

Hygienic Design Criteria and Cleaning Validation for Dairy Equipment & CIP Systems

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Cleaning Validation—Is it Required? United States

- **Food: No?**
 - CGMP for food Manufacturers requires that food contact surfaces shall be cleaned, and equipment designed for adequate cleaning.
 - Milk Ordinance requires cleaning records and identifies cleaning frequency. Regulatory agency shall test to determine efficiency of sanitization.
- **Biotech and Pharmaceuticals: Yes**
 - CGMP for Drug manufacturers part 211 requires that they develop and verify procedures for cleaning their manufacturing equipment. Cleaning schedules are required along with inspections for cleanliness.
 - Cleaning Validation required to obtain facility operating license.

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Cleaning Validation—Is it Required? Machinery Directive 98/37/EC

- **2.1 Agri-foodstuffs machinery**
 - Where machinery is intended to prepare and process foodstuffs...must be so designed and constructed as to avoid any risk of infection, sickness or contagion and observe the following hygiene rules...
 - **Materials:** Food-grade and designed for cleaning
 - **Surfaces:** smooth and without ridges nor crevices, radii to allow for thorough cleaning
 - **Liquids:** foodstuffs, cleaning & disinfectant fluids must be drainable without impediment

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Why Validate Cleaning Processes?

- The combined component applications are equally as important as the equipment standard for sanitary design.
- To improve the level of food safety
- Reduce liability by showing due diligence
- **Confirm and Document:**
 - Reproducibility of CIP system
 - Reproducibility of Manual Cleaning Procedures
 - Removal of allergens, product residues and cleaning solutions
 - Cleaning System Performance
 - Master plan for inspection, Start-Up and Cleaning operations

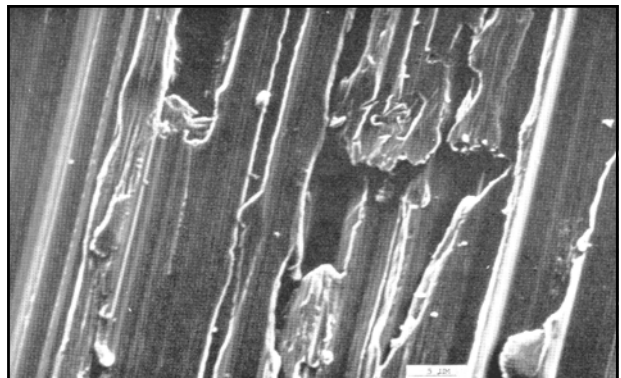
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What makes a surface cleanable?

- **Hygienic Design**
 - **Surface Finish:** No pits, cracks, crevices, smooth welds...
 - **No dead ends**
 - **Self-Draining**
 - **Compatible Materials**
 - **Accessibility**

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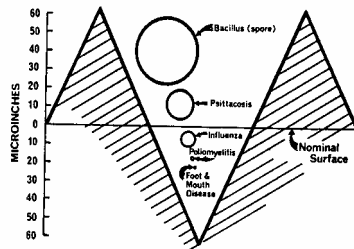


150 Grit (No. 4) Stainless Steel

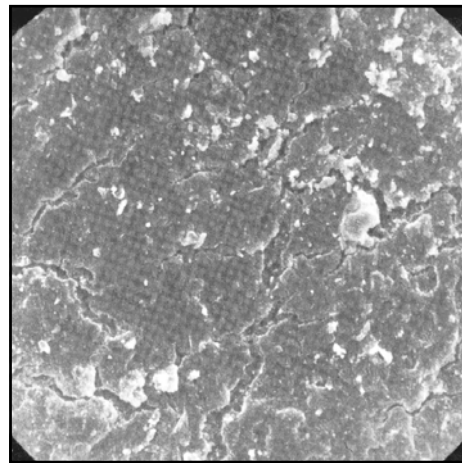
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Zottola and L.L. McKay. 1981. J. Food Prot. 44 (3) 206



Surface roughness vs. Biofilm formation



Relationships between a machined surface ($R_a 1.0 \mu$) and different organisms. Source: Biological Handbook for Engineers-, Marshall Space Flight Center, NASA, 31 March 1966. Sustainable Cleaning Systems WDS 2004



Rubber surface after 30 soiling/washing cycles.

