Cleaning and Sanitation Validation: What Does Clean Look Like?

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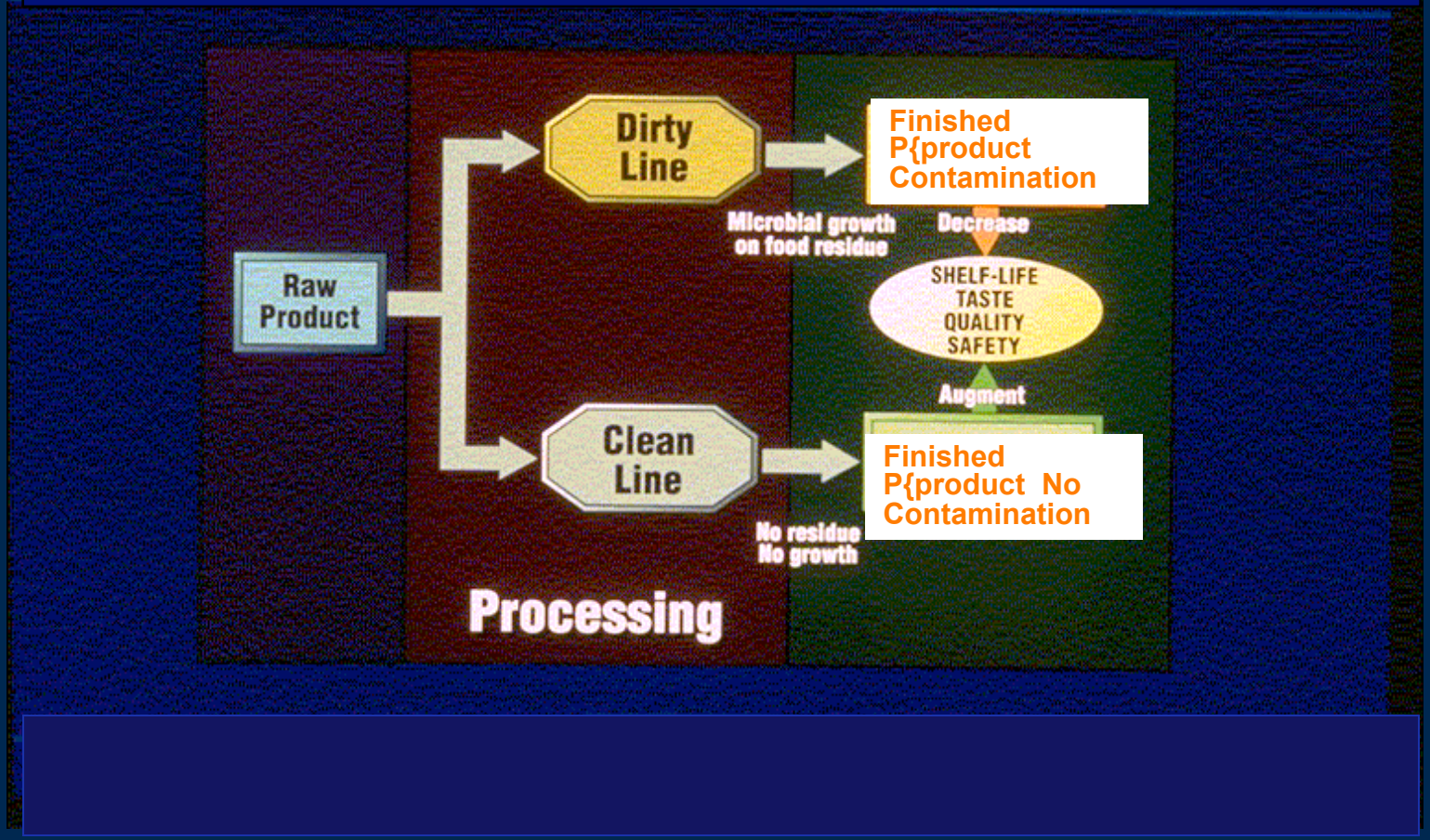
Cleaning and Sanitation Validation: What Does Clean Look Like?

- Introduction
- Cleaning, Sanitation and Hygiene – What does it mean?
- Surface sampling methodology for monitoring and validation of cleaning and sanitation
- Rapid Hygiene Monitoring - ATP and non- ATP swabs
- Consideration in Environmental monitoring
- Summary

Food Processors must…

- Prevent contamination
- Eliminate or reduce the numbers of microorganisms
- Minimize growth and activity of surviving organisms
- Prevent post-processing contamination

Clean line = safety, quality and shelf life



Monitoring Cleaning and Sanitation Efficacy..

- Why ?
- What ?
- When?
- How ?
- Who ?

WHY CLEANING AND SANITATION ??

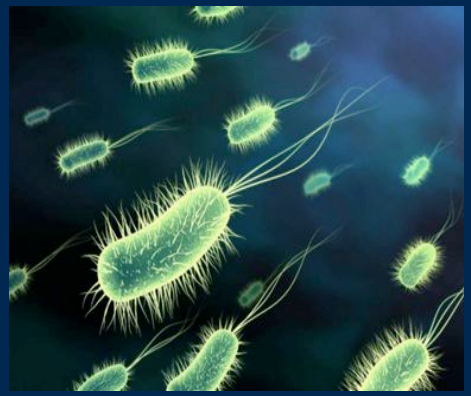
- It's the Law!
- It's a good business
- It's related to product quality and shelf life and consumer satisfaction
- Loss of reputation and Brand protection

WHY CLEANING AND SANITATION ??

Its The LAW !!!

- 1990s USDA/FDA GMP SSOP Prerequisite to HACCP
- EEC Council Directives
  - 89/392/on machinery including Agri-food stuff machinery
  - 93/94 on the hygiene of food stuff 1993
  - 1990 Food safety Act (U.K)

WHY CLEANING AND SANITATION ??



Its good business

- Aesthetics and Process Efficacy
- Equipment Performance/ maintenance
- Spoilage, K.Q and Shelf life
- Vendor compliance

Universal Emphasis on Hygienic Design and Cleanability of Food Processing Equipment

What is Cleaning and Sanitation ?

- **Cleaning**

  Removal of all soil, food product residue, dirt, grease or other objectionable matter.

- **Sanitation**

  All precautions and measures which are necessary in the production, processing, storage and distribution, in order to assure an unobjectionable, sound and palatable product which is fit for human consumption

What is Cleaning and Sanitation ?

- **Sanitation/ Sanitizing**

  Application of any effective method or substance to clean surface for the reduction of the bacterial count of pathogens, to a safe and acceptable level and of other organisms to as far as practicable. Such treatments shall nor adversely effect the equipment, the product or the health of the consumer and shall be acceptable to the health authority.

What is Cleaning and Sanitation ?

- ***Disinfection***

  The reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability.

- ***Hygiene***

  Conditions or practices conducive to maintaining health and preventing disease, esp. through cleanliness.

What is Cleaning and Sanitation ?

- *Cleaning alone, may remove some bacteria. However*, it is NOT adequate to reduce the bacterial populations to an acceptable low level
- Clean before sanitation
- Pre-op sanitation

What is a ‘Clean’ Surface?

- Physically

  Removal of all soil, and product residue

- Chemically

  Removal of cleaning and sanitizing material by rinsing

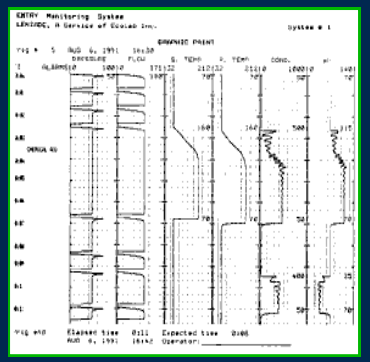
- Microbiologically

  Reduction to an acceptable level of microorganisms

Monitoring Cleaning and Sanitation Efficacy..

Hygiene monitoring – How?

- Visual Inspection
- Checking Cleaning Conditions
- Microbiological Tests
- Rapid Hygiene monitoring Tests (ATP/ non-ATP)



Monitoring : Visual Assessment

- Sensory/visual assessment of equipment/ surfaces
- “Sensitive” or “Worst case” scenario
- Skill and experience of inspector
- Apparent cleanliness can be misleading!

