DESIGNING AN EFFECTIVE SANITATION PROGRAM

BUILDING WORLD CLASS MICROBIOLOGICAL FOOD SAFETY SYSTEMS FOR THE COMING STORM

MARCH 20- 22, 2017

David Blomquist

DFB Consulting LLC

651-324-6158

TODAY'S TOPICS

- General Goal of Sanitation
- General Sanitation Process
- Soil Types
- Sanitation Process
- Biofilms and best practices for removal
- Sanitary Design and Why it is Critical

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"

World Health Organization (WHO)

- 1st Priority – Management Commitment
- NOT limited to Cleaning and Sanitizing

GENERAL GOALS OF SANITATION

- Removal of unwanted residues from surfaces of equipment
- Removal of soils from the environment
- Elimination of pathogenic bacteria from processing area
- Elimination or control of spoilage organisms in the environment

GENERAL CLEANING CONSIDERATIONS

- Determine appropriate level of Clean and required cleaning methodology for each activity, taking into account the following:
  - Allergens
  - Microbiological sensitivity of the food and manufacturing system
  - Regulatory requirements (USDA-FSIS, FDA, etc.)
  - Cleaning restrictions (e.g. organic)
- Keep dry areas dry!
- Controlled wet cleaning in both wet and dry facilities.

GENERAL CLEANING CONSIDERATIONS:

WHAT IS CLEANING?

REMOVAL OF ALL UNWANTED MATERIAL ON A SURFACE.

Four Phases of Wet Cleaning:

- Soil penetration - Surface wetting
- Soil dispersion
- Soil suspension
- Prevent re-deposition of removed soil

GENERAL CLEANING CONSIDERATIONS:

What is soil & how do we classify it in the food industry?

Soil Classification - *Chemistry*

- **Protein**
- **Fat**
- **Carbohydrates**
- **Mineral Salts**

Inorganics

Soils generally are not a pure composition, but a mixture of all of these.

GENERAL CLEANING CONSIDERATIONS:

- Water Soluble
  - Salts & Sugars
- Water Insoluble
  - **Alkali Soluble**
    - Fats & Oils, Complex Carbohydrates
  - **Alkali / Oxidizer (Chlorine, Peroxide, Peracid) Soluble**
    - **Protein**
  - **Acid Soluble**
    - Inorganics/ Minerals
    - Complex Carbohydrates
    - Un-Denatured Protein
- **Water Insoluble & Acid / Alkali Insoluble**
  - Fiber (Cellulose), Carbon, TiO_2

FORMULATED / BUILT DETERGENTS

Optimized chemistry = Cleaning efficiency & efficacy

- **Handle variety of soils**
  - **Soils generally are not a pure composition**
- **Handle various water conditions**
- **Clean with less caustic**
  - Lower alkalinity
  - Lower pH
  - Less rinsing needed to bring back to a neutral pH
- **Better at biofilm removal**
  - (Antoniou & Frank. 2005. JFP 68(2):277-281)

FORMULATED / BUILT DETERGENTS

- **Alkaline** **or *Acid*** ***(Not normal – e.g. undenatured whey protein)***
  - **Dissolve proteins**
- **Oxidizing Agent – e.g. chlorine or peroxyacetic acid**
  - **Hydrolyze proteins**
- **Enzyme (protease)**
  - **Catalyst to hydrolyze proteins**
  - However, when using these at normal concentrations, temperature & contact time we probably **do not** achieve >80% hydrolysis, which renders the protein non-allergenic.

FORMULATED / BUILT DETERGENTS

- **Temperature**
  - Important in removal of all soils, but especially with fats & greases.
- **Surfactants**
  - Wetting/penetration
  - Emulsification
  - Suspension
- **Alkaline**
- **Solvents**

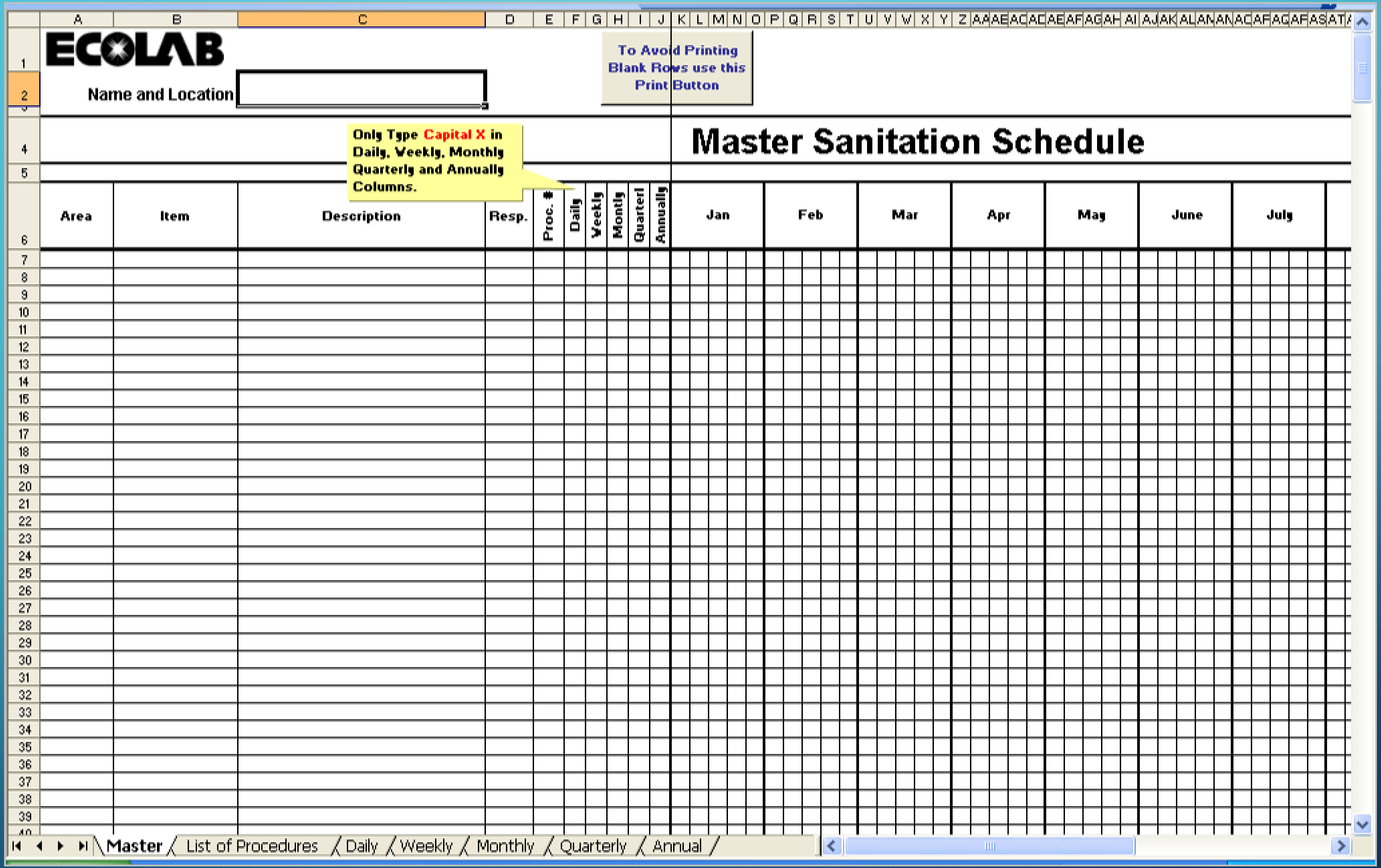
FORMULATED / BUILT DETERGENTS

- **Sugars**
  - Soluble in warm water
- **Starches**
  - **Alkaline or Acid Cleaner**
    - Sulfamic acid
  - **Enzyme (Amylase)**

REQUIREMENTS:

- Master Sanitation Schedule
- Sanitation SSOP
- Daily Cleaning Procedure

EXAMPLE MASTER SANITATION SCHEDULE



Complete list of all equipment and areas of the facility and their cleaning frequency

EXAMPLE SANITATION SSOP

Plant:
Processing Area:
Equipment:
Cleaning Frequency:

Date:
Revision Date:

Task Description	Chemicals Required	Chemicals Used	Cleaning Equipment	Completion Check List
I. Preparation:				
1.				
2.				
II. Pre-Rinse				
3.				
III. Application of Cleaning Chemicals				
4.				
5.				
6.				
7.				
8.				
IV. Post Rinse:				
9.				
V. Inspection of Equipment				
10.				
11.				
VI. Sanitizer Application				
12.				

Approved by: ______________________

Date: ______________________

Detailed procedure for management review and documentation of process

EXAMPLE DAILY CLEANING PROCEDURE

	A Partnership in Sanitation	**ECOLAB** Food & Beverage Division

Kettles

Safety Precautions

- **Chemical Emergency Call: 800-328-0026.**
- When using Chemicals always wear goggles/face shield, boots, gloves, and chemical apron.
- Use lockout/tagout as required by plant procedures.
- Use Confined space entry as required by plant procedures when entering these areas.
- Use caution when walking on wet floors.
- Read and understand all product labels and Material Safety Data Sheets (MSDS).

