

3A Standards Meeting

Milwaukee WI

Joe Stout

President Commercial Food Sanitation

May 17 2011

Equipment Design

Agenda

- Sanitation Acronyms
- Putting Consumers First
- Regulatory Environment
- Microbiology & Sanitary Design
- Staying ahead of the Curve – Engineering leadership
- Designing it right the first time

Sanitation Acronyms and Other General Information

Sandwich	A contact point between two materials that is not hermetically sealed.
CIP	Clean in place
COP	Clean out of place in a heated water bath with chemicals and agitation
Chlorine	Sodium Hypochloride solution (12%) fast acting & inexpensive sanitizer legal @ 200 PPM
Quat	Quarternary Ammonium sanitizer used for product contact surfaces - 200 PPM and environmental surfaces.
Caustic	Base builder for cleaners. At times chlorine is added to help remove protein soil, but has no sanitizing effect.
Hot Water	Water in excess of 120 F
SWABS	A small sponge to collect samples for Listeria.
High Pressure	Water pressure to cause dispersal of soil in water from a surface

Sanitation Acronyms and Other General Information

Species	The genus <i>Listeria</i> includes 6 species (<i>L. monocytogenes</i> , <i>L. ivanovii</i> , <i>L. innocua</i> , <i>L. welshimeri</i> , <i>L. seeligeri</i> , and <i>L. grayi</i>). Both <i>L. ivanovii</i> and <i>L. monocytogenes</i> are pathogenic in mice, but only <i>L. monocytogenes</i> is consistently associated with human illness.
Serotype	There are 13 serotypes of <i>L. monocytogenes</i> which can cause disease, but 90% of human isolates belong to 3 serotypes: 1/2a, 1/2b, & 4b. Four B is responsible for up to 50 percent of human cases and for all major outbreaks in N. America since the 1980s.
PFGE	Pulsed field gel electrophoresis
Pulsenet	A network of the CDC which brings together public health and food regulatory agency laboratories in the US. Through the network, groups can share PFGE results which act as fingerprints to distinguish strains of pathogens including Salmonella and Listeria
Outbreak	An occurrence of disease greater than would otherwise be expected. It may be a small group or impact thousands of people across a continent. Two linked cases may be sufficient to constitute an outbreak.

US Dairy Food Safety Task Force Recommendation

1.17.11 FINAL for Board presentation Jan. 26

Food Safety Workshop

Pilot workshop curriculum was developed by these eleven cheese and dairy colleagues, working together pre-competitively in an Innovation Center volunteer task force to promote food safety for the entire dairy industry.



Task Force Members

- Dean Foods: Ray McCoy, Paul Hill - Subject Matter Expert (SME)
- DFA: Keith Gomes/Jeff Acker, Kristen Dixon (SME)
- Foremost Farms: Brian Cords
- Glanbia Foods: Jeff Williams, Barney Krueger
- Hilmar: Warren Climo, Anne-Marie Fisher (SME)
- HP Hood: Peggy Poole, Stephen Lally (SME)
- IDFA: Clay Hough, Jon Gardner (SME)
- Land O'Lakes: Fernando Palacios, Sara Mortimore, Judy Fraser-Heaps (SMEs)
- Leprino: Edith Wilkin, Helena Soedjak (SME)
- Prairie Farms: Joe Delaney, Thomas Benthien (SME)
- Schreiber Foods: Tom Hedge, Staci Richardson (SME)
- Facilitator / Consultant: Joseph Stout

Business Case for Food Safety

- Dairy is not Immune - 2010 partial list
 - Bravo Farms recalls artisan cheeses for Listeria and E. coli
 - Estrella Family cheese recall due to Listeria
 - Saputo processed cheese slices recall due to Listeria
 - Morningland Dairy recalls raw milk cheese due to Listeria
 - Umpqua Dairy recalls products due to Salmonella infections
- FDA “assignments” expected to increase due to heightened artisan cheese focus



Our mutual call-to-action: CEO certainty regarding the food safety performance of the enterprise within their charge

Task Force Objective

To improve manufacturing conditions *in all* dairy processing facilities to prevent food safety recalls that could compromise the reputation of the dairy industry across all plants in the United States.