Surface sampling methodology for monitoring and validation of cleaning and sanitation

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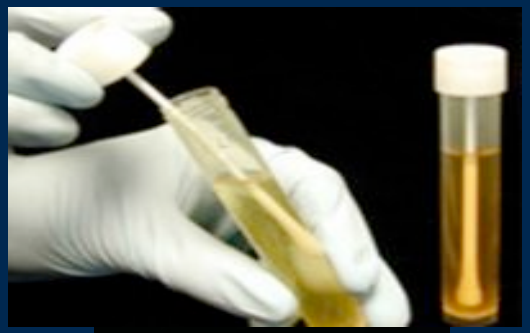
University of Wisconsin - River Falls

Presented at
2011 IAFP Pre Annual meeting workshop
Milwaukee, Wi
July 29, 2011

Microbiological Assessment of Food Contact Surfaces

- Swab/ Sponge tests
- Rinse tests
- Agar Contact Methods- RODAC
- Direct Surface Agar Plating (DSAP)
- Sticky Tape Technique
- Dye reduction tests
- ATP bioluminescence tests

Sponges and Swabs



Swab Tests

- Simple
- Most common method
- Sample a surface with a sterile cotton swab followed by standard plate count
- Poor recovery of residual microorganisms
- Poor reproducibility
- Not suitable for specific “index” organism
- Improved results with refinements

Total Microbial Counts for a Cannery

Grade	Microbial Counts (cfu/ft^2) after swabbing
Satisfactory	0 - 5,000
Fairly satisfactory	5,000 - 25,000
Unsatisfactory	> 25,000

[1]From Shapton and Shapton (1991)

Rinse Method

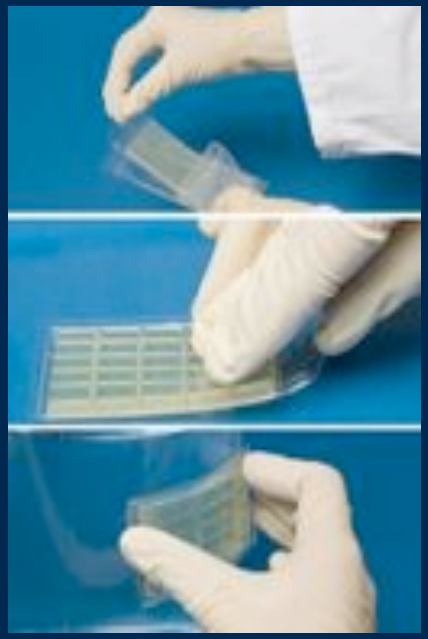
- Collection of contamination by rinsing of entire surface followed by standard plate count
- Suitable for small surfaces/area
- Higher recovery
- More accurate than swab test
- Can be used with membrane filtration

Agar Contact Methods

- Pressing plates containing agar against a surface followed by incubation and counting
  - RODAC
  - Petrifilm
  - Hycheck
  - Monoflex
- Agar Syringe and Agar "Sausage"

Agar Contact Method

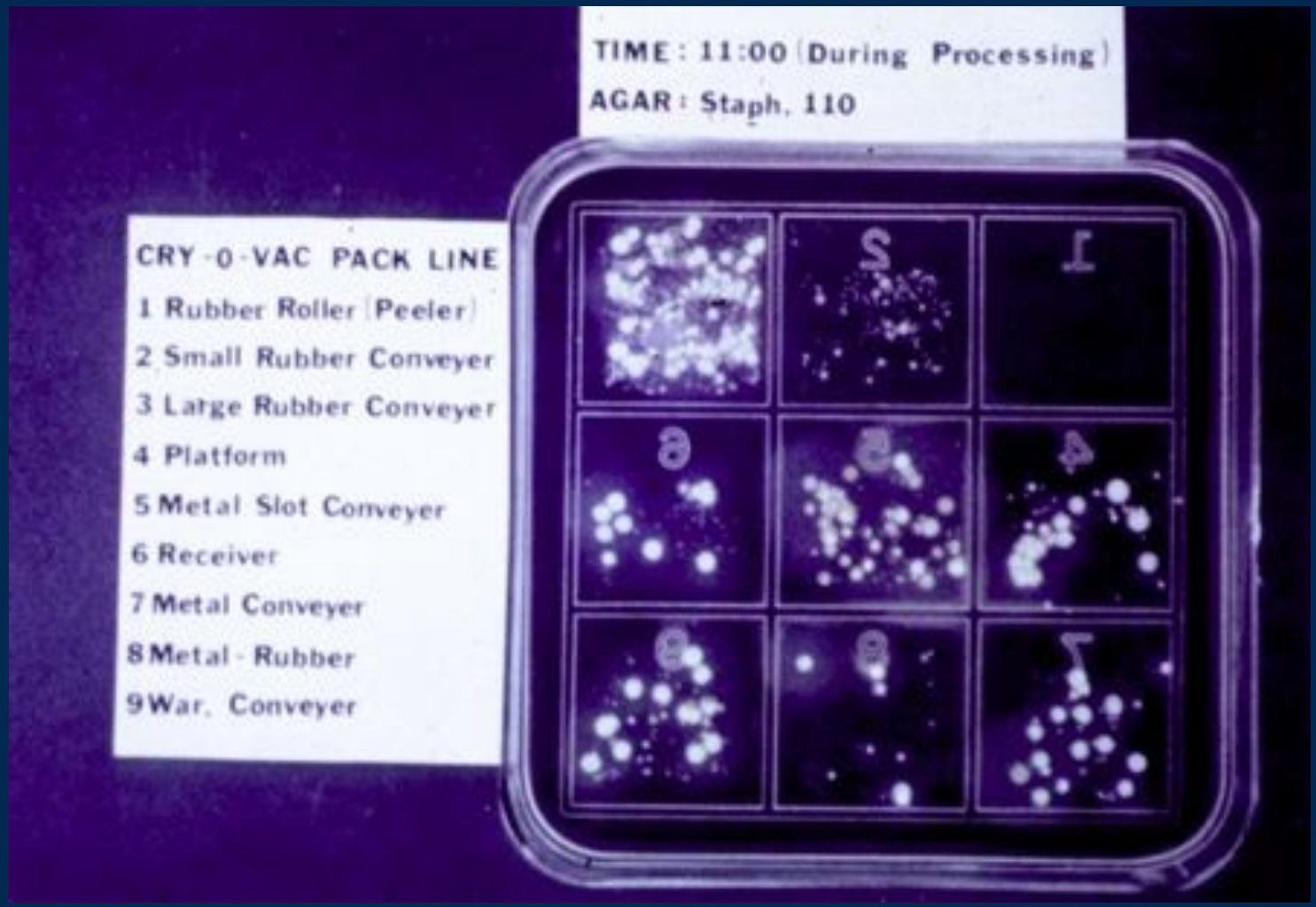
Biotest
Contact
Slides



Petrifilm application

Sticky Tape Technique

- Sterile cellophane tape applied to surface to be tested, reapplied to agar surface followed by incubation and counting
- CON-TACT-IT®
- Simple, easy, economical
- Similar limitations as agar contact methods
- Potential contamination by the transfer step


TIME : 11:00 (During Processing)
AGAR : Staph. 110
CRY-O-VAC PACK LINE
1 Rubber Roller (Peeler)
2 Small Rubber Conveyer
3 Large Rubber Conveyer
4 Platform
5 Metal Slot Conveyer
6 Receiver
7 Metal Conveyer
8 Metal - Rubber
9 War. Conveyer

Agar Contact Methods – Advantages and Limitations

- Simple
- Commonly used
- Versatile
- Generally suitable for flat surfaces
- Confluent colony/spreaders

Direct Surface Agar Plating (DSAP)

- *In situ* assessment of surface contamination by pouring a melted medium, allowing to solidify followed by incubation at room temperature
- Suitable for eating utensils
- Can't use equipment during the test period
- Confluent colony/spreaders

Miscellaneous Methods

- Indicator/Dye reduction
- *in situ* use of redox dye(NitroBlue, Tetrazolium)
- Catalase method
- Epiflurescence Microscopy
- Molecular detection

Rapid Hygiene Monitoring

- Simple, effective, cleanliness measurement
- Immediate results
- “Actionable” results

