using Indicator sites and “Not for Cause Investigations”
- Best Practices

FSIS Regulatory Testing for *Listeria monocytogenes* in RTE Meat and Poultry Products[1]



[1] All data sourced from the Food Safety Inspection Service (FSIS), results of ready-to-eat products analyzed for *Listeria monocytogenes* – summary by all projects. Specific sample numbers tested prior to 2001 are no longer available, only percent positives.

*2003 – FSIS began target sampling of RTE products based on Directive 10,240.3

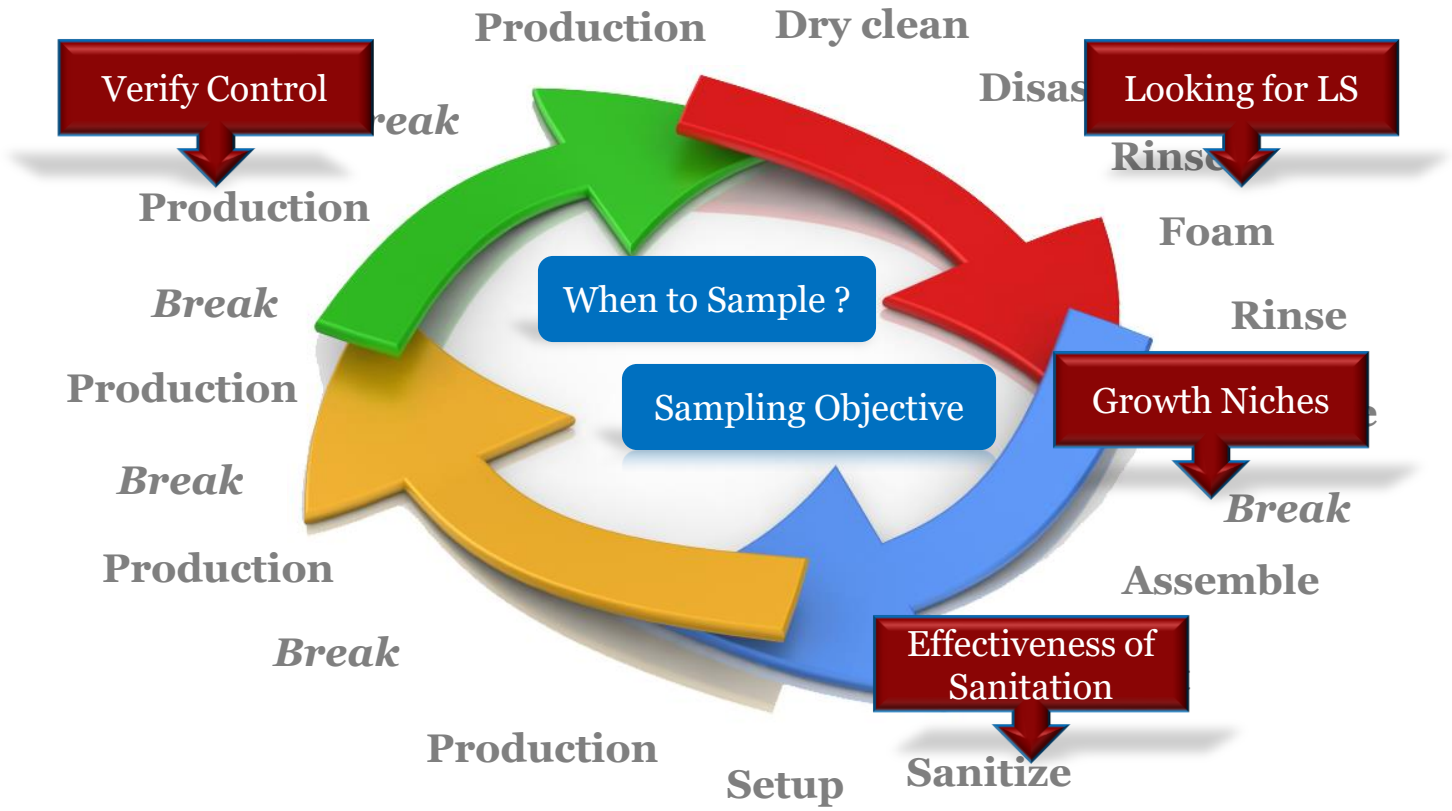
** 2004 – Sampling method changed to ALLRTE and RTERISK1

***2006 – RLm sampling plan implemented

****2013 – RTEPROD_RAND and RTEPROD_RISK sampling plans implemented

Listeria Control Success

There has not been a direct link of a listeria illness or death associated with a federally inspected meat plant in the u.s. since 2003.



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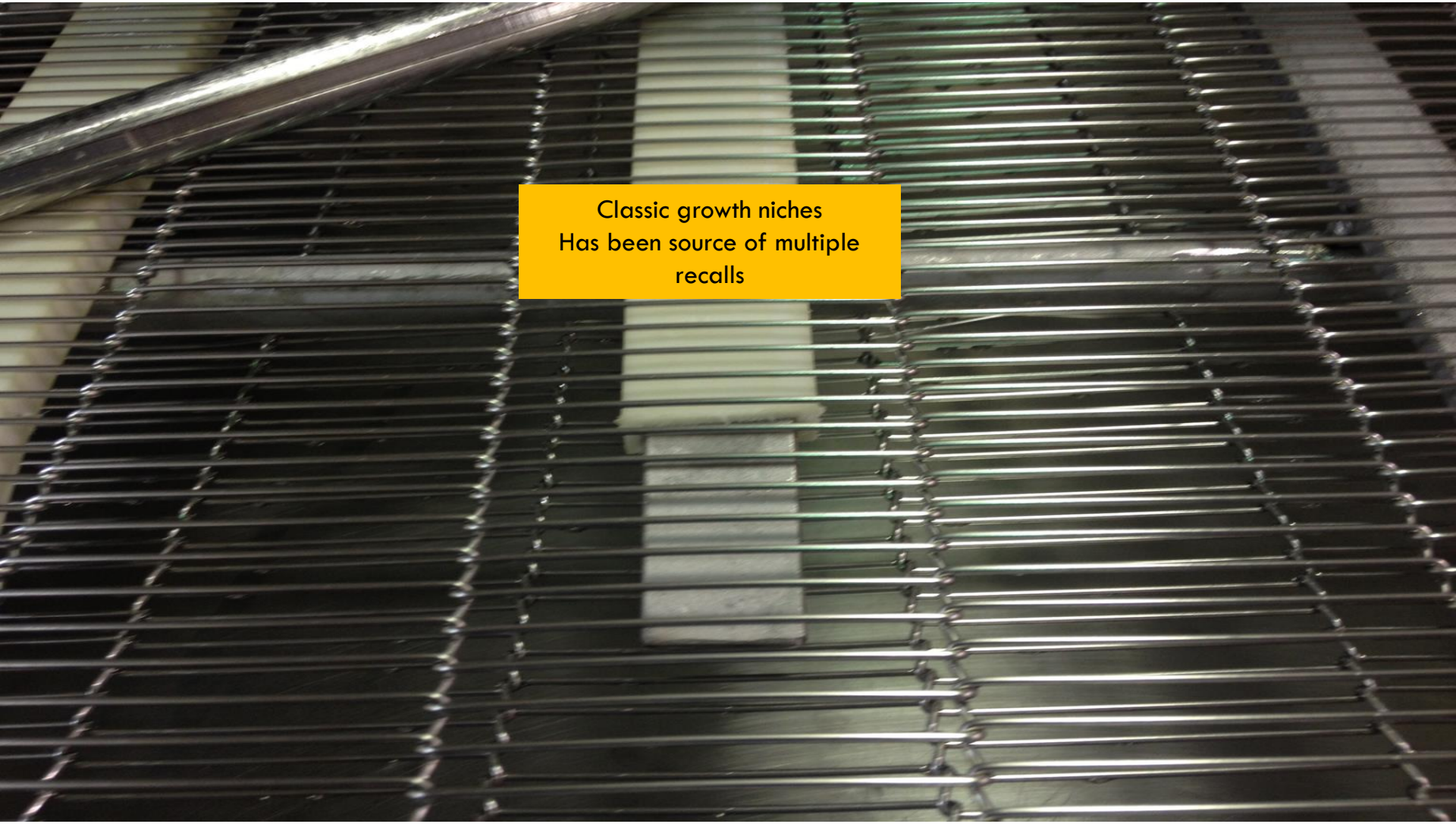
Transfer point

