Hygienic by Design: Reducing Risk in Your Facility

2023 3-A SSI Education Event

Minneapolis, MN

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May 2023

Food Industry's Nightmare: Costly and Brand Damaging Recalls

Example:
ConAgra's peanut butter case in 2007

- In February 2007 Conagra recalled peanut butter after *Salmonella* outbreak
- The *Salmonella* contamination sickened more than 625 people in 47 states
- **ConAgra spent around $78 million on the recalls.** In addition, **peanut butter sales declined by 63% in 2007**

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Sanitary Design Issue = Severe Consequences

Example:
Peanut Corporation of America in 2009

- *Salmonella* typhimurium outbreak
- Peanut butter and peanut paste
- 744 cases, 166 hospitalizations, 9 deaths
- ~3,900 products containing peanuts recalled
- Company no longer in business
- Criminal investigation

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Peanut Corporation of America from Inception to Indictment: A Timeline

BY **GRETCHEN GOETZ** | FEBRUARY 22, 2013

The Peanut Corporation of America shut down in 2009 after a massive outbreak of Salmonella Typhimurium linked to its products left the company bankrupt. Evidence that company officials knowingly released contaminated product onto the marketplace first surfaced in February of 2009 following an investigation by the U.S. Food and Drug Administration. Now, four years later,...

the link was found to King Nut peanut butter, and then traced to the Blakely, GA plant. The plant produced both peanut butter and peanut paste that was then sold to other companies for use in cookies, cakes, ice cream, candy, nutrition bars, and dog treats. To date 43 states and Canada have reported illnesses. There have been 501 confirmed illnesses, 125 hospitalizations and eight deaths. Over 31 million pounds of peanut products have been recalled. That number is expected to rise.

Source: http://www.marlerclark.com/press_releases/view/marler-clark-adds-punitive-damage-claim-to-peanut-butter-salmonella-lawsuit

Marler Clark Adds Punitive Damage Claim to Peanut Butter Salmonella Lawsuit Against PCA

January 28 2009

The FDA found:

- 12 positive tests of Salmonella in product manufactured by PCA
- 4 different strains of Salmonella detected on site in Blakely, GA
- Failure to maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination
- Failure to perform mechanical manufacturing steps so as to protect food against contamination
- Failure to store finished food under conditions that would protect against microbial contamination
- Plant is not constructed in such a manner as to allow ceilings to be kept in good repair
- Design of equipment and utensils fails to preclude the adulteration of food with contaminants
- Proper precautions to protect food and food-contact surfaces from contamination with microorganisms cannot be taken because of deficiencies in plant construction and design
- Devices and fixtures are not designed and constructed to protect against recontamination of clean, sanitized hands
- Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food
- Effective measures not being taken to protect against contamination of food on the premises by pests

A New Day Has Dawned…
And It's A Day With Consequences!

A Rare Conviction for Food Executives in Deadly *Salmonella* Outbreak

By Susan Berfield
September 22, 2014

Deadliest Foodborne Outbreak in US History:

Stewart Parnell, Owner: Guilty – Sentenced to 28 yrs.

Michael Parnell, Brother & Peanut Broker: Guilty – Sentenced to 20 yrs.

Mary Wilkerson, QA Manager: Guilty – Sentenced to 5 yrs.

Sanitary Design Issue = Business at Risk

Example:
Jensen Farms' whole melons case in 2011

- Outbreak of *Listeria monocytogenes*
- Associated with whole melons (Rocky Ford brand)
- 147 cases and 33 deaths reported
- FDA Investigation:
  - Positive in 5/10 melon samples
  - Positive in 13/39 environmental samples
  - Unsanitary soil conditions – standing water
  - **Poor equipment design, fit for purpose**
  - No pre-chilling, possible cross-contamination from growing and harvesting operations
  - Possible cross contamination by bovines

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Sanitary Design Issue = Business at Risk

In the News

Yesterday Them, Today? Tomorrow?

FOODBORNE ILLNESS INVESTIGATIONS

Flour Prime Suspect in 2009 Cookie Dough Outb

BY MARY ROTHSCHILD | DEC 10,

Another

BY NEWS DES

The Michiga
a similar pro
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Back in Febr
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FOOD RECALLS

Pistachios Recalled

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics

Peanut Butter and other Peanut Containing Products Recall List

Processed Peanut Recalls of 2009 Linked to *Salmonella*

One of the Largest Food Recalls in U.S. History Is Linked to Processed Peanuts

its and flour

Trail Mix Bars, Fresh & Easy

were all recalled in 2010

U.S. Food and Drug Administration
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Safety

Home > Safety > Recalls, Market Withdrawals, & Safety Alerts > Major Product Recalls

Recalls, Market Withdrawals, & Safety Alerts

Major Product Recalls

Hydrolyzed Vegetable Protein Product Recalls

The U.S. Food and Drug Administration is actively investigating findings of *Salmonella* Tennessee in hydrolyzed vegetable protein (HVP) manufactured by Basic Food Flavors, Inc., in Las Vegas, NV. HVP is a flavor enhancer used in a wide variety of processed food products, such as soups, sauces, chilis, stews, hot

Spotlight

Searchable Database of

ILLNESS OUTBREAKS

Salmonella Outbreak Linked to Dog Food Has Sickened 22 in 13 States

BY HELENA BOTTEMILLER | JUN 14, 2012

Protica Inc. Recalls Product Because Of Possible Health Risk

The problem with the lots below were discovered when investigating the processing parameters for all manufactured products.

Food Safety

- **Definition:**
  - Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Source: Codex Alimentarius

"I am the one asking you—on behalf of myself, my family, and the 1500 others who were sickened—please make our food system safe."

—Testimony from the congressional hearing, "The Outbreak of *Salmonella* in Eggs," held September 22, 2010

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Food Safety Hazards

- **Definition:**
  - Biological, chemical or physical agents in, or conditions of, food with the potential to cause an adverse health effect

Source: Codex Alimentarius

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Significance of Microorganisms in Food

Helpful

- Yeast for bread and wine
- *Lactobacillus* for yogurt
- *Streptococcus lactis* for cheese-making

Harmful - The Enemy

- Spoilage organisms (20-30% of the world's food supply lost to spoilage prior to being processed/consumed)
- Pathogens

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Sources of Microbial Contamination

- **Prior to Processing**
  - Raw materials
  - Harvesting
  - Storage
- **During and After Processing**
  - Added ingredients
  - Processing equipment
  - Personnel
  - Distribution and storage

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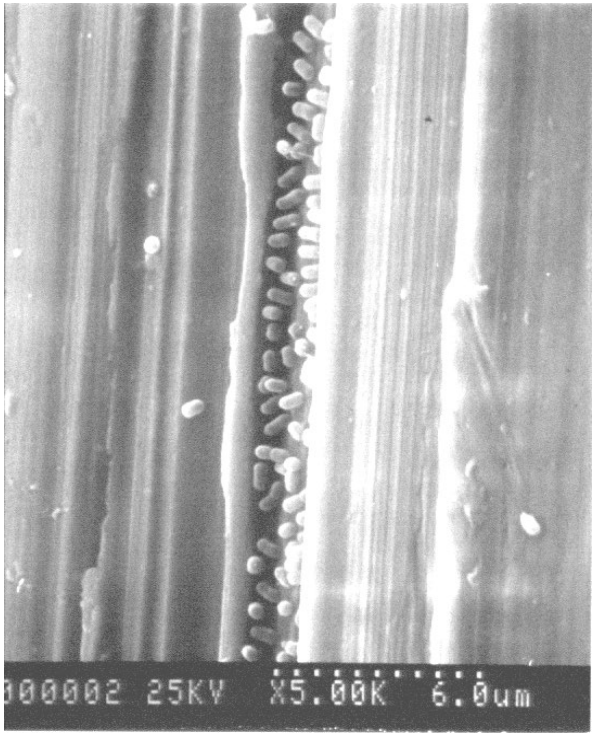
Microbial Ecology of the Food Processing Environment

