Case Study: What Went Wrong?

Dr. Jim Gorny, PMA
Core Lessons Learned from Outbreaks
Or
What the Heck Went Wrong?

Jim Gorny, Ph.D.
Vice President of Food Safety & Technology
Multi-State Outbreak of Listeriosis Associated with Consumption of Fresh Whole Cantaloupe, 2011
Key Questions

❖ Why did this foodborne illness outbreak occur?

❖ What are the potential contributing factors and can they be risk ranked?

❖ How could it have been avoided?

❖ Are we constantly flirting with disaster or was this case an exception?
3 Legs of Foodborne Illness Outbreak Investigation

1) **Epidemiology**
   - Surveillance Detects the Outbreak
   - Interview ill persons (cases)
   - Compare ill persons to non-ill persons
   - Determine the most likely food vehicle

2) **Traceback / Trace Forward**
   - Helps rule-in / rule-out likely food vehicle (plausibility)

3) **Sample Positives**
   - Product or environmental samples
   - Matching + samples rarely occur in perishable foods
Profile of the Outbreak

- 146 persons in 28 states infected
- 5 Lm outbreak strains
- 33 deaths and one miscarriage
- Deadliest foodborne disease outbreak in the United States in nearly 90 years.
- 1st Lm outbreak associated with fresh whole cantaloupe
- Lm previously considered a fresh-cut issue

From: McMcollum et al, 2013
Odds Ratio (OR) a Statistical Measure of:

❖ Provide Magnitude & Direction Re: Food Vehicle

❖ Probability of chance alone (p-value, confidence interval)
  - OR > 1 suggests odds of exposure are positively associated to illness compared to the odds of not being exposed.
  - OR = 1 suggests no difference between those who consumed product X being ill.
  - OR < 1 suggests odds of exposure are negatively associated to illness compared to the odds of not being exposed.

Case-control: Odds Ratio (OR):

The odds that one was exposed to X, if ill
The odds that one was exposed to X, in NOT ill
# Identification of the Food Vehicle

**Table 2. Consumption of Specific Foods among Patients with Outbreak-Related Listeriosis as Compared with Patients with Sporadic Listeriosis Previously Reported to the Listeria Initiative.**

<table>
<thead>
<tr>
<th>Food Consumed</th>
<th>Outbreak Cases</th>
<th>Sporadic Cases</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. exposed/total no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sept. 9</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delicatessen-style ham</td>
<td>7/11 (64)</td>
<td>360/774 (47)</td>
<td>2.0 (0.5–9.4)</td>
</tr>
<tr>
<td>Watermelon</td>
<td>5/10 (50)</td>
<td>49/82 (60)</td>
<td>0.7 (0.1–3.2)</td>
</tr>
<tr>
<td>Cantaloupe</td>
<td>11/11 (100)</td>
<td>54/85 (64)</td>
<td>8.5 (1.3–∞)</td>
</tr>
<tr>
<td><strong>Sept. 12</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cantaloupe</td>
<td>13/13 (100)</td>
<td>54/85 (64)</td>
<td>10.1 (1.6–∞)</td>
</tr>
<tr>
<td><strong>Sept. 14</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cantaloupe</td>
<td>19/19 (100)</td>
<td>54/85 (64)</td>
<td>14.9 (2.4–∞)</td>
</tr>
</tbody>
</table>

From: McMcollum et al, 2013
# Identification of the Food Vehicle

<table>
<thead>
<tr>
<th>PFGE Pattern No.</th>
<th>PulseNet Pattern Name*</th>
<th>Serotype</th>
<th>Illnesses (N=147)</th>
<th>Deaths (N=33)</th>
<th>Source of Cantaloupe Samples†</th>
<th>Environmental Swabs from Processing Facility?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascl Restriction Enzyme</td>
<td>Apal Restriction Enzyme</td>
<td>no. (%)</td>
<td>no. of samples</td>
<td>no. of samples</td>
<td>Farm A Cooler</td>
<td>Retail Location</td>
</tr>
<tr>
<td>1</td>
<td>GX6A16.0029</td>
<td>GX6A12.0069</td>
<td>1/2a</td>
<td>48 (33)</td>
<td>12 (36)</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>GX6A16.0019</td>
<td>GX6A12.0227</td>
<td>1/2b</td>
<td>40 (27)</td>
<td>10 (30)</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>GX6A16.0099</td>
<td>GX6A12.0001</td>
<td>1/2a</td>
<td>28 (19)</td>
<td>3 (9)</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>GX6A16.0001</td>
<td>GX6A12.0001</td>
<td>1/2a</td>
<td>30 (20)</td>
<td>7 (21)</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>GX6A16.1471</td>
<td>GX6A12.2154</td>
<td>1/2b</td>
<td>1 (&lt;1)</td>
<td>1 (3)</td>
<td>0</td>
</tr>
</tbody>
</table>

From: McMcollum et al, 2013
A. Growing Environment

- All environmental samples collected in the growing fields were negative for Lm.
  - soil,
  - wild animal excreta,
  - perimeter and furrow drag swabs,
  - agricultural water,
  - pond water, and
  - cantaloupe.

