

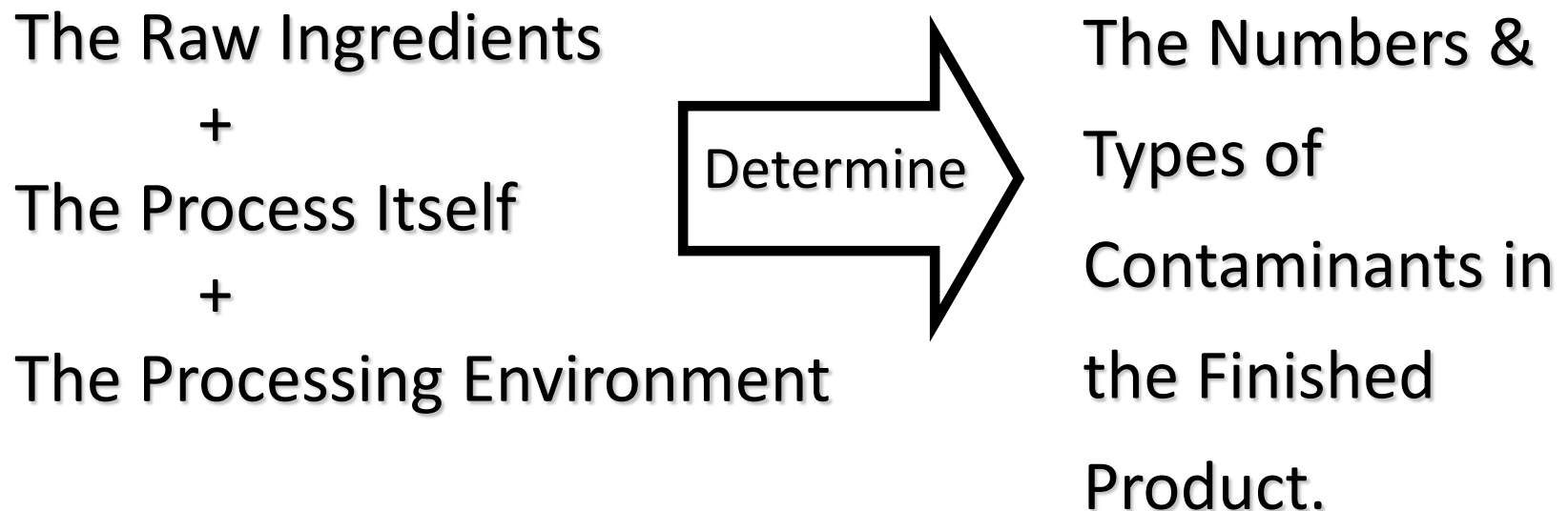


# Environmental Monitoring in the Age of FSMA

Thomas Jones  
DFA of California



Environmental monitoring can be defined as testing the processing environment for contaminants. Why do we want to do that?



## The Objectives of the Program Can Vary

- Pathogen detection/elimination.
  - ✓ Eliminate niches/harborage.
- Validation and verification of cleaning and sanitation programs.
  - ✓ Procedures & frequency.
- Determine if plant maintenance is needed.
  - ✓ Change gaskets, filters.
- Evaluate hygienic design of the facility.



# The Significance of Environmental Monitoring

- Measures the success of your food safety programs (Sanitation ➡ HACCP ➡ GFSI).
- Many foods do not receive a kill step before reaching the consumer.
- The monitoring functions as an “early warning system” to detect problems early.
- Contamination=spoilage, foodborne illness & recalls!





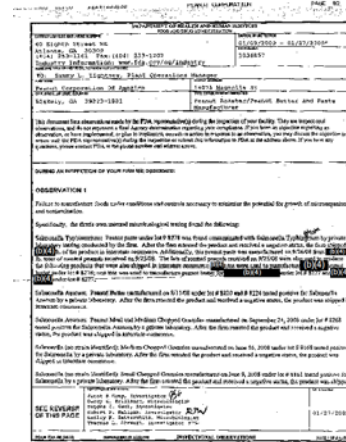
# The Costs of Environmental Contamination Can Be High...

2008-2009 Peanut Corporation of America (PCA):

- Foodborne illness outbreak (*Salmonella typhimurium*).
- Tied to peanut butter and peanut paste from PCA.
- 714 illnesses, 166 hospitalizations, 9 deaths.
- Eventual recall of 3,900 products containing peanut-derived ingredients.
- PCA is no longer in business.



- Lack of adequate pest controls
- Insanitary air circulation system.
- Insanitary food contact surfaces.
- Positive environmental samples for *Salmonella* (floor crack, cooler floor).
- Retesting/releasing (+) lots.



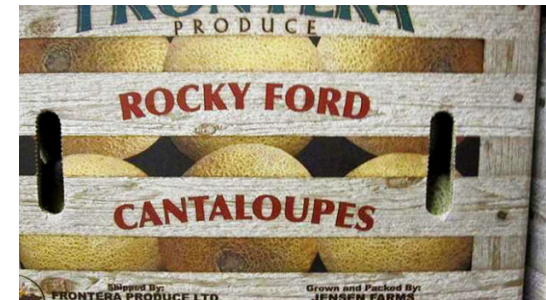
**FDA FOOD SAFETY  
MODERNIZATION ACT**

- FSMA
- Federal prison sentences.



## 2011 Jensen Farms (Holly, Colorado):

- Foodborne illness outbreak (*Listeria monocytogenes*).
- Tied to whole cantaloupes (Rocky Ford brand).
- 147 illnesses and 33 deaths.
- Jensen Farms filed bankruptcy.



## The FDA investigation:

- The outbreak strain was repeatedly found:
  - ✓ 5/10 cantaloupe samples.
  - ✓ 13/39 environmental samples.

## Jensen Farms Investigation (con't).

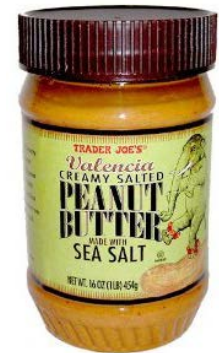
- Insanitary floor conditions:
  - ✓ *Standing water.*
  - ✓ *Difficult to clean.*
- Poor equipment design:
  - ✓ *Difficult to clean/sanitize.*
  - ✓ *Designed for another commodity.*
- No pre-cooling of fruit.
- Possible cross-contamination (cattle).
- Possible contamination from growing & harvesting operations.



# The Stakes Have Gotten Higher

## 2012 Sunland Farms:

- Foodborne illness outbreak (*Salmonella bredeney*).
- Linked to creamy peanut butter.
- 42 illnesses.
- 240 products recalled.



## The FDA Investigation:

- Shipped positive lots of product!
- Insanitary design of equipment, floors.





## Sunland Products Investigation (cont'd)

- Wet food contact surfaces (in a low moisture product).
- Inadequate pest control, worker hygiene practices, sanitation practices.
- 28 positive swab results for *Salmonella*:
  - ✓ *Floors, drains, broom bristles, structural supports, conveyor cover, roaster.*
- FDA suspended Sunland's registration!
  - ✓ *New authority under FSMA.*
  - ✓ *Company went bankrupt.*





## What Does FSMA Say?

- *“We propose to require environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples”.*
- *“Environmental monitoring would be a verification activity to ensure that sanitation controls are being implemented and are effective.”*

**-Preventive Controls Rule (September 17<sup>th</sup>, 2015)**

## What Does FSMA Say?

- *“For example, environmental monitoring would be required to verify effectiveness of sanitation controls when an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure...that would significantly minimize the pathogen...”*

**-Preventive Controls Rule (September 17<sup>th</sup>, 2015)**

## What Does FSMA Say?

- *“Foods such as peanut butter, soft cheeses, dried dairy products for use in RTE foods, and roasted nuts are among the products for which manufacturing operations would need to have an environmental monitoring program when such foods are exposed to the environment”*

- Preventive Controls Rule (September 17<sup>th</sup>, 2015)

- Environmental monitoring is “must do” for most RTE foods!