- 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, employee, condensation)
- Survive/grow within the plant
- Become potential sources of contamination



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Relationship Between the Environment and Product Stream

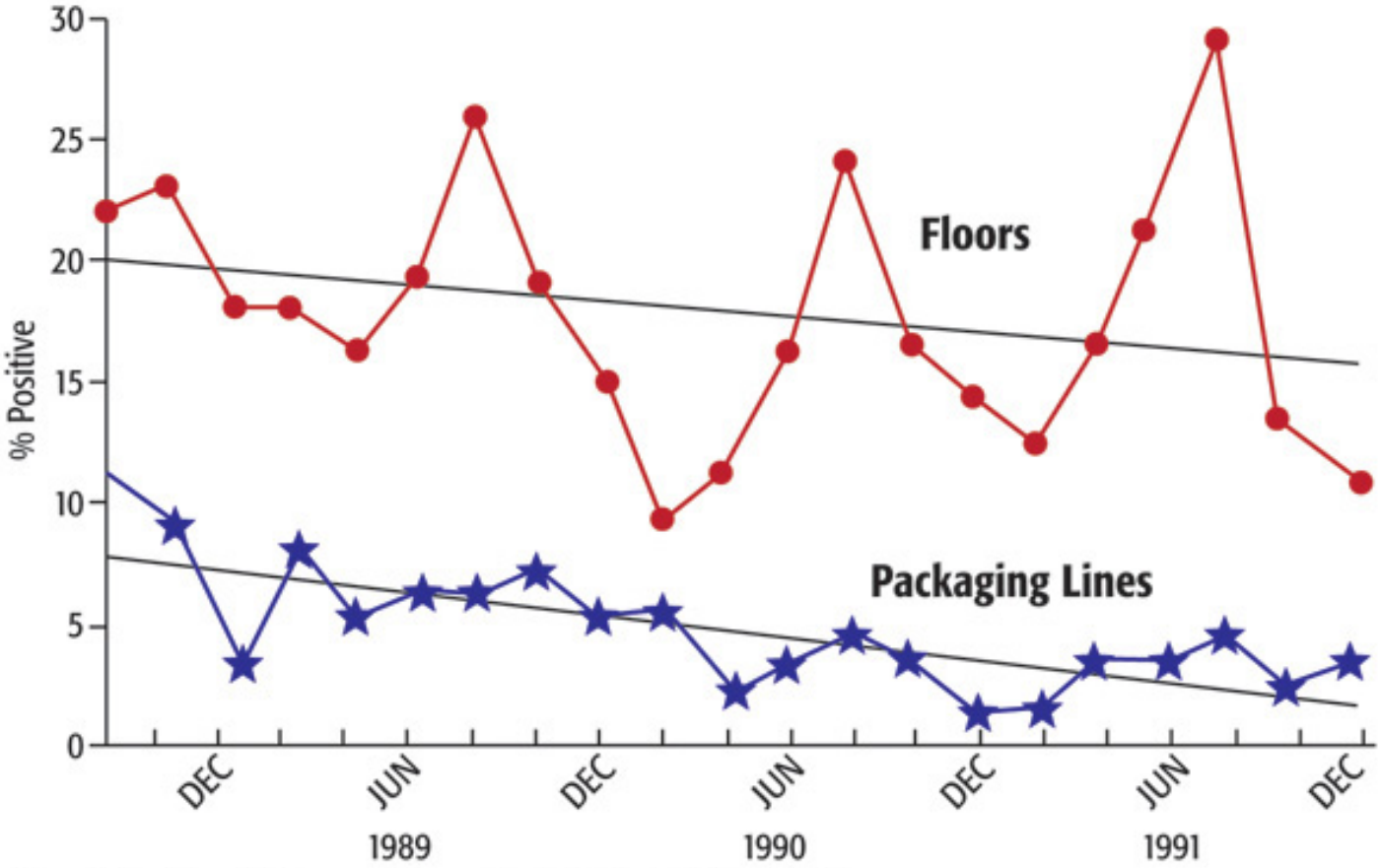

Figure 4: Correlation of Listeria spp. on Floors and Packaging Lines in RTE Meat Plants[10]

Tompkin, R.B., L.N. Christiansen, A.B. Shaparis, R.L. Baker and J.M. Schroeder. 1992. Control of *Listeria monocytogenes* in processed meats. *Food Aust* 44:370–376.

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Microbial Ecology of the Food Processing Environment

Types of microorganisms:

- Transient
- Resident
  - Most persistent: *L. monocytogenes*, *Salmonella*
  - Somewhat persistent: *S. aureus, E. coli* O157:H7*, Y. enterocolitica, B. cereus, C. botulinum, C. perfringens*
  - Not persistent: *S. typhi, Shigella, C. jejuni*, viruses, parasites

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Pathogenic Bacteria

- ***Listeria monocytogenes***
  - *Listeria* spp. includes 6 species and found commonly in soil
  - *Listeria monocytogenes* is a human pathogen – 13 strains
  - Likes wet and cold areas of the facility (drains, condensate, chillers, refrigerated products)
  - Harborage sites include areas where food and water are present (cracks, hard to clean areas)
  - May grow and form biofilm on processing equipment, making its removal more difficult and lead to product contamination
  - Good sanitation and environmental controls are critical for its control