Chemical Step	Product	Amount	Concentration	Time	@ Temperature
Foam cleaning	Questar Acid		2-6 oz./gal.	5-15 min.	Ambient
Acid cleaning	Questar Acid NF		2-4 oz/gal	60 min	150oF
Sanitize	Vortexx		1-2 oz/ 6 gal	1 min	Ambient

Sanitation Procedures

Preparation

1. Thoroughly rinse all corn soils from the kettle using warm water from hose.
2. Foam the outside of the kettle with QUESTAR ACID, covering surfaces from bottom to top. Allow the foam to stay in contact with the surfaces for 10-15 minutes. DO NOT ALLOW FOAM TO DRY ON THE SURFACE.
3. Rinse the foam thoroughly.
4. Fill the kettle, then add QUESTAR ACID NF to the kettle to achieve 5000-7500 ppm.
5. Turn on agitator, set temperature for 150°F, and allow to clean for 60 minutes.
6. At the end of the wash, dump acid solution, or transfer it to another vessel for cleaning.
7. Inspect kettle for any areas not cleaned completely. Foam with QUESTAR ACID and brush clean.
8. Rinse kettle thoroughly inside and out.
9. Sanitize with Vortexx at 1300 - 2600 ppm total product.
10. Allow to air dry.

Step by step instructions for employees performing the actual cleaning

STEPS OF EFFECTIVE WET SANITATION

1. Dry Clean - remove food and packaging
2. Pre-rinse
   - Removes lose soils to allow the cleaners to penetrate the soils
3. Soap and Scrub
4. Rinse and Inspect
5. Assemble
6. Pre-Op Inspection & Cleaning Verification
7. Sanitize – EPA Registered Food Contact Sanitizer

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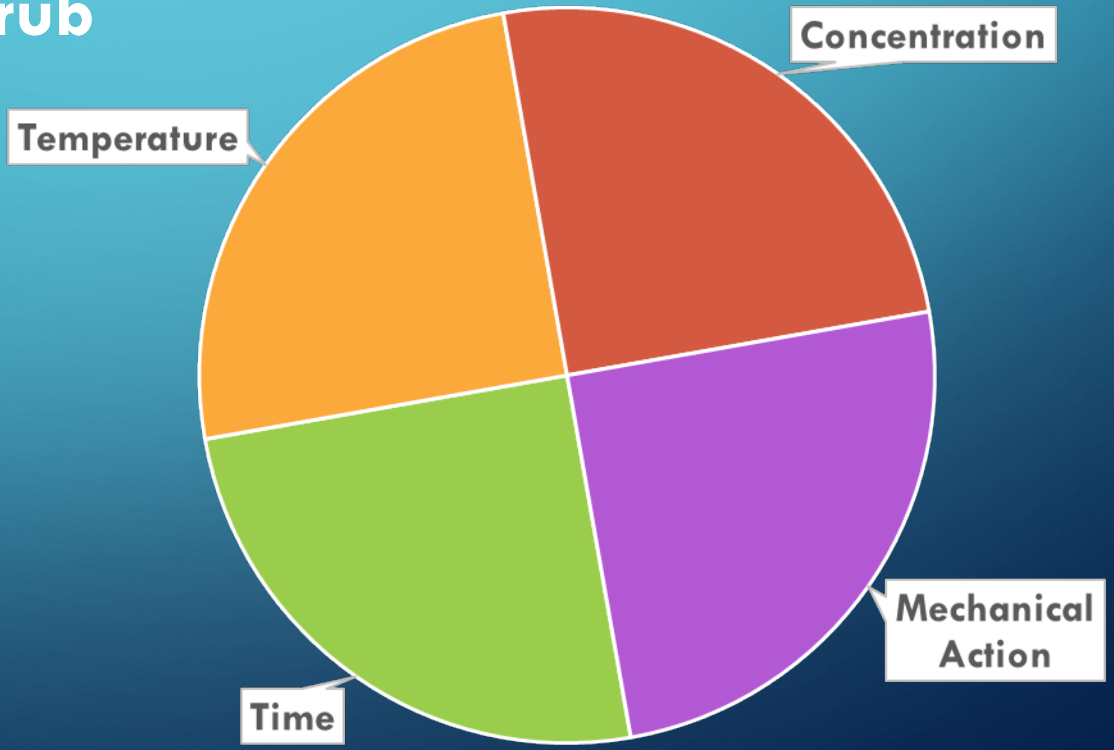

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3. Soap and Scrub
4. Rinse and Inspect
5. Assemble
6. **Pre-Op Inspection & Cleaning Verification**
    - Visual
    - ATP
    - Microbial
    - Allergen

STEPS OF EFFECTIVE WET SANITATION

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    - Removes lose soils to allow the cleaners to penetrate the soils
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4. Rinse and Inspect
5. Assemble
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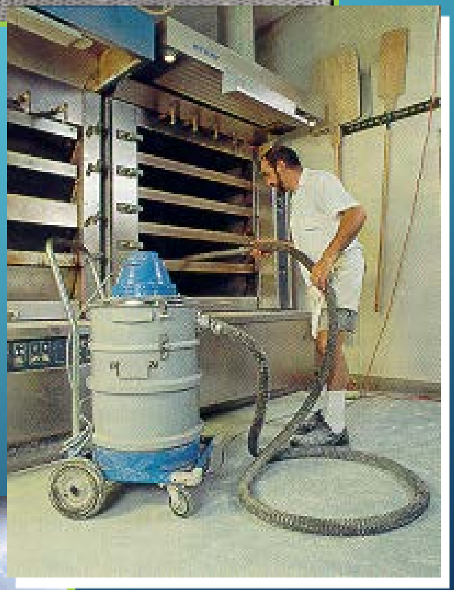
STEPS OF EFFECTIVE DRY SANITATION

1. **Sanitation preparation**
2. **Secure & disassemble equipment**
3. **Dry clean -** *(or isolated wet clean – ensure dry before returning)*
4. **Detail Clean – Work Top Down – which method will you use?**

METHODS OF DRY CLEANING

- Sweeping
- Brushing / Scraping
- Vacuuming[1]
- *Blowing – Compressed air*[2]
- *Blasting*[3]



[1] Must be HEPA Filtered

[2] Not recommended – blows soil around, not contained and captured

[3] Residue must be contained

CLEANING CAPABILITIES

- **Soda Blast**
  - Hard inelastic soils
- **ExaStrip SensiClean**
  - Hard inelastic soils
- **Dry Ice Blast**
  - Hard inelastic soils
  - Soils that freeze harden
- **Hand Clean Dry**
  - All soil types

Photo source: Ecolab

LOW PRESSURE STEAM - AMERIVAP

Benefits

- Moderate capital cost
- Allows for use of wet chemistry
- High temperature - sanitizing
- No dust
- No media

Has been shown to be effective for allergen removal

Limitations

- Steam vapor
- Residual water
- Adequate electrical supply
- May not work on some soils

Source: AmeriVap

STEPS OF EFFECTIVE DRY SANITATION

1. Sanitation preparation
2. Secure & disassemble equipment
3. Dry clean - *(or isolated wet clean – ensure dry before returning)*
4. Detail Clean – **Work top down**
5. Post inspection & reclean
6. Pre-Op Inspection, cleaning verification & reassembly
7. Sanitize – Non-aqueous EPA Registered Food Contact Surface Sanitizer

EPA CATEGORIES

- Sterilant – Complete kill of all organisms
- Disinfectant – Complete kill of vegetative organisms
- Sanitizer - Provides a 5 log (99.999% reduction) of bacteria within 60 seconds

Must contact the organism to kill it

SANITIZERS

- Chlorine
- Iodine
- Quaternary Ammonia
- Peroxyacetic Acid
- Mixed Peroxyacetic Acid
    - Peroctanoic acid
    - Persulfonate
- Aqueous Chlorine Dioxide
- Ozone
- Perquat (Hydrogen Peroxide and Quaternary Ammonia)

SANITIZERS

- Chlorine
  - Quick kill - oxidizer
  - Effective against yeast & mold
  - Affected by organic matter

SANITIZERS

- Chlorine
- **Iodine**
  - Oxidizing sanitizer- quick kill and effective against yeast & mold
  - More tolerant of soil than chlorine
  - Can cause staining and can be corrosive
  - If temperatures are >100 degrees it will sublime and deposit iodine on equipment surfaces

SANITIZERS

- Chlorine
- Iodine
- **Quaternary Ammonia**
  - Soft metal safe
  - Provides residual effect so is useful for environmental sanitizing
  - Works on cell wall

SANITIZERS

- Chlorine
- Iodine
- Quaternary Ammonia
- Acid Anionic Sanitizers
  - Requires low pH <3.8 -4.0
  - Effective against bacteriophage
  - Low pH provides control of minerals
  - pH must be below 3.0

SANITIZERS

- Chlorine
- Iodine
- Quaternary Ammonia
- Acid Anionic Sanitizers
- Fatty Acid Sanitizers
  - Low foam for CIP application
  - Efficacious up to pH 3.8 – 4.0

