Listeria monocytogenes
Intervention & Control Workshop

JULY 18-19
PLANO, TX

Hygienic Design Survival Techniques
Joe Stout
Commercial Food Sanitation

United Fresh
Produce Association

PMA
Produce Marketing Association
Sanitary Design Defined

Sanitary Design is the application of design techniques which allow the timely and effective cleaning of the entire manufacturing asset.

Design Motivations
- Effectiveness & Efficiency of cleaning
- Pathogen control
- Micro & Insect Control
- Be Sanitation Friendly
- Maintain a sanitary Environment
- Keep product off the floor and out of the air
- Cost Effective
- Keep plants open and people employed
The Risk of Not Being 100% Perfect

<table>
<thead>
<tr>
<th>Produce 2 billion portions and Safety Risks</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>99% Food Safe</td>
<td>20,000,000</td>
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<tr>
<td>99.9% Food Safe</td>
<td>2,000,000</td>
</tr>
<tr>
<td>99.99%</td>
<td>200,000</td>
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<tr>
<td>99.999%</td>
<td>20,000</td>
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<tr>
<td>99.9999%</td>
<td>2,000</td>
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<tr>
<td>99.99999%</td>
<td>200</td>
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<tr>
<td>99.999999%</td>
<td>20</td>
</tr>
<tr>
<td>99.9999999%</td>
<td>2</td>
</tr>
<tr>
<td>99.99999999%</td>
<td>.2</td>
</tr>
</tbody>
</table>

Perfection can be lost in a split second with the wrong decision.
The Race to Zero Resident Pathogens
Whole Genome Sequencing

Key Points
• Between 2002 and 2011 only 40% of outbreaks were solved using PFGE methods because testing was not definitive.
• WGS can map out DNA sequence of strains of pathogens which is much more specific than PFGE
• FDA is collecting samples from plants for their data base to connect outbreaks to plants and suppliers
• This is excellent news for food safety and will minimize extended food outbreaks.
• However if you are not perfect, your company is at risk of a recall and the associated pain. If your product contains a pathogen it will be identified.
This is a race to Zero Resident Pathogens.
Getting control of Pathogens or getting hygienic design is not just turning a switch. It is an intuitive process based on Continuous Improvement.

Three Questions.

- Are we doing the right things?
- Are the right things working?
- How do we get better?
Zero means forever – not for a year

History shows that fewer issues = less focus on Sani, Qual S design & and food safety.

Red bars show time spent on sanitary design, Sani, Qual & Food Safety.

Goal is to have an ever increasing focus on sanitation, sanitary design and food safety over time.
Change Intersect Points in 2017 & beyond
Intersect Points in 2017 & beyond

The perfect storm

less protection and more scrutiny
It looks clean

Food that tests negative for pathogens

We have been in business for 50 years and never had an illness

Its Clean

Safe Food

Safe Food
Food that tests negative for pathogens.

We have been in business for 50 years and never had an illness.

Food made under sanitary conditions and tests negative for pathogens.
Spending on the ‘Clean’ Continuum

Which direction do you think regulators and processors are moving?

Design Out
Sanitation Labor

Spend capital budget? Spend resource budget?
The Future

Survival of the Fittest and Focused
Top 5 Food Safety Concerns

Survey respondents voted these as their top food safety problems:

- Deficient employee training 94%
- Poor plant design and construction 75%
- Poor plant and equipment sanitation 75%
- Contamination of raw materials 75%
- No preventative maintenance 69%

Sertkaya, Food Protection Trends, Vol 26, No 5 pages 310-315

- #1 Separate Raw From RTE
- #2 GMP’s Followed
- #3 Controlled Floor Conditions
- #4 Sanitary Design Equipment and Building
- #5 Effective Sanitation Procedures and Controls
- #6 Environmental Monitoring

This is where design makes it happen!

= Pathogen Control
New United FreshTEC Event Announced For Food Safety Community

If your company is faced with hygienic design challenges in equipment or facility design, you won’t want to miss the 2017 Hygienic Design Summit, hosted by United FreshTEC, the Global Cold Chain Expos, and the International Association for Cold Storage Construction.