## Where Do We Start?

- Pathogen Environmental Monitoring.

- ✓ *Pathogens pose the highest risk.*

- ✓ *FDA is focused here.*

- Sanitation Verification.

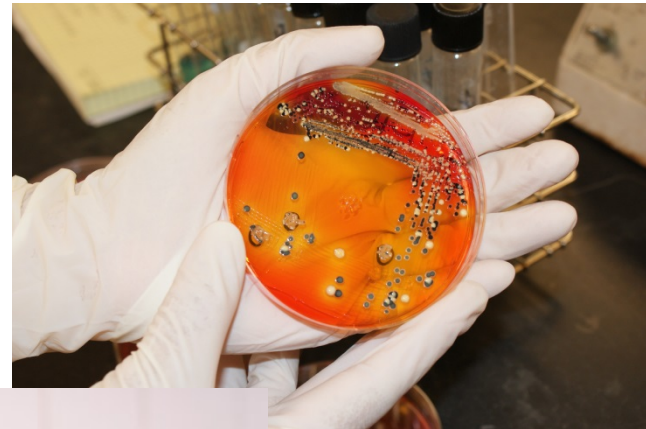
- ✓ *Includes non-traditional methods (ATP).*

- Program Management & Interpretation:

- ✓ *What do I do with this data once I get it?*



# Pathogen Environmental Monitoring



# Pathogen Environmental Monitoring (PEM)

- An ongoing sampling & testing process that measures the effectiveness of the pathogen contamination control measures in a plant.
- Pathogens of greatest concern are *Salmonella*, *Listeria* and *E. coli* O157.





# The Plant Environment

- Pathogens enter the plant in many ways (raw products, ingredients, pests, workers).
- Once inside, they persist in niches and move through the facility (dust, traffic flow, condensation).
- Grow/survive within the plant.
- This a perfect recipe for recontamination!



# Concerns with *Salmonella*

- There are over 2,400 serotypes of *Salmonella* bacteria.
- May infect several million Americans/yr. via tainted food (CDC).
- Survives well in the environment and is known to tolerate heat and dry conditions.





## FDA Perspective on *Salmonella*

*“Salmonella spp. is usually the environmental pathogen of concern for most dry (e.g. low-moisture) RTE food environments.”*

-Proposed Preventive Controls Rule, FDA

### Harborage Sites for *Salmonella*:

- Areas where food particles accumulate.
  - ✓ *Plant environment vs. processing equipment.*
- Escape the dry cleaning process.
- *Salmonella* grows when these areas get wet.
- Eventually contaminate food contact surfaces.

# The *Salmonella* Control Equation



TRAFFIC CONTROL  
(PERSONNEL &  
EQUIPMENT)  
+  
DUST CONTROL  
+  
WATER CONTROL  
+  
SEPARATION OF  
RAW & PASTEURIZED  
PRODUCT  
+  
EFFECTIVE  
CLEANING &  
SANITATION

---

**SALMONELLA  
CONTROL**



## **The Primary *Salmonella* Control Area (PSCA)**

- The area with the highest hygiene requirements (& risks).
- Product is exposed prior to final sorting/packaging.
- Especially sensitive with post-lethality-treated product.





# The Primary *Salmonella* Control Area (PSCA)

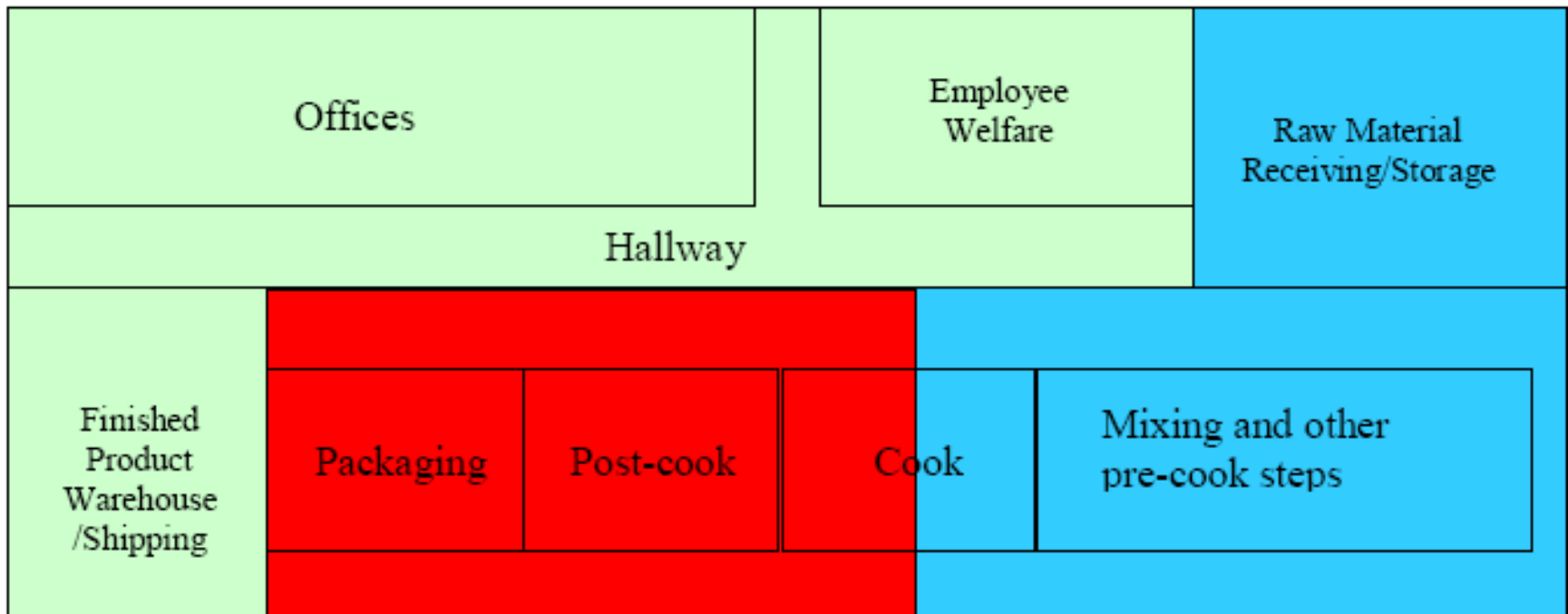
- Should be physically separate from the rest of the facility.
- PSCA controls include:
  - ✓ *Barriers.*
  - ✓ *Airflow changes/filtration.*
  - ✓ *Traffic control (people, materials).*
  - ✓ *Special sanitation measures.*








# PSCA Example

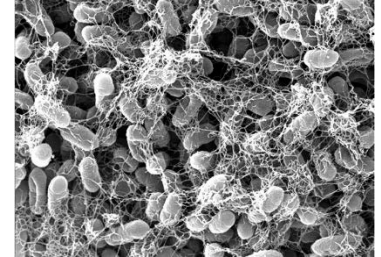
Main  
Entrance



-  PSCA (Primary *Salmonella* Control Area)
-  Basic GMP area
-  Non-process areas

## ***E. coli* O157:H7**

- O157 survives well in the environment (spinach) and is pH resistant (fruit juices).
- Isolated from food contact surfaces (Ex: meat processing facilities).
  - Not routinely tested in most PEM programs.
- Survival at low moisture?
  - Contamination of nuts, wheat flour reported.
  - Challenge studies suggest survival ranking of *Salmonella* > O157 > *Listeria*.