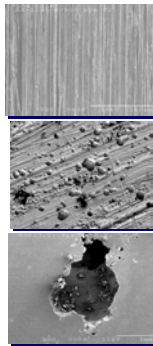
Dunsmore D. G., A Twomey, W. G. Whittlestone and H. W. Morgan. 1981 J. Food Protection 44 (7): 621-624.



Choosing CIP Chemicals Based on: Surface To Be Cleaned

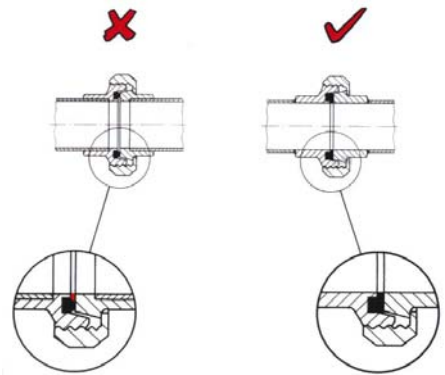
- Composition
 - Resistance to chemicals
- Smoothness
- Corrosion / Degradation
 - pH (acidic)
 - Chloride concentration
 - Contact Time
 - Temperature
 - Equipment Composition & Condition
 - Passive Layer

Factors That Influence Corrosion Potential:



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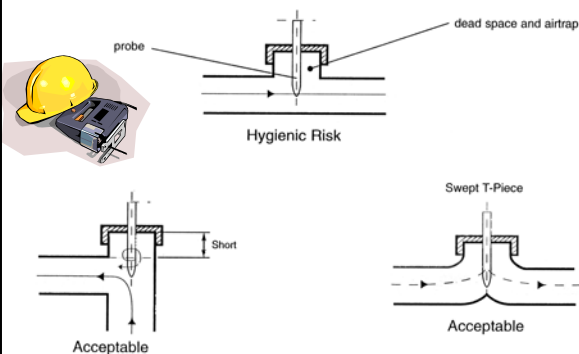
Joints



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Instrumentation



What is Soil?

Soil is unwanted matter on the surface to be removed prior to sanitizing.

- Product Residue
- Water
- Airborne Contamination
- Transient Soil from Workers
- Detergent Ingredients
- Microorganisms

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Not only can they multiply quickly!!



They can hang on!!!

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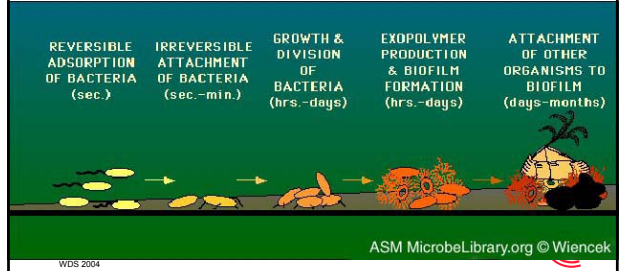


Authors

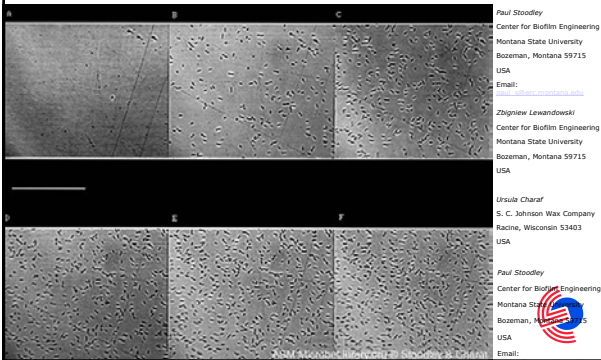
Rysz Wiencek
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Environmental Biofilms: Sources of contamination