- ATP Bioluminescence
- Non-ATP swabs

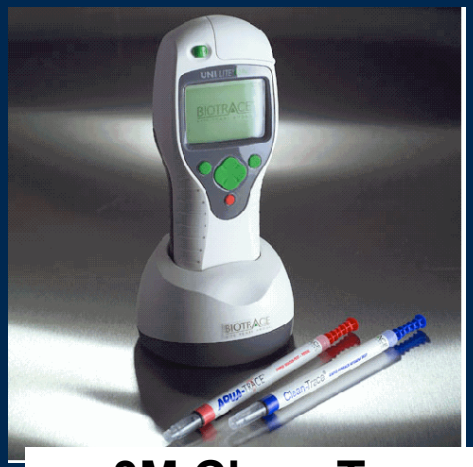
Rapid Hygiene Monitoring using ATP Bioluminescence

- Total ATP - Hygiene
- Rapid - Real Time
- Microbial vs. somatic ATP

Some commercially available luminometers

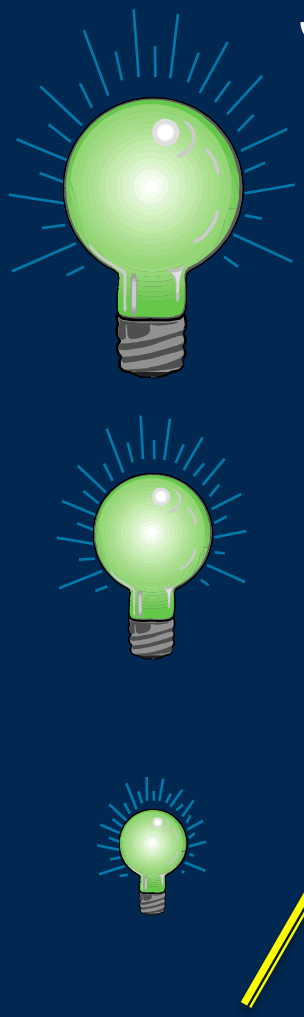
Biocontrol

Charm



3M Clean Trace

ATP Bioluminescence :
Simple, Quantitative Relationship

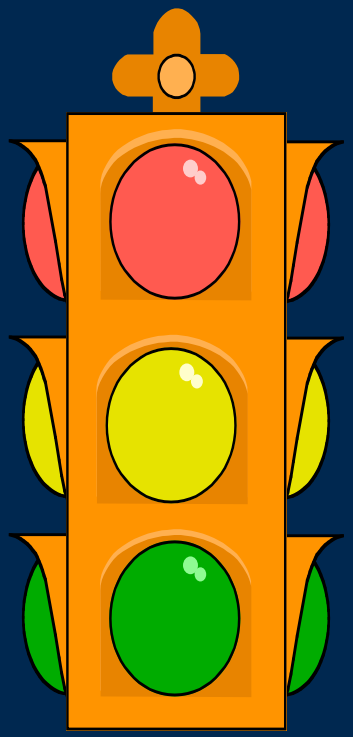


increase in light (RLU)

increase in ATP levels

increase in organisms or product residues

Interpretation of Results



Red - Yellow - Green
Fail - Caution - Pass

Sanitation failure
Re-clean prior to start-up

Results trending upward
Needs attention

Production may begin
Plant is clean

Criteria for Assessing Cleaning Efficacy of Food Contact Surfaces

Cleaning Efficacy	RLU [1]	Zone units[2]
Efficient	< 5	< 2.0
Moderate/ poor	5 - 50	2.0 - 2.5
Unclean	> 100	> 3.0

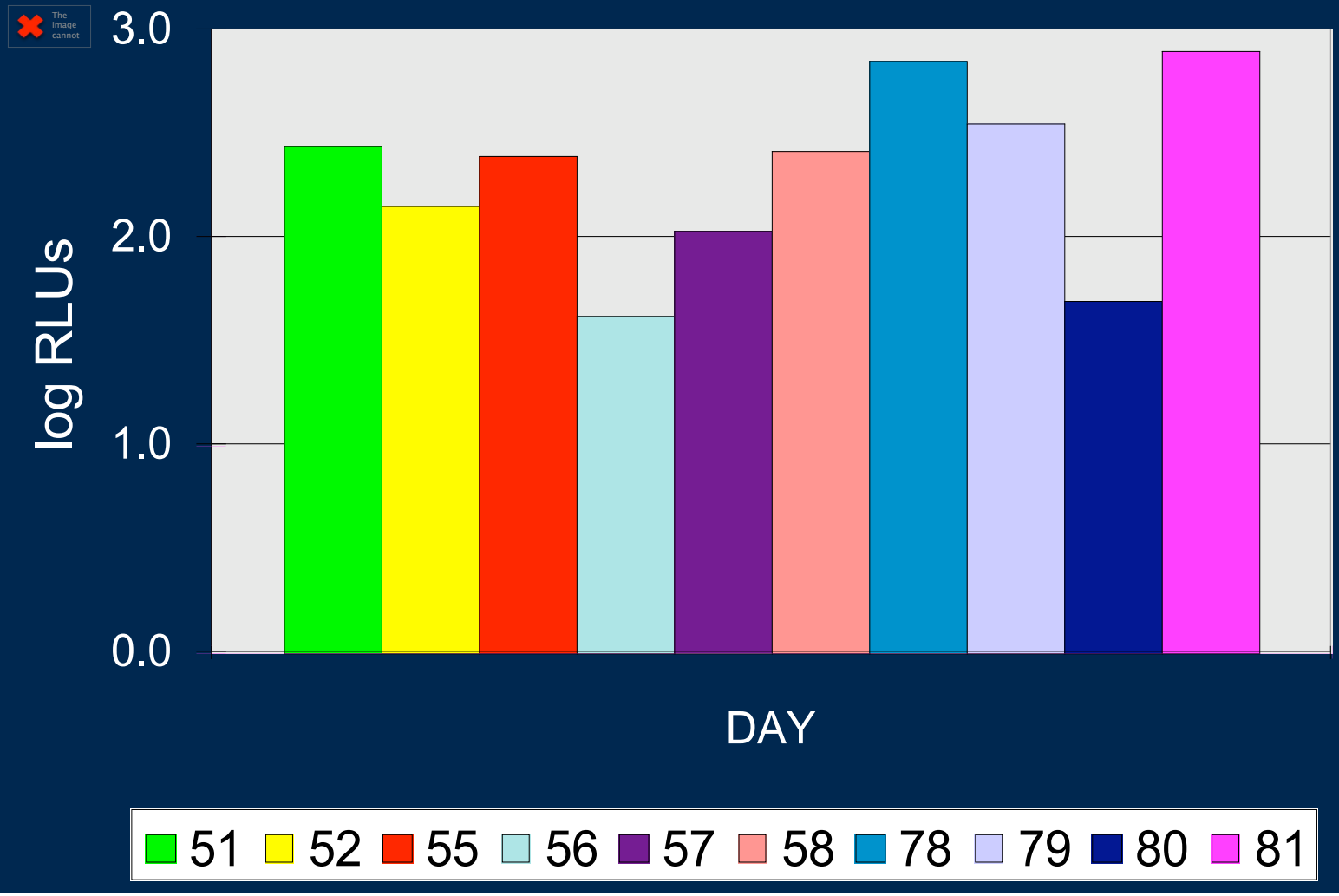
[1]Relative Light Units; [2]Used with Lightning Luminometer

