

“The Latest in Listeria Control”

Pre-Conference Workshop

Tuesday, May 9th, 2017

8am-12.30pm



Solutions *for* TODAY
Planning *for* TOMORROW[®]

Agenda

8-10am

- Welcome, Introductions & Thank you
- Why are we here? Sharon Birkett, OSI Group
 - What is Listeria and why is it important?
 - What is the impact?
- Retailer Perspective Gillian Kelleher, Wegmans
 - The Consequences of Listeria
- Equipment sanitary design principles, equipment vendor Joe Stout, CFS relationships and immediate actions for legacy equipment
- Effective sanitation procedures, separation, entry Doug Craven, Hormel
Operational sanitation practices (GMPs)
- Seek and Destroy, Maturity Model Steve Tsuyuki, Maple Leaf Foods
- **Break** – Aseptic swab demonstration Matt Henderson, Land O’Frost



Agenda continued...

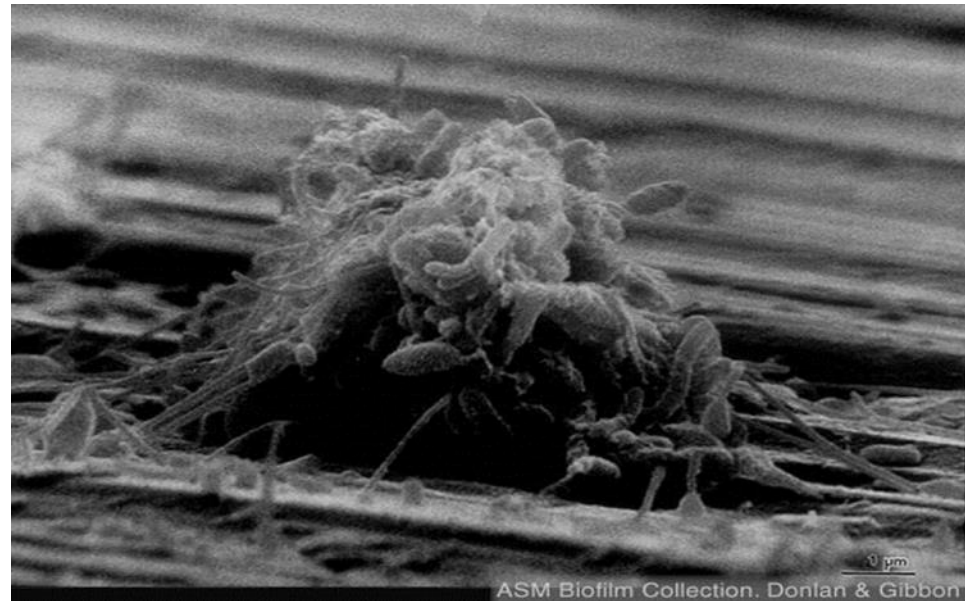
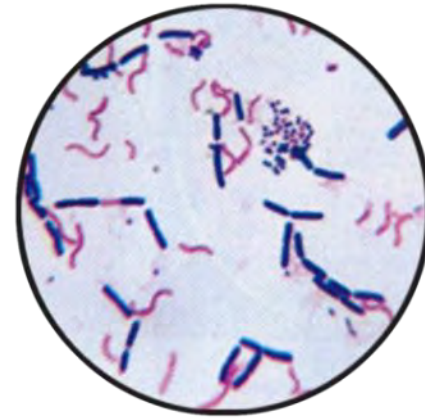
10.15am-12.30pm

- Regulatory perspective Mickey Parish, FDA
 - 2017 FDA Draft Lm Guidance for RTE products
- Changes happening in Produce Natalie Dyenson, Dole
- Sliced Apple Case Study Ozgur Koc, Crunch Pak
 - (Where we were before and where are we now – our journey)
- Listeria Outbreak Case Studies: Matthew Wise, CDC
 - Frozen Vegetables, Caramel Apples, and Blue Bell:
the investigation process
- Panel Q & A All
- Wrap up Gillian & Sharon



Listeria – what is it?

- Gram-positive bacteria
- Rod-shaped
- Able to grow at low temps
29.3° to 113 °F
- pH: 4.3 to 9.4
- Water activity: 0.92
- Facultative anaerobe
- Grows with or without O₂
- Non-spore forming
- Can develop biofilm



ASM Biofilm Collection, Donlan & Gibbon

Why should we care?

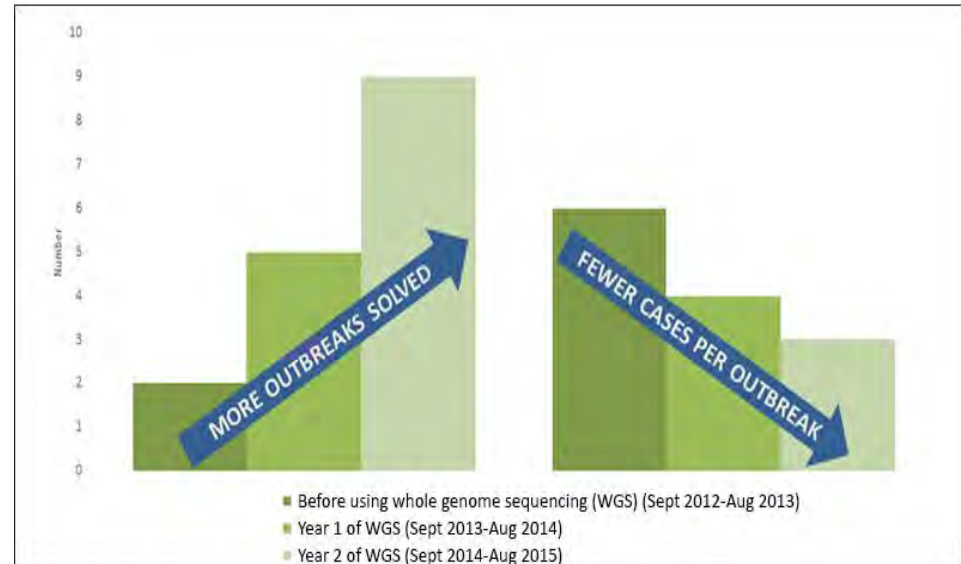
Listeria Foodborne Illness

- High mortality rate: 1 in 5 cases of Listeriosis leads to death
 - Death toll is higher among pregnant, newborns, and unborn
- 3rd most costly foodborne pathogen in US
- High cost per Case: \$1.7MM

	<i>Listeria</i>	<i>Salmonella</i>
Mean Annual Cost	\$2.8 Billion	\$3.7 Billion
Number of Cases	1,591	1.2 Million
Cost per Case	\$1.7 Million	\$3,568

What's Happening

- **Faster Detection & response**
- 1985: 31 days to public warning after outbreak
- 2011: 7 days to public warning after outbreak
- 2016: 3 days with WGS and smaller case numbers



Outbreak Examples

RTE Meat - 2008

- RTE sliced meat contaminated with *Listeria monocytogenes*
- Result: 23 deaths & 57 illnesses
- Cost to Producer: >\$27MM



Cantaloupes - 2011

- Cantaloupes contaminated with *Listeria monocytogenes*
- Result: 33 deaths & 147 illnesses
- Cost to Producer: Estimates from \$125-150MM
(Food Safety News)
- 5 years probation, 6 months home detention, fined \$150,000 each and 100 hours community service for the Jensen brothers



