Embracing Hygienic Design: Opportunities and Challenges

3-A Educational Session – "The Bridge to Hygienic Design"

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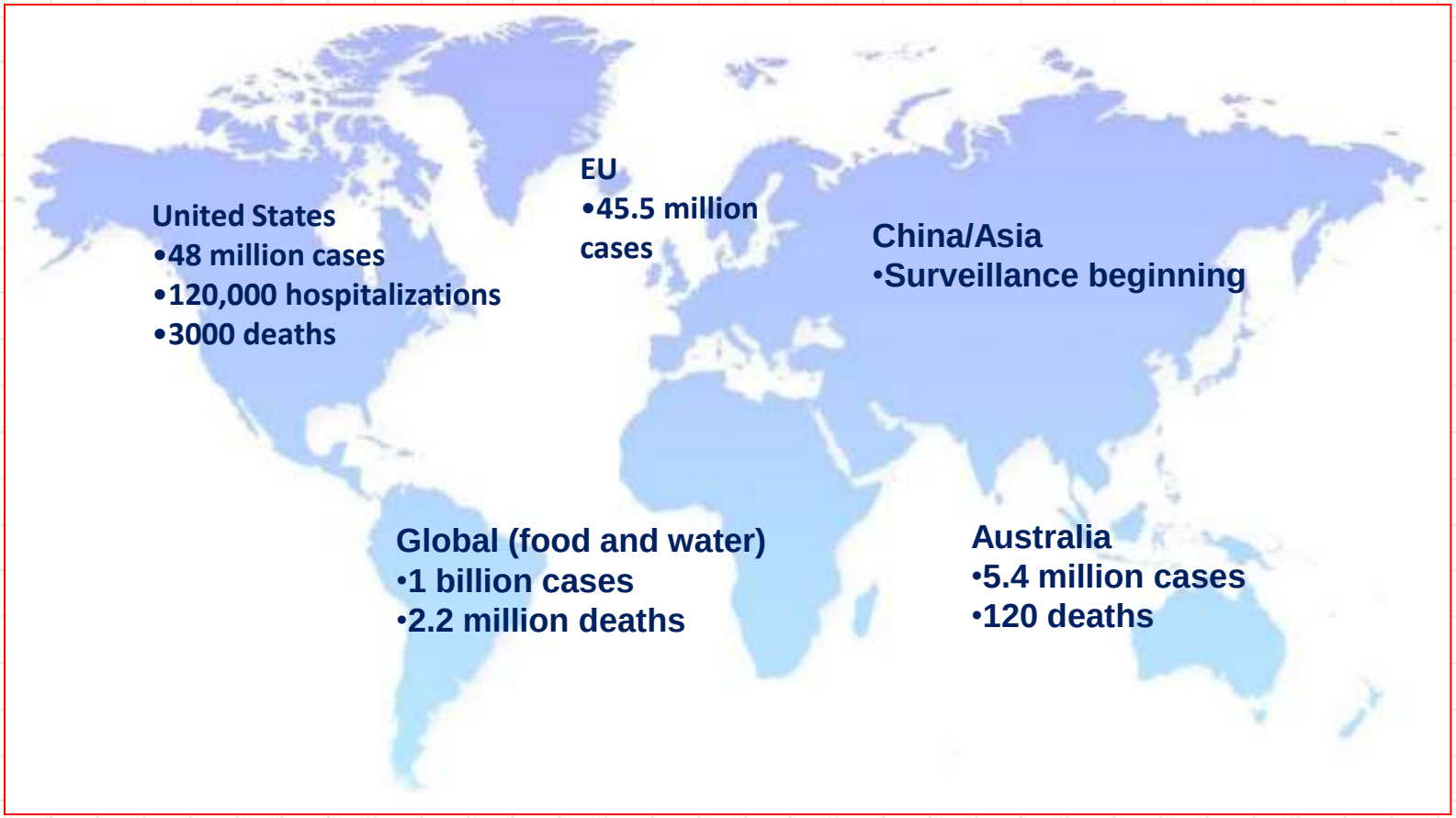
May 12, 2015