SANITIZERS

- Chlorine
- Iodine
- Quaternary Ammonia
- Acid Anionic Sanitizers
- Fatty Acid Sanitizers
- Peracetic Acid Sanitizers
    - Oxidizing sanitizers
    - Not as affected by organic materials
    - Fast acting oxidizing sanitizer

SANITIZERS

- Chlorine
- Iodine
- Quaternary Ammonia
- Acid Anionic Sanitizers
- Fatty Acid Sanitizers
- Peracetic Acid Sanitizers
- Mixed Peracetic Acid Sanitizers
    - Peroctanoic acid
        - More efficacious on yeast & mold

SANITIZERS

- Chlorine
- Iodine
- Quaternary Ammonia
- Acid Anionic Sanitizers
- Fatty Acid Sanitizers
- Peracetic Acid Sanitizers
- Mixed Peracetic Acid Sanitizers
- Ozone
  - Strong oxidizer
  - Quick kill but not very soluble in water

SANITIZERS

- Chlorine
- Iodine
- Quaternary Ammonia
- Acid Anionic Sanitizers
- Fatty Acid Sanitizers
- Peracetic Acid Sanitizers
- Mixed Peracetic Acid Sanitizers
- Ozone
- Aqueous Chlorine Dioxide
  - Strong oxidizer
  - Quick kill but not very soluble in water (more soluble than ozone)

SANITIZERS

- Chlorine
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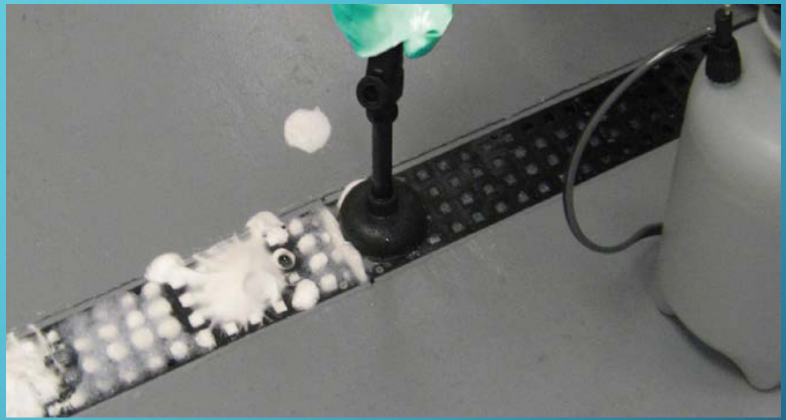
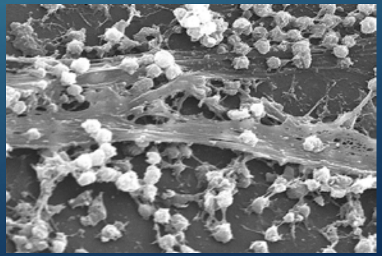


- Perquat disinfectant
  - Both powdered and liquid forms available
  - 2 part liquid mixed together create bubbles that penetrate otherwise inaccessible areas
  - Have been shown to be very effective in reducing environmental contaminants e.g. salmonella or *Listeria*

BIOFILMS

A biofilm is any group of microorganisms in which cells stick to each other and often these cells adhere to a surface. These adherent cells are frequently embedded within a self-produced matrix of extracellular polymeric substance (EPS).

Source: Wikipedia



New Approaches to Improving Your Profitability by Controlling Spores

3-A SSI 2015 Education Conference

- The Bridge to Hygienic Design

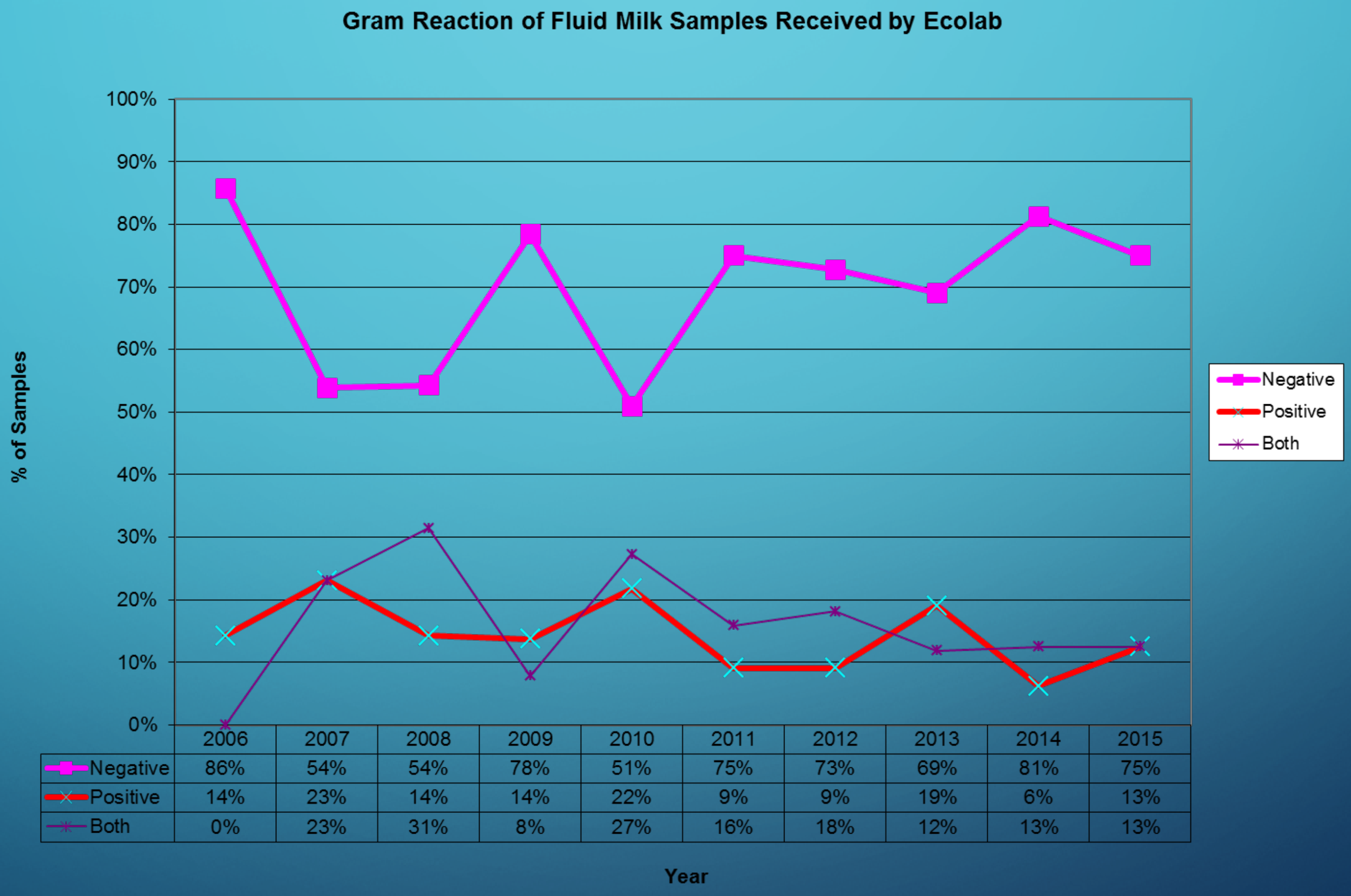
May 12 2015

David Blomquist Executive Technical Affairs Specialist

CAUSES OF SPOILAGE – PASTEURIZED REFRIGERATED DAIRY PRODUCTS

- Gram Negative Bacteria
  - Post pasteurization contamination
- Gram Positive Bacteria
  - Can survive pasteurization
- Heat Tolerant Enzymes
  - Rare occurrence but are due to raw milk issues

AS SHELF LIFE HAS INCREASED, GRAM POSITIVE ORGANISM ISSUES HAVE TOO.



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Negative	86%	54%	54%	78%	51%	75%	73%	69%	81%	75%
Positive	14%	23%	14%	14%	22%	9%	9%	19%	6%	13%
Both	0%	23%	31%	8%	27%	16%	18%	12%	13%	13%

WHERE DO HEAT RESISTANT PSYCHROTROPHS (HRP'S) COME FROM?

One problem is the low level of contamination in the raw milk:

- Dr Mansel Griffiths of the University of Guelph reported the average contamination level of Heat Resistant Psychrotrophs (HRP's) at 17 cfu/L → *Chances of finding it in a typical 5 mL lab pasteurization (SMEDP 17th edition) sample is approximately 1 in 60*

Data Courtesy of Darryl Bigalke
QMI Systems

What are build-up points?

Paper from the Australian Journal of Dairy Technology Volume 47 – May 1992
Bacterial Growth During Continuous Milk Pasteurisation – F.L. Lehmann, P.S. Russell, L.S. Solomon and K.D Murphy

"Total Bacterial numbers increased slightly over the initial 8-9 h, then more rapidly, sometimes exponentially, over the remaining period of operation, reaching in excess of one million per mL and exceeding the total bacterial numbers in the raw milk…. A 20 minute caustic miniwash of pasteurisers after 10 h of continuous operation was shown to reduce bacterial numbers in pasteurized milk…"

Biofilm

What are build-up points?

