Welcome!

3-A SSI and the Basics of Hygienic Design

Bloomington, MN
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Welcome!
Greg Marconnet, Program Chair
Special Welcome!
Student Travel Award Recipients
Student Travel Award Recipients

- Akhil Reddy Bora, Texas Tech University
- Diego Casas, Texas Tech University
- Yungi Huang, Ohio State University
- Ishwar Katawal, Texas Tech University
- Subbiah Nagappan, Ohio State University
Key Topics of Learning Objectives

• 3-A SSI history and overview of current structure
• Basic introduction to food regulatory
• Key Concepts of the Hygienic Design Process
• Hygienic Design Considerations
• Manufacturing Techniques
• 3-A Marketplace Benefits
• Holistic Approach Sanitary Design
Overview of 3-A SSI

- Intro to 3-A SSI
- The 3-A SSI Consensus Process
- 3-A Symbol Authorization & Certificates
Intro to 3-A SSI

- Not-for-profit 501 (c) (3) corporation
- Represents three stakeholder groups with a long history of collaboration
  - Regulatory Sanitarians
  - Processors (Users)
  - Fabricators
Brief History of 3-A SSI

1920
First Standard

1944 USPH
Participation

1956
New Symbol

2002
3-A SSI
Before 2002

Standards Writing
FPWA

Publishing
IAFP

3A Symbol Council

After 2002

Standards Writing-Publishing-TPV-Symbol
Training-Education-Harmonization

3-A Sanitary Standards, Inc.
Who Leads 3-A SSI?

- Founding Member Organizations
  - International Dairy Foods Association (IDFA)
  - Food Processing Suppliers Association (FPSA)
  - International Association for Food Protection (IAFP)
  - American Dairy Products Institute (ADPI)
  - 3-A Symbol Administrative Council (dissolved)

- Chair of the 3-A Steering Committee
- One USDA and one FDA representative
Role of 3-A SSI

- Standards Writing and Publishing
- Industry Education and Training
- 3-A Symbol Licensing & Certificate Programs
- Harmonization and Liaison With Other Organizations
The Consensus Process

3-A SSI is an ANSI-accredited Standards Developer Organization (SDO)

- 3-A Sanitary Standards
- 3-A Accepted Practices
Consensus Process - Overview

**Management**

- 3-A Steering Committee

**Development**

- Work Group
- Work Group
- Work Group

**Approval**

- Canvass Group
3-A SSI Voluntary Certificates

- Require independent Third Party Verification (TPV) of compliance by an independent credentialed authority – a Certified Conformance Evaluator (CCE)
- TPV certification performed via agreement between CCE and Symbol holder
- Scope of TPV program set by 3-A SSI
Why a TPV Requirement?

TPV brings added assurance that equipment shown on the certificate fully conforms to the applicable 3-A Sanitary Standard or criteria.
Purpose of TPV Inspection

- 3-A Symbol licensing for equipment built to 3-A Sanitary Standard.

- Other voluntary certificate programs:
  - Replacement Parts & System Component Qualification Certificate
  - 3-A Process Certification
What is the 3-A Symbol?

- A registered mark used to show the conformity of equipment designed and manufactured to a 3-A Sanitary Standard
- Available for use on a voluntary basis subject to licensing requirements of 3-A SSI
Basics of Hygienic Design
Greg Marconnet

The Symbol of Assurance
Holistic Approach to Hygienic Design

- Equipment Design
- Facility Design
- Quality & Regulation
- Operational Design & GMP
- Cleaning & Sanitizing
Challenges under FSMA

• Hazard Analysis...identification of biological, chemical, physical
• Preventive Controls
• Corrective Actions
• Accurate Monitoring & Verification
• Operator Qualification
• Sanitary Design and cGMP’s
• Operations, Sanitation & Maintenance implications
FSMA Hazards

biological, chemical, physical hazards need to consider...

- **Raw materials** and other ingredients;
- **Formulation** of the food;
- **Manufacturing/processing procedures**;
- **Sanitation**, including employee hygiene;
- Condition, function, and **design of the facility and equipment**;
- Transportation practices;
- Packaging and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use; and
- **Any other relevant factors**, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).
Risk Analysis with HARPC/HACCP review for equipment

• Biological
  • Parasites, pathogens
  • Spoilage organisms
  • Pests

• Chemical
  • Allergens, gluten
  • Unapproved additives such as sanitizers, lubricants
  • Materials of construction, odors

• Physical
  • Extrinsic: wood, plastic, metal, glass, stones, cloth, packaging, hypodermic needles, golf balls
  • Intrinsic: seeds, bones, shells, over processed product
  • Material compatibility – ingredients, chemicals
  • Equipment parts, damage or debris during maintenance
Key Steps in Hygienic Design Process

• Define Intended Uses & Risks
• Define Product Zones
• Define Cleaning Method
• Select Approved Materials of Construction
• Provide Accessibility to Clean and Inspect
• Design and Build to Meet Hygienic Criteria
## Define Intended Uses & Risks

