AN OVERVIEW
SANITARY DESIGN

Use a “Preventative Mindset”

John Butts
Land O’ Frost
CMC - Toronto 2009
1. Evolution of Listeria Control
2. Data Requirements for Sanitary Design
3. Sanitary Equipment Design
4. Sanitary Facility Design
# The Evolution of Environmental Pathogen Control

<table>
<thead>
<tr>
<th>Stage</th>
<th>Sampling Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awareness</td>
<td>Contact Surface and Product positives</td>
</tr>
<tr>
<td>Enlightenment</td>
<td>Expanded and regular sampling of contact surfaces and environmental sites. Intermittent positives on contact surfaces. Routine positives on environmental sites</td>
</tr>
<tr>
<td>Preventative</td>
<td>Early preventative phase positive results dominated by indicator sites such as post rinse. In final phase of preventative, only rare Contact Surface positives. No Product Positives. Investigative facility based positives dominate RTE.</td>
</tr>
<tr>
<td>Predictive</td>
<td>No Contact surface positives. Zone 4 positives predominate. Hurdle transfer point sampling produces rare positives.</td>
</tr>
</tbody>
</table>
# The Evolution of Environmental Listeria Control

<table>
<thead>
<tr>
<th>Stage</th>
<th>Control Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awareness</td>
<td>Sample product. Recognition of environmental nature of Listeria.</td>
</tr>
<tr>
<td>Enlightenment</td>
<td>Recognized existence of growth niches. Sample contact surfaces and some floor and environmental areas. Starting the redesign phase.</td>
</tr>
<tr>
<td>Predictive</td>
<td>Aggressive early warning sampling in place. Intervention practices in place with all RTE equipment. Focus on zone 4 and facilities. Advanced phases of both Equipment and Facility redesign.</td>
</tr>
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# The Evolution of Environmental Listeria Control

<table>
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<tr>
<th>Stage</th>
<th>Verification Samples &amp; Sites</th>
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<tbody>
<tr>
<td>Awareness</td>
<td>Product</td>
</tr>
<tr>
<td>Enlightenment</td>
<td>Product &amp; Contact Surfaces</td>
</tr>
<tr>
<td>Preventative</td>
<td>Product, Contact Surfaces &amp; Primary Transfer Vectors in RTE Area</td>
</tr>
<tr>
<td>Predictive</td>
<td>Product, Contact Surfaces &amp; Transfer Points in RTE Area</td>
</tr>
</tbody>
</table>
Commitment Model

- Resistant – don’t believe it has value
- Accepting – why not
- “Buy-in” – we will do it
- Engagement – involved in solution
- Commitment – hold self and others accountable for achieving results

Bob Reinhard – Sara Lee
The Role of Sampling and Data in Sanitary Design

- Existing Facility and Equipment design improvements must be data driven.
- Sampling Programs must produce positive results to provide a basis and justification for improvement.
Data

- Sampling data must define the pathway when improving existing facilities and processes
- Sampling data can be classified into two types
  - Control
  - Verification
- Examples
  - Control
    - Data collected to find and control a growth niche.
      - This includes investigative sampling as well as growth niche indicator site monitoring
    - Data collected to measure the effectiveness of a hurdle or barrier to perform their respective function
  - Verification
    - Finished product
    - Contact surfaces
Equipment and Facility Design

Improvements Must be Supported and Guided by a Sampling Program Designed to Identify Problems requiring Improvement

- These sampling efforts must correctly identify the problems and necessary control factors
- Sampling to avoid *Regulatory Consequences* will not direct or measure the improvement needs and efforts
Data Requirements

“We have been down this path before”
What do you mean “the sample is positive!”
Normal cleaning and sanitation

Observe flood sanitization

Observe assembly

Observe Post assembly sanitizer application

Observe normal setup and start up activities

Stop operation before product is placed on the line

Disassemble to normal daily sanitation level

Disassemble any remaining machine components

Clean and flood or heat sanitize all disassembled line components

Are all parts and components being adequately sanitized (chemical or heat)?

Are GMP's followed?

Inspect and swab any suspect areas

Evidence of unacceptable organic buildup?

Is degree of disassembly acceptable?

Are cleaning methods acceptable?

If area is Ls positive then it is a growth niche

If APC growth is supported then the suspect area is a potential growth niche
Clearly and Concisely Define the Scope of the Investigation as a Physical Area
Time Study

A Time Study consists of sampling the line components and everything that comes to the line over a period of time.