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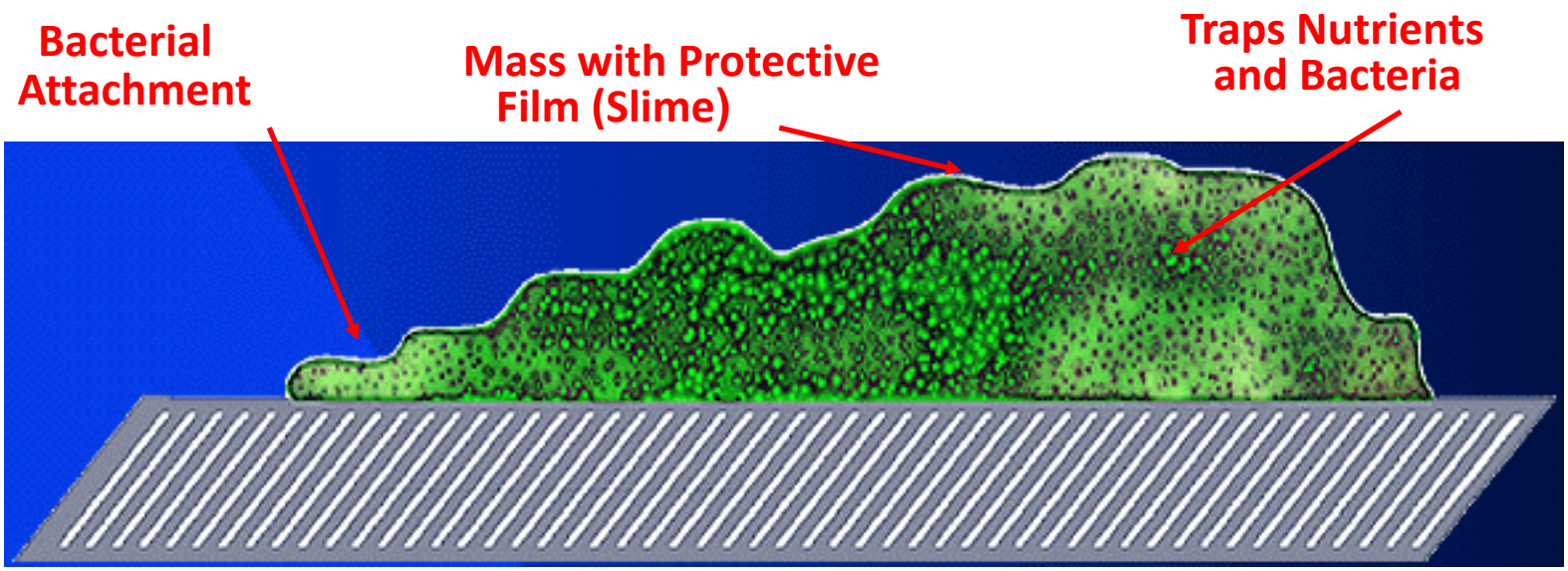
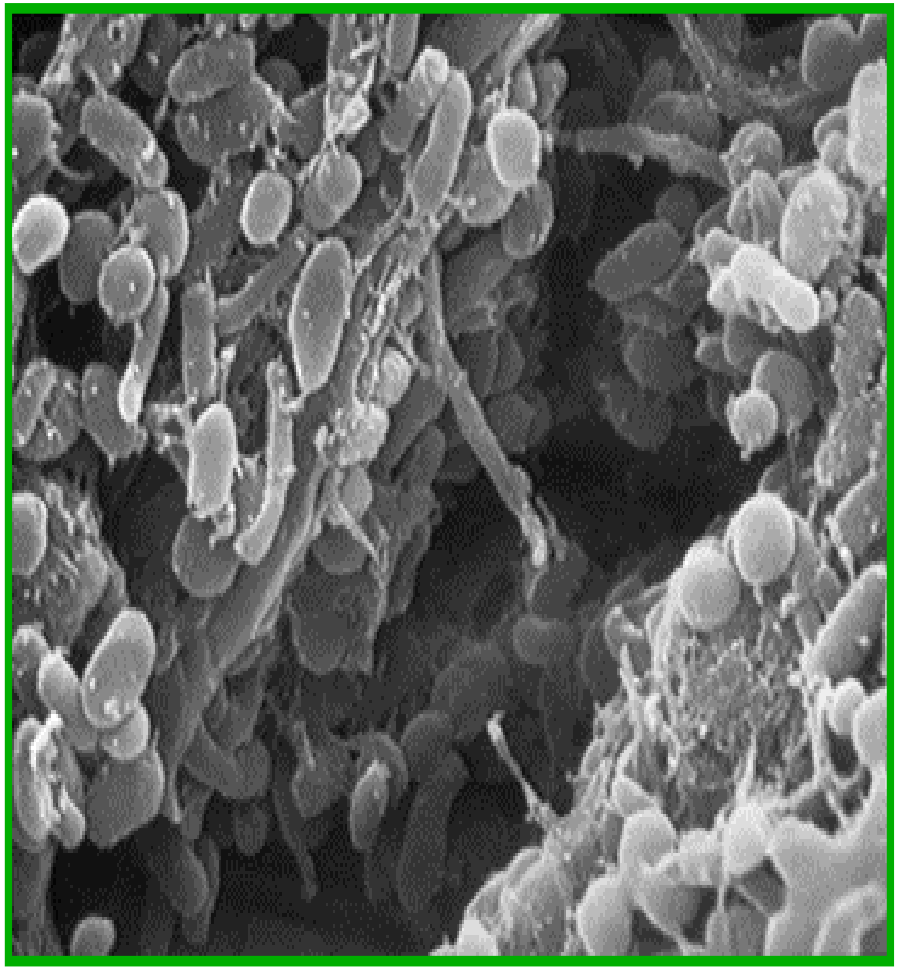
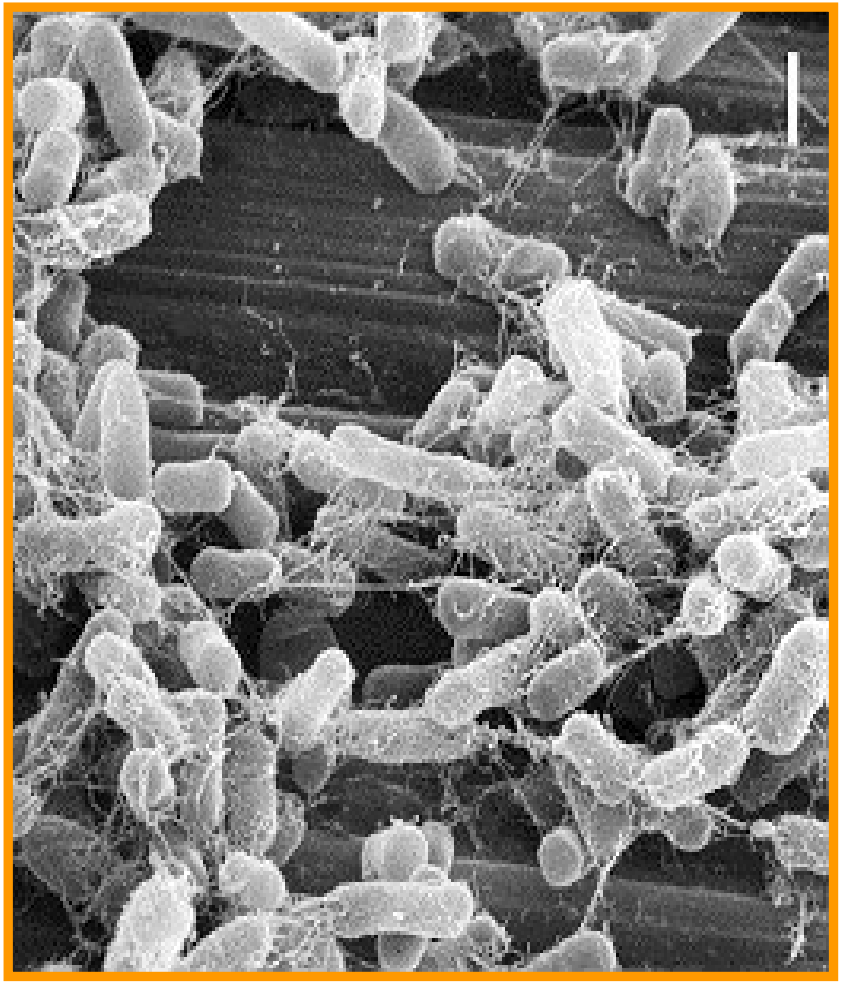
Biofilms: A Problem!!!

- A film of microbes that becomes difficult to remove if not properly cleaned - **regularly**
- <u>If NOT totally eliminated</u>, organisms can be shed from the biofilm into the food being produced
- Prevents antimicrobial action of sanitizers



Biofilms Up-Close





Pathogenic Bacteria

- ***Salmonella***
  - Over 2,400 serotypes of *Salmonella* bacteria
  - Infects several million Americans/year via tainted food (CDC)
  - Survives well in the environment and is known to tolerate heat and dry conditions
  - Harborage is where foods accumulate
  - Can escape the dry-cleaning process
  - Can grow when these areas get wet and contaminate the food contact surfaces

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Pathogenic Bacteria

- ***E. coli O157:H7***
  - Survives well in the environment (produce) and is pH resistant (fruit juices)
  - Has been isolated from food contact surfaces (meat processing facilities)
  - Not routinely tested as part of the PEM
  - Can survive in low moisture foods
  - Challenge studies suggest survival ranking of *Salmonella* > *E. coli* O157 > *Listeria*

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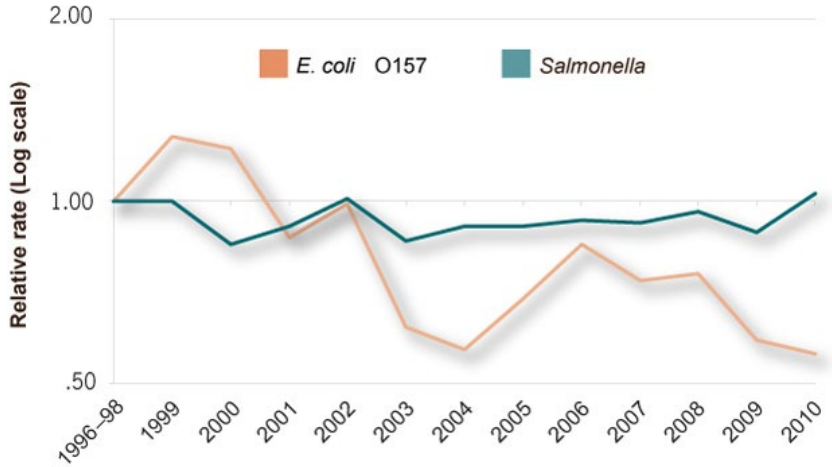
Pathogenic Bacteria in Low Moisture Product

Why is it a problem?