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Unfortunately this biofilm is not completely removed by conventional short washes and returns more quickly the second time

Biofilm

Biofilm Formation

- Vegetative cell population is needed to get spores
- Residual soil acts as hybrid biofilm/soil matrix
- Nooks and Crannies
  - Gasketed joints
  - Valves
  - Plate heat exchangers
  - Evaporators
- Low flow areas
- Biofilms generated/rejuvenated during long runs
- Spores quickly attach and are TENACIOUS

SPORES ARE TENACIOUS

10^2 cfu/ml spores in suspension

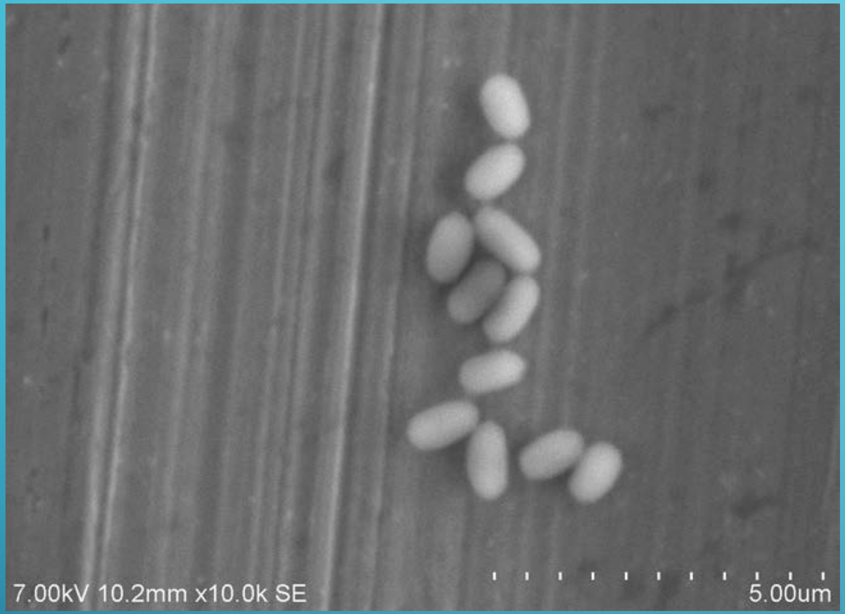
316 Stainless Steel coupons

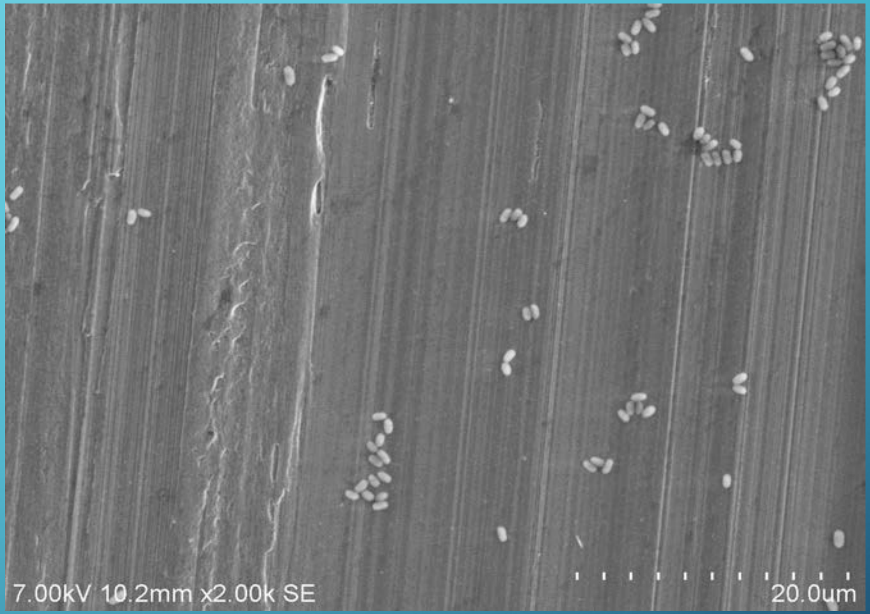
Soaked in dairy plant isolate spore cocktail suspended in milk

Rinsed THOROUGHLY with sterile DI water

Covered in nutrient agar w/ metabolic dye (dark spots)

SPORE ADHESION TO STAINLESS STEEL

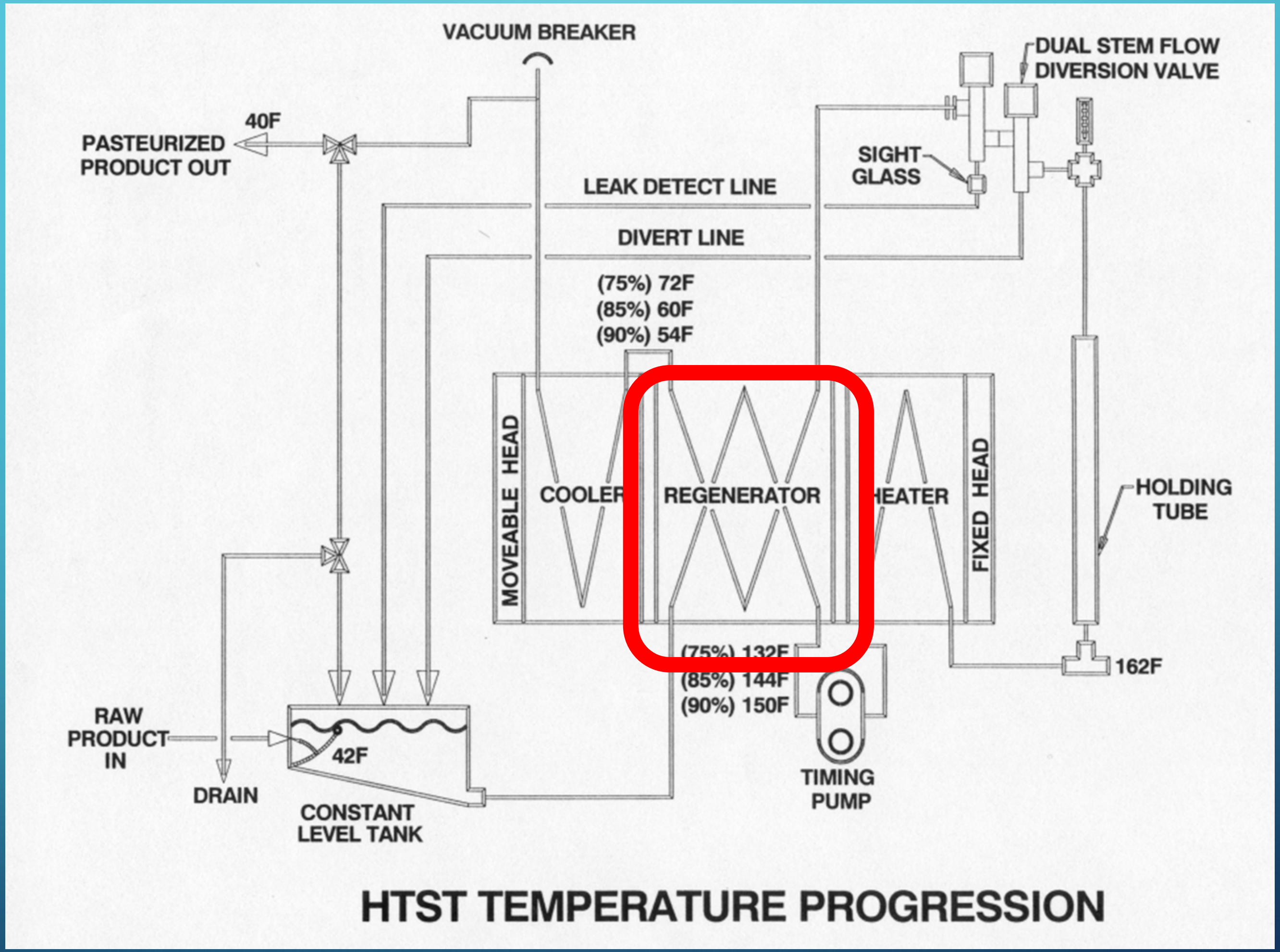




Cleaning with strong caustic DID NOT REMOVE THE SPORES

Peroxide/peracid cleaning removed most of the soil but did not get all the bacterial residue off the surface. (No viable cells recovered)

What are build-up points?



