Current Perspective on Listeria Control

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Perspectives – “Lessons Learned” from the 2008 Listeriosis outbreak

Going Forward - Focus on Listeria Management and Control in RTE

CFIA policy, industry progress and the future
Listeria control in RTE is critical to public health

Listeria control is not easy

Listeria control in RTE is the “new normal”

Strong, and consistent regulatory oversight is crucial

Listeria control is about …Details, Details, Details

Listeria control is not easy
In August 2008 Maple Leaf initiated the largest recall in the Company’s history

- Three SKU’s of deli products manufactured at our Bartor Road facility were found contaminated with *Listeria monocytogenes* and linked to illness and death
  - 22 deaths; 56 total cases confirmed

- Total three recalls:
  - August 17: First recall initiated immediately upon learning of positive test results for *Listeria monocytogenes* in two products
  - August 20: Expanded recall initiated following positive test of a third product
  - August 23: Expanded recall to include all production from the two affected lines when product linked to outbreak strain (191 products)

- Some products were distributed to health care facilities, where some people have a higher risk for contracting listeriosis

- This involved a large recall of 191 products, even though only a small number were affected
As manufacturers we must demonstrate the highest level of responsibility & accountability possible

- Take accountability
- Put public health and consumer interests first
- Lead in open and fact based communication
- Implement decisive action plan
The ultimate test of Corporate Values:

- “Do what’s right”
- “Dare to be transparent”

Immediate public apology by CEO and commitment to fix the problem

Put consumer interests ahead of financial and legal interests
Strengthened approach to environment, equipment and product sampling testing and data analysis to find any potential contamination sooner

- Doubled the number of testing sites and frequency of sampling on every line across our 24 RTE plants
- Sampling results reviewed individually and collectively to assess potential patterns

Documented new protocols into new Standard Operating Procedures, obtained CFIA approval, and rolled them out across all RTE plants including training of our
Enhanced *Listeria* Testing

- Nearly 1,500 environmental tests weekly across 24 RTE plants comprised of 119 production lines
  - Approximately 75,000 routine test samples taken annually
  - Positive incident rate of less than 1%, well within U.S. FSIS reported data
  - Additional targeted sampling allows for in-depth line analysis and research to eliminate harbourage points
- Random product testing on each line monthly
  - Approximately 1,300 routine product samples annually, excluding additional targeting sample as part of ‘hold and release’
- Daily senior management call to review testing results
Listeria Control
Background
Three General Scenarios of Foodborne Listeriosis

1. Isolated case

2. Cases due to a single event or lot of food

3. Clusters and isolated cases scattered by time and location.

Scenario No. 1: The Isolated Case

- An individual case of listeriosis with no apparent link to others.

- The conditions leading to isolated cases are varied and often uncertain or unknown.

- Some may be part of a cluster or outbreak that was not detected.

Scenario No. 2: Cases Linked by a Single Lot of Food

- One lot of contaminated food that leads to a cluster of cases.
- One or more food handling errors may be involved.
- The outbreak ceases when the lot of food is no longer available.

Scenario 3: Clusters or outbreaks involving multiple lots of food from a single source

- The cases may be scattered by time and location.
- An unusually virulent strain of *Lm* has become established in a food operation.
- Multiple lots of food are contaminated over time.
- The food supports the growth of *Lm*.

Industry Priorities

1. Prevent conditions that lead to extended outbreaks (scenario 3).

2. Control conditions to minimize the risk of isolated cases and clusters (scenarios 1 and 2).

3. Control conditions to satisfy regulatory requirements.
The keys to *Listeria* control in the food processing plant:

- Aggressive environmental testing for *Listeria* – FIND IT!
- Aggressive corrective actions when positives detected – FIX IT!!
Foundations for Effective *Listeria* Management

