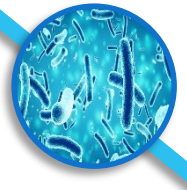
Introduction to Hygienic Design

Scott Hoffmeyer

Learning Objectives

Define Hygienic Design

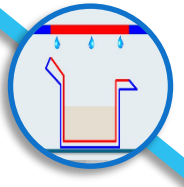


Review microbiology facts

Discuss the concept of the Holistic Approach to the Hygienic Design

Identify the Key Steps of the Hygienic Design Process

Define risks in food production



Classify contact surfaces

What is Hygienic Design?

Hygienic Design is a design process or a set of design principles to manage hazards and reduce food safety risks in food processing equipment, processes and facilities

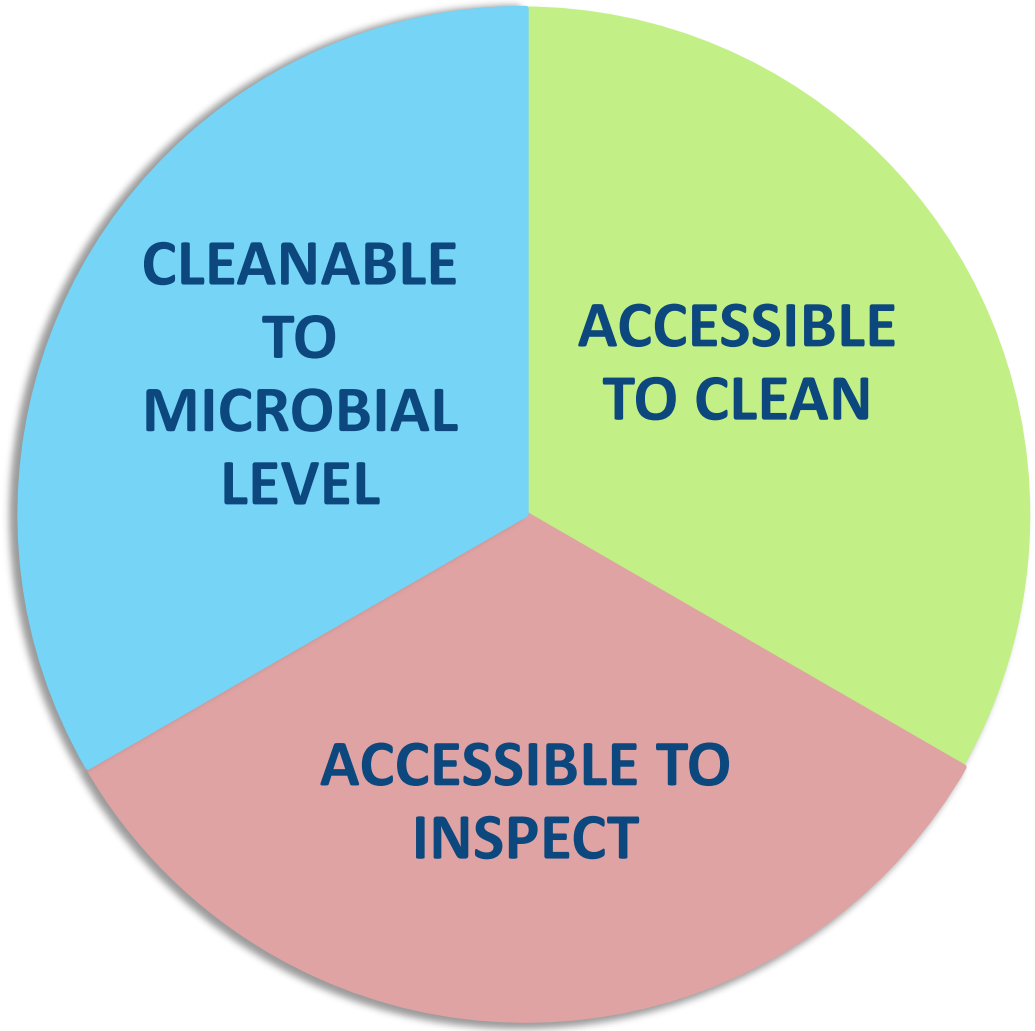
Addresses hazards and food safety risks

Ensures cleanability and accessibility

Food Safety Hazard Risk Analysis for Equipment

CHEMICAL	• Allergens, gluten • Unapproved additives • Odors
BIOLOGICAL	• Parasites, pathogens • Spoilage organisms • Pests
PHYSICAL	• Extrinsic • Intrinsic • Material compatibility

