Control of *Listeria monocytogenes*: Guidance for the US dairy industry

Tim Stubbs, Vice President Product Research & Food Safety
Innovation Center for U.S Dairy

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Illness</th>
</tr>
</thead>
<tbody>
<tr>
<td>dairy</td>
<td>656951</td>
</tr>
<tr>
<td>meat</td>
<td>844006</td>
</tr>
<tr>
<td>Poultry</td>
<td>653622</td>
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<tr>
<td>Produce</td>
<td>985807</td>
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<tr>
<td>Fruits/Nuts</td>
<td>230636</td>
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<tr>
<td>Vegetables</td>
<td>755171</td>
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<tr>
<td>Leafy Greens</td>
<td>188327</td>
</tr>
<tr>
<td>Vine stalk</td>
<td>436546</td>
</tr>
</tbody>
</table>

% Hospitalization & Death by Food Commodity
* 66% of all dairy related recalls during 2010-2013 were due to environmental pathogen contamination.
Refer to CDC website for full list of recalls
Innovation Center -- Food Safety Team

- Jack Jeffers - Dean Foods
- Jeff Acker - DFA
- Brian Cords - Foremost Farms
- Jeremy Travis - Hilmar Cheese Company
- Danny Tyndell - HP Hood
- Clay Hough - IDFA
- Sara Mortimore - Land O’Lakes
- Edith Wilkin - Leprino
- Joe Delaney - Prairie Farms
- Greg Desautels - Saputo
- Janet Raddatz – Sargento
- Tom Hedge - Schreiber Foods
- Mark Wustenberg - Tillamook
- Steve Baxley - United Dairymen of AZ
- Bill Graves, Tom Suber, Tim Stubbs - DMI
- Joseph Stout, Jim Mueller, Tom O’Connell – Facilitators
- +40 additional Subject Matter Experts
IC Food Safety Committee Objective

Strengthen manufacturing practices in all dairy processing facilities and advance science-based tools to diminish food safety risks that could compromise the reputation of the U.S. dairy industry
<table>
<thead>
<tr>
<th></th>
<th>Food Safety Action Platforms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pathogen Control - <em>Dairy Plant Food Safety</em> workshops</td>
</tr>
<tr>
<td></td>
<td>□ Best practices, uniform approach to in-plant pathogen control programs</td>
</tr>
<tr>
<td>2</td>
<td>Supplier Food Safety Management</td>
</tr>
<tr>
<td></td>
<td>□ Risk control tools and training to mitigate risk from materials / services</td>
</tr>
<tr>
<td>3</td>
<td>Artisan / Farmstead Cheese Food Safety</td>
</tr>
<tr>
<td></td>
<td>□ Mitigate pathogen risks in small operations</td>
</tr>
<tr>
<td>4</td>
<td>Verification via Auditing</td>
</tr>
<tr>
<td></td>
<td>□ Strengthen audit standards. Dairy input to GFSI, BRC, &amp; SQF</td>
</tr>
<tr>
<td>5</td>
<td>Regulatory Roundtable</td>
</tr>
<tr>
<td></td>
<td>□ Engagement strategy to enhance relationships and dialogue with regulators</td>
</tr>
<tr>
<td>6</td>
<td>Listeria Control Guidance Document</td>
</tr>
<tr>
<td></td>
<td>□ Comprehensive written guide to controlling Listeria</td>
</tr>
<tr>
<td>7</td>
<td>Listeria Research Platform</td>
</tr>
<tr>
<td></td>
<td>□ IC collaboration and consortium funding model for Listeria research</td>
</tr>
</tbody>
</table>
Dairy Plant Food Safety Workshop

- Two day workshops
- Volunteer industry expert trainers
- Lectures, hands-on exercises, peer learning, expert Q&A
- Started 2011, 25 sessions, 1350+ trained
- Traditional and “Dry / Powders” versions
- Online tools
Supplier Food Safety Management Workshop

- Two day workshops
- Volunteer industry trainers
- Started 2011, 8 sessions, 157 trained
- Audience of quality, supplier quality, purchasing, and suppliers
- A goal is for companies to learn & adopt risk mitigation tools
- How to assess and address risks in the supply chain
  - Risk Assessment Calculator
  - Food Safety Guidance Document
  - Online tools
  - Will help with FSMA Domestic Supplier Controls
2016 Food Safety Training

Non-Profit Training programs developed by the Dairy Industry for the Dairy Industry and trained by Food Safety professionals from Industry