Hygiene validation – Chees plant surfaces

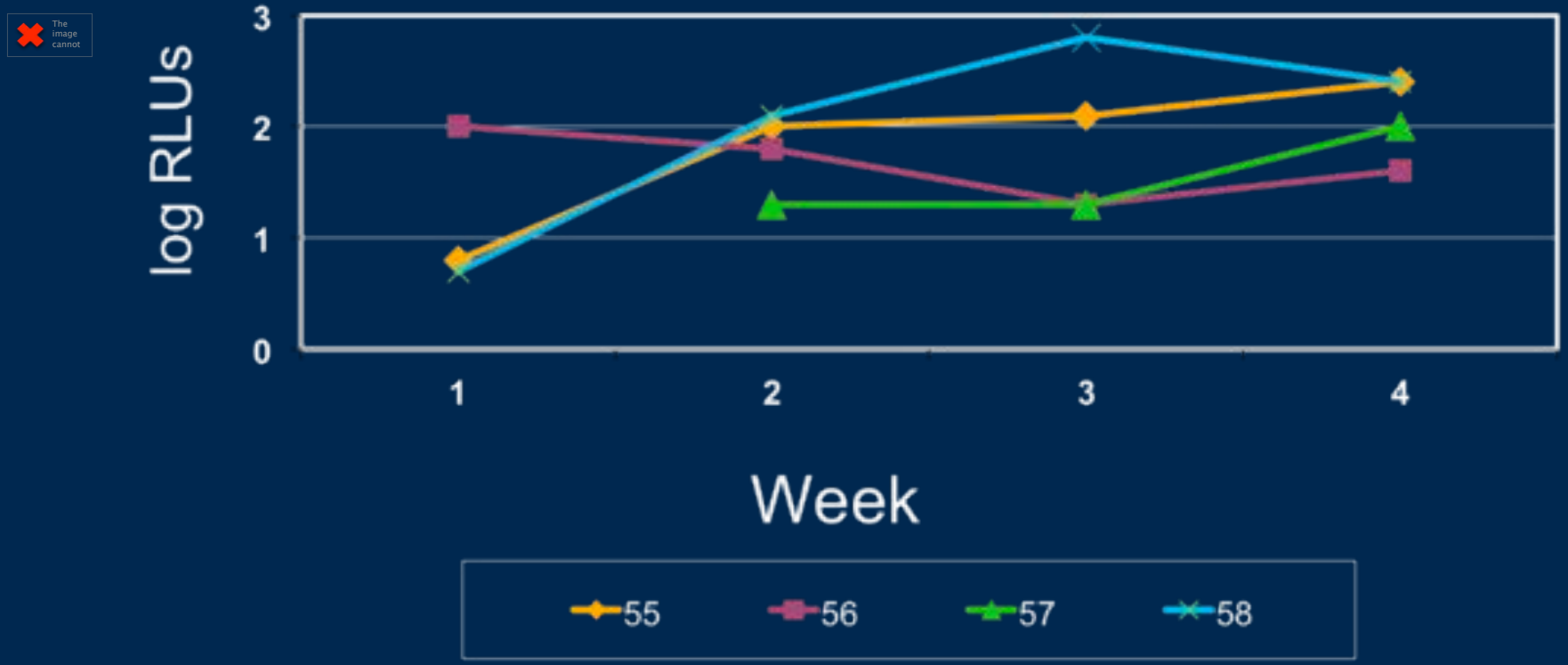
Surfaces evaluated by	Pass	Fail
Visual Inspection	119	0
Aerobic Plate Counts	47	72
ATP	42	77

Source: Kyrikides et. Al. 1990.

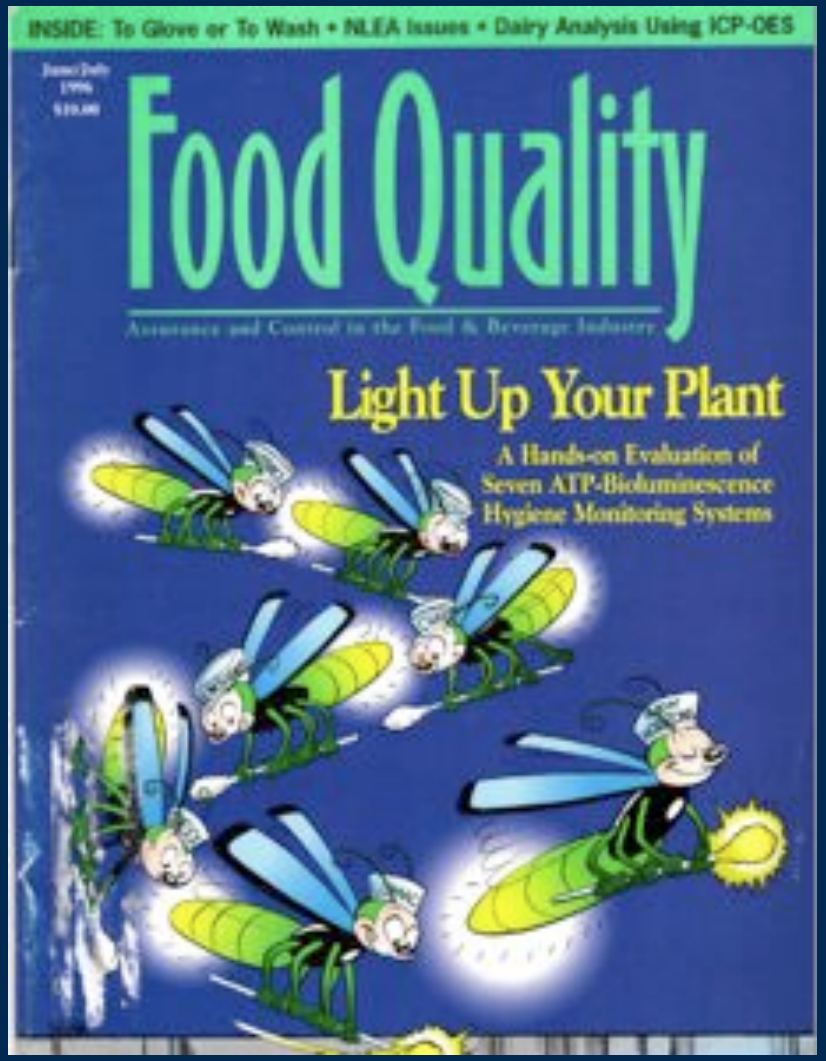
Results from a Particular Day

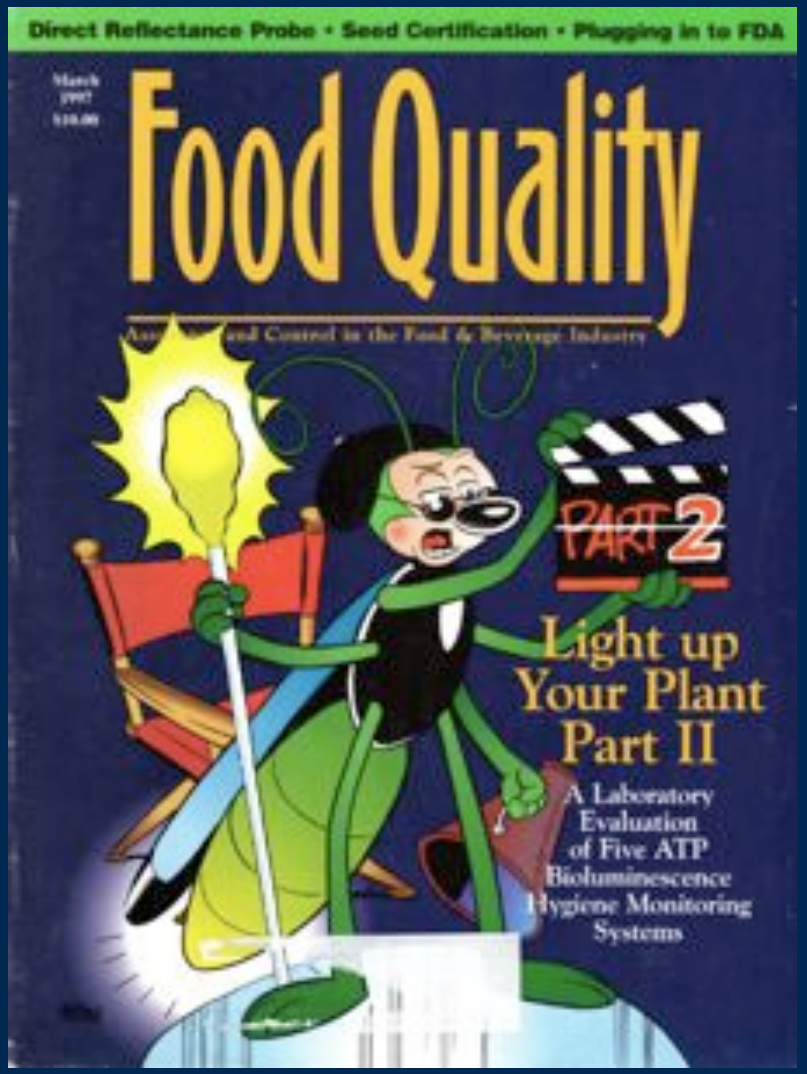


Weekly Sample Data



ATP Luminometer Performance evaluation

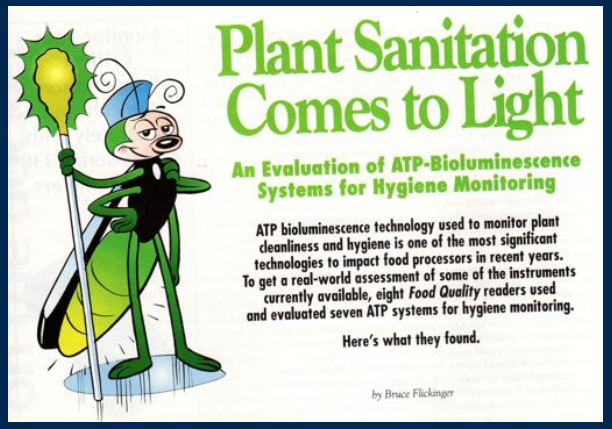




Hygiene Monitoring

	Visual assessment	Microbiological tests	ATP
Rapid	✓	X	✓
Objective	X	✓	✓
Sensitive	X	✓	✓
Detect product residues	✓	X	✓
Simple	✓	✓ (Lab required)	✓

Selection Criteria and Considerations



Plant Sanitation Comes to Light

An Evaluation of ATP-Bioluminescence Systems for Hygiene Monitoring

ATP bioluminescence technology used to monitor plant cleanliness and hygiene is one of the most significant technologies to impact food processors in recent years. To get a real-world assessment of some of the instruments currently available, eight *Food Quality* readers used and evaluated seven ATP systems for hygiene monitoring.