Key Hygienic Design Criteria



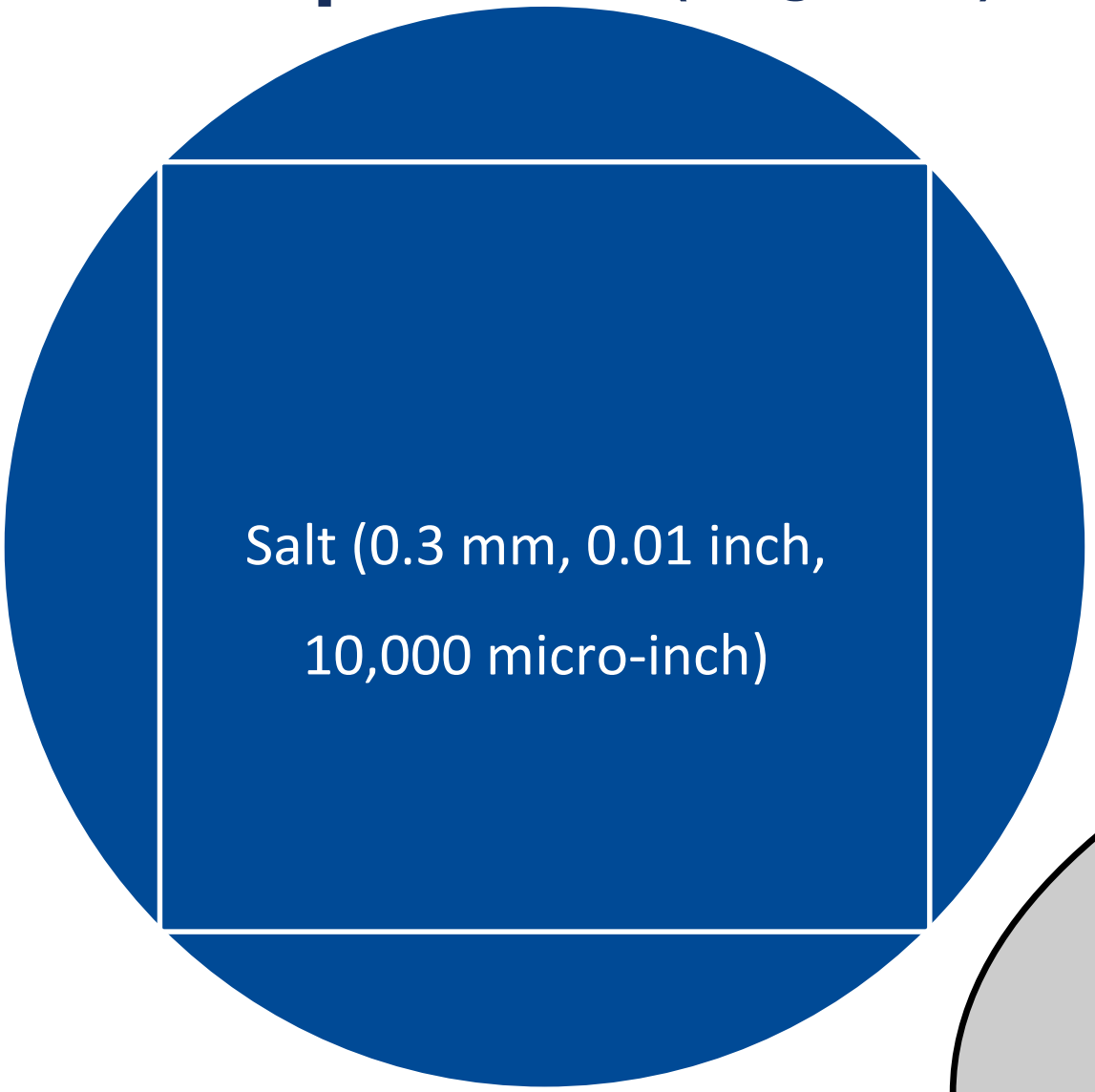
Benefits of Hygienic Design

- Reduces hazardous risks
- Improves the product quality
- Allows for cleaning to the microbiological level
- Allows for cleaning of allergens
- Cleaning and sanitizing:
  - More reliable
  - Faster
  - Lower labor cost

Microbiology 101 for Hygienic Designers

1. Incredibly small
2. Multiple extremely fast
3. Very dangerous or destructive
4. Easy to destroy with sanitizers
5. Need food, water, and shelter

Micro Size Comparison (magnified)



- Yeast (0.05 mm),
  (0.00019 inch, 190 micro-inch)
- Mold spore (0.03 mm),
  (0.00012-inch, 120 micro-inch)
- Listeria (0.0005 mm),
  (0.00002 inch, 20 micro-inch)
  Not visible with human eye

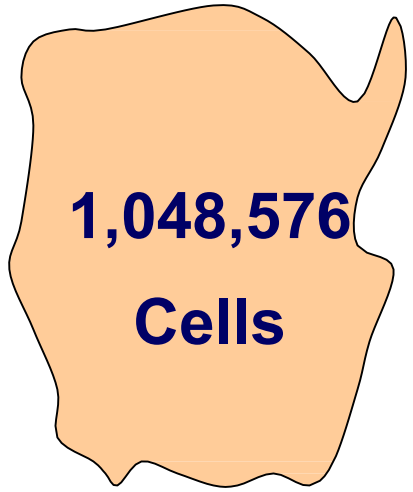
Pin head (1.5 mm, 0.06-inch diameter,
60,000 micro-inch)
(only half shown)

How Fast Do Microorganisms Multiply?