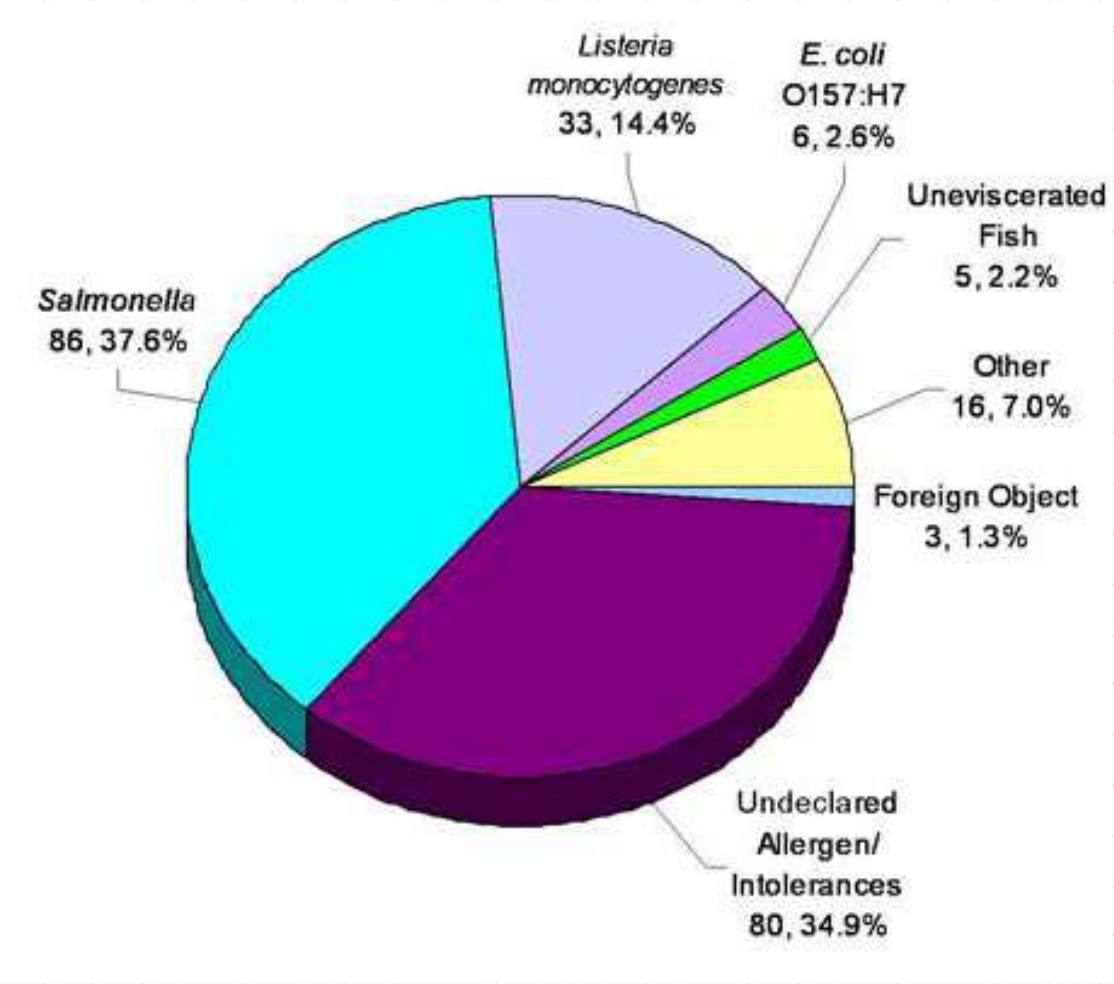
Embracing Hygienic Design

1. Design Opportunities
2. Appropriate design – the risk assessment
3. Design Solutions

Foodborne Illness Estimates



FDA Reportable Food Registry By Hazard 2010



Peanut Corporation of America

- Eight Deaths
- 19,000 Sickened
- 76 Department of Justice Indictments
- Owner, Brother, Plant Manager, Operations Manager, Quality Manger all Convicted.
- Prime Mover Behind Food Safety Modernization Act

Blue Bell Creameries

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

SEARCH

CDC A-Z INDEX

Listeria (Listeriosis)

Listeria (Listeriosis)
Definition & Symptoms
Outbreaks
Blue Bell Creameries Ice Cream Products
Advice to Consumers, Institutions & Retailers
Information for Health Professionals
Case Count Map
Epi Curves
Signs & Symptoms
Key Resources
Commercially Produced, Prepackaged Caramel Apples
Oasis Brands, Inc.

CDC > Listeria (Listeriosis) > Outbreaks

Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries Products

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Posted April 21, 2015 11:45 AM ET

Highlights

- Read the Advice to Consumers, Institutions, and Retailers>>
- Read the Information for Health Professionals>>
- On April 20, 2015, Blue Bell Creameries voluntarily recalled all of its products currently on the market made at all of its facilities, including ice cream, frozen yogurt, sherbet, and frozen snacks, because they have the potential to be contaminated with *Listeria monocytogenes*. Blue Bell announced this recall after sampling conducted by the company revealed that Chocolate Chip Cookie Dough Ice Cream half gallons produced on March 17, 2015 and March 27, 2015 contained the bacteria.
- CDC recommends that consumers do not eat any Blue Bell brand products, and that institutions and retailers do not serve or sell them

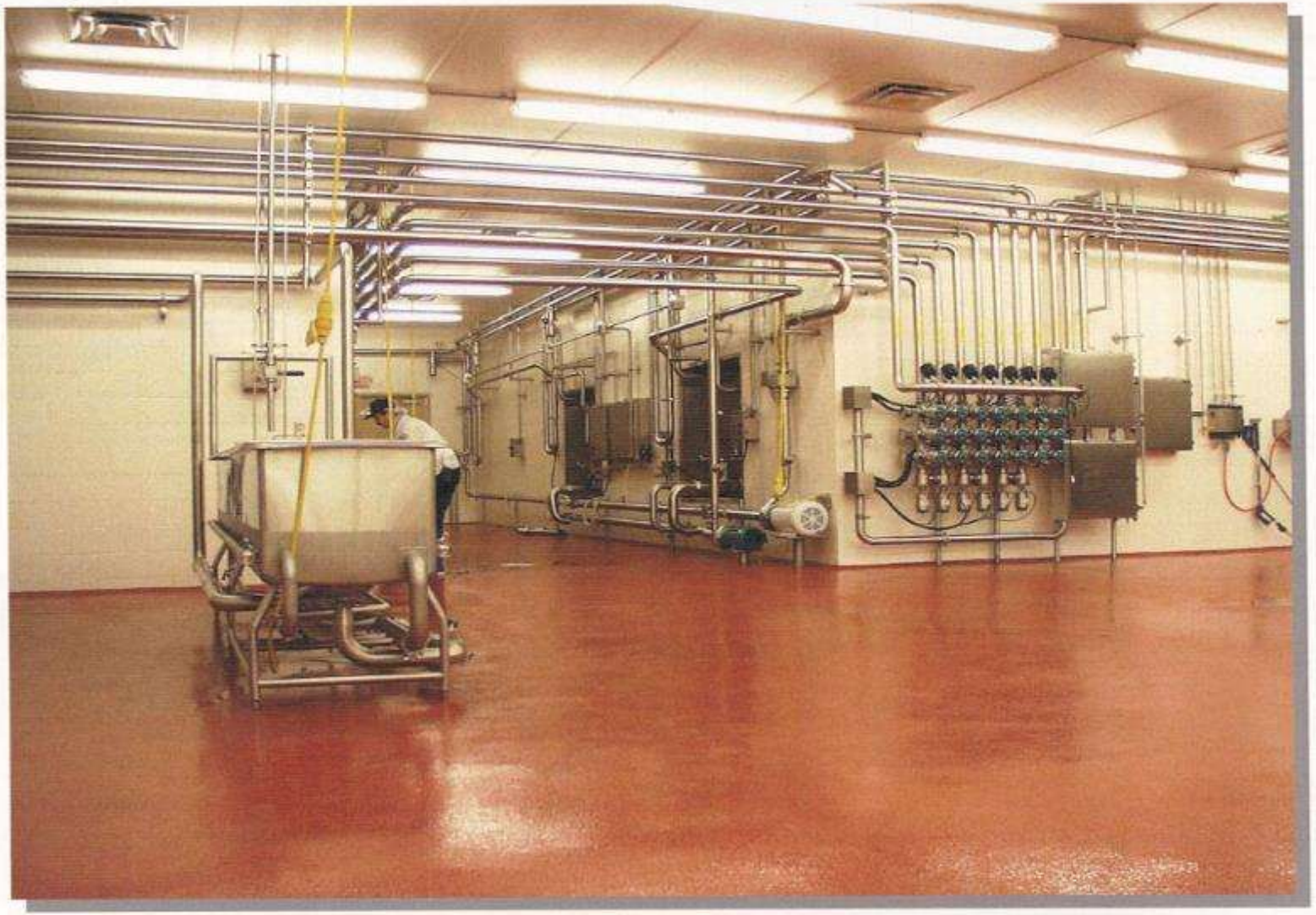
At a Glance:

- Case Count: 10
- States: 4
- Deaths: 3
- Hospitalizations: 10
- Recall: Yes

LISTERIA AND BLUE BELL ICE CREAM

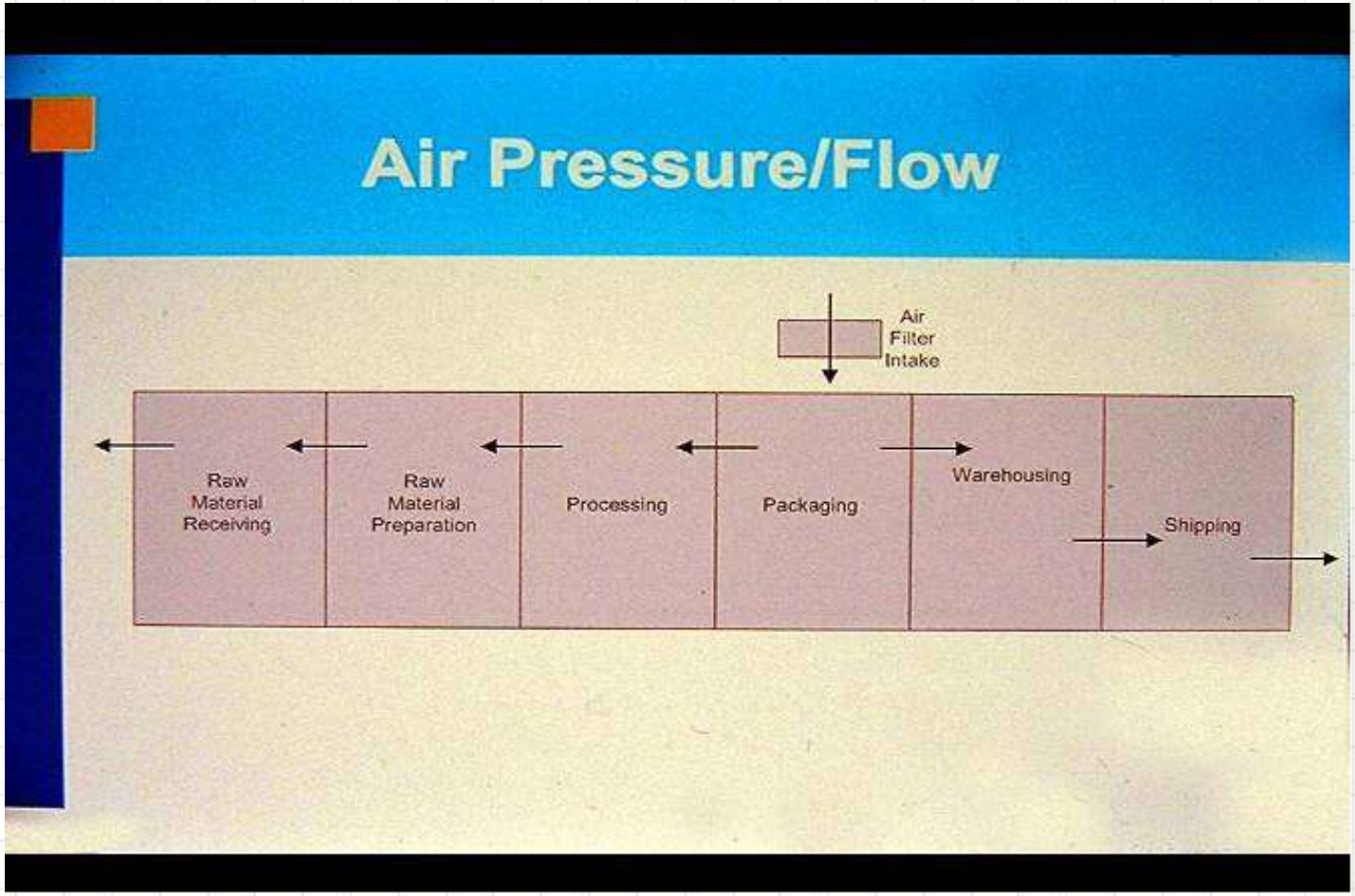
Our Challenge…protecting zones 2 and 1 for filling and closing