The Listeria Control Equation



Verify control through routine monitoring



Monitoring



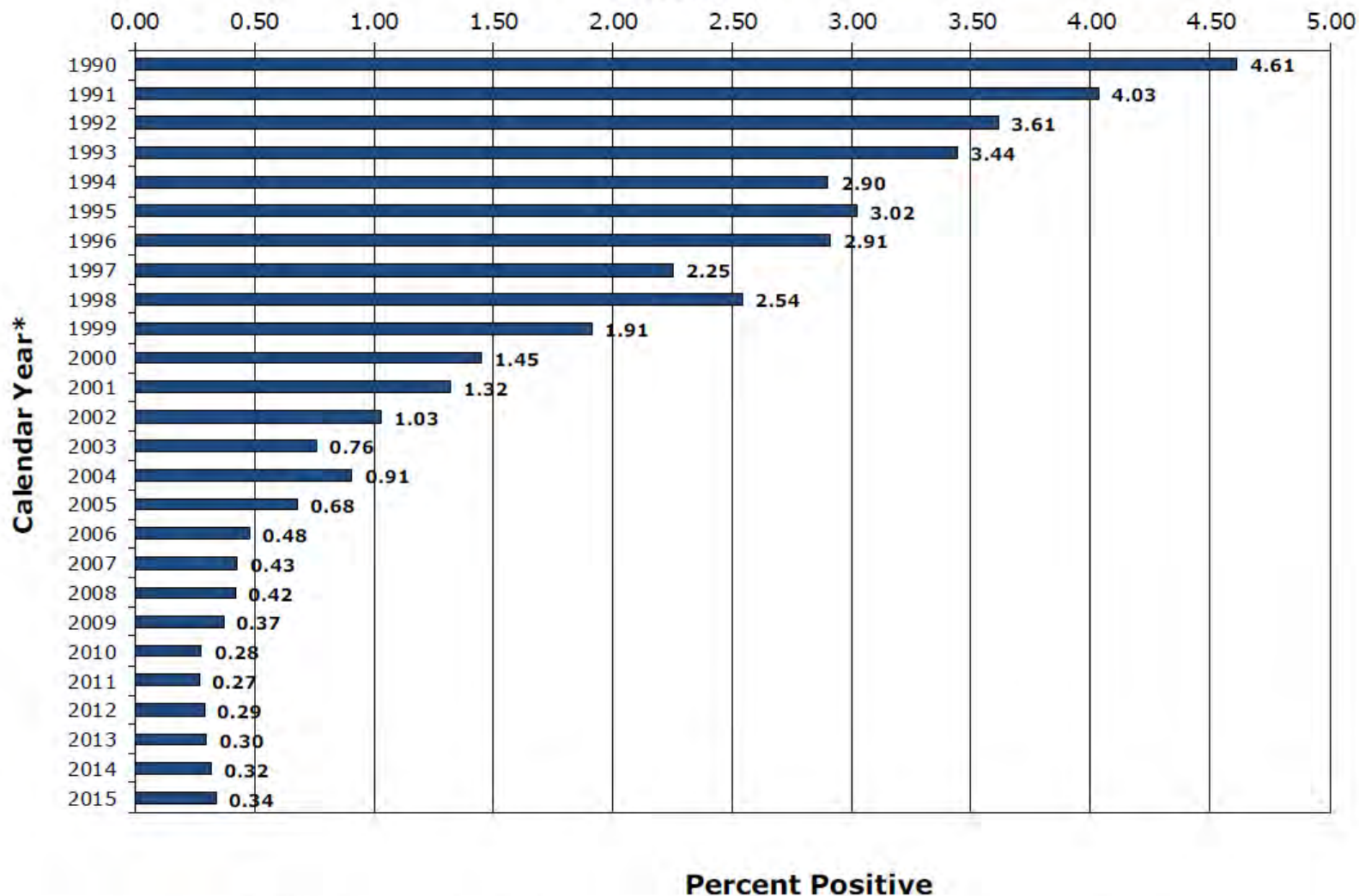
Corrective Actions



FSIS Regulatory Testing for LM in RTE Products

by Calendar Year 1990-2015*

(All Years All Projects)



*Starting with CY2008, annual microbiological results are reported by sample collection date as opposed to analysis end date.



A Retailer's Perspective

- Why is this issue so important?

- We need to provide safe and wholesome food products to all our customers

Wegmans



Wegmans' Approach

- Our #1 Food Safety Priority
- Collaboration and Outreach
- Food safety is not competitive
- TRANSPARENCY
- Learn from others



Putting a Spotlight on *Listeria*: HBS Case Study

January 6, 2015



HARVARD | BUSINESS | SCHOOL

N9-915-412

JANUARY 6, 2014

RAY A. GOLDBERG
CHRISTINE SNIVELY

Wegmans and *Listeria*: Developing a Proactive Food Safety System for Produce



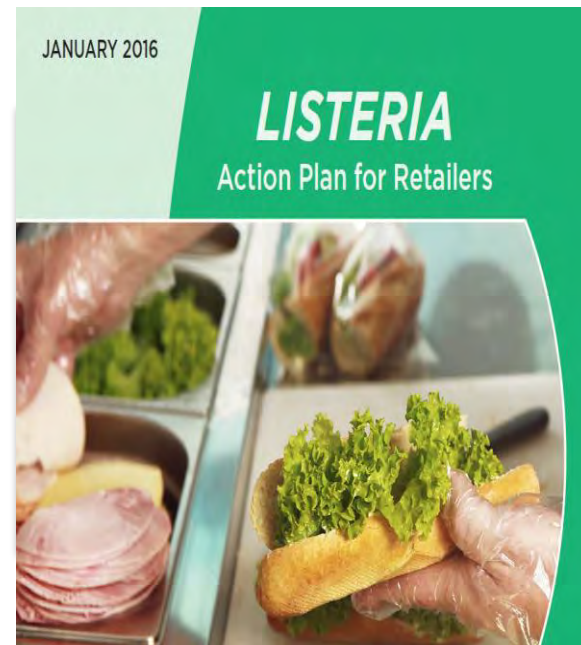
FMI's *Listeria* Action Plan (2016)

Simple

Actionable

Easy to read/ follow

Moving beyond the
Deli



Background

In preparation for our WB
supplier symposium

We worked with STOP
Foodborne Illness
members who were not
Wegmans customers

Several families agreed
to participate and share
their stories

These are two of those
stories

Listeria Control

- Putting a Face on the Issue

“The Consequences
of *Listeria*...”



Listeria Control – A Retailer's Perspective

- This is an industry issue
- We are stronger if we all work together
- We have to learn from each other
- Our customers trust us. That trust is precious and we never want to lose it



Food Safety Summit Hygienic Design May 9th 2017

**Joseph Stout RS.
joe.stout@cf-san.com
President Commercial Food Sanitation**

Hygienic Design

Agenda

- Thought starters
- Getting to Zero
- Intersect points in a changing food safety landscape
- Hygienic Design Approaches
- Hygienic Design Summits
- Design Examples

Thought Starters

- Know your plant
- Have an aggressive HD defense against Listeria.
- Collaborate with your company colleagues' and suppliers for better designs.
- Use Periodic Equipment Cleaning (PEC) for bad designs.

The Risk of Not Being 100% Perfect

• Produce 2 billion portions and Safety Risks

•99 % Food Safe	20,000,000
•99.9% Food Safe	2,000,000
•99.99%	200,000
•99.999%	20,000
•99.9999%	2,000
•99.99999%	200
•99.999999%	20
•99.9999999%	2
•99.99999999%	.2

Perfection can be lost in a split second with the wrong decision.

Can you get to Zero?

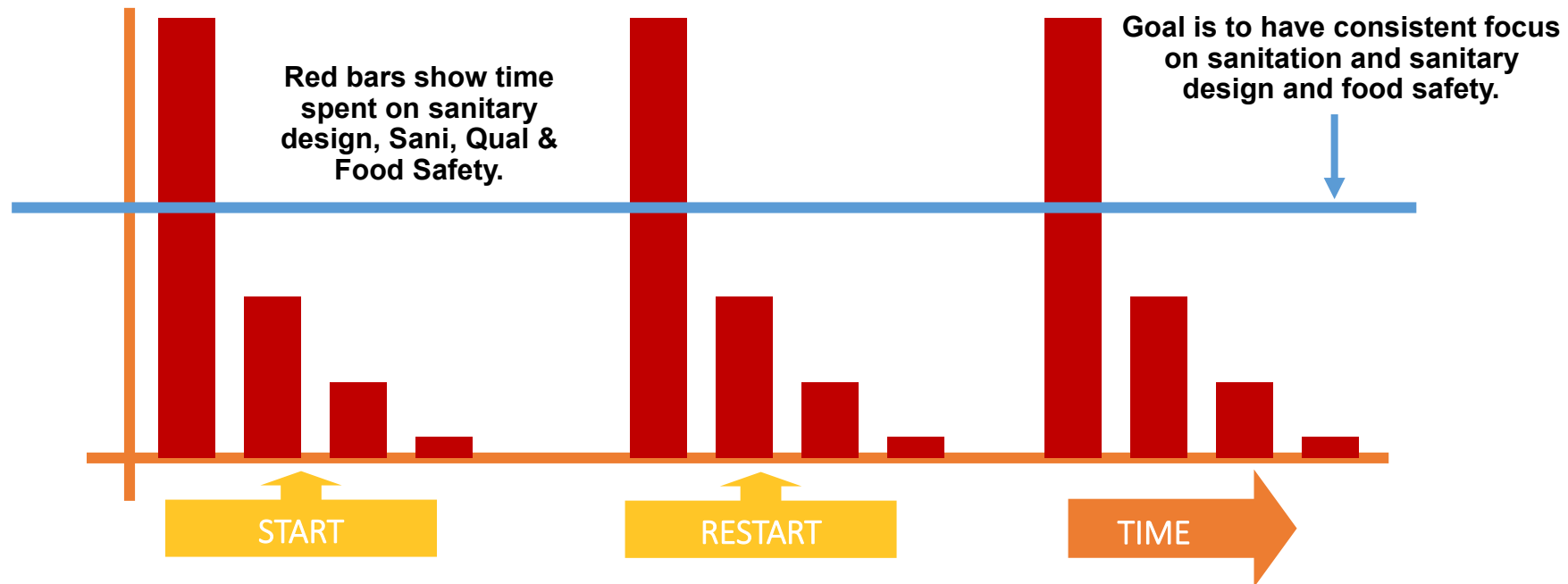
**IF YOU THINK IT CAN'T BE DONE,
YOU'RE RIGHT**

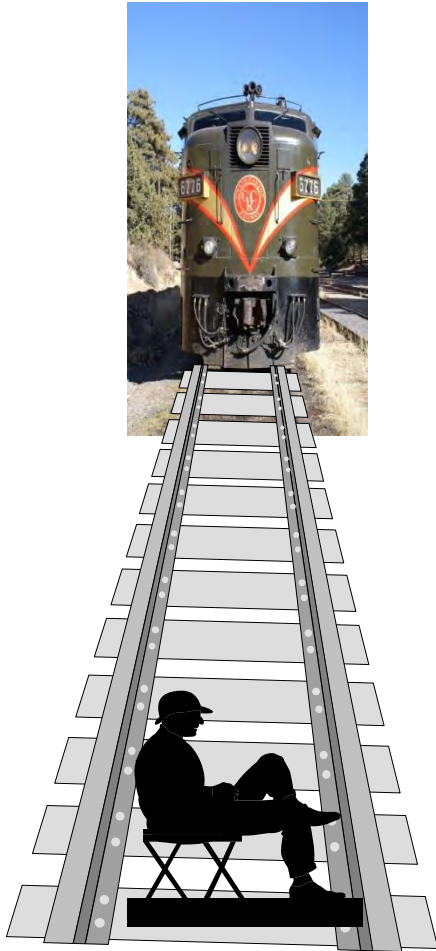
**IF YOU THINK IT CAN BE DONE,
YOU'RE RIGHT!**

WHAT DO YOU THINK?

