Welcome!

3-A SSI and the Basics of Hygienic Design

Bloomington, MN
May 1, 2017

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

3-A SSI Sponsors

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

3-A SSI Executive Director
Tim Rugh

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

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

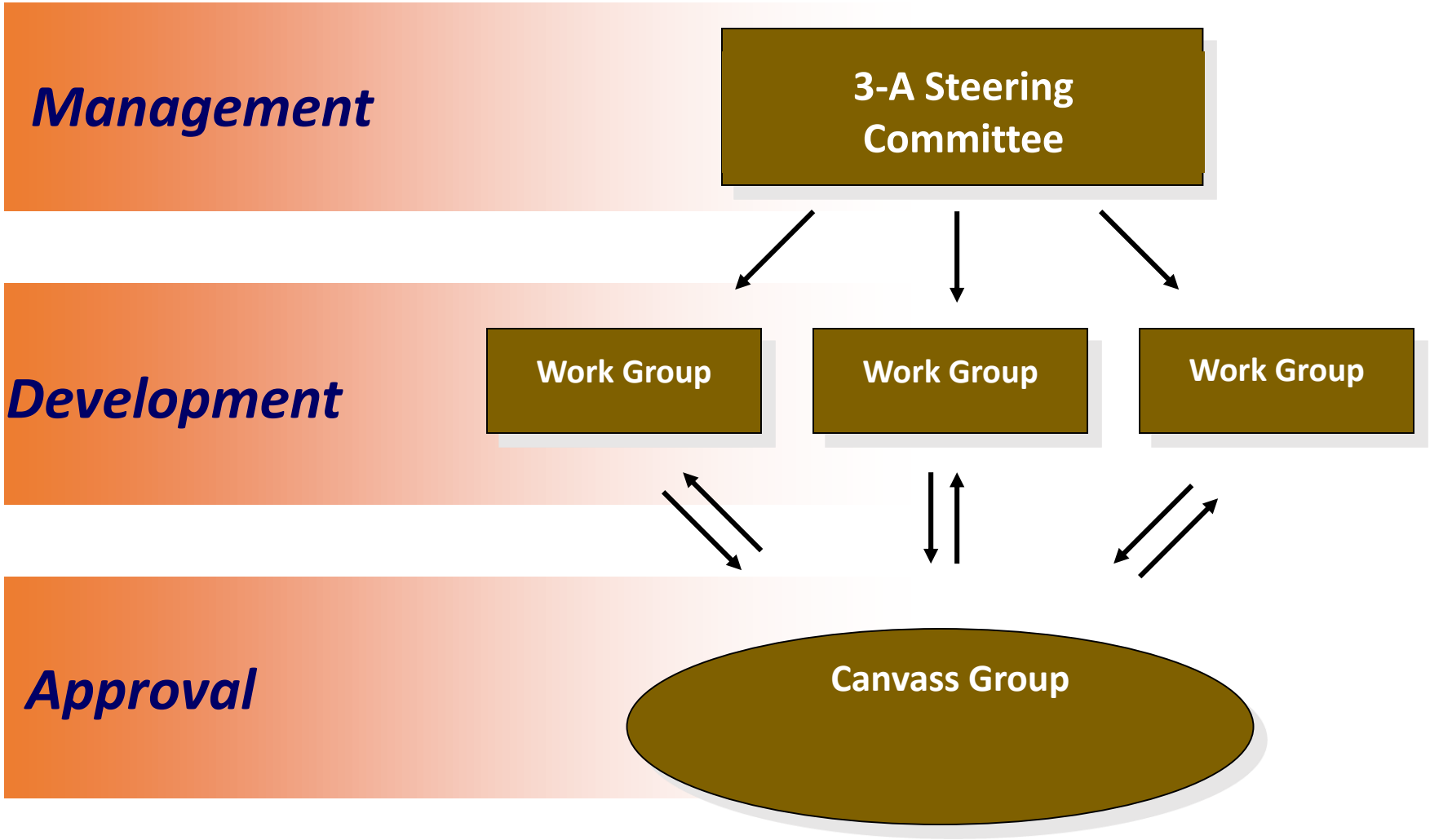
- Standards Writing and Publishing
- Industry Education and Training
- 3-A Symbol Licensing & Certificate Programs
- Harmonization and Liaison With Other Organizations

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



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.

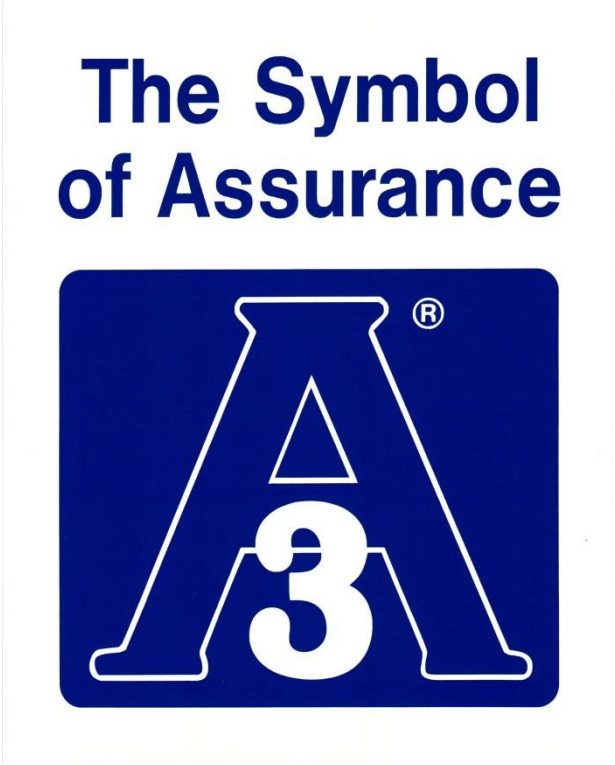
Purpose of TPV Inspection

- 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



Holistic Approach to Hygienic Design

~~Challenges~~ *Opportunities* 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

FDA FOOD SAFETY MODERNIZATION ACT

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

Risk Level	Intended Use and Products	Process Type	Customer
High	Injectable Drugs Infant Formula RTE Foods	Post Thermal Treatment	Infant Elderly Pregnant Immune Deficient
Medium	Low Acid Foods Fresh	Pre- Thermal Treatment	Healthy Children
Low	High Acid Foods Raw Foods to be Cooked	In package	Healthy Adults

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

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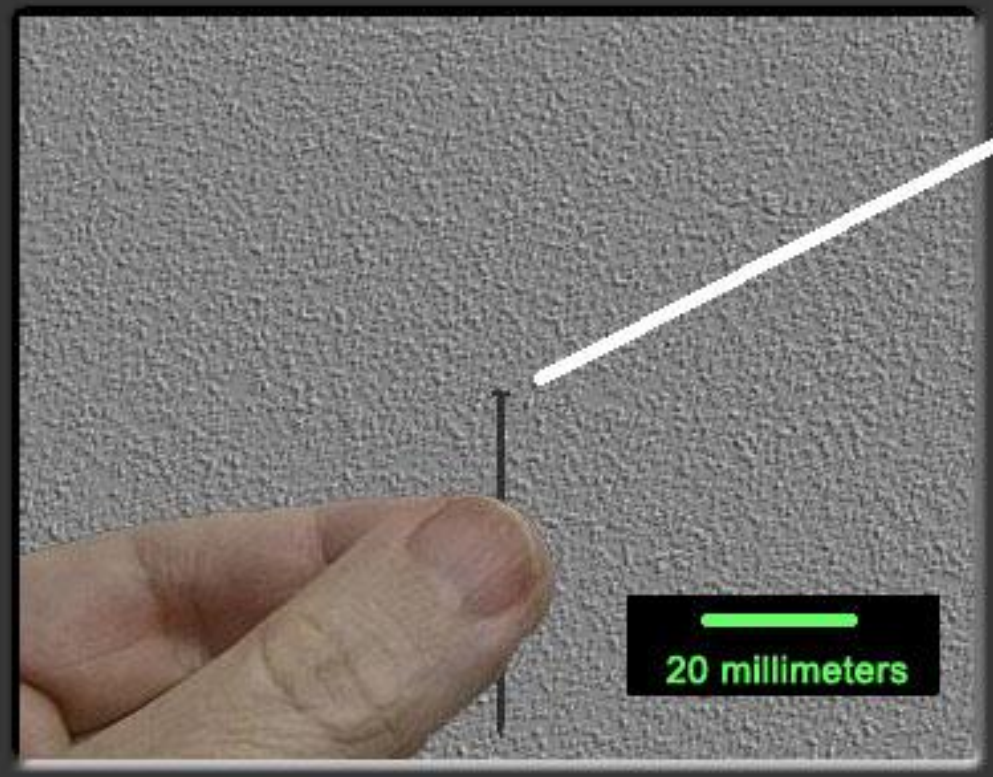

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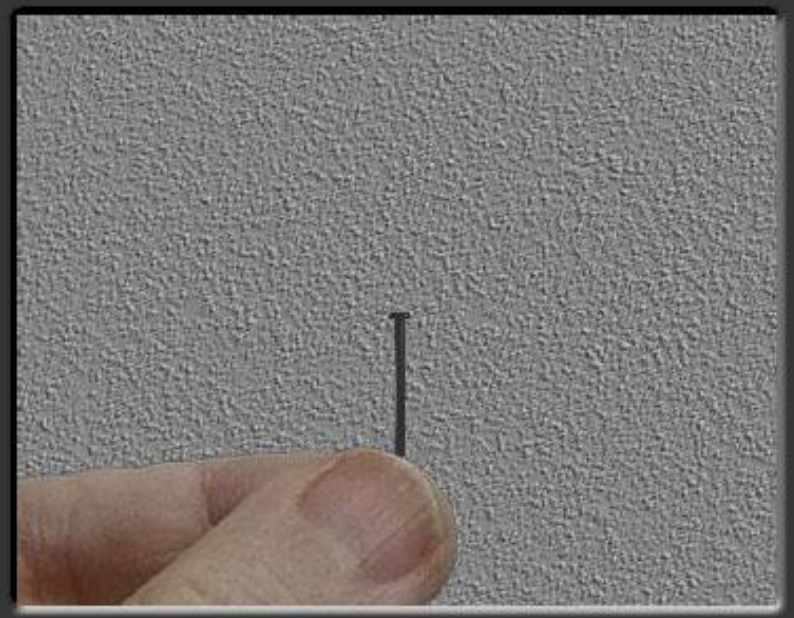

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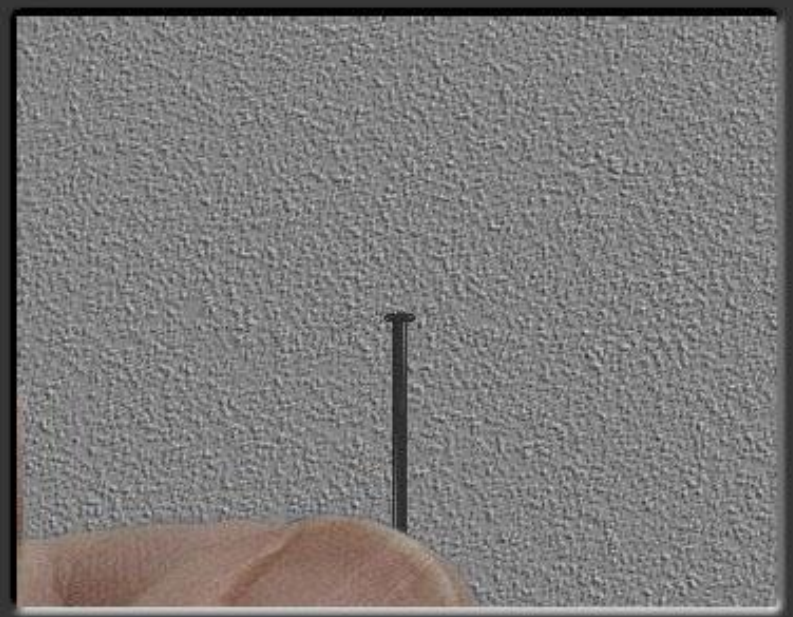

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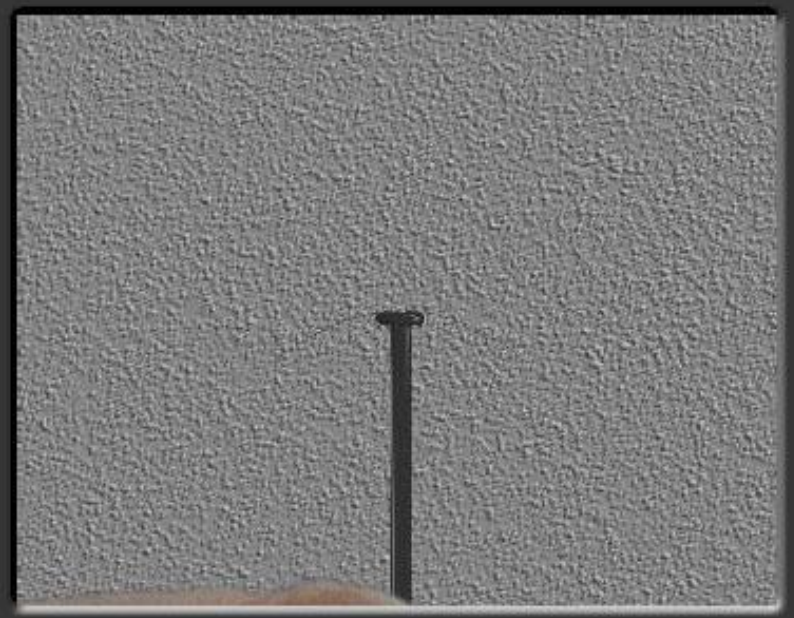

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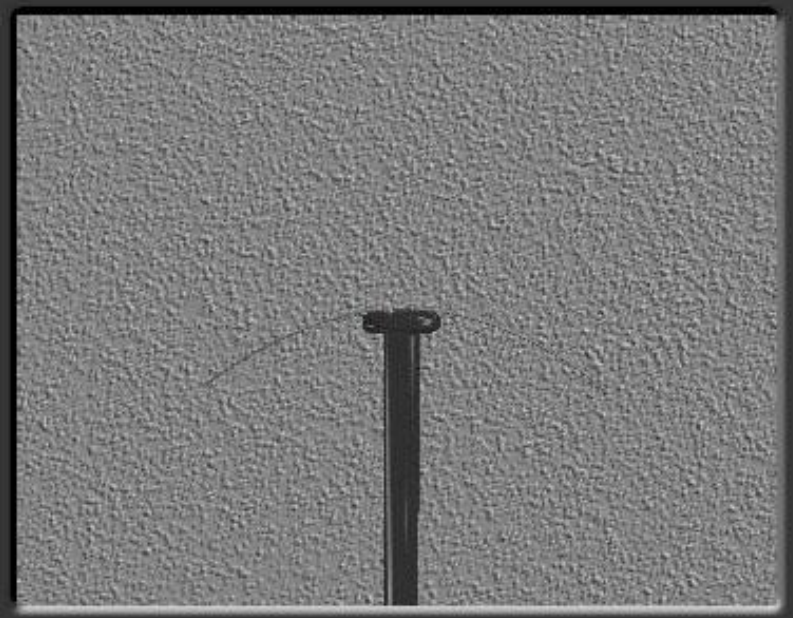