- The Food Safety Task Force is chartered to
 - Agree on principles and competencies required for success
 - Assemble and organize them in a useable format
 - Develop a strategy for implementation across the industry, shared and supported by Task Force companies

Executive Summary

- Recommend standard guidelines for Pathogen Control Programs and Audits protocol be supported immediately
- Recommend Supply Chain Food Safety program (plant vendor through customer shelf) be developed for subsequent Innovation Center Board review
- Communicate Food Safety guidelines, techniques, and approaches for the Dairy Industry via Training and Education Conferences with a Pilot in May/June, 2011 and a full rollout beginning Fall, 2011
 - Innovation Center member-companies requested to commit 'people' and seed funding resources to focus on technical content
 - Leverage IDFA expertise in education delivery and meeting logistics planning
 - Carry forward an "all inclusive" Dairy Industry approach: all dairy processors and manufacturers of all sizes and current food safety capabilities
- Create an Innovation Center standing Food Safety Committee
- IDFA to schedule and facilitate semi-annual exchanges between government regulators (FDA) and the Innovation Center Food Safety Committee executives

Food Safety Legislation

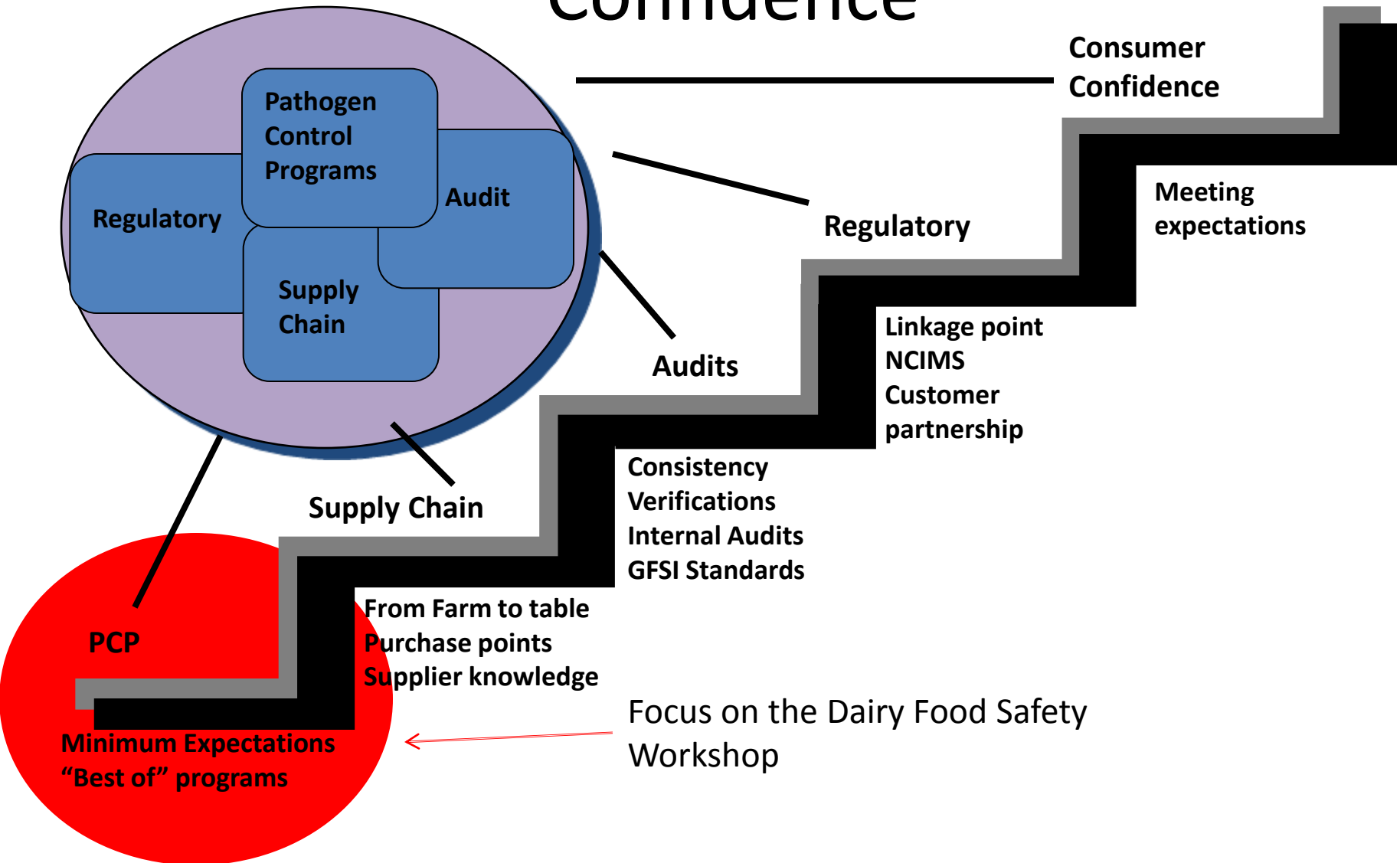
Summary of Food Safety Modernization Act:

- New food safety legislation signed into law by President Obama January 4th will provide FDA enhanced responsibility to help ensure the nation's food safety by providing FDA:
 - New powers to recall tainted foods, increase inspections, demand accountability from food companies and oversee farming
 - Greater authority to initiate recalls, rather than waiting for food companies to voluntarily recall food products
 - Legislation requires most food producers to develop hazard prevention plans and environmental monitoring programs, and gives FDA access to those records when requested
 - The legislation calls for FDA to increase inspections of foreign food facilities; the riskiest domestic facilities would be inspected within 5 years of enactment and every 3 years thereafter

Task Force Established Work Teams Across Four Action Platforms to Address Potential Risks

- **I. Pathogen Control** – Recommend a uniform approach to in-plant pathogen control programs (PCP)
- **II. Regulatory** – Recommend an engagement strategy to enhance relationships and dialog with regulators
- **III. Verification via Auditing** – Recommend strengthening internal audits to a common standard and link to Global Food Safety Initiative (GFSI)
- **IV. Supply Chain** – Recommend program to address disparity in supplier knowledge and practice

Food Safety Road Map to Consumer Confidence



I. Pathogen Control Programs (F

■ Objective

- ❑ Raise the bar on environmental pathogen control by implementing the Pathogen Control Equation as a checklist of principles
- ❑ Establish Minimum Expectations

Minimum Expectation

Cross traffic (RAW to RTE) is controlled due to effective procedures. Traffic barriers such as rails, fences, vestibules, walkways, are used as active control measures. Traffic plans and zoning maps are developed, implemented and followed for employee and other traffic in the facility

Best Of Class

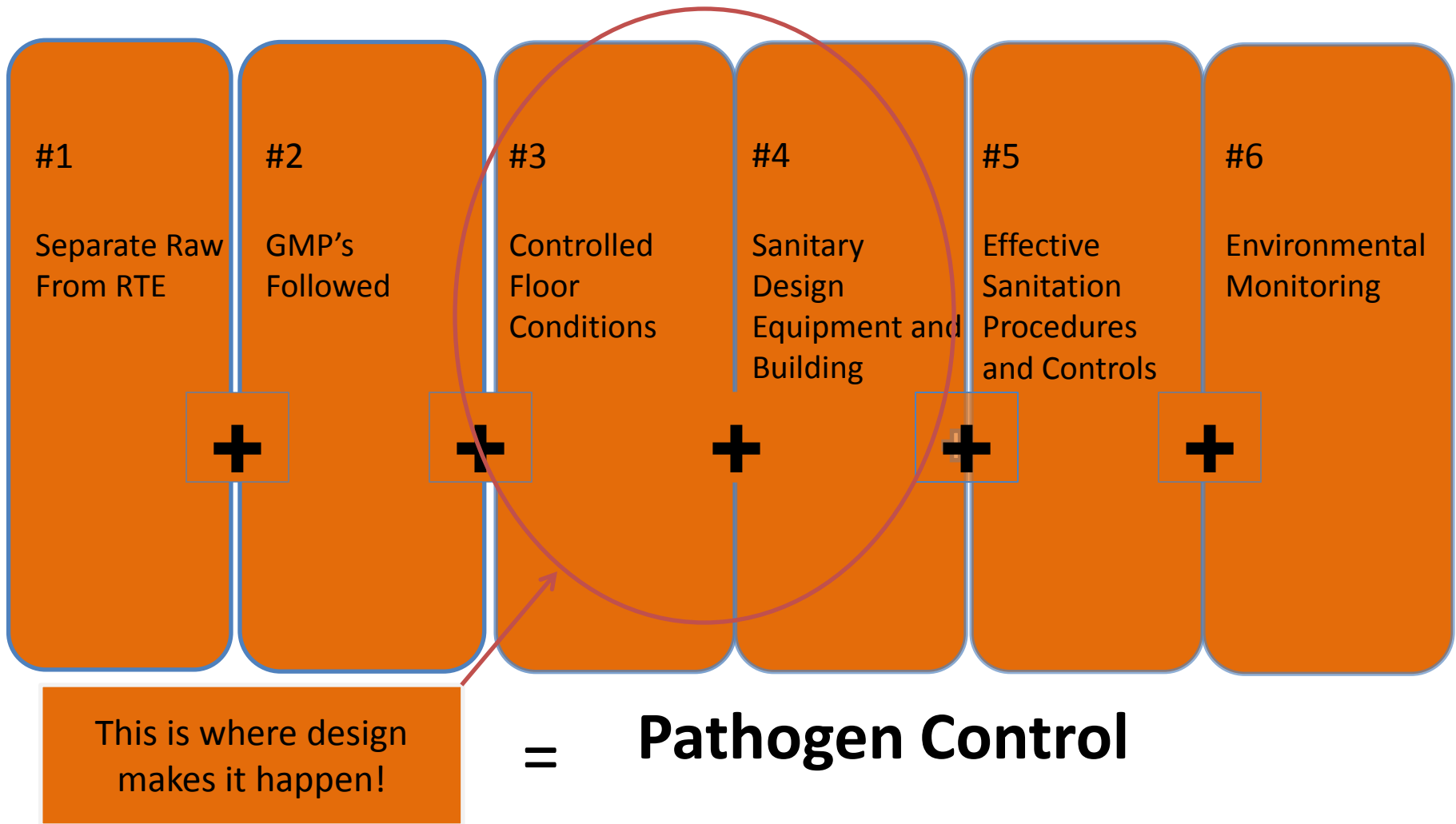
(Minimum Expectations +)
There is clear active separation of RAW and RTE areas using physical walls or barriers which prevent undesired behaviors.