Taking place Wednesday, June 14 from 4-6 pm, the Hygienic Design Summit brings together food safety experts, facility and equipment designers, and produce packers and processors to discuss sanitary design in temperature-controlled food facilities. The event kicks off with a hygienic design education program led by Joe Stout with Commercial Food Sanitation, followed by a networking reception. Attendance is free and open to all registered show attendees, however we ask that you pre-register for this event.

Register For The Hygienic Design Summit

Are you an exhibitor specializing in equipment or facility design? You have the opportunity to reserve a complimentary roundtable, allowing one-on-one discussion with attendees about the solutions your company offers. All exhibitors must pre-register for a table no later than May 12. Space is limited and available on a first-come, first-served basis. In addition, exhibitors will be listed in a Hygienic Design Summit Map, allowing attendees to find your booth on the show floor for further engagement.
Hygienic Design Summits

Key Learnings

• Started with a SWOT analysis by Processors and Suppliers (equipment and facilities)
• The Hygienic design elephants in the room were discussed – cost, PMs, realization of importance and collaboration is needed.
• Suppliers biggest concern is a lack of PMs and destruction of equipment following delivery.
• Processors concern is lack of knowledge about the need for cleaning.
• Most --- important new designs are not coming tomorrow. What to do in the meantime?
Master Sanitation Schedule
& PEC
Master Sanitation Schedule (MSS)

Period Cleaning
- Infrastructure (PIC)
- Equipment (PEC)

Seasonal
Janitorial
Routine
MSS Category Examples: Period Cleaning – PIC

Periodic Infrastructure Cleaning (PIC)
- Non-processing equipment

Examples
- Hallways
- Coolers
- Warehouse areas
- HVAC - impacts air quality
- Lights
- Shops
- Stairways
- Boiler rooms
- Pump rooms
- Shipping and receiving areas
MSS Category Examples: Period Cleaning – PEC

Periodic Equipment Cleaning (PEC)
- All processing equipment

Examples
- Removal of conveyor belts
  - Inner framework
  - Wear strips
  - Sprockets
  - Guards
- Product transfer valves and pumps
- Electrical boxes / control panels
- Chillers
- Spin dryers
- Bucket scales
- Slicing equipment
- Cutting equipment
Why PEC?

Equipment has Sanitary Design flaws which create harborage points
  • Microbiological
  • Foreign Material
  • Pest Control

Preventative approach
  • Avoid food safety recall
  • Avoid quality / customer issues
  • Negative business impact
  • Plant closure / loss of employment
  • Illness or loss of life
Periodic Cleaning Program Validation Importance

- Protection from microbial growth
- Prevent product build-up / bio films
- Downtime reduction
- Cost control
  - Staffing
  - Supplies
  - Lost production
- Other risks

**Important:** The frequency of PEC should always be validated with micro testing!
GMPS and Packing Houses

- The Food Safety Modernization Act rules governing packing houses has stirred up many questions for affected facilities. Get the answers you need to see how the new regulations apply to your organization.

- **Question:** Are packing houses subject to current good manufacturing processes (GMPs)?

- **Answer:** This area has been a point of confusion for some time. Many packing houses thought they were exempt from this requirement. But “packing houses have been subject to GMPs all along and that hasn’t changed,” said Jenny Scott, Senior Advisor with FDA/CFSAN’s Office of Food Safety

- **Question:** Are packing houses subject to FDA *Listeria* Guidance?

- **Answer:** Yes Intended for those persons who are subject to our regulation, in 21 CFR part 117 (part 117) entitled “Current Good etc. and who manufacture, process, pack or hold RTE Foods.
Subpart B--Current Good Manufacturing Practice

§ 117.10 - Personnel.
§ 117.20 - Plant and grounds.
§ 117.35 - Sanitary operations.
§ 117.37 - Sanitary facilities and controls.
§ 117.40 - Equipment and utensils.
§ 117.80 - Processes and controls.
§ 117.93 - Warehousing and distribution.
§ 117.95 - Holding and distribution of human food by-products for use as animal food.
§ 117.110 - Defect action levels.
Common Themes in Updated CGMPs

- Training
- **Cross contamination**
  - Allergens
  - Pathogens
  - Foreign Material
  - Sanitary Operations
  - Pests (represent insanitary conditions and pathogen contamination)
Who Are Your Sanitary Design “Partners”? 

