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CONFERENCE PROCEEDINGS*
A Team Approach for Management of the Elements of a *Listeria* Intervention and Control Program

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ABSTRACT

Listeria control in federally inspected processed meat plants has improved over the last 25 years. A model method is presented. This method couples local plant teams with investigative tools and a list of critical factors for process control. Diligence in the application of these tools and implementation of "Best Practices" enables the plant food safety culture to move from the Awareness phase to the Enlightenment phase; next to the Preventative phase and ultimately to the Predictive phase. Once the plant is in the Preventative and Predictive phases efforts spent firefighting problems are dramatically reduced and a state of control evolves.

Keywords: S&D, Seek and Destroy, Timed Study, Swat Team, Firefighting, Critical Factors, Listeria, Environmental, Awareness, Enlightenment, Preventative, Predictive, Team, Teamwork, Intervention, Control, AMI, Post Rinse, Investigation, Growth Niche

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INTRODUCTION

The control of *Listeria* in the U.S. federally inspected meat plants has dramatically improved in the last twenty years (Figure 1). This effect is being measured and monitored by FSIS sampling of finished product from establishments hat produce post-lethality exposed.

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This success has several interrelated factors:

1. Root causes (growth niches) can be identified and either eliminated or managed.
2. Transfer vectors within RTE area can be managed in such a manner to minimize the transfer of the *Listeria*.
3. Hurdles to entry into RTE area can minimize cross contamination.

Please note that managing these factors will not totally control or prevent product contamination (HACCP CCP). These factors do, however, minimize the poten-