• Key Elements

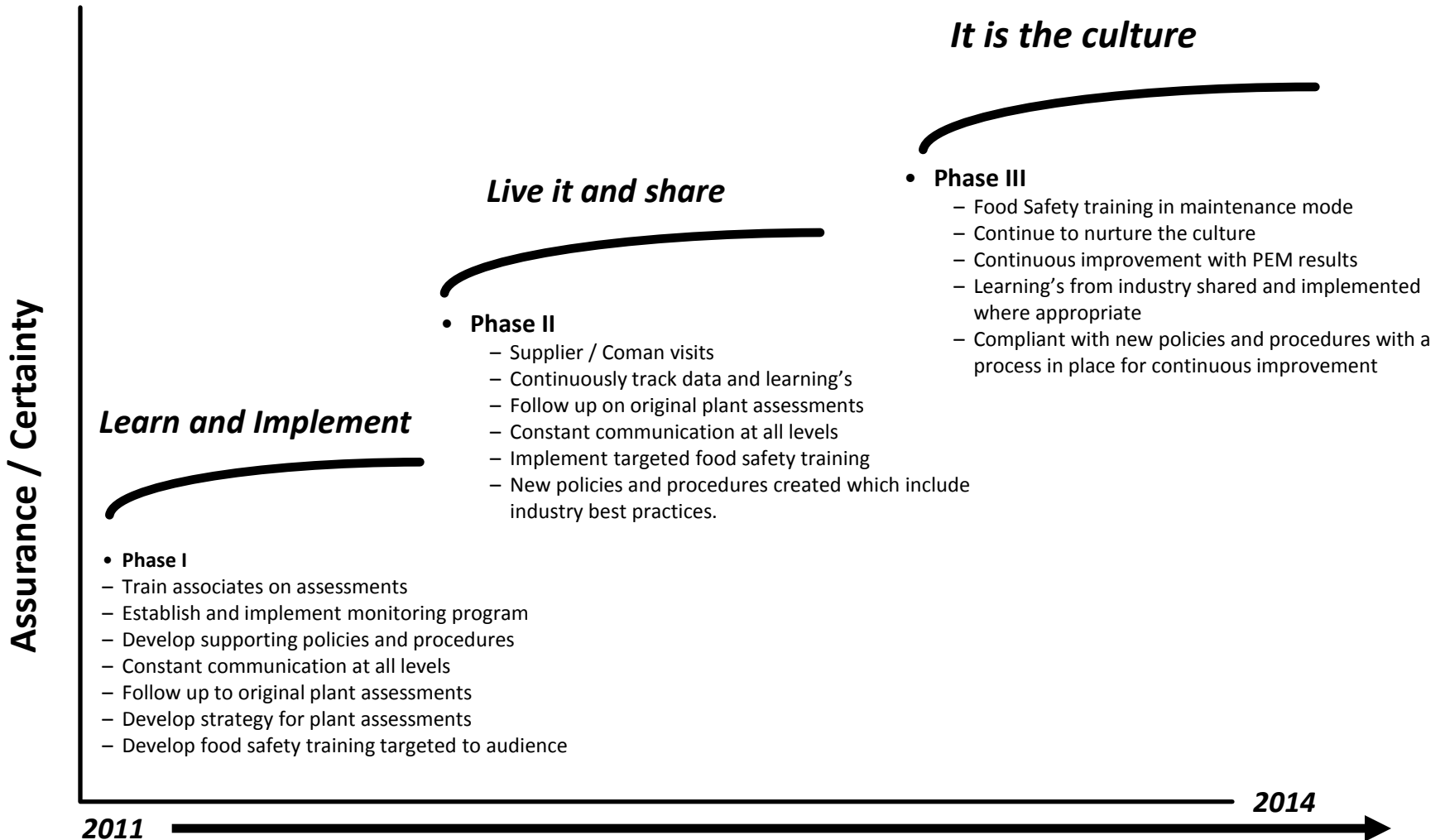
- **PCP checklist**
- **Internal Assessments** based on PCP checklist
- **Training program for the dairy industry** developed by SMEs based on PCP documents and hosted by IDFA
- **Continuous improvement** from SMEs, using surveys, together with the dairy industry