Beginning with the end in mind



Design opportunities - negative plant

Design opportunities- air balance



Design opportunities –indirect zone 1 risk

Design solution

Design opportunities- unsealed interface

Design opportunities – poor utility installation

Design opportunities – uncleanable interface

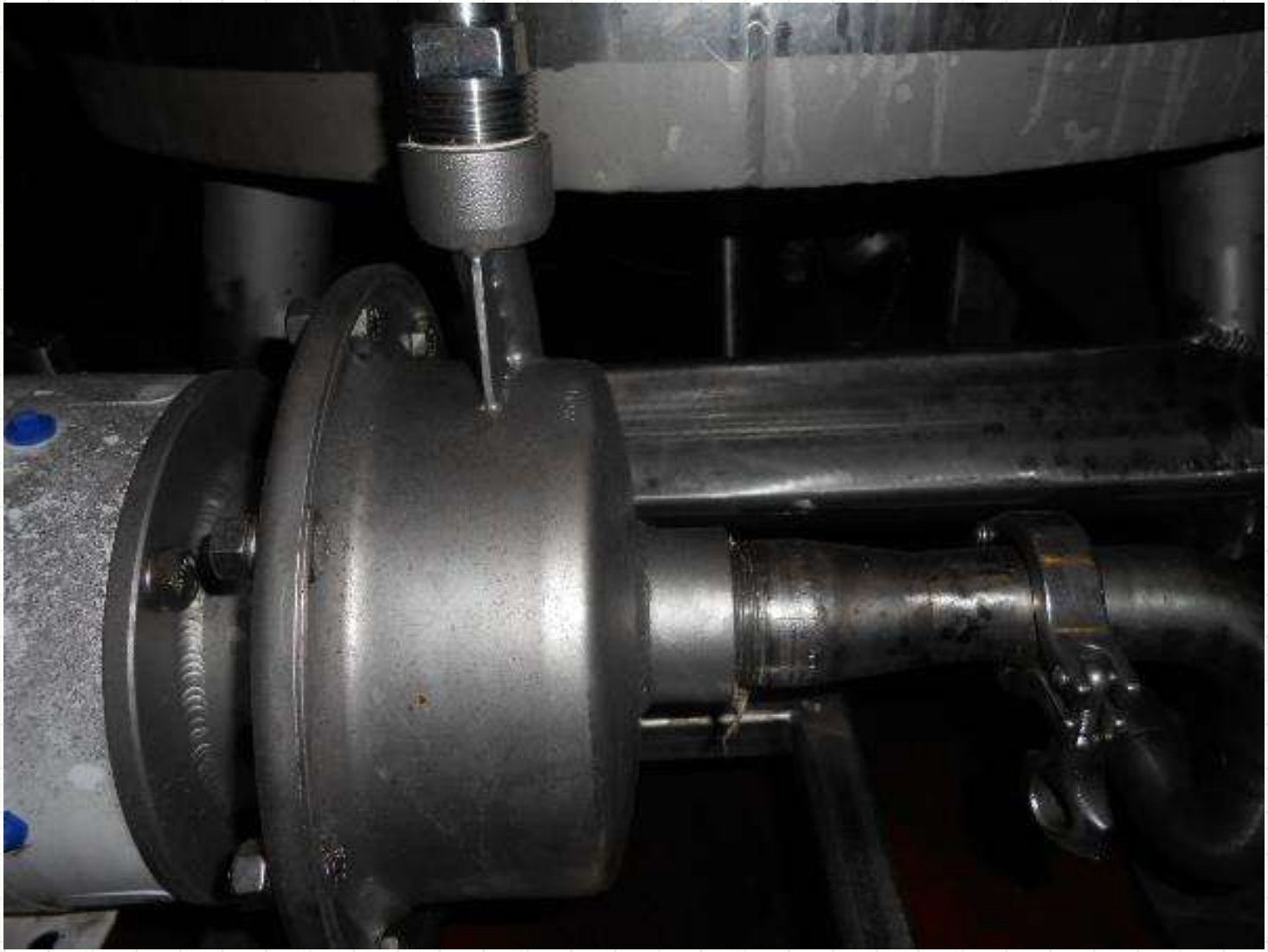
Design opportunities – dead end

Design opportunities – split flows

Design opportunities – insanitary valves

Design opportunities – insanitary valves

Design opportunities – insanitary pump



Design opportunities – butterfly valve

Design opportunities

Fermentation tank with intermittent failures due to design issues.

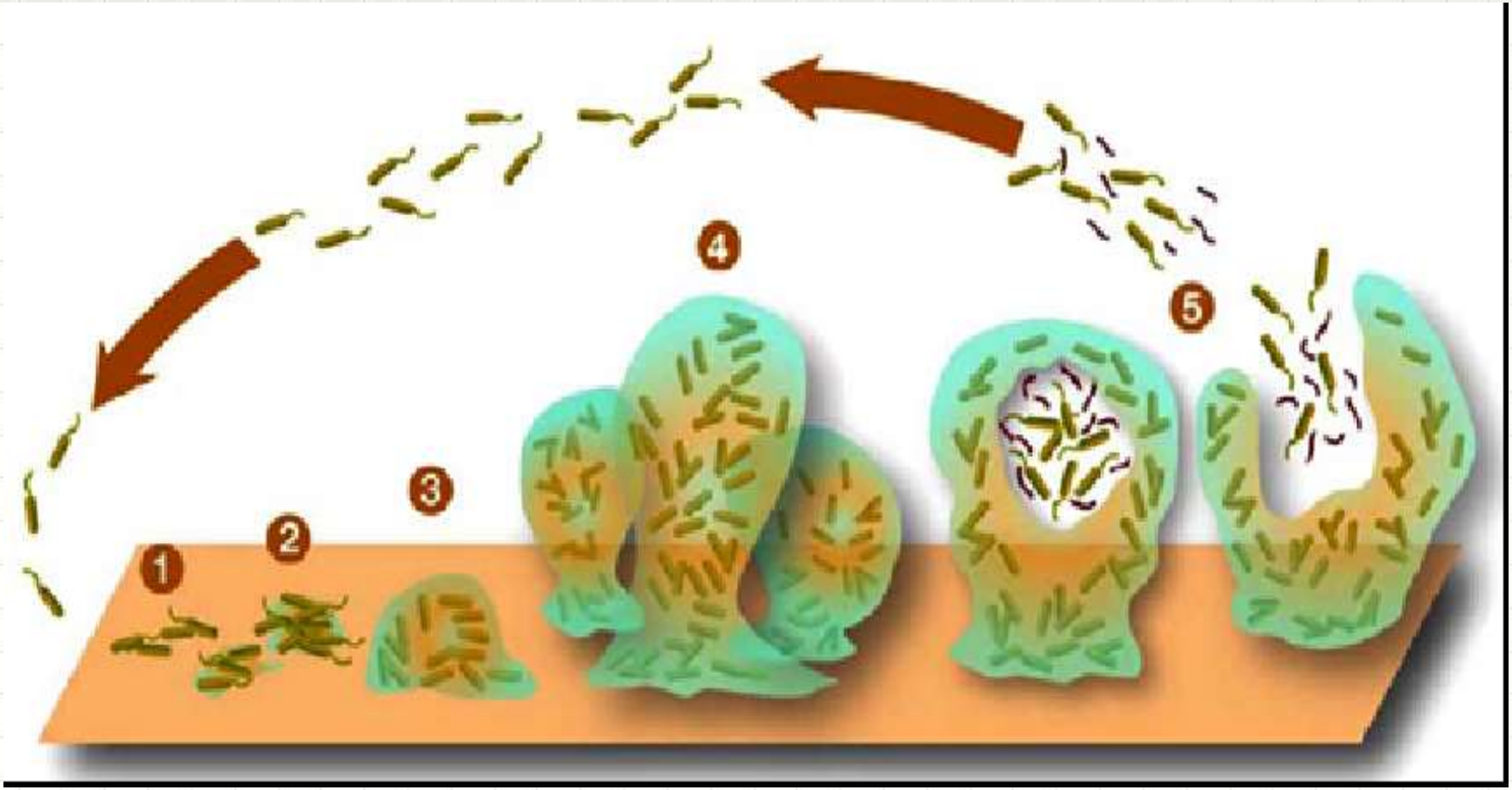
Biofilms – the result of poor design

Biofilms are caused when there is incomplete soils removal / sanitization on equipment and in the environment.

- Poor Sanitary design / insufficient sanitation on equipment with pits, folds, inclusions, crevices and out of product path, inaccessible areas will leave a desirable substrate behind for bacteria to grow.
- Pathogenic bacteria such a Listeria, E. Coli and Salmonella are the cause of a large number of illnesses and deaths annually. These bacteria, especially E.Coli 0157:H7 and Salmonella are often found in mixed culture biofilms.
- Biofilms are also a common cause for spoilage incidents.