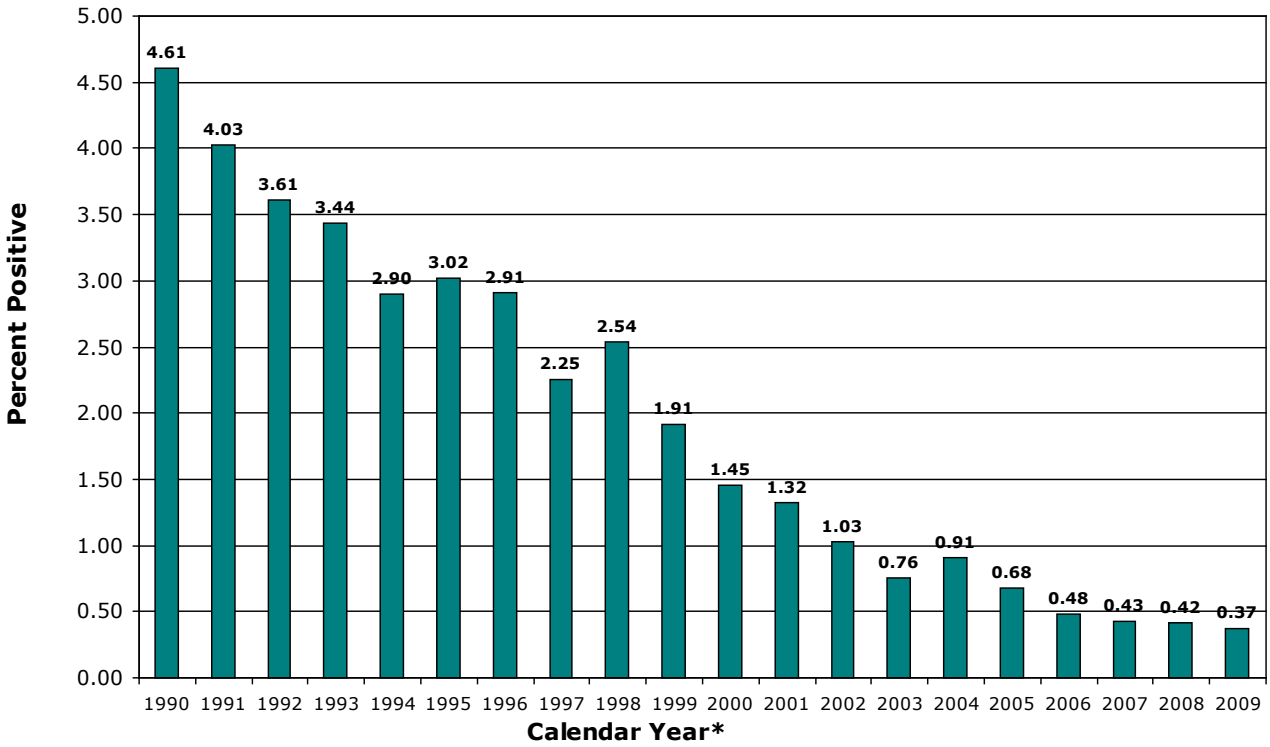

Figure 1. FSIS Regulatory testing for *Listeria monocytogenes* in RTE products by Calendar year 1990-2009 (FSIS, 2099).

tial for contamination. The key to control is the management of total system which I will call "process management."

Process management is based on managing many interrelated factors. These include:

1. The development of Best Practices associated with AMI Principles of Sanitary Facility and Equipment Design.
2. These principles and audit items, when combined with the Global Food Safety Initiative (GFSI) audit questions, provide establishments and local management the basis for a continuous improvement system. The U.S. meat industry has agreed that food safety is not a competitive arena and they have fully-shared their Best Practices.
3. This "teamwork" is best demonstrated by the AMI *Listeria* Intervention and Control Workshops. The presenters at each workshop consist of a diverse group experienced in food safety. The focus and basis of the workshops is control and intervention. The scientific basis of control is presented and discussed. Case studies and group problem-solving supplement the learning experience. Real life situations are presented in an environment that enables the participants to share and apply "Best Practices" to control high risk situations.
4. The implementation of "Best Practices" has resulted in plant monitoring data showing the effect of process improvement. The continuous improvement cycle has been fueled by success after success. The net effect was a documented reduction in samples found to be positive for *Listeria*.
5. Microbiological process control over the past 25 years has seen our company and other

Table 1. Four stages of environmental control within plants.

Stage	Sampling Results	Control Methods	Verification
Awareness	Contact Surface and Product positives	Sample product. Recognition of environmental nature of Listeria.	Product
Enlightenment	Expanded and regular sampling of contact surfaces and environmental sites. Intermittent positives on contact surfaces. Routine positives on environmental sites	Recognize existence of growth niches. Sample contact surfaces and some floor and environmental areas. Starting the redesign phase.	Product & Contact Surfaces
Preventative	Early preventative phase positive results dominated by indicator sites such as post rinse. In final phase of preventative, only rare Contact Surface positives. No Product Positives. Investigative facility based positives dominate RTE.	Potential Growth niches mapped. Some scheduled intervention practices in place. Managing "Critical Factors" of the Sanitation process. Engaged in Equipment and Facility redesign.	Product, Contact Surfaces & Primary Transfer Vectors in RTE Area
Predictive	No Contact surface positives. Zone 4 positives predominate. Hurdle transfer point sampling produces rare positives.	Aggressive early warning sampling in place. Intervention practices in place with all RTE equipment. Focus on zone 4 and facilities. Advanced phases of both Equipment and Facility redesign.	Product, Contact Surfaces & Transfer Points (Zones 1, 2 & 3) in RTE Area

companies go through a series of transition phases as the success in *Listeria* control evolved. These transition phases can be divided into four stages (Table 1).

THE EVOLUTION OF ENVIRONMENTAL CONTROL

Individual stages are characterized by how a plant views and controls *Listeria*, sampling methods and results along with their perspective on the difference between samples taken for control purposes versus verification of control. Specifically, these stages are defined by action taken in response to *Listeria* species positives and high APC counts from investigation and monitoring programs.

Table 1 relates sampling methods and results to actions taken. It defines perception of verification vs. control. Verification vs. control is easy when a CCP exists. When no CCP exists, the most significant factors affecting control must be identified. These "critical factors" then become the focus and basis of control.

Microbiological monitoring of these processes then becomes the basis of "microbiological process control measurements." The measurement system continues co-evolve. Verification sites grow in numbers and size as the process control sites evolve. The process control sites become "indicators of control" and are verified by verification sites. Verification sites continue to move further and further away from the product and represent a decrease in risk level. The overall effect on the system is that verification becomes more precise and control measures more accurate. The transition points in the evolution require management to change their course of action and perspective.