- Surfaces that are exposed to cleaning and sanitation and can serve as points of contact facilitating the transfer of an organism from one surface to another, e.g., gloved hands.
- Transfer points should not be growth niches when effective cleaning and sanitizing procedures are used on equipment of good sanitary design.

Transfer pathway

- Path of travel an organism takes to move from transfer point to transfer point
  - The pathway between the harborage site and a contact surface or product
- This typically reflects transfer of a pathogen by objects or people.
  - Water, employees, equipment, product, materials, and aerosols are common transfer vectors.


Classic growth niches
Has been source of multiple recalls

The Effects of Listeria Can be Minimized or Controlled

1. Eliminate Residents
2. Control Transfer of the Organism
3. Deploy Process Management Techniques

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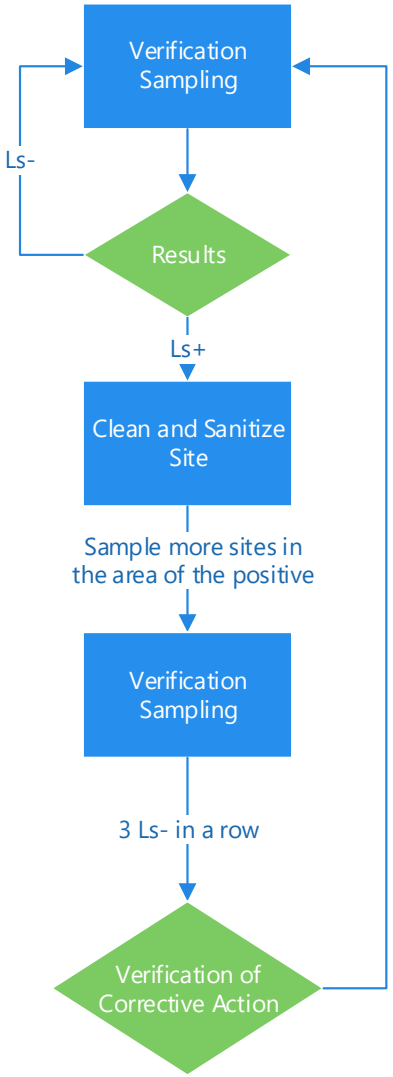
Eliminate the source

Resident organisms “Pets”

The same organism that caused the first fatality in processed meats was the source of an out break 12 years later.

Same Plant, Same bug.

Verification Sampling and Corrective Action



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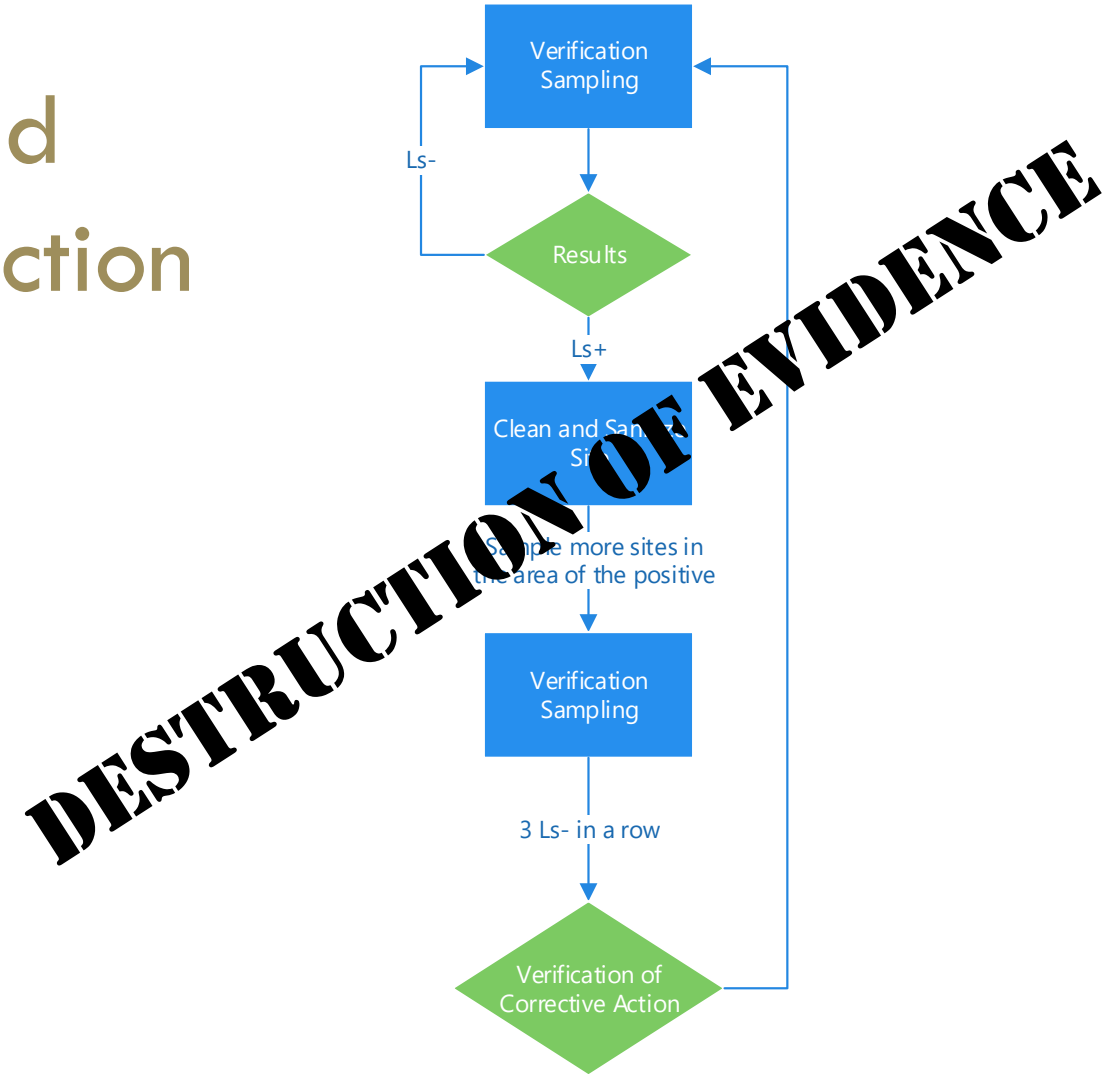
Verification Sampling and Corrective Action