10 Years

1 Year

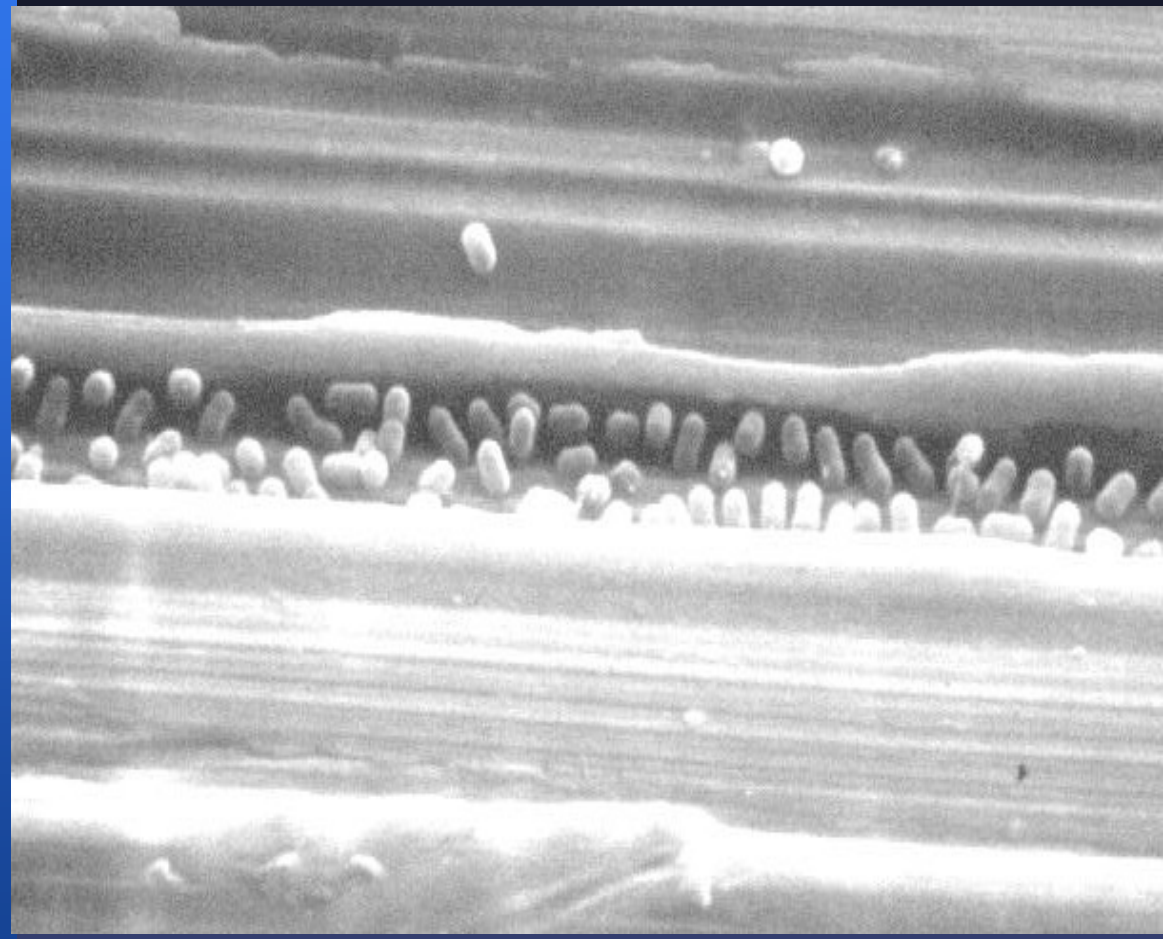
10 Hours



Microbiology Math Problem

Minutes	Number of Bacteria
0	1
20	2
40	4
?	64

2 hours!

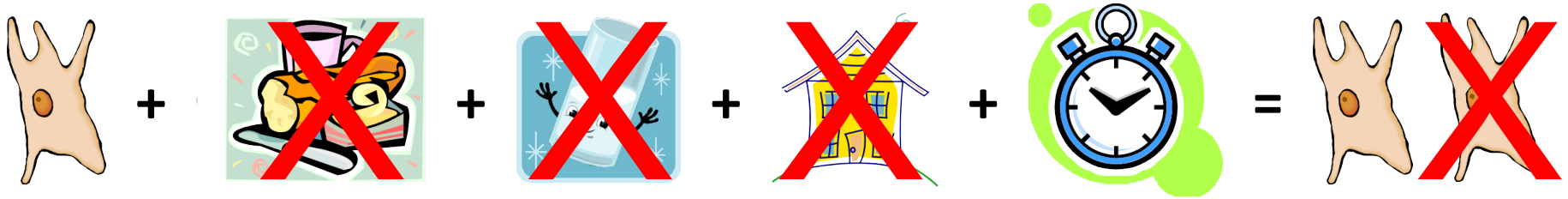


Infective Dose

Microorganism	Quantity	Units
Listeria monocytogenes	<1,000	Cells
E. Coli O157:H7	10	Cells
Bacillus Cereus	10^6	Cells/Gram
Perfringens	10^8	Cells
Staphylococcus	100,000	Cells/Gram
Salmonella	15-20	Cells
Campylobacter	400-500	Cells
Shigella	10	Cells
Hepatitis A	10-100	Virus Particles