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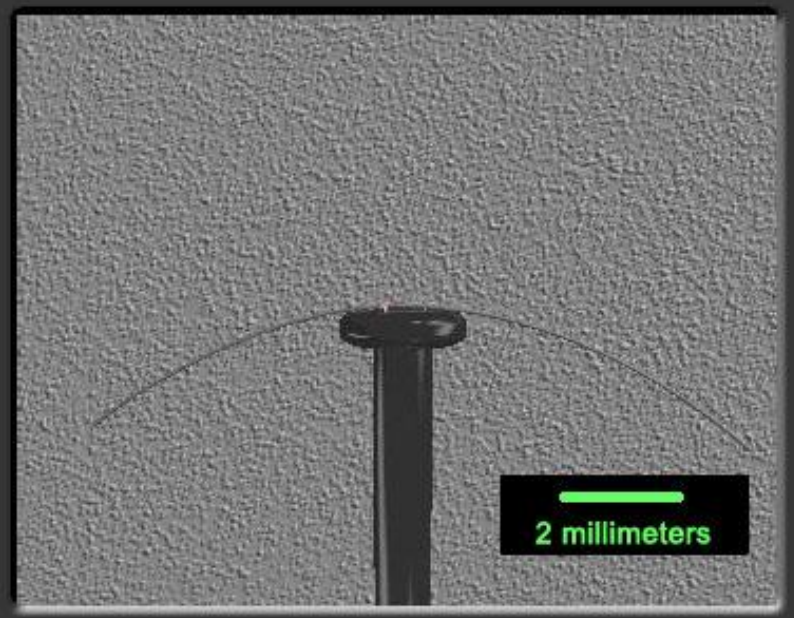

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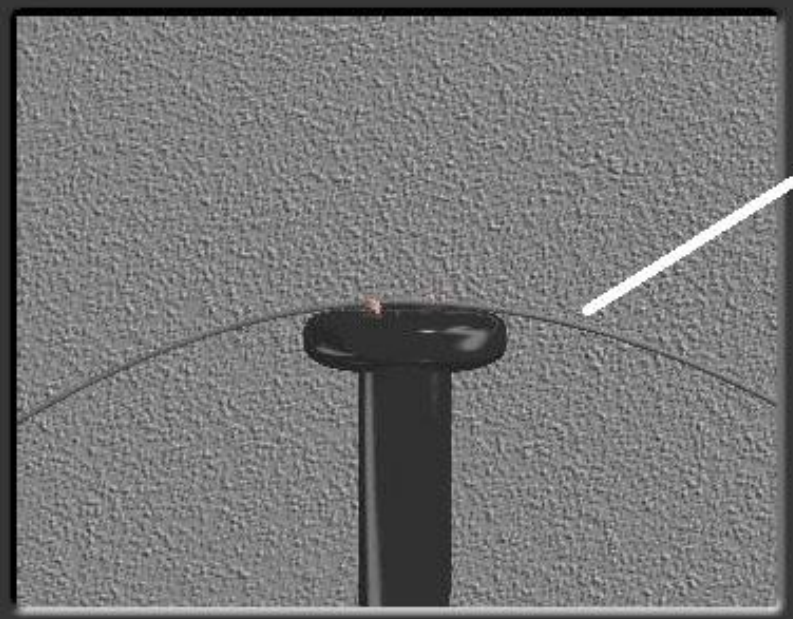

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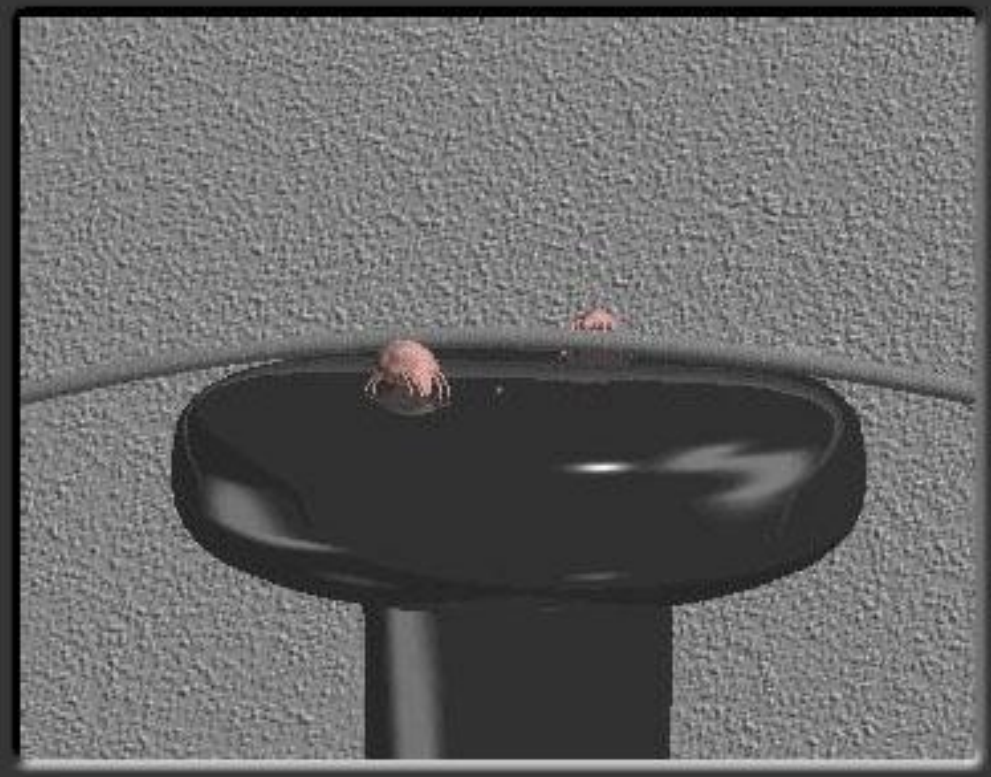

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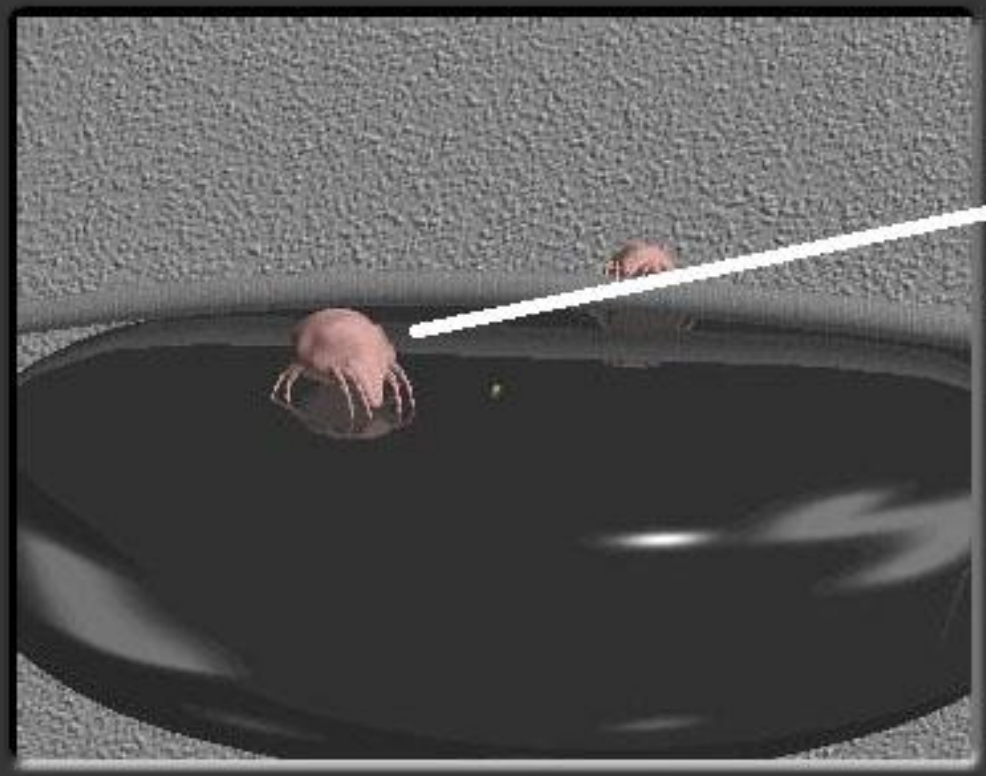

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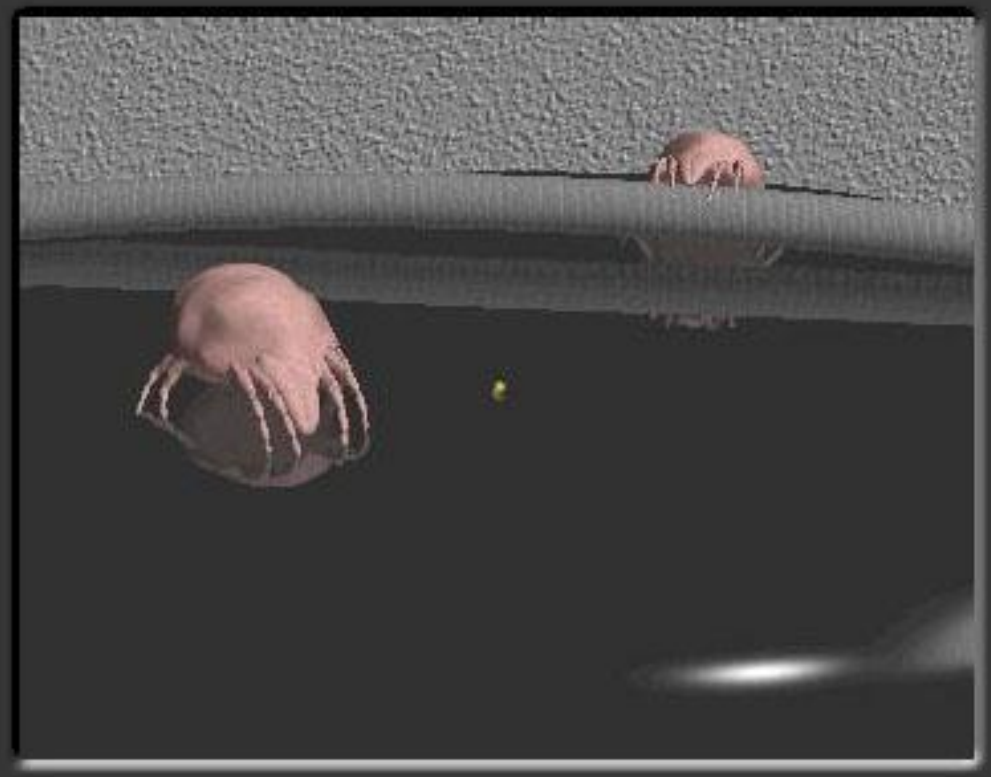

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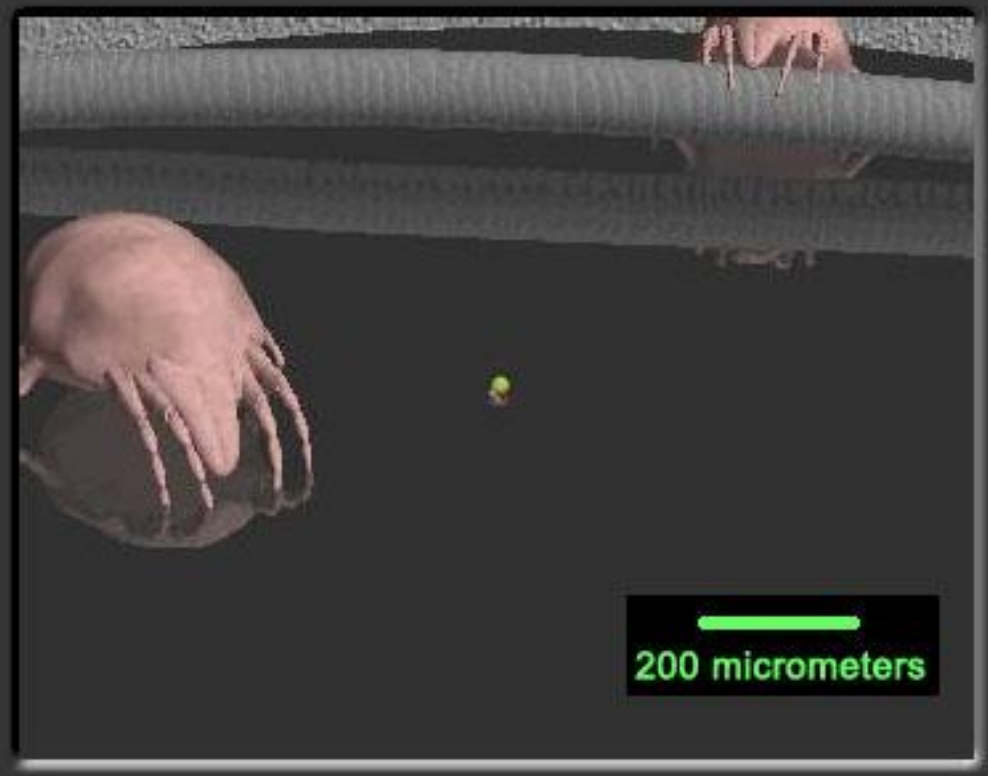

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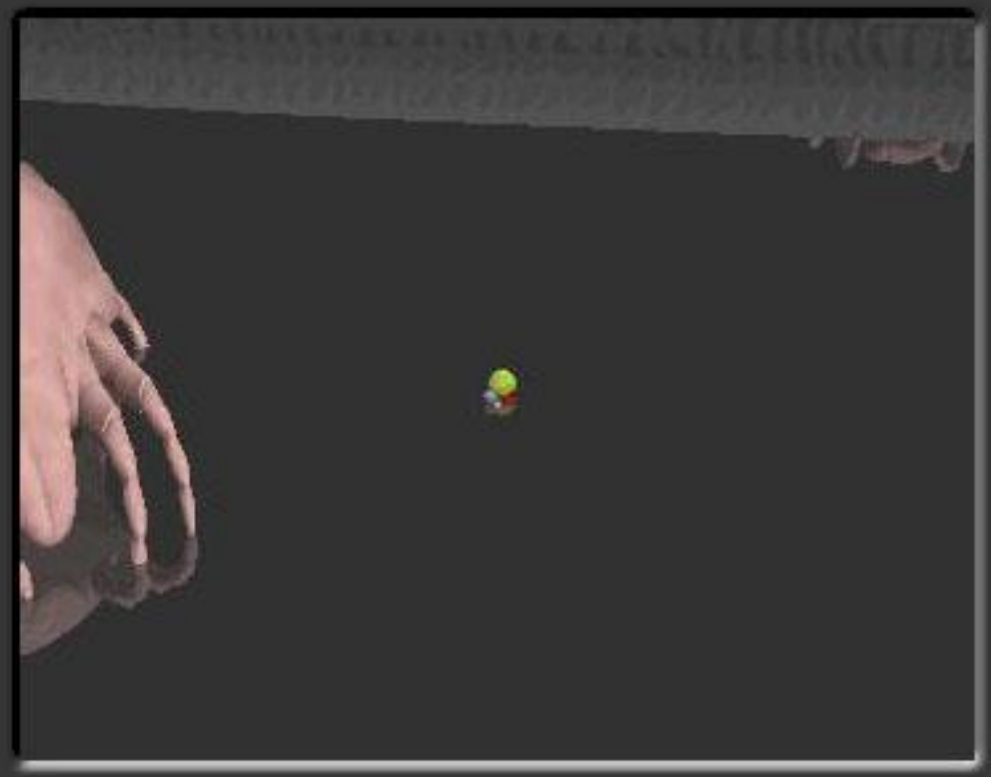