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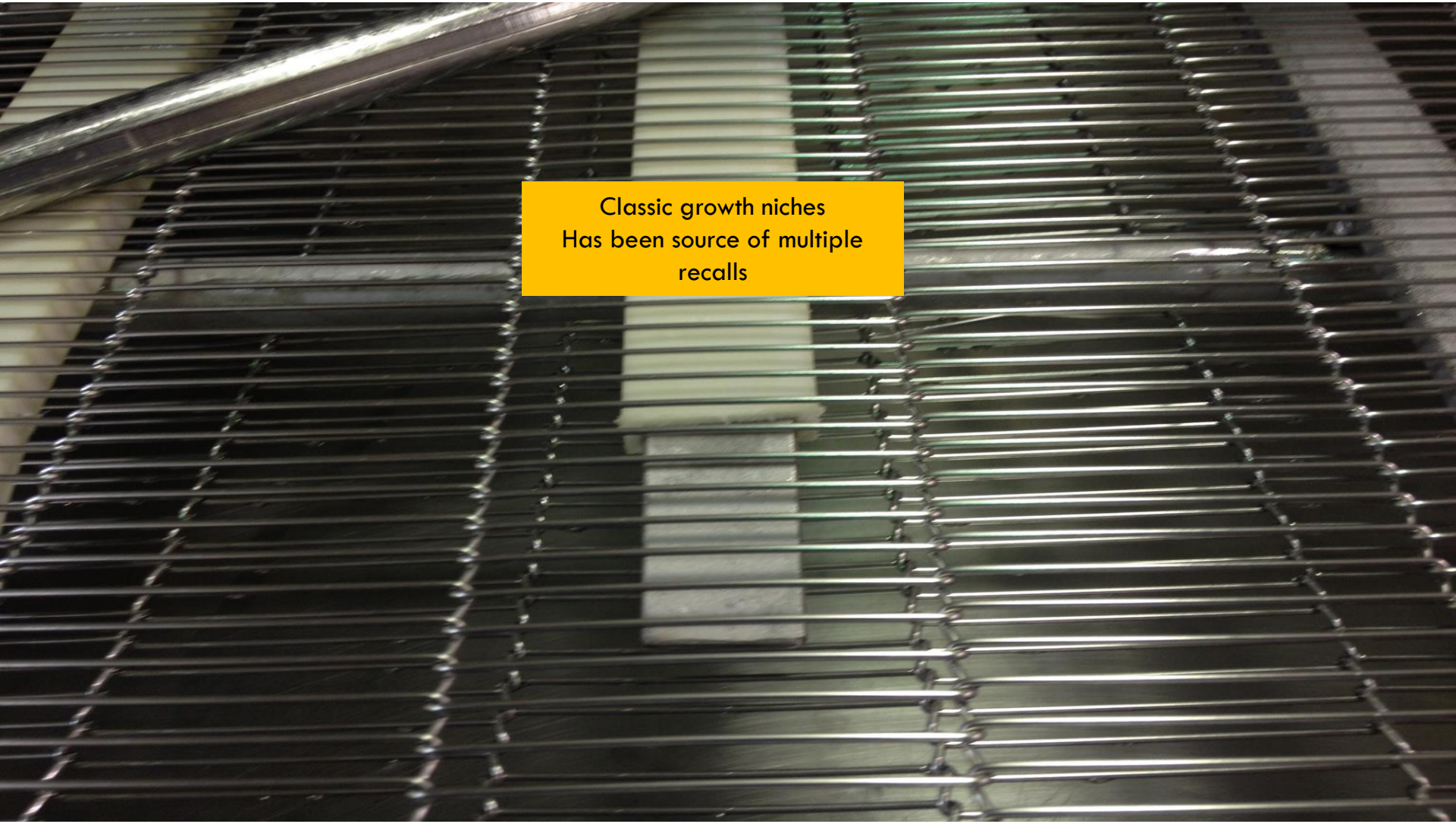
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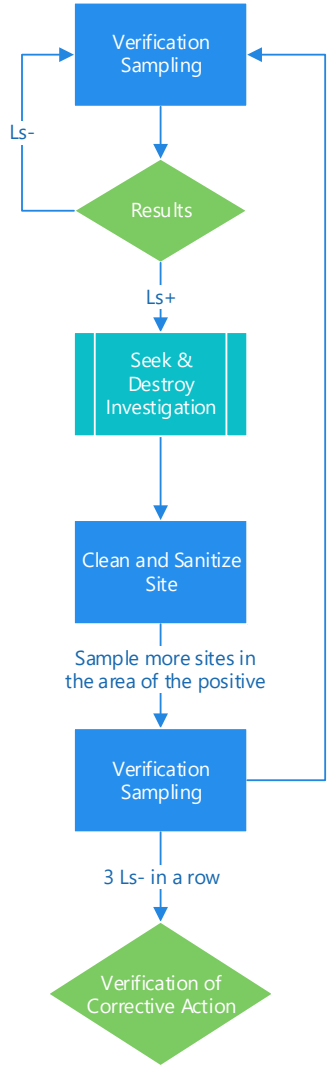
Investigate to Find Harborage Site



