Lessons Learned in the Meat Industry:

Control of Listeria in RTE Meat and Poultry Products

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CMC Annual Technical Conference
Toronto, Canada
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“Selling Safe Food is the Right Thing to Do -- It is Good for Business and Good for Consumers”
Cycle of Control

**Awareness:** Detect Problem

**Predictive:** Measure impact of interventions

**Enlightenment:** Collect data to understand the problem

**Preventative:** Implement Interventions and Best Practices

**Preventative:** ID appropriate points of control

Share Best Practices across industry
Evolution of Control

Awareness phase

Early 90s

- Product and contact surface sampling dominated
- Growth niches discovered in hollow rollers
- Industry recognized benefits and needs of separation
  - painted lines on floor
Evolution of Control

*Enlightenment Phase*

**Mid 90s**
- Equipment teardown became common
  - Seek & Destroy concept developed
- Internal equipment redesign became commonplace
- Suppliers were informed of design problems
  - Conflicting design expectation evolved
  - Equipment manufacturers given a moving target
- Floor problems persisted
  - Floors/drains were recognized as harborage and chronic problem areas
  - Methods to clean floors continuously failed
  - Drains were not expected to be Ls free
Evolution of Control

Enlightenment Phase (con’t)

Mid 90s

- Persistent deep equipment growth niches were discovered and recognized as root cause problem areas
- Facility areas were recognized as sources of *Listeria* harborage
  - walls, freezer walls, absorbent materials in doors, wet floors and cracks in floors
- Mid-shift cleanups were recognized as problem causing sources of recontamination
Evolution of Control

Preventative Phase

Late 90s

- Benefits of dry floors were realized
- Cooking/pasteurization of equipment became commonplace
- Large area sampling became commonplace
- DNA linkage evolves
- Methods for "construction process control" evolves
- Spread of organisms from growth niches became more understood
- Physical separation of RTE areas became commonplace
Evolution of Control

Predictive Phase

2000
- First AMI Workshop – June, 2000
  - Consensus in methods and Best Practices was attained
  - Six “Strategies for Control” developed
  - Over 15 workshops held reaching over 1000 industry employees

October 2001
- AMI Board declared “Food Safety Not Competitive”

2001 to today
- Many lines and processes brought under control
- Elimination of single growth niches produced new levels of control
- More aggressive sampling was deployed
Evolution of Control

*Predictive Phase*

2001 to today
- Pasteurization of large chubs and roasts became common place
- The use of DNA analysis (ribotyping, PFGE, Rep PCR) to ID sources of growth niches and degree of the diversity of RTE contamination
- AMI Equipment Design Task Force - 2003
- Some plants had achieved new levels of control
  - One year without drain positive
- Lactate –diacetate recognized to control growth
- AMI Facility Design Task Force - 2004
- Most (>90%) of the Lm recalls are due to plant not holding product being tested
## The Evolution of Environmental Pathogen Control

<table>
<thead>
<tr>
<th>Stage (<em>mindset</em>)</th>
<th>Control Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awareness</td>
<td>Sample Product</td>
</tr>
<tr>
<td>Enlightenment</td>
<td>Recognize existence of Growth niches. Sample contact and some floor and environmental to surfaces control. Starting the redesign phase.</td>
</tr>
<tr>
<td>Predictive</td>
<td>Early warning sampling in place. Scheduled intervention practices in place with all RTE equipment. Focus on zone 4 and facilities. Advanced phases of both Equipment and Facility redesign.</td>
</tr>
</tbody>
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The Evolution of Environmental Pathogen Control

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<td>No Contact surface positives. Zone 4 positives predominate. Hurdle transfer point sampling produces rare positives.</td>
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Appreciate the efforts of the following companies:
Lessons Learned

“The battle with this organism (Listeria) has caused more change for producers of RTE deli meat products than any one single factor or event in the last 30 years. Our scars are numerous and deep.”

Dr. John Butts
V.P. Research
Land O’ Frost

Great Tasting Lunchmeats™
Investigation and Corrective Action

“Follow the data trail to the source but always be alert and aware to the organism’s ubiquitous presence and pervasive nature.”