# *Listeria*

- Includes 6 species of common soil bacteria. One species (*Listeria monocytogenes*) is a human pathogen.
- Likes wet areas of the facility (drains, condensate, chillers).
- Good sanitation & environmental monitoring are critical to control.





## FDA Perspective on *Listeria*

***“L. monocytogenes is usually the environmental pathogen of concern for most wet RTE food production environments. It is important to sample areas where the organisms are likely to be present in relatively high numbers.”***

-Proposed Preventive Controls Rule, FDA

### Harborage Sites for *Listeria*:

- Where food & moisture are present.
- May grow on processing equipment.
- Contaminate food during production.

## Pathogen Comparisons

	<i>Listeria monocytogenes</i>	<i>E. coli</i> O157	<i>Salmonella</i>
Incubation Time:	3 to 70 days	1-6 days	12 to 72 hours
Infectious Dose:	>1,000 cells (?)	<100 cells	10-100 cells
Cases/year: (US)	1,700	73,000	4.8 million
Death Rate: (US)	30 %	5-10 %	<1%

# Establishing the PEM Program

- Step one is pick your team (like HACCP).
  - ✓ Sanitation, quality, production, maintenance, consultants.
- Evaluate the process flow & risks.
  - ✓ Recontamination threats!
- Define your hygiene areas:
  - ✓ PSCA.
  - ✓ Basic GMP Area.
  - ✓ Non-process Area.





# Establishing the PEM Program

- Based on their findings, the team selects sampling sites.

- The “swabbing equation”:

$$\uparrow \text{Potential Risk} = \uparrow \text{Frequency}$$

- “Zoning” is a helpful concept in site selection...



#### **ZONE 4**

locker rooms, cafeteria, halls  
warehouse, loading dock

#### **ZONE 3**

phones, hand trucks, forklifts, walls,  
floor and drains

#### **ZONE 2**

nonproduct contact surfaces in close  
proximity to product (exterior of  
equipment, chill units, framework,  
equipment housing)

#### **ZONE 1**

product contact  
surfaces (slicers,  
conveyors, peelers,  
strip tables, utensils,  
racks, work tables,  
employee hands,  
dicers, pumps)

## Zone 1 Sites

- Direct product contact surfaces.
- Exposed product prior to package sealing.
- Examples:
  - ✓ Conveyors/buckets
  - ✓ Utensils
  - ✓ Employee hands (ex: sorters).
  - ✓ Slicers/pitters.
  - ✓ Hoppers/bins/bin liners.
  - ✓ Fillers.



# Zone 1 Sites



## Zone 2 Sites

- Non-product contact sites adjacent to Zone 1.
- Examples:
  - ✓ Equipment framework.
  - ✓ Drip shields/housing.
  - ✓ Control panels/buttons.
  - ✓ Pipes over Zone 1.
  - ✓ Computer screens.
  - ✓ Maintenance tools.





## Zone 2 Sites





## Zone 3 Sites

- Non-product contact sites adjacent to Zone 2 (not Zone 1).
  - ✓ Cross-contamination risk.
- Examples include:
  - ✓ Floors/walls/ceilings.
  - ✓ Hoses/air handling units.
  - ✓ Drains.
  - ✓ Foot mats/baths.
  - ✓ Forklifts.
  - ✓ Brooms/mops
  - ✓ Pallets.



# Zone 3 Sites



## Zone 4 Sites

- Areas remote from Zone 1.
  - ✓ Cross-contamination of Zones 1-3 from Zone 4 can occur!
- Examples:
  - ✓ Locker/break rooms, offices.
  - ✓ Warehouses/freezers/cold storage.
  - ✓ Restrooms.
  - ✓ Loading docks.
  - ✓ Maintenance shop.



## Zone 4 Sites





# Taking Samples

- Samples of the plant environment may include:
  - ✓ Surface swabs.
  - ✓ Dust, scrapings.
  - ✓ Water/air.
- Sampling Tools can include:
  - ✓ Swabs (sponge & “Q-tip®” style).
  - ✓ Sterile scoops, spatulas & sample cups.



# Sample Collection

- Work out from Zone 1 to Zone 4.
- Samplers must practice good hygiene:
  1. Wash/sanitize hands.
  2. Put on sterile gloves before handling swab.
  3. Change gloves/sanitize between swabs.
  4. Only non-sterile surface the swab should touch is the sample site!!



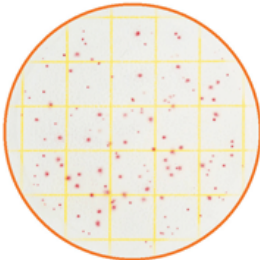
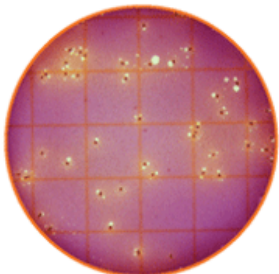


# Sample Collection

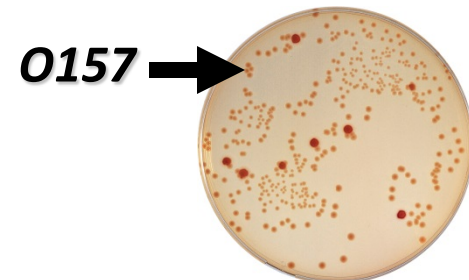
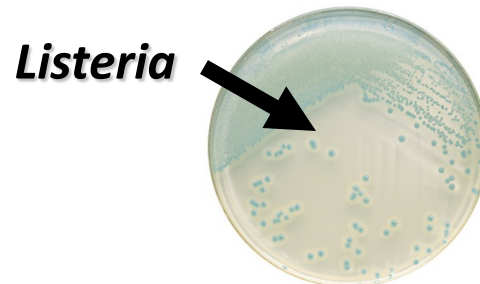
- The area sampled can vary:
  - ✓ 40-200 in<sup>2</sup> for indicators.
  - ✓ 40-400 in<sup>2</sup> for pathogens.
- Wipe Zone 1 sites with alcohol-based sanitizer after sampling.
- Always submit a negative control swab:
  - ✓ Removed from bag & returned w/o being used.
- Submit samples promptly!
  - ✓ Transport < 45 °F.
  - ✓ Test ≤ 48 hrs.



# Types of Sample Testing:

- Indicator Organisms.
  - ✓ Non-pathogens.
  - ✓ Indicators for contamination.
  - ✓ Examples:
    - Aerobic plate count (APC). → 
    - Coliforms.
    - Total Enterobacteriaceae (TEB). → 

- Pathogens...



# Sample Testing by Zone

- Zone 1 testing is typically indicators.
  - ✓ (+) pathogen = product holds/recalls.
  - ✓ Indicators allow you to quantify sanitation efforts.
  - ✓ Sample after cleaning/before sanitizing.
- Zones 2-4 are tested for pathogens.
  - ✓ Raw process areas will have some (+) hits.
  - ✓ Usually taken during production.



## **FSMA PEM Program Requirements**

- Procedures must be written and scientifically valid.
- Identify the test organism (pathogen or indicator).
- Locations and number of test sites:
  - “must be adequate to determine whether preventive controls are effective”.
- Test methods used and testing laboratory identified.
  - Recommend accredited laboratories.
- Identify Corrective Action Procedures.