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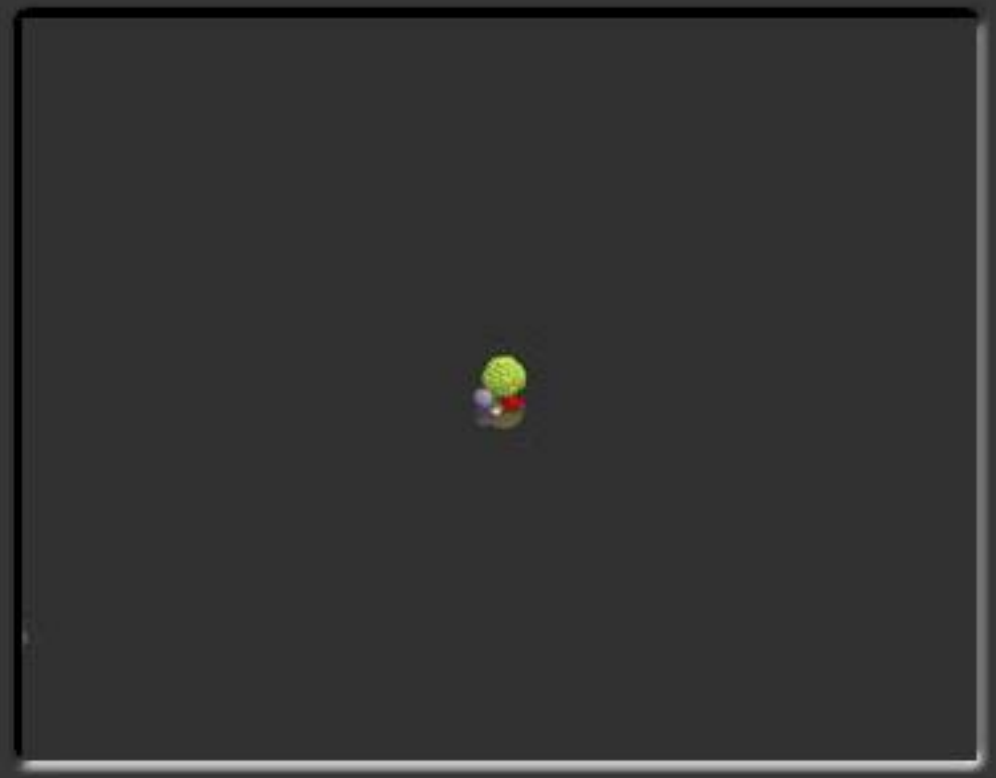

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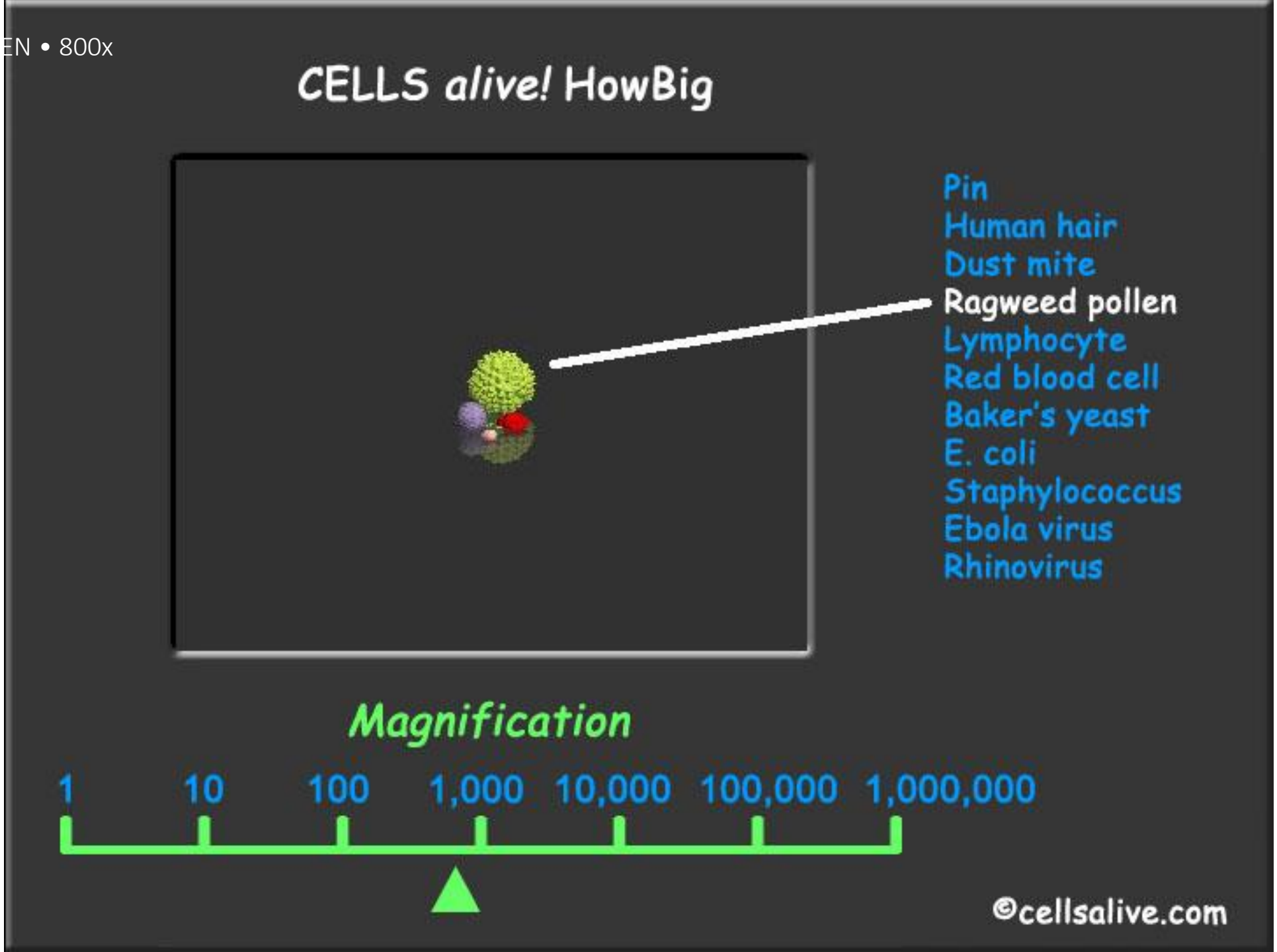
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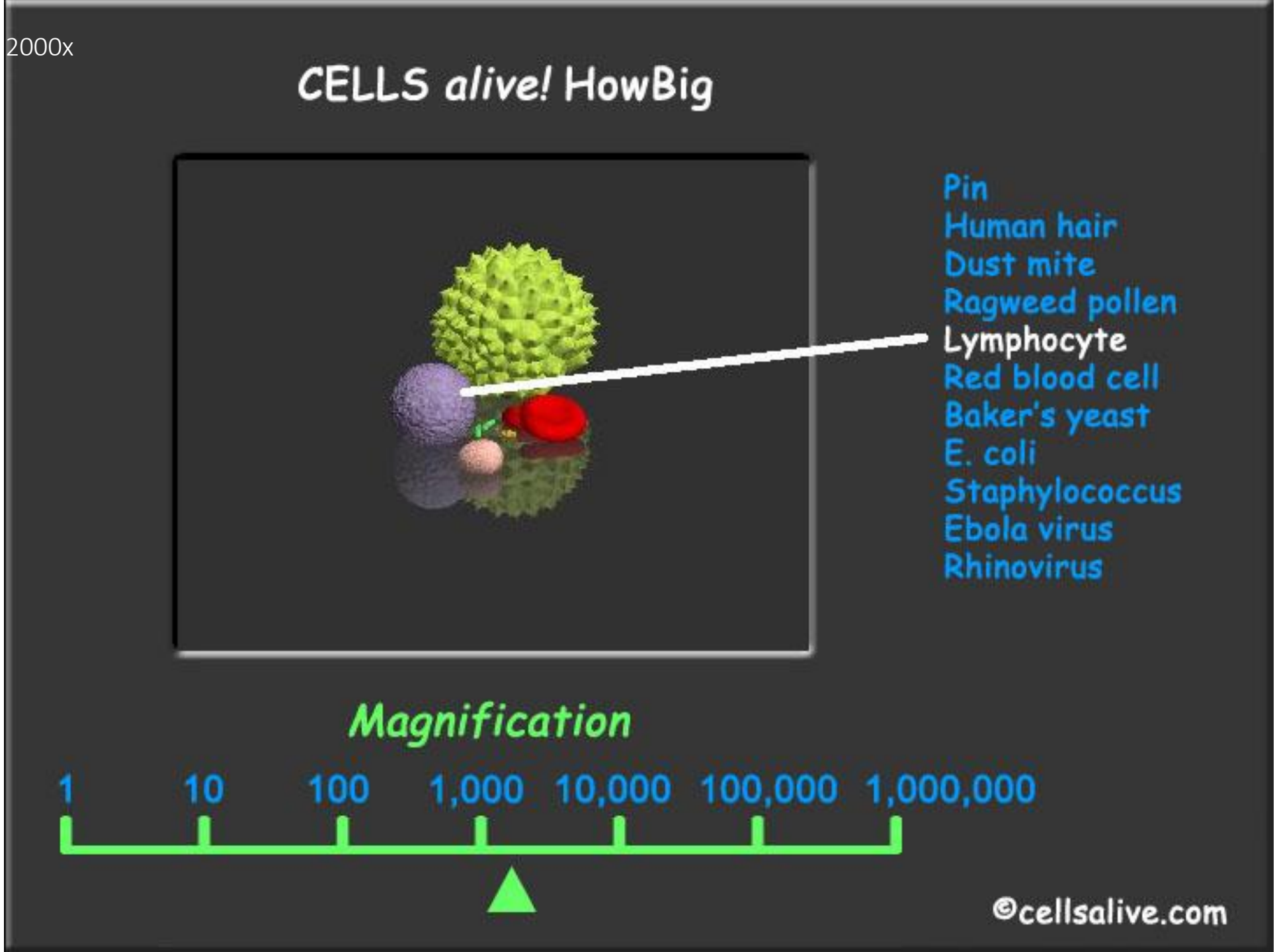
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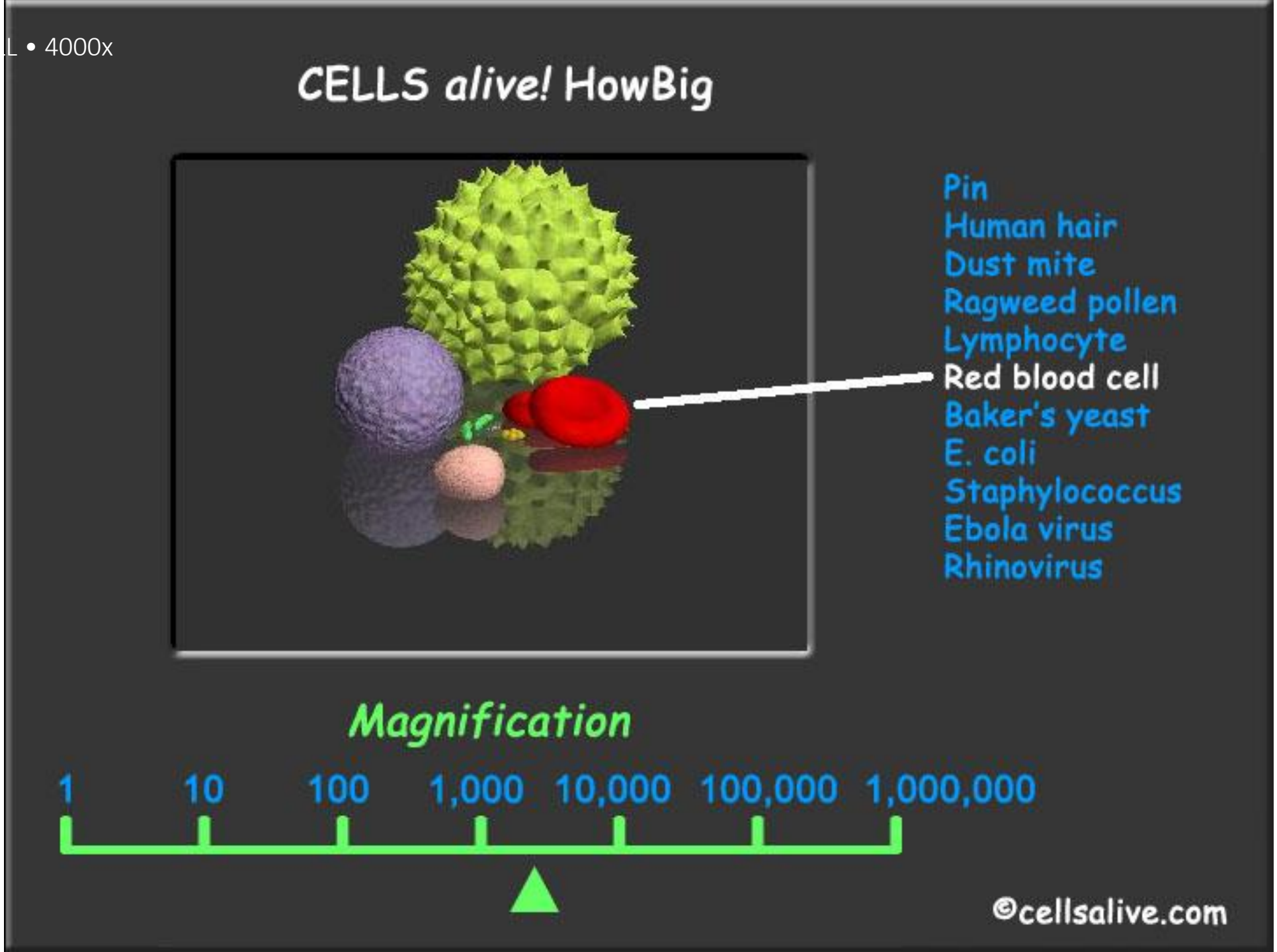
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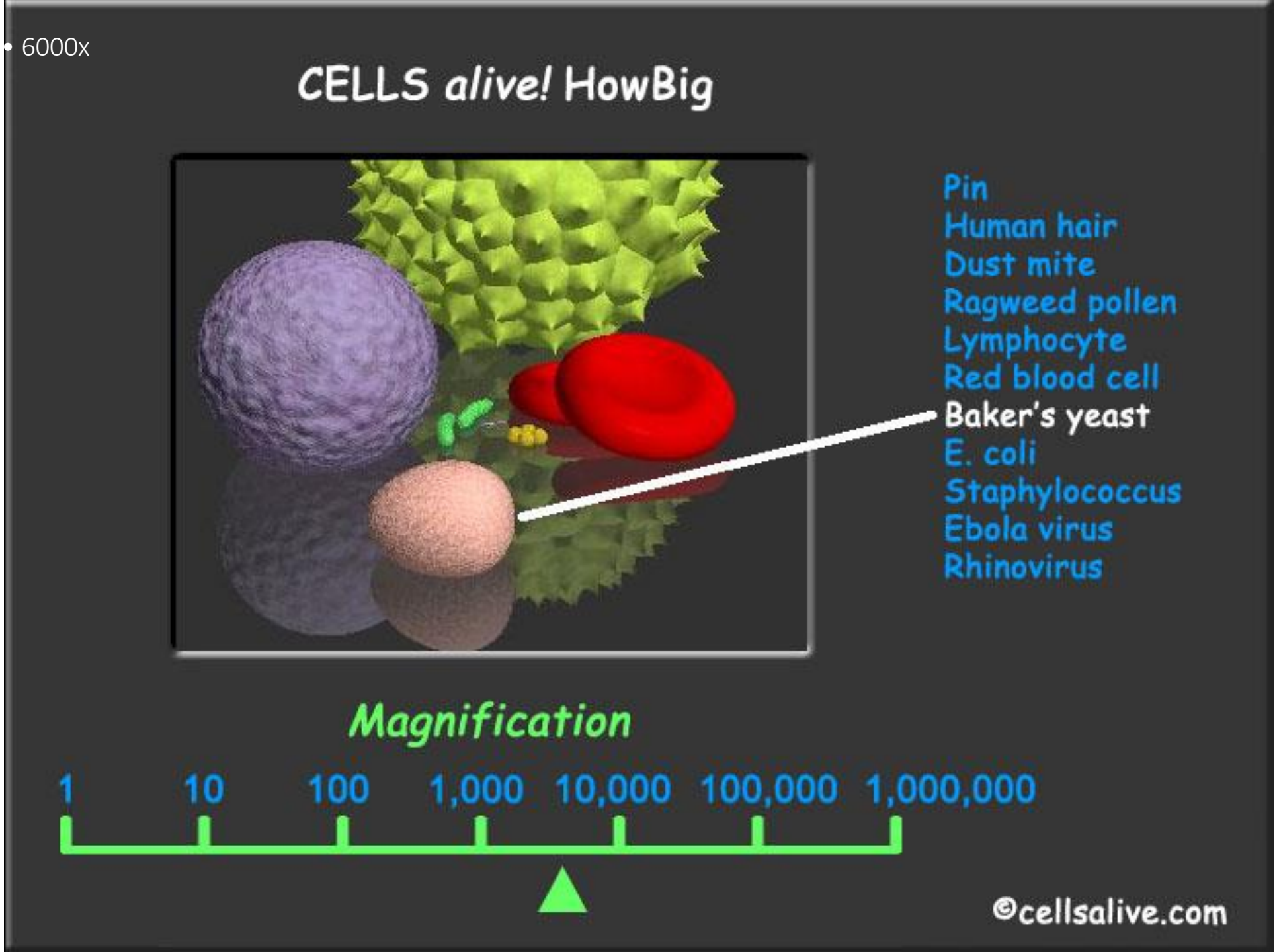
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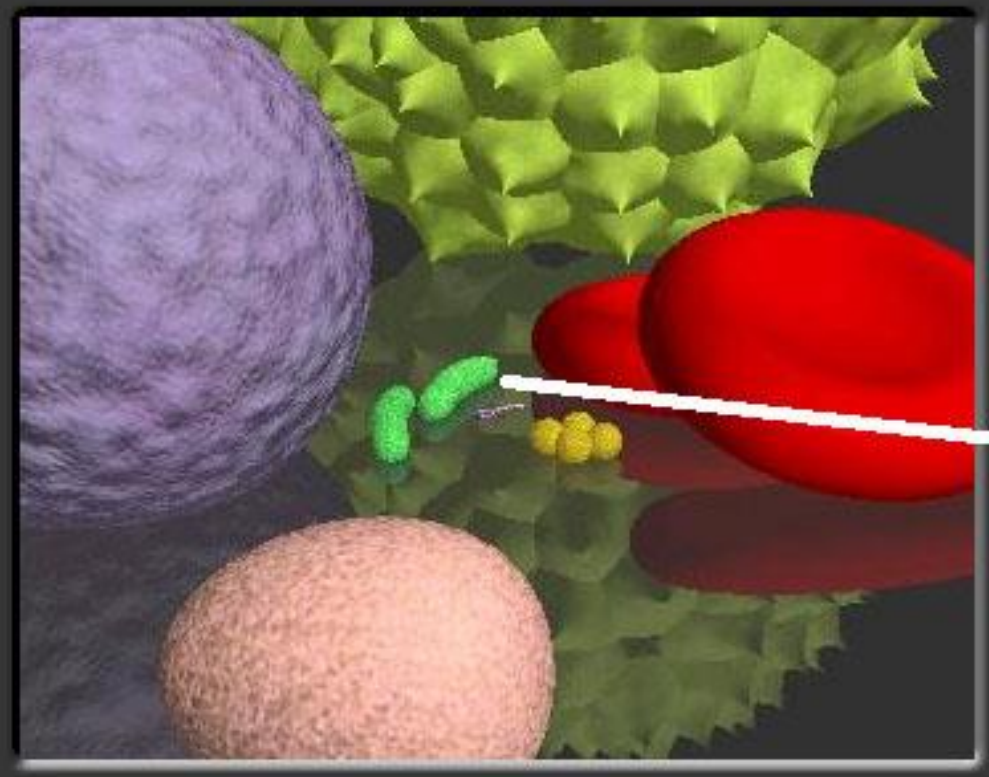