Management practices play a key role in the evolution of control. Bob Reinhard of Sara Lee

has characterized the management commitment in the following manner (Figure 2):

Commitment Model Employee & Management
• Resistant – don't believe it has value
• Accepting – why not
• "Buy-in" – we will do it
• Engagement – involved in solution
• Commitment – hold self and others accountable for achieving results
Bob Reinhard – Sara Lee

Figure 2. Management commitment model

When this commitment model is overlaid on a continuous improvement model, we see plants moving away from a firefighting mode where the same problem is solved over and over again during the buy-in and engagement stages.

Listeria control requires the identification of root causes (growth niches). They must be either eliminated or managed. Success requires commitment on the part of all employees. Not all growth niches can be eliminated and transfer vectors are going to exist whenever a food product is exposed to the environment. Management engagement and employee commitment is necessary for effective control.

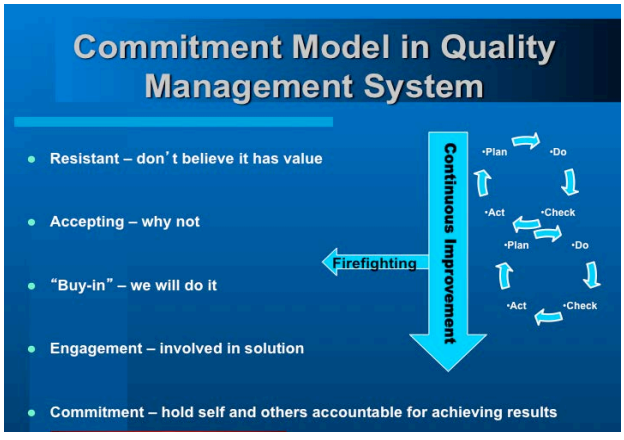

Figure 3. Commitment model combined with continuous improvement

Next, the "Evolution of Control" is overlaid on the Commitment and Continuous Improvement Model (Figure 3). The development and deployment of preventive practices eliminates "firefighting". The success of these practices leads to further implementation of preventative practices. Success under supportive management conditions, continuous improvement and preventive practices empowers the management team and workforce.

A "dose of science" in the sampling methodology enables predictive practices for intervention deployment. A preventative practice can become a predictive practice when deployed based on a defined need. Indicator sites are established to signal this deployment. Indicator sites need to be located at points in the system to provide an early warning of the presence of the organisms. These points include samples from a known or potential harborage site, hurdle to entry, or a transfer point that indicates the organism was located in an area that suggests harborage or could have been impregnated in the piece of equipment in the exposed product area below the normal level of disassembly. A positive indicator site (Ls+) could prompt the pasteurization of a conveyor belt for example. Regular sampling of indicator sites then become the predictive trigger for the application of an intervention to individual components, pieces of equipment, line components or an entire line.

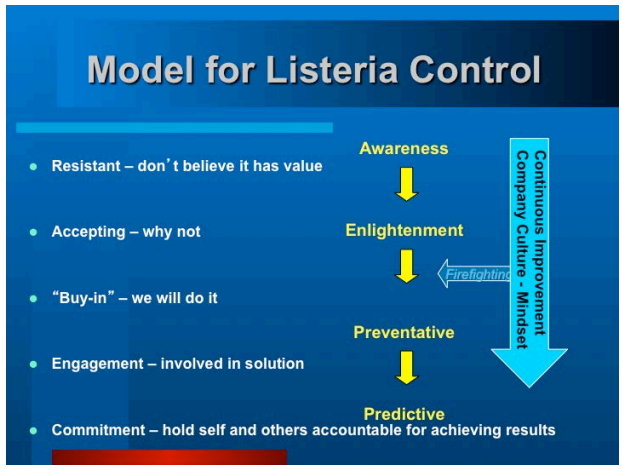

Figure 4. Model for *Listeria* control

The effectiveness of a system of environmental validation sites and indicator sites can be monitored by a post rinse sampling program. Post Rinse samples are samples taken after disassembly and the initial rinse. The Post Rinse sites are located on large areas

of equipment that collect spatter from the initial rinsing process. Typical sites are the sides of machines, framework, underneath assemblies and exposed components that may receive spatter from other machine parts and the floor. Post rinse sites can be composited therefore providing a large coverage area for one analysis. A post rinse positive does not mean there was contamination, but only indicates the presence of the organism in the area sampled. Action to take is to follow with multiple days of daily sampling (i.e. 10). If a positive is found in the follow up sampling then an investigation is warranted. A positive from post rinse can be from the following sources:

1. The organism may have entered the area from outside the exposed product RTE area and would be eliminated during the normal cleaning and sanitization procedures
2. A growth niche within a piece of equipment or within the facility may have shed the organism into the environment or
3. A transient site such as product tote, rework pan, electric pallet jack or trash container may have been responsible.

After a second positive Post Rinse sample, an investigation is needed to locate the source of the organism be it a growth niche or transfer vector bringing the organism into the RTE area. Indicator sites are not validation sites, but sites measuring the control at a specific point in the process.

Teamwork is the deployment vehicle for the transformation of the cultural change. Management must make verification sites the key process indicators (KPI's) and reward employee success in finding out of tolerance or out of control indicator sites rather than taking punitive action This understanding enables the teams to focus on prevention and develop early detection methods. Teamwork has been a successful management tool to develop and sustain the gains in environmental pathogen control. Control systems can be broad, but must be focused on specific root causes. Investigational data identifies these critical factors over time. We have deployed two teams: one focused on equipment design and maintenance, as well as sanitation process control; the other is focused on the facility. These multi-disciplinary teams are held accountable by management for attaining and maintaining control of environmental pathogens. They are empowered to take the appropriate action necessary for that task.

PROCESS CONTROL TOOL BOX

Proven control methods and investigative techniques are used to investigate for the existence and location of growth niches. The Seek and De-

Seek & Destroy Team Charter

Purpose:

The purpose of the Seek and Destroy Team is to maintain and continuously improve the equipment design, Sanitation Process Control procedures, Operational GMP's as well as providing corrective and preventative action for any microbiological monitoring issues.

Methods:

1. Utilize the S&D audits to investigate, evaluate and qualify equipment and processes.
2. Assign projects to highest risk ranked projects
3. Utilize the Preventative Maintenance Computer program to schedule and help manage preventative sanitary practices

Results Expected:

1. Monitor sanitation effectiveness
2. Conduct regular audits of lines in the RTE area.
   - Execute corrective action on those audit items that can be easily fixed
   - Assign projects to items needing more detailed correction action
3. Monitor all microbiological results and perform corrective and preventative action as necessary to maintain microbiological process control
4. Evaluate and qualify all new equipment to be used in the RTE area
5. Reach consensus on microbiological process control procedures
6. Develop or approve training materials, methods for GMP and Sanitation Process Control
7. Continuously monitor the effectiveness of GMP Training
8. Recommend or direct employee training as needed

Figure 5. Sanitation and Destroy Team Charter

Facility Design Team Charter

Purpose:

The purpose of the team is to maintain and continuously improve the facility by evaluating the facility sanitary design and determining the areas where improvements/repairs are needed.

Methods:

1. Utilize the AMI Sanitary Facility Design Checklist and SQF (GFSI) facility related audit requirements.
2. Assign risk values to plant areas & checklist items
3. Use Risk assessment to assist in prioritizing major projects

Results Expected:

1. Determine room groupings as described in the AMI Sanitary Facility Design Checklist.
2. Conduct regular audits of the facility as a group and individually.
3. Revise audit results as conditions change
4. Analyze audit results to determine where resources are best utilized.
5. Recommend the purchase of additional equipment as needed to complete the purpose.
6. Recommend construction activities as needed to complete the purpose.
7. Prioritize construction projects.
8. Forward audit issues to Facilities maintenance in the form of work orders and Power Point presentations.
9. Recommend capital expenditures to maintain and improve the facility.