Here's what they found.

by Bruce Flickinger

- Sensitivity
- Reproducibility
- Repeatability
- Simplicity
- Instrument
- Reagents and Swabs
- Training
- Technical Service
- Industry acceptance

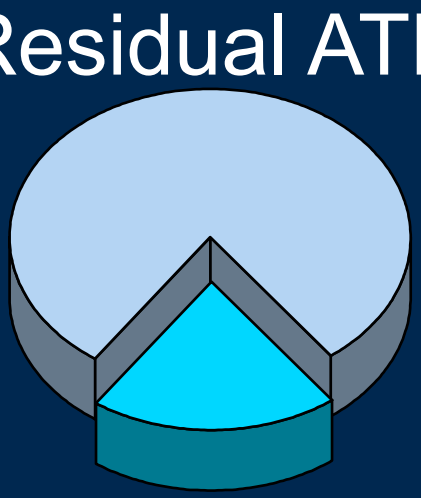
Important considerations

- Surface to be tested
- Method selected
- Lab and skills requirements
- Data handling and interpretation

CFU to RLU Correlation

Relative light Units do not equal Colony forming Units

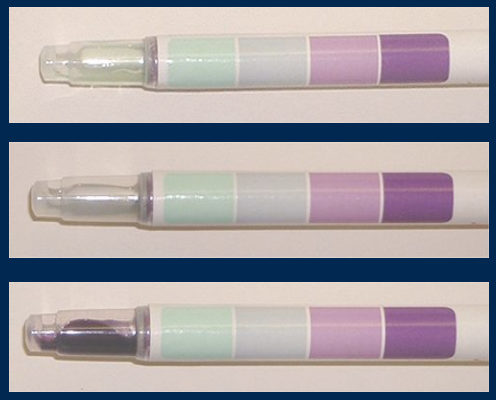
RLU correlates well to CFU with pure culture



Correlation does not occur because in real world environment there is residual ATP as well as microbial ATP.

Non-ATP swabs

- **Detects levels of protein, sugar and other compounds associated with food and microbial contamination.**
- **Semi-Quantitative – darker color/faster color development = more protein present**
- **Can detect as little as 50µg of protein**



Green - Pass

Grey – Caution

Purple - Fail

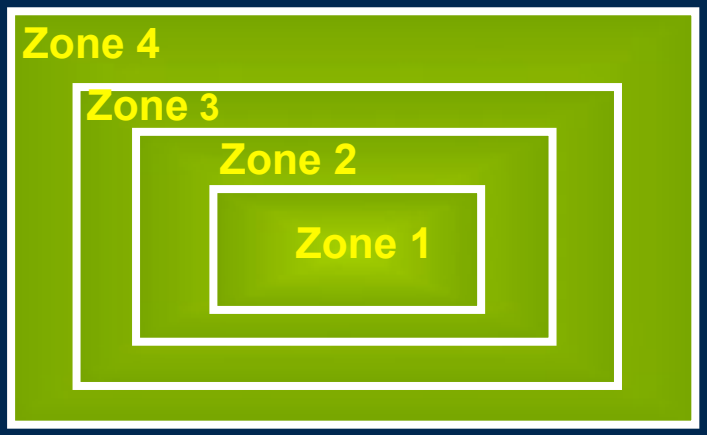
Assessment of cleanliness with AssurSwab/ Swab’N’Check and the ATP methods

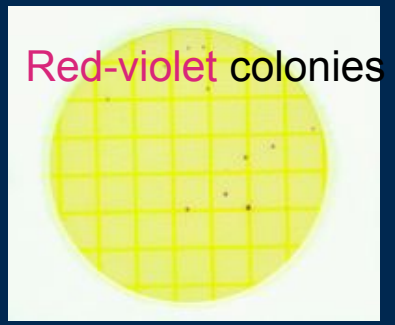
	Swab ‘N’ Check[1]	ATP[2]
SS Meat cooking table before washing	4	5300
SS Meat cooking table after washing	1	50-66
Plastic meat processing device after washing w/water alone	4	4100
Plastic meat processing device after washing / sanitizing	2	53, 64

1. Cleanliness level 1- 4(1= Clean, 4 = Dirty), 2. RLU

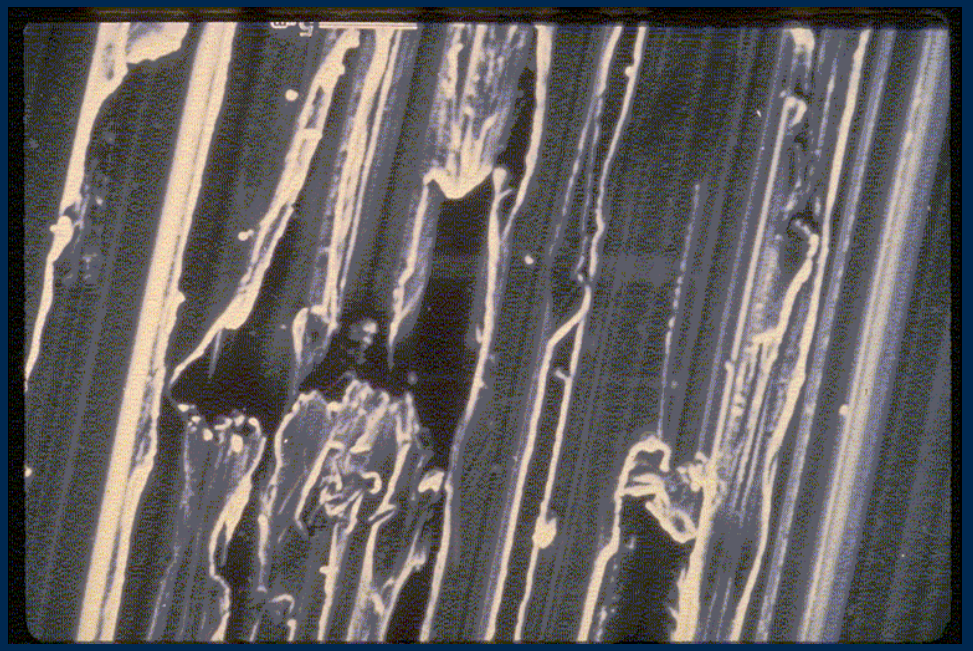
Some Recent Developments

- Biofilm
- Indicator and Specific Pathogen testing
  - Listeria spp. or Listeria-like organisms
  - E. coli, E. coli 0157:H7
- Surveillance of hot spots
- Zone testing