John Butts
Land O’ Frost
CMC
Toronto Sept 2008
Documentation

- First and foremost documentation provides history for the workers responsible for Food Safety.
- Results of prior investigations
  - Often provide insights into actions to take for subsequent investigations.
  - They also provide insight into why certain policies and procedures are in place.
  - Management can sometimes forget, particularly in times of turnover, why certain things must be done.
- Listeria is living proof that history does repeat itself.
Sources of Ls in High-Risk RTE Area

• Transferred from Zone 4 area outside of the High-Risk RTE area
  ▸ Homeless, but looking for a harborage location
  ▸ Typically found with a transfer point monitoring positive

• Growth niches within High-Risk RTE area
  1. This means they are established, and have found a protective home in equipment or facility.
  2. They may exist in a transient home such as rework pans, trash containers or other difficult to clean mobile container / environment.
Many positive sites found during monitoring are not growth niches. They are transfer points (i.e., a product handler’s gloved hands, floor sample in high traffic pathway).

Transfer points are not growth niches because the organism is eliminated during the cleaning and sanitizing process.
GROWTH NICHES

Locations harboring the organism after the routine sanitation process for that area has been completed.

Examples

- Hollow roller on conveyor transporting food product
  - Hollow rollers not disassembled cleaned and sanitized or heat treated in a manner to eliminate any contaminating organisms can become growth niches.
Factors affecting growth niche development

- Design problem
- Operational conditions
  - Product debris works its way into a uncleanable location
    - Mid shift cleanup
- Use of high pressure during cleaning
Growth Niches

Hollow roller with solid stainless steel shaft in center (almost press fit). When center shaft removed organic matter is evident.
# Challenge Guideline or “Conventional Wisdom” of Boosted & High Pressure Rinsing

## Degree of Growth Niche Development and Penetration

<table>
<thead>
<tr>
<th>High</th>
<th>Moderate</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boosted pressure</td>
<td>Boosted pressure</td>
<td>Regular dairy hose tap water delivery pressure</td>
</tr>
<tr>
<td>Difficult to rinse product</td>
<td>Dry non-sticky products</td>
<td>Difficult to rinse product</td>
</tr>
</tbody>
</table>
GROWTH NICHES

Must either be designed out of the system or managed as a part of the process.

• Design Examples

  ‣ Equipment is redesigned to eliminate or seal hollow areas

    • Hollow areas of equipment (e.g., frames, rollers) must be eliminated where possible or permanently sealed (caulking not acceptable). Bolts, studs, mounting plates, brackets, junction boxes, name plates, end caps, sleeves and other such items must be continuously welded to the surface of the equipment and not attached via drilled and tapped holes.

AMI Equipment Design Task Force
Growth Niches

Minimize with process control techniques

• *The potential to support growth still exists within the machine, part or area*

  » Whenever this becomes the chosen path remember to implement methods that will hold the gains with turnover in both hourly and management ranks.
Growth Niches

- Examples of how to minimize with process control techniques
  - Disassemble clean and sanitize
  - Heat sanitize
    - Cook in oven or smokehouse
    - Cover with tarp and inject steam
    - Place in COP tank
Sanitation Process Control Steps Necessary for Effective Control of Complex Equipment

Equipment at End of Production

Routine / Daily

Normal level

Clean & Sanitize

Disassamble to a greater level

Predefined Interval based on need

Intensive level

Hand Clean & Sanitize. Parts to COP

Predefined Interval based on need

Clean & Sanitize

Cooking level

Hand Clean & Sanitize, Small Parts to COP and Large Parts to Smokehouse

Clean & Sanitize

Pasteurize
Transfer Points

Interim or Temporary Locations
Harboring the Organism
Transfer Points

• Any surface between the growth niche and the product.

• Almost all contact surfaces are transfer points, not growth niches.

• Contact surfaces are “indicator sites” of potential product contamination.

• Contact surfaces are probably not the best early warning predictors of potential product contamination.