SEPARATOR/CLARIFIER

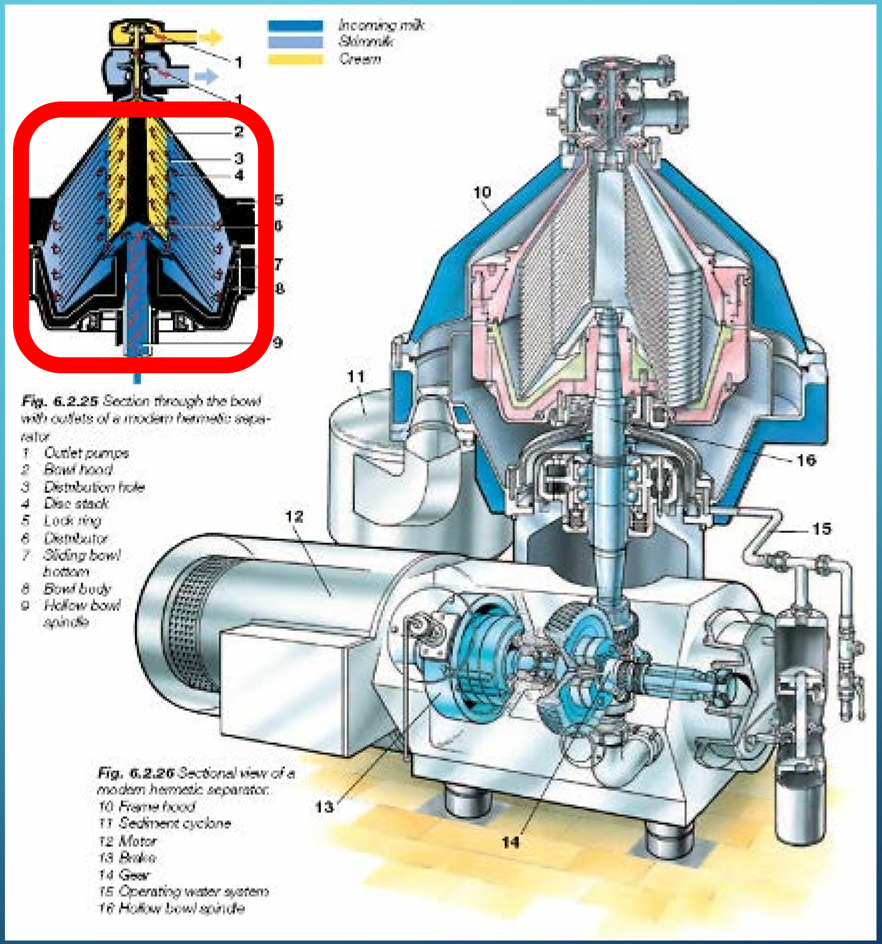
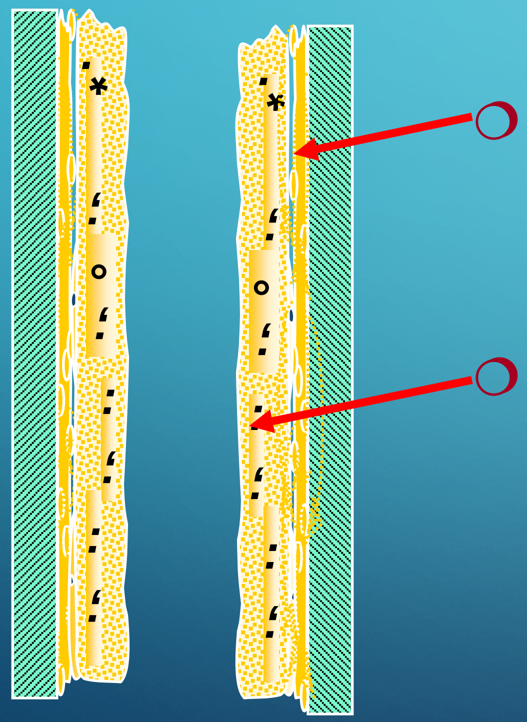


Fig. 6.2.25 *Section through the bowl with outlets of a modern hermetic separator*
1 Outlet pumps
2 Bowl hood
3 Distribution hole
4 Disc stack
5 Lock ring
6 Distributor
7 Sliding bowl bottom
8 Bowl body
9 Hollow bowl spindle

Fig. 6.2.26 *Sectional view of a modern hermetic separator.*
10 Frame hood
11 Sediment cyclone
12 Motor
13 Brake
14 Gear
15 Operating water system
16 Hollow bowl spindle

FOULING MECHANISM THEORY TUBE EXAMPLE

How does fouling build-up in heat exchangers?

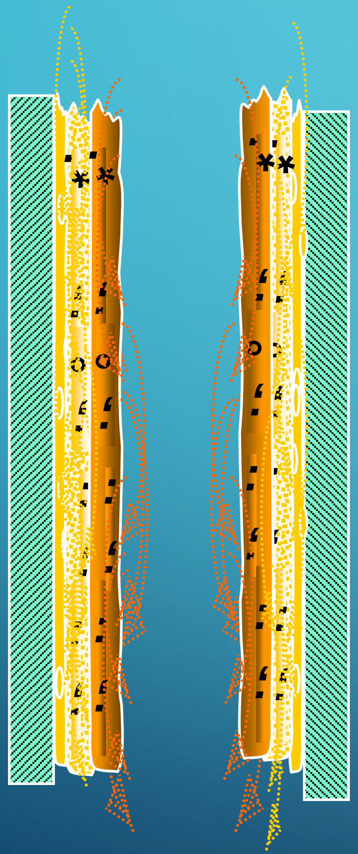


The fouling layer is built-up by two different types of deposit:

- On the stainless steel surfaces of the pipe a dense mineral deposit layers is formed
- On top of this first layer forms a second layer consisting of a matrix of proteins, fat, and carbohydrate depending on process stream

CAUSTIC CLEANING DETAILS DAIRY EXAMPLE

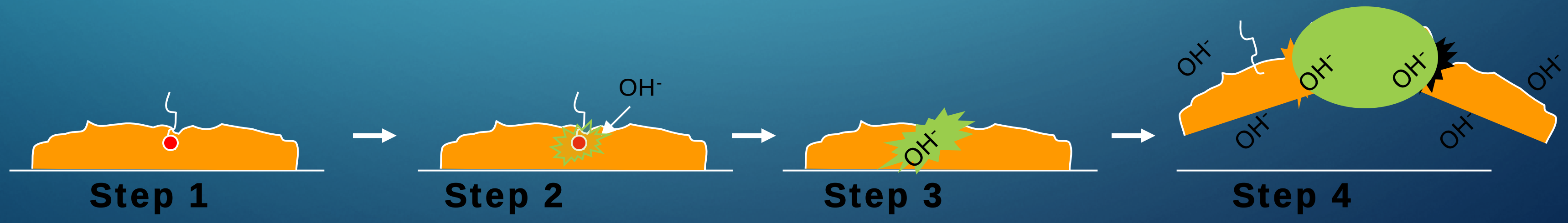
The influence of NaOH concentration



- High caustic concentrations cause the fouling layer to swell causing gel formation of the protein (rubber-like top layer), thus preventing further penetration of the alkaline cleaning solution into the soil layer.
- Consequently the soil removal takes more time.
- The degree of “polymerisation” depends on NaOH concentration, soil temperature and contact time.

STEP-BY-STEP CLEANING APPROACH

- **STEP 1:** The pre-treatment product (peroxide/peracid) is circulated through system prior to alkaline wash - active ingredients penetrate the soil layer
- **STEP 2**: Immediately following Step 1, an alkaline detergent is circulated through the system; the rise in pH triggers Step 3
- **STEP 3:** The hydroxide ions interact with the oxygen components, triggering a reaction that ruptures the burnt-on soil matrix into pieces
- **STEP 4:** With the soil removed from the surface and broken into smaller pieces the mixed cleaning solution easily removes the remaining soil



NEW CLEANING PROCEDURE – HEATED SURFACES

- Pre-Rinse
- Alkaline Wash
  - Add peroxide/peracid additive
  - Circulate for 1-2 circuits (time varies with size of equipment)
  - Add caustic and heat to 170° F
- Post Rinse
- Normal acid wash
- Post Rinse
- Sanitize with mixed peracid at 140 degrees

NEW PROCEDURE – COLD WALL EQUIPMENT – FILLERS, LINES, TANKS, TRUCKS

- Prerinse
- Alkaline wash with peroxide/peracid additive
  - Add peroxide/peracid and circulate for 1-2 rounds as it is heating up
  - Add alkaline cleaner as heating continues and wash at normal temperatures
- Post rinse
- Sanitize with mixed peracid sanitizer at 140 degrees
- If needed, cool the surfaces with sanitizer at ambient

CASE STUDY: SKIM MILK EVAPORATOR

- Challenge:
  - Soiled evaporator that was not passing inspection
  - Fouled and plugged tubes reducing efficiency
- Results:
  - Significantly improved cleaning results
  - Reduction in plugging of tubes