Zero means forever – not for a year

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





The Alternative

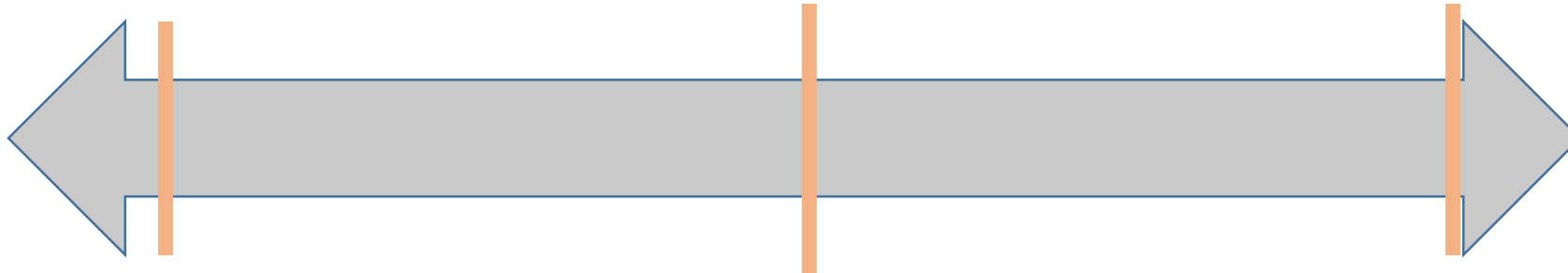
If you think you are on the right track and sit on it, you will be run over by a train.

Intersect Points in 2017 & beyond



Spending on the 'Clean' Continuum

Which direction do you think processors should move?

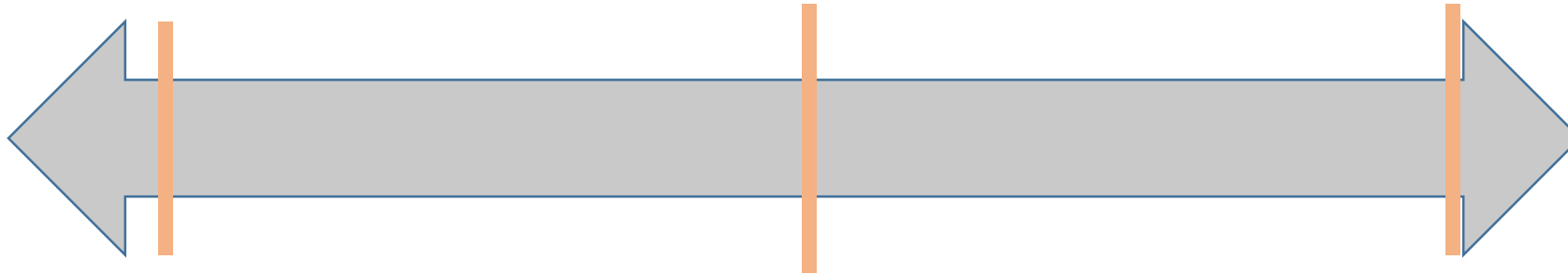


Spend capital budget on Designs?

Spend resource budget?

Spending on the 'Clean' Continuum

Which direction do you think processors are moving?



Spend capital budget on Designs?

Spend resource budget?

The Winner is:

Spend capital on better equipment and better designs.

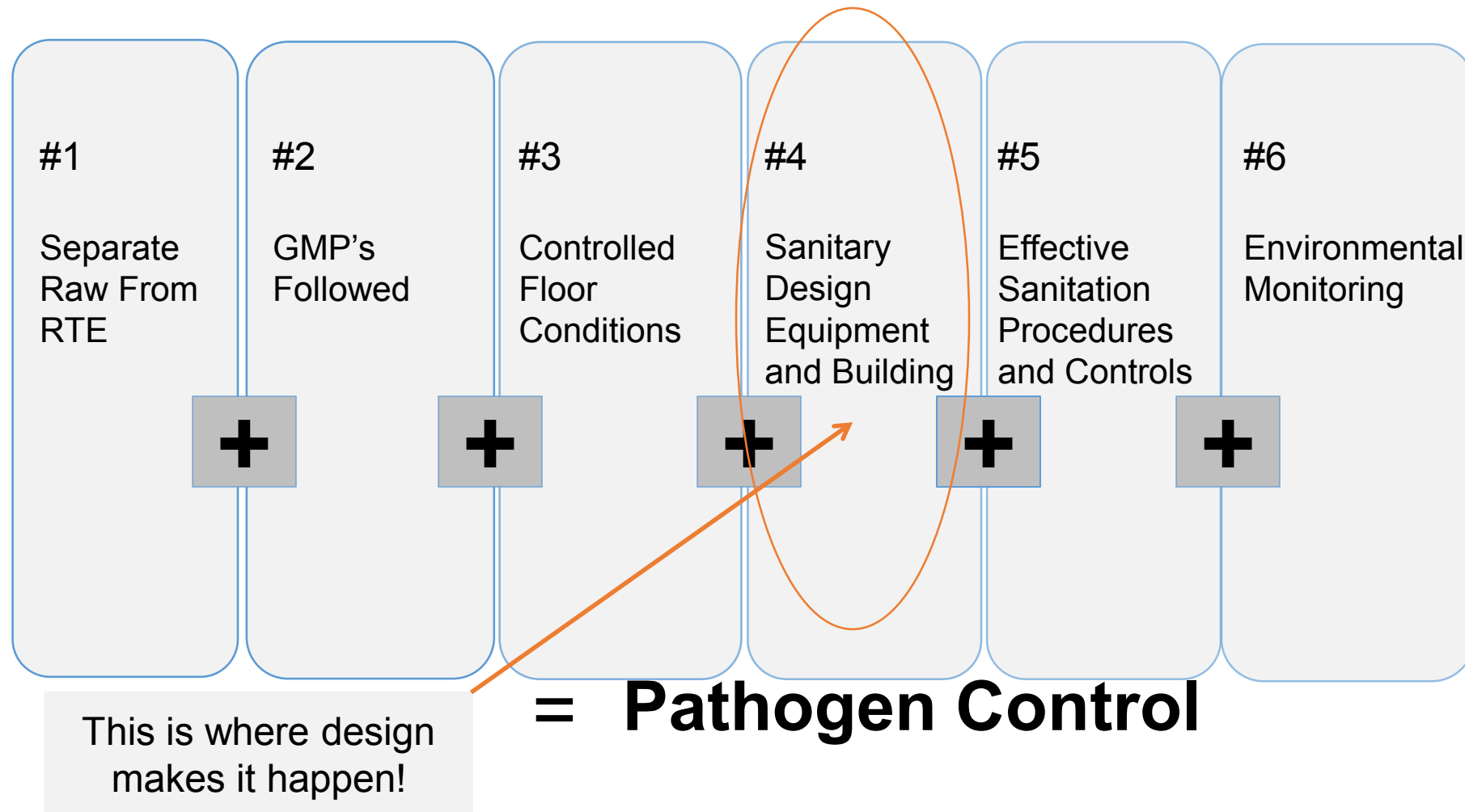
Automation Examples

Typical approach

- Use the 7 step cleaning process.
- Move soil / food debris from equipment to the floor.
 - Clean equipment
 - Clean the floor

Hygienic Design Details

The Pathogen Control “Equation”: A Food Safety/Quality Principles Approach

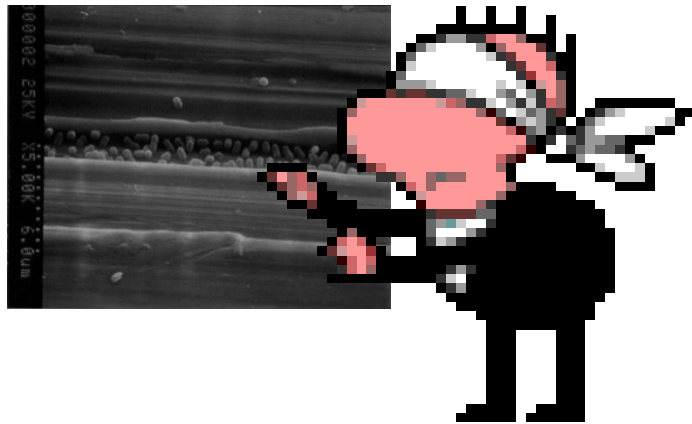


Hygienic Design Defined

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

Common Sense Approach to Hygienic Design

IF YOU CAN'T SEE IT



AND

YOU CAN'T REACH IT

YOU CAN'T CLEAN IT!