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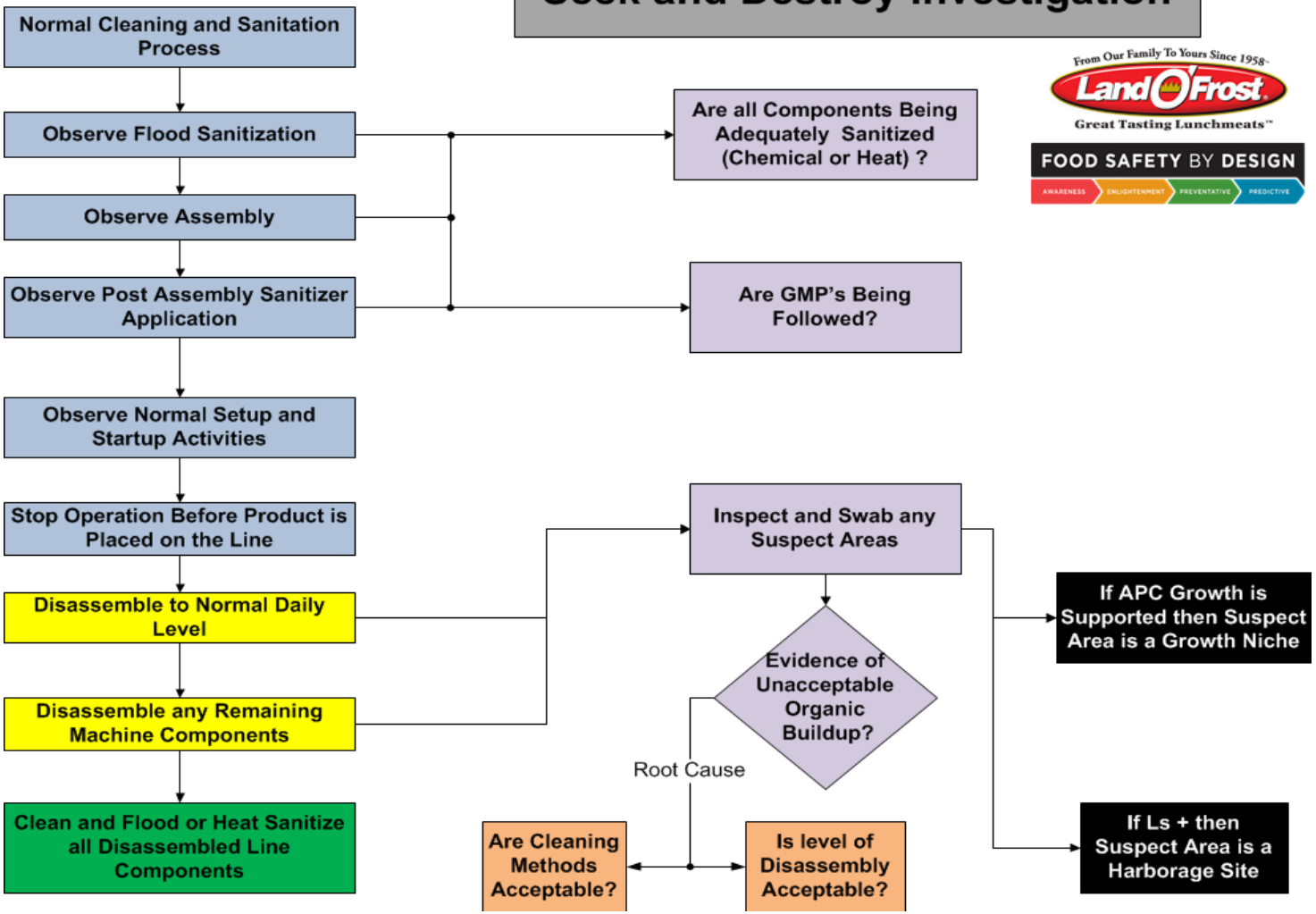
Seek and Destroy Investigation



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Operational Definitions

The Seek & Destroy Process

is a systematic approach to finding sites of persistent strains (niches) in food processing plants, with the goal of either eradicating or mitigating effects of these strains.

Three Fundamental Types of Sampling

Agressive Process Control Sampling

Find Positives with Process Control Sampling

Verification Positives Indicate Process Control Failure

- Verification
  - Product
  - Z1 contact surfaces
  - Z2 & Z3 transfer pathways and vectors
- Process control
  - Indicator sites
    - Facility and equipment sanitary design concerns
    - Z4 to Z3 transfer pathways (hurdles)
    - Effectiveness of hygienic zoning
    - Post initial rinse
- Investigative
  - For Cause
    - Sampling after Verification positive
  - Not for Cause
    - For purposes of Process Control

Verification Monitoring Program

Find the organism in motion as it is being transferred from a harborage site to the product

- Routine program to verify the effectiveness of the sanitation process control program; includes sampling of
  - Product
  - Zone 1, 2, and 3 environmental sites during operation in the RTE area. This program is used for regulatory compliance
    - a part of an establishment's HACCP or SSOP program.
    - A part of FDA plant's Preventive Controls Program.

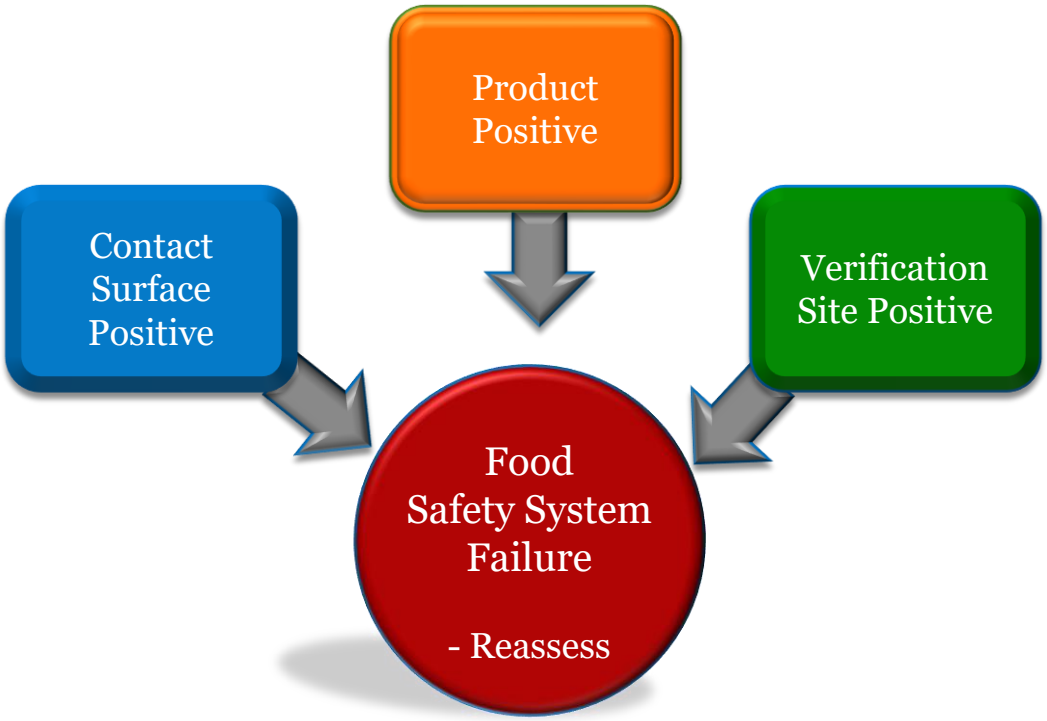
Verification sites contact surface (zone 1)

- Testing of zone 1 (food contact surface) sites is typically the primary verification measure *in FSIS regulated plants* for the effectiveness of the environmental pathogen control program to prevent product contamination.
- In high-risk product production, these sites should be evaluated weekly; lower risk lines may be evaluated less frequently as long as the process is under control.

Verification sites (zones 2 and 3)

- Locations sampled during operations to detect the presence of the organism in the normal operating environment.
- Verification sites are surfaces that are exposed during the normal operating conditions and are likely to serve as transfer points (i.e., they are located in transfer pathways).
- Monitoring of verification sites detects the organism as it is being moved from its harborage location to a contact surface or the product.
- Indicator sites are not part of the verification monitoring program. When an exposed surface is suspected to be a harborage site, then preoperative sampling should be used to measure the effectiveness of the sanitation process (e.g., a damaged plastic container).