# Sampling Summary

Zone	Examples of Sampling Sites	Microbiological Test	Minimum Frequency of Sampling	Typical Number of Samples
<b>1</b>	<b>Product Contact Site</b> (conveyers, hoppers, utensils, etc.)	<b>Indicator Organisms</b> (APC, coliforms, TEB) <b>pathogens sometimes.</b>	<b>Weekly, post-cleaning pre-sanitizer application.</b>	<b>Line Dependent</b>
<b>2</b>	<b>Adjacent to Zone 1</b> (framework, control panels, catwalks, etc.)	<b>Pathogens</b>	<b>Weekly</b>	<b>10-15</b>
<b>3</b>	<b>Further From Zone 1</b> (forklifts, floors, drains, walls, brooms, etc.)	<b>Pathogens</b>	<b>Weekly</b>	<b>10-15</b>
<b>4</b>	<b>Outside the Process Area</b> (warehouse, plant entrance, restrooms, office, etc.)	<b>Pathogens</b>	<b>Monthly</b>	<b>5-10</b>

# Sampling Frequency

- Initial sampling is intensive to establish a baseline...
  - ✓ 25-50 swabs/zone/day for a month!
- Routine sampling:
  - ✓ Weekly in Zone 1 (# can vary).
  - ✓ 10-15/week in Zones 2-3.
  - ✓ 5-10/month in Zone 4.
- Rotate sites.
  - ✓ Allow monitor discretion in site selection
  - ✓ Test each site 4 times/year.





# The Results...

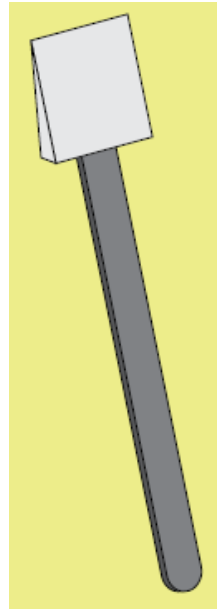
- The quantitative data from Zone 1 can be used to evaluate sanitation programs:

Table 3. Recommended Microbiological Indicator Limits for Equipment Cleaning Before and After Application of Sanitizer

Quantitative Microbiological Indicator Test	Target/ Acceptable Limits	Post-Heat Treatment Taken Before Sanitizer (cfu/40 in <sup>2</sup> )	Post-Heat Treatment – Pre-op Taken After Sanitizer (cfu/40 in <sup>2</sup> )
Aerobic Plate Count	Target	< 100	< 10
	Acceptable	< 500	< 100
Coliforms	Target	< 10	< 10
	Acceptable	< 100	< 50
Total Enterobacteriaceae	Target	< 10	< 10
	Acceptable	< 100	< 50

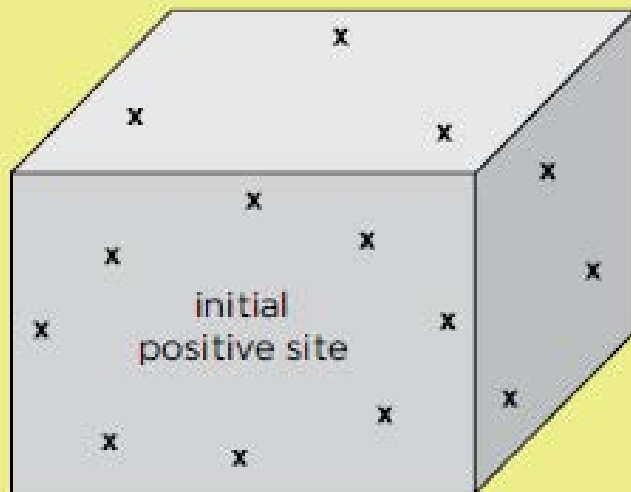
# Pathogen Results

- A response for (+) pathogen results is essential. Some typical corrective actions:
  - ✓ Cease production/quarantine the affected area (& product if zone 1).
  - ✓ Vector swab site & adjacent areas (zones 2&3).
  - ✓ Breakdown lines for inspection, swabbing & cleaning (zones 1&2).
  - ✓ Thoroughly clean site (50 ft. radius, zones 3&4).
  - ✓ Increase sampling frequency to daily until 3 (-) results occur.



# Example of Vector Swabbing

Figure 5. Vector Sponge/Swab Sampling Starburst Pattern Around the Initial *Salmonella* Presumptive Positive Site.



# Positive Result Follow-up...

- Reassemble your team.
  - ✓ *Root cause investigation (what happened?).*
  - ✓ *Review facility practices.*
  - ✓ *Possible causes include:*
    - *Maintenance/construction events.*
    - *Structural damage/roof leaks.*
    - *Changes in personnel, traffic patterns.*
    - *Changes in cleaning/sanitation.*



## Positive Result Follow-up...

- Use the team's findings to improve operations:
  - ✓ Reinforce training (GMPs).
  - ✓ Cleaning/sanitation.
  - ✓ Repairs/improvements.
  - ✓ Traffic patterns.



## Positive Result Follow-up...

- Proper disposition of product (zone 1 positive).
  - ✓ Product placed on hold.
  - ✓ Product can be re-worked or condemned.
    - **Validated processes only.**
  - ✓ Testing alone is not a suitable method of clearing product!