• Contact surface sampling measures the effect of upstream process control efforts.
Sampling Transfer Points

• Monitoring
  ‣ Biased not random method to monitor areas such as floors
  ‣ Each plant is different, but common traffic ways exist in each plant
    • The most heavily traveled areas can serve as potential problem indicators

• Targeted
  ‣ Investigative sampling of questionable areas
  ‣ Trying to find transfer vector or growth niche
Transfer Point Management

Cannot eliminate transfer points
-- Must minimize their effect
Operational Definitions for Corrective Action

High Risk Situations
High Risk Situations

- Drain backup
- A packaging line is moved or modified significantly.
- There is an equipment breakdown.
- Personnel are used interchangeably between raw and cooked products.
- Construction in or adjacent to CPA.
- Warm room
- Wet area or process

If one of the above High Risk situations exists then a documented and auditable process control program should be deployed.
High Risk Situations

- Transfer equipment from storage or another plant
- Loss of refrigeration in a room
- Use of high pressure water or air on floor or in a drain
- Wet in-process clean up
- Rinsing or cleaning equipment on the floor
- Equipment used interchangeably between raw and cooked products.
- Crack in floor that retains water
- Cooked product is transported through a raw product area

If one of the above High Risk situations exists then a documented and auditable process control program should be deployed.
Methods or Procedures for Investigation

• Plan, Do, Check, Act (Shewhart PDCA Cycle)
Methods or Procedures for Investigation

Plan

• Define the scope of the investigation
  ▸ Affected area from cleanup through clean up during all shifts.
  ▸ Analyze data with blueprints and flow charts. Trace movement of product, people, & equipment.
  ▸ Small areas are easier and more manageable.
  ▸ Small areas have a higher risk of not including the growth niche
Clearly and Concisely Define the Scope of the Investigation as a Physical Area
Clearly and Concisely Define the Scope of the Investigation as a Physical Area

Ancillary Equipment used during production ie tables, tubs or totes etc.
Clearly and Concisely Define the Scope of the Investigation as a Physical Area

Machine Component 1

Machine Component 2

Machine Component 3

Machine Component 4

Machine Component 5

Machine Component 6

Machine Component 7
Methods or Procedures for Investigation

Do

Conduct investigations

- Investigative Sampling Methods
  - Seek and Destroy
  - Timed Studies
  - Swat Team Sampling--- Discuss AMI Workshop

- Process Reviews
  - Operating procedures
  - GMP’s.
  - Review SSOP’s and Line Separation documentation
A Time Study consists of sampling the line components and every thing that comes to the line over a period of time.

The Time Study typically starts during setup and assembly. Samples will be taken as workers and product come to the line, repeated after line is running then every 2 hrs thereafter.
Swat Team Sampling

- Sample during an idle period after sanitation, before production i.e. 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 – COP basket handle
Methods or Procedures for Investigation

Check

- Define indicator areas to test for effectiveness of corrective action.
- Sample then test indicator areas.
- Analyze results.
Methods or Procedures for Investigation

**Act**

- Put into practice corrective actions that minimized or prevented the contamination to occur.
  - SSOP changes
  - Training program changes
  - Equipment redesign
Methods or Procedures for Investigation

< PDCA Cycle >

Part I
- Location of Growth Niche
  - First phase is directed towards finding and eliminating the growth niche
- Recycle if growth niche not found
  - Expand scope of investigation

Part II
- GMP’s & Transfer point Management
  - Second phase focuses on procedures and process control systems to minimize or control growth niches or transfer points
  - Use time studies to identify when and where transfer take place
- Process is recycled until qualification is achieved
The Plant Must Run!
Procedures for Investigation & Corrective Action

< PDCA Cycle >

**Part I** Find source
- Investigate – Seek and Destroy Mission

**Part II** GMP’s – Transfer Point Management
- Time Study – sample every 2 hrs
- Brainstorm with group of employees

**Recycle** if growth niche not found
  - Expand scope of investigation

< Enhanced Sanitation and Operating Activities to Assure Control >
- Heat treat the equipment in question.
- Deep Clean
- Multiple Sanitizer applications to assure coverage
- High Concentration Sanitizer
- Quat foam entire area
- Heat process all ancillary equipment
- Intensify monitoring activities in the area of the indicator site
## Corrective Action for a Packaging Line Contact Surface Positive

*< PDCA Cycle >*

### Find Growth Niche

<table>
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</table>
| • Use blue print analysis to identify equipment/area in question  
  ▶ The scope of the investigation should include surfaces that are within the process or line area.  
| • Collect and analyze each sample individually.  
| • Define an appropriate sampling rate for the affected line during the investigation and qualification stages.  
| • Use rapid test methods such as ELISA to reduce turn around time. |