Dairy Plant Food Safety Workshop
- Dairy Industry Quality, Sanitation, Engineering…
- Corporate & Plant (QA, management, sanitation, maintenance…)
  - Feb 10 & 11    Collinsville IL
  - May 17 & 18*  Denver CO
  - June 7 & 8    Plymouth WI
  - Aug 23 & 24   Beachwood OH
  - Oct 25 & 26   Arden Hills MN

Supplier Food Safety Management Workshop
- Dairy Food Safety, Quality, and Supply Chain leaders
- Supplier Quality and Purchasing Leaders
- Suppliers of Ingredients, Packaging, and Services
- Upcoming Workshops
  - May 24 & 25   Rosemont, IL
  - Sept 20 & 21  Rosemont, IL

Additional information at - [www.usdairy.com/foodsafety](http://www.usdairy.com/foodsafety)
Listeria Control Guidance Document

- Comprehensive guide to controlling *Listeria*
- Dairy industry specific
- Built on “Pathogen Equation” & DPFS
- Industry wide effort
  - 13 primary authors
  - Industry, Academic, Government reviewers
- Expands activation beyond workshops
- Published October 15, 2015
Control of *Listeria*

- *Listeria monocytogenes* and Listeriosis
- *Listeria monocytogenes* (Lm) control in dairy plants
- Preventive Controls for Human Food Regulation Integration
Control of *Listeria*

- Separate Raw from RTE
- Good Manufacturing Practices and Controlled Conditions
- Sanitary Facility and Equipment Design
- Effective Sanitation Procedures and Controls
- Environmental Pathogen Monitoring
- Effective Pathogen Control

www.usdairy.com/food safety
Separate Raw from RTE

Hygienic Zoning to prevent cross contamination

- Defined hygiene levels & Controls
- Defined Access and Exit Protocols
- Attire & Behaviors within each zone
  - Permitted
  - Prohibited
- Pre-determined mitigation plans

Examples
- Pasteurized/ finished product operations physically separated from raw operations
- Red line or transition rooms
- Facility air filtered & flow balanced to lower hygiene locations
- Defined employee and vehicle traffic flow
- Dedicated uniforms, tools and utensils, transport vehicles
Facility zone map
Mitigating Zoning Challenges

- Raw Milk Storage
- Pasteurizer
- Cheese making/curd draining
- Curd cheddaring finishing
- Product and Ingredient Cooler
- Cheese Packaging
- Utilities and storage
GMP’s and Controlled Conditions

Behavior Expectations
- Plant uniforms outer clothing
- Captive plant footwear
- Product protection focused SOP’s:
  - Handwashing
  - Compatible duty assignments

Controlled Conditions
- Defined employee and vehicle traffic flow
- Dry floor philosophy
- Condensation Control
- Compressed air and high pressure water hoses
- Proper product temperature
## Sanitary Facility and Equipment Design

- **Sanitary Design Standards**
- **Mitigating existing design challenges**
- **Aging facility upkeep**
  - Floor & wall tiles and grout
  - Ceiling panels
  - Floor drains
- **Electrical equipment**
  - Computers, keyboards, pointers
  - Junction boxes, raceways
  - Control panels

### Dairy Facility Design Principles

<table>
<thead>
<tr>
<th>Principle #1</th>
<th>Distinct Hygienic Zones Established In The Facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle #2</td>
<td>Personnel &amp; Material Flows Controlled to Reduce Hazard</td>
</tr>
<tr>
<td>Principle #3</td>
<td>Water Accumulation Controlled Inside Facility</td>
</tr>
<tr>
<td>Principle #4</td>
<td>Room Air Flow and Room Air Quality Controlled</td>
</tr>
<tr>
<td>Principle #5</td>
<td>Site Elements Facilitate Sanitary Conditions</td>
</tr>
<tr>
<td>Principle #6</td>
<td>Building Envelope Facilitates Sanitary Conditions</td>
</tr>
<tr>
<td>Principle #7</td>
<td>Interior Spatial Design Promotes Sanitation</td>
</tr>
<tr>
<td>Principle #8</td>
<td>Building Components and Construction Facilitate Sanitation</td>
</tr>
<tr>
<td>Principle #9</td>
<td>Utility Systems Designed To Prevent Contamination</td>
</tr>
<tr>
<td>Principle #10</td>
<td>Sanitation Integrated Into Facility Design</td>
</tr>
</tbody>
</table>

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**Innovation Center for U.S. Dairy**

**Healthy People • Healthy Products • Healthy Planet**

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Sanitary Facility and Equipment Design

...if you can’t see it, and you can’t reach it, you can’t clean it!