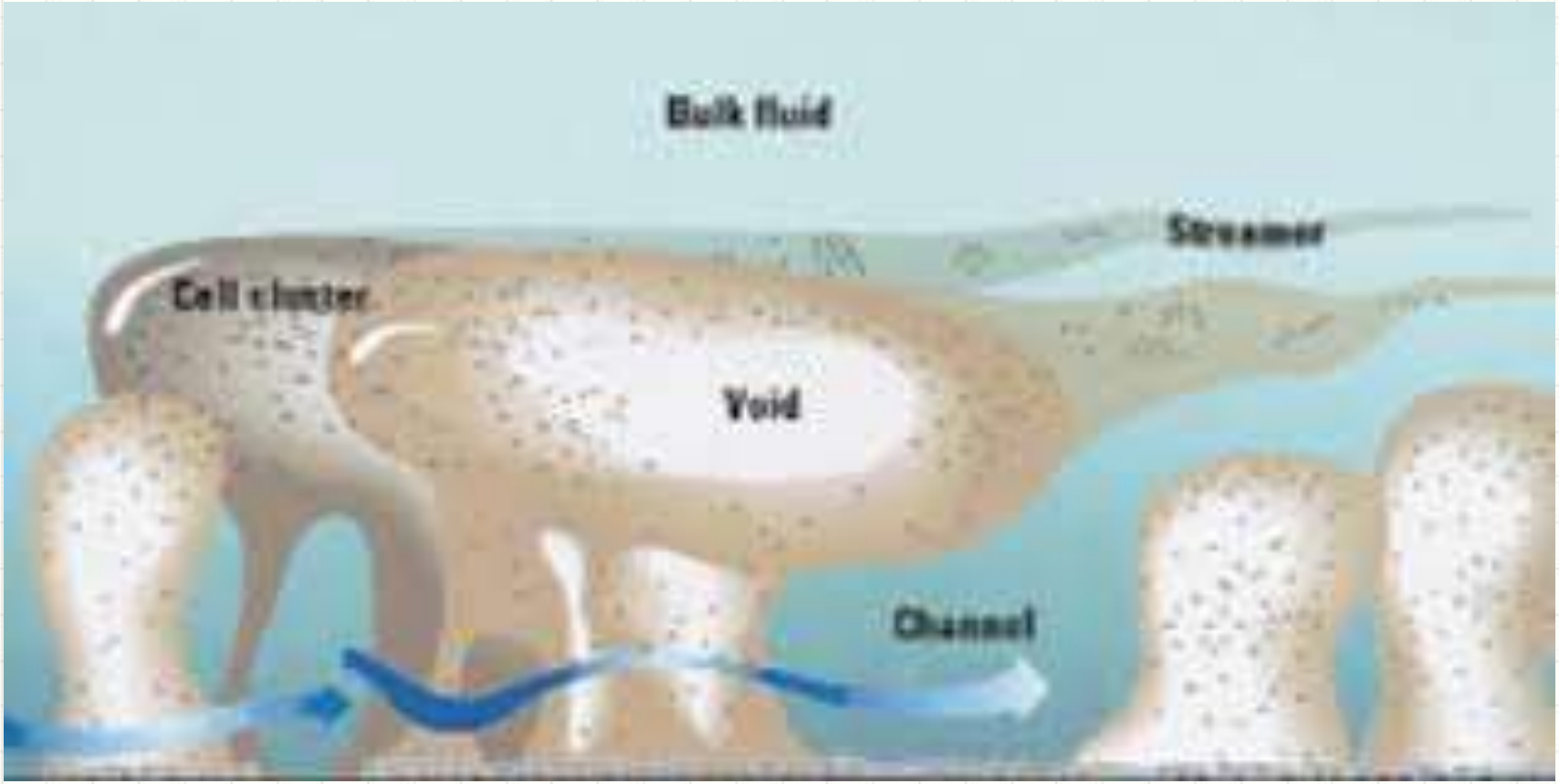
Biofilms

Beneficial Biofilms – Human gut biofilm



Biofilms – the symbiotic community

Water channels carry nutrients, dissolved oxygen and potentially, antimicrobials to the cells. Promotes high degree of thickness and complexity.



Biofilms

Dental Plaque Biofilm

Biofilms

How do we design to the right level? What is process appropriate?

CONDUCT A RISK ASSESSMENT!

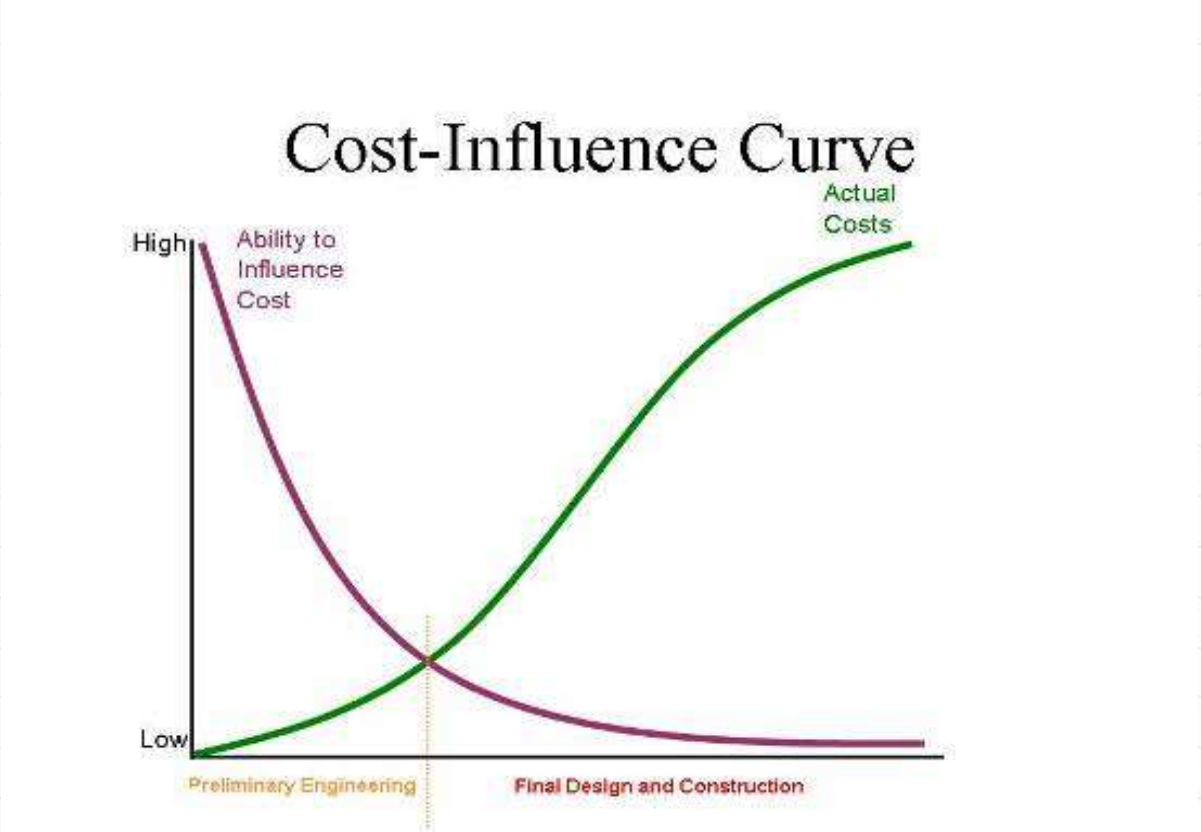
Design solutions – The risk assessment

Thorough risk assessment requires a cross functional leadership team working with the project engineer:

- Engineering
- Sanitation
- Quality
- Business Unit leadership
- Operations
- Corporate Food Safety
- R&D