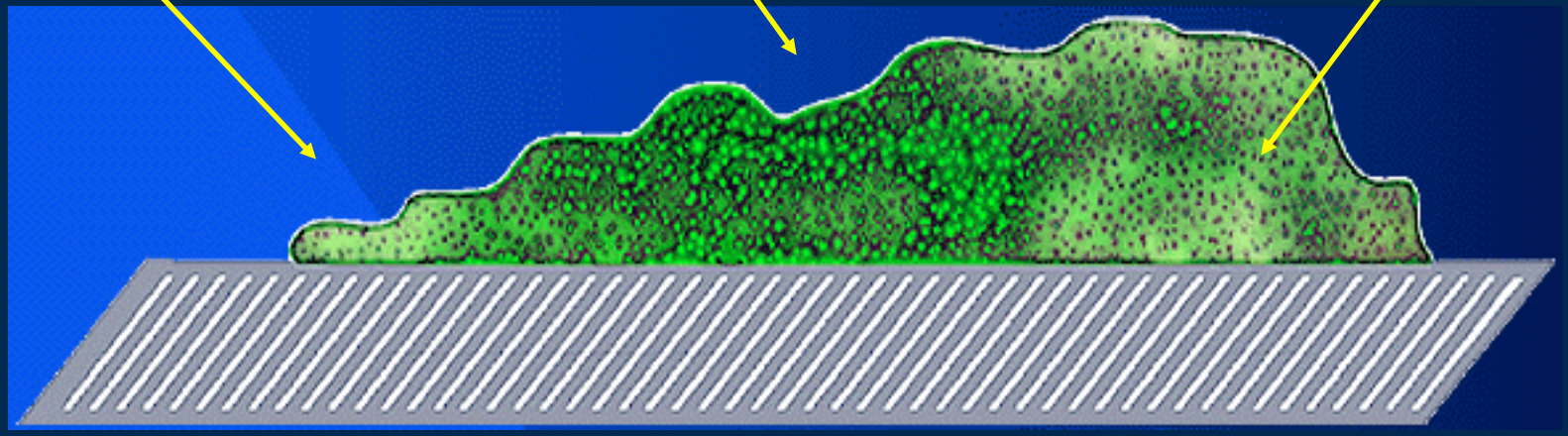


Biofilms



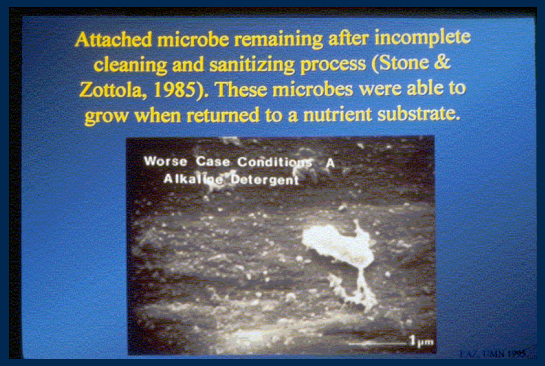
Biofilms

- Bacterial Attachment
- Mass with Protective Film (Slime)
- Traps Nutrients and Bacteria



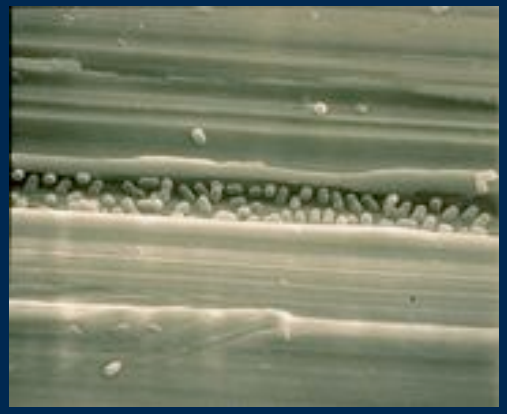
- Prevents Anti-Microbial Action
- Effective Cleaning Required

Microbial Attachments and Biofilms



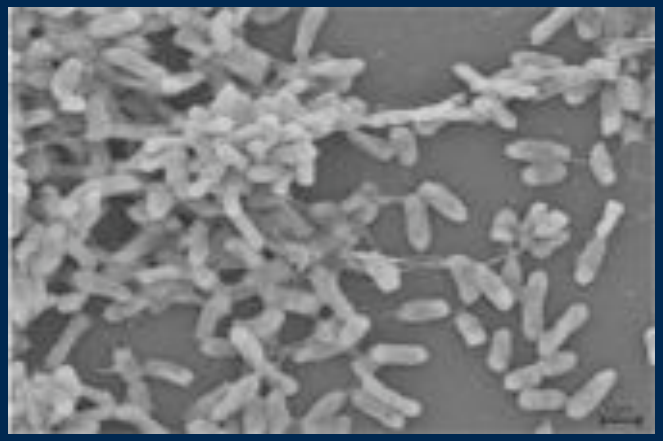
- Microorganisms e.g. *L. m.* & *Pseudomonas* can attach to food contact surfaces and form biofilms.
- Attached microorganisms (*P. fragi*) are not removed or inactivated under less than optimal cleaning and sanitizing of milk pipeline.
- Numbers of attached microorganisms in the biofilm increase to a point where they may resist inactivation by cleaning and sanitizing if intervals between cleaning and sanitation > 8 hr.

Microbial Attachments and Biofilms



- Attached microorganisms may resist treatment with sanitizer e.g. Micro-colonies of L. monocytogenes require 12-20 min. treatment with benzalkonium chloride, vs. 30 sec. for unattached cells.
- *P. fragi, L. monocytogenes, B. subtilis* and *Enterococcus* attached in biofilm to stainless steel more resistant to disinfectants and sanitizers than unattached cells.
- Portion of attached cells may survive a heat treatment of 70 ^{0}C for 5 min.

Microbial Attachments and Biofilms



- Age of biofilm affects the resistance of microorganisms to sanitizers
- Na-hypochlorite and Quats effective against a

  24 hr. biofilm of L.m. on food contact surfaces
- Resistance to chlorine increase with biofilm age

“… It is important that sufficient emphasis be placed on correct cleaning and sanitizing procedures in food processing systems.”

Microbial attachment and Biofilm formation
IFT Scientific Status Summary, July, 1994.

Environmental Applications

- Indicator and Specific Pathogen testing
- Listeria spp. or Listeria-like organisms, E. coli, E. coli 0157:H7
- Petrifilm™ Environmental Listeria Plate
- P/A, semi-quantitative or quantitative results

Environmental monitoring for Listeria

Dairy, Food and Environmental Sanitation, Vol. 19, No. 8, Pages 551-562

Guidelines to Prevent Post-Processing Contamination from *Listeria monocytogenes*

R. Bruce Tompkin,[1] Virginia N. Scott,[2]* Dane T. Bernard,[2]
William H. Sveum,[3] and Kathy Sullivan Gombas[4]

SUMMARY

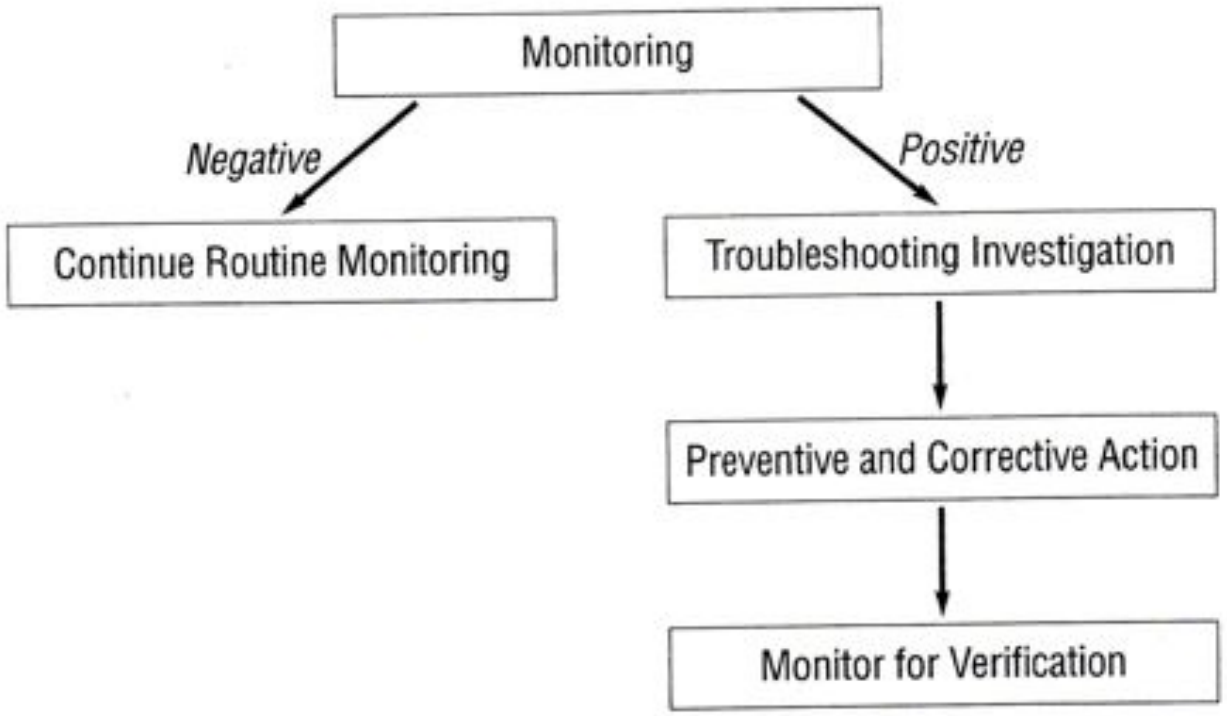
Extensive efforts to control *Listeria monocytogenes* can reduce the frequency and level (CFU/g or cm²) of contamination, but it is not possible, given currently available technology, to eradicate it from the processing environment or totally eliminate the potential for contamination of finished products. Because of the serious nature of listeriosis in the susceptible population, industry must take stringent measures to control *L. monocytogenes*