Figure 6. Facility design team charter

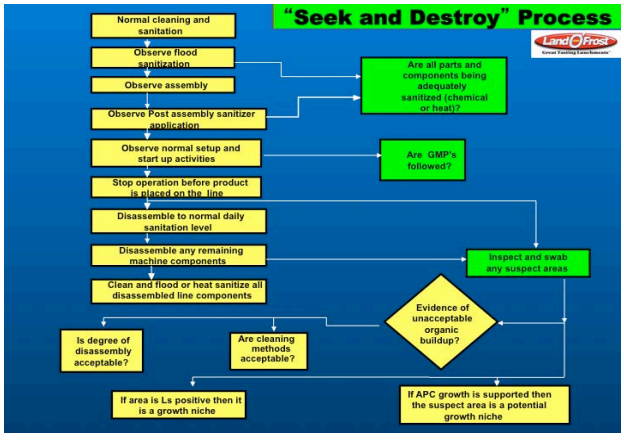

Figure 7. "Seek and Destroy" process

stroy (S&D) Investigation Process (Figure 7) is a tool with many applications.

The Seek & Destroy Process is a scientific method to:

1. Find pathogenic growth niches
2. Find potential growth niches requiring monitoring and control
3. Define normal level of disassembly
4. Define periodic deep level of disassembly
5. Define frequency of periodic deep level of disassembly
6. Qualify a new piece of equipment (run for 90 days then conduct Seek & Destroy Mission)
7. Validate effectiveness of equipment cleaning protocol
8. Validate effectiveness of intervention applied to a piece of equipment (heat treatment or other method)

The piece of equipment should be completely and fully disassembled. Samples are taken for both APC and *Listeria* species. Observations for excessive organic matter are conducted. Data is produced to determine if the organism was harboring in that piece of equipment.

TIMED STUDIES

Transfer vectors are defined and measured using Timed Studies. Here is an example of a Timed Study being used to locate a transfer vector bringing the organism to a line (Figure 8). In this case the line equipment had been proven to not harbor the contaminant (S&D Mission had been performed and all sites were negative) but a subsequent positive indicated a potential for contamination still exists.

This method of sampling identifies the pathway and vehicles of transport to a line from the environment. Once a Transfer Point in the Transfer Vector is identified, the Timed Study method is deployed to trace back to the source of contamination which

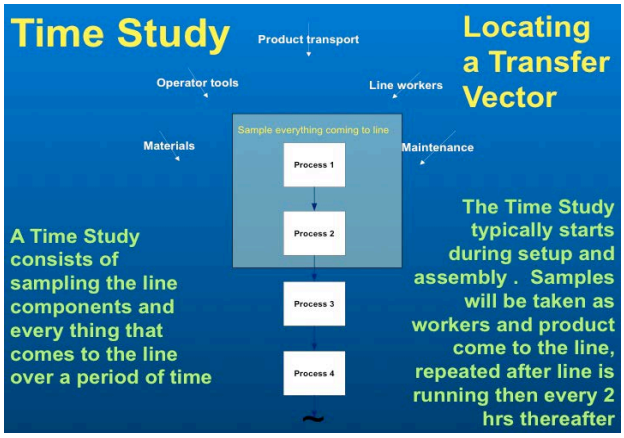

Figure 8.

may be a piece of equipment, facility harborage site, or a barrier failure separating the high risk area from other parts of the plant.

Growth niches in transient sites such as rework tubs, product totes, product racks, electric pallet jacks, and hand tools are often the hardest to locate in a large facility. The "Swat Team" sampling approach is the most successful method to find these mobile sources of contamination.

SWAT TEAM SAMPLING

- Sample during an idle period after sanitation, before production, ie. Saturday when no production is running.
- Sample large areas using sponges or gauze.
- Sample areas not typically sampled during routine sampling

We found a transient growth niche using this method – (spell out) COP basket handles

INVESTIGATION TOOLS

Table 2. Scientific methods for investigation following a positive sample

Tool	Source of Environmental Contamination
S&D	Growth niche in line equipment
S&D	Growth niche in ancillary equipment
Swat Team	Growth niche in transient equipment
Timed Study	Growth niche in facility
Timed Study	Transfer of organism form outside exposed product RTE area to inside exposed product RTE area
Timed Study	Transfer vectors moving the organism within the exposed product RTE area.