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Intended Use and Products</th>
<th>Process Type</th>
<th>Customer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High</strong></td>
<td>Injectable Drugs</td>
<td>Post Thermal Treatment</td>
<td>Infant, Elderly, Pregnant, Immune Deficient</td>
</tr>
<tr>
<td></td>
<td>Infant Formula RTE Foods</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td>Low Acid Foods Fresh</td>
<td>Pre- Thermal Treatment</td>
<td>Healthy Children</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>High Acid Foods Raw Foods to be Cooked</td>
<td>In package</td>
<td>Healthy Adults</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Microbiology 101 for Hygienic Designers

• **Only Five Things to Remember About Microorganisms**
  • Incredibly Small
  • Multiple Extremely Fast
  • Very Dangerous or Destructive
  • Easy to destroy with sanitizers
  • Need Food, Water, and Shelter
“How Big is” – Molds-Bacteria – Viruses

• While we walk through “How Big is” Presentation think about
  • Surface finish of materials
  • Cracks, crevices and pit in materials and welds
  • Bolted joint

Microsoft
oint 97-2003 Presc
CELLS alive! HowBig

Pin
- Human hair
- Dust mite
- Ragweed pollen
- Lymphocyte
- Red blood cell
- Baker's yeast
- E. coli
- Staphylococcus
- Ebola virus
- Rhinovirus

Magnification

20 millimeters

Magnitude:
1 10 100 1,000 10,000 100,000 1,000,000
CELLS alive! HowBig

Magnification

1  10  100  1,000  10,000  100,000  1,000,000

- Pin
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CELLS alive! HowBig

Magnification

1 10 100 1,000 10,000 100,000 1,000,000

Pin
Human hair
Dust mite
Ragweed pollen
Lymphocyte
Red blood cell
Baker's yeast
E. coli
Staphylococcus
Ebola virus
Rhinovirus

200 micrometers
CELLS alive! How Big

- Pin
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Magnification

1  10  100  1,000  10,000  100,000  1,000,000

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BAKER'S YEAST

CELLS alive! HowBig

- Pin
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- Rhinovirus

Magnification

1 10 100 1,000 10,000 100,000 1,000,000

©cellsalive.com
CELLS alive! HowBig

Magnification

1  10  100  1,000  10,000  100,000  1,000,000

2 micrometers

Pin
Human hair
Dust mite
Ragweed pollen
Lymphocyte
Red blood cell
Baker's yeast
E. coli
Staphylococcus
Ebola virus
Rhinovirus

©cellsalive.com
40,000 X

CELLS alive! How Big

Pin
Human hair
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Ragweed pollen
Lymphocyte
Red blood cell
Baker's yeast
E. coli
Staphylococcus
Ebola virus
Rhinovirus

Magnification

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Magnification

1 10 100 1,000 10,000 100,000 1,000,000

200 nanometers
CELLS alive! HowBig

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Magnification

1 10 100 1,000 10,000 100,000 1,000,000
Equipment Cleaning

Cleaning needs to be at a Microbiological Level!

Right now there are 64!!!

2 hours
Double every 20 minutes!

When was there just 1?
How Fast Do Microorganisms Multiple

- 10 Years
- 1 Year
- 10 Hours

1,048,576 Cells
Infective Dose - FDA Bad Bug Book

- Listeria monocytogenes – less than 1,000 cells
- E. Coli O157:H7 -- as few as 10 cells
- Bacillus Cereus – $10^6$ cells/gram
- Perfringens – $10^8$ cells
- Staphylococcus – 100,000 cells/gram
- Salmonella -- 15 to 20 cells
- Campylobacter – 400-500 cells
- Shigella -- as few as 10 cells
- Hepatitis A – 10 to 100 virus particles
Easy to Destroy

Heat

Iodine

Chlorine

Bleach

Quats

Peracetic Acid
Necessities of Life of a Microorganism

1 cell + Food + Water + Shelter + 30 Minutes = 2 cell

Diagram showing the necessities of life of a microorganism, with symbols for cell, food, water, shelter, and time, all marked with an 'X' to indicate they are necessary for the cell to divide.
Key Steps in Hygienic Design Process

- Define Intended Uses & Risks
- Define Product Zones
- Define Cleaning Method
- Select Approved Materials of Construction
- Provide Accessibility to Clean and Inspect
- Design and Build to Meet Hygienic Criteria
Define Surface Zones

• Product Contact
• Non-Product Contact
DEFINITION: PRODUCT CONTACT SURFACES

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.
DEFINITION: PRODUCT CONTACT SURFACES

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.
DEFINITION: NON-PRODUCT CONTACT SURFACES

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.
DEFINITION: NON-PRODUCT CONTACT SURFACES

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.
Key Steps in Hygienic Design Process

- Define Intended Uses & Risks
- Define Product Zones
- Define Cleaning Method
- Select Approved Materials of Construction
- Provide Accessibility to Clean and Inspect
- Design and Build to Meet Hygienic Criteria
Define Cleaning Method