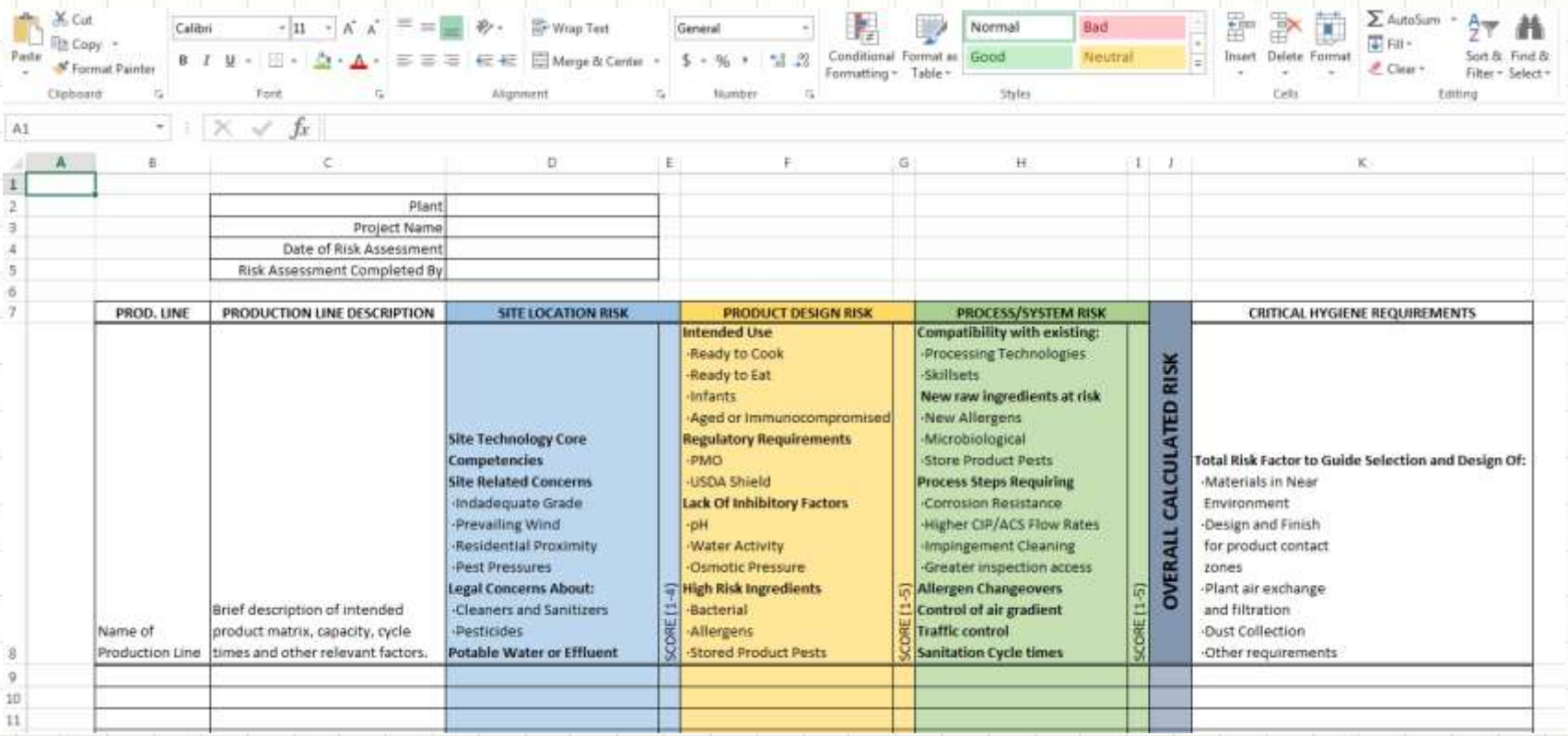
All Stakeholders are necessary to create the optimal design!

Design solutions – receive input early



This graph shows that many decisions influencing the cost of the project can be made at a very low cost (horizontal axis) at the very start of the project. All involved should be gathered at the very start (prior to the point where the lines cross) and take the time to thoroughly discuss and have input for the project. This would include Sanitary Design considerations.

Design solutions – The risk assessment



Plant	
Project Name	
Date of Risk Assessment	
Risk Assessment Completed By	

PROD. LINE	PRODUCTION LINE DESCRIPTION	SITE LOCATION RISK		PRODUCT DESIGN RISK		PROCESS/SYSTEM RISK		OVERALL CALCULATED RISK	CRITICAL HYGIENE REQUIREMENTS
Name of Production Line	Brief description of intended product matrix, capacity, cycle times and other relevant factors.	**Site Technology Core Competencies** **Site Related Concerns** ·Indadequate Grade ·Prevailing Wind ·Residential Proximity ·Pest Pressures **Legal Concerns About:** ·Cleaners and Sanitizers ·Pesticides **Potable Water or Effluent**	SCORE (1-4)	**Intended Use** ·Ready to Cook ·Ready to Eat ·Infants ·Aged or Immunocompromised **Regulatory Requirements** ·PMO ·USDA Shield **Lack Of Inhibitory Factors** ·pH ·Water Activity ·Osmotic Pressure **High Risk Ingredients** ·Bacterial ·Allergens ·Stored Product Pests	SCORE (1-5)	**Compatibility with existing:** ·Processing Technologies ·Skillsets **New raw ingredients at risk** ·New Allergens ·Microbiological ·Store Product Pests **Process Steps Requiring** ·Corrosion Resistance ·Higher CIP/ACS Flow Rates ·Impingement Cleaning ·Greater inspection access **Allergen Changeovers** **Control of air gradient** **Traffic control** **Sanitation Cycle times**	SCORE (1-5)		**Total Risk Factor to Guide Selection and Design Of:** ·Materials in Near Environment ·Design and Finish for product contact zones ·Plant air exchange and filtration ·Dust Collection ·Other requirements

Design solutions – The risk assessment

Wet Cleaning

- Basic Hygiene
- High Hygiene

Dry Cleaning

- Basic Hygiene
- High Hygiene

Design solutions – The risk assessment

Example criteria:

Wet Cleaning

High Hygiene

Design solutions – The risk assessment

Product / Process Characteristics

- **RTE products**
- **RTC products that require a Kill step by end user or consumer for safety**
- **Liquid Dairy and other non-shelf stable liquid products**
- **Products with an intended use that includes**
  - **Infants**
  - **Aged or Infirm**
  - **Immunocompromised**
- **Refrigerated products**
- **Some Aseptic CFR 113 and 114 environments**
- **Pharma non-shelf stable liquids**
- **Biological active operations**

Design solutions – The risk assessment

Product Examples

- Consumer packaged chocolate enrobed products
- Ice Cream Inclusions
- Bakery inclusions or toppings without end user steps
- Flavors or ingredients added to consumer beverages
- Infant food
- Cold processed cheese products
- Bioactive cultures and metabolites
- Confectionary products, dessert sauces, cores, bases
- Dairy and Culinary sauces and frozen inclusions

Design solutions – The risk assessment

Design Requirements

- A foot and wheeled traffic plan with contamination breaks including:
  - Dedicated MH equipment
  - Foot sanitization equipment to achieve a 3 log reduction
- Air handling systems pressurize processing rooms:
  - MERV 12-16 or HEPA for ESL or Aseptic.
  - De-humidified to prevent condensation.
  - A negative gradient may be present to adjoining rooms for allergen control.
- Permanently Installed tubeline systems and valves meet 3-A or EHEDG standards
- All product contact surfaces are Stainless Steel, or approved product contact plastics and elastomers
- Equipment is self-draining, sanitary under conditions of use, and free of pits, folds, cracks and inclusions allowing effective removal for microbial and allergen validation.