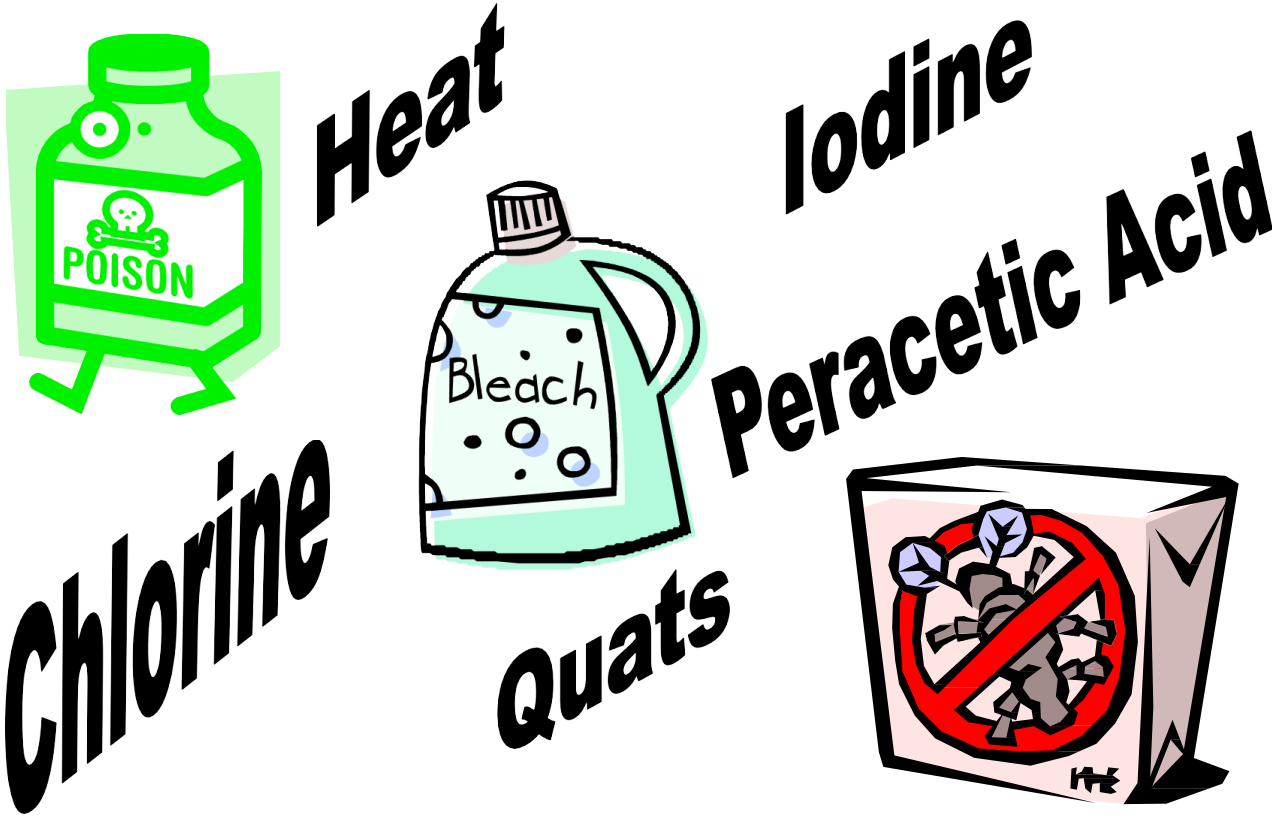
FDA Bad Bug Book

Hygienic Design Eliminates the Necessities of Life for a Microorganism



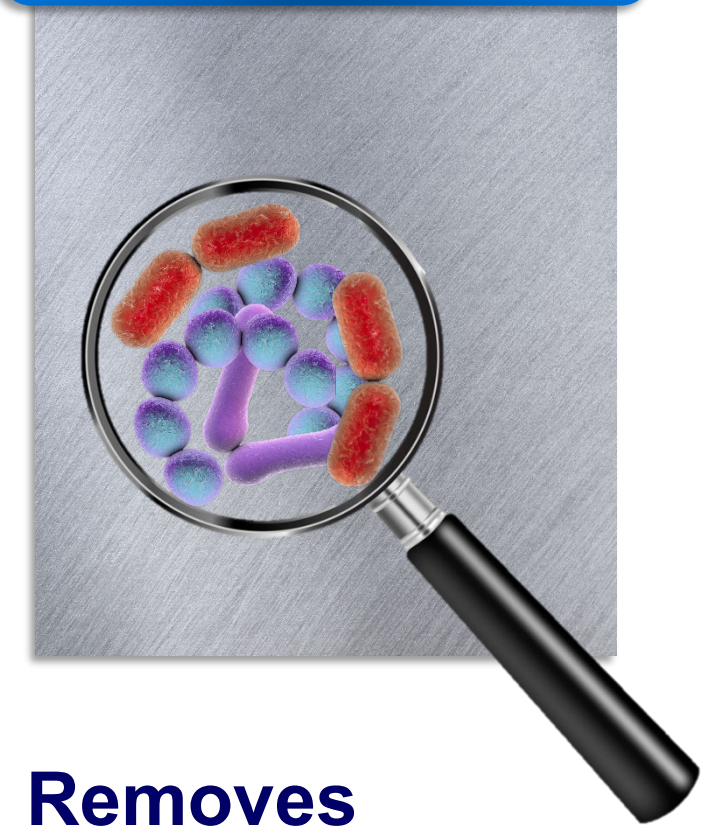
1 Cell + Food + Water + Shelter + 30 min. =