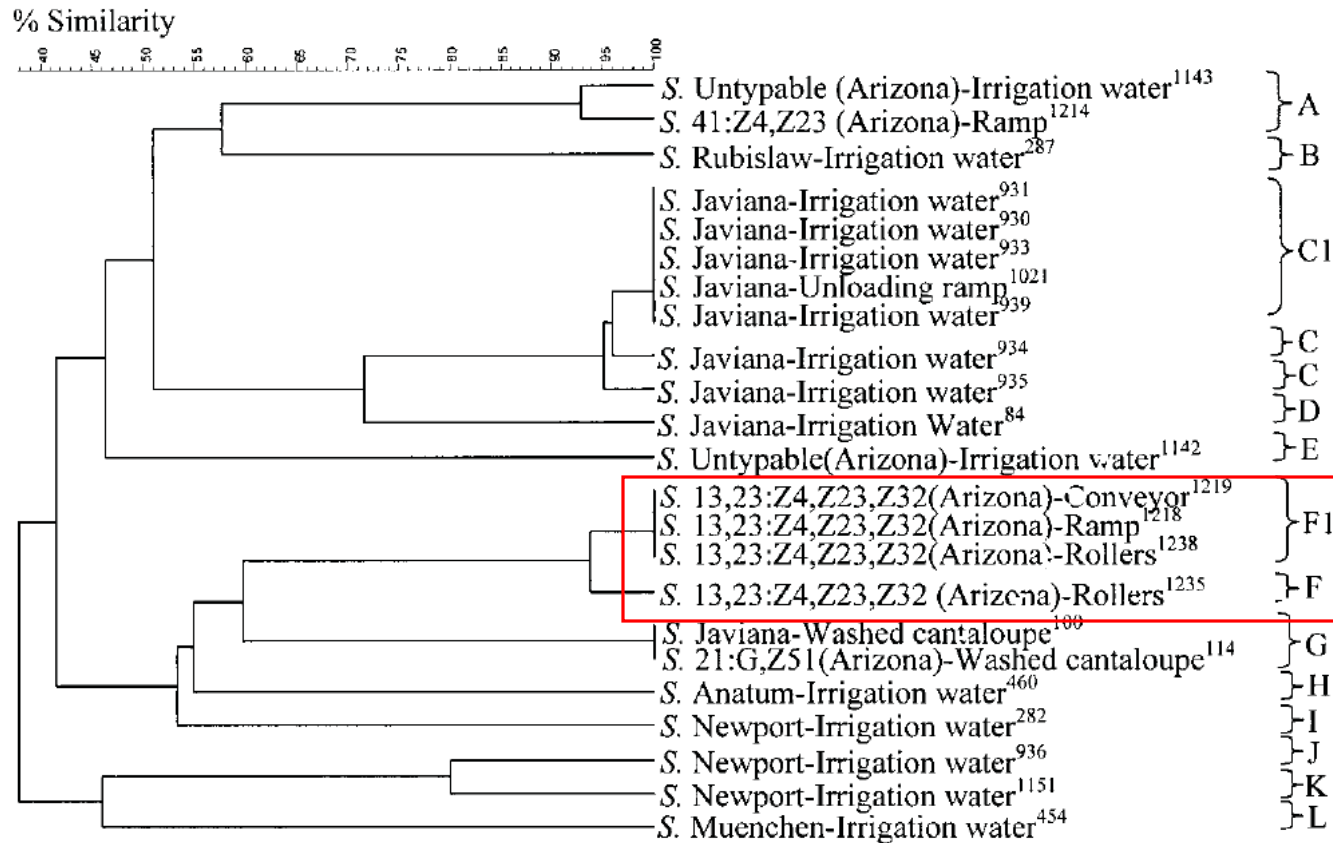




## Recurring Positive Results

- May indicate the presence of a resident strain:
  - ✓ Become established in “tough to clean areas”.
  - ✓ The same strain reappears and can contaminate product over long periods of time.
    - *S. agona* persisted for 10 years in a cereal facility!
- Transient strains:
  - ✓ Are “just passing through”...
  - ✓ Generally eliminated by cleaning/sanitation.

# Example of a Resident Strain:

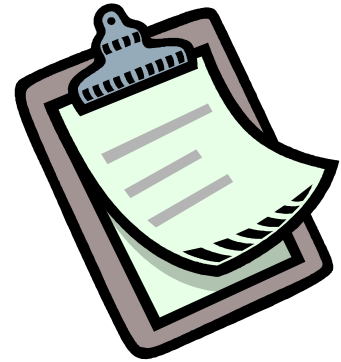


Equipment isolates are different from the fruit, irrigation water, etc!

Cantaloupe Study from Texas A & M (Duffy et. al, JFP, 2005)

# Documentation

- Monitoring:
  - ✓ Procedures & methods.
  - ✓ Training records
  - ✓ Assignment list.
  - ✓ Pre-operation Inspection logs.
- Corrective Action Records.
- Hold/Release Records.



## General Record-keeping Requirements (Subpart F)

- Original records, true copies or electronic.
- Must be accurate, indelible and legible.
- Contain actual observations, values.
- Created concurrently with the activity.
- Identify facility, date and time of activity.
- Signature or initials of creator.
- Retained for at least 2 years.
- Be retrievable within 24 hrs. of request.



# Two Recurring Issues with Programs

## 1. Not Enough Samples Are Taken.

- Too much time between samplings.*
- Not enough samples/day or zone.*



## 2. Positive Results Are Not Correctly Dealt With.

- Pathogen hits require immediate response!*

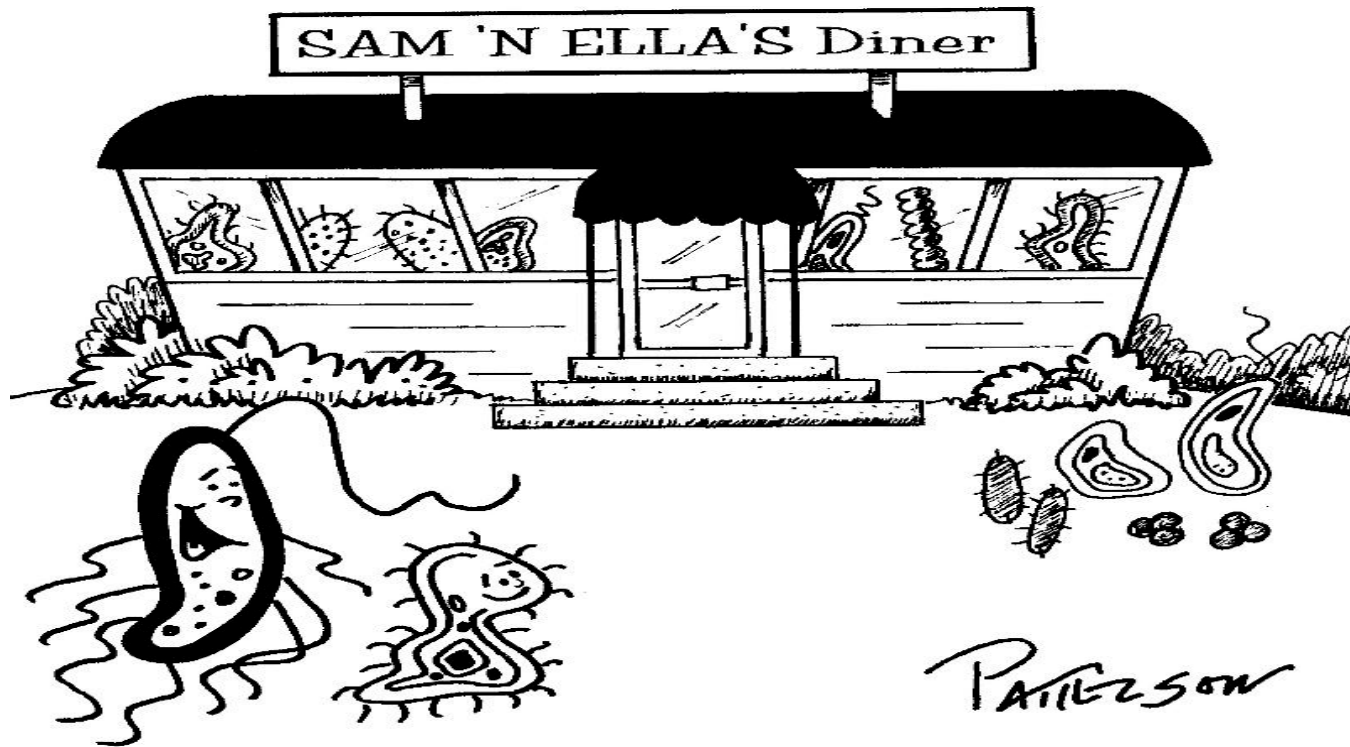
# The Value of a PEM Program

- It can make your operation better.
  - ✓ Eliminate niches/hot spots before they cause trouble.
- Demonstrates your food safety competence to visitors.
  - ✓ Auditors, buyers & regulators.
- A powerful training tool!
  - ✓ Can bring food safety home to workers!





## Questions on PEM?!



“Hey! – This looks like a good place!”

# Sanitation Verification



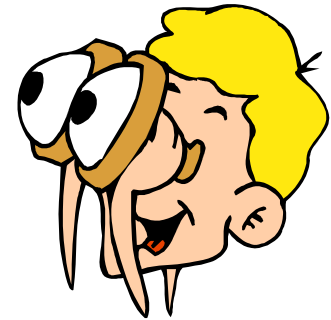
## **So What is Sanitation Verification?**

- A pre-operational examination of the food processing equipment/facilities.
  - ✓ Emphasize Zones 1 & 2.
- Determines if cleaning & sanitation have been effective.
- Establishes corrective steps to be taken if sanitation has been inadequate.
- Provides documentation of this process.

## Verification Techniques

Two of the oldest methods around use our own senses...