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

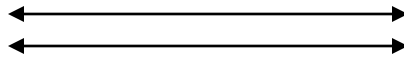
Pathogen
Control
Programs



Long Term Dairy Vision



The challenge – building the connection between designs – difficulty to clean and the consumer!



**Industry agreement that pathogens
are the enemy with perfection the
goal.**

The Risk of Not Being 100% Perfect

• *Produce 2 billion portions and Safety Risks*

•99 % Food Safe	20,000,0000
•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.

Microbiology & Sanitary Design

Review — Persistence of *Listeria monocytogenes* in food industry equipment and premises

Brigitte Carpentier a,[✉], Olivier Cerf b

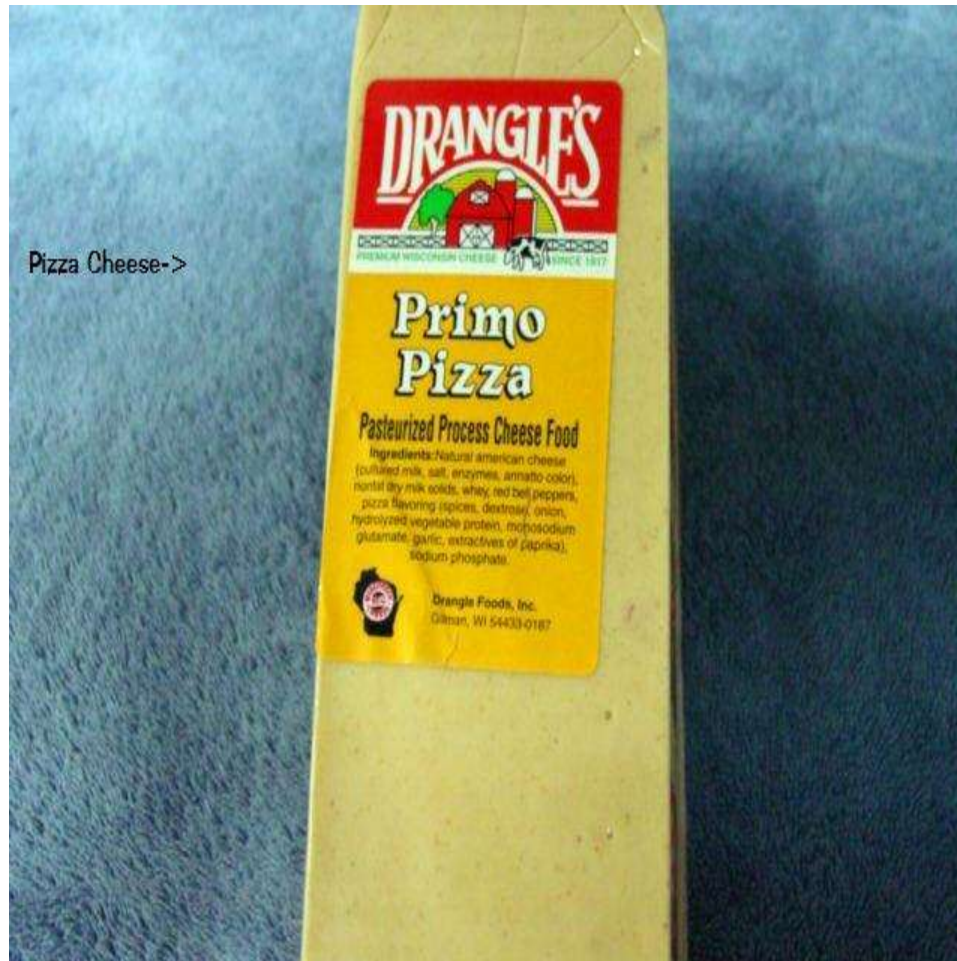
a Laboratory of Food Safety, French Agency for Food, Environmental and Occupational Health Safety (ANSES), Maisons-Alfort, France