Microorganisms are Easy to Destroy with Sanitizers, Disinfectants, or Heat



Cleaning vs. Sanitizing vs. Sterilization

CLEANING



Removes Product/Soi
l

SANITIZING

Removes 99.999% of bacteria

STERILIZATION

Removes 100% of bacteria

Holistic Approach to Hygienic Design

Hygienic Design
Regulations vs. Standards vs. Guidelines

	Regulations	Standards	Guidelines
Scope	Basic criteria	Very specific criteria	General recommendations
Legal Requirements	Minimum criteria	Voluntary unless specified by Regulations	Voluntary
Evaluation Criteria	General compliance to Regulations	Strict	General overview - to strict

Food Safety Regulation & Codes

- **Equipment hygienic design criteria within food safety regulations**
  - FSMA – Food Safety Modernized Act –Preventive Controls
  - FDA – 21CFR 117.40 Equipment and Utensils
  - Meat & Poultry 9 CFR 416.3 Equipment and Utensils
  - PMO – Pasteurized Milk Ordinance
  - Hazard Analysis and Risk-Based Preventive Controls (HARPC)
  - Hazard Analysis and Critical Control Points (HACCP) Prerequisite
  - FDA – 21CFR Parts 170-199 Materials

- **Global Food Safety Initiatives (GFSI) Codes**
  - Safe Quality Foods (SQF)
  - British Retail Consortium (BRC) ISO/Food
  - Safety System Certification (FSSC) 22000

3-A Standards and Accepted Practices

Vessels

Fillers

80+ Standards & Accepted Practices

Valves & Fittings

Pumps & Mixers

Heat Exchangers

Conveyors & Feeders

Instruments

Concentrating Equipment

Farm Raw Milk

Cheese & Butter Equipment

Process & Cleaning Systems

Plant Support Systems

Materials & Materials Testing

Hygienic Equipment Design Criteria

CLEANABLE

ACCESSIBLE TO CLEAN

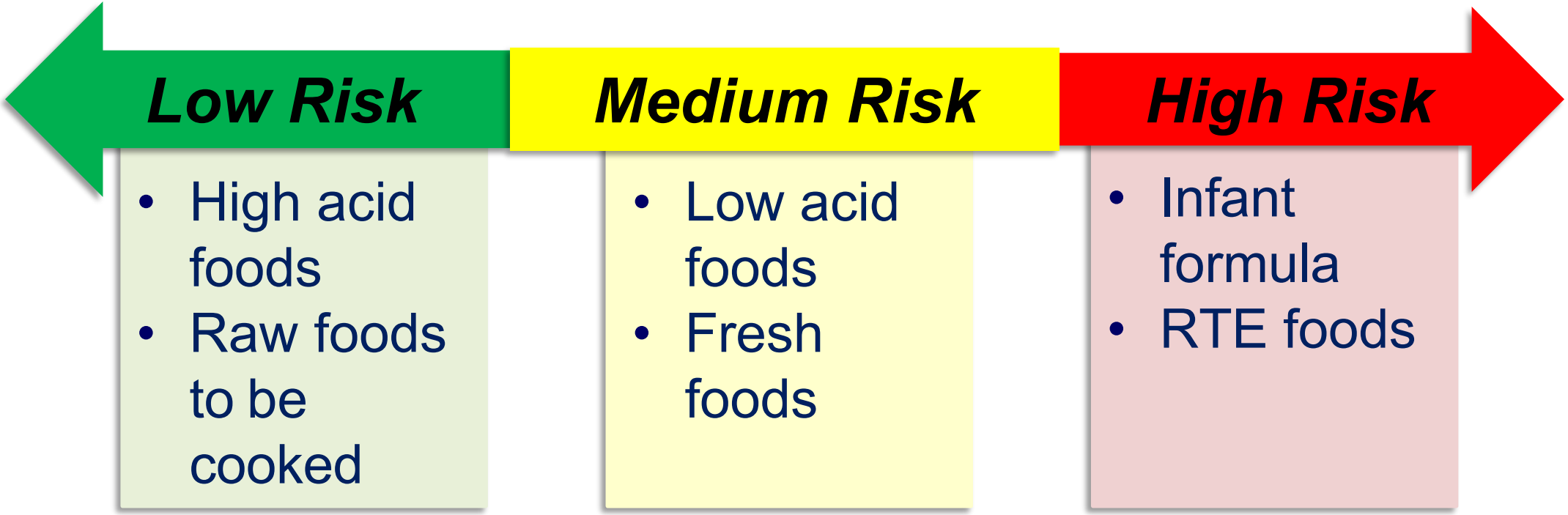
ACCESSIBLE TO INSPECT

- Cleaning Methods
- Types of Surfaces
- Materials of Construction
- Surface Finishes
- Joint Design
- Radii
- Free Draining
- Other Design Specifications