The Effect of Verification Driven Control



Process Control

S&D Process - Critical Factors of Sanitation Process Control

GROWTH NICHE CONTROL

Sanitation Critical Factors

- Degree of disassembly
- Chemical sanitizer treatment
  - Effective coverage (Flood sanitation)
  - Time
  - Chemical concentration
- Hand scrub Contact Surfaces

GROWTH NICHE CONTROL

Sanitation Critical Factors **cont'd**

- Heat treatment
  - Small parts (COP tank)
  - Localized steam
- Non Daily scheduled sanitation
  - Rotational deep cleaning
  - Equipment pasteurization
- Effective GMP's after flood sanitization

Hygienic Zoning

- Raw to Cooked
  - Absolute – Active Control
- Risk Control
  - Separate facility areas with each pathogen reduction hurdle
    - Separate Flume containing an antimicrobial
    - Separate before and after an Antimicrobial spray
    - Separate progressive cleaning steps

Sanitary Design

- Apply Sanitary Design Principles (NAMI)
  - Facility & Equipment
  - Continuously upgrade by following the data
- Recognize Sanitary Design Faults
  - Apply routine Indicator Site sampling to monitor risk

Operational Definitions – S&D Process

Process Control *(Not For Cause)* **Investigation**

- **<u>Food Safety has not been compromised</u>**
  - Examples:
    - Samples taken to find a new growth niche
    - Samples taken to find a new transfer vector / pathway
    - Samples taken to establish or qualify a hurdle or barrier system
    - Samples taken to establish a monitoring procedure or process
    - Samples taken to assess or characterize risk of a control procedure, part of facility or process change

Operational Definitions – S&D Process

Process Control *(Not For Cause)* **Investigation**

- **<u>Food Safety has not been compromised</u>**
  - Examples:
    - Can be triggered by a Z3 or Z4 indicator site positive. *(Z2)?*
      - These indicator sites are strategically located in close proximity to a known growth niche, barrier or hurdle. Movement of the organism from the indicator site through a verification site or area would be required before violation of food safety.
      - These indicator sites over time measure the strength of the barrier or hurdle or the effectiveness of the management of growth niches

Operational Definitions – S&D Process

Process Control *(Not For Cause)* **Investigation**

- **Food Safety has not been compromised**
  - Examples:
    - Seek and Destroy Investigation on a new piece of equipment to develop sanitation methods and identify potential areas of risk
    - Seek and Destroy Investigation on a piece of equipment that has been in operation without any linked Verification positives. The purpose of this investigation is to measure effectiveness of sanitation methods below the normal level of disassembly.
    - Seek and Destroy Investigation on a piece of equipment to define the normal and periodic deep level of disassembly
    - Investigative sampling to identify optimal locations for placement of indicator sites in either Z3 or Z4
    - Measurement of risk in Z4 area

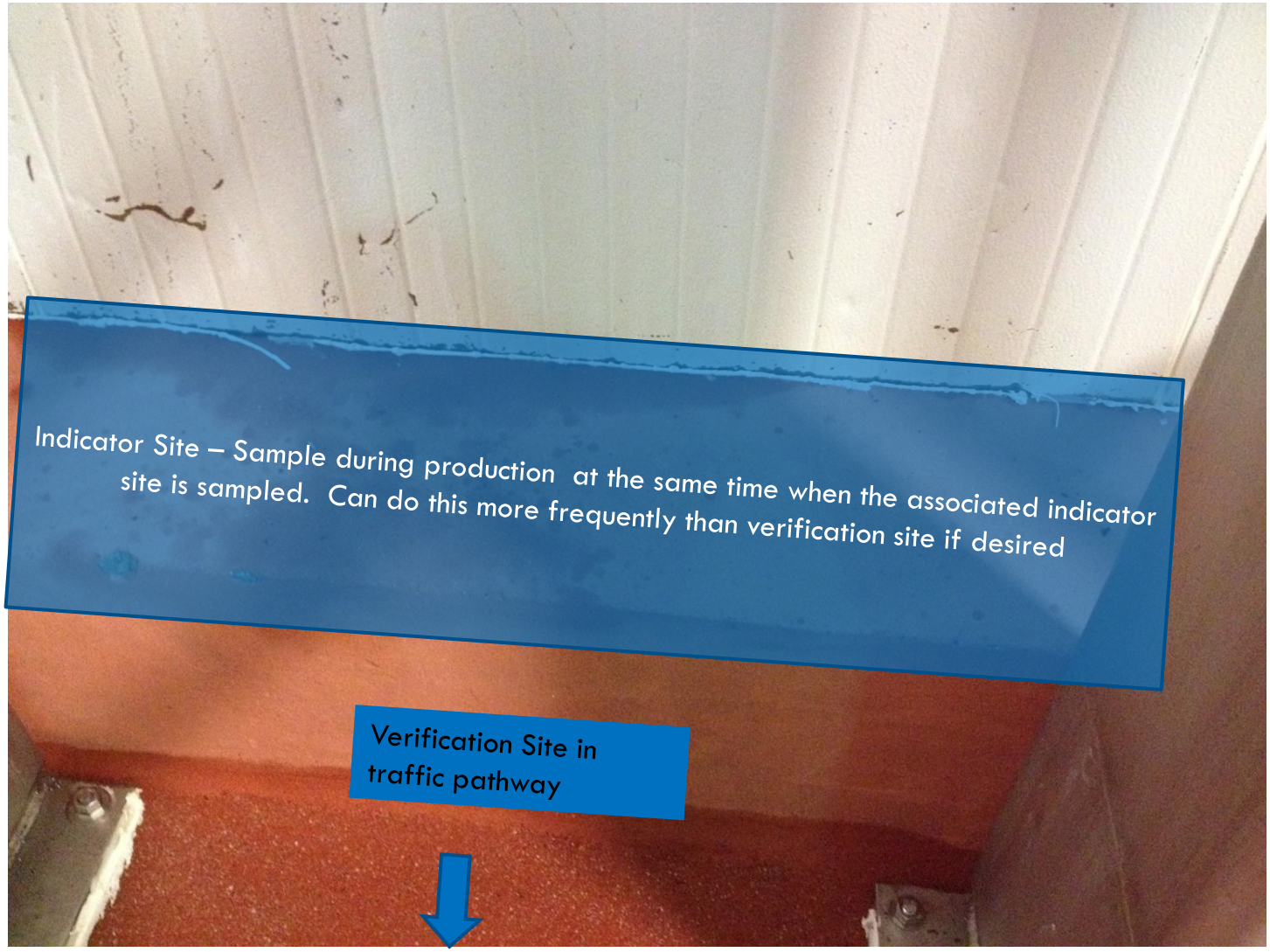
Indicator Sites

Measurement System for Process Control.

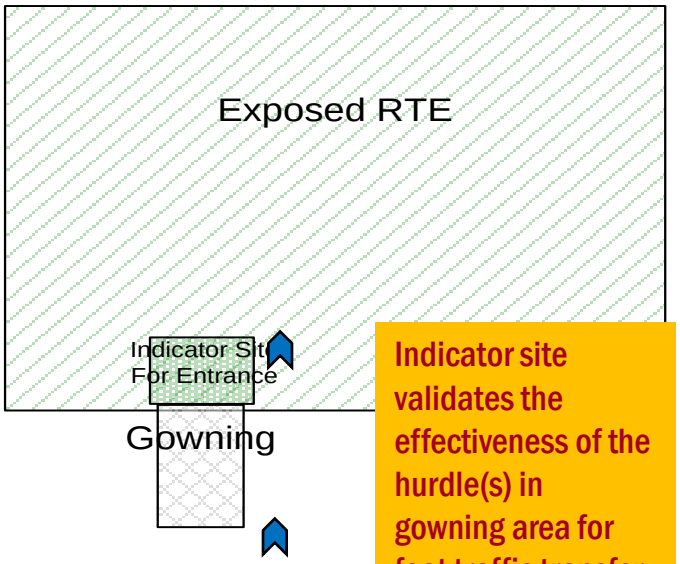
"Risk Based" Process Control Sampling Methodology.