- Sanitation program that prevents listeria harborage in the processing plant
- Aggressive environmental sampling plan that is designed to constantly seek out *Listeria* spp. harborage points and management commitment to celebrate finding positive samples
- Aggressive seek and destroy process that is triggered when positive samples are found
- Ongoing re-design of facilities and equipment to improve sanitary design and ease of cleaning
- Implementation of effective interventions in the process and in the products
- Ongoing analysis and reporting of data and evaluation of effectiveness of remedial actions
• FCS and non-FCS testing
  - Ten (10) Level 1, Three (3) Level 2, Two (2) Level 3, and Two (2) Level 4 swabs from every line, every plant, every week
  - Sample sites are varied by week
  - Day of the week sampling varies

Levels:

• **Level 1 - Food Contact Surfaces** e.g. Slicers, conveyers, peelers, tables, utensils', brine chill

• **Level 2 - Non Food Contact Surfaces adjacent to RTE line** e.g. equipment framework, equipment surfaces, switches, housings

• **Level 3 - Non Food Contact Surfaces not adjacent to RTE line** e.g. Walls, Drains, Floors, Overhead Structures, Phones, Forklifts, Jiggers

• **Level 4 – Other areas in the facility** e.g. Cafeteria, Hallway, Lockers, Locker Rooms
Every production line is tested **every week** on product contact surfaces (L1 sites) and non-product surfaces (L2-4 sites).

*Listeria* spp. testing will provide more positive results than testing for *Listeria monocytogenes*, giving a greater opportunity to identify sanitation deviations. This is the most conservative approach to food safety and is global best practice.
# Seek and Destroy Process

**Guidelines**

**Step 1**: Positive Listens results  
*Purpose of the visit*

**Step 2**: Communicate  
*Meet with the Plant leadership team regarding the process and goal*

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Plan logistics and timing</td>
</tr>
<tr>
<td>Step 2</td>
<td>Gather information on the area of focus</td>
</tr>
<tr>
<td>Step 3</td>
<td>Perform root cause analysis</td>
</tr>
<tr>
<td>Step 4</td>
<td>Set hypothesis</td>
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<tr>
<td>Step 5</td>
<td>Brainstorm on corrective actions</td>
</tr>
<tr>
<td>Step 6</td>
<td>Categorize and prioritize corrective actions</td>
</tr>
<tr>
<td>Step 7</td>
<td>Execute corrective actions</td>
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<tr>
<td>Step 8</td>
<td>Document corrective actions</td>
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<tr>
<td>Step 9</td>
<td>Confirm results</td>
</tr>
<tr>
<td>Step 10</td>
<td>Hold &amp; Release</td>
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</tbody>
</table>

**Step 3**: Assemble team  
*Identify plant resources and expectations (6S tools: Communicating plan完成后)*

**Step 4**: Plan logistics and timing  
*First, tour the site to see positive results and tour at different times of the day (pre-op, start-up, break, lunch, etc) and forward start-up and second shift start-up*

**Step 5**: Gather information on the area of focus  
*Analyze all available data (bacteria, TPC, ATP bioluminescence testing)*

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<tr>
<td>Step 1</td>
<td>Change in the process: involve the plant staff. Start with: Management team (GA, plant, production and maintenance managers, dept. managers, etc.); and supervision</td>
</tr>
<tr>
<td>Step 2</td>
<td>Principals, key people in the team (upstream, downstream, etc.)</td>
</tr>
<tr>
<td>Step 3</td>
<td>Worksheet: outline team strategies (document, all decisions)</td>
</tr>
</tbody>
</table>

**Step 6**: Review SOPs for cleaning process to identify gaps. Meet with sanitation (if necessary, at end of shift) and sanitizer

**Step 7**: Perform root cause analysis  
*Review all findings with the team (data analysis, pictures, interviews, etc.)*

**Step 8**: Brainstorm on corrective actions  
*Using a value stream map with the team (6S tools: Process Map, Value Stream Map)*

**Step 9**: Categorize and prioritize corrective actions  
*Take into consideration the effects of a corrective action on other areas (For example, TPC: Combination – PCMA, Cost and Effect Diagram)*