### Transfer Points – GMP’s

<table>
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</table>
| • Use flow chart and brainstorming  
  ▶ The scope of the investigation should include transfer points and potentially all surfaces directly touched by any person or transport equipment in the line area.  
| • Define processing factors that may contribute to transferring the organism.  
| • Define Transfer Point Sampling Plan. |
**Corrective Action for a Packaging Line Contact Surface Positive**

*< PDCA Cycle >*

<table>
<thead>
<tr>
<th>Find Growth Niche</th>
<th>Transfer Points – GMP’s</th>
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<tr>
<td><strong>Do</strong></td>
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<tr>
<td>• Review High Risk Process Controls</td>
<td>• Review and evaluate changes in processing conditions, GMP’s, sanitation and manufacturing operating procedures</td>
</tr>
<tr>
<td>• Seek and Destroy on line</td>
<td>• Review SSOP’s and Line Separation documentation</td>
</tr>
<tr>
<td>• Increase frequency of indicator site sampling</td>
<td>• Time study sampling at defined frequency (i.e. 2 hr)</td>
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Corrective Action for a Packaging Line Contact Surface Positive

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<tr>
<td>• Analyze data</td>
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<tr>
<td>• Plot results on blueprints</td>
<td>• Plot results on flow charts</td>
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## Corrective Action for a Packaging Line Contact Surface Positive

< PDCA Cycle >

### Find Growth Niche

**Act**
- Implement corrective action (permanent process changes)
  - Redesign to eliminate
  - Modify level of critical factor to control
- Expand scope and recycle PDCA if results continue to be unacceptable or process will not re-qualify

### Transfer Points – GMP’s

**Act**
- Implement corrective action (permanent process changes)
- Modify training program
- Change frequency of administration of training program
- Require testing as part of training program
- Qualify process if probable cause has been found and eliminated or controlled
- Expand scope and recycle PDCA if results continue to be unacceptable or process will not re-qualify
Corrective Action

Validation

- The growth niche itself and surfaces affected by the growth niche need to be measured negative for 3 consecutive samples.
Prevention and Control Trends

Old way......
• Reactionary mode
• React to Contact Surface positive
• Minimal indicator site sampling
• Corrective Action on Contact Surface

New way......
• Preventative mode
• React to Indicator Site positive
• Indicator sites react before CS sites
• Corrective Action on any positive
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<td>- Minimal hurdles to prevent entry into RTE</td>
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<td>- Deep Clean when Ls+</td>
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<tr>
<td>- Minimal equipment Heat Treating</td>
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<td>- Have not disassembled equipment to find problem growth niches</td>
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<tr>
<td><strong>New way……</strong></td>
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<td>- Multiple hurdles to prevent entry into RTE</td>
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<td>- Scheduled Deep Cleaning</td>
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<td>- Scheduled equipment Heat Treating</td>
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<tr>
<td>- Know location of deep growth niches and treat accordingly</td>
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The Evolution of Environmental Pathogen Control

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Pillars of Microbiological Process Control Technology

1. Eliminate the organism from Exposed Product Area
2. Control transfer of the organism
3. Deploy Process Management Techniques
Eliminate the Organism From the Exposed Product Area
Requirements for effective control
Listeria spp. in a plant:

1. Investigation coupled with corrective and preventive action must lead to locating the growth niches.
2. Process control must be data-driven; data will be derived from monitoring, qualification and investigative work.
3. Product and contact surface sampling results will validate the effectiveness of the program.
Development of Interventions and Indicator Sites

- Each piece of equipment needs an intervention (a process that is capable of eliminating the organism from the most likely point of contamination to the deepest most difficult to remove location).
- Indicator sites should be deployed to define the effectiveness of the intervention.
- Indicator site sampling over time determines if residency has been eliminated or contained and controlled.
Development of Interventions

- Each piece of equipment needs an **intervention** *(a process that is capable of eliminating the organism from the most likely point of contamination to the deepest most difficult to remove location).*
Development of Interventions