b Alfort Veterinary School, Maisons-Alfort, France

We conclude by proposing that there are no strains of *L.monocytogenes* with unique properties that lead to persistence, but harborage sites in food industry premises and equipment where *L. monocytogenes* can persist.

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Basic Microbiology



Microorganisms
are so small that
in a cup cheese
could find
approx. 10^{10} cells
**= 10 times the
whole world's
population!**

Pathogens are enemies that are invisible,
silent and deadly to people companies and
jobs

Seven Steps of Effective Wet Sanitation (one step at a time)



Enable
Effective
Sanitation



Direct Link
to Poor
Sanitation



Can lead to
Poor Sanitation
when not
maintained



1. GMPs
2. Continuous employee training
3. Hand Scrub
4. Continuous inspection
5. Flood sanitize
6. Single use cleaning aids
7. Synchronized process
8. Flashlights issues
9. ATP verification
10. Dedicated trainers & training tools
11. Dedicated tool storage

Step 1: Dry Clean

- ☐ **LOTO**, secure and disassemble equipment.
- ☐ Remove gross soils from the equipment and floor.
- ☐ Remove production supplies from the room.
- ☐ Remove trash from room.
- ☐ Drain baskets emptied.

Step 2: 1st Rinse

- ☐ Remove remaining visible soils with hot water (95% as a benchmark).
- ☐ Gross soils prohibit surface cleaning if not removed prior to soaping.
- ☐ Parts rinsed and ready to be placed into COP tanks for cleaning.

Step 3: Soap & Scour Proper PPE Required

- ☐ Foam the walls, then the floor, and then the equipment.
- ☐ Set contact time. Do not allow soap to dry, may form a stronger soil.
- ☐ Scour to remove films, fats, & proteins.
- ☐ Drains cleaned prior to starting step 4.

Step 4: Post Rinse & Inspect

- ☐ Remove chemical and soils via flood rinse.
- ☐ Rinse in the order the soap was applied. Walls, floor, then equipment.
- ☐ **Avoid spraying** the floor once the post rinse of equipment begins.
- ☐ Use a flashlight to verify clean. Should occur throughout step 4.
- ☐ 100% free of soils, hazes, or water beads. Verify by sight, feel, & smell.

Step 5: Remove & Assemble

- ☐ Put on clean outerwear.
- ☐ Sanitize hands.
- ☐ Verify all chemical is removed (sight, Ph paper).
- ☐ Remove all standing water & overhead condensation.
- ☐ Standing water prevents sanitizer contact with the surface.
- ☐ **Preop inspect parts** that will not be accessible after assembling.
- ☐ **Sanitize inaccessible parts** prior to assembling.
- ☐ Assemble (**follow LOTO**).
- ☐ Relubricate where needed.



1. High pressure water & air
2. Reusable cleaning tools
3. Switches
4. Bearings
5. Congestion
6. Door seals

Step 6: Preop

- ☐ Inspect to ensure free of chemicals, tools, cleaning supplies before starting the equipment, and guards are in place.
- ☐ Run equipment prior to inspecting.
- ☐ Complete the formal preop spelled out in the plant's SSOP (sight, smell, touch, ATP are recommended tools)
- ☐ Correct all deficiencies and provide feedback to the sanitor responsible.

Step 7: Disinfect & Sanitize

- ☐ Make sure there is no standing water before beginning.
- ☐ Foam disinfect entire processing area walls (5 ft min), floor, & equipment (i.e. 800-1000 ppm Quat for 10 min). Follow label.
- ☐ Low pressure low volume rinse with portable water the product contact surfaces only.
- ☐ Ensure there is no pooling water.
- ☐ Foam sanitize no rinse concentration the product contact surfaces.