Hygienic Design Process for Equipment

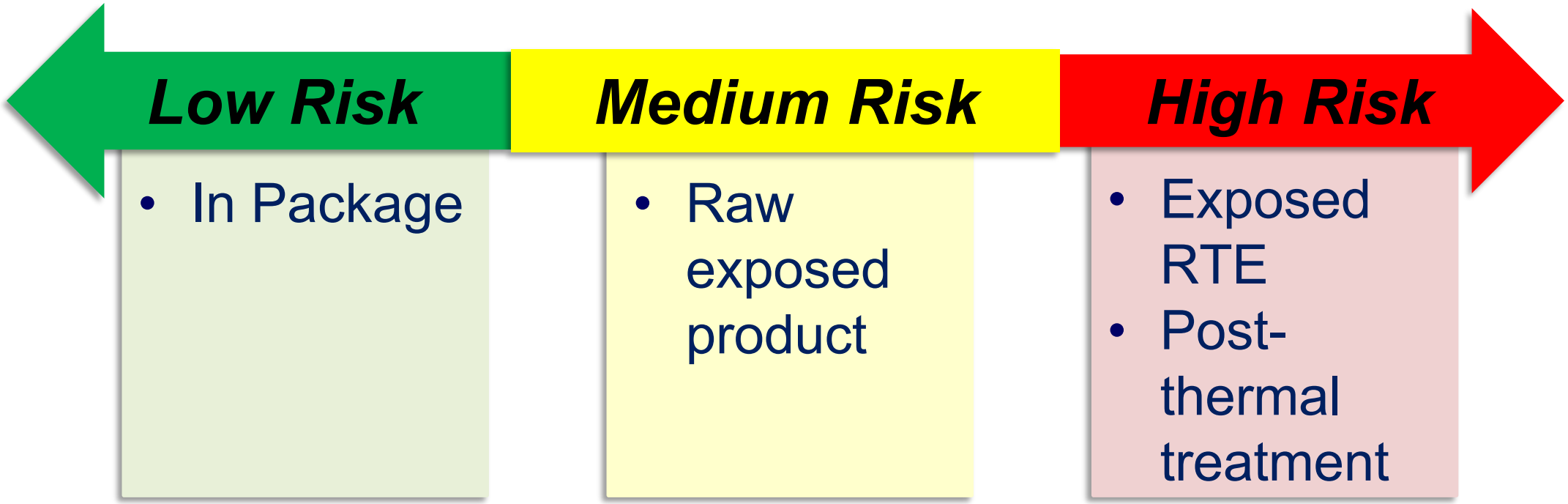
Intended Application and Risks

Product: _____ **Application:** _____



Process Type Risks

Process Type: _____



Consumer Risks

Consumer: _____

Hygienic Design Process for Equipment

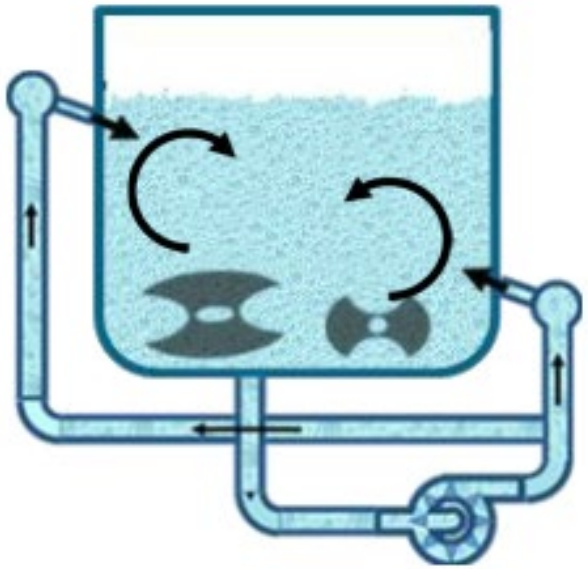
Cleaning Methods

Manual Cleaning

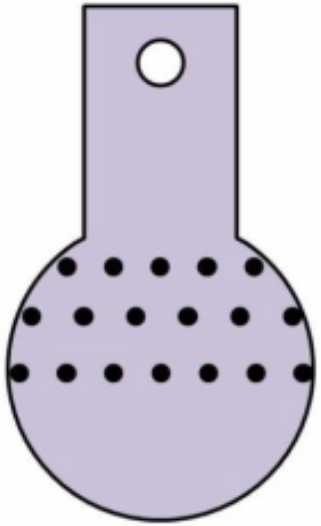
Wet

Dry

COP Cleaning



CIP Cleaning



Define Cleaning and Sanitizing Methods

Cleaning Method

- ☐ Dry Clean only
- ☐ CIP Circulation and/or Sprays
- ☐ COP Tanks
- ☐ Manual Cleaning (Bucket and Brush)