INTRODUCTION

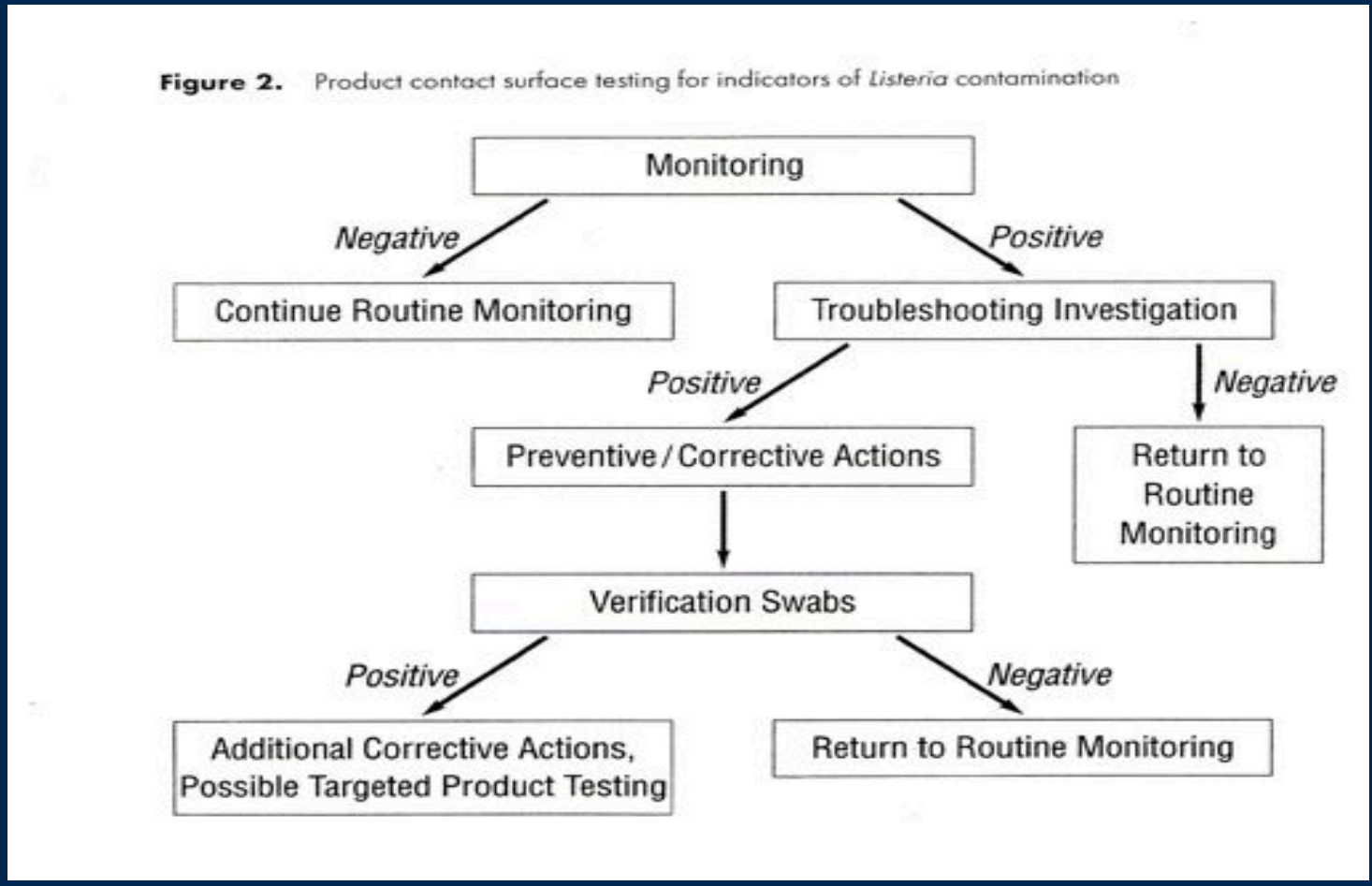
This document is intended to apply to refrigerated, ready-to-eat (RTE) foods that support the growth of *Listeria monocytogenes*, although the guidelines may be applied to other products to minimize contamination with *L. monocytogenes*. However, not all the guidelines listed below apply in all situations. The controls for *L. monocytogenes* will be product, process and plant specific; therefore, these

Environmental monitoring for Listeria

Figure 1. Non-product contact surface testing for indicators of *Listeria* contamination