Or sample it

Ten Principles of Facility Design

	Facility Design Principles
Principle #1	Distinct Hygienic Zones Established In The Facility
Principle #2	Personnel & Material Flows Controlled to Reduce Hazard
Principle #3	Water Accumulation Controlled Inside Facility
Principle #4	Room Air Flow and Room Air Quality Controlled
Principle #5	Site Elements Facilitate Sanitary Conditions
Principle #6	Building Envelope Facilitates Sanitary Conditions
Principle #7	Interior Spatial Design Promotes Sanitation
Principle #8	Building Components and Construction Facilitate Sanitary
Principle #9	Utility Systems Designed To Prevent Contamination
Principle #10	Sanitation Integrated Into Facility Design

An Example of The Checklist

#	Description	S	M	U	NA	Comments	Deducted	Available
PRINCIPLE #1 - CLEANABLE								
1.1	Equipment is designed & constructed to be maintained in a cleanable condition.						-	15
1.2	Surfaces can be cleaned to visually clean standard and meet pre-op inspection requirements.						-	15
1.3	Representative surfaces can be monitored prior to start up for allergen residue or microbiological activity.						-	15
1.4	Construction of equipment meet the GMP definition of "easily cleanable".						-	15
1.5	A HACCP based product risk assessment was completed during the design phase to understand risks associated with the product type.						-	15
1.6	Method of cleaning needed for the product risk was incorporated into the chosen design of the equipment.						-	15
1.7	Equipment design meets cleaning time targets established by the customer.						-	10
1.8	Equipment has no apparent flaws that will fail over its life and make it uncleanable.						-	15
1.9	If belting is used as product contact surfaces, they should be non-absorbant and cleanable and should be designed to the cleaning methods employed at the location (wet or dry).						-	15
		130	130					130

Ten Principles of Equipment Design

	Equipment Design Principles
Principle #1	Microbiologically Cleanable
Principle #2	Made Of Compatible Materials
Principle #3	Accessible For Inspection, Maintenance, & Cleaning/Sanitation
Principle #4	No Liquid Collection
Principle #5	Hollow Areas 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

Hygienic Design Summits

Key Learnings

- The Hygienic design elephants in the room are discussed
- Started with a SWOT analysis by Processors and Suppliers (equipment and facilities)
- Close collaboration is a must.
- 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.
- More to come.....



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.

Register for the **HYGIENIC DESIGN SUMMIT**

JUNE 14, 2017 | 4:00 - 6:00 PM

Meet & network with food safety experts, facility and equipment designers, and produce packers and processors to discuss sanitary design topics!



Relax after the show with a reception and education kicked off by Joe Stout, Commercial Food Sanitation, followed by networking where attendees can meet with exhibitors from United FreshTEC or Global Cold Chain Expo.

www.freshtec.show/hygienic-design-summit

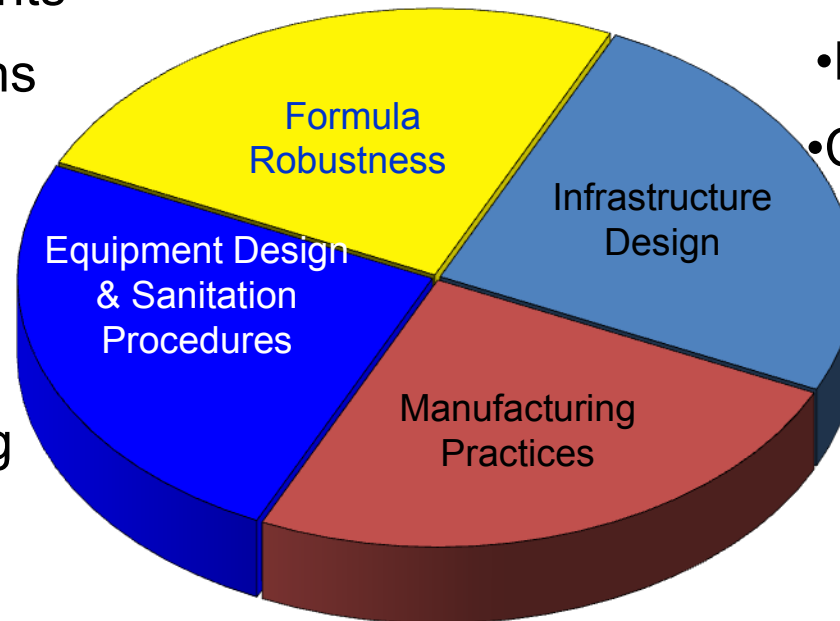
Balancing Hygienic Designs with Formulations for Micro-Sensitive products

Hygiene Practices

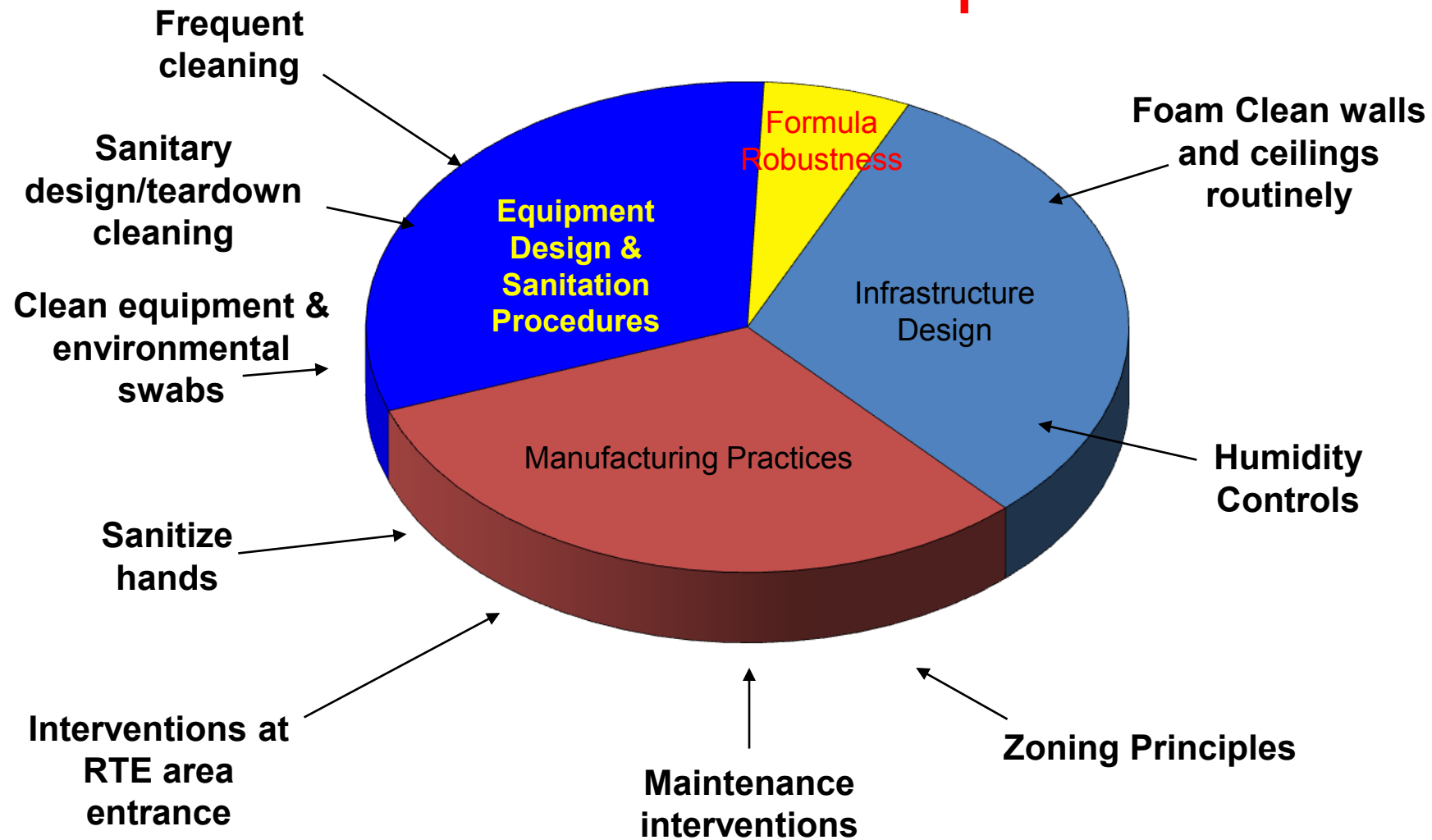
- Hand washing
- Hair/beard restraints
- Jewelry restrictions
- Personal hygiene practices
- Appropriate clothing
- Designated eating areas
- Housekeeping responsibilities
- Traffic patterns