Change in *E. coli* O157 and *Salmonella* infection, 1996–2010



Source: Foodborne Diseases Active Surveillance Network, 2010

- Small dose of *Salmonella* may cause infection

- Survival of *Salmonella* in dry environment
- Increased resistance of *Salmonella* to thermal processes under dry conditions
- Low moisture products are usually used as ingredients in food systems where water is readily available for pathogen growth
- Improper cleaning and sanitation, resulting in harborage sites and/or growth niches in presence of residual water
- Contamination from the processing environment

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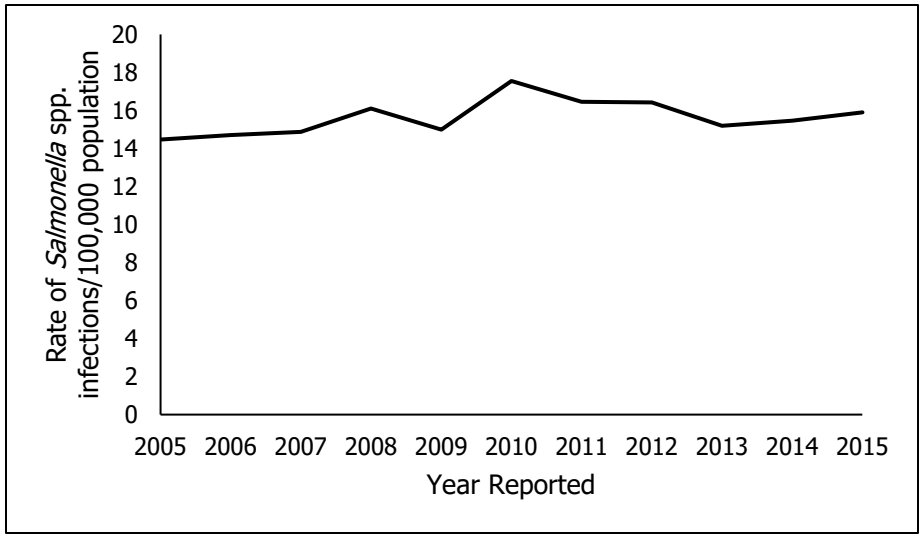
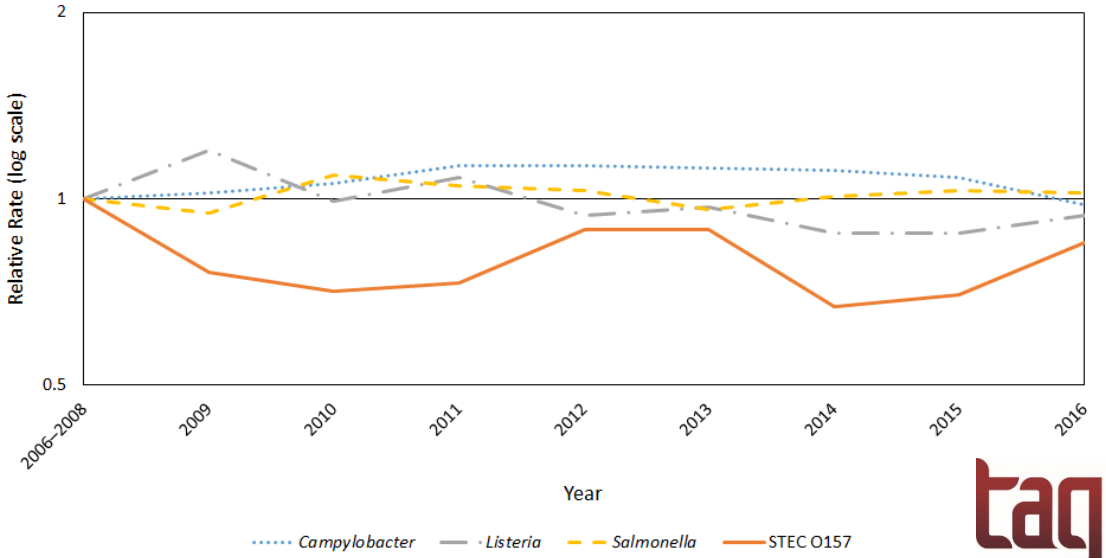
Incidence of Foodborne Pathogens



Overall incidence of *Salmonella* spp. infections in the US for 2005-2015, per 100,000 population

Source: FoodNet, 2006-2017

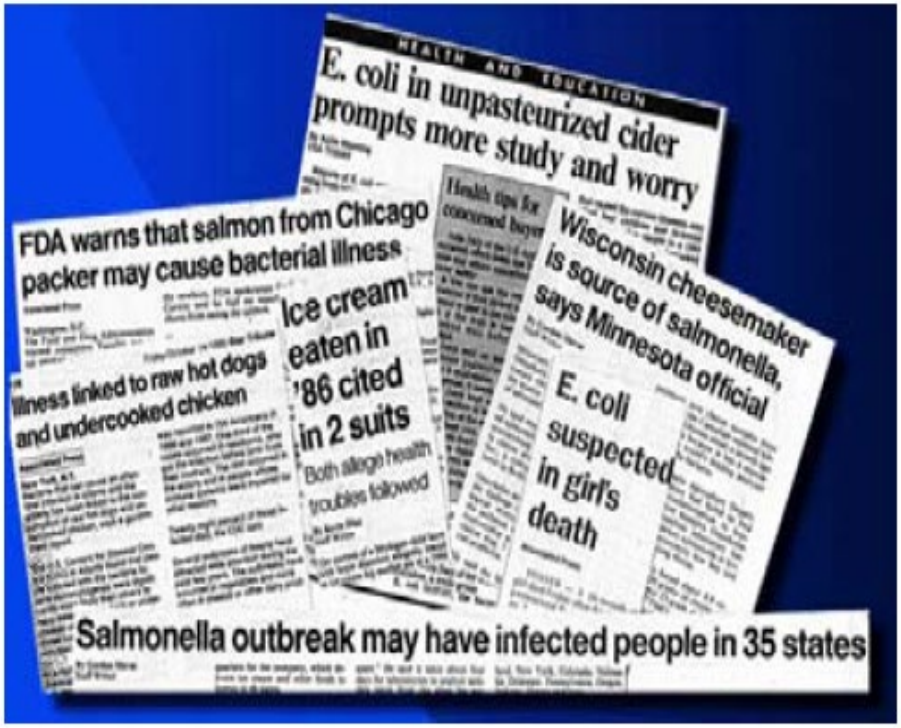
Relative rates of confirmed infections with *Campylobacter*, STEC O157, *Listeria*, and *Salmonella* compared with 2006–2008 average annual incidence, by year, FoodNet, 2006–2016