• How are the surfaces being cleaned:
  • Manually in place
  • Disassembled and COP cleaned
  • Cleaned without disassembly fully automated CIP system
  • Combination of Manual, COP and CIP
Key Steps in Hygienic Design Process

• Define Intended Uses & Risks
• Define Product Zones
• Define Cleaning Method
• Select Approved Materials of Construction
• Provide Accessibility to Clean and Inspect
• Design and Build to Meet Hygienic Criteria
Select Approved Materials of Construction

• What is the corrosive issues with product or process?
  • Low pH – High pH
  • Temperature

• What is the Material of Construction?
  • Metal
  • Plastic
  • Elastomer
HYGIENIC REQUIREMENTS: MATERIALS OF CONSTRUCTION

**Physical Properties**
- Inert
- Nontoxic
- Non-corrosive
- Non-reactive
- Non-contaminating
- Non-porous
- Impervious

**Mechanical Properties**
- Durable
- Smooth
- Free of cracks and crevices

**Operational Properties**
- Cleanable
- Reduced maintenance

304 Stainless Steel Meets Requirements
Key Steps in Hygienic Design Process

• Define Intended Uses & Risks
• Define Product Zones
• Define Cleaning Method
• Select Approved Materials of Construction
• **Provide Accessibility to Clean and Inspect**
• Design and Build to Meet Hygienic Criteria
ACCESSIBILITY AND INSPECTABILITY

Hygienic equipment shall be designed where:

- Surfaces are accessible for cleaning
- Surfaces are accessible for sanitizing
- Surfaces are accessible for inspection

Applies to all cleaning methods
- Manual, CIP, and COP

IF YOU CANNOT SEE IT, YOU CANNOT CLEAN IT!
Key Steps in Hygienic Design Process

- Define Intended Uses & Risks
- Define Product Zones
- Define Cleaning Method
- Select Approved Materials of Construction
- Provide Accessibility to Clean and Inspect
- Design and Build to Meet Hygienic Criteria
Key Cleanability Design Considerations

- Material of Constructions
- Surface Finishes
- Joint Design
- No Cracks or Crevices
- Free Draining
- No Dead Legs – Blind Spots - Hollows
- Accessibility to Clean
- Accessibility to Inspect

Let’s look at a series of design failure before we proceed to the next section “Hygienic Design & Fabrication Considerations and Techniques
Materials of Construction-Corrosion Failure
Pitting Corrosion
Bad Weld Cannot be Clean
Joint Design – Hygienic Failure
Bolted Joint
Plates removed
Crevice Failure
Draining Failure
Hollow Roller Failure
Access to clean failure
• Gearbox over product
Avoid Hygienic Design Failure
Follow The Hygienic Design Process

• Define Intended Uses & Risks
• Define Product Zones
• Define Cleaning Method
• Select Approved Materials of Construction
• Provide Accessibility to Clean and Inspect
• Design and Build to Meet Hygienic Criteria
## Hygienic Hazards Contributed during Equipment Design

<table>
<thead>
<tr>
<th>Design Area</th>
<th>Possible Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleanable</td>
<td>Is the design difficult to clean?</td>
</tr>
<tr>
<td>Accessible</td>
<td>Are areas difficult to inspect or clean?</td>
</tr>
<tr>
<td>Compatible</td>
<td>Are the materials incompatible and do they lead to contamination?</td>
</tr>
<tr>
<td>No Niches</td>
<td>Are niches present that can collect debris, harbor bacteria or allergens?</td>
</tr>
<tr>
<td>Pooling, Ponding</td>
<td>Are surfaces prone to collect liquid and/or debris?</td>
</tr>
<tr>
<td>Durable</td>
<td>Are surfaces resistant to damage in normal use, that result in niches, cracks, warping, etc.?</td>
</tr>
<tr>
<td>Sealed</td>
<td>Are there internal cavities that create harborage sites?</td>
</tr>
<tr>
<td>Enclosures</td>
<td>Do enclosures and similar hardware contribute to non-hygienic condition?</td>
</tr>
<tr>
<td>Operationally Safe</td>
<td>Do operational functions contribute to non-hygienic conditions? e.g., reaching over a product area, control touch panels,</td>
</tr>
<tr>
<td>Foreign Objects</td>
<td>Are there parts that can come loose or fall off? How are glass, stones, metal fragments handled?</td>
</tr>
<tr>
<td>Installation</td>
<td>Can equipment be improperly installed resulting in a hazard?</td>
</tr>
<tr>
<td>Maintenance</td>
<td>When and how to perform, when is a part worn out?</td>
</tr>
<tr>
<td>Lubrication</td>
<td>Type, where used, when used? (is equipment designed to protect from lubrication encroachment?)</td>
</tr>
</tbody>
</table>

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Any Questions Before We Move on to

“Hygienic Design & Fabrication Considerations and Techniques”