1. DRAIN BACK UP
2. Standing water
3. Aerosols
4. Hollow Rollers
5. Biofilms
6. Mops and foam squeegees
7. Fibrous belting
8. Co-mingling
9. Not accessible

Staying ahead of the Curve

How Does Equipment Design Lead?

How does Sanitary Design Lead the
Way?

Effective and Efficient
Designs (E&E)

Ten Principles of Facility Design for Dairy

	Dairy 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

Ten Principles of Equipment Design for Dairy

	Dairy Equipment Design Principles (outside of pipe)
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

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

CHECKLIST SUMMARY

<u>CATEGORIES</u>	<u>Points / Possible</u>			<u>% Earned</u>
PRINCIPLE #1 - MICROBIOLOGICALLY CLEANABLE	0.0	/	125.0	0.0%
PRINCIPLE #2 - MADE OF COMPATIBLE MATERIALS	0.0	/	100.0	0.0%
PRINCIPLE #3 - ACCESSIBLE FOR INSPECTION, MAINTENANCE, & CLEANING/SANITATION	0.0	/	150.0	0.0%
PRINCIPLE #4 - NO LIQUID COLLECTION	0.0	/	80.0	0.0%
PRINCIPLE #5 - HOLLOW AREAS HERMETICALLY SEALED	0.0	/	130.0	0.0%
PRINCIPLE #6 - NO NICHES	0.0	/	165.0	0.0%
PRINCIPLE #7 - SANITARY OPERATIONAL PERFORMANCE	0.0	/	100.0	0.0%
PRINCIPLE #8 - HYGIENIC DESIGN OF MAINTENANCE ENCLOSURES	0.0	/	50.0	0.0%
PRINCIPLE #9 - HYGIENIC COMPATIBILITY WITH OTHER SYSTEMS	0.0	/	50.0	0.0%
PRINCIPLE #10 - VALIDATED CLEANING & SANITIZING PROTOCOLS	0.0	/	50.0	0.0%
Total	0.0	/	1,000.0	0.0%
Rating System				
Satisfactory = Full points				
Marginal = 1/2 points				
Unsatisfactory = zero points				

A Sanitation Centric integrated "Safe Food" Supply Chain

Concept

Design

Review

Install

Operate

Clean

Safe Food



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

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

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

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

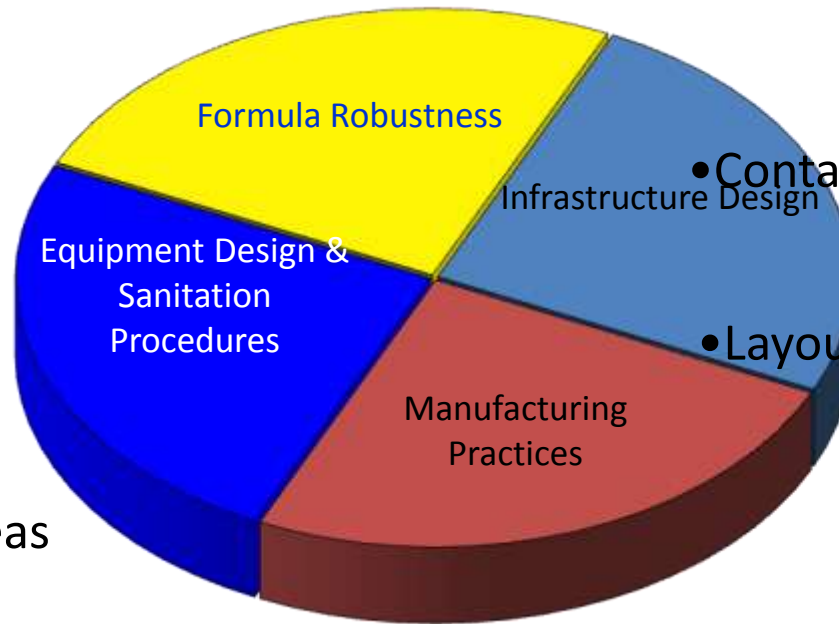
- Sanitary Operational performance
- In process monitoring
- Employee concerns
- Easy for employees to do it right things