Illustration of Aquatic Biofilm Formation Sequence

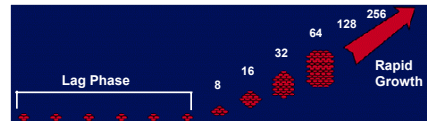


Time Sequence of Bacterium Growing on a Stainless Steel Surface (1 hr intervals)

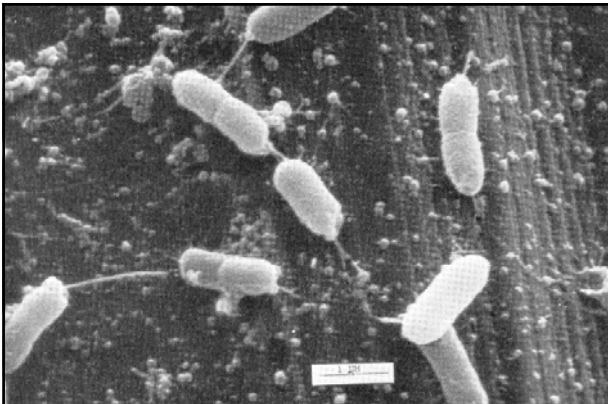


General Guideline for Disinfectant/Sanitizer Application

1. Disinfectant applied as the final step in the cleaning program
2. Re-disinfect if time between completion of disinfection program and startup exceeds four hours



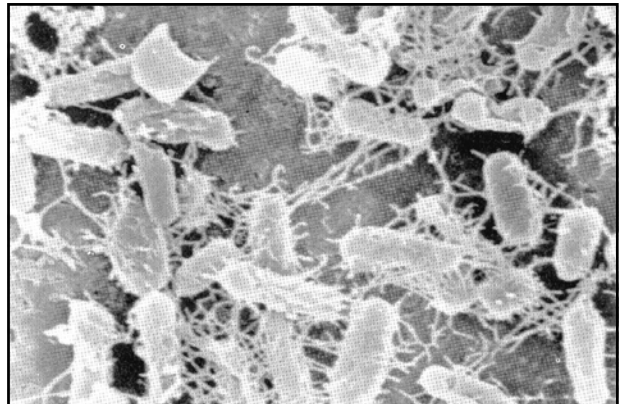
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***Pseudomonas fragi* 4973 on stainless steel.**

Zoltai, P.T., E.A. Zottola and L.L. McKay. 1981. J. Food Prot. 44 (3) 207

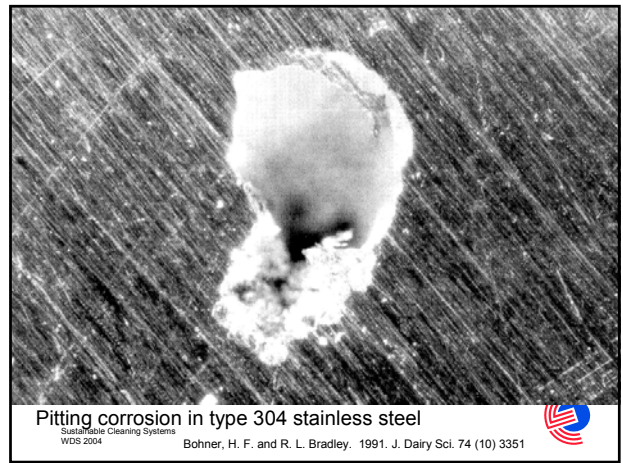


***S. typhimurium* biofilm with extra-cellular matrix on Buna-n**

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Ronney B. and Amy C. L. Wong. 1993. J. Food Protect. 56 (9) 753.