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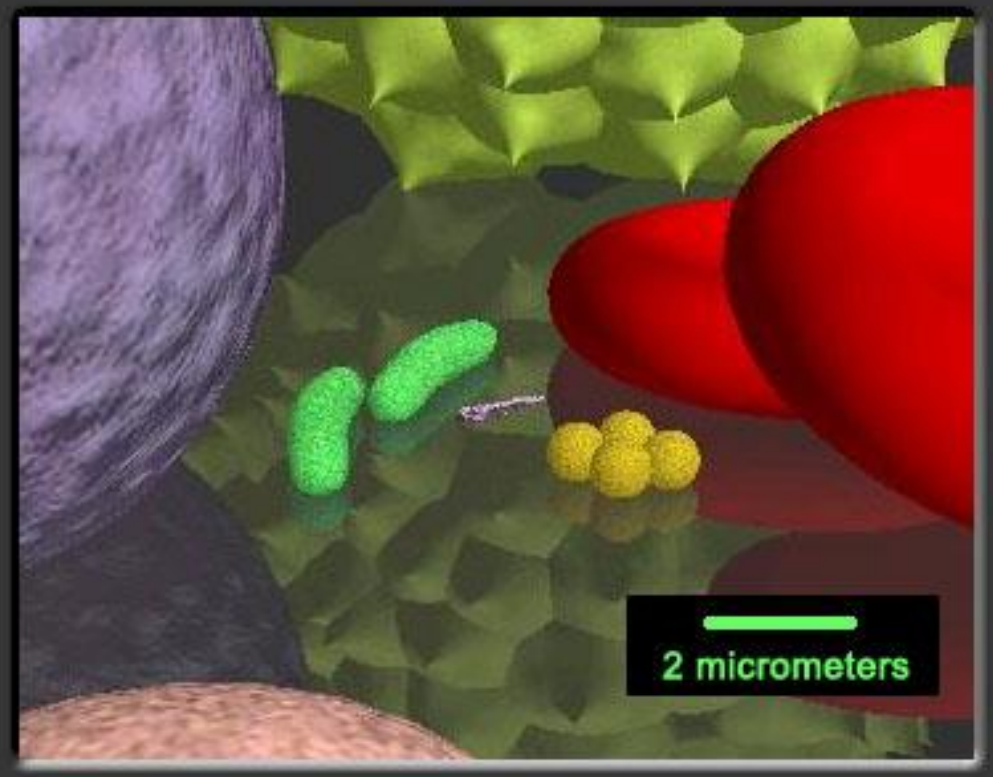

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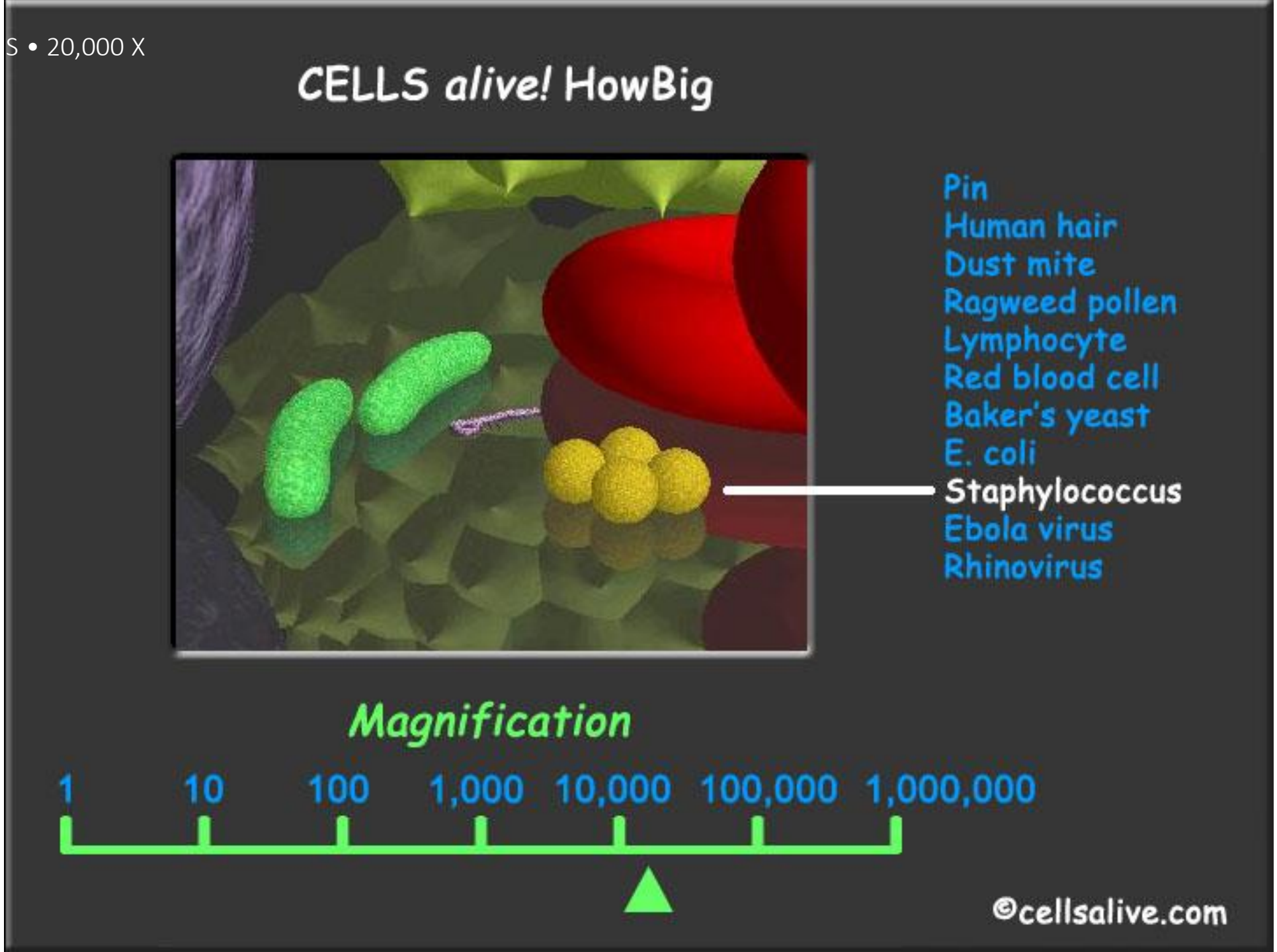
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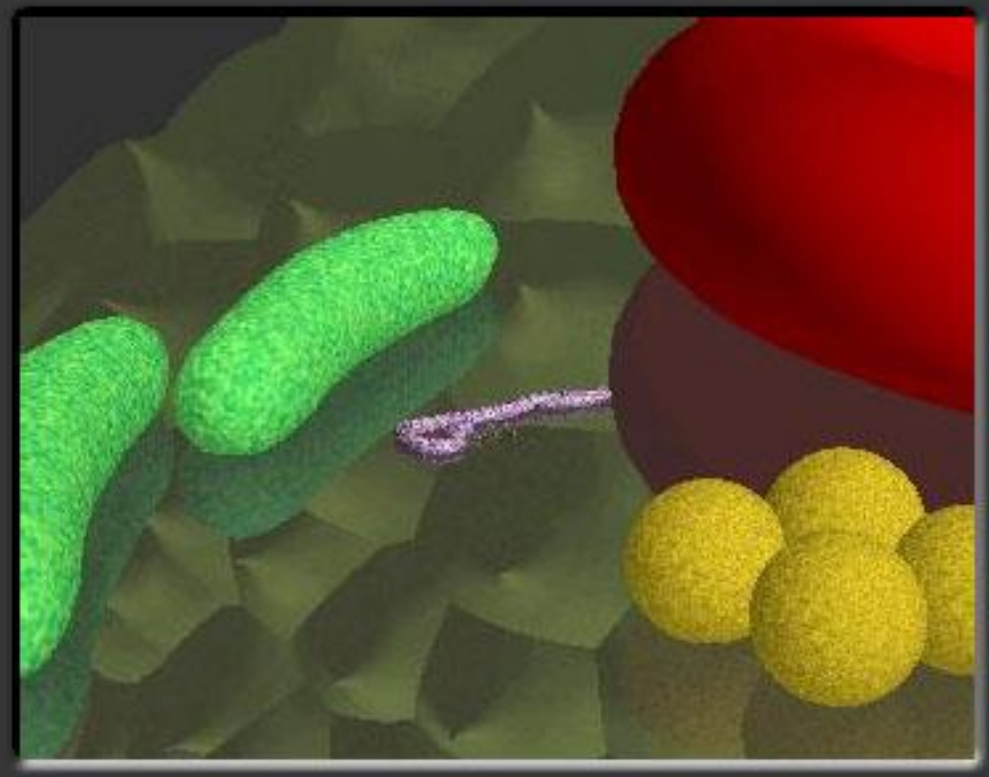

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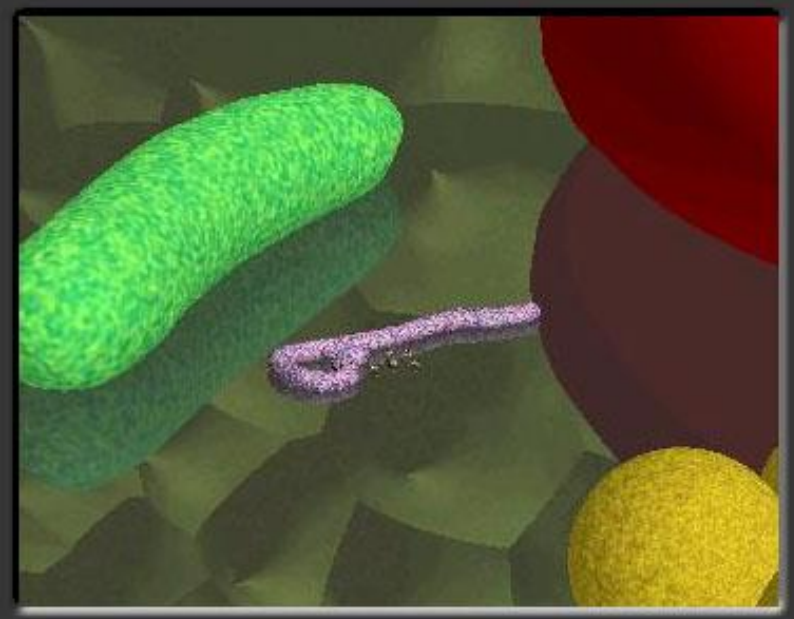