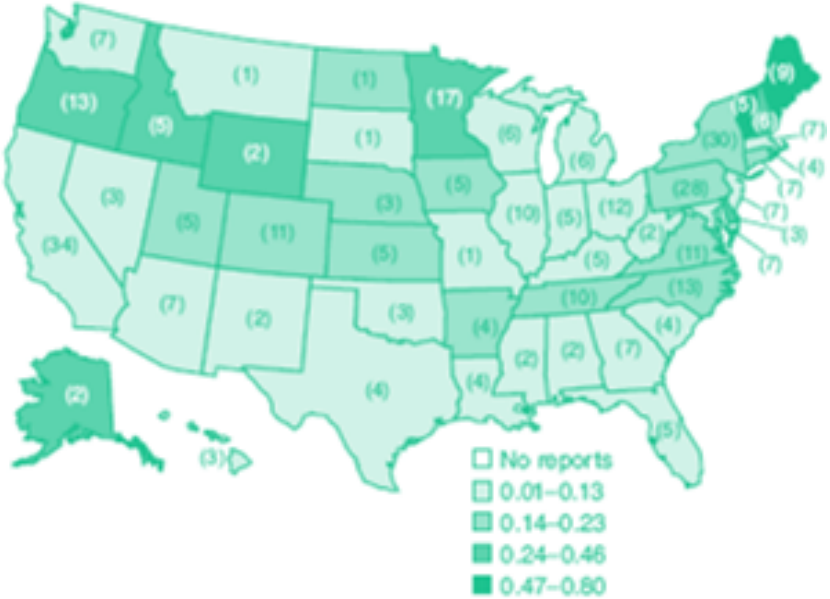


Source: CDC, 2017

Impact of Foodborne Illness in the US

- Each year 48 million people get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases (CDC)
- *Escherichia coli* O157:H7, *Salmonella*, and *Listeria monocytogenes* among top 5 causes of hospitalization or death
- $77.7 billions is the annual cost of foodborne illness outbreaks
- Recall cost for individual companies: SEVERAL million dollars





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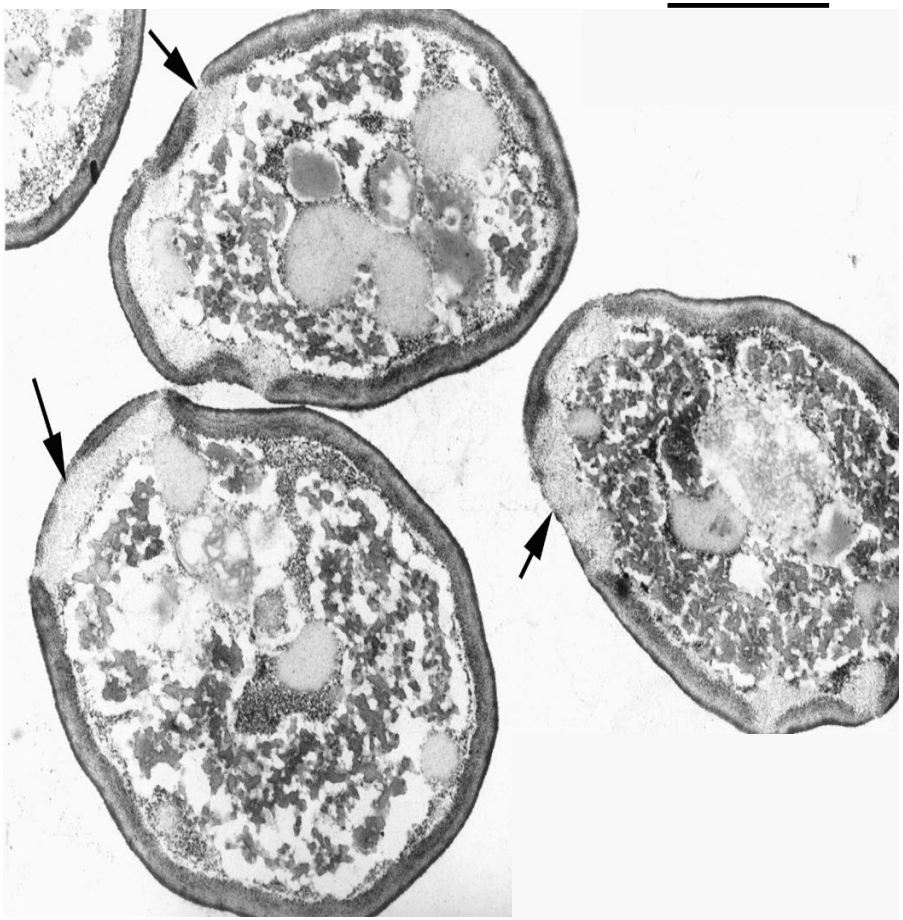
Spoilage Microorganisms

Yeast



Single cell, egg-shaped, 3 microns minimum

Larger than bacteria, approximately 20 microns

Can grow aerobically or anaerobically

Reproduce by binary fission or spore

Beneficial in food fermentation

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Spoilage Microorganisms

<u>Mold</u>

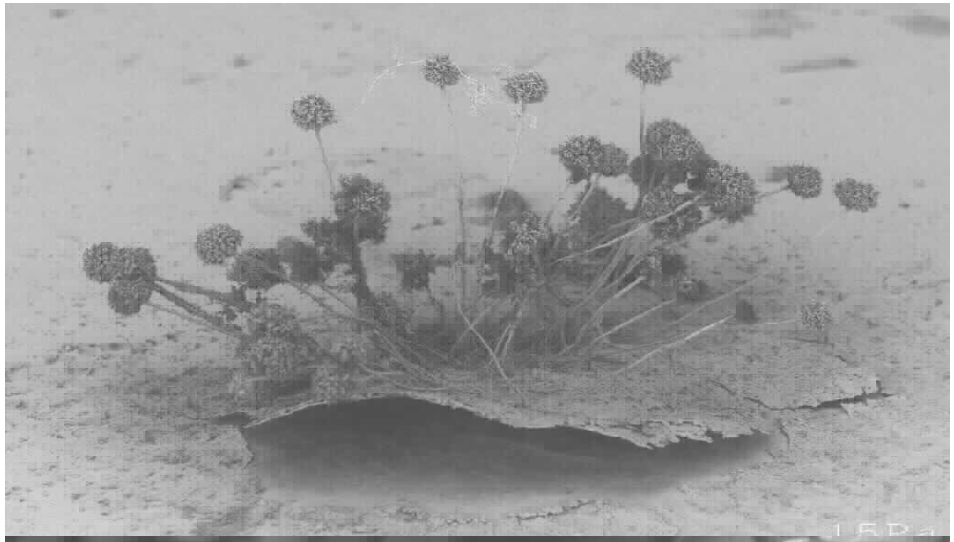
Resistant to environmental conditions

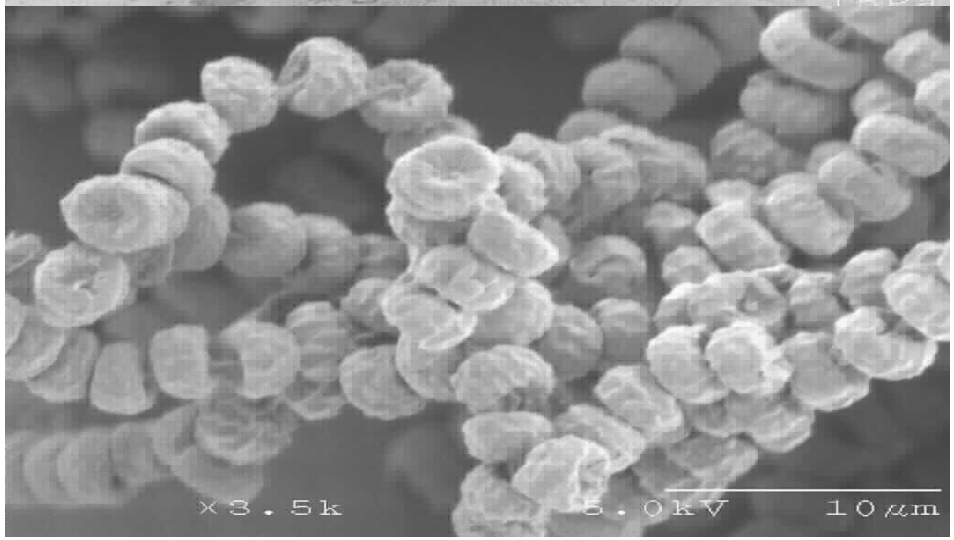
2-3 microns

Multiple cells, microns to millimeters

Strictly aerobic

Spores to reproduce





Allergens

- A food allergy is a reproducible adverse reaction to a particular food that involves the immune system
- Nearly all allergens are proteins
- On a global basis approximately 1-2% of adults and 5-8% of children suffer from food allergy
- Death and serious health problems can result from allergic reactions
- In some cases, 1 mg can trigger a reaction and even death
- Approximately 100 deaths in US due to peanut allergy in 2006