CONTROL AFTER CONVENTIONAL CIP PROGRAM

AFTER ADVANCED CLEANING CIP PROGRAM

Photos: Paul Schacht - Ecolab

PEROXIDE CLEANING PROGRAM BENEFITS

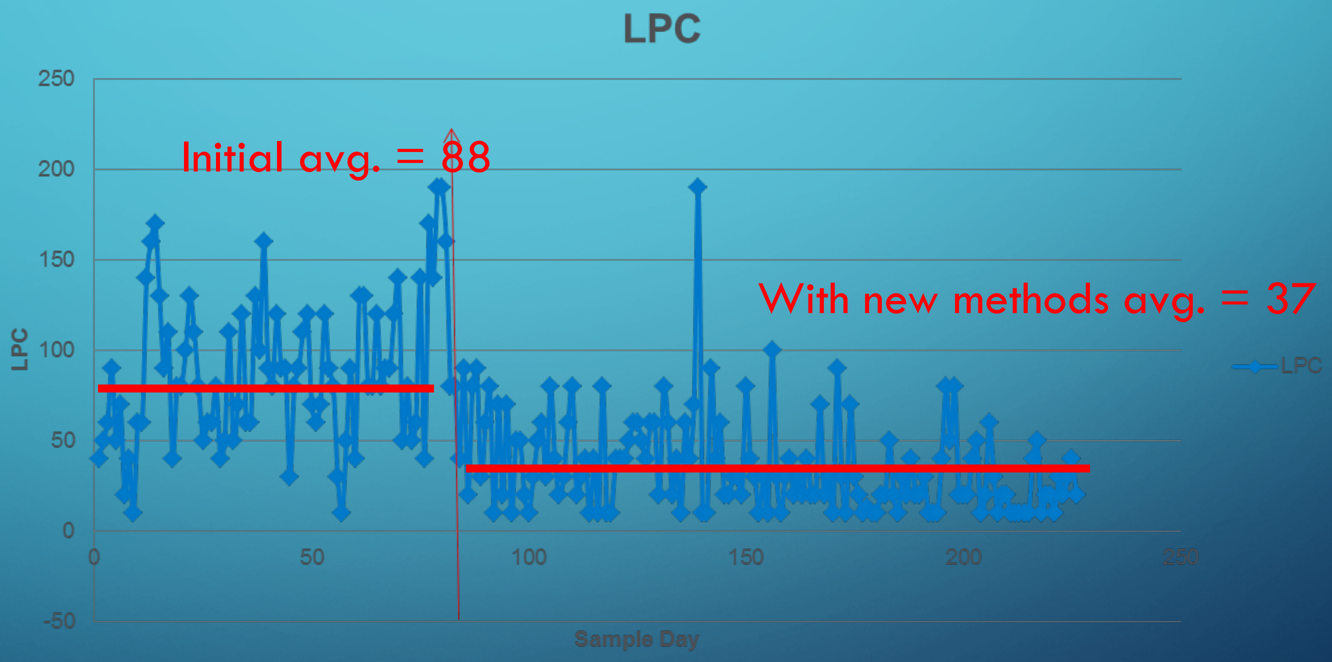
- Penetration of cracks and crevices for better cleaning – helps remove soils in damaged gaskets
- Temperatures above 170° F and alkaline solutions break down peroxide & peracid to give mechanical action
- The oxidizing effect of the additives and the additional mechanical action have shown to remove soils more effectively
- Time savings have been achieved by faster removal of soils
- Significantly lower SPC counts have been documented in powder operations
- Spore related defects have been eliminated in Swiss cheese
- Late blowing defect has been controlled in cheddar cheese

PEROXIDE CLEANING PROGRAM POTENTIAL DRAWBACKS

- Oxidizing effects of products may decrease life of gaskets
  - Effect is not likely to be more than the use of nitric acid
- Odor of high temperature peracid may be objectionable
  - Reduced with new peracid - Synergex

COST BENEFITS OF THE PROGRAM

- Powder plant was able to make 8 fold increase in low spore count product. Increased sales dollars by approximately $15,000,000
- Farm saw LPC counts stabilize. ***Monthly Premium was $25,000*** when average <50



FARM PROGRAM CHALLENGES & SOLUTIONS

- Most farms can't achieve high temperature
  - Even at temperatures below 170 degrees, the peroxide/peracid additive provides oxidizing ability which will remove soils
  - Alternately a low temperature two part cleaner provides mechanical action to achieve better soil removal
- Most farms use a chlorinated alkaline cleaner
  - The peroxide and chlorine produce an "exited oxygen molecule" (singlet oxygen species) that also enhances the soil removal

HOW DO YOU DETECT A BIOFILM?

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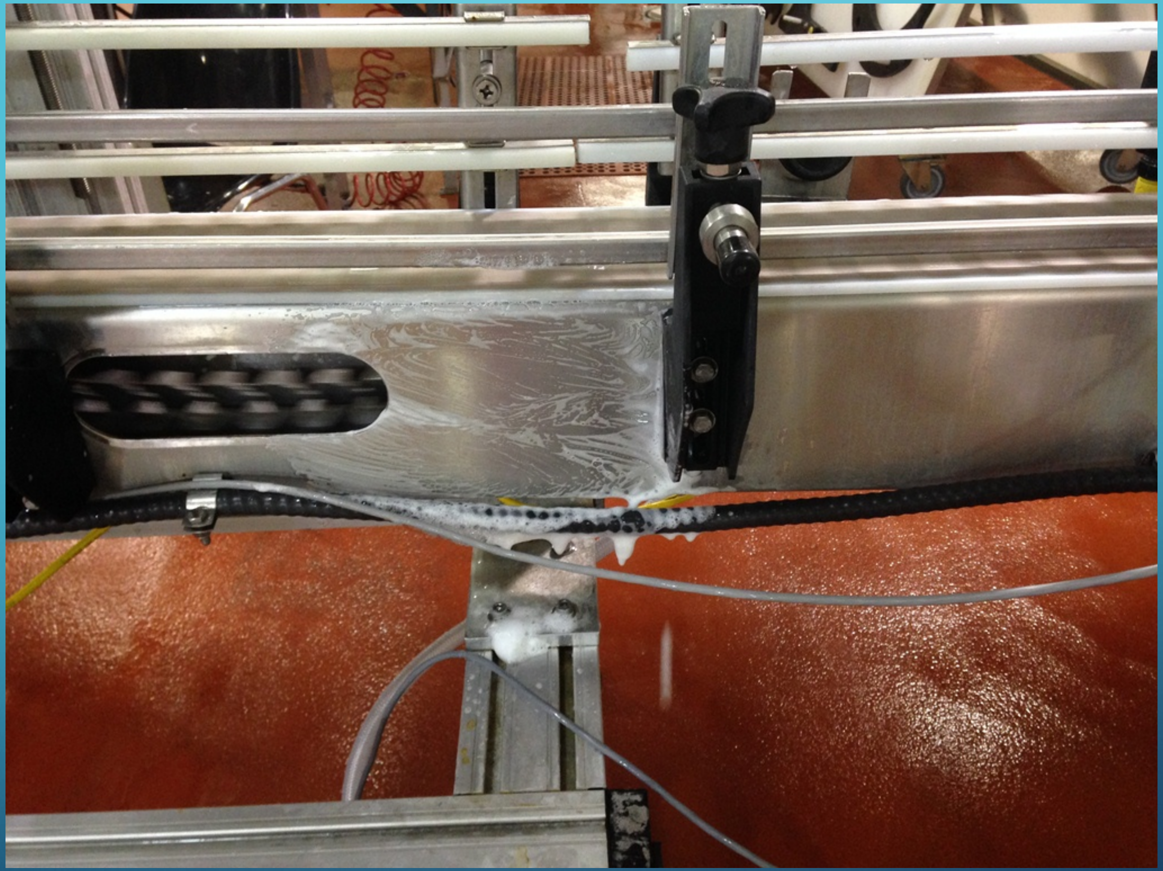
- ATP testing can provide an indicator:



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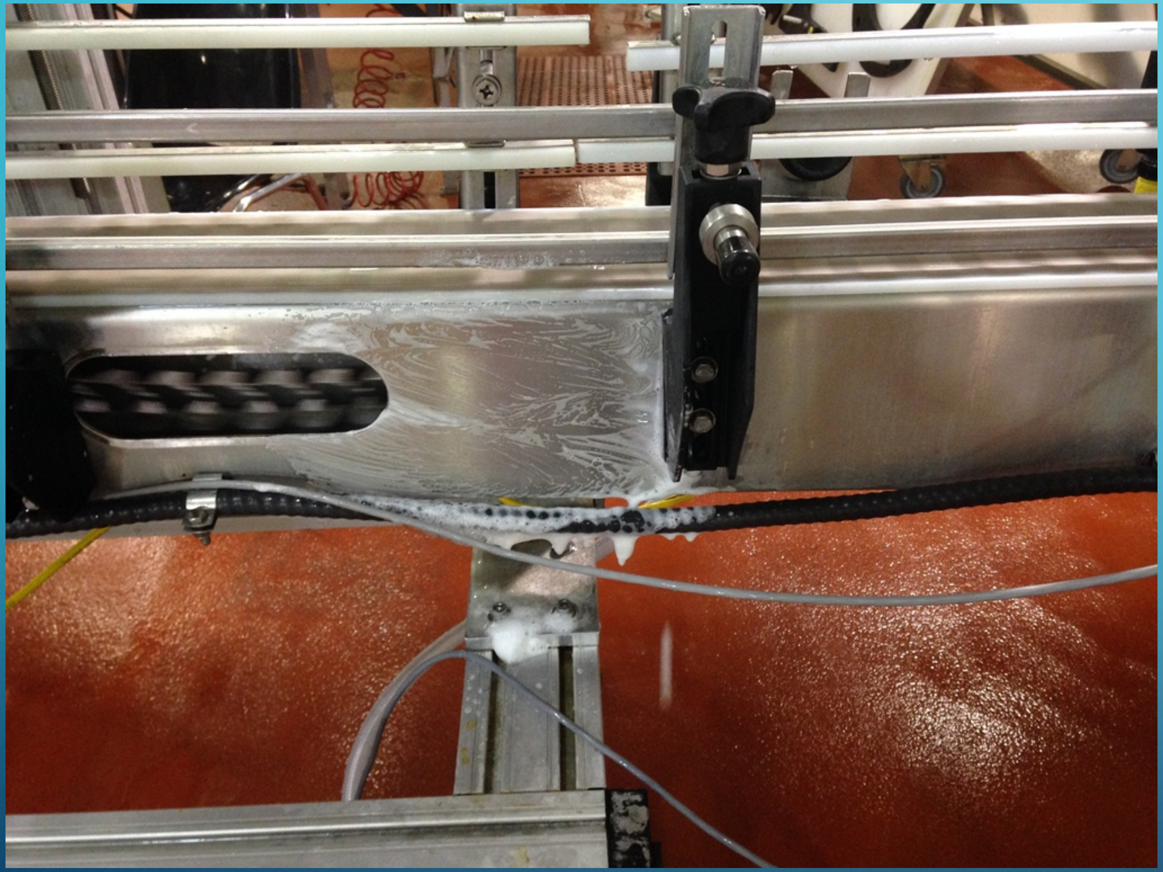