Ideal Indicator Sites

- Locations close to the growth niche that can identify an active growth niche
- Locations that can identify suspect organisms before they become attached to or imbedded within the equipment.
- Z4 to Z3 Transfer areas
- Sanitary Facility & Equipment Design issues

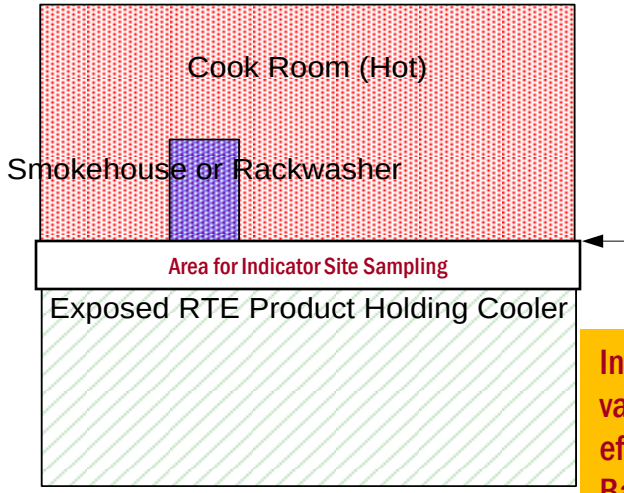

Indicator Site – Sample during production at the same time when the associated indicator site is sampled. Can do this more frequently than verification site if desired
Verification Site in traffic pathway

Indicator Site: Z4 to Z3



Indicator site validates the effectiveness of the hurdle(s) in gowning area for foot traffic transfer into RTE area

People Traffic



Indicator site validates the effectiveness of the Barrier Wall to prevent transfer into RTE area

Infrastructure

Indicator Sites

Post rinse

- Sample large areas that collect “spatter”
- Composite sampling acceptable
- Improve sampling efficiency
- Positive results will direct investigation team to a line, pair of lines, or section on a line.

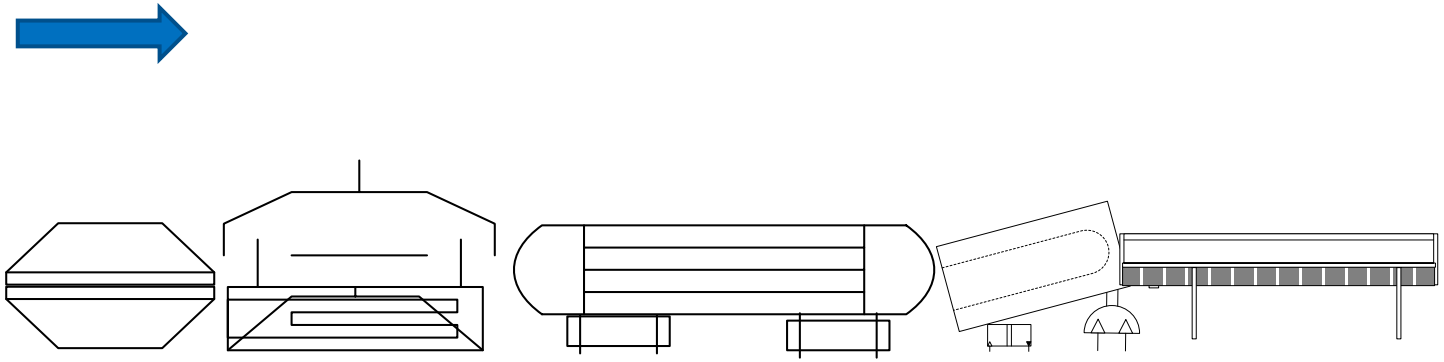
Postrinse Sampling

Postrinse sampling is an indicator potential risk.

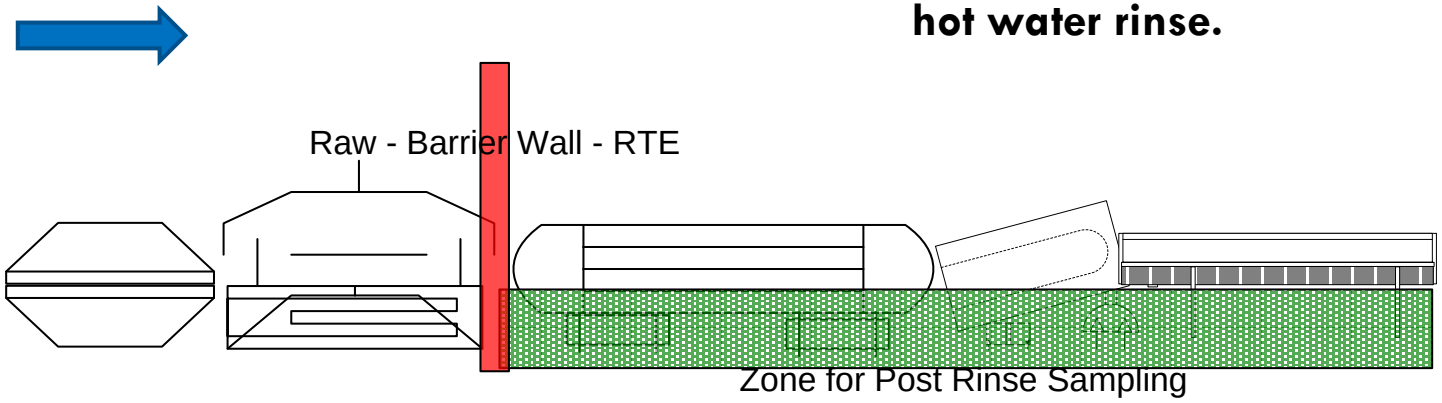
- Typical sites are below the product line and in areas that tend to collect spatter from the rinsing process (e.g., machine sides, legs, support structure, floor wall juncture).
- Detection of the organism does not mean there is a harborage site within the scope of the sampled area.
- Positive post rinse samples will typically trigger aggressive sampling or "not for cause" investigative sampling.
  - PR 10 days in a row