**Step 10**: Execute corrective actions  
*Present to the plant leadership team the: Observations, Hypothesis and Treatment (6S tools: Visual Aids)*

**Step 11**: Document corrective actions  
*Document the corrective action in the process (6S tools: Process Map)*

**Step 12**: Confirm results  
*The plant leadership team is responsible to document results of corrective actions*

**Step 13**: Hold & Release  
*Follow-up on the action plan until completion*

**Step 14**: Lessons learned  
*In addition to the team, document lessons learned and share with: EIC Food Safety Manager, Steve Trupkin (Food Safety); VP, Food Safety; EIC Food Safety Manager, Steve Trupkin (VP, Food Safety); EIC Food Safety Manager, Steve Trupkin (VP, Food Safety); EIC Food Safety Manager, Steve Trupkin (VP, Food Safety); EIC Food Safety Manager, Steve Trupkin (VP, Food Safety) and VP Manufacturing.*

*Note: The corrective action log should be audited by EIC Food Safety Manager within the next month.*
## Seek – DMA (Define, Measure, Analyze)

### Guidelines

**Step 1: Positive Listens results**
- Purpose of the visit

**Step 2: Communicate**
- (if not, issues handled by the plant or Tiger team)
- Identify roles and expectations (ES tools: Communication plan, GRPS)

**Step 3: Assemble team and problem statement**
- Identify plant resources and expectations and formulate problem statement.

**Step 4: Plan logistics and timing**
- First, tour the site of positive results and tour at different times of the day (pre-ops, start-up, breaks, lunches, end of shift and second shift start-up)
- Take pictures of any suspicious sites (coolers, line, celling, ralls, etc.)
- Do not limit the tour to the site of positives; tour product and people flows
- Action plan communicated during the first day
- Meet daily with the team for progress update
- Daily objectives planned with the team as needed (Document all decisions)

**Step 5: Gather information on the area of focus**
- Analyzed all available data (Listeria, TPC, ATP bioluminescence testing).
- Look for trends, verify sanitation records, etc.
- Change in the process: Interview the plant staff. Start with Management team (QA, plant, production and maintenance managers), dept. supervisors, etc., and sanitation.

**Step 6: Investigate and audit**
- Be present while swabbing and request investigative swabs
- Observe and take pictures of all suspicious sites
- Seek & Destroy audit. Use Seek & Destroys document
- Review SOPs for cleaning process to identify gaps. Meet with sanitation (if necessary, be present during cleaning)
- Document all observations

**Step 7: Perform root cause analysis**
- Revise all findings with the team (data analysis, pictures, interviews, etc.)
- Perform a brainstorming session. Ex. using a value stream map with the team. (ES tools: Process map, value stream, 5 Whys)

**Step 8: Set hypothesis and recommendations**
- Set potential hypothesis for root causes and communicate them

**Step 9: Brainstorm on corrective actions**
- Conduct a brainstorming session with the team
- Focus on corrective actions for root causes, not symptoms (ES tools: 5 Whys)

**Step 10: Categorize and prioritize corrective actions**
- Take into consideration the effects of a corrective action on other areas
- (ES tools: Fishbone, Process analysis - FMEAs, Cause and Effect Diagram, Impact-KsToT Map)
- If a Tiger team was sent, a report is completed and the plant leadership team complete the process
Destroy – IC (Improve, Control)

**Step 11: Execute corrective actions**
- Present to the plant leadership team: Observations, Hypothesis and Recommendations (in a PowerPoint format with pictures and facts, etc.)
- Presentation to be sent to Steve Tsuuki (Food Safety - 6S Lead), Iain Stewart (Sr. VP Food Safety & Transformation), Steve Dowbiggin (Sr. VP Further Processed Manufacturing), VP Manufacturing and plant leadership team.
- Document corrective actions performed with all necessary details in “Seek & Destroy Corrective Action Log V1.1” Excel file

**Step 12: Document corrective action log**
- List of all changes made following the corrective actions execution
- Use “Seek & Destroy Corrective Action Log V1.1” Excel file

**Step 13: Confirm results**
- The plant leadership team is responsible to document results of corrective actions
- Use “Seek & Destroy Corrective Action Log V1.1” Excel file
- When completed, send to: IOC Food Safety Manager, Steve Tsuuki (Food Safety - 6S Lead), Iain Stewart (Sr. VP Food Safety & Transformation), Steve Dowbiggin (Sr. VP Further Processed Manufacturing), VP Manufacturing and plant leadership team.