Sample Source	ATP – RLU
1. Conveyor in photo – Just past Labeler	151967
1. Re-cleaned with HC-10	768
1. 2nd recleaning with HC-10	0
1. Cleaned using Bonfoam plus chlorine	1253
1. Repeat cleaning using Bonfoam and chlorine	0

EQUIPMENT SANITARY DESIGN

FDA inspectors now consider ANY area in a RTE plant of <20,000 square feet outside of zone 1 areas to be a zone 2

Any environmental positive will be considered a significant issue

EQUIPMENT SANITARY DESIGN

As FDA continues with new FSMA regulations, elimination of pathogens in the plant production environment will become more important

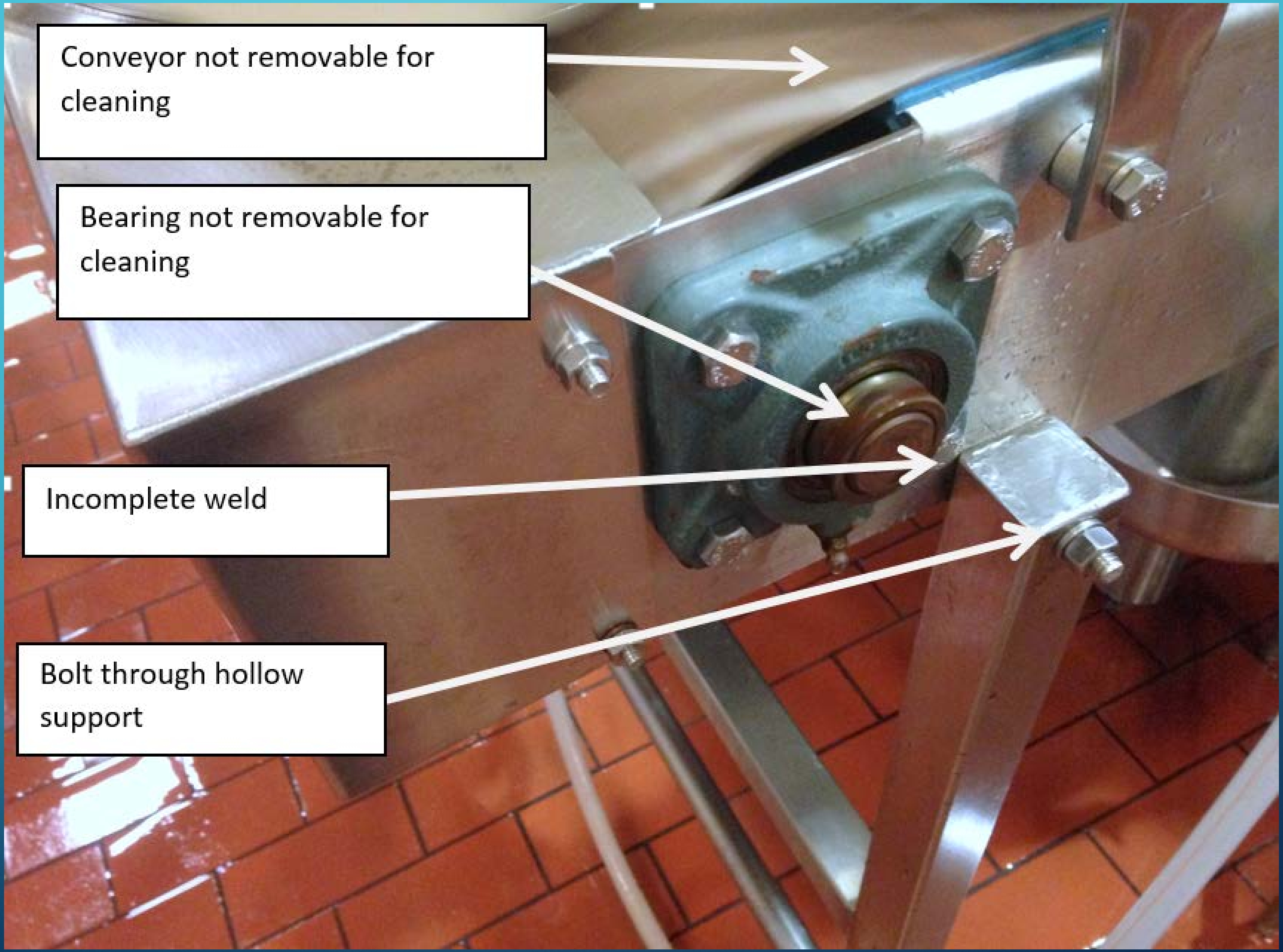
EQUIPMENT SANITARY DESIGN

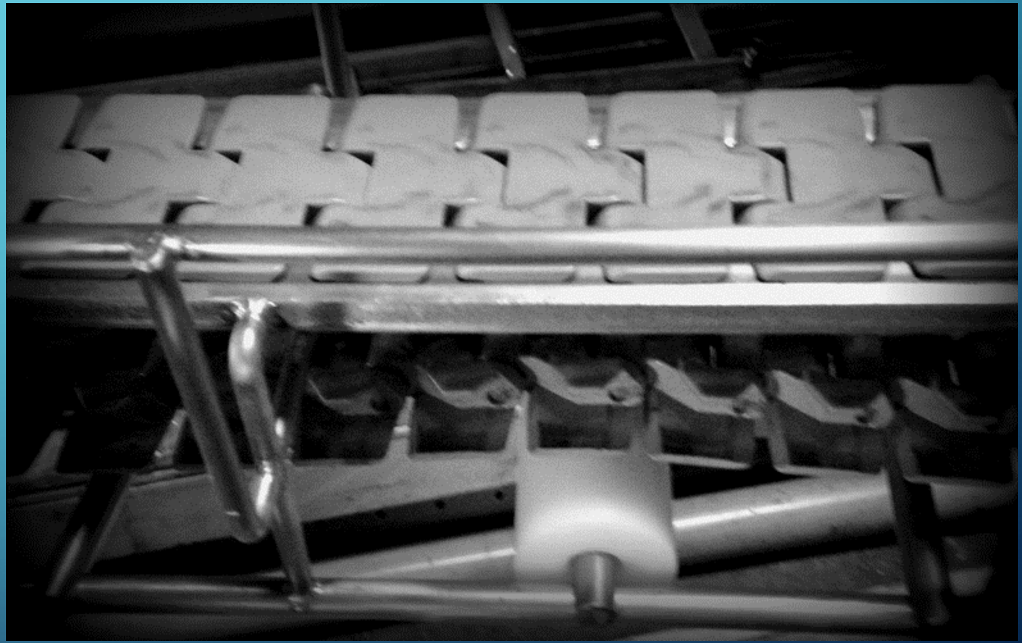
Design of equipment to allow better cleanability will become paramount to success.

