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
FDA Reportable Food Registry by Hazard - 2013

Figure 2: Distribution of Primary RFR Entries by Food Safety Hazard, Year 4

- **Salmonella**, 58 (29%)
- **Listeria monocytogenes**, 35 (17%)
- **Undeclared Allergens**, 88 (44%)
- **Nutrient Imbalance**, 6 (3%)
- **Unviscerated Fish**, 1 (0.5%)
- **Drug Contamination**, 4 (2%)
- **Pathogenic *E. coli***, 4 (2%)
- **Other**, 3 (1.5%)
- **Foreign Object**, 1 (0.5%)
- **Undeclared Sulfites**, 2 (1%)
# 2015 Food Safety Report

**Measuring progress toward Healthy People 2020 goals**

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Healthy People 2020 Target Rate*</th>
<th>2015 Rate†</th>
<th>Change Compared with 2006-2008‡</th>
<th>Emoji</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Campylobacter</em></td>
<td>8.5</td>
<td>12.97</td>
<td><strong>+9%</strong></td>
<td>😞</td>
</tr>
<tr>
<td><em>E. coli O157</em></td>
<td>0.6</td>
<td>0.95</td>
<td><strong>-30%</strong></td>
<td>😊</td>
</tr>
<tr>
<td><em>Listeria</em></td>
<td>0.2</td>
<td>0.24</td>
<td>No change</td>
<td>😞</td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>11.4</td>
<td>15.89</td>
<td>No change</td>
<td>😞</td>
</tr>
<tr>
<td><em>Vibrio</em></td>
<td>0.2</td>
<td>0.39</td>
<td><strong>+34%</strong></td>
<td>😞</td>
</tr>
<tr>
<td><em>Yersinia</em></td>
<td>0.3</td>
<td>0.29</td>
<td>No change</td>
<td>😞</td>
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</tbody>
</table>

*Per 100,000 population
†Culture-confirmed infections per 100,000 population
‡1506-2008 were the baseline years used to set targets for Healthy People 2020 report
Our Challenge...protecting zones 2 and 1 for filling and closing
Beginning with the end in mind
Design opportunities - negative plant
Room Air Flow and Room Air Quality
Design opportunities – indirect zone 1 risk
Design solution
Design opportunities- unsealed interface
Design opportunities – uncleanable interface
Design opportunities – dead end
Design opportunities

Fermentation tank with intermittent failures due to design issues.
Design opportunities – split flows
Design opportunities – insanitary valves
Design opportunities – insanitary valves
Design opportunities – butterfly valve
Design opportunities – insanitary pump
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 as 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

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

CONDUCT A RISK ASSESSMENT!
Hygienic Design – The Risk Assessment for appropriate design

- The Risk Assessment – Process appropriate designs
  - What is the product platform? – Process technology and intended use?
  - Involve a Cross-functional group early – Engineering, Sanitarians, Operations, Quality, Product development
  - Environmental considerations, Air Quality/gradient, materials of construction
  - Optimize the Sanitation cycle
  - Automation or manual?
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>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Production Line</td>
<td>Brief description of intended product matrix, capacity, cycle times and other relevant factors.</td>
<td>Site Technology Core Competencies</td>
<td>Intended Use</td>
<td>Compatibility with existing: Processing Technologies, Skillsets</td>
<td>Total Risk Factor to Guide Selection and Design Of: Materials in Near Environment, Design and Finish for product contact zones, Plant air exchange and filtration, Dust Collection, Other requirements</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Site Related Concerns</td>
<td>- Ready to Cook</td>
<td>- New raw ingredients at risk, New Allergens</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>- Inadequate Grade</td>
<td>- Ready to Eat</td>
<td>- Microbiological</td>
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<tr>
<td></td>
<td></td>
<td>- Prevailing Wind</td>
<td>- Infants</td>
<td>- Store Product Pests</td>
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<tr>
<td></td>
<td></td>
<td>- Residential Proximity</td>
<td>- Aged or Immunocompromised</td>
<td>- Process Steps Requiring</td>
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<tr>
<td></td>
<td></td>
<td>- Pest Pressure</td>
<td>Regulatory Requirements</td>
<td>- Corrosion Resistance</td>
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<tr>
<td></td>
<td></td>
<td>Legal Concerns About:</td>
<td>- IMHO</td>
<td>- Higher CIP/ACS Flow Rates</td>
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<tr>
<td></td>
<td></td>
<td>- Cleaners and Sanitizers</td>
<td>- Lack Of Inhibitory Factors</td>
<td>- Impingement Cleaning</td>
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<td></td>
<td></td>
<td>- Pesticides</td>
<td>- pH</td>
<td>- Greater inspection access</td>
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<td></td>
<td></td>
<td>- Potable Water or Effluent</td>
<td>- Water Activity</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- Osmotic Pressure</td>
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<td>High Risk Ingredients</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- Bacterial</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- Allergens</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>- Stored Product Pests</td>
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<td></td>
<td></td>
<td></td>
<td>Sanitation Cycle times</td>
<td></td>
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</tbody>
</table>

### Score (1-5)

- Intended Use
- Site Technology Core Competencies
- Site Related Concerns
- Legal Concerns
- Site Technology Core Competencies
- Site Related Concerns
- Legal Concerns
Design solutions – The risk assessment

Product / Process Characteristics for High Hygiene design requirements
• 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 Hygienic Zoning / foot & wheeled traffic plan with contamination breaks including:
  - Dedicated MH equipment
  - Hygiene Junctions for Employee movement or...
  - 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 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
  - Oxidative chemicals to achieve sterility
Embracing Hygienic Design

DESIGN SOLUTIONS
Design solutions – setting expectations
Design solutions – distinct hygiene zones
Design solutions – minimize floor contact
Design solutions – Equipment mounting
Design solutions – utilities, tubelines
Hygienic Design

Square Corner/Radius

Unacceptable

SQUARE CORNER

Acceptable

RADIUS

(Required size of radius depends upon application)
Hygienic Design

Drainage of Vessels

Unacceptable
not drainable design

Acceptable
drainable design

Source: EHEDG and Trends in Food Science and Technology (1995) Vol. 6(9) pp. 307 (modified)
Hygienic Design

Dead Ends

Unacceptable

Acceptable

Dead space
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)
Hygienic Design – Sanitary Plungers
Hygienic Design – Toolless fastened Butterfly valve
Hygienic Design
CIP’able
Blend
Tank
Sanitary Design – Surface finish

- **2B Finish, Bead Blasted**
  - 35-45Ra

- **2B Finish Mill Finish**
  - 20-30Ra

- **#4 Finish 180 Grit**
  - 13-20Ra
Sanitary welded pipe shall be free of cracks, crevices and rough interior surfaces in and on which soil residue and bacteria can harbor.

Reference: AWS 18.1, 18.2, 18.3
Acceptable Weld

Outside

Inside
Poor Welds
QUESTIONS?