The Time Study typically starts during setup and assembly. Samples will be taken as workers and product come to the line, repeated after line is running then every 2 hrs thereafter.
Focus on there is more to Lm control than just eliminating the growth niches on slicers.

John N. Butts, 9/14/2008
Swat Team Sampling

- Sample during an idle period after sanitation, before production i.e. Saturday when no production is running
- Sample large areas using sponges or gauze.
- Sample areas not typically sampled during routine sampling
  - We found a transient growth niche using this method – COP basket handle
PROCESSES FLOW CHART FOR DESIGN REVIEW

Manufacturer & Customer Review Equipment
Design Against the Checklist Tool

- Redesign

- Acceptable?

Third Party Review (optional)

- Acceptable?

- OR

Purchase and Install Equipment
Training and Start-up

- Cleanability/Microbiological Review (90 day)

- Acceptable?

- NO

- Redesign/Sanitation Control

- Yes

Close Contract

AMI Equipment Design Task Force
When designing equipment:

- Keep it simple
- Less is better
- Strive for minimum ‘parts’
- All parts and assemblies accessible
- Role play the ‘sanitation employee’

“The difficult thing about engineering great designs is to make them simple.”

An Engineer’s Perspective
The original design may have been correct. As equipment ages, it tends to collect a “compounded level” of difficult to clean potential growth niches.
10 Principles of Sanitary Design

<table>
<thead>
<tr>
<th>Principle</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.</td>
<td>Cleanable to a Microbiological Level</td>
</tr>
<tr>
<td>2.</td>
<td>Made of Compatible Materials</td>
</tr>
<tr>
<td>3.</td>
<td>Accessible for Inspection, Maintenance, Cleaning and Sanitation</td>
</tr>
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</table>

**1. Cleanable to a Microbiological Level**

Food equipment must be constructed and maintainable to ensure that the equipment can be effectively and efficiently cleaned and sanitized over the life of the equipment. The removal of all food materials is critical. This means preventing bacterial ingress, survival, growth and reproduction. This includes product and non-product contact surfaces of the equipment.

**2. Made of Compatible Materials**

Construction materials used for equipment must be completely compatible with the product, environment, cleaning and sanitizing chemicals, and the methods of cleaning and sanitation. Equipment materials of construction must be inert, corrosion resistant, nonporous, and nonabsorbent.

**3. Accessible for Inspection, Maintenance, Cleaning and Sanitation**

All parts of the equipment shall be readily accessible for inspection, maintenance, cleaning, and/or sanitation. Accessibility should be easily accomplished by an individual without tools. Disassembly and assembly should be facilitated by the equipment design to optimize sanitary conditions.
10 Principles of Sanitary Design

4. No Product or Liquid Collection
   Equipment shall be self-draining to assure that food product, water, or product liquid does not accumulate, pool, or condense on the equipment or product zone areas.

5. Hollow areas Hermetically Sealed
   Hollow areas of equipment (e.g., frames, rollers) must be eliminated where possible or permanently sealed (caulking not acceptable). Bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps, sleeves, and other such items must be continuously welded to the surface of the equipment and not attached via drilled and tapped holes.

6. No Niches
   All parts of the equipment shall be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets and dead ends. All welds must be continuous and fully penetrating.

7. Sanitary Operational Performance
   During normal operations, the equipment must perform so it does not contribute to unsanitary conditions or the harborage and growth of bacteria.
8. Hygienic Design of Maintenance Enclosures

Maintenance enclosures (e.g., electrical control panels, chain guards, belt guards, gear enclosures, junction boxes, pneumatic/hydraulic enclosures) and human machine interfaces (e.g., pushbuttons, valve handles, switches, touchscreens) must be designed, constructed and be maintainable to ensure food product, water, or product liquid does not penetrate into, or accumulate in or on the enclosure and interface. The physical design of the enclosures should be sloped or pitched to avoid use as a storage area.

9. Hygienic Compatibility with Other Plant Systems

Design of equipment must ensure hygienic compatibility with other equipment and systems, e.g., electrical, hydraulics, steam, air, water.

