EMBRACING HYGIENIC DESIGN: OPPORTUNITIES AND CHALLENGES

3-A Educational Session – “The Bridge to Hygienic Design”

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May 12, 2015
Embracing Hygienic Design

1. Design Opportunities

2. Appropriate design – the risk assessment

3. Design Solutions
Foodborne Illness Estimates

United States
• 48 million cases
• 120,000 hospitalizations
• 3000 deaths

EU
• 45.5 million cases

China/Asia
• Surveillance beginning

Global (food and water)
• 1 billion cases
• 2.2 million deaths

Australia
• 5.4 million cases
• 120 deaths
Peanut Corporation of America

- Eight Deaths
- 19,000 Sickened
- 76 Department of Justice Indictments
- Owner, Brother, Plant Manager, Operations Manager, Quality Manager all Convicted.
- Prime Mover Behind Food Safety Modernization Act
Blue Bell Creameries

Centers for Disease Control and Prevention

Listeria (Listeriosis)

Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries

Products

Posted April 21, 2015 11:45 AM ET

Highlights

- Read the Advice to Consumers, Institutions, and Retailers>
- Read the Information for Health Professionals>
- On April 20, 2015, Blue Bell Creameries voluntarily recalled all of its products currently on the market made at all of its facilities, including ice cream, frozen yogurt, sherbert, and frozen snacks, because they have the potential to be contaminated with Listeria monocytogenes. Blue Bell announced this recall after sampling conducted by the company revealed that Chocolate Chip Cookie Dough Ice Cream half gallons produced on March 17, 2015 and March 27, 2015 contained the bacteria.

At a Glance:

- Case Count: 10
- States: 4
- Deaths: 3
- Hospitalizations: 10
- Recall: Yes
Our Challenge...protecting zones 2 and 1 for filling and closing
Beginning with the end in mind
Design opportunities - negative plant
Design opportunities - air balance
Design opportunities – indirect zone 1 risk
Design solution
Design opportunities - unsealed interface
Design opportunities – poor utility installation
Design opportunities – uncleanable interface
Design opportunities – dead end
Design opportunities – split flows
Design opportunities – insanitary valves
Design opportunities – insanitary valves
Design opportunities – insanitary pump
Design opportunities – butterfly valve
Design opportunities

Fermentation tank with intermittent failures due to design issues.
Biofilms – the result of poor design

Biofilms are caused when there is incomplete soils removal / sanitization on equipment and in the environment.

- Poor Sanitary design / insufficient sanitation on equipment with pits, folds, inclusions, crevices and out of product path, inaccessible areas will leave a desirable substrate behind for bacteria to grow.
- Pathogenic bacteria such a Listeria, E. Coli and Salmonella are the cause of a large number of illnesses and deaths annually. These bacteria, especially E.Coli 0157:H7 and Salmonella are often found in mixed culture biofilms.
- Biofilms are also a common cause for spoilage incidents.
Biofilms

Beneficial Biofilms – Human gut biofilm
Biofilms – the symbiotic community

Water channels carry nutrients, dissolved oxygen and potentially, antimicrobials to the cells. Promotes high degree of thickness and complexity.
Biofilms

Dental Plaque Biofilm
Biofilms
How do we design to the right level? What is process appropriate?

CONDUCT A RISK ASSESSMENT!
Design solutions – The risk assessment

Thorough risk assessment requires a cross functional leadership team working with the project engineer:

- Engineering
- Sanitation
- Quality
- Business Unit leadership
- Operations
- Corporate Food Safety
- R&D

All Stakeholders are necessary to create the optimal design!
Design solutions – receive input early

This graph shows that many decisions influencing the cost of the project can be made at a very low cost (horizontal axis) at the very start of the project. All involved should be gathered at the very start (prior to the point where the lines cross) and take the time to thoroughly discuss and have input for the project. This would include Sanitary Design considerations.
Design solutions – The risk assessment