Manufacturing Practices

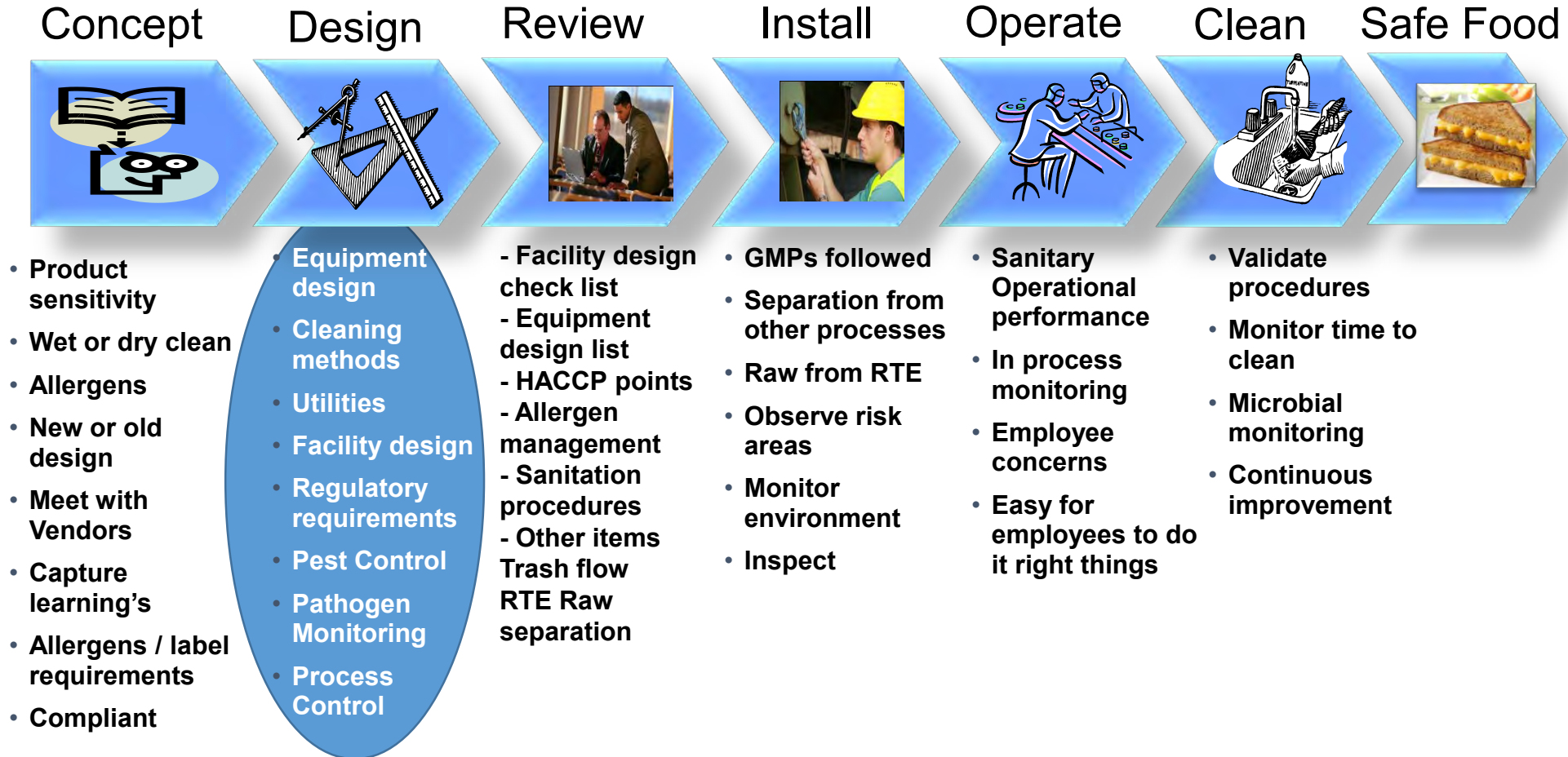
- Equipment & Facility design
 - Facility maintenance
- Pest Control programs
- Container identification system
 - Employee training
- Layout and physical separation
 - Roofing maintained
- Condensation control
- Allergen Management
 - Traffic patterns



Balancing Hygienic Designs with Formulations for Micro-Sensitive products



A Sanitation Centric integrated “Safe Food” Supply Chain



Design Examples





Looks Clean to Me – It passed Pre-op.



Master Sanitation Schedule (MSS)

Period Cleaning

Seasonal

Janitorial

Routine

Infrastructure (PIC)

Equipment (PEC)

Can you get to Zero?

IF YOU THINK IT CAN'T BE DONE,
YOU'RE RIGHT

IF YOU THINK IT CAN BE DONE,
YOU'RE RIGHT!

WHAT DO YOU THINK?

Summary

- Know your plant
- Have an aggressive HD defense against Listeria.
- Collaborate with your company colleagues' and suppliers for better designs.
- Use Periodic Equipment Cleaning (PEC) for bad designs.

RTE Sanitation

Control for Wet or Refrigerated High Risk Production areas
Control of Conditions for Growth

Douglas Craven –
Corporate Manager of Sanitation
Hormel Foods
507-437-5398

Topics

- RTE Sanitation Process
- Periodic Deep Cleaning (Preventive)
- Operative Sanitation controls and GMP's
- Verification

7 Steps of Effective Wet Sanitation

- Dry Clean
- Pre-rinse
- Soap and Scrub
- Rinse and Inspect
- Assemble
- Pre-Op
- Sanitize

Step 1: Dry Clean

- Lock Out Tag Out
- **Disassemble equipment**
- Remove majority of gross soils
- Remove production supplies
- Empty drain baskets
- Remove trash

Keep it Dry!



Step 1: Dry Clean

Clean and Cover electronics

- Wipe all surfaces with Alcohol based Cleaner Sanitizer
- Cover with disposable cover
- Inspect for damage



Step 2: Pre-rinse

- Remove remaining soils with hot water
- Water System
 - 120°F - 140°F Hot enough to melt fat, too hot will bake on soil.
 - Boosted pressure - 200 psi with 3/16 nozzle (Avoid high pressure as it will create aerosols containing bacteria)



Step 3: Soap and Scrub

- Chemical application controls
 - ✓ The right chemical
 - ✓ Concentration controls
 - ✓ Mechanical action where needed
- Foam entire room (walls, floor, equipment)
- Clean floor drains
- Focus cleaning activities on the whole room not just on the equipment

•

•

Drain Cleaning

- Designated brushes (Black)
- Do cleaning with a designated sanitation employee at the end of their shift - before floor sanitizing
- Use Chlorinated Alkaline Cleaner
- Clean all surfaces
- Sanitize with Quat (800 ppm), Iodine (75ppm) or Chlorine (800 ppm)
- Fully scrub a minimum of weekly
- Periodic jetting (drain maintenance) - Preventive Action



Step 4: Rinse and Inspect

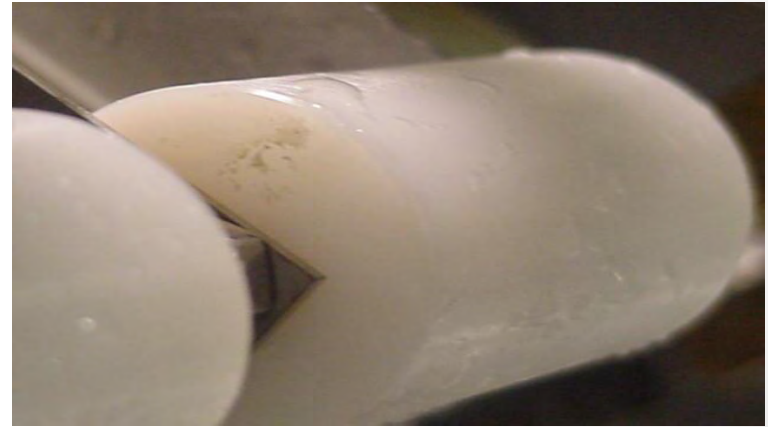
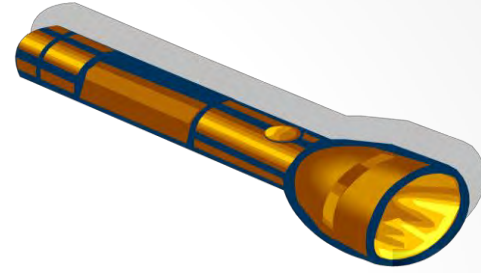
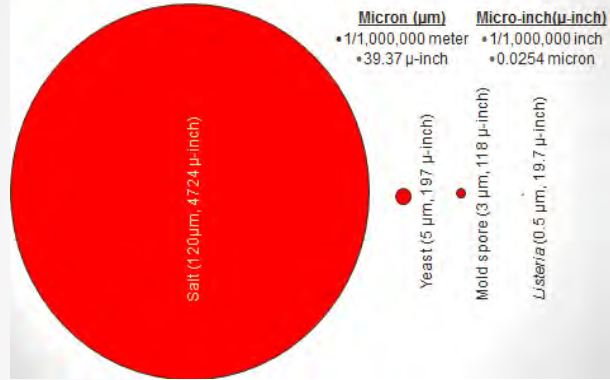
- Flood rinse to remove chemical
- Rinse in the order soap was applied – rinse before chemical dries
- Visually inspect using a flashlight
- 100% free of soils, hazes, water beads
- Verify by sight, touch, and smell

Can you See an Growth Niche?

•

•

THE "INVISIBLE" BACTERIA



Is this Clean?

What are we looking for?

What does it mean?

- Loose soil (food or meat scrapes)
 - Rinsing, overspray,
- Adhered product residue
 - Mechanical action, initial rinse, Chemical application
- Greasy feel – beaded water
 - Water temp
 - Proper chemical
 - Concentration
- Look for conditions for growth
 - Wet soil accumulation



What is acceptable?

- Did the cleaning Process work?
 - Just missed a few spots
 - Failure in Sanitation – Do it again!
- **Do not** pre-op the facility clean!
- A poor pre-op is a process failure!
 - Avoid the bucket brigade
- **Predictive** Pre-op mindset for action – solve it before it is an issue.

Step 5: Assemble

- Put on clean RTE outerwear
- Wash and sanitize hands
- Verify chemical removal
- Sanitize parts not accessible when assembled
- Assemble equipment
- Remove standing water
- Control condensation

•

•

Step 6: Formal Pre-Op

- Cycle equipment
- Complete pre-op inspections according to plant's SSOP
- Correct all deficiencies
- Monitor for effectiveness
 - Visual - Detail, Know where to look
 - ATP Bioluminescence- Swab to find problem areas. Pass before releasing. Use to improve training
 - Does not replace Total Count and Environmental Sampling
- Predictive controls - it is all about what you do with the data.