A postrinse sampling positive is NOT an indicator of a food safety hazard

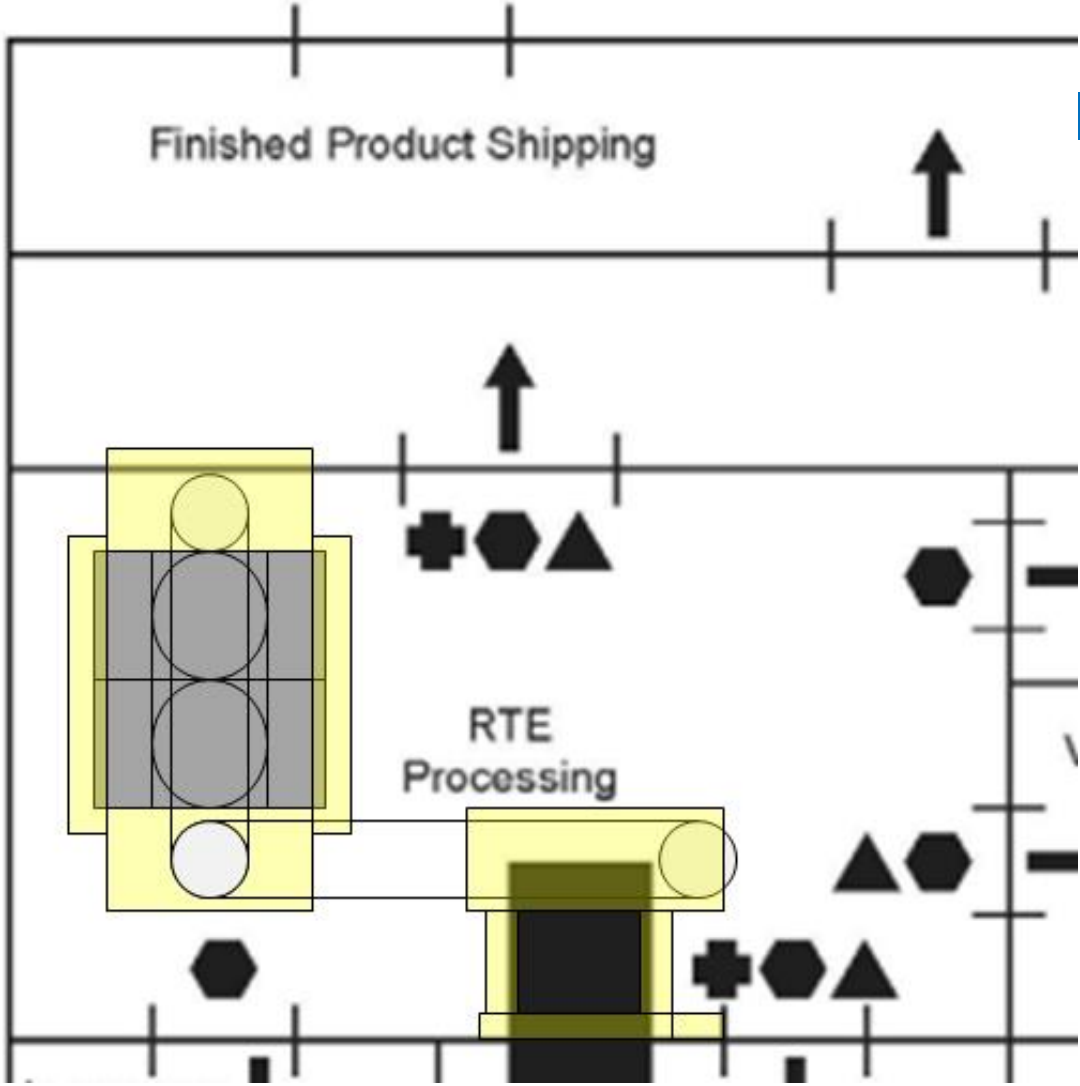
Production Line to Demonstrate Post Rinse Sampling



Post Rinse samples are taken after disassembly, dry pickup and the initial hot water rinse.



Equipment Post Rinse Sites – Overlaid on FDA Guidance example



The S&D Process "Best Practices"

- Observe peoples practices
  - 5s – simplify and declutter the area
- Development of Preventive Controls
  - Interventions
    - All equipment
      - Deploy COP on small parts and tools
      - Cook all plastic ware, pallet jacks, slicers, conveyors and electric pallet jacks
  - Physical Barriers
    - Separate raw from cooked,; exposed product from packoff (cartoning & casing)
  - Hurdles
    - Sanitizer at entrance and on floors
      - Boot wash or sole scrubber at exit of Raw and entrance to RTE
        - Step off into a bed of dry quat

The S&D Process "Best Practices"

- Measurement system
  - APC to manage growth niches
  - APC at Preop to measure effectiveness of Sanitation
    - Expect 99% large area swabs (Plant KPI) to be < 100 cfu (total area)
- Use Maintenance PM program to manage Master Sanitation Schedule
- S&D Team
  - Rotate chair and members to get greater buy-in and engagement
- Sanitizer Application
  1. Apply high concentration sanitizer after final rinse before assembly
  2. Send crew to lunch
  3. Rinse contact surfaces with water or contact concentration sanitizer
  4. Apply contact concentration sanitizer on all surfaces touched during setup and assembly

The S&D Process "Best Practices"

- Sample more Indicator Sites than Verification Sites
- Reward finding positives
- Sanitation Auditor
  - Arm with a tablet PC, verify critical factors, train when needed

The S&D Process "Best Practices"

"Best Practices"

Industry Wide Shared Learnings

- Clean Dry Uncracked Floors
- One Tool or No Tool Equipment Disassembly
- COP for Small Parts, Equipment Subassemblies & Hand tools
- Heat Intervention for Large Equipment
- Critical Air Handling Systems
- Interstitial Spaces above Processing Areas
- Physical Separation of Raw and RTE
- 5s – Declutter

Seek & Destroy Maturity Model

Listeria Control in Processed Meats

Stage 1 **Doubt**	Stage 2 Awareness	Stage 3 Enlightenment	Stage 4 Preventive	Stage 5 Predictive
No testing or only testing as required to meet regulatory requirements	*Initially sampled finished product, then some contact surfaces and environmental sites* *Environmental sampling and corrective action resulted in giving the drains to Listeria.*	*Growth niches recognized in both equipment and facilities*	*Interventions developed and applied to manage growth niches. Sanitary design applied to eliminate.*	*Comprehensive indicator site process controlling facility and equipment growth niches combined with hurdles and barriers to control transfer pathways.* *Indicator sites used to measure risk and signal when to apply intervention or strengthen hurdle*

Maturity Model for Ls Control Sampling Results

Stage	Awareness (Know of)	Enlightenment (React To)	Preventive	Predictive
Sampling Results	Contact Surface and Product positives	Expanded and regular sampling of contact surfaces and environmental sites. Intermittent positives on contact surfaces. Routine positives on environmental sites	Early preventive phase positive results dominated by indicator sites such as post rinse. In final phase of preventive, only rare Contact Surface positives. No Product Positives. Investigative facility based positives dominate RTE	No Contact surface positives. Zone 4 positives predominate. Hurdle transfer point sampling produces rare positives

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FDA - Guidance

Verification:

- The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Preventive controls:

- Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packaging, or holding at the time of the analysis.

Food-contact surfaces (FCS):