**Look** for visible product residues, scrape for biofilms.



**Smell** for spoilage/microbial growth (fermentation, rancidity).

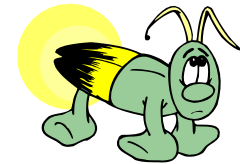
## Verification Techniques

- Microbiological swabs from the PEM program.
- Key indicator organisms can also include:
  - ✓ Yeast/Mold Counts (major spoilage organisms).
  - ✓ Coliforms (sanitizer effectiveness).
  - ✓ E. coli (FDA allows <0.36/gram in tree nuts).
- Waiting for results is a disadvantage...



# Chemical Methods of Verification

- ATP/Bioluminescence.
  - Detects food residues/microbes.
  - Limit of Detection = 1,000 microbes.
- Allergens
  - ELISA Kits
  - Specific for each type.
- Protein
  - Can be used for allergens.
  - Not sensitive enough for microbes.



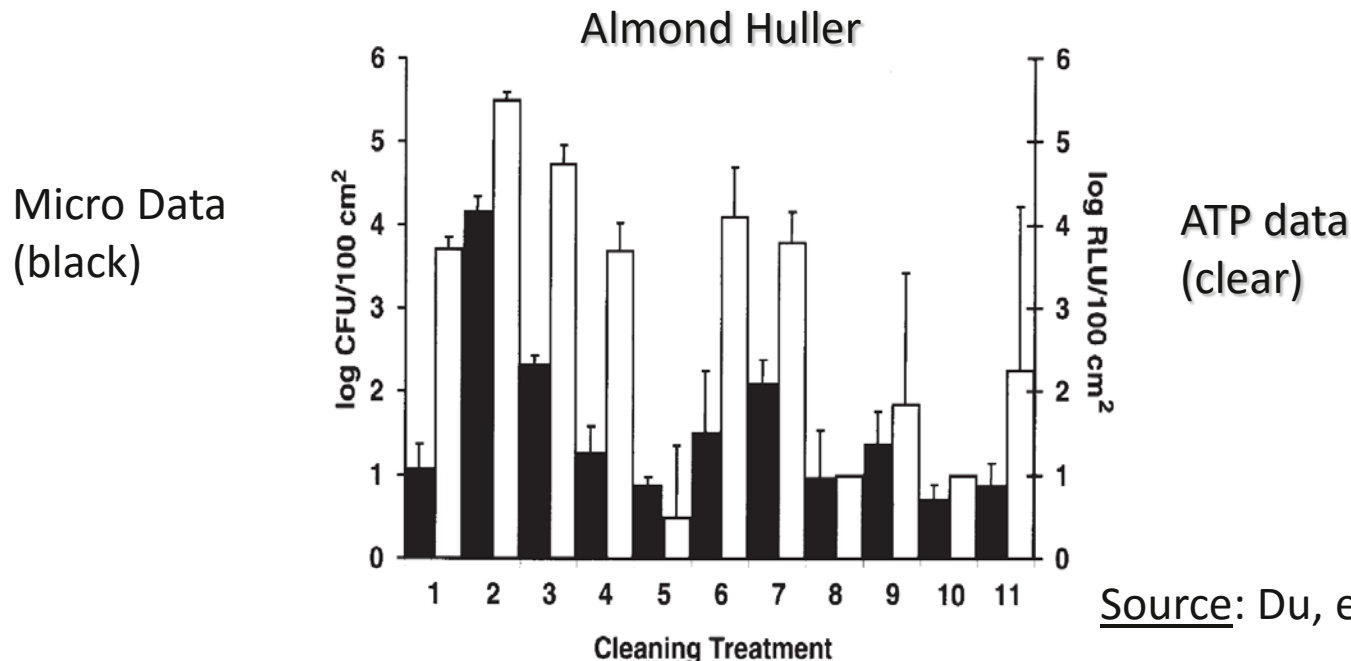
BioKits  
Walnut Assay Kit





# ATP/Bioluminescence

- Some drawbacks:
  - ✓ Calibrate for each process line (ATP levels vary).
  - ✓ Doesn't always work in a dry process:



Source: Du, et. al, FPT, 2007

# Establishing the Verification Program

- Same approach as establishing the PEM:
  - Assemble your team.
  - Establish sampling sites.
  - Determine your limits:
    - Industry standards (ABC data).
    - Collect your own baseline data
  - Set up routine monitoring:
    - Weekly for micro.
    - After each sanitation cycle (ATP).



# Establishing the Verification Program

- Results > Acceptable Limit = Sanitation Failure
- A failing result requires a response!
- Corrective actions include:
  - ✓ Repeat sanitation & verification (visual/ATP/allergen).
  - ✓ Product holds, review of sanitation practices & product testing (microbiological swabs).
  - ✓ Documentation is critical!

## Data Interpretation

- Tracking the data from each monitoring site can detect problems with sanitation:
  - ✓ Positive trending:  $\uparrow$  value =  $\downarrow$  sanitizer efficacy
  - ✓ Increased variability = inconsistent cleaning.
  - ✓ Increased readings & variability: cleaning and sanitizing are both in trouble!



# Success in Sanitation = Success in Swabbing!



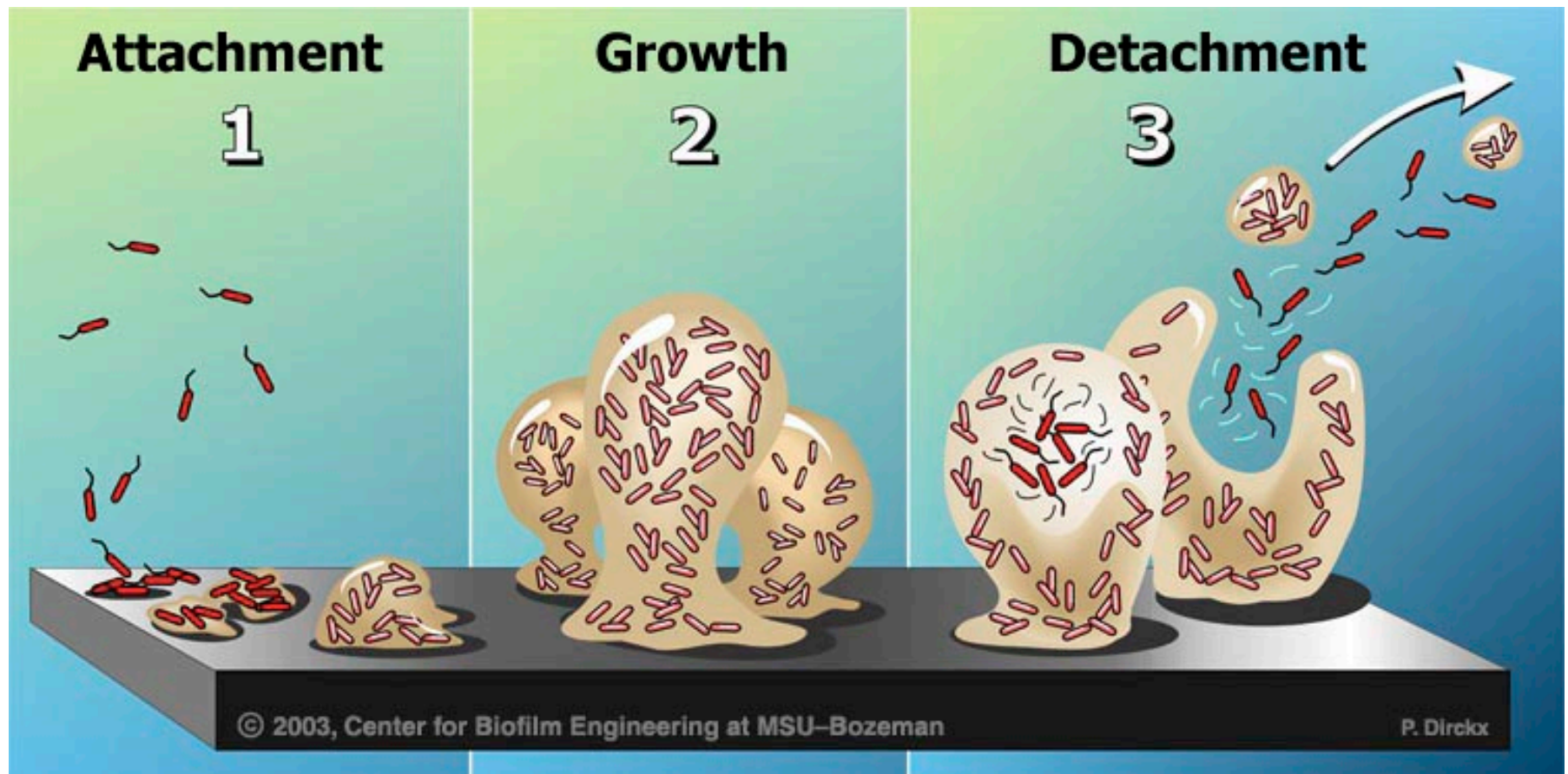
With that in mind, let's review sanitation basics...