**Step 14: Are we seeing 3 consecutive negative results?**
- If yes, go to step 16
- If no, go to step 15

**Step 15: Hold & Release**
- If NO to question of step 14
  - Initiate the product testing and file the Food & Safety Incident Report (FSIR)
  - Notify IOC Food Safety Manager, Steve Tsuuki (Food Safety - 6S Lead), Iain Stewart (Sr. VP Food Safety & Transformation), Steve Dowbiggin (Sr. VP Further Processed Manufacturing), VP Manufacturing and plant leadership team.
  - Test the product testing and the Food & Safety Incident Report (FSIR)
  - Follow-up on the action plan until completion

**Step 16: Closing the case**
- If YES to question of step 14
  - Update SOPs and training
  - Complete the product testing and the Food & Safety Incident Report (FSIR)

**Step 17: Lessons learned**
- In a debrief session with the plant leadership team, document lessons learned and share with IOC Food Safety Manager, Steve Tsuuki (Food Safety - 6S Lead), Iain Stewart (Sr. VP Food Safety & Transformation), Steve Dowbiggin (Sr. VP Further Processed Manufacturing), and VP Manufacturing.
- Corrective actions to be audited by IOC Food Safety Manager within the next month.
High risk situations

• Drain backup
• Use of high pressure water or air on floor or in a drain
• A packaging line is moved or modified significantly
• An equipment breakdown
• Personnel used interchangeably between raw and cooked products area (CPA)
• Construction in or adjacent to CPA
• Warm room
• Wet area or process
• Crack in floor that retains water
• Rinsing or cleaning equipment on the floor
• Others.....
## 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>
<tr>
<td>Stage</td>
<td>Sampling Results</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Awareness</td>
<td>Contact Surface and Product positives</td>
</tr>
<tr>
<td>Enlightenment</td>
<td>Expanded and regular sampling of contact surfaces and environmental sites. Intermittent positives on contact surfaces. Routine positives on environmental sites</td>
</tr>
<tr>
<td>Preventative</td>
<td>Early preventative phase positive results dominated by environmental positives. In final phase of preventative, only rare Contact Surface positives. No Product Positives. Investigative facility based positives dominate RTE.</td>
</tr>
<tr>
<td>Predictive</td>
<td>No Contact surface positives. Zone 4 positives predominate. Hurdle transfer point sampling produces rare positives.</td>
</tr>
</tbody>
</table>
The Food Safety Journey A Continuous Process

Awareness
Detect Problem

Enlightenment
Collect data to understand Problem

Prevention
Implement best practices

Prediction
Measure impact of interventions

Refinement of Capabilities & Knowledge
CFIA Listeria Testing Requirements
Effective April 1, 2009

- CFIA Mandated
- CFIA
- Operator Mandated
- Product Testing M200
- Food Contact M205
- Product Testing Operator
- Food Contact Operator

- Industry Voluntary Programs
- Product Testing
- Environmental Monitoring Program
- Investigational Swab Testing
## Risked Based Product Sampling

<table>
<thead>
<tr>
<th>Alternative</th>
<th>Control measure</th>
<th>Sampling frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alternative 1</td>
<td>AMA/P + PLT are in place</td>
<td>1 sample per year</td>
</tr>
<tr>
<td>Alternative 2A</td>
<td>PLT</td>
<td>3 samples per year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1 per 4 month)</td>
</tr>
<tr>
<td>Alternative 2B</td>
<td>AMA/P</td>
<td>6 samples per year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(every other month)</td>
</tr>
<tr>
<td>Alternative 3</td>
<td>Sanitation only</td>
<td>12 samples per year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Once a month)</td>
</tr>
</tbody>
</table>