- Equipment Vendors? 
- Regulations? 
- Trade Organizations? 
- Facility Designers and Builders? 
- Company Management?
A Sanitation Centric integrated “Safe Food” Supply Chain

Concept
- Product sensitivity
- Wet or dry clean
- Allergens
- New or old design
- Meet with Vendors
- Capture learning’s
- Allergens / label requirements
- Compliant

Design
- Equipment design
- Cleaning methods
- Utilities
- Facility design
- Regulatory requirements
- Pest Control
- Pathogen Monitoring
- Process Control

Review
- Facility design check list
- Equipment design list
- HACCP points
- Allergen management
- Sanitation procedures
- Other items
- Trash flow RTE Raw separation

Install
- GMPs followed
- Separation from other processes
- Raw from RTE
- Observe risk areas
- Monitor environment
- Inspect

Operate
- Sanitary Operational performance
- In process monitoring
- Employee concerns
- Easy for employees to do it right things

Clean
- Validate procedures
- Monitor time to clean
- Microbial monitoring
- Continuous improvement

Safe Food
Balancing Hygienic Designs with Formulations for Micro-Sensitive products

**Hygiene Practices**
- Hand washing
- Hair/beard restraints
- Jewelry restrictions
- Personal hygiene practices
- Appropriate clothing
- Designated eating areas
- Housekeeping responsibilities
- Traffic patterns

**Manufacturing Practices**
- Equipment & Facility design
- Facility maintenance
- Pest Control programs
- Container identification system
  - Employee training
- Layout and physical separation
  - Roofing maintained
- Condensation control
- Allergen Management
  - Traffic patterns
Balancing Hygienic Designs with Formulations for Micro-Sensitive products

- Frequent cleaning
- Sanitary design/teardown cleaning
- Clean equipment & environmental swabs
- Sanitize hands
- Interventions at RTE area entrance
- Maintenance interventions
- Zoning Principles
- Formula Robustness
- Equipment Design & Sanitation Procedures
- Infrastructure Design
- Manufacturing Practices
- Humidity Controls
- Foam Clean walls and ceilings routinely
Hygienic Design for Equipment and Environment for Processing RTE and RTC Products to Maintain a Sanitary Environment and Clean Equipment.
Equipment Design Checklist

Principle #1 – Cleanable to a Microbiological Level
Principle #2 – Made of Compatible Materials
Principle #3 – Accessible for Inspection, Cleaning & PMs
Principle #4 – No Liquid Collection
Principle #5 – Hollow Areas are Hermetically Sealed
Principle #6 – No Niches
Principle #7 – Sanitary Operational Performance
Principle #8 – Hygienic Design of Maintenance Enclosures
Principle #9 – Hygienic Compatibility with Other Systems
Principle #10 – Validated Cleaning & Sanitizing Protocols
### Equipment Sanitary Design Checklist for Produce

**S** = Satisfactory  
**M** = Marginal  
**U** = Unsatisfactory  
The Score will automatically calculate on the Summary page

#### Principle #1 - Distinct Hygienic Zones Established in the Facility

<table>
<thead>
<tr>
<th>#</th>
<th>Criteria</th>
<th>S</th>
<th>M</th>
<th>U</th>
<th>NA</th>
<th>Comments</th>
<th>Points</th>
<th>Points Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Equipment is designed to be constructed &amp; maintained in a cleanable condition to prevent the ingress, survival &amp; multiplication of microorganisms (measured post installation).</td>
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<td>0</td>
</tr>
<tr>
<td>1.2</td>
<td>All surfaces are cleanable as measured by &lt;1 CFU per 25 square centimeters, &lt;1 CFU per 10 ml when the item is rinsed, acceptable RLU (device specific) when measured by residual ATP, and/or negative for residual protein or carbohydrate when using swabs to detect residual protein or carbohydrate (measured post installation).</td>
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<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>1.3</td>
<td>All surfaces are accessible for mechanical action during cleaning &amp; treatment to prevent biofilms formation (measured post installation).</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>1.4</td>
<td>When requested, data are available to demonstrate that soiled equipment is cleanable (as defined above) by an individual using the cleaning protocol provided by the equipment supplier (measured post installation).</td>
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<td>0</td>
</tr>
<tr>
<td>1.5</td>
<td>Surfaces are clean visually and to touch, &amp; pass pre-op inspections using sight, touch &amp; smell (measured post installation).</td>
<td></td>
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<td></td>
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<td></td>
<td>0</td>
</tr>
<tr>
<td>1.6</td>
<td>A HACCP based product risk assessment was completed during the design phase to understand risks associated with the product type</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>1.7</td>
<td>Method of cleaning needed for the product risk was incorporated into the chosen design of the equipment</td>
<td></td>
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<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>1.8</td>
<td>Equipment has no apparent flaws that will fail over its life and make it uncleanable</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