Cleaner: Type _____ @ ____°F @ _____Concentration

Sanitizing Method

Sanitizer: Type _____ @ _____°F @ _____Concentration

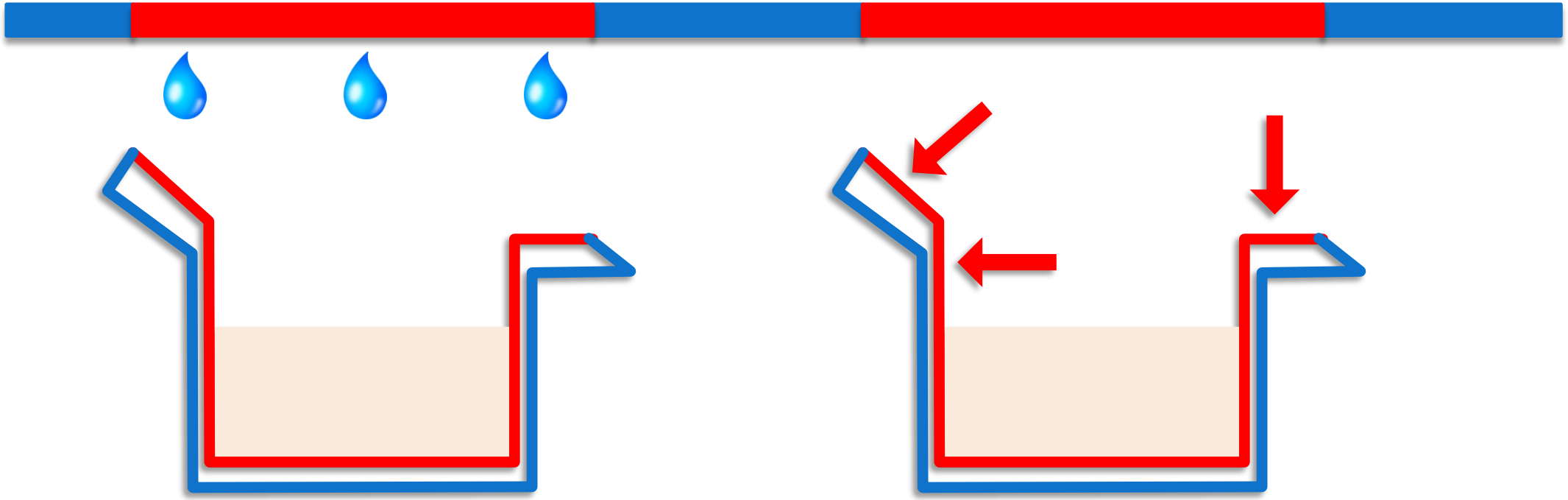
Hot Water: Time and Temperature _____min. @ _____°F

Steam: Time, Temperature, Pressure _____min. @ _____°F @_____ psi

Hygienic Design Process for Equipment

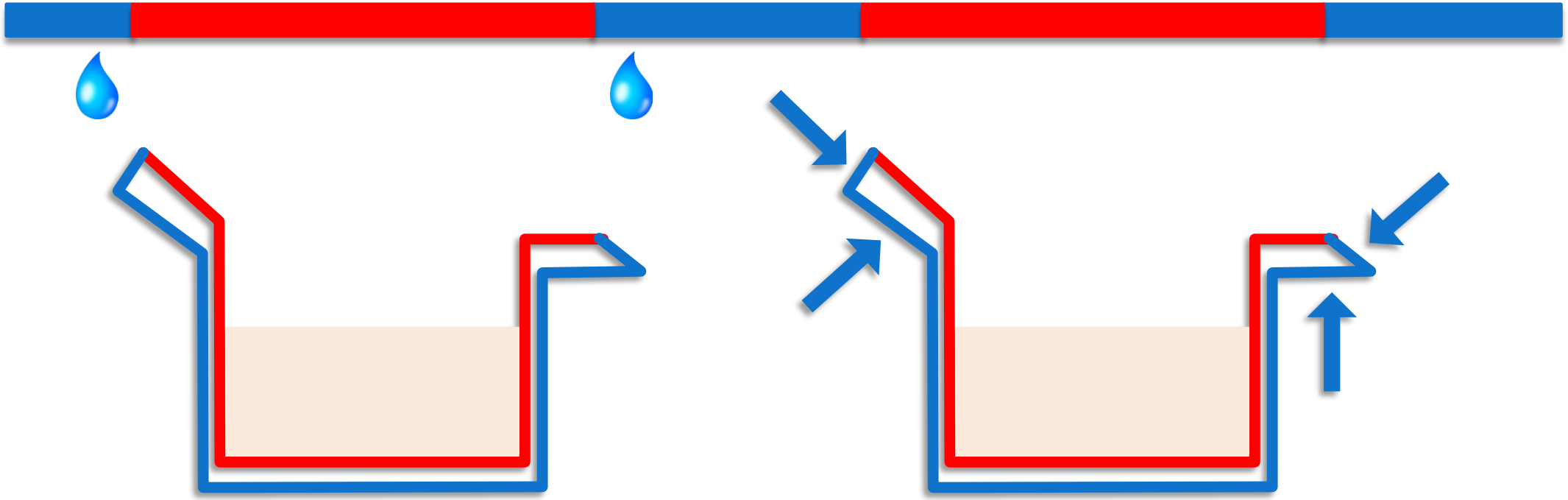
Product Contact Surfaces (PCS)