10. Validate Cleaning and Sanitizing Protocols

The procedures prescribed for cleaning and sanitation must be clearly written, designed and proven to be effective and efficient. Chemicals recommended for cleaning and sanitation must be compatible with the equipment, as well as compatible with the manufacturing environment.
Applying the 10 Principles of Sanitary Design to RTE Equipment
Sanitary Design Processing

Key Criteria for Food Equipment

- Minimize surface area to clean
- Parts and assemblies easy to access and inspect
- Disassembly can be completed by hand or with simple tools
- Cleaning and sanitizing procedures can be repeated by all employees
Visual
– this will be the first measure, but will only take you so far because of …
THE “INVISIBLE” BACTERIA

**Micron (µm)**
- 1/1,000,000 meter
- 39.37 µ-inch

**Micro-inch (µ-inch)**
- 1/1,000,000 inch
- 0.0254 micron

- Salt (120µm, 4724 µ-inch)
- Yeast (5 µm, 197 µ-inch)
- Mold spore (3 µm, 118 µ-inch)
- Listeria (0.5 µm, 19.7 µ-inch)
MEASURES OF CLEAN

- Test for bacteria
  - <1 CFU (colony forming unit) per 25 square centimeters or <1 CFU in 10 ml of rinse water
- Acceptable RLU (relative light unit)
  - as generated by an ATP reader; ATP indicates the presence of organic material
MEASURES OF CLEAN

Measures will be taken in difficult to clean areas
1. **Cleanable to a Microbiological Level**  
   (how we measure to this level)

**Supplies Needed to Collect Micro Swab Samples**

- Sterile neutralizing buffer/broth to moisten the sponges or gauze pads
- Whirl-Pak bags
- Sterile sponges or gauze pads
- Marking pen
- Sterile gloves
1. Cleanable to a Microbiological Level

From This To This

Previous Design  Sanitary Redesign

Belt supports bolted in place (attached to frame w/threaded bolts)

Removable belt supports
1. Cleanable to a Microbiological Level

Easy to Inspect / Full Disassembly

From This

Previous Design

To This

Sanitary Redesign

Not disassembled

Difficult to inspect or sample

Easy access to belts
2. Made of Compatible Materials

6061 Aluminum

Bearing Corrosion Salt Brine Test

Bearing 1 is plated. Some bearings on the market are 400 Series stainless steel. 400 Series will rust. Choose wisely!

Use aluminum ONLY when necessary, and when so, anodize (or applicable process) to inhibit corrosion and wear. No coatings in Zone 1.
Rusty surfaces have been shown to be harborage points. These surfaces can be protective of a Lm biofilm.
3. Accessible for Inspection, Maintenance & Cleaning/Sanitation

All equipment parts and components shall be readily and easily accessible for inspection, maintenance, troubleshooting, cleaning, and sanitizing. Accessible without using tools or with a simple tool set is required. Disassembly for sanitation is enhanced by customized parts bins and design considerations for size and configuration.
3. Accessible for Inspection, Maintenance & Cleaning/Sanitation

Equipment shall not contribute to bacterial growth, bacterial harborage or enhance unsanitary conditions during operation. Residue or soil build-up must be kept to a minimum.

From This | To This
--- | ---
Previous Design | Sanitary Redesign
4. No Food Product or Liquid Collection

- Free standing moisture
- Pitched surfaces, self-draining
- Rounded edges
- Single piece construction

From This | To This
Previous Design | Sanitary Redesign
Must be Self Draining

Open slots to make self draining

From This
Previous Design
Sanitary Redesign
To This
5. Hollow Areas Hermetically Sealed

Zone 1 – easily missed & unexpected
5. Hollow Areas Hermetically Sealed
5. Hollow Areas Hermetically Sealed

- Hollow roller not die filled
- Easily disassembled provides access to the fixed shaft and roller interior

From This

Previous Design

To This

Sanitary Redesign
6. Free of Growth niches

The frequency for Non-daily scheduled sanitation tasks to disassemble and clean mating surfaces must be established.
Uncleanable plastic-metal interface
6. Free of Growth niches
6. Free of Growth niches
6. No Niches

Numerous metal to metal contact points

From This

Previous Design

To This

Sanitary Redesign

Solid shafts

Solid roller

Bolted components
## Challenge Guideline or “Conventional Wisdom” of Boosted Pressure Rinsing

