Getting Ahead
with an effective
Environmental Monitoring Program (EMP)

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1985... Listeria...
need not and should not be secured at the expense of healthy functioning pelvic organs, a beautiful straight back and other features... thrown out of plumb by high heels.”

1940 The average American could now expect to live until 63, we said, thanks to pasteurized milk, vaccines and other improvements. Today that number is 77.8.

1950 “Tell Me, Doctor,” a physician-written column, made its debut. Previously taboo
Lessons Learned

“Those who fail to learn from history are doomed to repeat it.”

...Sir Winston Churchill
Lessons Learned from Other Commodity Groups

“The battle with this organism (*Listeria monocytogenes*) has caused more change for producers of RTE deli meat products than any one single factor or event in the last 30 years...

...the scars are numerous and deep.....”

John Butts... Land O Frost Chair, AMI SAC Committee
CONTROL OF SALMONELLA IN LOW-MOISTURE FOODS

February 4, 2009

• To minimize the risk of Salmonella contamination in low-moisture products.

• To be used to develop a new food safety system or augment an existing system already employed by a manufacturer or supplier.
The most effective tool for determining the effectiveness of a facility’s *Salmonella* controls is the implementation of an **aggressive** Pathogen Environmental Monitoring Program (PEM).

A PEM is an **on-going measure** of the **effectiveness** of the overall *Salmonella* control program in the plant.

It is **not**, in itself a *Salmonella* control program.

It provides **feedback** on where efforts need to be directed for the overall control program.

One size program does not fit all.
Getting Started...

- Assemble your team; designate a team leader
- Assemble a cross functional team familiar with your operation to help identify potential areas of risk or concern, including:
  - Quality manager
  - Microbiologist
  - Sanitation
  - Operations Manager
  - Plant Engineer
  - Maintenance
  - Line Supervisor
  - Warehousing
Getting Started…

• ...understand your process flow with an emphasis on identifying potential points of product recontamination
  • Blueprints and flow diagrams; walk the plant floor

• ...conduct environmental monitoring in raw and non-productions areas - understand that you will occasionally find Listeria/Salmonella in those areas. Need to determine and understand the risk!
Plant layout - Hygienic Zones of Control Assessment

- Conduct a hygienic zone assessment to determine what is considered the *Primary Pathogen Control Area (PPCA)* in your facility
  - areas where RTE post-lethality treated/finished product is exposed to the environment → high hygiene or high risk area.

- The objective of hygiene zones:
  - is to identify areas of high and low risk to the product within the manufacturing operation.
  - to prevent the spread of pathogens into the PPCA where protection of the exposed post-lethality product is critical.
Plant Layout - Hygienic Zones of Control Assessment

- Conduct a hygiene zone assessment of the entire facility and create a color-coded map:
  - Evaluate all production areas, storage, receiving, warehousing and loading docks, employee facilities such as cafeterias, break rooms, locker rooms, washrooms, maintenance areas, offices/conference rooms, etc.
  - Designate the PPCA, basic GMP areas, transition areas, and non-processing areas.
  - Pay particular attention to areas within the facility where ingredients, products, or the environment could be a potential source of *Listeria*, *Salmonella* and other pathogens and a high potential to recontaminate post-lethality treated product.
  - Also pay attention to non-process areas such as forklift charging stations, refuse/recycling areas, restrooms and others that could impact the PPCA.
Plant Layout – Hygienic Zones of Control

Main Entrance

Offices

Employee Welfare

Raw material Receiving/Storage

Hallway

Finished Product Warehouse/Shipping

Packaging

Post-lethality

Lethality

Pre-lethality Steps (Mixing, Grinding, Sifting)

PPCA (Primary Pathogen Control Area)

Basic GMP Area

Non-process areas
Plant Layout – Hygienic Zones of Control

Main Entrance

- Offices
- Employee Welfare
- Raw material Receiving/Storage
- Hallway
- Finished Product Warehouse/Shipping
- Packaging
- Mixing steps

PSCA (Primary Pathogen Control Area)
Non-process areas
Sample Locations & Sanitary Zoning within a Room/Area

1st - Map out the hygienic zones of control in the facility.

2nd – Select specific sampling sites within each room/area.

Use the sanitary zoning concept to aid in site selection and in tracking environmental data (the sanitary zoning concept is different than mapping hygienic zones of control within the facility).