- Challenges in controlling due to:
  - Improper segregation
  - Improper cleaning due to water exclusion
  - Improper labeling

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Environmental Controls Equation

GMPs + Sanitary Design + Sanitation Procedures

= Effective Microbial and Allergen Control in the Processing Environment

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Sanitary Design Definition

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

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Pictorial Definition of Sanitary Design

Sanitary Design Scope

- Applies to the ***entire manufacturing asset***
    - **Facility**
    - **Equipment**
- Focuses on the ***entire life cycle*** of the asset
- Ensures the ***proper and efficient cleaning*** of the assets at three key levels:
    - **Physical**
    - **Chemical**
    - **Microbiological**

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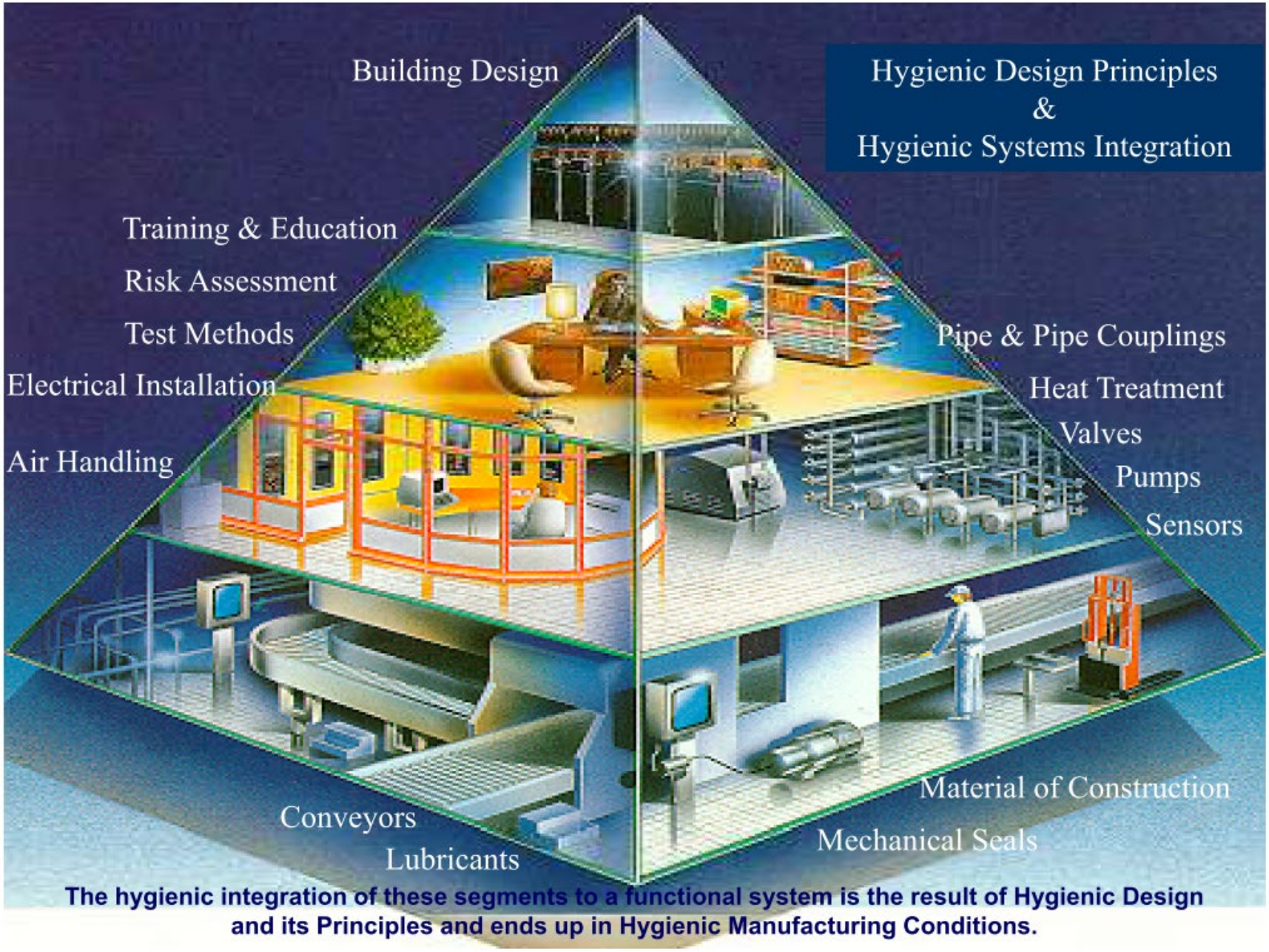

The hygienic integration of these segments to a functional system is the result of Hygienic Design and its Principles and ends up in Hygienic Manufacturing Conditions.

Lessons Learned

I have to clean this for the next 20 years?
What were they thinking?...

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Lessons Learned

I have to clean this for the next 20 years?
What were they thinking?...

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$$$ & Time Spent on Condensate Control