Design solutions – The risk assessment

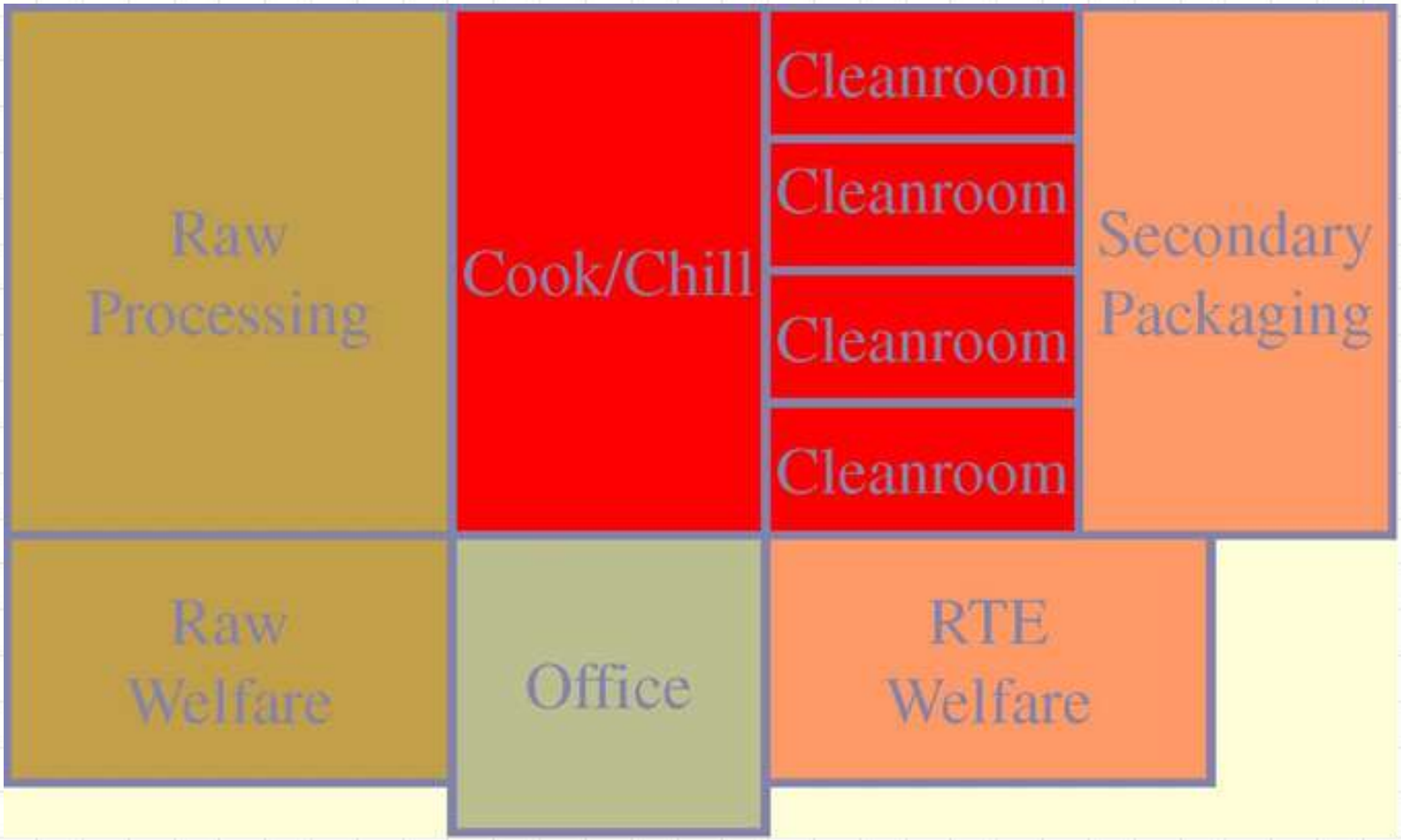
Design Requirements (continued)

- Welds:
  - Compliant with AWS 18.1, 18.2, 18.3
  - Stitch welding is prohibited
- Materials of construction are compatible with food soils and sanitation process
- Where sterilization is required, equipment is designed to withstand:
  - High thermal process (>250 degrees F) for prolonged periods
    OR
  - Oxidative chemicals to achieve sterility