GROWTH NICHE CONTROL

Complex production equipment offers many opportunities for the development of growth niches. Growth niches evolve because the organism entering into a hard-to-dissemble and clean area. A common mode is from the rinsing process where the high pressure rinse water can force the organism into areas not disassembled such as press fit shafts on hollow rollers. The goal of sanitary design is to eliminate as many of these niches as possible. Those that cannot be eliminated by design need the ability to be easily exposed to the cleaning and sanitizing chemicals. Routine cleaning and sanitation including periodic deep cleaning should be able to maintain containment and prevent outgrowth to the point that shedding of the organism from growth niches creates a risk seeding a transfer vector capable of transferring the pathogen to the product or a product contact surface. Those growth niches that cannot be exposed need an alternative source of control such as the application of heat to pasteurize the equipment or equipment part.

Sanitary design of the facility and equipment supplemented with Sanitation Process Control has been effective in preventing product contamination. Sani-

tation Process Control is defined by the critical factors of the process. The critical factors cannot work alone; each must be effectively deployed during the cleaning and sanitizing cycle.

SANITATION CRITICAL FACTORS

- Degree of Disassembly
- Chemical Sanitizer Treatment
  - Effective coverage (flood sanitation)
  - Time
  - Chemical concentration
- Hand scrub contact surface
- Heat Treatment
  - Small parts (COP tank)
  - Localized steam
- Non Daily Scheduled Sanitation
  - Preventative and predictive deep cleaning
  - Equipment pasteurization
- Effective GMP's after flood sanitization

Sanitation Process Control is supplemented with the control of transfer vectors, equipment interventions and periodic cleaning and sanitation procedures. During operations transfer vectors are controlled by:

- Distinct hygienic zones established in the facility
- Physical separation of raw ingredients from RTE finished product
- Personnel and material flows are controlled to reduce hazards
- Water accumulation is controlled inside the facility
- Operational GMP's are designed and executed to establish control and to prevent cross-contamination

SUMMARY

Process management is attained by Sanitation Process Control Critical Factors and Interventions for all equipment within the exposed product RTE area. Control methods and indicator site sampling are developed to maintain control.

Indicator sites are designed to provide an early warning of a potential breach of control. Indicator sites trigger deployment of specifically targeted interventions . Verification sites identify a loss of control. When control is breached or lost, the teams are responsible for regaining control. Verification sampling of product, contact surfaces and transfer points along the various transfer vectors of people, materials, equipment and product movement prove system capability.

The elements of environmental control programs should address each of the following factors or items listed in Figure 9:

Requirements for an Effective Listeria Control Program

- The Sanitation process has been proven effective
- The Sanitation process and Sanitary Manufacturing Operating Procedures are defined and repeatable.
- General employee and Sanitation Operator Training programs clearly define and effectively communicate the process requirements necessary to maintain microbiological control.
- Sanitation Process Control "Critical Factors" are identified and monitored.
- Trained operators are used at each essential step.
- If a new problem emerges, the monitoring and corrective action process will identify and direct the Corrective Action Team towards the location of the growth niche.
- Random isolated strikes are proven to not be repeatable.
- Consumer safety is assured by product sampling if process control appears to be violated.
- Growth niches in any location within the Exposed Product Area are identified and are either eliminated or managed.
- The environment within the Exposed Product Area is controlled to minimize microbial outgrowth.
- Multiple barriers or hurdles create a "torturous pathway" to minimize the possibility of entry by a pathogenic organism from outside the Exposed Product Area.

- Physical transfer of microorganisms within the Exposed Product Area is addressed by the presence of multiple hurdles.
- Additions or changes to the process or equipment within the Exposed Product Area are monitored and qualified to not introduce or harbor microorganisms.Data from investigation, indicator and verification sites should support each item. These items, when summarized, identify the pillars for microbiological process control technology:
    - Apply interventions to eliminate the organism from exposed product area
    - Control transfer of the organism
    - Deploy process management techniques

Figure 9. Requirements for an effective *Listeria* control program

"Teamwork is the fuel that allows common people to attain uncommon results" - Unknown

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