In the sanitary zoning concept the plant operations are divided into four zones based on level of risk.
Sanitary Zones

Zone 1
Product Contact Surfaces
(Slicers, strippers, peelers, fillers, hoppers, screens, conveyor belts, air blowers, employee hands, knives, racks, work tables)

Zone 2
Non-Product (Near) Contact Surfaces
(exterior, under, & framework of equipment; refrigeration units, equipment housing; switches)

Zone 3
Other Areas within RTE Room
(air return covers, phones; hand trucks, forklifts, drains, wheels)

Zone 4
Areas Outside of RTE Room
(Locker rooms, cafeteria, hallways, loading dock, maintenance areas)
Zone 1

Zone 1 - Areas in the plant that are direct product contact surfaces after the lethality or microbial reduction step (e.g. roaster) and before the product is sealed in the primary package

- If there is no lethality step in the process - sites where the product is exposed to plant equipment and environment prior to sealing in the primary packaging
  - Conveyor belts/buckets
  - Utensils
  - Employee hands (if touching product)
  - Slicers/dicers; Product hoppers/bins/bin liners
  - Discharge Chutes; Fillers
  - Air blowers
  - Control buttons/switches
Zone 1 Sampling
Zone 2

Zone 2 – Non-product (Near) contact areas in the plant that are closely adjacent to product contact surfaces

- Equipment Exterior, under & Equipment framework
- Drip pans/shields/housings
- Control panels/buttons
- Overhead lights, refrigeration units/drip pans, conveyors, rail systems and pipes directly over zone 1 surfaces – Don’t forget to look up!
- Computer screens
- Maintenance tools
- Drains located directly under equipment
- Motors located adjacent to lines
Zone 2 Sampling
Zone 3

Zone 3 – Non-product contact surfaces that are in open post-lethality product processing areas, but no closely adjacent to zone 1 surfaces

- Zone 3 surfaces have the possibility of leading to product recontamination

  > Floors, walls, ceilings
  > Hoses
  > Drains
  > Condensate drip pans
  > Trolleys, forklifts, walk-alongs, carts*
  > Toolboxes*
  > Trash containers*
  > Pallets
  > Foot baths/mats
  > Brooms/mops
  > Fans

*Don’t forget the wheels!!*
Zone 3 Sampling
Zone 4

Zone 4 – Areas that are more remote from post-lethality product processing areas

• Zone 4 areas if not maintained in good hygienic condition can lead to cross-contamination of zone 1–3 areas
  ✓ Hallways
  ✓ Loading docks
  ✓ Bathrooms; Locker rooms
  ✓ Employee cafeteria/break rooms
  ✓ Raw material Coolers/freezers/Warehouses
  ✓ Maintenance shop
  ✓ Office areas
Zone 4 Sampling
Where are the bacteria hiding?

Microbial Growth Niches

- Locations, often “hard to reach” places, harboring the organism after the routine sanitation process for that area has been competed.

- Places within food processing equipment and/or a food processing environment where microorganisms become established and multiply.

- Serves as a reservoir from which microorganisms are dispersed and contaminate equipment during operation.
Microbial Growth Niches

- Conveyors
- Framework of equipment
  - Especially hollow
- Electrical panels
  - Inside panel box
  - Around gaskets
- In and around start/stop buttons and emergency shut-offs
- Rollers on belts
  - Especially hollow rollers
Microbial Growth Niches

- Behind O-rings, seals and gaskets on equipment and around doors (especially if old and brittle)
- Spaces between metal:metal and metal:plastic joints and parts
- Chain guards, motor covers and housings
- Water-saturated insulation (e.g. in old spiral freezers, wrapped around pipes or behind fiberglass wall panels)
Microbial Growth Niches

- Drains
  - Usually harbor some standing water
  - Biofilm (including rust, corrosion, product debris, etc.)
- Cracks/crevices in floor, at curb/wall or cove/wall junction
  - Especially those which harbor water
- Inside walls
  - Look for “waterfalls” atop curbs
Microbial Growth Niches

- Cleaning aids
  - Mops & mop buckets (including those used for overheads)
  - Squeegees
  - Brushes
  - Pump up sprayers and spray bottles
  - Brooms with permeable bristles
  - Scrub pads and rags
- Floor scrubbers
- Hoses
Growth Niches

Must either be designed out of the system or managed as a part of the process.

- Design Examples
  - **Equipment is redesigned to eliminate or seal hollow areas**
    - 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, name plates, 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.
How do microbes move around

- Movement of equipment parts during processing can dislodge organisms (from niche areas) into the environment
- Via tools & other maintenance equipment
- Via parts removed from equipment & set on food-contact surfaces
- Supplies, ingredients, people, equipment moved between and through hallways, non-product and raw areas.
How do microbes move around

- Via moisture droplets or aerosols
  - Operations
    - Drain back-ups
    - Kicked up by hose sprays
  - Sanitation
    - Kicked up by hose sprays
    - From wash areas
- By hitch-hiking on dust or lint particles
- Through compressed air lines (point of use filter); air from automatic bag openers
Microbial Transfer Points

**Transfer Point**: Sites or carriers, such as employees and product handler’s gloves/clothing/boots, equipment or equipment parts, or maintenance tools, supplies and/or ingredients that may cross contaminate from one source to another prior to or during operations.
Corrective Actions....in Response to a Positive Result

- Your facility should have a pre-determined action plan that would be implemented in the event of a *Salmonella*, *Listeria* (or *Cronobacter*) positive result
  - The action plan should be specific for each of the four zones and include
    - Type of immediate corrective actions to be taken by zone
    - Actions to be taken to verify *Salmonella*/*Listeria*/*Cronobacter* has been eliminated from the area in question
    - A root cause analysis to find the source of the contamination so that it can be prevented in the future
Corrective Actions

- In the event of a *Pathogen* (*Salmonella/Listeria/Cronobacter*) positive, the response team should conduct an in-depth investigation looking at:
  - Any maintenance disruptions/activities
  - In-plant construction
  - Unplanned down time
  - Other non-standard production activities (e.g. R&D plant trial)

- The response team should look at these factors and all relevant records and documents from last full microbiological cleanup/sanitation to the current positive finding.