Choosing CIP Chemicals Based on: SOIL CONDITIONS

- High or low solids
- Burnt or cooked soils
- Fat, grease, or protein
- Fluid milk, yogurt, ice cream, buttermilk, cheese, condensed, culture.
- Nuts, fruit portions
- Stabilizers, flavoring, chocolate
- Biofilms

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Cleaning

- Clean—What is it?
 - adj.— free from dirt: unsoiled; unstained
 - v.— to perform or undergo a process of cleaning by the removal of soil particles from surfaces by manual, mechanical or chemical methods
- Critical Cleaning Steps
 1. Time
 2. Temperature
 3. Concentration
 4. Mechanical Action/Turbulent Flow

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CIP SYSTEM DESIGN CRITERIA

- Largest/ smallest lines to be cleaned
- Largest/ smallest tanks to be cleaned
- Length of lines /fittings / devices
- Type of equipment / fillers, dryers, evaporators, pasteurizers, etc.
- Equipment Manufacturers recommendations/ limitations
- What are the expectations for system performance?

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CIP System Design Criteria

- Spray devices
- Tank outlet sizes / height
- Return lines
- Valve clusters
- Detergent Cleaning regimen/ built product or add CL2
- Number / type detergent pumps / controls
- Acid wash/ override / Method of sanitizing
- Total quantity of CIP & sanitize cycles

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Methods of Cleaning Validation

- Visual Inspection
- Soiling
- Fluorescence detection with UV
- Inoculation



Cleaning and Sanitizing in the Milking System

Philip T. Tybor, Former Extension Food Science & Technology; Warren D. Olson, Extension Dairy Science

Improperly cleaned milking systems can be visually determined by the dairyman and the employees. Careful inspection of equipment or utensils will result in the detection of various films or deposits. The following cleaning and sanitizing trouble table describe the various types of films and deposits, the visible signs, the causes, a means for removal and methods for prevention.

<http://www.ces.uga.edu/pubcd/B1025-W.HTML>



Signs of Poor Cleaning

Problem Identification	Cause*	Removal	Prevention
Film on equipment having blue rainbow hue	Protein Residue	Basic clean-up with chlorinated alkaline detergent and hot water (140-160°F). Manual or mechanical cleaning action required.	1. Adequate pre-rinse with 110-120°F water.
	1. Using improper cleaner		2. Use of chlorinated alkaline detergent.
	2. Inadequate pre-rinse		3. Proper cleaning technique with proper chemical dilution and rinse after each usage.
	3. Improper (sporadic or periodic) cleaning		
White to yellow deposit	4. Improper initial clean-up	Basic cleaning procedure	
	Milk Stone/Water Stone		Regular and proper cleaning procedures coupled with acidified rinse.
	1. Mineral deposit from milk		
	2. Mineral deposit from water		

*Films and deposits are usually caused by improper cleaning, rinsing, hard water or incompatible products. In mechanical cleaning, problems may be also due to malfunction of the system or lack of proper solution control.



Hygienic Challenge Test for Filling Machines "Buttermilk Test"

Principle

- Provide cleaning treatment to filler product contact
- Assure adequate chemical contact time.
- Assure no product safety issues

Criteria

- Adequate cleaning of various products

Verification Test

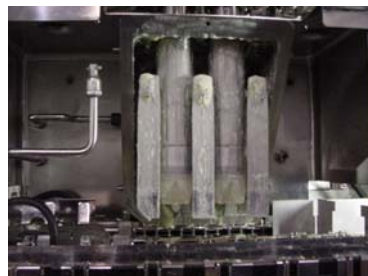
- Circulate full fat buttermilk with fluorescent dye for 3 hours through filler
- Allow to dry minimum of 1 hour
- Run CIP with low level cleaning chemicals, rinse with water, dry overnight
- Tear down filler and observe for fluorescent residuals with black light. Verify product with ATP.



Fill Nozzle CIP Enclosure



Soiled Filler Nozzles with Buttermilk & Dye



Manually Cleaned, only one flex nozzle removed



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Fill Nozzles after CIP



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Fill Nozzle CIP Enclosure Drain



- This test method was adopted by EHEDG, July 2000 – Doc 21 “Challenge tests for the evaluation of the hygienic characteristics of packing machines”.