Embracing Hygienic Design

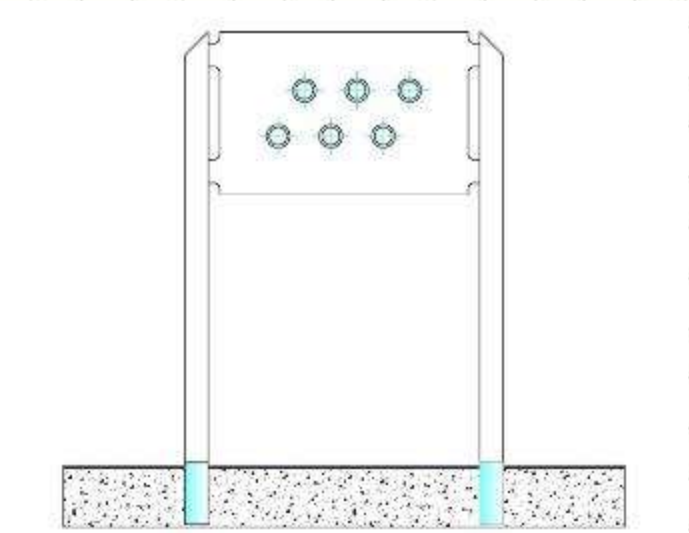
DESIGN SOLUTIONS

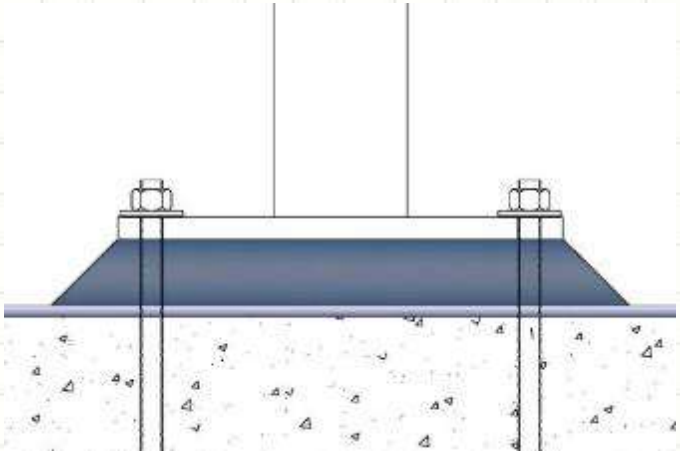
Design solutions



Design solutions – setting expectations

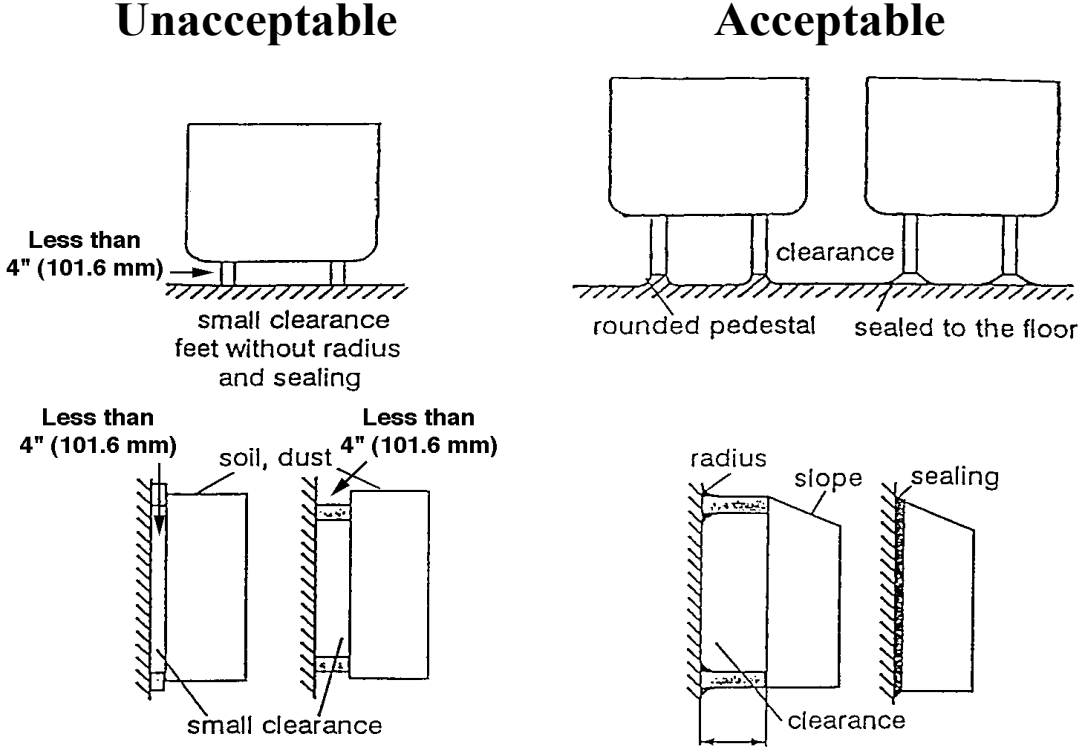
Design solutions – Equipment mounting





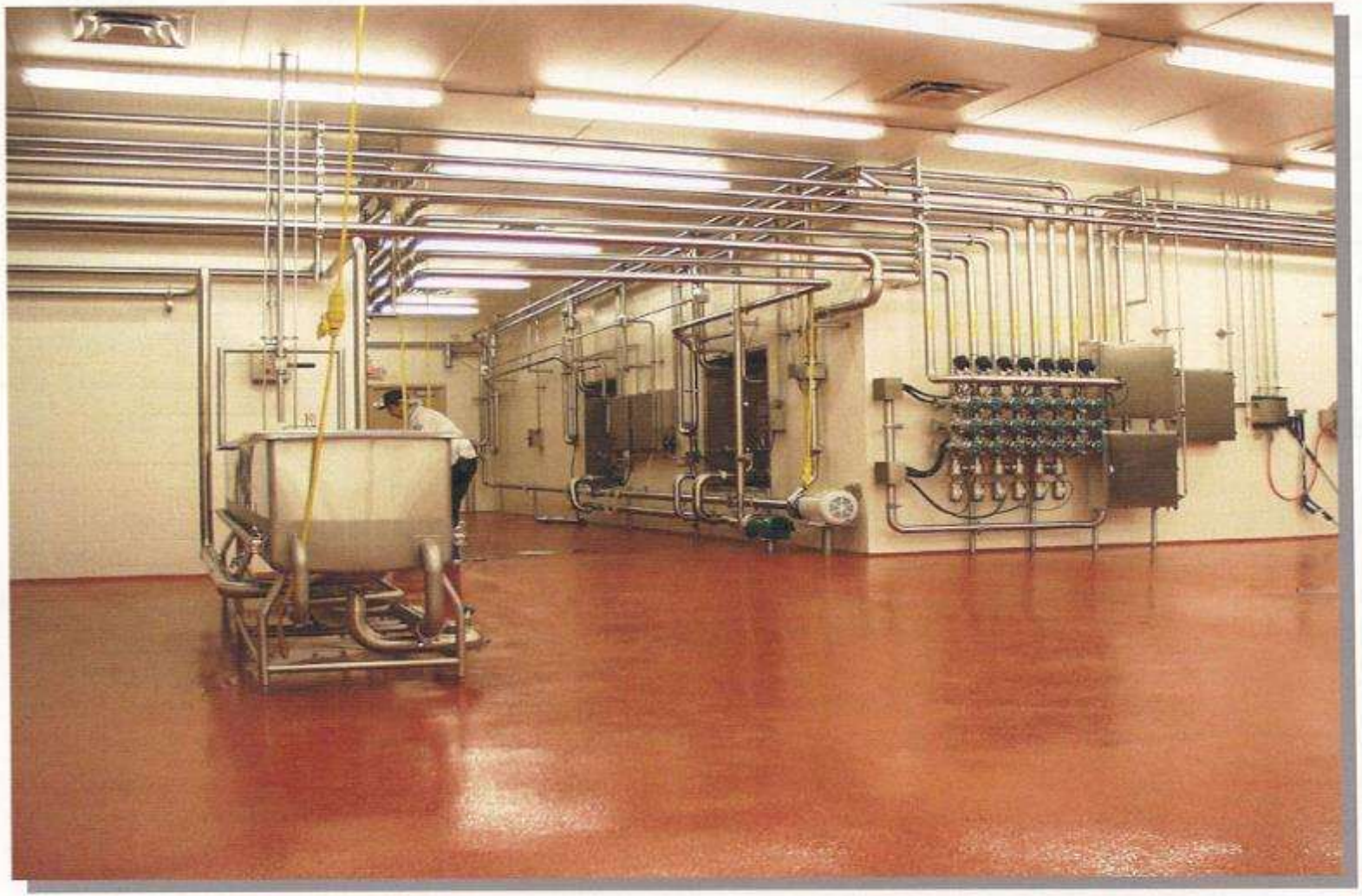
Design solutions – equipment mounting

Equipment Supports and Mounting



Source: EHEDG and Trends in Food Science and Technology (1995 Vol. 6(9) pp. 305-310) (modified)

Design solutions – minimize floor contact



Design solutions – utilities, tubelines

Portable Pump cart - roundstock

Cycle time reduction, run time extensions

QUESTIONS?