Step 7: Sanitize

- Remove standing water
- Application - Flood Method - Coverage
- Foam sanitize walls and floors (800 ppm Quat)
- Use cool water to blend with sanitizer (< 110°F)
- Choice of sanitizers
 - Chlorine 200 PPM
 - Iodine 25 PPM
 - Quaternary based sanitizers 200 PPM
 - Peracetic/Organic Acids
- Double Sanitizing

•

•

Use of Sanitizers

- Maintain the systems
- Verify Sanitizer Concentration
 - Measure ounces/gallon water
 - Test Tape / titration
- **Control and Coverage Key to success!**



Using Heat Treatment Systems

- Time / Temperature relation
 - Flood equipment with 180° F water
 - Steam Sanitizing Equipment
 - 180° F Sprays on conveyors
- Oven heating cycle
 - Place cleaned equipment in oven set temp at 170dry/170wet for 1 hour 45 minutes, then 120 dry/ 0 wet for 15 minutes
- Validate and Document Heat Procedures



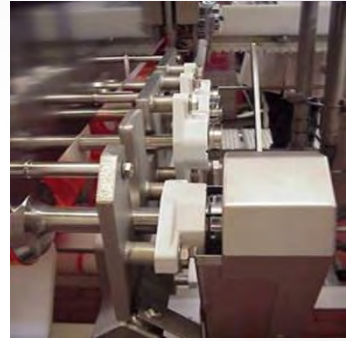
Preventive Heat Treatments

- Supports Regular Sanitation Procedures
- Regular sanitation procedures remove visible and assessable soil.
- Heat Interventions treat invisible or inaccessible surfaces.



Grease and Bearings

- Apply grease on a scheduled bases
- Hand wipe excess grease from bearings
- Do not spread grease to other surfaces during cleaning
- Clean and inspect bearing areas daily
- Open all chain guards for a thorough cleaning a minimum of weekly



Overhead Cleaning & Cooler Cleaning

- Do Monthly (minimum)
- Include all overheads (lights, pipes, etc.)
- Use 7 step method
- Refrigeration units - Clean using non - chlorinated Alkaline Cleaner
- Sanitize by foaming on Quat 800ppm Do not rinse



Equipment Deep Cleaning

- Inside Control Panels
- Inside mechanical enclosures
- Belt removal – conveyor deep cleaning
- Non daily clean equipment assemblies
 - Packaging machines
 - Vacuum lines



Special Equipment Cleaning

- Keep squeegees and brooms clean
- Store in sanitizer (Quat at 800ppm) - Clean storage containers and change sanitizer daily
- Replace equipment as needed
- Personal equipment
- Make sure equipment design is sanitary



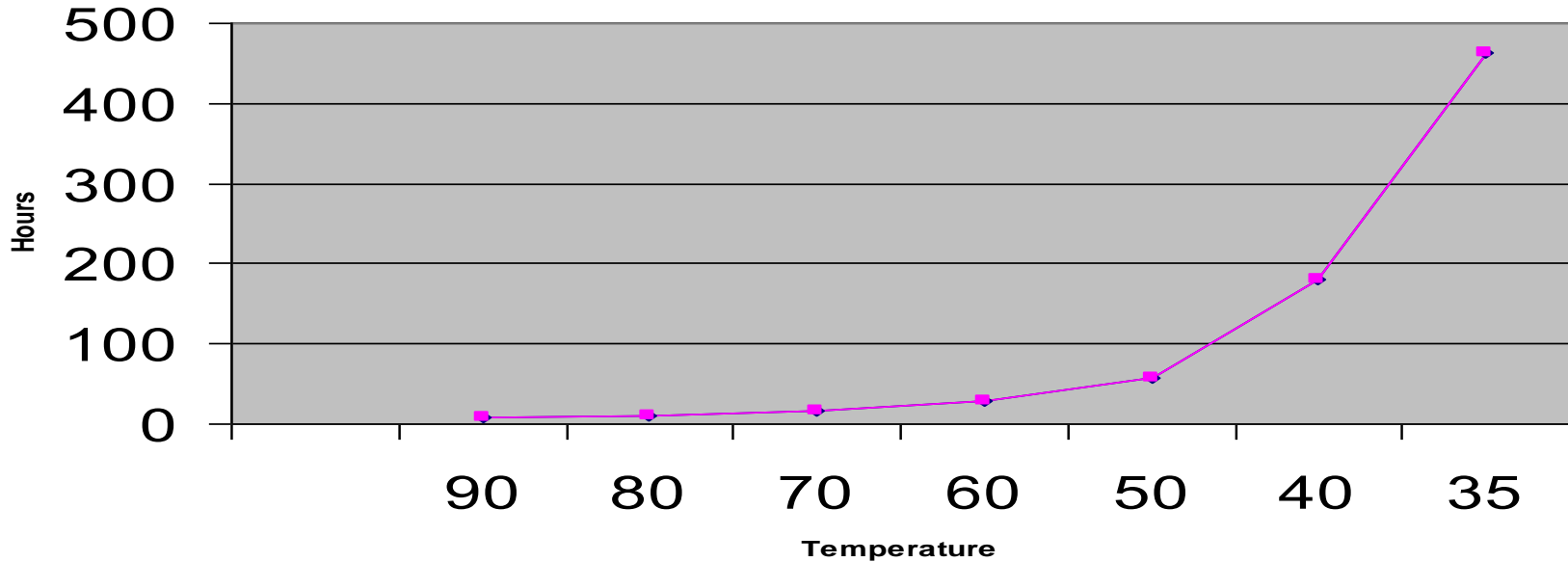
Operative Sanitation

Maintaining a Sanitary Environment

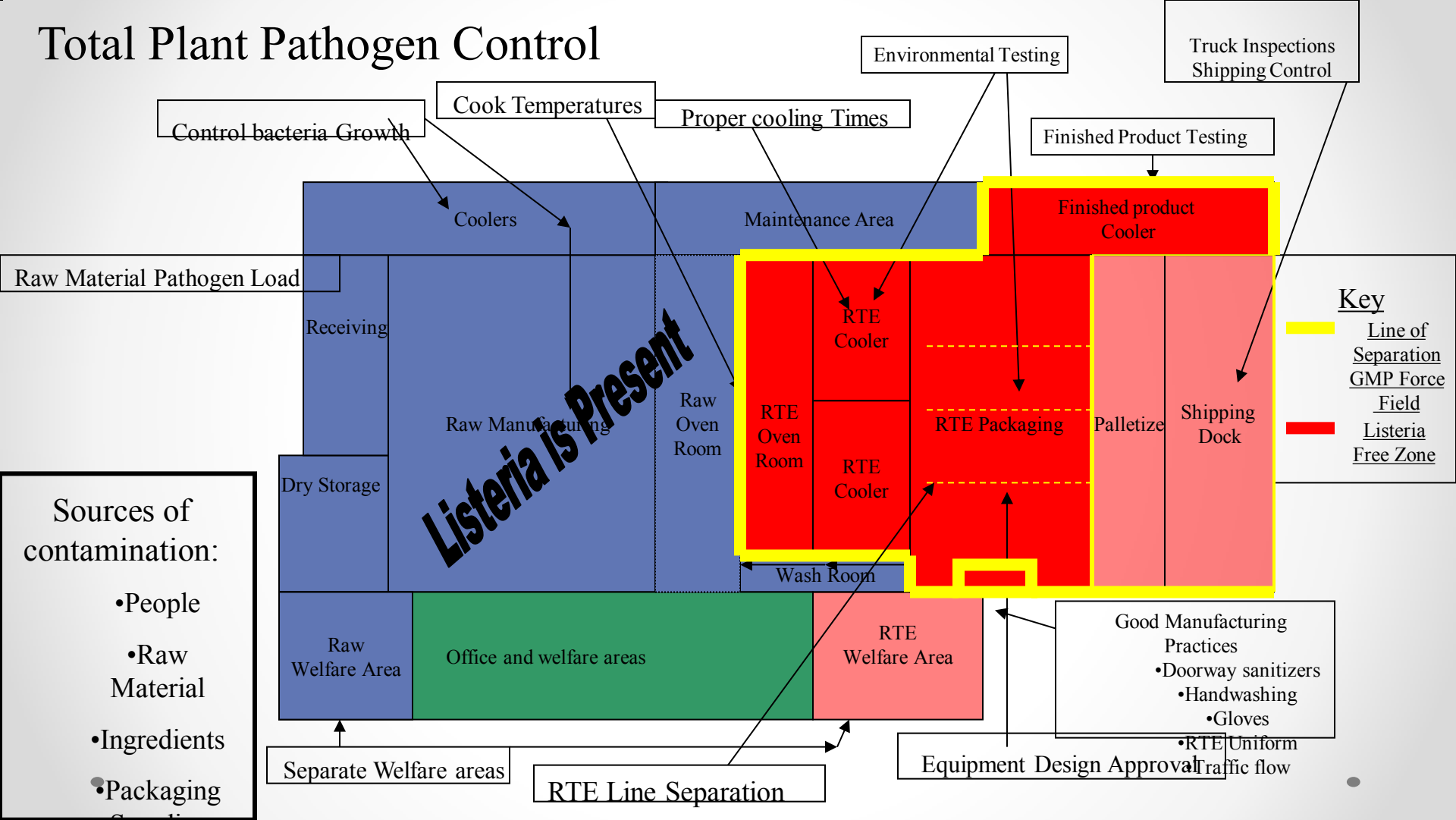
- Control Bacteria Growth Factors
- Minimize risk of entry
- Minimize risk of line to line cross contamination