# Sanitizing Without Cleaning is Pointless

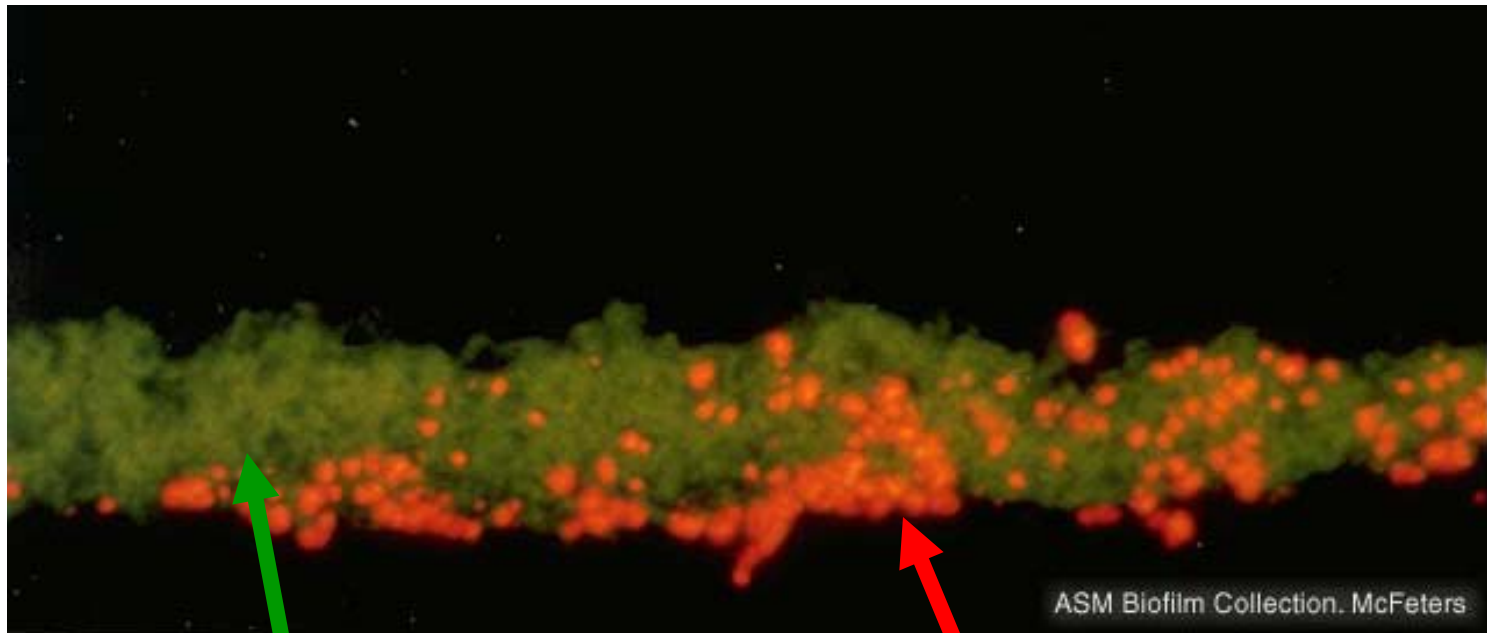
- Soils can inactivate the sanitizer before it kills the microbes. Ex: Hypochlorites and proteins.
- Microbes will form biofilms on a dirty surface.
- Biofilms are **highly resistant** to sanitizers..