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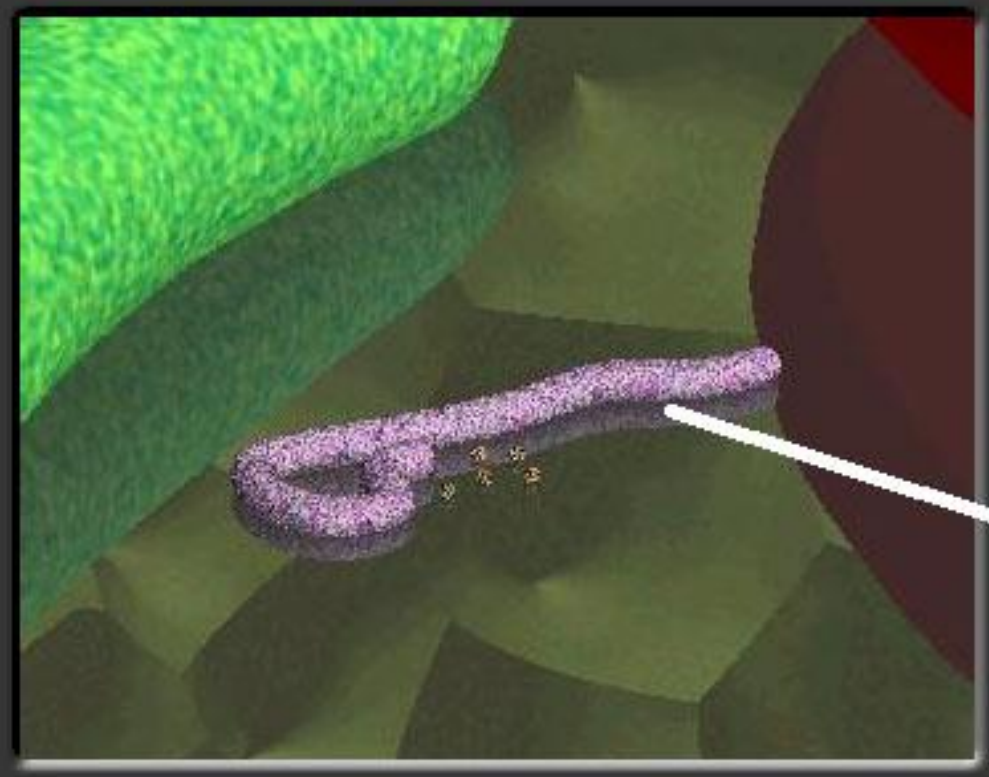

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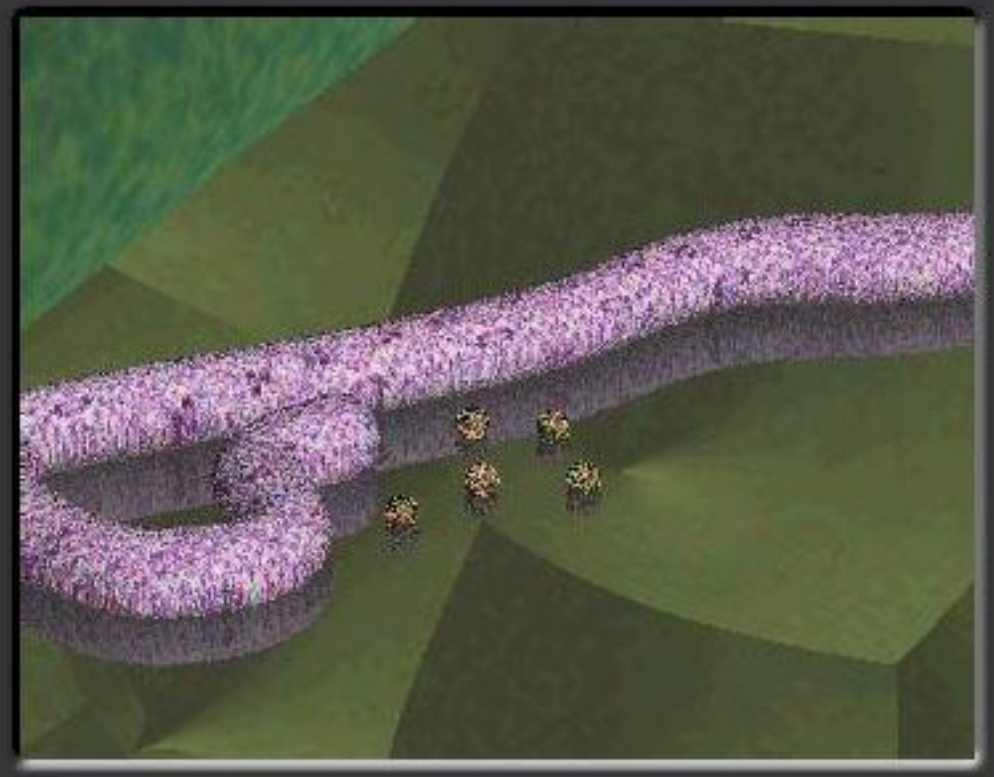

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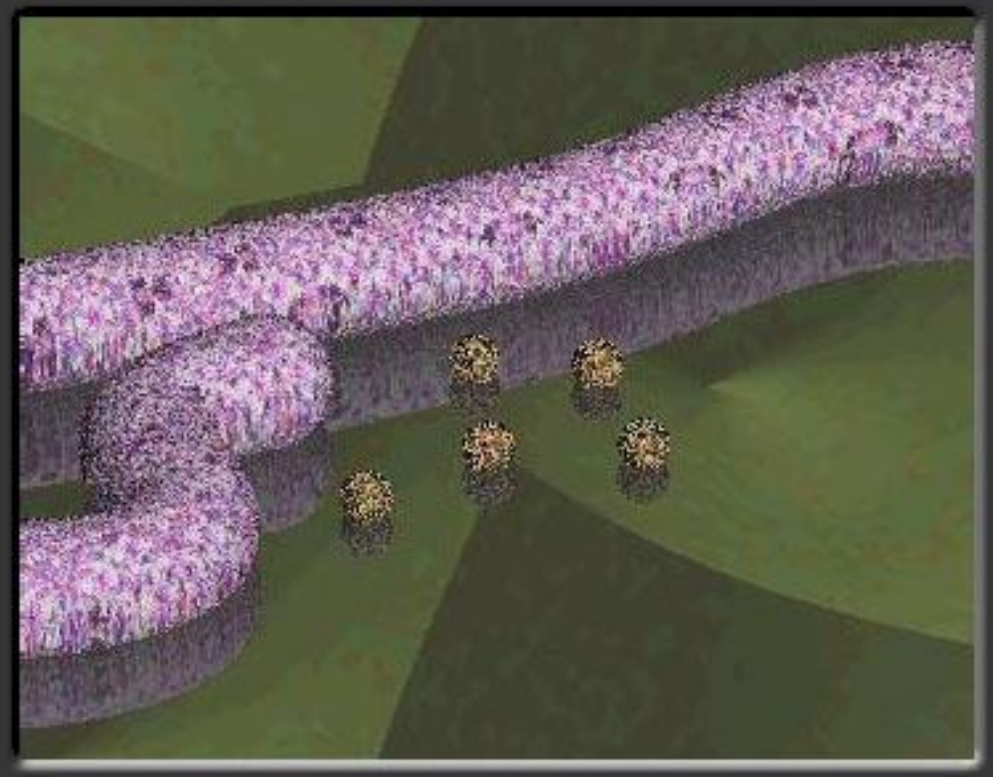

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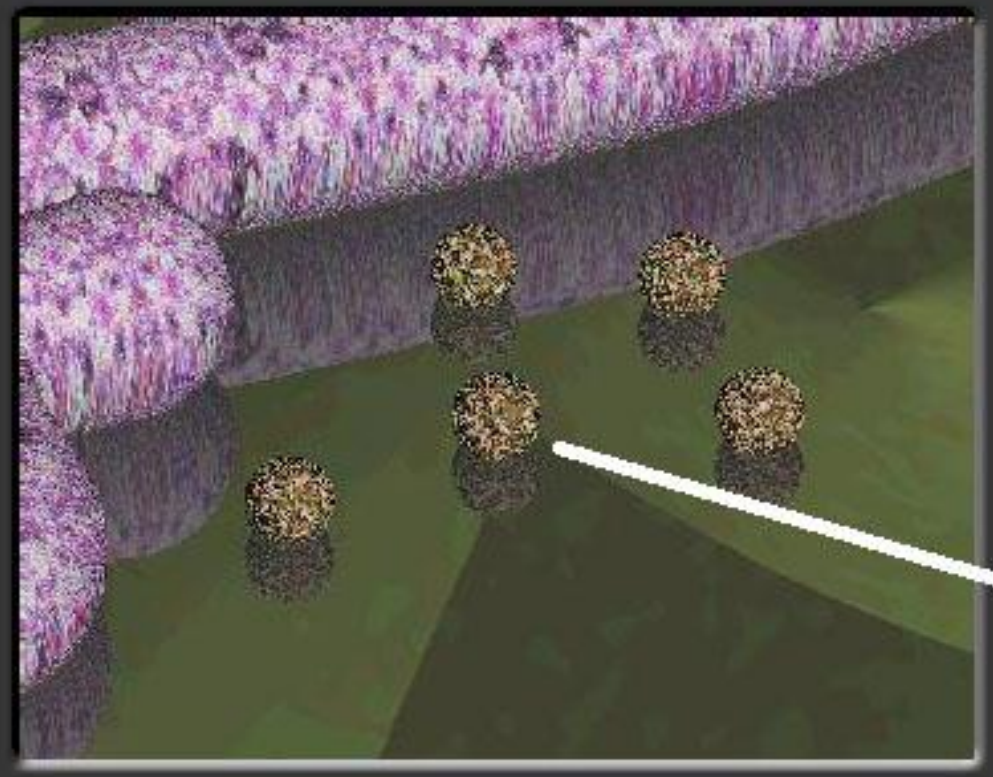

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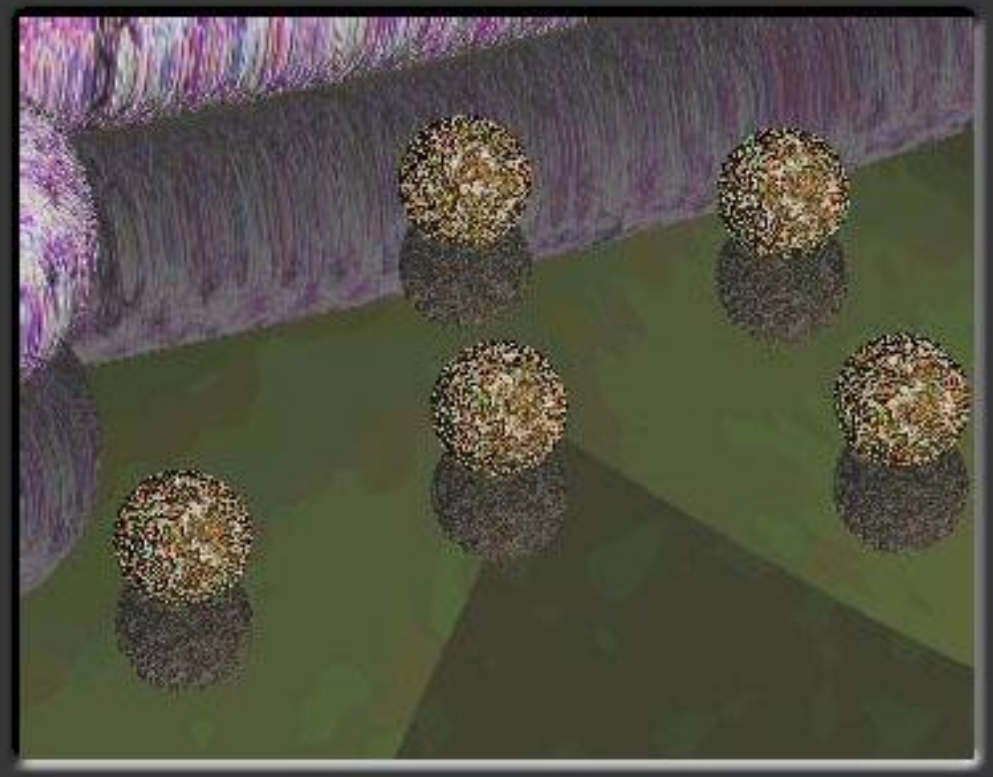

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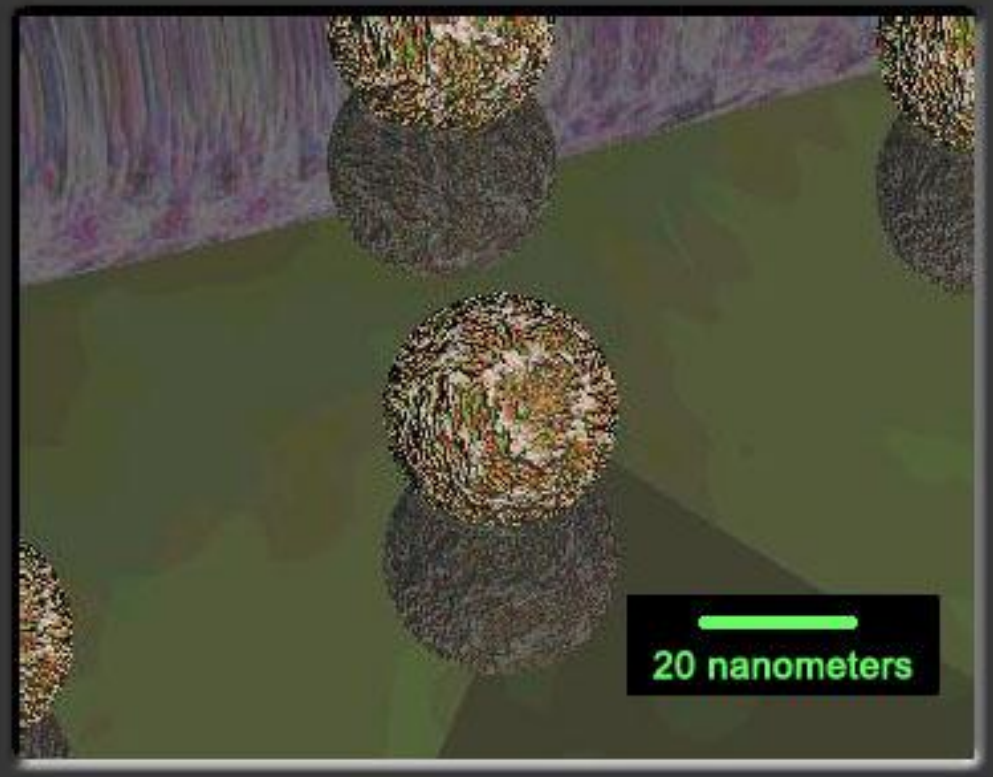
Baker's yeast
E. coli
Staphylococcus
Ebola virus
Rhinovirus

Magnification

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

CELLS *alive!* HowBig



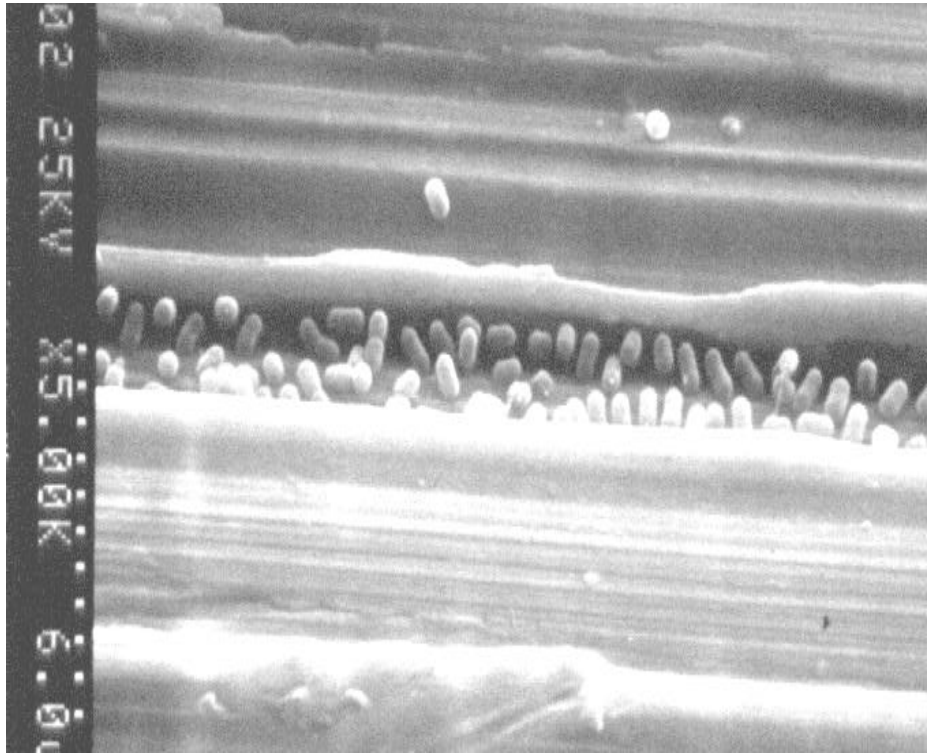
Pin
Human hair
Dust mite
Ragweed pollen
Lymphocyte
Red blood cell
Baker's yeast
E. coli
Staphylococcus
Ebola virus
Rhinovirus

Magnification

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

Equipment Cleaning

Cleaning needs to be at a Microbiological Level!