<table>
<thead>
<tr>
<th>Degree of Growth Niche Development and Penetration</th>
<th>Boosted Pressure</th>
<th>Regular Dairy Hose Tap Water Delivery Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Boosted pressure</td>
<td>Regular dairy hose tap water delivery pressure</td>
</tr>
<tr>
<td>Boosted pressure</td>
<td>Boosted pressure</td>
<td>Difficult to rinse product</td>
</tr>
<tr>
<td>Difficult to rinse product</td>
<td>Dry non-sticky products</td>
<td>Dry non-sticky products</td>
</tr>
<tr>
<td>Low</td>
<td>Regular dairy hose tap water delivery pressure</td>
<td>Dry non-sticky products</td>
</tr>
</tbody>
</table>
7. Sanitary Operational Performance

Applying the 10 Principles of Sanitary Design

From This

Previous Design

To This

Sanitary Redesign

Product residue/buildup

Belt scraper
7. Sanitary Operational Performance

- Open Design
- Multiple collection points
- Minimal product contact area

From This
Previous Design

To This
Sanitary Redesign
8. Hygienic Design of Maintenance Enclosures

Sensitive Equipment Cleaning

- Hand wipe all equipment control panels with 800PPM Quat
- Regularly clean and sanitize the inside of control panels and other maintenance enclosures.
8. Hygienic Design of Maintenance Enclosures
8. Hygienic Design of Maintenance Enclosures

- Cabinet location (can moisture & soils accumulate?)
- Cabinet location (can moisture drain, drop, or diffuse onto product?)
- Open design
9. Hygienic Compatibility with Other Plant Systems

Can you clean this?

Pedestal design

Sealed cabinet

Ample floor clearance

From This

Previous Design

To This

Sanitary Redesign
10. Validate Cleaning & Sanitizing Protocols

- Graphics
- Multi use document
  - Training
  - Reference
- Can it be use on the floor?
- Can it withstand the environment?
AN OVERVIEW
SANITARY FACILITY DESIGN

Use a “Preventative Mindset”
1. Distinct Hygienic Zones Established In The Facility

Maintain strict physical separations that reduce the likelihood of transfer of hazards from one area of the plant, or from one process, to another area of the plant or process, respectively. Facilitate necessary storage and management of equipment, waste and temporary clothing to reduce the likelihood of transfer of hazards.
1.7 Separate storage areas for tools and spare parts exist to minimize contamination for RTE/high risk and non-RTE/lower risk zones
1.10 Separate support and storage areas for sanitation crews exist for RTE/high risk and non-RTE/lower risk zones.
1.15 Trash collection is properly located and locations are cleanable & maintainable
2. Control the movement of personnel and materials flows to reduce hazards

Establish traffic and process flows that control the movement of production workers, managers, visitors, QA staff, sanitation and maintenance personnel, products, ingredients, rework and packaging materials to reduce food safety risks.
Passive Control

RTE Area

Cross Traffic Aisle

Active Control

Magnetic Lock

Access Control Card Reader

From This
Design

To This More
Sanitary Design
SANITARY DESIGN PRINCIPLES FOR FACILITIES

PRINCIPLE #3

WATER ACCUMULATION CONTROLLED INSIDE FACILITY
Ponding water … requires designs that facilitate free draining of any moisture that is introduced into the facility environment.

Pooling water is a sign of trouble.
3.2 All floor joints & cracks are sealed

Monolithic crack repair

Example of good crack repair ...
3.3 Wall & curb surfaces drain freely without pockets, ledges & nooks
SANITARY DESIGN PRINCIPLES FOR FACILITIES

PRINCIPLE #4

ROOM TEMPERATURE & HUMIDITY CONTROLLED
HOW TO CLEAN TO A MICROBIOLOGICAL LEVEL?

... requires a design that maintains the prescribed temperature, controls condensation and eliminates fog during the sanitation process.
Critical Air Handling System

- Flame Sterilizer
- Pre Filter (30% 1 m)
- Fan
- Final Filter Bank (95% 1 m)
- Refrigeration Coils

- Outdoor make up air inlet
- Bird screen
- Exhaust return air from RTE Area
- Access Doors (24x 72”)

Intake → Outlet
Air Handling System
Clean Up Mode

Sanitation Processes
• Pre-Rinse
• Soap
• Rinse
• Flood sanitize

Fresh Air Intake

Flame sterilized – Heated and Dried

Exhaust – Moist air

High rate of air changes
• Allows room to warm up to ~ 75F
• Continuously removing moisture
• Keeps fog down