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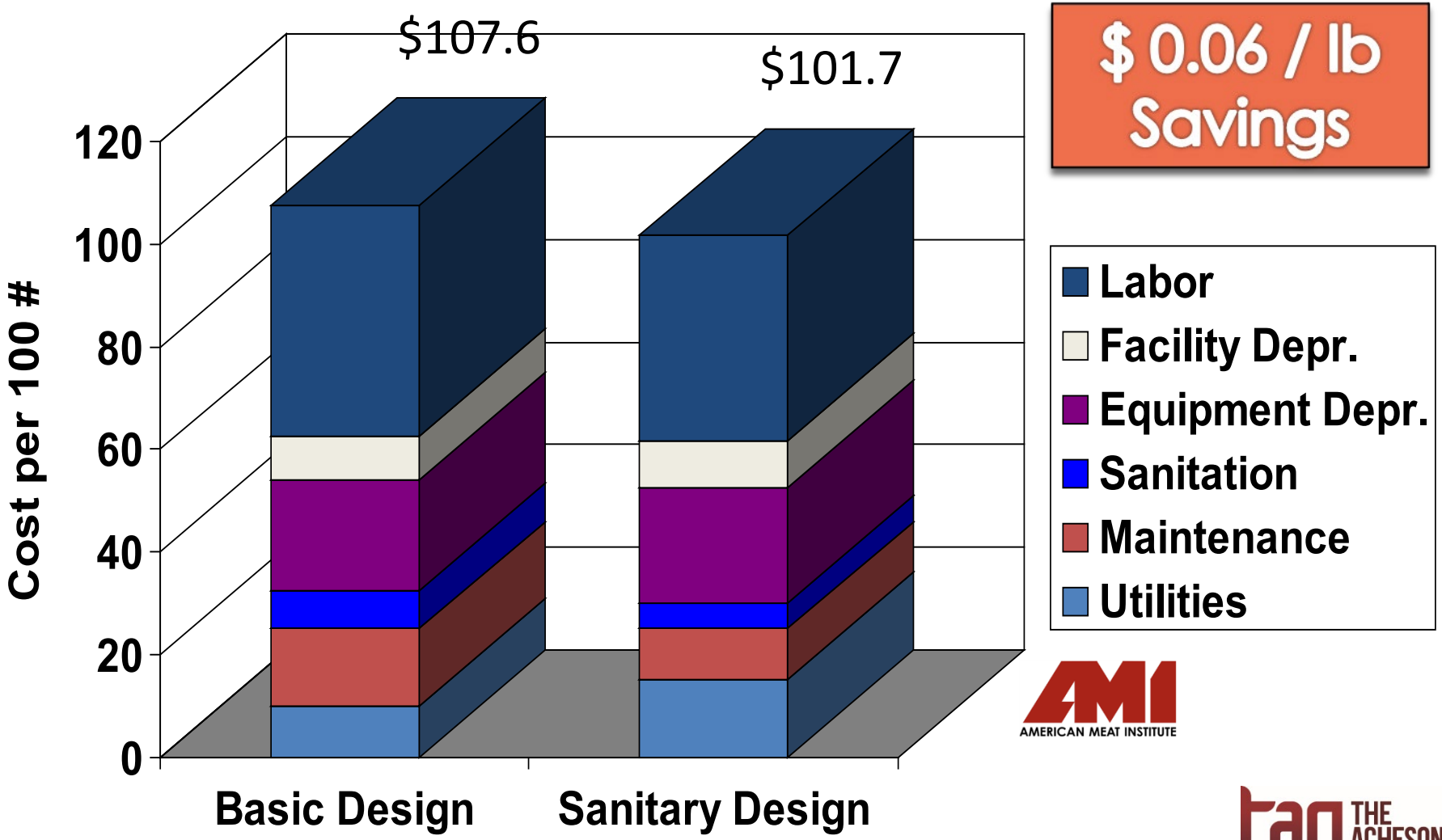
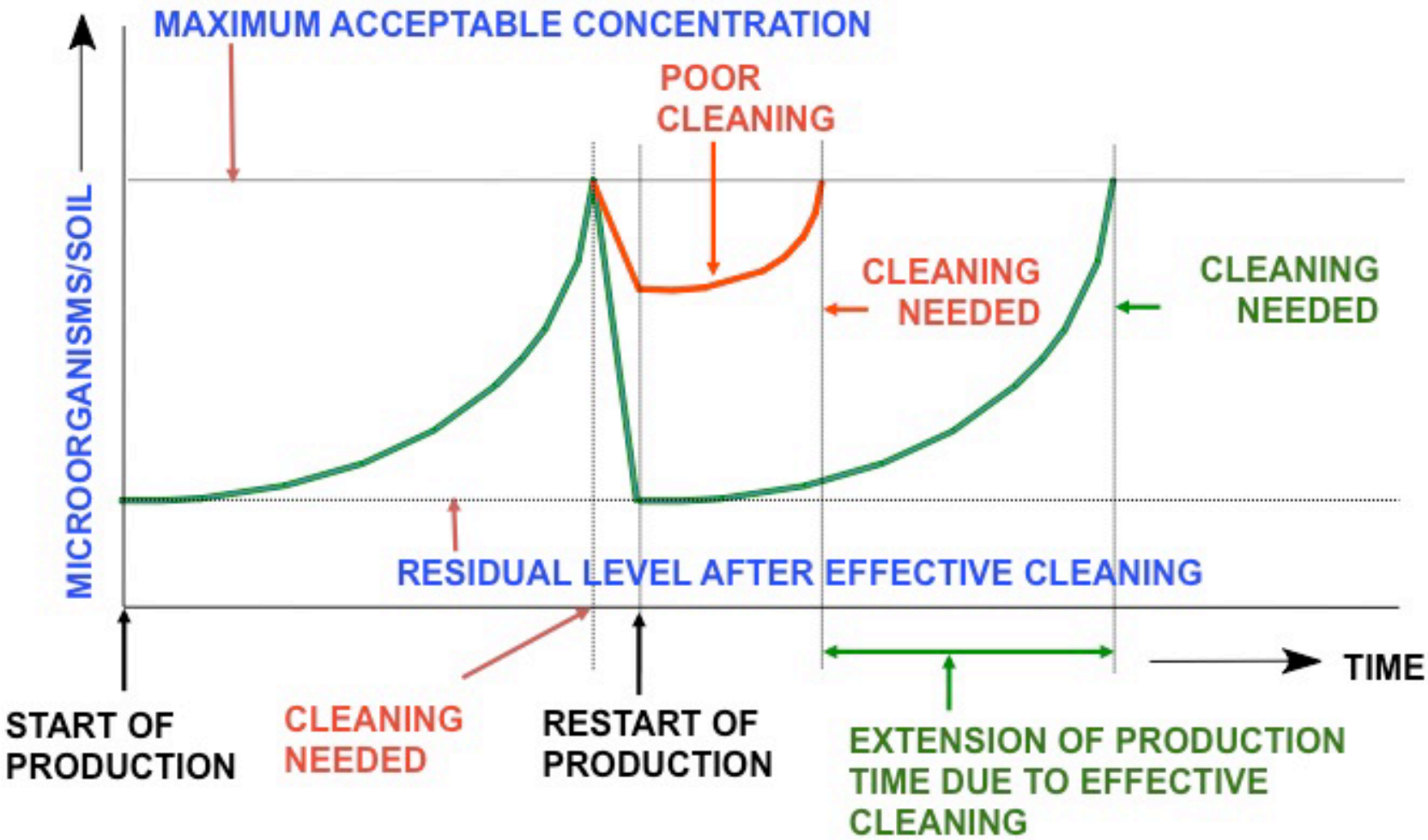
Sanitary Design Reduces Plant Operational Costs - $$$



Sanitary Design
Impacts the Bottom Line



Courtesy: Huub Lelieveld, GHI

Example of Principles of Sanitary Design

- PRINCIPLE #1 - CLEANABLE TO A MICROBIOLOGICAL LEVEL
- PRINCIPLE #2 - MADE OF COMPATIBLE MATERIALS
- PRINCIPLE #3 - ACCESSIBLE FOR INSPECTION, MAINTENANCE, CLEANING AND SANITATION
- PRINCIPLE #4 - NO FOOD OR LIQUID COLLECTION
- PRINCIPLE #5 - HOLLOW AREAS HERMETICALLY SEALED
- PRINCIPLE #6 - NO NICHES
- PRINCIPLE #7 - HYGIENIC OPERATIONAL PERFORMANCE
- PRINCIPLE #8 - HYGIENIC DESIGN OF MAINTENANCE ENCLOSURES
- PRINCIPLE #9 - HYGIENIC COMPATIBILITY WITH OTHER SYSTEMS
- PRINCIPLE #10 - VALIDATED CLEANING & SANITIZING PROTOCOLS

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Principles of Sanitary Design – Sample Checklist

Equipment Design Checklist for Low Moisture Foods

Version 2.0 - May 2010

For detailed directions on the use of the checklist, please click on the tab marked "Directions."

Date:	
Completed By:	
Location:	
Equipment:	

Purpose or Use (check one)	RTE	Further Processing

Facilities, equipment and machinery must meet all federal, state and local food safety requirements as well as personnel safety requirements during operation, cleaning and sanitizing. Any modifications must not affect compliance with these requirements.