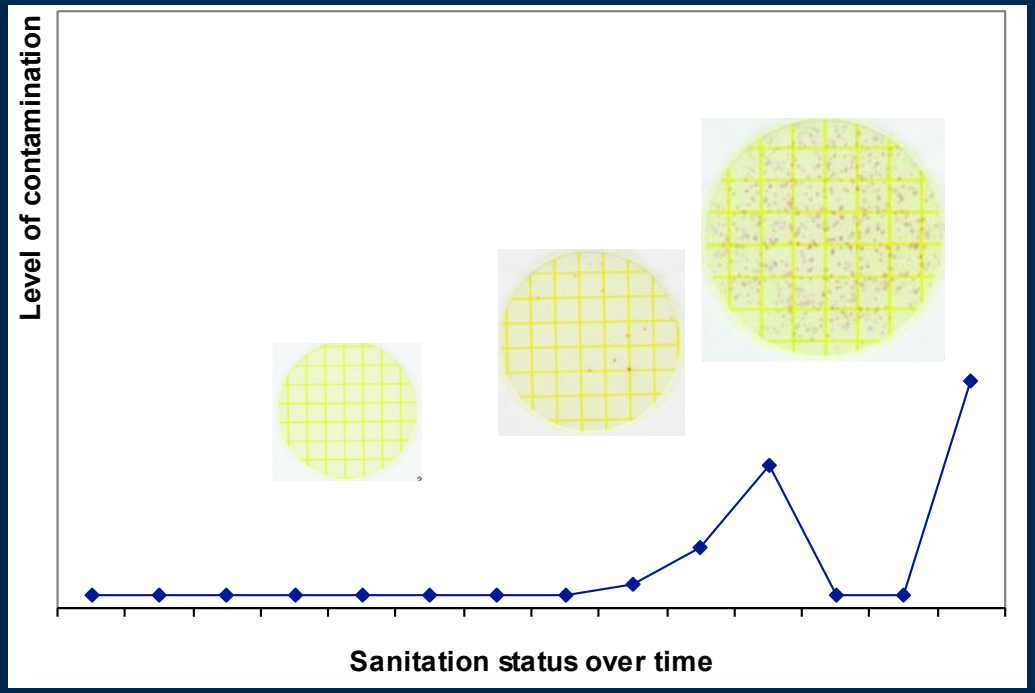


Environmental monitoring for Listeria

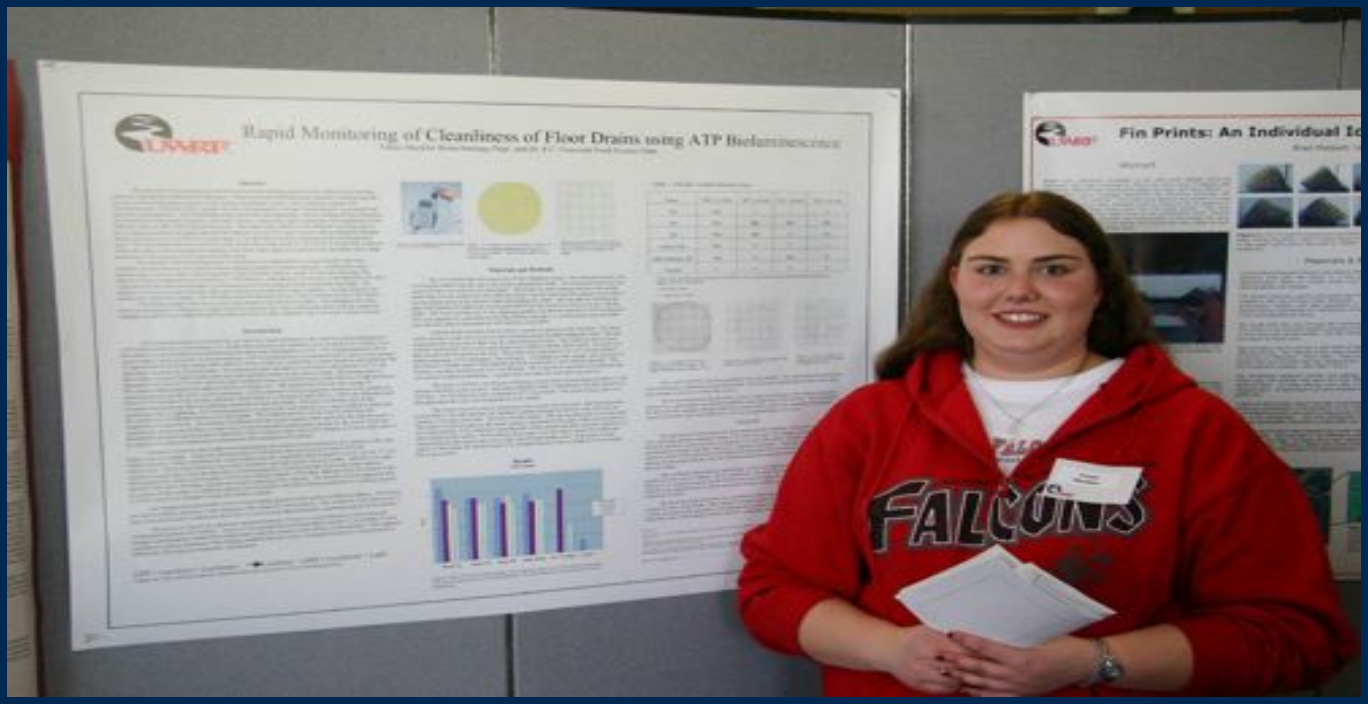


Environmental Applications

- P/A, semi-quantitative or quantitative results



Application of ATP Swabs and ELP plates



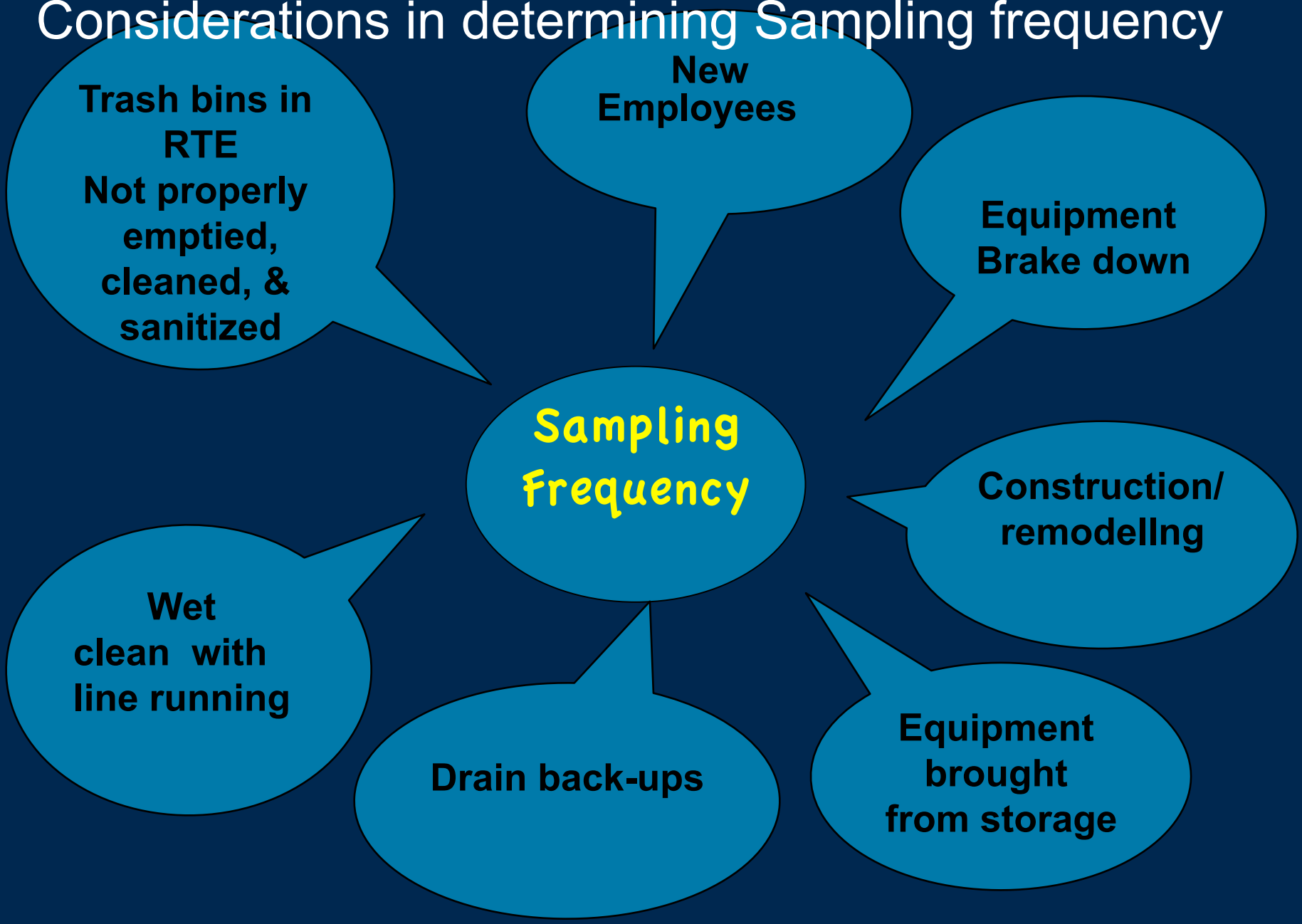
Environmental Monitoring

- Program developed using sponges/swabs to assess microbiological environment of plant
- Used to assess if sanitation procedures are effective
- Identifies key areas to monitor for presence of bacteria
- Sanitation measures can be modified to avoid potential product contamination

Consideration in Environmental Monitoring

- EM program includes several aspects
  - Sampling frequency
    - Pre-Op vs. Operation samples
  - Sampling sites
  - Sampling techniques
  - Sample area size

Considerations in determining Sampling frequency



Sample Size

- Ideal sample size
  - 40 Square inches of area with sponge/swab
  - Use horizontal and vertical motion
  - Pressure should not cause the sponge to crumble
  - Smaller sample area is acceptable for area that is not easily sampled

Sampling sites

- Non-product and product contact surfaces are selected.
- Zone Concept

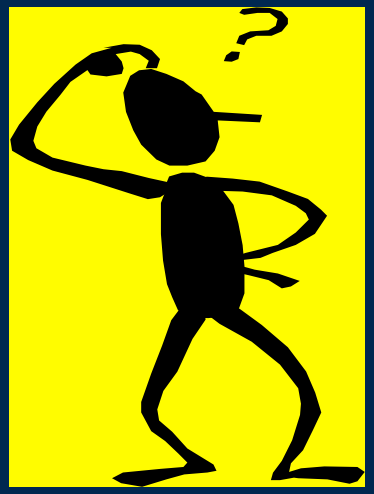
Summary and Conclusions

- Main objective of cleaning and sanitation is to control Microorganisms
- Effective sanitation programs include monitoring sanitation efficacy
- Monitoring may be done visually or by checking cleaning conditions but microbiological testing can confirm cleaning and sanitation efficacy
- Several methods for microbiological monitoring are available
- ATP hygiene monitoring and zone testing are popular option for hygiene monitoring
- ATP bioluminescence based methods gives Total cleanliness of surfaces (microorganisms + food residue) but readings may not correlate with SPC
- Protein Swabs give " relative" data, Hard to quantify

Acknowledgements..

- IAFP and the Dairy Sanitaion PDG
- Various companies marketing microbiological testing equipment and supplies. Mention of a brand name does not necessarily imply endorsement.
- UW River Falls

Any Questions ???



Thank You !!