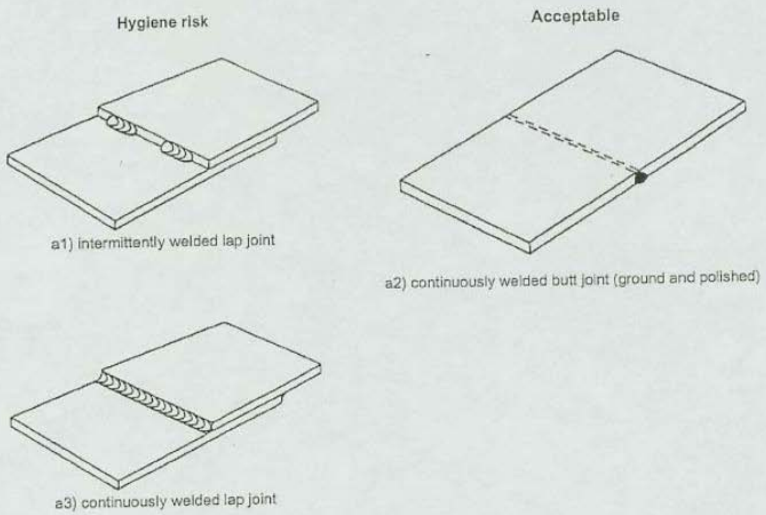
EQUIPMENT SANITARY DESIGN: AMI SANITARY DESIGN PRINCIPLES

1. Cleanable to a microbiological level
2. Made of compatible material
3. Accessible for inspection, maintenance, cleaning and sanitation
4. No product or liquid collection
5. Hollow areas should be hermetically sealed
6. No niches
7. Sanitary operational performance
8. Hygienic design of maintenance enclosures
9. Hygienic compatibility with other plant systems
10. Validated cleaning and sanitizing protocols

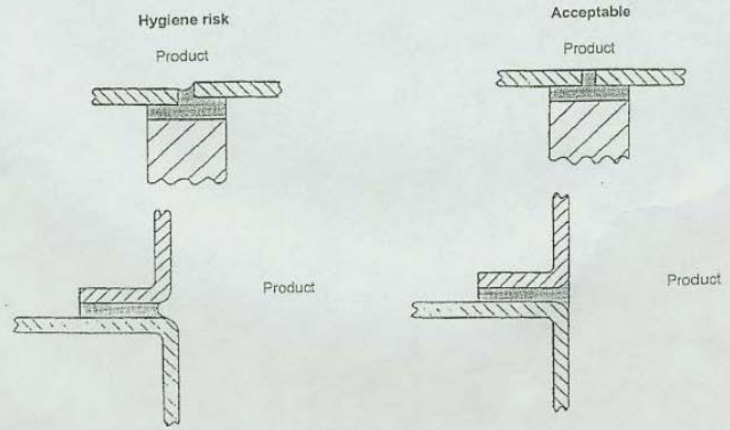
SOURCE: https://www.meatinstitute.org/index.php?ht=a/GetDocumentAction/i/11006


Conveyor not removable for cleaning
Bearing not removable for cleaning
Incomplete weld
Bolt through hollow support





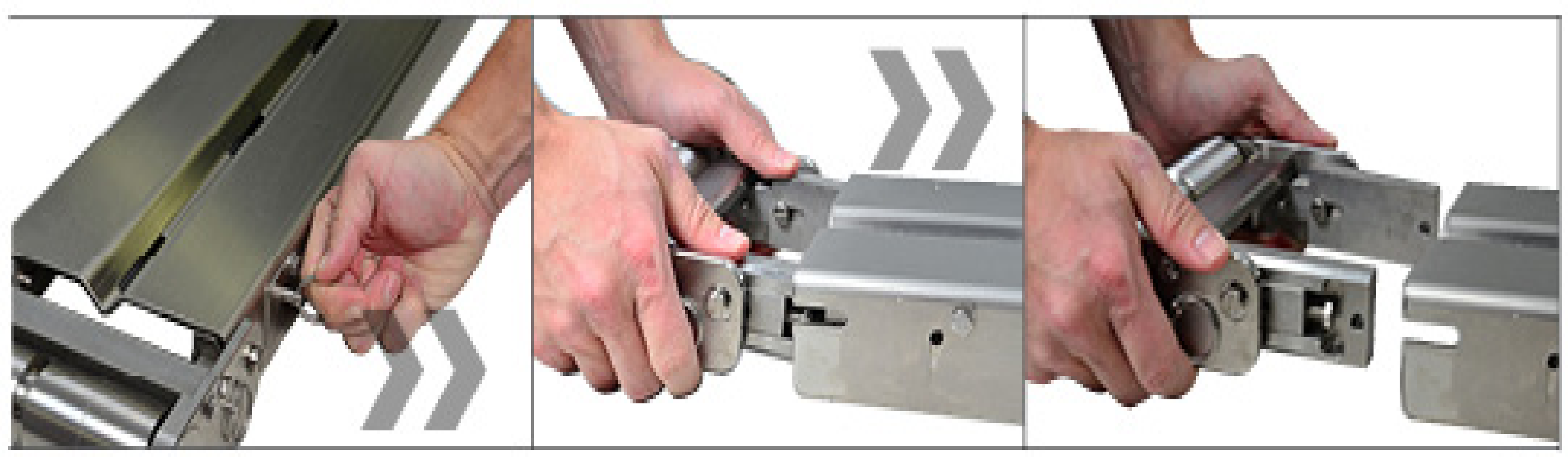
(a) welded joints



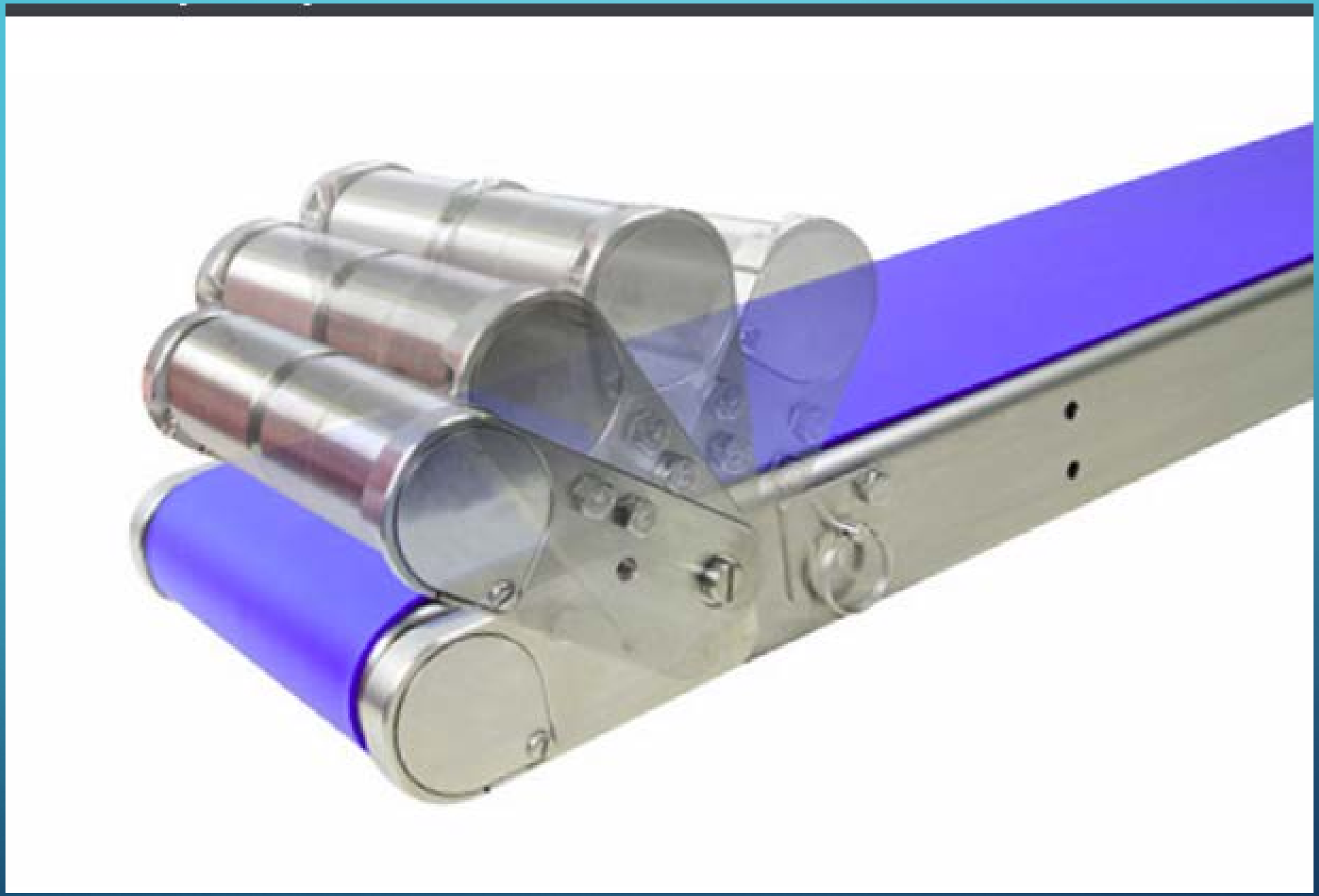
(b) bonded joints

Figure B.4 – Permanent joints

http://qcconveyors.com/conveyors/sanitary-series/hydroclean/tool-less-cleaning.html



From http://qcconveyors.com/conveyors/sanitary-series/hydroclean/tension-release.html




CURTAIN HEATERS
PUMP
WIRE BELT


GLOBALTEK

Resources:

http://www.foodsafetymagazine.com/magazine-archive1/junejuly-2003/10-principles-of-equipment-design-for-ready-to-eat-processing-operations/

http://www.foodsafetymagazine.com/magazine-archive1/december-2012january-2013/food-equipment-hygienic-design-an-important-element-of-a-food-safety-program/

RECOMMENDATION:

Start making design improvements in equipment NOW making changes every year to prevent HUGE expenditures that will be needed when FSMA is fully enforced by FDA

SUMMARY

- Review your cleaning program to determine gaps
- Review your equipment design for areas to improve
- Review your process to determine areas where biofilm are likely

QUESTIONS?

Dave Blomquist
DFB Consulting LLC
651-324-6158