#### Principle #2 - Made of Compatible Materials

<table>
<thead>
<tr>
<th>#</th>
<th>Criteria</th>
<th>S</th>
<th>M</th>
<th>U</th>
<th>NA</th>
<th>Comments</th>
<th>Points</th>
<th>Points Available</th>
</tr>
</thead>
</table>

0 160
### Equipment Sanitary Design Summary for Produce

<table>
<thead>
<tr>
<th>CATEGORIES</th>
<th>Points / Possible</th>
<th>% Earned</th>
<th>COMMENTS</th>
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<tbody>
<tr>
<td>PRINCIPLE #1 - CLEANABLE TO A MICROBIOLOGICAL LEVEL</td>
<td>-</td>
<td>160</td>
<td>0.0%</td>
</tr>
<tr>
<td>PRINCIPLE #2 - MADE OF COMPATIBLE MATERIALS</td>
<td>-</td>
<td>100</td>
<td>0.0%</td>
</tr>
<tr>
<td>PRINCIPLE #3 - ACCESSIBLE FOR INSPECTION, MAINTENANCE, &amp; CLEANING/SANITATIC</td>
<td>-</td>
<td>165</td>
<td>0.0%</td>
</tr>
<tr>
<td>PRINCIPLE #4 - NO LIQUID COLLECTION</td>
<td>-</td>
<td>85</td>
<td>0.0%</td>
</tr>
<tr>
<td>PRINCIPLE #5 - HOLLOW AREAS HERMETICALLY SEALED</td>
<td>-</td>
<td>180</td>
<td>0.0%</td>
</tr>
<tr>
<td>PRINCIPLE #6 - NO NICHES</td>
<td>-</td>
<td>115</td>
<td>0.0%</td>
</tr>
<tr>
<td>PRINCIPLE #7 - SANITARY OPERATIONAL PERFORMANCE</td>
<td>-</td>
<td>100</td>
<td>0.0%</td>
</tr>
<tr>
<td>PRINCIPLE #8 - HYGIENIC DESIGN OF MAINTENANCE ENCLOSURES</td>
<td>-</td>
<td>60</td>
<td>0.0%</td>
</tr>
<tr>
<td>PRINCIPLE #9 - HYGIENIC COMPATIBILITY WITH OTHER SYSTEMS</td>
<td>-</td>
<td>50</td>
<td>0.0%</td>
</tr>
<tr>
<td>PRINCIPLE #10 - VALIDATED CLEANING &amp; SANITIZING PROTOCOLS</td>
<td>-</td>
<td>45</td>
<td>0.0%</td>
</tr>
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<td></td>
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<td>1,060</td>
<td>0.0%</td>
</tr>
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</table>
Design Standards

- 3A Standards
- EHEDGEC
- NSF 3A 14159-1
- EN 1672
- ANSI Z50.2
- One Voice
- AWS American Welding Standards
- Principles of Facility and Equipment Design
  - AMI Principles
  - Dairy outside the Pipe
  - Low Moisture Food
  - Produce

Don’t argue about Standards – pick one and follow it!
Common Sense Approach to Sanitary Design

IF YOU CAN’T SEE IT

AND

YOU CAN’T REACH IT

YOU CAN’T CLEAN IT!

Or sample IT
Bad Designs & Bad to Better
Enemy #1

Harborage Points
A Sandwich
Summary

• Work on PIC and PEC to protect consumers
• Spend time with Design Partners to create better designs – it is a team sport.
• Think cleanable equipment and infrastructure for RTE and RTC foods.
Questions