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European Hygienic Engineering & Design Group (EHEDG)

- A method for the assessment of in-place cleanability of food processing equipment, Document No. 2 (2000).
- Test item soiled with soured milk containing spores
- Pressurized @ 5 bar
- Cleaned, drained and dismantles
- Item covered with pH sensitive agar and incubated @ 58 C



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Campden Test Rig





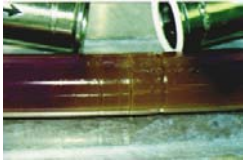
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Cleanability Trials on Pipe Joints.



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Spray Performance Testing

- Spray Pattern Testing Confirms Spray Device Coverage
- Typical Procedure
 - Equipment Product Contact Surfaces Coated with Riboflavin Solution
 - Equipment is rinsed Using CIP Spray Devices for a Volumetric Preset, and Drained
 - Equipment inspected with UV light for Fluorescence
- Indication of Spray Performance and Equipment Cleanability

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Summary of Cleaning Verification Methods

- Visual
- Soiling with product
- Fluorescent dye
- Bacterial spores
- Riboflavin Spray
- Chemical/Microbial Testing

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Tools for Cleaning Verification & Surface Hygiene

- ATP
- Sugar
- Protein
- Allergen
- Agars Methods (BAM)
- Modified Agar Methods



Tools for Cleaning Verification & Surface Hygiene

ATP

(Adenosine Triphosphate)

- ATP is the universal energy carrier in all living organisms.
- Microorganisms, milk, juice contain large amounts of ATP
- ATP + luciferine/luciferase=light
- Product residues and micro-organisms
- Surface or water testing
- AccuPoint
- Biotrace Uni-Lite XCEL
- Charm Lum-T / Firefly
- BioControl Lightning MVP



Tools for Cleaning Verification & Surface Hygiene

Sugar Tests

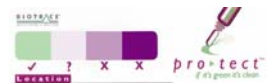
- Pro-Tect (reducing sugars)
- Spot check (glucose)
- Spot check+ (glucose/lactose)
- Simple sugars are oxidized using Benedict's reagent to produce a color change.



Tools for Cleaning Verification & Surface Hygiene

Protein Tests

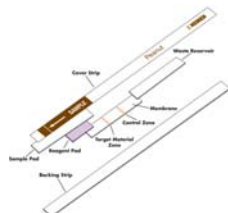
- Pro-Tect (Biotrace)
- VERiclean (Charm Sciences)
- Flash (BioControl)
- Protein (and reducing sugars) reduces copper (Cu^{++} to Cu^{+}) from the copper sulphate. Bicinchoninic acid (BCA) under alkaline conditions forms a purple complex.



Tools for Cleaning Verification & Surface Hygiene

Allergen Tests

- Allergenic Proteins: "The Big 8"



Tools for Cleaning Verification & Surface Hygiene

Allergens

- Screening or Quantitative
- Compare against known controls
- CIP, Swab or Product (in-process or finished)



Negative



Positive

Quantitative – 5 controls



Tools for Cleaning Verification & Surface Hygiene

Agar Methods

- Traditional Methods (Swab, RODAC)
- Acumedia
- Difco/BBL
- EM Science



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Tools for Cleaning Verification & Surface Hygiene

Modified Agar Methods

- Iso-Grid
- Total Bacteria Count



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Tools for Cleaning Verification & Surface Hygiene

Modified Agar Methods

- Agar Paddles
- 3M Petrifilm
- Hycheck (Difco)



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Summary of Verification Tools

Listed by test time to get result

- ATP – quick results but general information
- Protein / Sugar Tests (10 minutes) more specific, groups of proteins & sugars
- Allergen (10-60 minutes) more specific; specific proteins are concern
- Agar (24 - 72 hours) more specific; groups and specific organisms
- Advantages and disadvantages with each method regarding test time, cost and specificity.

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Making the Right Choice for Food Safety

Design, Operation, Maintenance

- Hygienic Design Equipment
 - Food Grade Materials
- Operational Plant Lay-Out
 - Valve Clusters
 - No dead-ends
- CIP System Design
(Clean In Place—Not Just Circulate in Place)
 - Spray devices
 - Return lines
 - Appropriate Chemical Selection
- Validation

Results: **Clean Equipment, Tanks and Lines**

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