Keep RTE Areas Cold

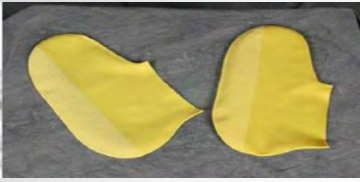
Time in Which Log Growth Occurs With Temperature Change



Total Plant Pathogen Control



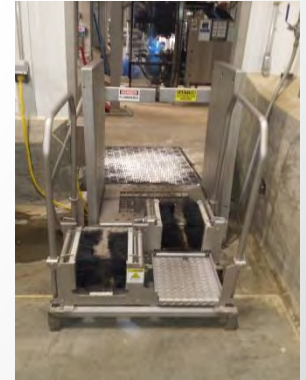
Controlled Entry



- Dedicated cleanable footwear
- Controlled for GMP compliance
- Boot scrubbers
- Dedicated uniforms



No Footbaths



Hand Washing Behavior

- Washed hands after using public restrooms
- Overall 61% Men, 74% Women

2,129 people observed, American Society for Microbiology, 1996

HAND WASHING PROCEDURE

- Wet Hands
- Apply Soap and work into hands for minimum of 10 seconds
- Rinse with warm water
- Sanitize with an Alcohol sanitizer
- Wear vinyl gloves



Sanitary equipment Set-up

Tool Cleaning and sanitizing

- Dedicated tools for RTE
 - Clean and sanitize daily - Alcohol based products
-
- Separation of inedible and edible tasks

Disposable Gloves & Aprons

- Hands must be washed, dried and sanitized before putting on gloves
- Environment on gloved hand very conducive to multiplication of bacteria
- Change gloves as needed
 - Holes
 - After touching inedible items
 - Sanitize gloves often
- Change aprons if they are soiled or



Keep RTE Areas Dry

- Direct cooling water to the drains
- Shrink tunnels
- Exhaust steam / Condensation
- Moisture around foot sanitizers should be sanitizer
- Sink traps

Wet vs. Dry

- If the process creates free moisture in the packaging area then wet procedures may need to be followed
- Same clean-up and sanitize as already discussed
- Sanitize the equipment with 200ppm chlorine or 25ppm Iodine sanitizer at each break (more often)
- Remove heavy soil
- Sanitize the floor with 800ppm Quat at breaks - USE CARE NOT TO SPLASH OR ATOMIZE ONTO PRODUCT
- Test standing water for the presence of sanitizer
- Keep good control on sanitizer concentrations

•

•

Product Handling

- Sanitize just before you start to handle product
- Re-sanitize any time you deviate from product handling
- Change gloves and rewash hands as needed (Handle dropped product, handle trash)
- Keep inedible items away from edible surfaces
- Store all packaging materials in sanitary manner
- Watch what we touch
- Use only disposable wipes and dispose of them after each use



Traffic Patterns

- Control employee traffic as - eliminate the movement from raw to RTE
- All lifts or hand jacks need to be cleaned and sanitized before they enter the RTE areas - dedicated
- Trash containers stay in RTE
- If employees are relocated from a raw to RTE area they must change uniforms, clean footwear, clean helmets and thoroughly wash hands

Controlled entry



Operative Inspections

- Required daily by USDA
- Use it to Verify and support RTE practices
- Observe and react
- Dirty is the “natural “state – we need to ...

Keep it Clean!



Who does this apply to?



Everyone
The Whole Team

Special Control Situations

- Cross traffic Oven
- Construction

When things go wrong!!

- Roof leaks
- Drain Backups



RTE Sanitation

We need to be the cleanest we can be
The best we can be
It is the Only way to be!!

Questions?

Douglas Craven - Corporate Manager of Sanitation
Hormel Foods 507-437-5398

Seek and Destroy

A Problem Solving Approach to Address Environmental Positives

2017 Listeria Workshop
Steve Tsuyuki, Maple Leaf Foods

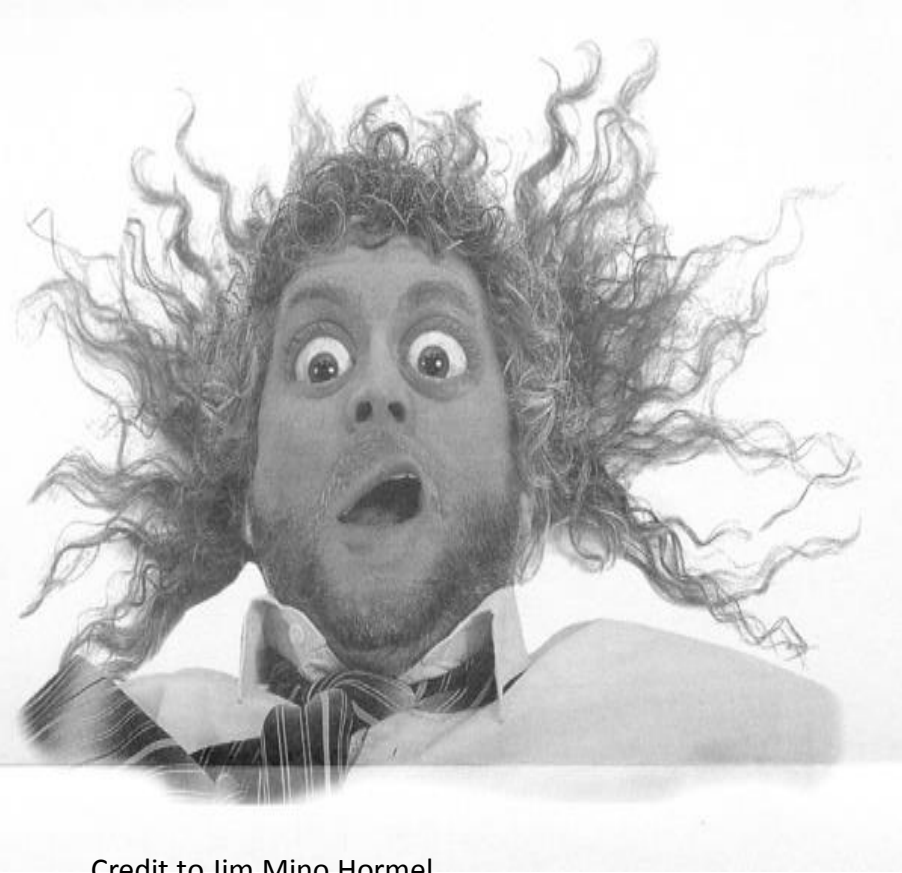


Solutions *for* TODAY
Planning *for* TOMORROW[®]

Situation: A “Positive” Finding During Routine Monitoring

A positive finding usually leads to one or all of the following emotions:

- Denial: The results are wrong. Can we resample?
- Anger: Sanitation screwed up again!
- Fear: Go out there and “nuke” the area right away!



Credit to Jim Mino Hormel



Most Recent Seek and Destroy (S&D) Reference

Journal of Food Protection, Vol. 78, No. 2, 2015, Pages 436–445

doi:10.4315/0362-028X.JFP-13-507

Copyright ©, International Association for Food Protection

General Interest

Seek and Destroy Process: *Listeria monocytogenes* Process Controls in the Ready-to-Eat Meat and Poultry Industry

THOMAS J. V. MALLEY,¹ JOHN BUTTS,² AND MARTIN WIEDMANN^{1*}

¹Department of Food Science, Cornell University, Ithaca, New York 14853; and ²Land O'Frost, Inc., Lansing, Illinois 60438, USA

MS 13-507: Received 25 November 2013/Accepted 25 September 2014

“S&D is an **investigative technique** that includes an **aggressive, systematic approach** to identifying harborage sites and niche locations where microbes survive (or persist) despite cleaning and sanitation measures”.

“The present article was prepared to **provide formal support** for the use of the S&D process and its associated environmental sampling protocols as a **scientifically valid approach to control** *L. monocytogenes* contamination in RTE foods”.



Seek and Destroy(S&D)

S&D is a systematic two step problem solving tool:

Seek:

- **Aggressive** sampling to determine the root cause(s) of the positive finding – **FIND IT!**

Destroy:

- Effective corrective actions and preventive measures that are **sustainable** – **FIX IT!**