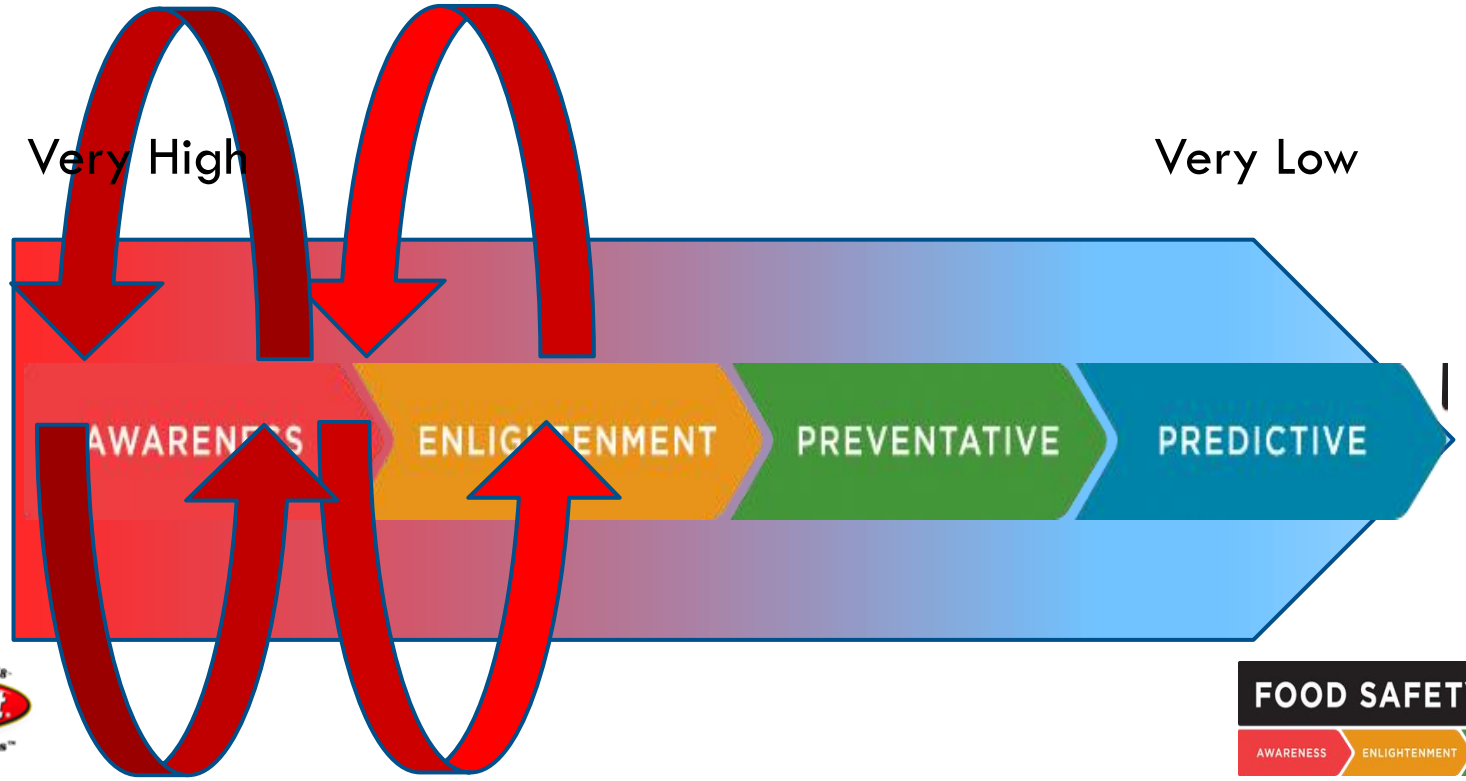
- Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operation. “Food contact surfaces” includes utensils and food-contact surfaces of equipment.

Non-food-contact surface (non-FCS)

- any surface that, under normal operating procedures, does not contact food or the food-contact surfaces of equipment. Examples of non-FCSs include, depending on the circumstances, equipment, vents, fixtures, drains, walls, floors, and employee clothing, shoes, and accessories.

Firefighting Intensity

Learn to Recognize Firefighting in your own Organization



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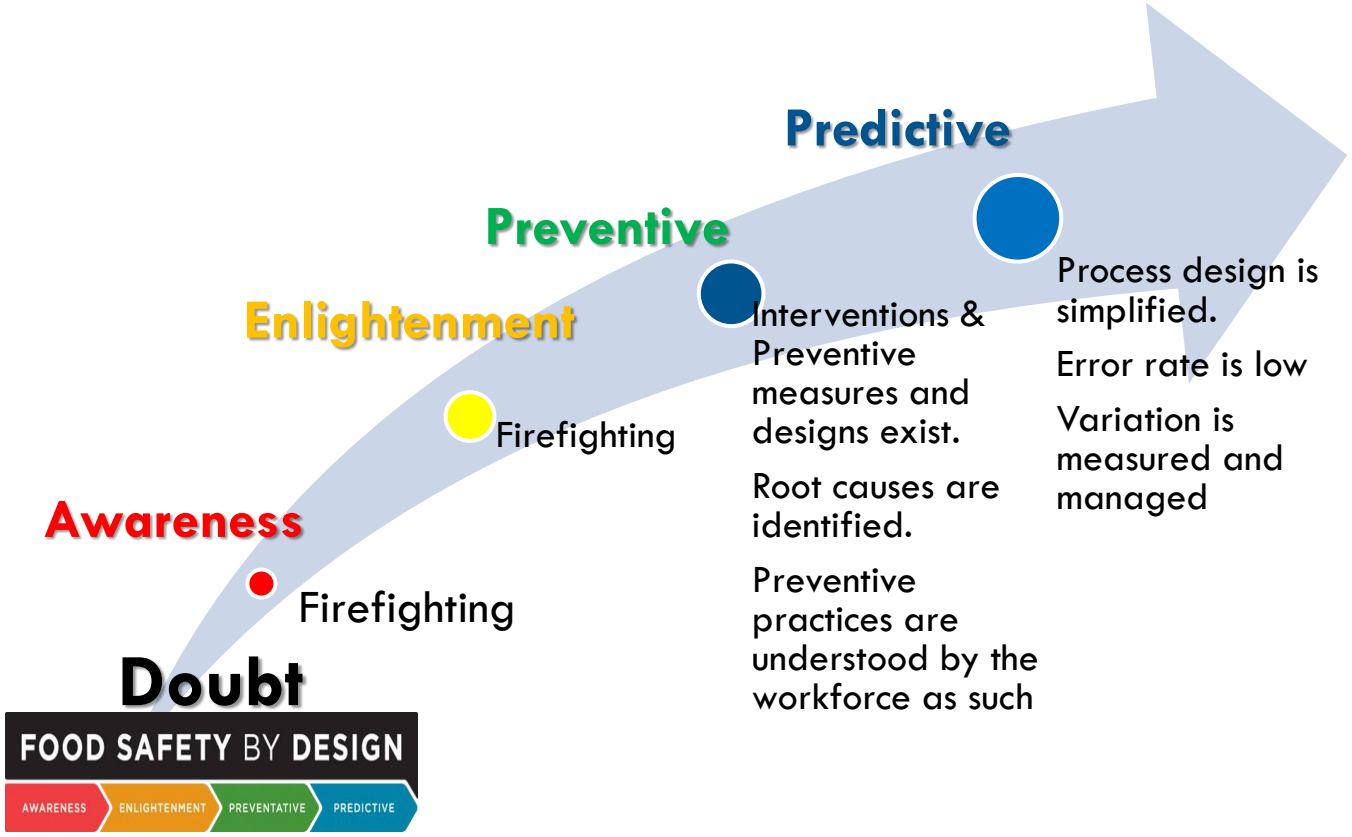
Verification Positives

Indicator Site Positives

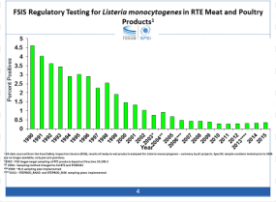
Visual Evidence of the Maturity Level of Organizational Process Thinking & Environmental Monitoring



Become Preventive and Predictive

- Develop and Deploy
  - Indicator Sites
    - Post Rinse, Z3 sites, Z4 – Z3 transfer sites
  - Preventive Control (Not For Cause) Investigations
    - Manage growth niches
- Find the problem before it reaches the Verification sampling sites.
  - Now the Plant Manager can buy pizza!

Questions?



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