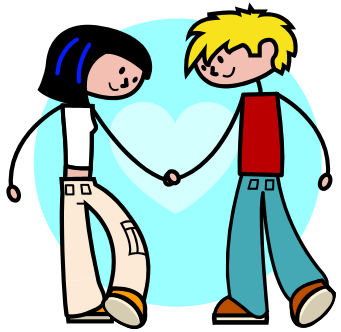


Right now there are 64!!!

2 hours
Double every 20 minutes!

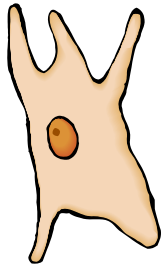
When was there just 1?

How Fast Do Microorganisms Multiple

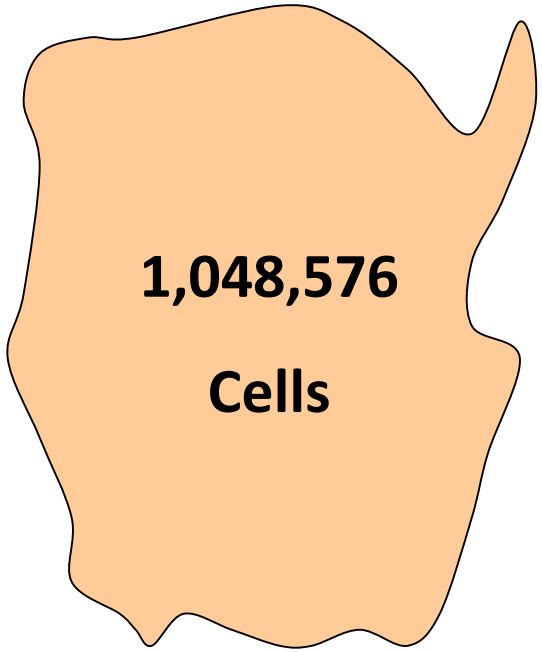


10 Years

1 Year



10 Hours



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

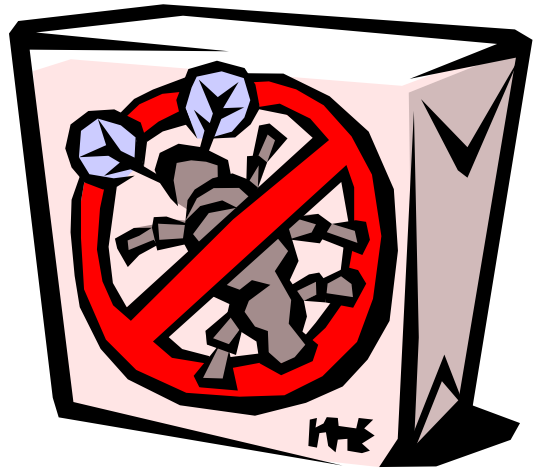
Heat

Iodine

Peracetic Acid

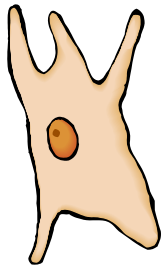
Chlorine

Quats

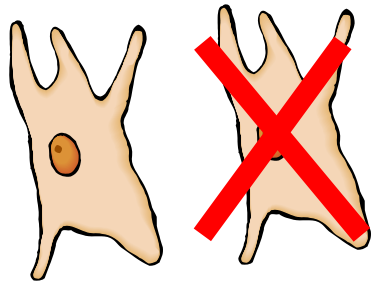


Necessities of Life of a Microorganism

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





Key Steps in Hygienic Design Process

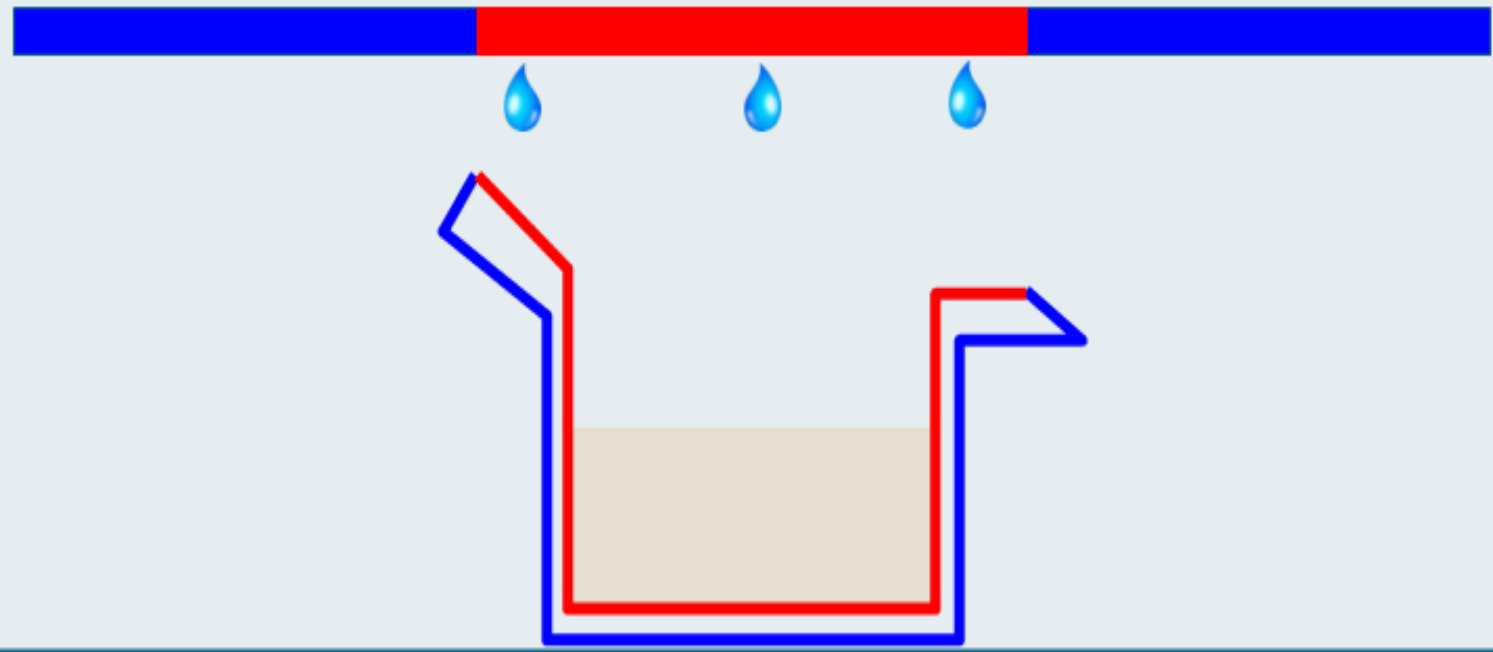
- Define Intended Uses & Risks
- Define Product Zones
- Define Cleaning Method
- Select Approved Materials of Construction
- Provide Accessibility to Clean and Inspect
- Design and Build to Meet Hygienic Criteria

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.



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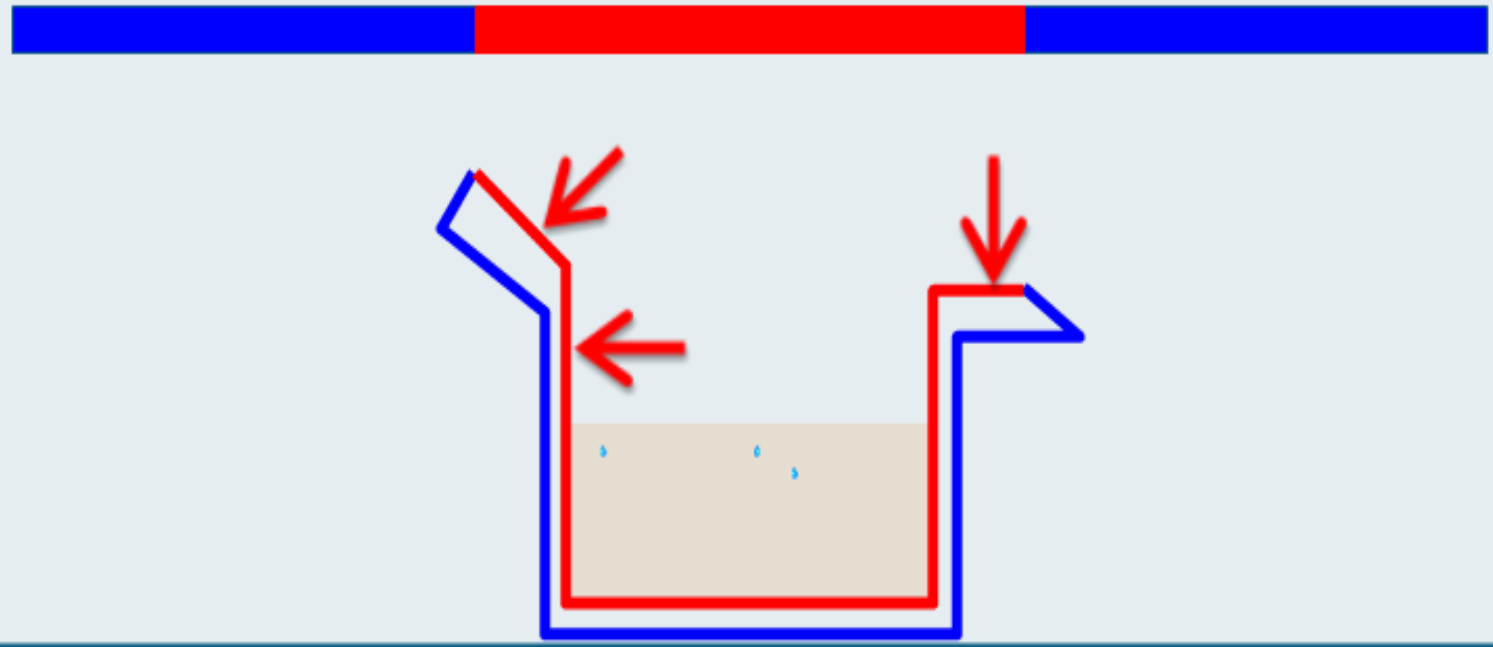
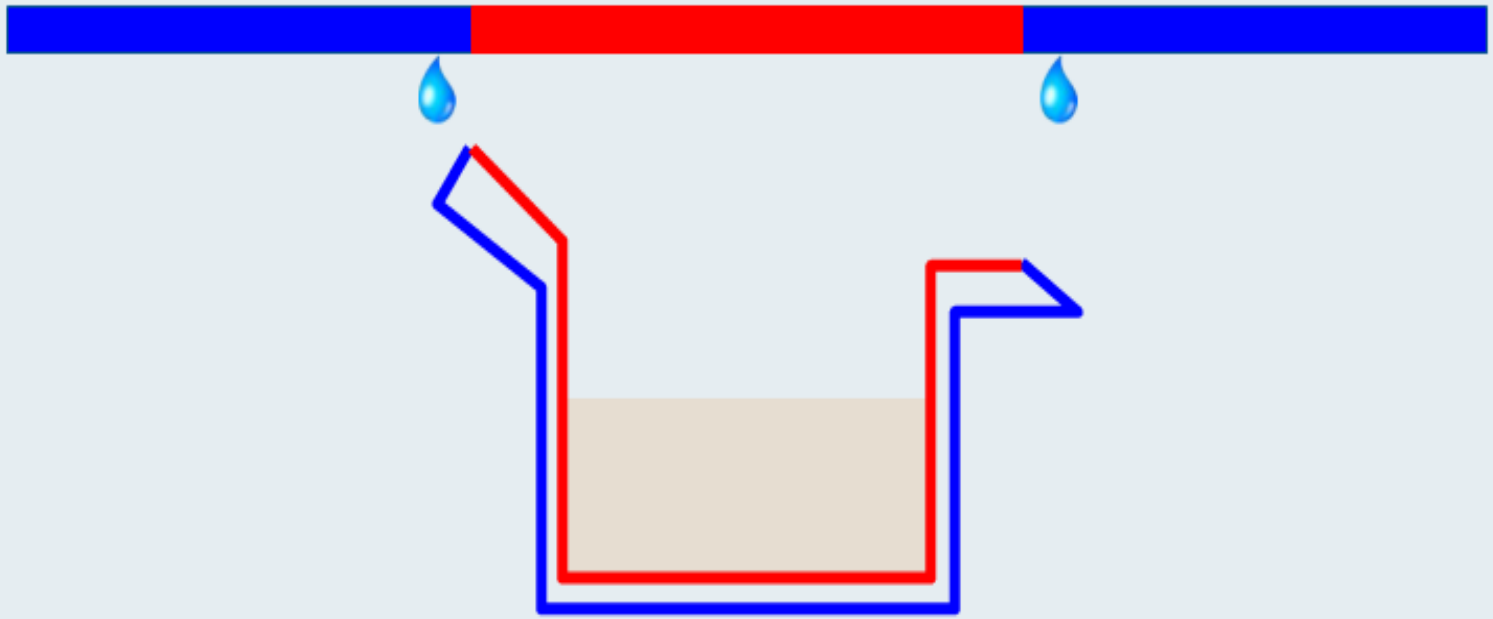


DEFINITION: NON-PRODUCT CONTACT SURFACES

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.