- Equipment at End of Production
  - Routine/ Daily
    - Normal Level Degree of Disassembly
      - Clean & Sanitize
      - Hand Clean & Sanitize, Parts to COP
    - Hand Clean & Sanitize, Small Parts to COP and Large Parts to Smokehouse
  - Intensive Level Degree of Disassembly
    - Clean & Sanitize
    - Intensive Level of Disassembly and Sanitation or Equipment
  - Predefined Interval based on need

- Cooking Level Degree of Disassembly
  - Predefined Interval based on need
  - Clean & Sanitize
  - Pasteurize

**INTENSIVE LEVEL OF DISASSEMBLY AND SANITATION OR EQUIPMENT**
**PASTEURIZATION MAY BE THE IDEAL INTERVENTION OPTION.**
Prevent Movement of the Organism
Control of Transfer Vectors

- Distinct Hygienic Zones are established in the facility
- Physical separation of raw from RTE
  - Personnel & material flows are controlled to reduce hazards:
- Water accumulation is controlled inside the facility
- Sanitation GMP’s
- Operational GMP’s are designed and executed to establish control and to prevent cross contamination
Process Management
Process Control Sampling

• A focused effort not directed towards process validation sites such as
  ▸ Product and
  ▸ Product Contact Surfaces
  ▸ High traffic floor flow patterns

• But directed to process control sites such as
  ▸ development of interventions and
  ▸ measurement of the effectiveness of hurdles.
Components of a Process Control Program

- Listeria positive results from all Operational Sampling Programs are investigated
- Contact Surface Sampling validates process control program
  - Each line is sampled weekly
- Large area sponge sampling
- Finding Ls+ is a “success”
- “One size does not fit all” sampling plans
- Sampling plans must be dynamic
- Data must drive the process of controlling the organism
Summary

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.
Summary

Requirements for an Effective Listeria Control Program

• 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.
Summary

Requirements for an Effective Listeria Control Program

• 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.
Summary

Requirements for an Effective Listeria Control Program

• 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.
Summary

Requirements for an Effective Listeria Control Program

• 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.

• Ingredient hurdles that minimize growth are not silver bullets!
Questions?
Myth Busting in Critical

*Use data and logic to focus resources*

Common misconceptions about root cause

- “The organism is airborne”
- “Raw meat is (20-40% Lm +) highly contaminated with the organism”
- “It cannot be removed from the processing environment”
- “Drains will always be positive”
Summary of “Lessons Learned”

- Data, Data, Data
- Let data guide the “Cycle of Control”
- Sampling and testing used strategically
- Vigilant re-evaluation of systems is critical
- Industry sharing of Best Practices
- Avoid misconceptions – use the data
- Flexible regulatory approach
Protecting Public Health

“Selling Safe Food is the Right Thing to Do -- It is Good for Business and Good for Consumers”

The Industry is Making Progress
**Listeria monocytogenes Recalls**

<table>
<thead>
<tr>
<th>Year</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008**</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>No. of Recalls</td>
<td>14</td>
<td>13</td>
<td>26</td>
<td>5</td>
<td>9</td>
<td>6</td>
<td>73</td>
</tr>
<tr>
<td>No. of Recalls due to Illness Investigation (%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No. of Recalls due to FSIS/Company Sample (%)</td>
<td>13*</td>
<td>12*</td>
<td>25*</td>
<td>5</td>
<td>9</td>
<td>5*</td>
<td>69</td>
</tr>
</tbody>
</table>

* In these years there were recalls due to state health agency testing
** 2008 data as of 9/08/2008
Industry Best Practices for Holding Tested Products

Coordinated By:
American Association of Meat Processors
American Meat Institute
Food Products Association
National Chicken Council
National Meat Association
National Turkey Federation
North American Meat Processors Association
Southwest Meat Association

Facilitated by:
International HACCP Alliance

September 2005
Prevalence of *Listeria monocytogenes* in RTE Meat and Poultry Products

*FSIS results of routine regulatory testing of ready-to-eat meat and poultry products analyzed for *Listeria monocytogenes*
Incidence of Foodborne Illness 1996-2007: *Listeria*

*Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food --- 10 states, 2007*
Save the Date!!!
AMI and CMC to Sponsor

Listeria Intervention and Control Workshop
February 3 – 4, 2009
Chicago, Illinois