# Birth of a Biofilm

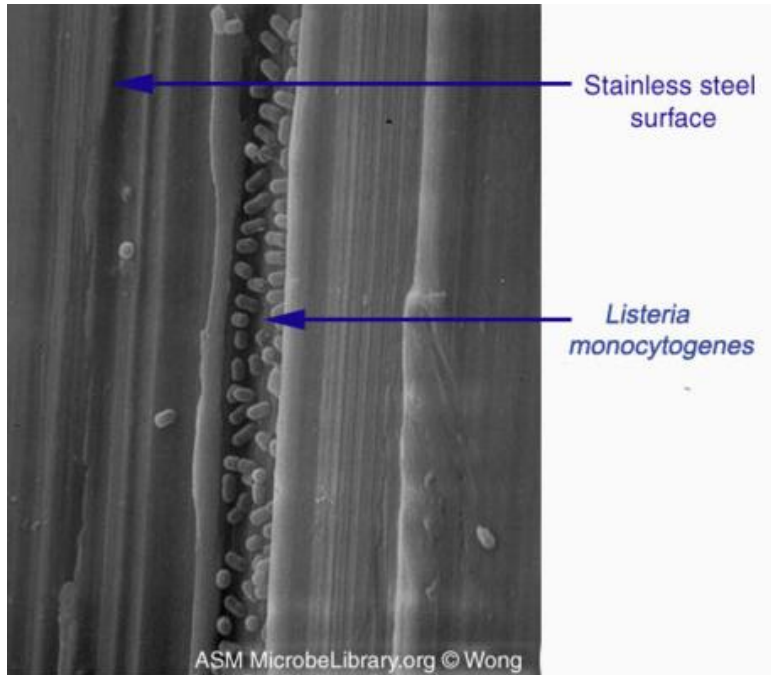


## 90 Minute Exposure to 4 ppm Chloramine



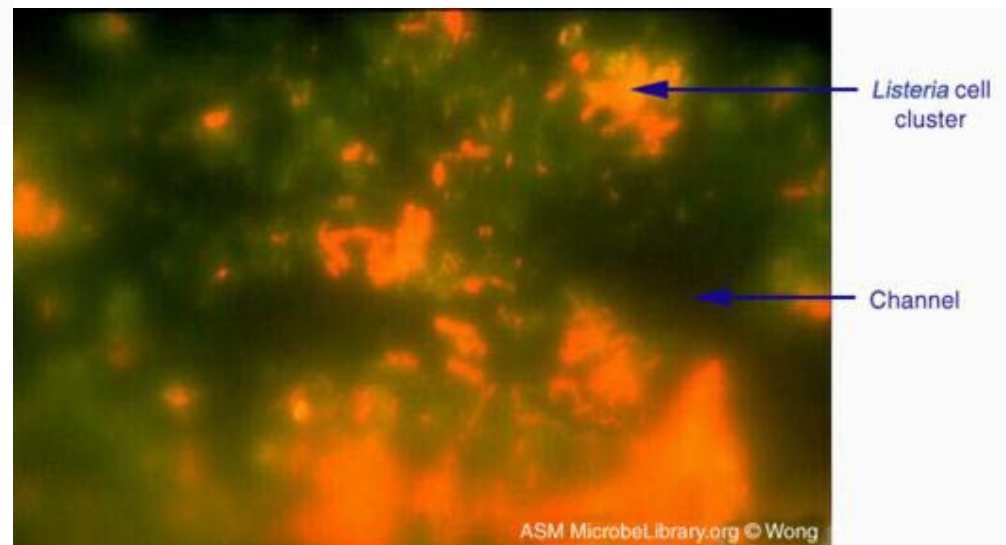
**Green (dead cells)**

**Red (living cells)**

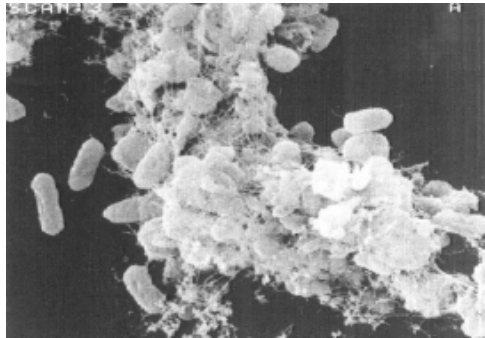


*Listeria* spp. form biofilms on many surfaces (stainless steel, rubber, polypropylene).

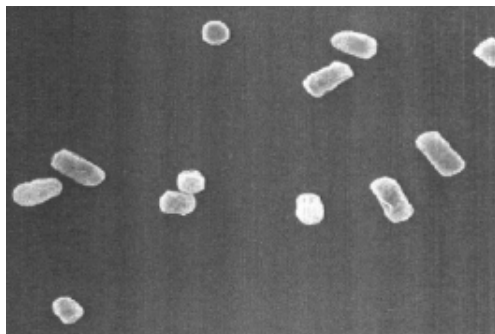
Biofilms can survive heat treatments, various sanitizers (hypochlorite, periacetic acid, quats).



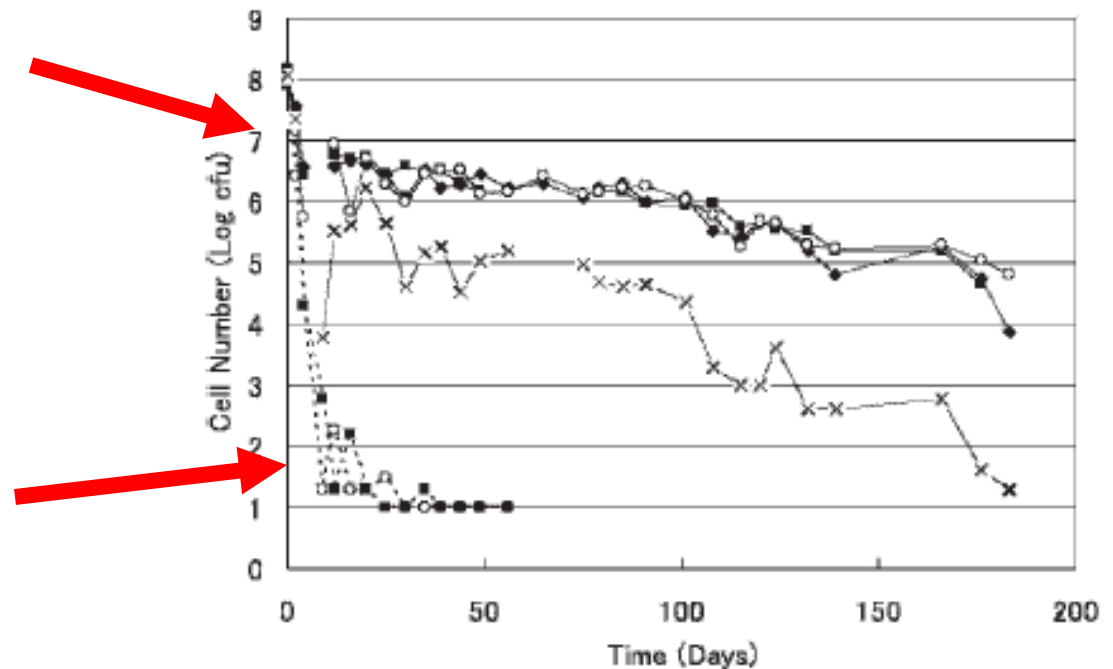
Biofilm (+) strains



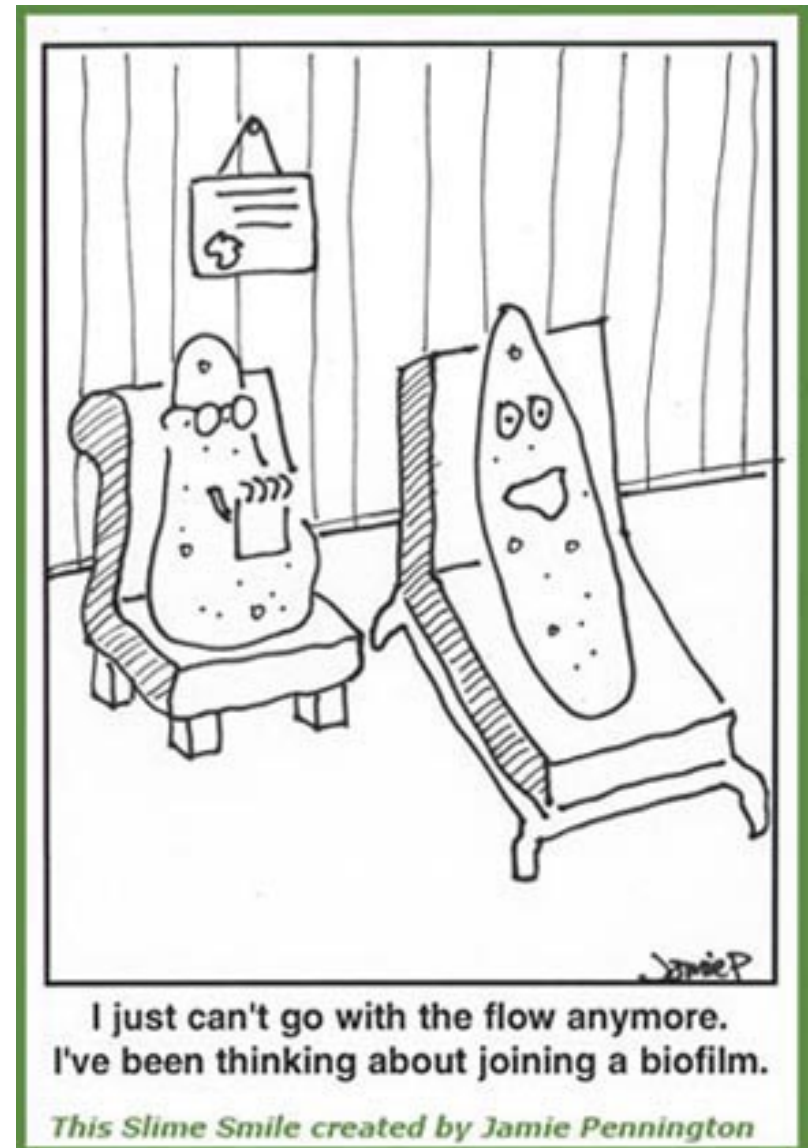
Biofilm (-) strains



Biofilm formation increases *Salmonella* survival in dry environments...



# Questions on Sanitation Verification?





## Concluding Remarks

- Environmental monitoring is your “early warning system”!
- Measures the performance of your food safety programs.
- Shows regulators & customers that you are serious about food safety.
- Provides valuable legal protection.