**Lower risk**

**Higher risk**
**CFIA Requirements for Operators**  
**Minimum Frequency of Sampling FCS**

**Lower risk**

<table>
<thead>
<tr>
<th>Establishment Category</th>
<th>FCS testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alternative 1</td>
<td>2/year/line</td>
</tr>
<tr>
<td>Alternative 2</td>
<td>4/year/line</td>
</tr>
<tr>
<td>Alternative 3</td>
<td>2/year/line</td>
</tr>
<tr>
<td>Non-deli, non hot-dogs</td>
<td>1/month/line</td>
</tr>
<tr>
<td>Deli, hot-dog Very small vol. est.</td>
<td>1/month/line</td>
</tr>
<tr>
<td>Deli, hot-dog Small volume est.</td>
<td>2/month/line</td>
</tr>
<tr>
<td>Deli, hot-dog Medium volume est.</td>
<td>3/month/line</td>
</tr>
<tr>
<td>Deli, hot-dog Large volume est.</td>
<td>4/month/line</td>
</tr>
</tbody>
</table>

**Higher risk**
Policy Challenges

- Turnaround time for CFIA results
  - Requirement for accredited lab / accredited method
  - Expectation by CFIA is 5 days to result
  - Experience demonstrates avg = 6 – 10 days with example at 14 days

- Definition of lot, line, and alternative category has been inconsistent

- Requirements on corrective action have lacked consistency
Summary of “Lessons Learned”

1. Growth niches can be identified and eliminated or managed.

2. Transfer points can be identified and their effect minimized with GMP practices.

3. Sampling techniques such as post rinse sampling can aid in discovering problems before contact surfaces or product are engaged.

4. Sanitation Process Control “Critical Factors” can provide the basis for attaining and maintaining control of microbial contaminants in High-Risk RTE areas.
5. Interventions are necessary for all equipment within the Exposed Product Area

6. Product, contact Surfaces, and key floor sites must be recognized as key measures of the effectiveness of the process control program in place.
Summary of “Lessons Learned” on Listeria control activities

- Data, Data, Data
- Let data guide decisions
- 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 critical
Suggested Reading

- **AMI, 1999.** Interim Guidelines – Microbial Control During Production fo RTE Meat and Poultry Products.


“Selling Safe Food is the Right Thing to Do -- It is Good for Business and Good for Consumers”
Prevalence of *Listeria monocytogenes* in RTE Meat and Poultry Products in U.S. *

*FSIS results of routine regulatory testing of finished RTE products analyzed for *Listeria monocytogenes*. Approx. 4,000-10,000 samples taken annually.*
Comparison of *Listeria* – United States Prevalence vs. Illness

<table>
<thead>
<tr>
<th>Year</th>
<th>Prevalence</th>
<th>Illness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>3.0</td>
<td>0.6</td>
</tr>
<tr>
<td>1999</td>
<td>2.5</td>
<td>0.5</td>
</tr>
<tr>
<td>2000</td>
<td>1.5</td>
<td>2.0</td>
</tr>
<tr>
<td>2001</td>
<td>2.0</td>
<td>1.0</td>
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<tr>
<td>2002</td>
<td>1.5</td>
<td>1.5</td>
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<tr>
<td>2003</td>
<td>1.0</td>
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<tr>
<td>2004</td>
<td>0.5</td>
<td>1.5</td>
</tr>
<tr>
<td>2005</td>
<td>0.2</td>
<td>1.0</td>
</tr>
<tr>
<td>2006</td>
<td>0.1</td>
<td>0.5</td>
</tr>
<tr>
<td>2007</td>
<td>0.0</td>
<td>0.1</td>
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</table>
Thank You