<table>
<thead>
<tr>
<th>PROD. LINE</th>
<th>PRODUCTION LINE DESCRIPTION</th>
<th>SITE LOCATION RISK</th>
<th>PRODUCT DESIGN RISK</th>
<th>PROCESS/SYSTEM RISK</th>
<th>CRITICAL HYGIENE REQUIREMENTS</th>
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<tr>
<td></td>
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<td>Site Technology Core Competencies</td>
<td>Intended Use</td>
<td>Compatibility with existing:</td>
<td>Total Risk Factor to Guide Selection and Design Of:</td>
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<td></td>
<td>Site Related Concerns</td>
<td>-Ready to Cook</td>
<td>Processing Technologies</td>
<td>-Materials in Near Environment</td>
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<td></td>
<td>Adequate Grade</td>
<td>-Ready to Eat</td>
<td>-Skillsets</td>
<td>-Design and Finish for product contact zones</td>
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<td></td>
<td>Prevailing Wind</td>
<td>-Infants</td>
<td>New raw ingredients at risk</td>
<td>-Plant air exchange and filtration</td>
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<td></td>
<td></td>
<td>Residential Proximity</td>
<td>Aged or Immunocompromised</td>
<td>New Allergens</td>
<td>-Dust Collection</td>
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<td></td>
<td>Pest Pressures</td>
<td>Regulatory Requirements</td>
<td>Microbiological</td>
<td>-Other requirements</td>
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<td>Legal Concerns About:</td>
<td>-PMO</td>
<td>Allergens</td>
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<td>Cleaners and Sanitizers</td>
<td>USDA Shield</td>
<td>Microbiological</td>
<td>-Sanitation Cycle times</td>
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<td>Pesticides</td>
<td>Lack Of Inhibitory Factors</td>
<td>-Osmotic Pressure</td>
<td>Sanitation Cycle times</td>
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<td>Potable Water or Effluent</td>
<td>High Risk Ingredients</td>
<td>-Bacterial</td>
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<td></td>
<td></td>
<td>-Allergens</td>
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<td></td>
<td></td>
<td></td>
<td>-Stored Product Pests</td>
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</table>
Design solutions – The risk assessment

Wet Cleaning
- Basic Hygiene
- High Hygiene

Dry Cleaning
- Basic Hygiene
- High Hygiene
Design solutions – The risk assessment

Example criteria:

Wet Cleaning

High Hygiene
Design solutions – The risk assessment

Product / Process Characteristics
• RTE products
• RTC products that require a Kill step by end user or consumer for safety
• Liquid Dairy and other non-shelf stable liquid products
• Products with an intended use that includes
  – Infants
  – Aged or Infirm
  – Immunocompromised
• Refrigerated products
• Some Aseptic CFR 113 and 114 environments
• Pharma non-shelf stable liquids
• Biological active operations
Design solutions – The risk assessment

Product Examples

• Consumer packaged chocolate enrobed products
• Ice Cream Inclusions
• Bakery inclusions or toppings without end user steps
• Flavors or ingredients added to consumer beverages
• Infant food
• Cold processed cheese products
• Bioactive cultures and metabolites
• Confectionary products, dessert sauces, cores, bases
• Dairy and Culinary sauces and frozen inclusions
Design solutions – The risk assessment

Design Requirements

• A foot and wheeled traffic plan with contamination breaks including:
  – Dedicated MH equipment
  – Foot sanitization equipment to achieve a 3 log reduction
• Air handling systems pressurize processing rooms:
  – MERV 12-16 or HEPA for ESL or Aseptic.
  – De-humidified to prevent condensation.
  – A negative gradient may be present to adjoining rooms for allergen control.
• Permanently Installed tubeline systems and valves meet 3-A or EHEDG standards
• All product contact surfaces are Stainless Steel, or approved product contact plastics and elastomers
• Equipment is self-draining, sanitary under conditions of use, and free of pits, folds, cracks and inclusions allowing effective removal for microbial and allergen validation.
Design solutions – The risk assessment

Design Requirements (continued)

• Welds:
  – Compliant with AWS 18.1, 18.2, 18.3
  – Stitch welding is prohibited
• Materials of construction are compatible with food soils and sanitation process
• Where sterilization is required, equipment is designed to withstand:
  – High thermal process (>250 degrees F) for prolonged periods
    OR
  – Oxidative chemicals to achieve sterility
Embracing Hygienic Design

DESIGN SOLUTIONS
Design solutions

- Raw Processing
- Cook/Chill
- Office
- Raw Welfare
- Secondary Packaging
- Cleanroom
- Cleanroom
- Cleanroom

RTE Welfare
Design solutions – setting expectations
Design solutions – Equipment mounting
Design solutions – equipment mounting

Equipment Supports and Mounting

Unacceptable

Acceptable

Source: EHEDG and Trends in Food Science and Technology (1995 Vol. 6(9) pp. 305-310) (modified)
Design solutions – minimize floor contact
Design solutions – utilities, tubelines
Portable Pump cart - roundstock
Cycle time reduction, run time extensions
QUESTIONS?