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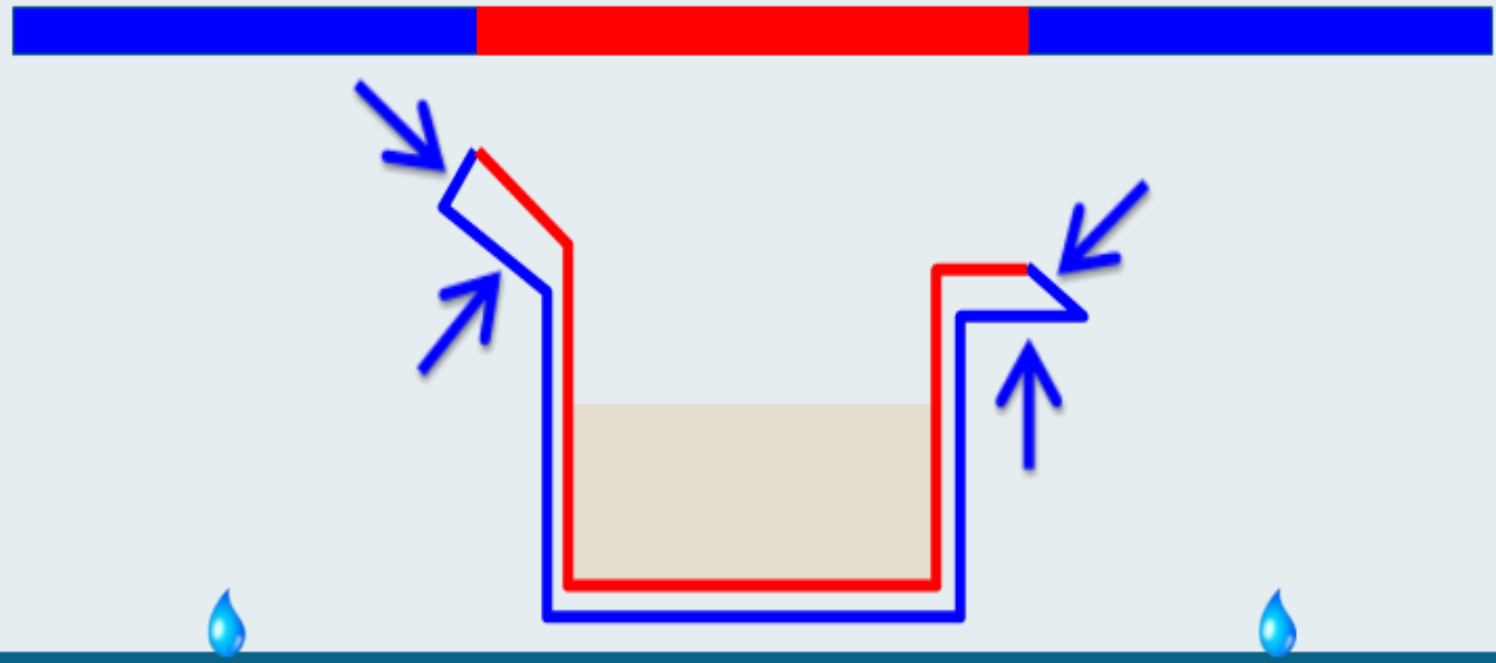

Key Steps in Hygienic Design Process

- Define Intended Uses & Risks
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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

Ma

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

ACCESSABILITY 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

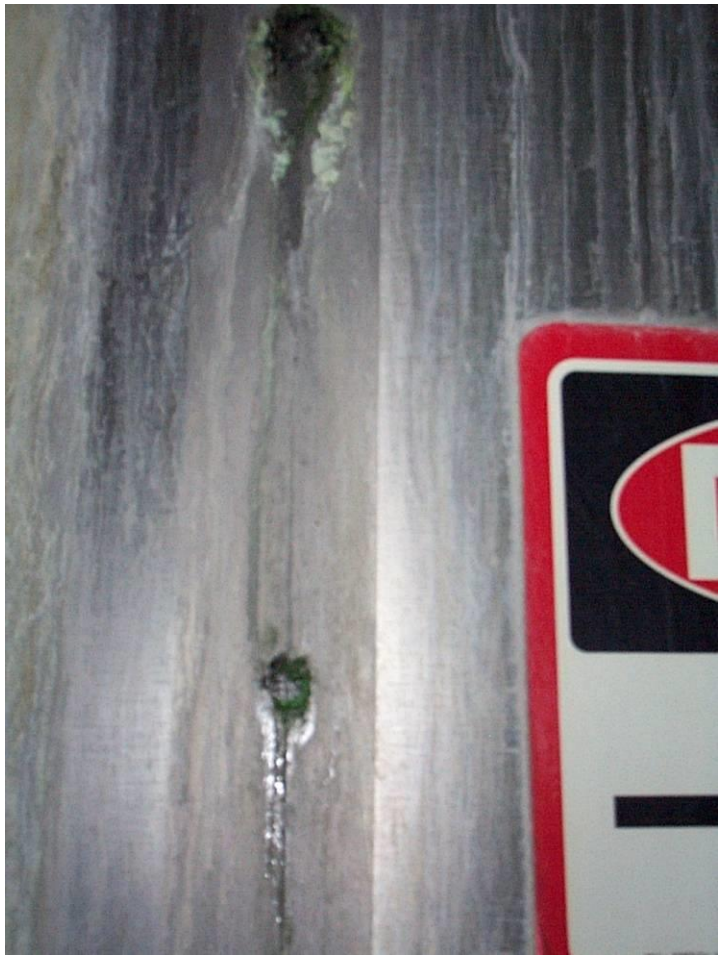
- Define Intended Uses & Risks
- Define Product Zones
- Define Cleaning Method
- Select Approved Materials of Construction
- Provide Accessibility to Clean and Inspect
- Design and Build to Meet Hygienic Criteria

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



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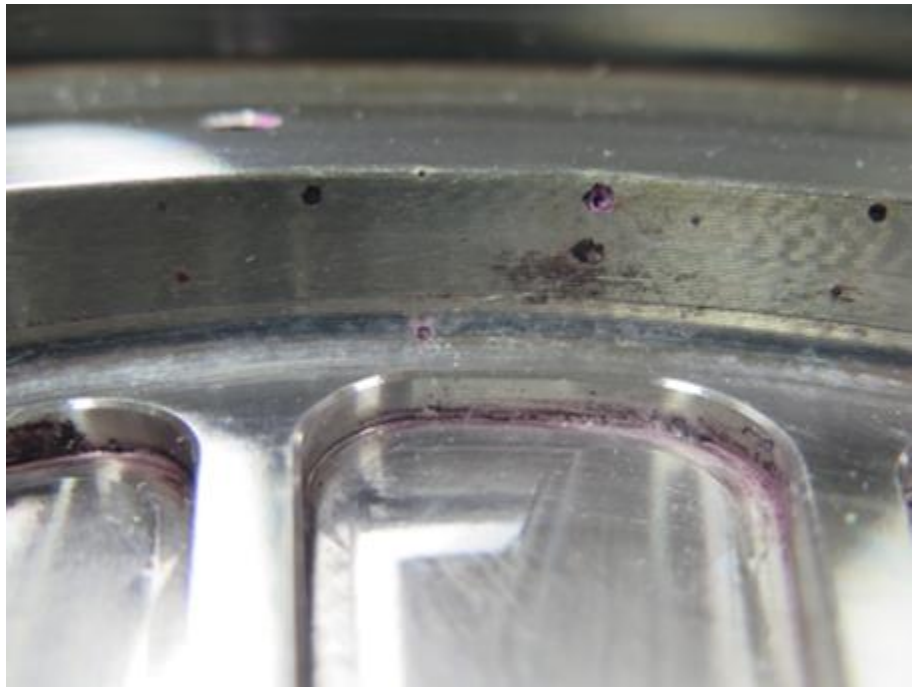
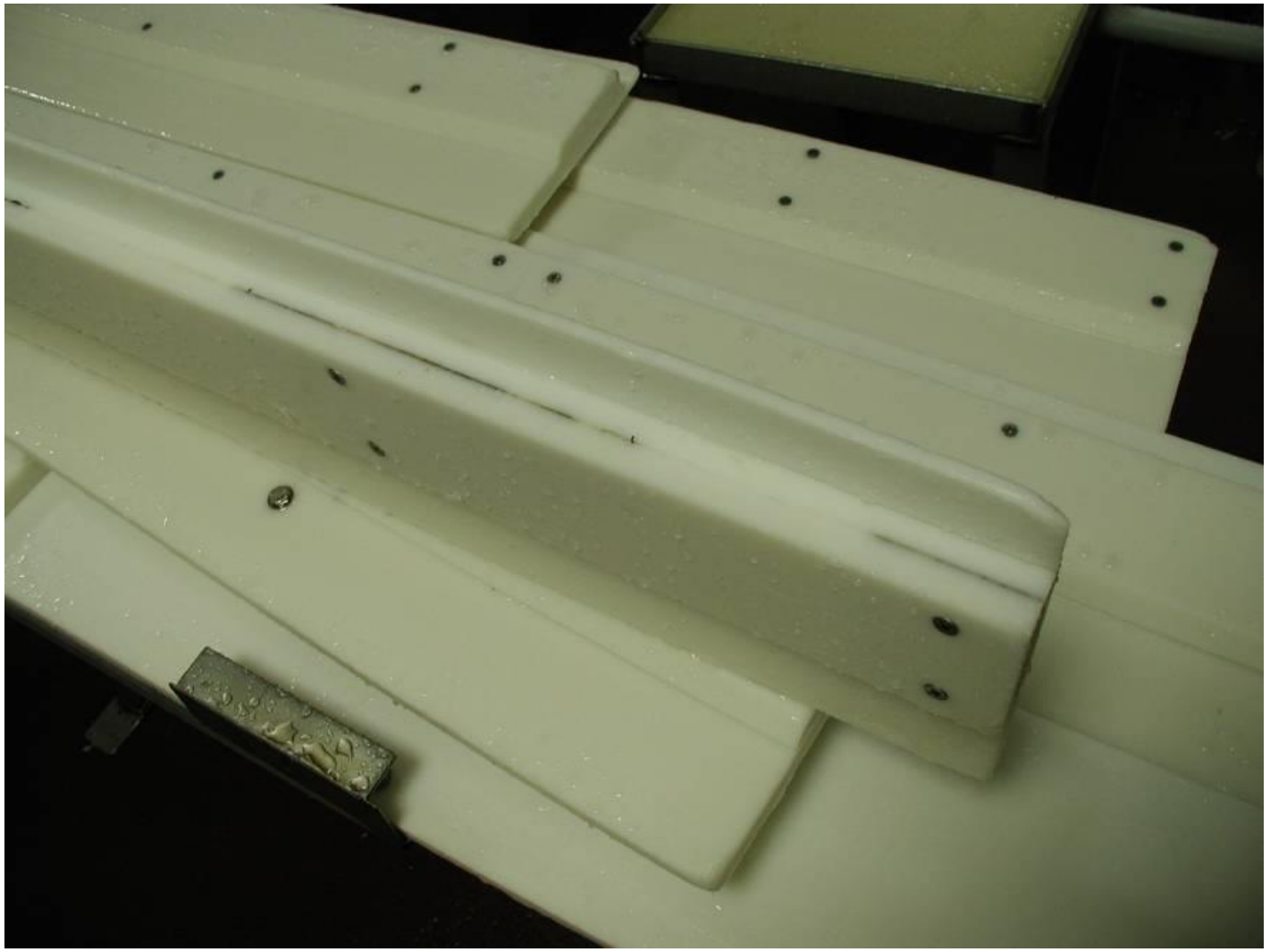
Pitting Corrosion