Warm Dry Air In ➔ Warm Moist Air Out
Air Handling System
Process Mode

- Fresh Air Intake
- Refrigerated air
- Exhaust - Moist air

Processes:
- Assembly
- Setup
- Pre-op
- Final sanitizer
- Production

Low rate of air changes:
- Cools room while removing moisture
- Floors dry by startup
- Equipment chilled to operating temp by startup
PRINCIPLE #5

... addresses airflow and air quality. Controlled pressurization and air flow cures a lot of ills. It reduces infiltration of warm, humid air that can cause condensation problems. It reduces dust and dirt problems at outside openings. It allows your exhaust systems to work properly and efficiently.
Typical Unit Cooler

Critical Process Air Handling System

From This

Design

To This More

Sanitary Design
5.6 HVAC/Refrigeration system components located to avoid risk of product contamination
5.1 All rooms have their pressures controlled to ensure airflow will be from more clean to less clean areas.
6.8 Storm water system is properly designed and maintained to prevent standing water on the site.
6.1 Driveways, parking lots and pedestrian walkways are paved and drained to prevent standing water
6.7 External operations (e.g. trailer cleaning, bulk storage, trash and waste management) are designed and positioned to prevent unsanitary impact on the facility.
8.3 There is sufficient access to clean the wall-floor interface.
8.4 Stationary equipment is elevated sufficiently to allow cleaning and sanitation underneath the equipment... difficult to clean
9.1 Interstitial spaces separate process areas from utility services & overhead structural components, and allow for access & cleaning

<table>
<thead>
<tr>
<th>Light enclosures</th>
</tr>
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</table>

9.2 Suspended ceilings are smooth, cleanable, and at a uniform height
9.5 All vertical surface to floor junctions have a cove and surfaces that are free of pits, erosion and voids

Poor example
- Ponding water
- Pitted floor surface
- No cove
9.6 Concrete surfaces are free of pits, erosions and voids, solid and smooth.

9.16 Bases of drains are supported to prevent settlement.
... failure to fully seal void associated with utility penetrations

7.8 All voids associated with utility penetrations are fully filled with appropriate materials, then sealed. Sprinkler penetrations insulated, sealed & heat traced
... inferior seal

From This

To This More

Design

Sanitary Design
9.19 Items attached directly to a building surface have standoffs

Good examples
9.21 Doors and windows are constructed to prevent harborage, impervious, easily cleanable and resistant to wear and corrosion.

**Poor example**
- Seams
- Damage prone

**Good example**

**From This**

**To This More**

**Sanitary Design**
10.1 Horizontal piping and conduits are not installed above exposed product or processing.

Poor example – piping above process equipment

Good example – piping in interstitial space
10.3 Piping and conduits are routed outside of process areas wherever possible.
10.21 Raw process & ready-to-eat process
sewers are separated

Bacteria is Present

Oven Room

Industrial sewer

Raw Materials

Raw Manufacturing

Over Roof

Wash Room

Office and welfare areas

RTE Welfare Area

RTE Packaging

Palletize

Shipping Dock

Maintenance Area

Finished product
Cooler

Raw sewer

RTE sewer
10.23 Where possible, cleanouts are installed outside the processing areas. Clean out access for room drains on other side of wall.
10.26 Process sewers are made of materials compatible with the temperature & corrosiveness of the waste stream.

10.31 Floor drains, hub drains & traps are made of corrosion-resistant materials suitable for area of installation (e.g. stainless steel in critical process areas).

- Stainless traps and drains

Other options:
- Polypropylene
- PVC, CPVC
- PVDF (Polyvinylidene Fluoride)

10.32 Floor drains in process areas have basket strainers.
SANITARY DESIGN PRINCIPLES FOR FACILITIES

PRINCIPLE #11

... addresses the need to integrate the utilities and equipment required to support the sanitation process into the facility design
11.4 Rinse systems are operated at minimum pressures adequate for cleaning to limit over-spray & creation of aerosols during use.

- Generally recommended as city pressure
- Either hot or cold per sanitation requirement
- Low pressure so can’t move contamination from floor to higher surface
11.6 Adequate interventions (e.g., foot baths, doorway foamers, boot washers) are provided at locations as required to maintain zones of control.
Sanitation hose station

Hand wash station with floor foamer
Questions?

Thank you