Dairy Equipment Design Principles

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>Microbiologically Cleanable</td>
</tr>
<tr>
<td>#2</td>
<td>Made Of Compatible Materials</td>
</tr>
<tr>
<td>#3</td>
<td>Accessible For Inspection, Maintenance, &amp; Cleaning/Sanitation</td>
</tr>
<tr>
<td>#4</td>
<td>No Liquid Collection</td>
</tr>
<tr>
<td>#5</td>
<td>Hollow Areas Hermetically Sealed</td>
</tr>
<tr>
<td>#6</td>
<td>No Niches</td>
</tr>
<tr>
<td>#7</td>
<td>Sanitary Operational Performance</td>
</tr>
<tr>
<td>#8</td>
<td>Hygienic Design Of Maintenance Enclosures</td>
</tr>
<tr>
<td>#9</td>
<td>Hygienic Compatibility With Other Systems</td>
</tr>
<tr>
<td>#10</td>
<td>Validated Cleaning &amp; Sanitizing Protocols</td>
</tr>
</tbody>
</table>
Effective Sanitation Procedures and Controls

- Clearly defined & assigned
  - Routine & Allergen
  - PIC, PEC, Seasonal, Janitorial
  - Non stationary equipment
  - SSOP’s & Personnel Training
  - Effectiveness Assessments

Considerations
- Design Opportunities
- Extended Runs
- Emerging cleaning technologies

WHAT?
WHEN?
WHO?
HOW?
Environmental Pathogen Monitoring

Robust Pathogen Environmental Monitoring (PEM) Seek & Destroy Eliminate!

- Refrigerated RTE-Lm
  - Informed by facility risk assessment and zoning
- Biased and targeted
- 12 month baseline
- Active Program Management
  - Tracking & Trending
  - Investigation & Corrective Action
- Employees understand monitoring and current status
- Documentation
Select Recent FDA Inspection Findings

- Condensation dripping into product & product contact surfaces
- Equipment and utensil design make them difficult to clean.
- Failure to provide water at a hot enough temperature for cleaning.
- Failure to clean ingredient hoppers frequently enough to protect against contamination.
- Observed employees not washing hands. Not wearing suitable outer garments to protect against food and food contact surface contamination.
- Failure to perform pathogen monitoring to detect contamination in the environment. \((Lm\) was also detected in product).
- Pasteurized product held above 45°F.
Consistent with PCHF regulation’s Preventive Food Safety Systems

Food Safety Plan
Including procedures for monitoring, corrective action and verification, as appropriate.

- Hazard Analysis
- Process Control
- Recall Plan
- Supply-chain Program
- Sanitation Control
- Allergen Control

GMPs and Other Prerequisite Programs

Separate Raw from RTE
Good Manufacturing Practices and Controlled Conditions
Sanitary Facility and Equipment Design
Effective Sanitation Procedures and Controls
Environmental Pathogen Monitoring
Effective Pathogen Control

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HEALTHY PEOPLE • HEALTHY PRODUCTS • HEALTHY PLANET
Key messages

- High public health burden of pathogens
- *Lm* control critical for refrigerated RTE food (cheese) safety
- *Listeria* Guidance Document is practical and authored by dairy industry personnel
- Reviewed and vetted by FDA and academic experts
  - Sanitary Facility and Equipment design
  - Hygienic Zoning and Practices verified by environmental pathogen monitoring
- PEOPLE
- Compatible with PCHF regulation
Listeria monocytogenes

- Gram-positive rod
- Only species responsible for serious human illness
- Ubiquitous: soil, sewage, decaying plant material, 10% of humans, wild and domestic animals.
- Slow growing
- Wide Growth Conditions:
  - 35°F to 110°F (Optimal 98.6°F)
  - pH 4.5-9.2 (Optimal 7)
  - $a_w$ 0.92 min.
  - 10% salt and can survive higher levels.
  - Aerobic, microaerophilic, facultative anaerobic
- Will grow in refrigeration
- Ecology
  - Persists in plant environment
  - Wet, Cool, Salty
  - Protective survival mechanisms
- Readily destroyed by pasteurization and cooking
- Zero Tolerance US standard