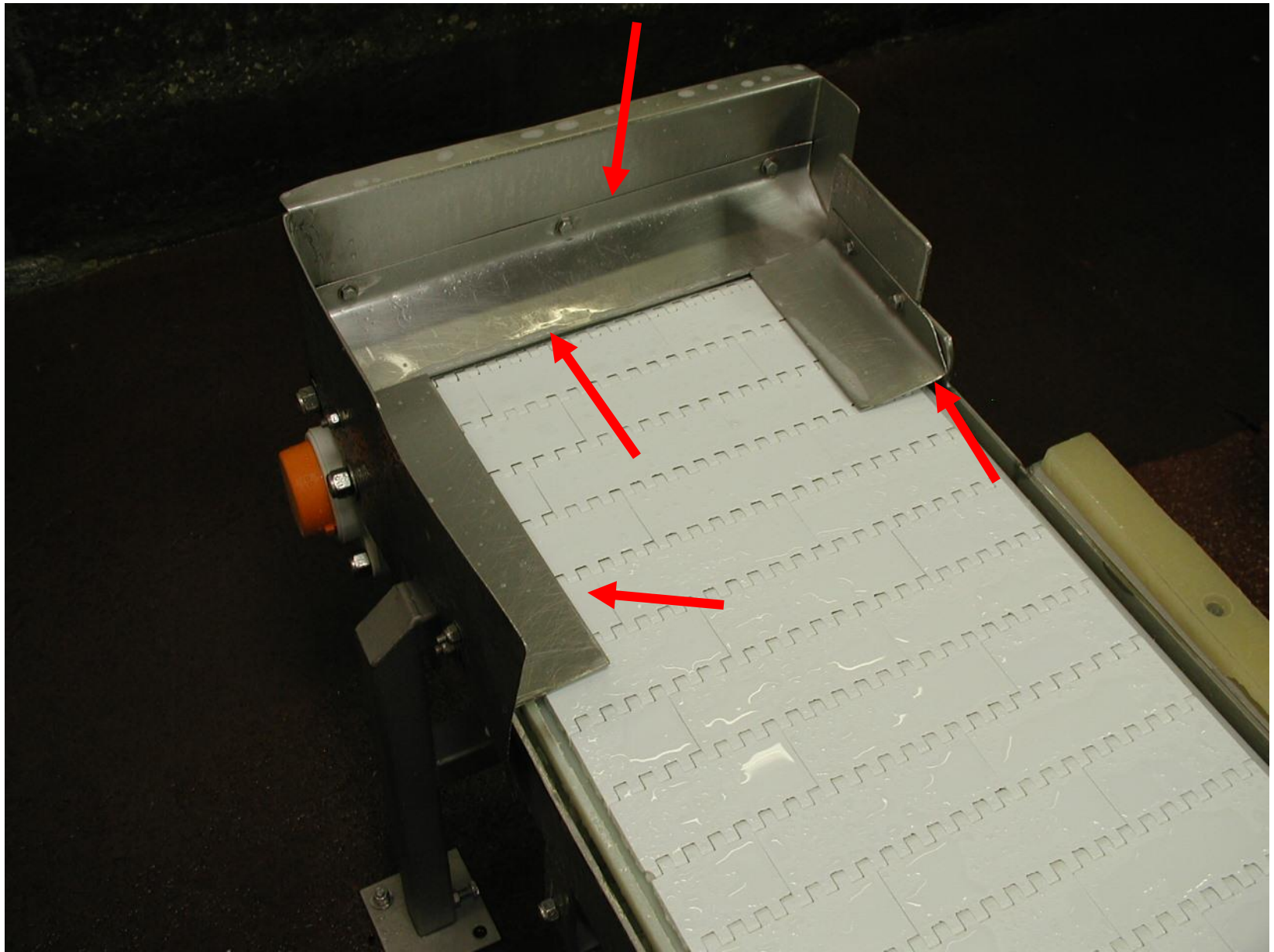
BLANK
19 4:04PM

Bad Weld Cannot be Clean

Joint Design – Hygienic Failure



Bolted Joint

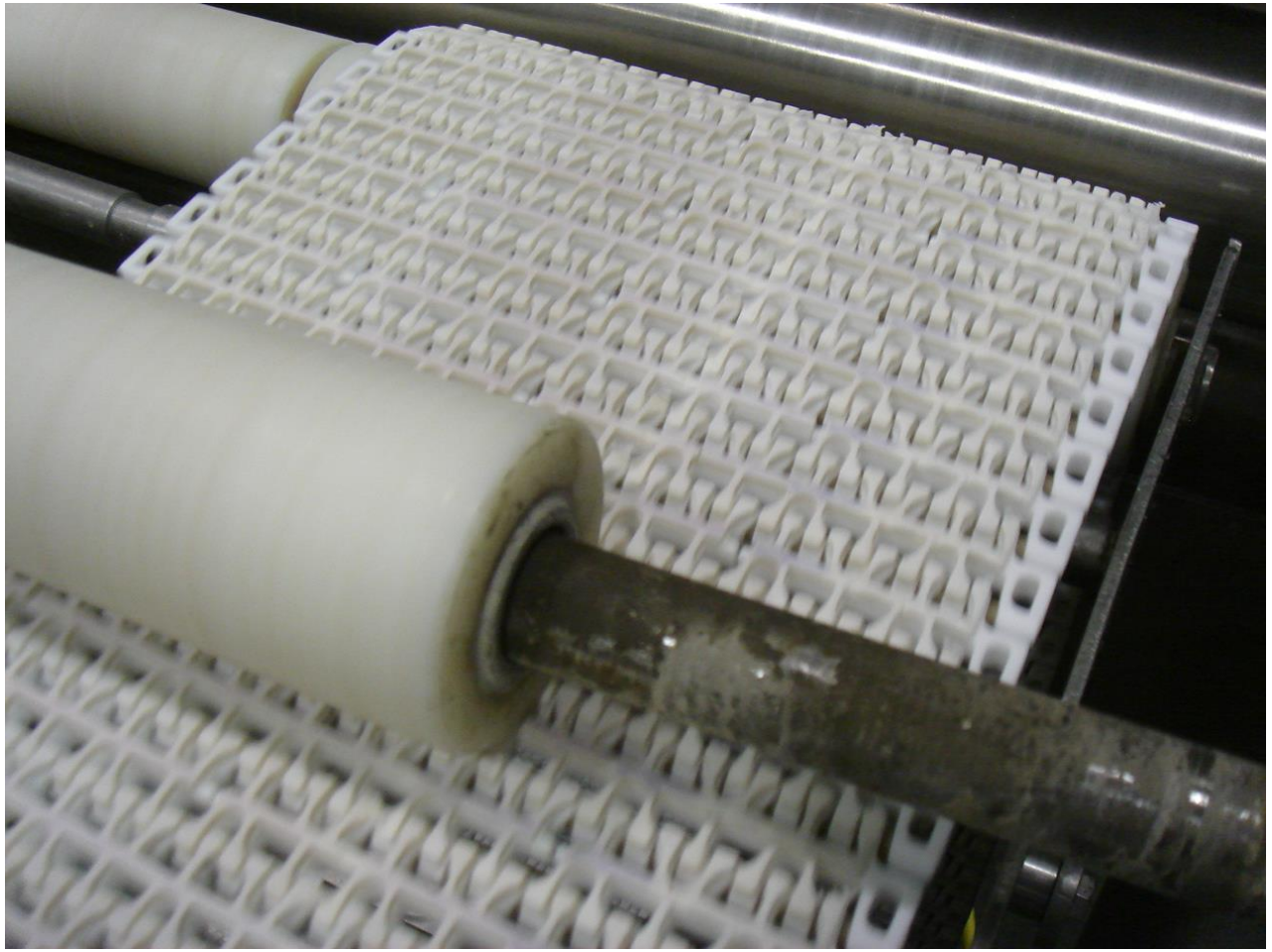


Plates removed

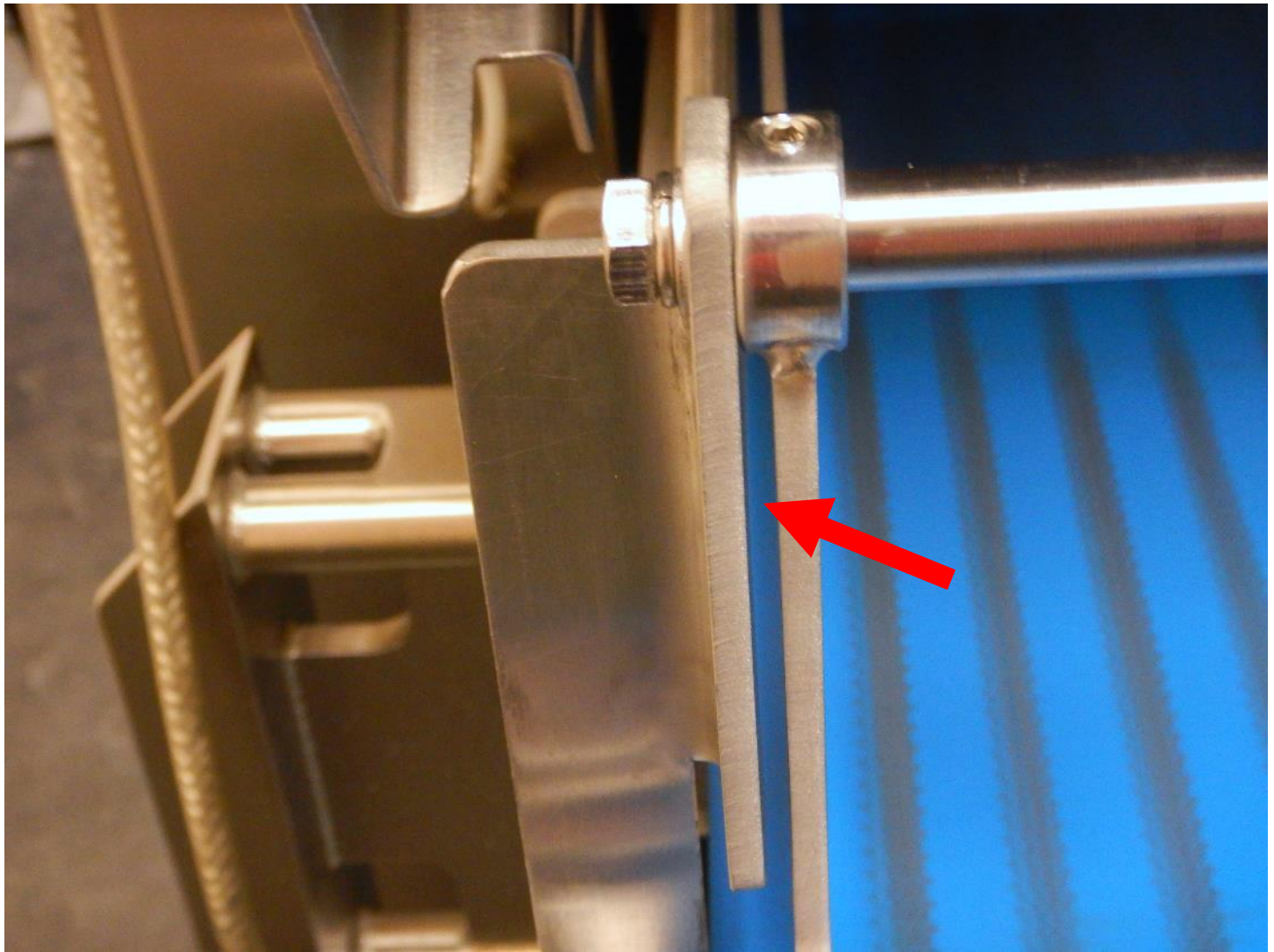
Crevice Failure

Draining Failure

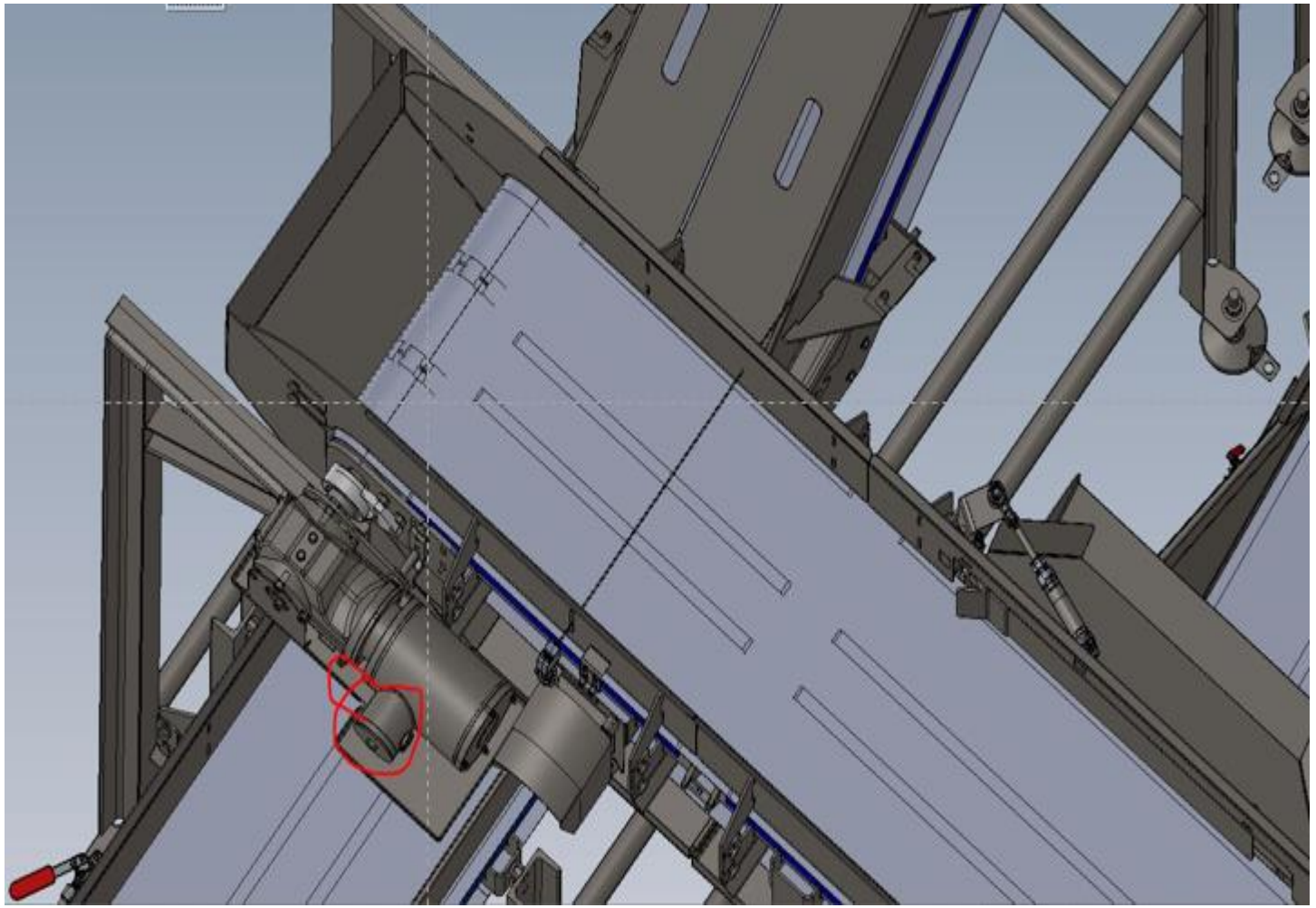
Hollow Roller Failure

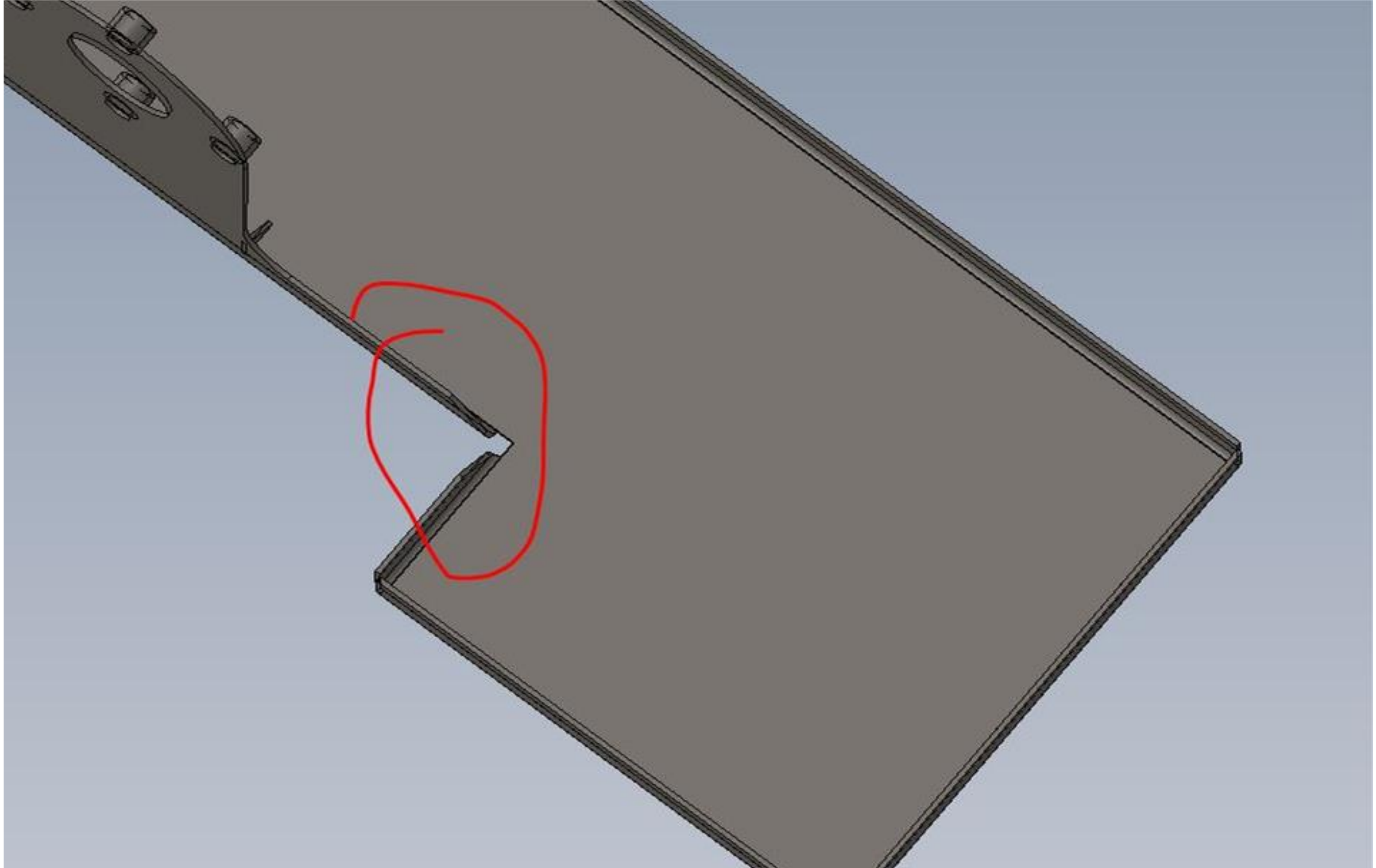


Access to clean failure



- Gearbox over product





Avoid Hygienic Design Failure
Follow The Hygienic Design Process

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

Hygienic Hazards
Contributed during Equipment Design

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

Used with permission & based on “A Process for Concurrent Hygienic Design and Risk Assessment” page 26 by Mettler – Toledo, 2016

Any Questions Before We Move on to

“Hygienic Design & Fabrication Considerations and Techniques”

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