#	Description	S	M	U	NA	Comments	Points Awarded	Points Available
PRINCIPLE #1 - CLEANABLE								
1.1	Surfaces can be cleaned to a visually clean standard and meet pre-op inspection requirements.						Needs X	15
1.2	Surfaces can be monitored prior to start up for a visually clean standard, and for allergen residues, ATP and microorganisms as needed.						Needs X	15
1.3	Construction of equipment meets the GMP definition of "easily cleanable" (21 CFR 110.40).						Needs X	15
1.4	A HACCP based product risk evaluation was completed during the product design/selection phase and the equipment is designed to address those risks. The choice of equipment has been validated as a proper choice for the product and operation.						Needs X	15
1.5	Method of cleaning needed for the product risk was incorporated into the chosen design of the equipment, or in choosing the proper equipment.						Needs X	15
1.6	Equipment design meets cleaning time targets established by the equipment user.						Needs X	10
1.7	Equipment has no apparent flaws that will fail over its life and make it uncleanable.						Needs X	15
1.8	If belting is used as product contact surfaces, it should be non-absorbent, fully encapsulated, cleanable and should be designed to be compatible with the cleaning methods employed at the location (wet or dry).						Needs X	15
TOTAL POINTS FOR THIS SECTION							0.0	115

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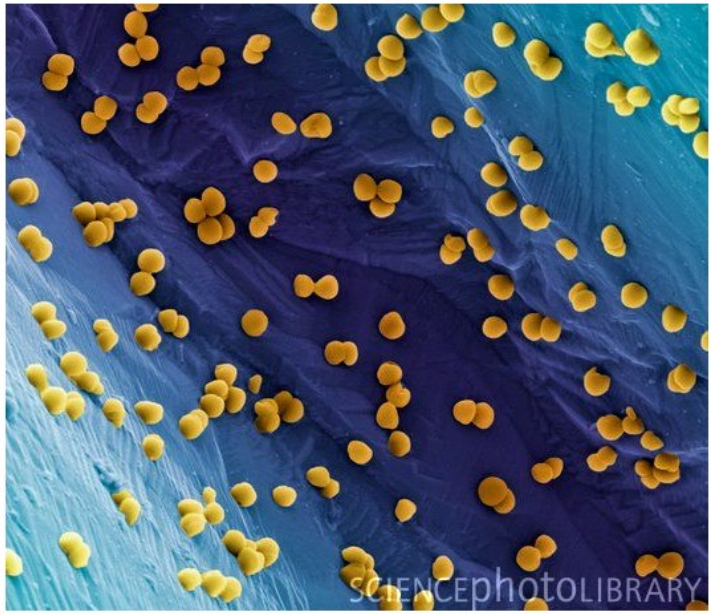
Food Safety in Sanitary Design – Equipment Manufacturers' Responsibility

- Ensure that basic elements for design and cleanability are fulfilled as specified in regulatory requirements and third-party guidelines

- Allowing for proper cleaning and sanitation enables safe food processing!



Sanitary Design Guidelines, Standards and Requirements

- United States
  - 3-A Sanitary Standards, Inc. (3-A SSI)
  - National Sanitation Foundation (NSF)
  - Baking Industry Sanitation Standards Committee (BISSC)
  - Grocery Manufacturers Association (GMA)
  - American Meat Institute (AMI)
  - One Voice
  - Food industry regulatory agencies
- Europe
  - European Hygienic Engineering & Design Group (EHEDG)
- Globally
  - Global Food Safety Initiative (GFSI)

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Why Sanitary Design?

- **Customers trust that the food they consume** is manufactured to meet their ***"zero tolerance"*** expectation for pathogens or other defects
- Employing sound Sanitary Design principles helps ensure that this expectation can be achieved!

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Why Sanitary Design?

Regulatory expectations

- **U.S. Department of Agriculture (USDA)**
  - Routinely performs reviews on equipment before it is installed in a plant and during plant inspections
- **U.S. Food and Drug Administration (FDA)**
  - “Equipment shall be designed and of such material and workmanship to be adequately cleaned and shall be properly maintained” (21 CFR 117.40)
  - Food Safety Modernization Act (FSMA)

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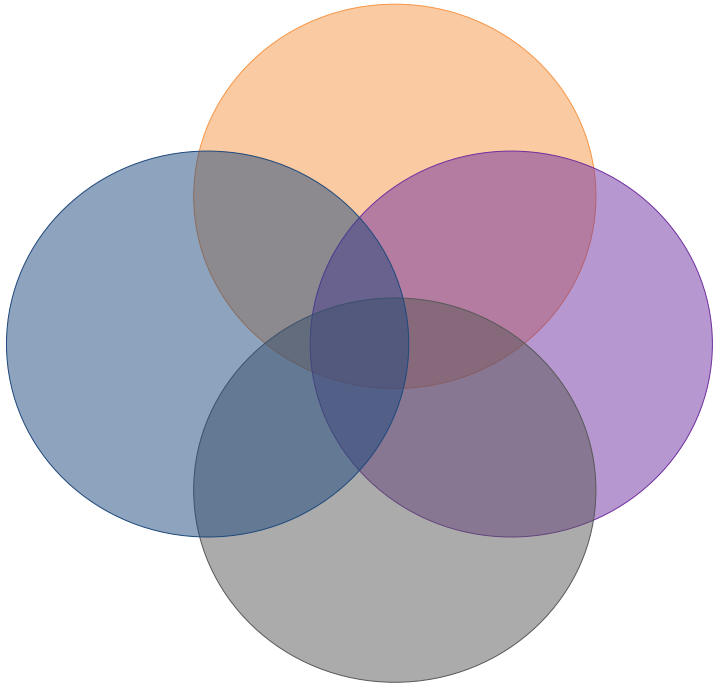
Food Safety Modernization Act

Prevention

Enhanced Partnerships



Increased Inspections
Enhanced Response

Import Safety
Apply Domestic Standards to Imported Foods

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Why Sanitary Design?

Regulatory expectations

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Embrace Sanitary Design

- Equipment manufacturers have a responsibility with respect to cleaning and sanitation.
- Sanitary design cannot be secondary to functionality of equipment.

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Why Sanitary Design?

Regulatory expectations

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Action Against Violations

- If FDA determines equipment is not suitable for its intended use, it will go after the manufacturers that use it.
- This will not be good for business – either manufacturers or their equipment suppliers.

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Why Sanitary Design?

Industry-driven initiatives

- **Global Food Safety Initiative (GFSI)**
  - Certification under one of its standards (e.g., BRC, SQF, FSSC 22000) required by major retail food outlets
  - Addresses food equipment design, construction and maintenance
  - http://www.mygfsi.com/

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Why Sanitary Design?

- Global Food Safety Initiative (GFSI)
  - British Research Consortium (BRC)

4.6 Equipment

All food processing equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.

Clause	Requirements
4.6.1	All equipment shall be constructed of appropriate materials. The design and placement of equipment shall ensure it can be effectively cleaned and maintained.
4.6.2	Equipment which is in direct contact with food shall be suitable for food contact and meet legal requirements where applicable.

  - Food Safety System Certification (FSSC) 22000
    - Expects that food contact equipment be designed and constructed *to facilitate appropriate cleaning; of durable materials; of materials designed for food use; be impermeable and rust- or corrosion-free; and meet established principles of hygienic design*

Why Sanitary Design?

- **Essential to ensuring food safety**
  - Ease and level of cleaning of equipment and manufacturing facilities are directly related to potential for cross-contamination (e.g., microorganisms or allergens) and other undesired safety and quality effects on food

Source: http://www.foodsafetymagazine.com/articlePF.asp?id=1163&sub=sub1

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Summary

- Consumers, regulations, industry standards and best practices require that equipment and facilities be designed in a hygienic manner so that they can be easily and thoroughly cleaned

- Facilitating proper cleaning and sanitation allows for safe food processing and helps mitigate public health, operational and reputational risk!

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Hygienic by Design: Reducing Risk in Your Facility

2023 3-A SSI Education Event

Minneapolis, MN

Rolando Gonzalez, PhD
rolando.gonzalez@achesongroup.com

May 2023