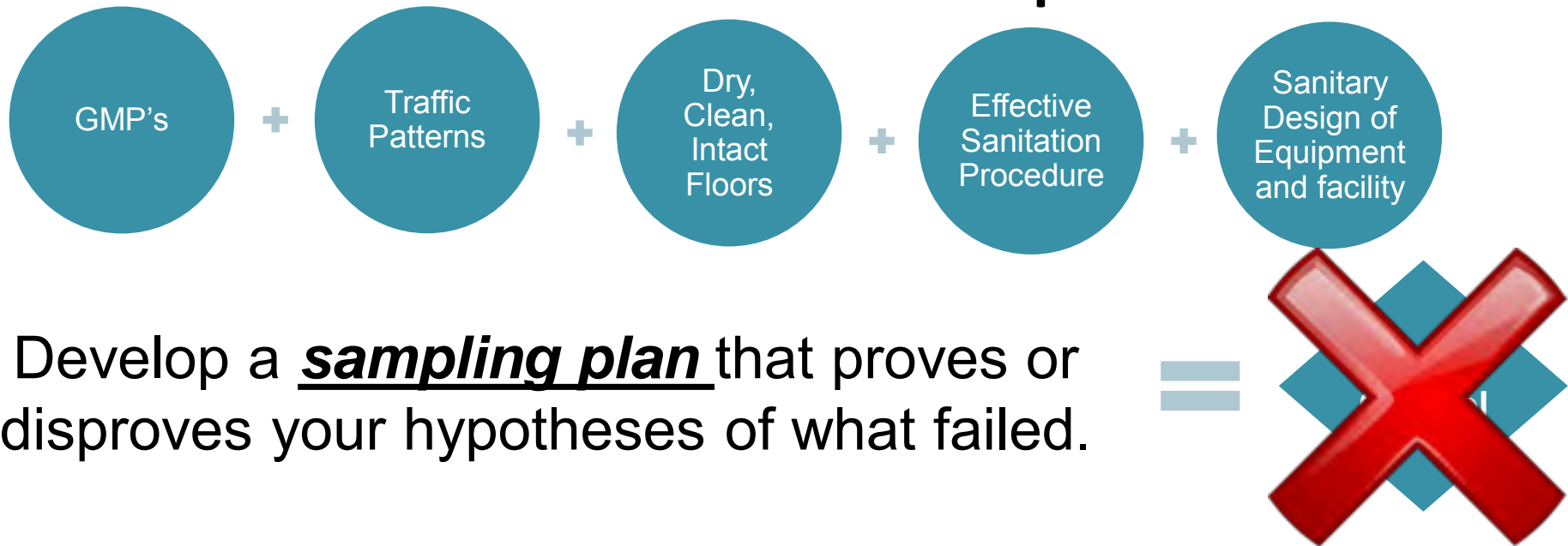
S&D Rules of Engagement

- It is a “team sport” and NOT QA’s problem to solve.
- Cleaning the affected equipment/area is NOT the first step. Observe production and the transition to sanitation. Stand there long enough to “blend in”.
- The loudest “voice” or the most senior person has no more voting rights than others. In fact, **the most important “voices” come from the front line employees.**
- Think outside the regular program and develop a sampling plan that:
 - Samples sites that are not normally swabbed.
 - Swabbed at times that are not normally taken.



A “For Cause” Finding Means One of More of the Control Factors Failed

The “Listeria Control Equation”



Develop a **sampling plan** that proves or disproves your hypotheses of what failed.



GMP's – People Behavior During Production



GMP's

What to sample:

- Items in motion (employee hands, tubs, tools etc.) in the sequence they occur.
- Surfaces upstream and downstream of the positive finding.
- Rogue items
- People (what is being done as part of their job)

Why:

- Attempt to find and understand the “organism” in motion.

When to sample:

- During production from T4 to the end of production
- Capture the events of the line (routine and non routine)

How to sample:

- Time Series
- Larger and broader than normal
- Observation (fresh pair of eyes)



Movement of People, Equipment and Product

Traffic Patterns

What to sample:

- Floors at all entry points to the exposed product RTE area.
- Overhead and anything that can contaminate the product from above.

Why:

- Verify the effectiveness of control measures for ANYTHING entering the exposed product RTE area.
- Are there conditions that have unintentional consequences? (is equipment in line turned off)

When to sample:

- During equipment/line setup to the end of production.

How to sample:

- Time Series swabbing
- Observation (product accumulation or purge)



Are Floors a Transfer Vector or Potential Source?

Dry,
Clean,
Intact
Floors

What to sample:

- Wet spots on the floor
- Non intact/damaged floor surfaces
- Loose floor penetrations

Why:

- The floor can either be a transfer vector and/or contamination source.

When to sample:

- During production

How to sample:

- Time Series swabbing
- Observation



In the Exposed Product Area, Are the Floors Wet or Dry?



The answer is binary



Are There Gaps in the Program?

Effective Sanitation Procedure

What to sample:

- Hard to clean surfaces are that either inaccessible during sanitation or designed to potentially be penetrable.
- Floors immediately below equipment

Why:

- Look for harborage sites that “shed” contamination when disturbed.

When to sample:

- Sanitation process either at the end of pre-rinse or the end of final rinse.
- Before and after intervention.

How to sample:

- Post rinse sampling
- Swabs
- Observation



How Can You Be Certain that Equipment is Listeria “Free”?



OR



Every piece of equipment in RTE must have an intervention process beyond daily sanitation procedures to mitigate the risk of “gaps” in sanitary design or issues of access.



Are the Inherent Risks Known and Managed?

What to sample:

- Inaccessible or “hard to reach” parts of the equipment.
- Wet spots on floor to wall junctions
- Drains (as “collection points”)

Why:

- Sanitary design issues and poor access to clean equipment may prevent the removal of soils to a microbial level.
- Inherent design or age of facility results in weakness of floors, walls ceilings etc.

When to sample:

- During equipment and line setup to the end of production.

How to sample:

- Going beyond one or more levels of disassembly done during daily sanitation.
- Observation

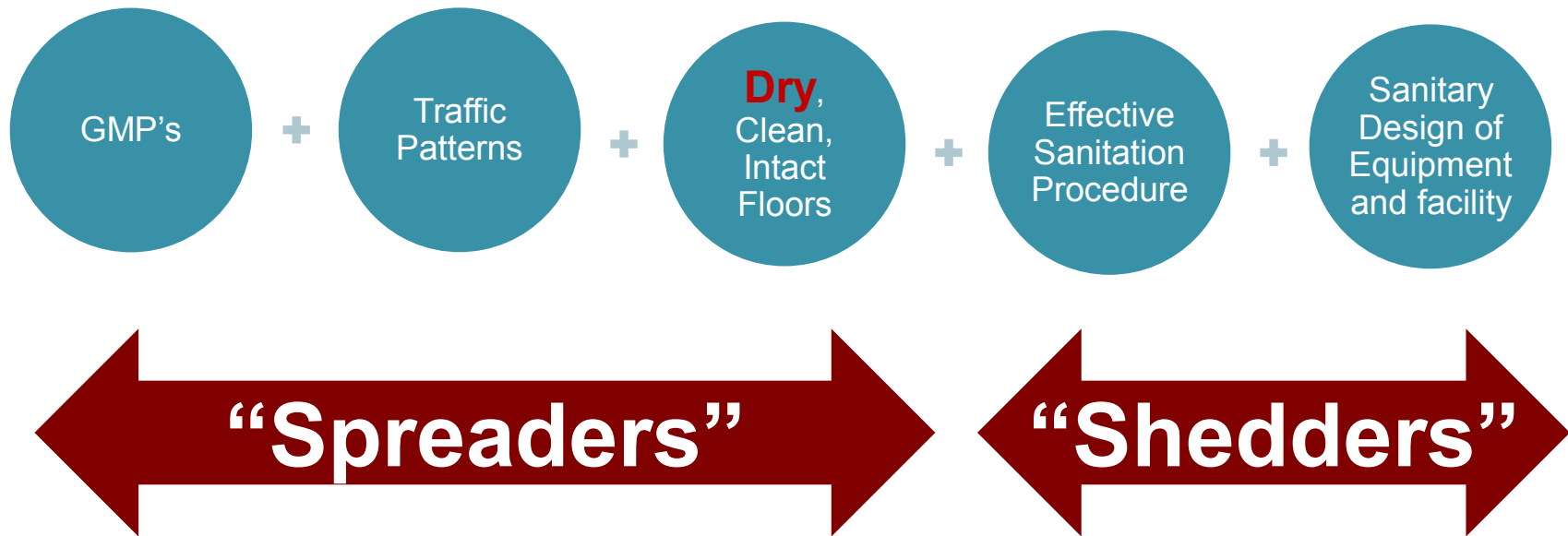
Sanitary
Design of
Equipment
and Facility





A “For Cause” Finding Means One of More of the Control Factors Failed

The “Listeria Control Equation”



Understand the Difference Between a Finding and the Contamination Source

Positive findings are NOT occupied growth niches (sources of contamination). They are transfer points (a product conveyor or equipment framework) that require Seek and Destroy to determine the root cause (contamination source) and transfer vectors involved.

Transfer points are not occupied growth niches because the organism is eliminated during daily cleaning and sanitizing processes.



You Found “Bio crud”, Now What?



Warning: If the S&D positive finding (source) either does NOT “match” the initial finding OR the S&D did not yield a positive finding, the plant must continue to investigate in spite of the completion of the testing requirements.



Destroy: Effective/Sustainable Corrective Actions and Preventive Measures

- Determine and implement corrective actions.
 - Replace or manage?
- Execute the “5 whys” to identify the equipment, procedure, culture gaps that contributed to the failure.
 - What led to the incident and can it happen again?
 - What changes need to be made?
- Deploy preventative measures and controls
 - Develop sampling plans that will “stress test” the corrective actions implemented and will provide an alert to a control failure BEFORE it is detected by verification monitoring.



Seek and Destroy Maturity Model

Awareness

Enlightenment

Preventive

Predictive

Not knowing all the factors to control.

Knowing the factors to control but not having a process that is either implemented or sustainable.

Having an effective and sustainable process not entirely data driven. Risk is mitigated.

A control process that is data and performance driven. Risk is designed out.

Fire Fighting

Fire Prevention

For Cause

Not For Cause

Complacency and Turnover



S&D as a Preventive Control Measure (“Not For Cause”)

- Evaluate new and existing equipment for potential areas of risk:
 - Is it cleanable on a daily basis? Is there an Intervention process in place?
 - Can risks be designed out?
 - Is there 360 degree access?
- Evaluate the current state of the facility.
- Optimize indicator site locations in Z3 and Z4 that are linked to known growth niches.
- Evaluate the impact of change:
 - Process
 - Movement
 - Product



Positive findings are to be celebrated



Thank You