- **Track and trend the results of testing!**
More Corrective Action Examples

- Review equipment for harborage areas, such as hollow rollers, rough welds, cracked or damaged surfaces.
- Extensive disassembly of equipment for thorough cleaning – intensified deep cleaning.
- Audit (including observation) of sanitation process to ensure adequacy.
- Extensive intensified deep cleaning and sanitizing of the room, peripheral areas, and holding coolers.
- GMP refresher with all employees including maintenance.
- Review of sanitation data/records.
- Review of environmental data in the area as well as adjacent areas.
- Audit (observe) employees and practices during operational sanitation, set-up, and production.
- Inspection of the area and equipment for potential harborage points.
- Complete a targeted clean of the area/line.
- Increase the number of swabs (and sites swabbed) – investigational.
FDA Testing of Establishments

- Where (what) are they sampling (types of firms and products tested): nuts & nut products; dairy; infant formula; hydrolyzed vegetable protein; egg farms; produce

- What are they testing for: Testing nuts and nut products for *Salmonella* (also *Cronobacter* in infant formula and powdered milk); Dried spice/herb - *Salmonella*; Soft cheese - *Listeria*; Seafood/Fish – *Listeria*; Produce – *Listeria, Salmonella, E. coli* O157:H7, non-O157 STECs

- Looking at persistent vs. transient strains

- FSMA?????
FDA Findings

- What are findings to date - cracks and crevices; dust; water pools, strip curtains, hollow frames of equipment; and employees.

- FDA root cause analysis findings
  - equipment & facility design inadequate
  - cleaning and sanitizing inadequate
  - must follow GMPs to prevent recontamination or cross-contamination
  - most plants not testing correctly - not testing large enough area, not testing correct sites, not digging in deep enough
  - do not consider each (+) as an opportunity

- FDA is working on best practices
The bottom line...Strategies to Control Pathogens *(Salmonella and Listeria monocytogenes)* in the Processing Environment


2. Management of microbial transfer points – people (esp. maintenance and supervisors), equipment, supplies and product traffic control.

3. Implementation of Interventions & Post-lethality Technologies (when appropriate) – Use of appropriate technologies (e.g. temperature control, antimicrobial additives/dip/sprays, post-packaging thermal and non-thermal treatments, freezing).


5. Validation, Data Management, Corrective Actions, Verification & Education – collect, manage (track/trend), respond, verify, analyze...educate!
“History will be kind to me for I intend to write it.”

...Sir Winston Churchill
# Foodborne Illness Acquired in the U.S.

## 9.4 Million Episodes Annually

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Episodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norovirus</td>
<td>5,461,731</td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>1,027,561</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em></td>
<td>965,958</td>
</tr>
<tr>
<td><em>Campylobacter</em></td>
<td>845,024</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>241,148</td>
</tr>
<tr>
<td><em>Escherichia coli non-O157 STEC</em></td>
<td>112,752</td>
</tr>
<tr>
<td><em>Yersinia enterocolitica</em></td>
<td>97,656</td>
</tr>
<tr>
<td><em>Escherichia coli O157:H7</em></td>
<td>63,153</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>1,591</td>
</tr>
<tr>
<td><em>Clostridium botulinum</em></td>
<td>55</td>
</tr>
</tbody>
</table>

Producing and selling safe food is the right thing to do – it is good for business and good for the consumer (protecting the public health)!

Thank you!

Margaret Hardin
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From the Processors Perspective
Fill heads
Area around filler
Filling room
Direct Adjacent rooms
Surrounding environments
Master Sanitation Schedule

- Does not include direct product contact areas
- Fits in well with 5-S (Shine/Sustain)
- Can have direct effect on environmental quality, but can also become Food Safety Concerns
  - Drains
  - Under tanks
  - Overhead conveyors
Sanitary Maintenance
Keep informed of Industry Trends
Equipment Design

- Is it designed to allow easy cleaning and sanitizing? If not, are there modifications we can make?
- Are there voids in the equipment that can easily harbor food soils and pathogens?
- Are there any rough welds or spot welds in the equipment?
- Is the equipment made of polished stainless steel? Are there incompatible metals for the cleaning chemistry?
- Are conveyors designed to be cleaned and sanitized?
Lets Take a Plant Tour.....
Employee Training
Plot Your Findings on a Map
OK-It’s In My Plant—What Now?

Look at the facility design. Is there some way that employee and forklift traffic can be separated by control zones? If not, consider use of doorway foamers that put a layer of foam on the floor at transition points.
Resources

A.M.I. – Equipment Sanitary Design Checklists

Industry Specific Websites & Organizations

Regulatory Websites

Vendor Websites
Questions ???????