All surfaces which are exposed to the product and from which splashed product, liquids, or soil may drain, drop, diffuse or be drawn into the product or onto surfaces that come into contact with product surfaces of packaging materials



Non-Product Contact Surfaces (NPCS)

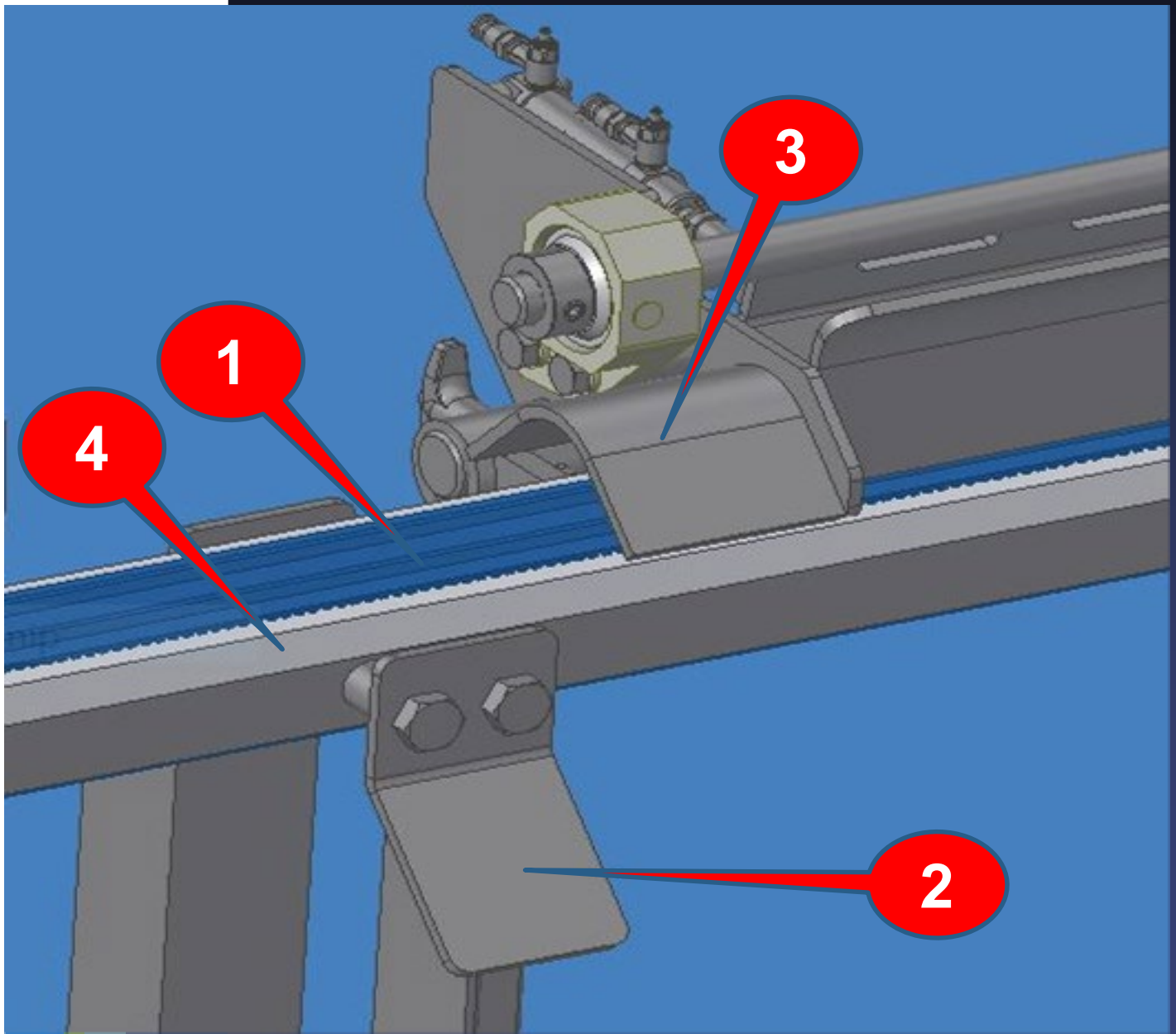
All exposed surfaces from which splashed product, liquids, or other soils cannot drain, drop, diffuse or be drawn into or onto the product, product contact surfaces, open packages, or the product contact surfaces of package components



Let's Discuss

With exposed product on the conveyor belt, which surfaces are product contact surfaces (PCS) or non-product contact surfaces (NPCS)?

1. **PCS**
2. **NPCS**
3. **PCS**
4. **PCS**



Hygienic Design Process for Equipment

Define Intended Uses & Risks

Define Cleaning Methods

Define Product Surfaces

Select Approved Materials of Construction

Design & Build to Meet Hygienic Criteria

Third Party Verification (TPV)

Today's Focus

Questions