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

Balancing Controls with Formulations

Hygiene Practices

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



Manufacturing Practices

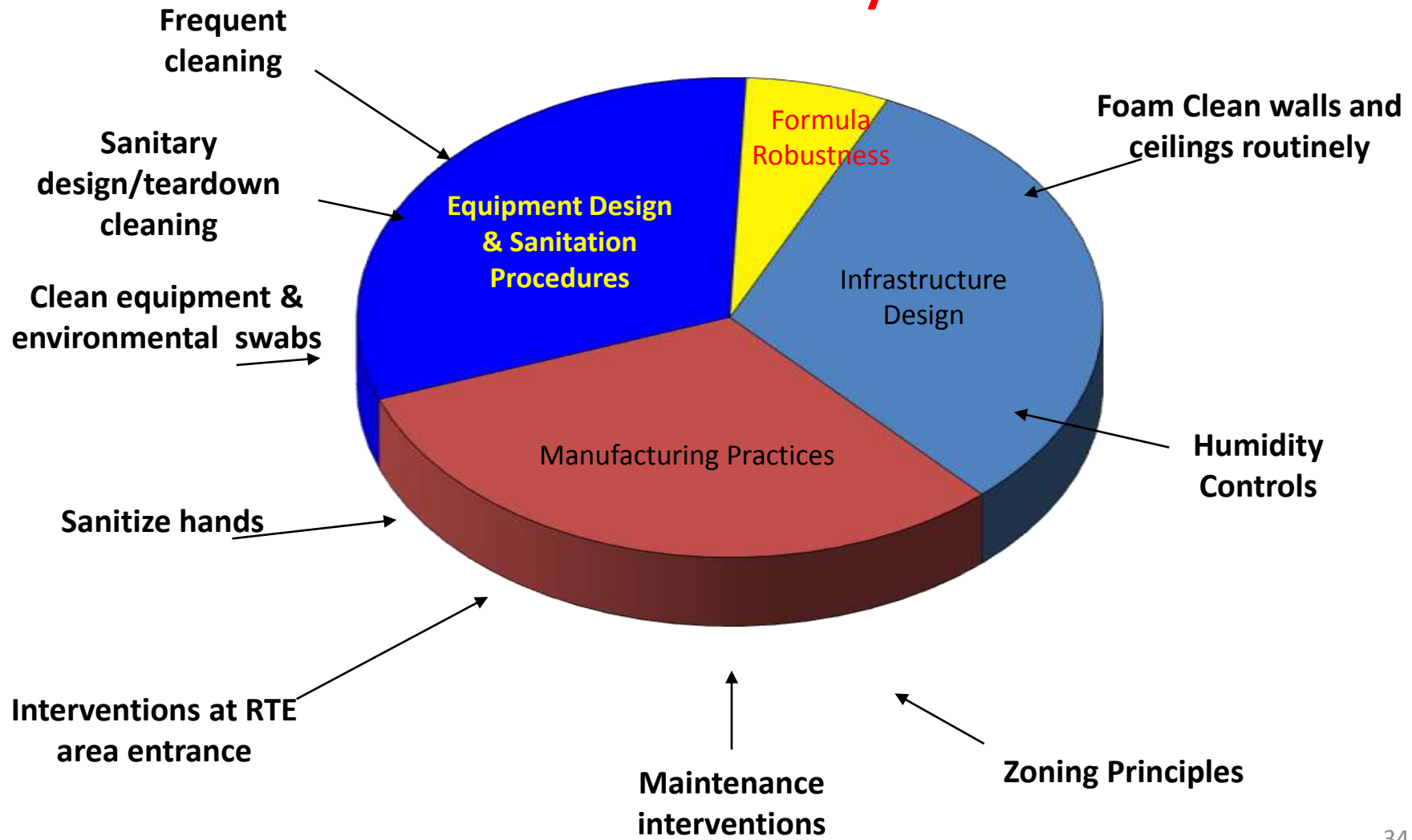
- Equipment & Facility design
- Facility maintenance
- Pest Control programs
- Container identification system
- Employee training
- Layout and physical separation
- Roofing maintained
- Condensation control
- Allergen Management
- Traffic patterns

Designing it Right for the Dairy Industry

Balancing Controls with Formulations

Ready to Eat Cheese

for Dairy



Sanitary Design Defined

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

Sanitary Design Continuous Improvement Cycle

Design Continuum

- Evaluate designs using check list
- Measure success factors
- Identify Risks (risk assessment)

Measure Improvements

- Did improvements made mitigate the risks identified?
- Are improvements sustainable?
- Communicate with enablers (Engineering, Suppliers etc.)

Create a plan

- Plan to includes how to manage design flaws and redesign as needed
- Communicate with enablers (Engineering, Suppliers etc.)

Measure and improve

- Measure plan progress at agreed upon frequency
- Modify action plans as needed