- Packing facility and cantaloupe collected in cold storage were Lm+.

- Growing fields are not a likely means of contamination.

- Low-level sporadic Lm+ for agricultural environment and incoming cantaloupes may have allowed for establishment of a harborage or niche for Lm in the packing facility and cold storage.
B. Packing Facility & Cold Storage  
(Samples Collected during September 10, 2011 inspection)

1. Product Samples
   ❖ Fresh whole cantaloupe from Jensen Farms Lm+ with PFGE patterns indistinguishable from outbreak strains

2. Environmental Samples
   ❖ 39 swabs – 13 confirmed positive

   ❖ PFGE patterns indistinguishable from outbreak strains collected from affected patients

   ❖ Of 13 positive environmental swabs:
     • 12 collected at packing line equipment/food contact surfaces
     • 1 collected in packing area.
Environmental Assessment Findings

B. Packing Facility & Cold Storage

The following factors may have contributed to the introduction, growth, or spread of Lm contamination:

1. Facility Design

2. Equipment Design

3. Postharvest Practices

4. Recommendations

From: FDA Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis  (October 19, 2011) http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm
1. Facility Design

- Refrigeration unit drain line, allowed for water to pool on the packing facility floor in areas adjacent to packing facility equipment, may have extended and spread the pathogen to food contact surfaces.

- Samples collected from areas where pooled water had gathered tested positive for an outbreak strain of Lm. And may have contributed to the introduction, growth, or spread of Lm.
Environmental Assessment Findings

1. Facility Design

❖ Packing facility floor where water pooled was directly under the packing facility equipment from which FDA collected environmental samples that tested positive for Lm with PFGE pattern combinations that were indistinguishable from outbreak strains.

❖ Packing facility floor was constructed in a manner that was not easily cleanable. Specifically, the trench drain was not accessible for adequate cleaning and may have served as a harborage site for Lm or contributed to the growth, or spread of the pathogen.

From: FDA Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis  (October 19, 2011) http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm
Environmental Assessment Findings

2. Equipment Design

❖ Environmental samples collected from the packing facility equipment tested positive for Lm with PFGE pattern combinations that were indistinguishable from three of the four outbreak strains.

❖ July 2011, the firm purchased and installed equipment for its packing facility that had been previously used at a firm producing a different RAC. Lm could have been introduced as a result of past use of the equipment.

From: FDA Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis (October 19, 2011) http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm
2. Equipment Design

❖ Packing equipment, including equipment used to wash and dry the cantaloupe, did not lend itself to be easily or routinely cleaned and sanitized.

❖ Several areas on both the washing and drying equipment appeared to be uncleanable, and dirt and product buildup was visible on some areas of the equipment, even after it had been disassembled, cleaned, and sanitized. Corrosion was also visible on parts of the equipment.

❖ Cantaloupe that is washed, dried, and packed on unsanitary food contact surfaces could be contaminated with Lm or could collect nutrients for Lm.
Environmental Assessment Findings

3. Postharvest Practices

❖ Free moisture or increased water activity of the cantaloupe rind from postharvest washing procedures may have facilitated Lm survival and growth.

❖ Cantaloupes were not pre-cooled to remove field heat before cold storage.

From: FDA Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis (October 19, 2011) http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm
Environmental Assessment Findings

3. Postharvest Practices

❖ The availability of nutrients on the cantaloupe rind, increased rind water activity, and lack of pre-cooling before cold storage may have provided ideal conditions for Lm to grow and outcompete background microflora during cold storage.

❖ Samples of cantaloupe collected from refrigerated cold storage tested positive for Lm with PFGE pattern combinations that were indistinguishable from two of the four outbreak strains.

From: FDA Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis (October 19, 2011) http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm
Key Questions

❖ Why did this foodborne illness outbreak occur?

❖ What are the potential contributing factors and can they be risk ranked?

❖ How could it have been avoided?

❖ Are we constantly flirting with disaster or was this case an exception?
4. FDA Recommendations for Prevention of Lm Contamination

❖ Employ GAPs and GHPs
❖ Assess produce facility and equipment design to ensure adequately cleanable surfaces and eliminate opportunities for introduction, growth, and spread of Lm and other pathogens.
❖ Assess and minimize opportunities for introduction of Lm and other pathogens in packing facilities.
❖ Implement cleaning and sanitizing procedures.
❖ Verify the efficacy of cleaning and sanitizing procedures.
❖ Periodically evaluate the processes and equipment used in packing facilities to assure they do not contribute to fresh produce contamination.

From: FDA Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis (October 19, 2011) http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm
Thank You

jgorny@pma.com

www.pma.com