1. Background on Hygienic Design (HD)

1.1. Why HD?

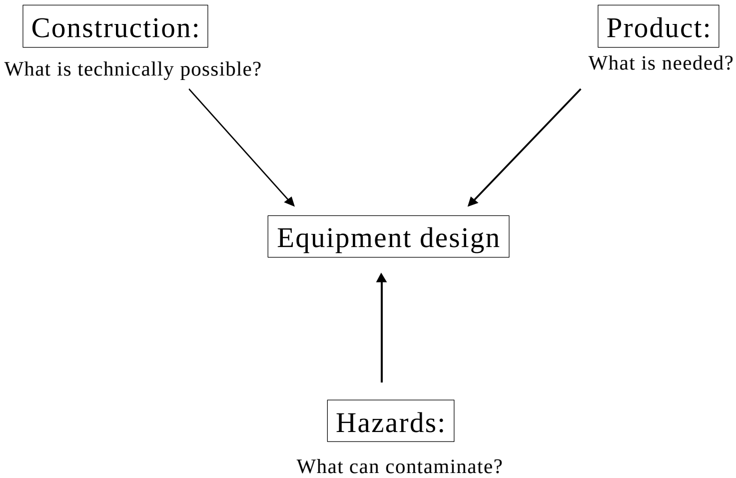
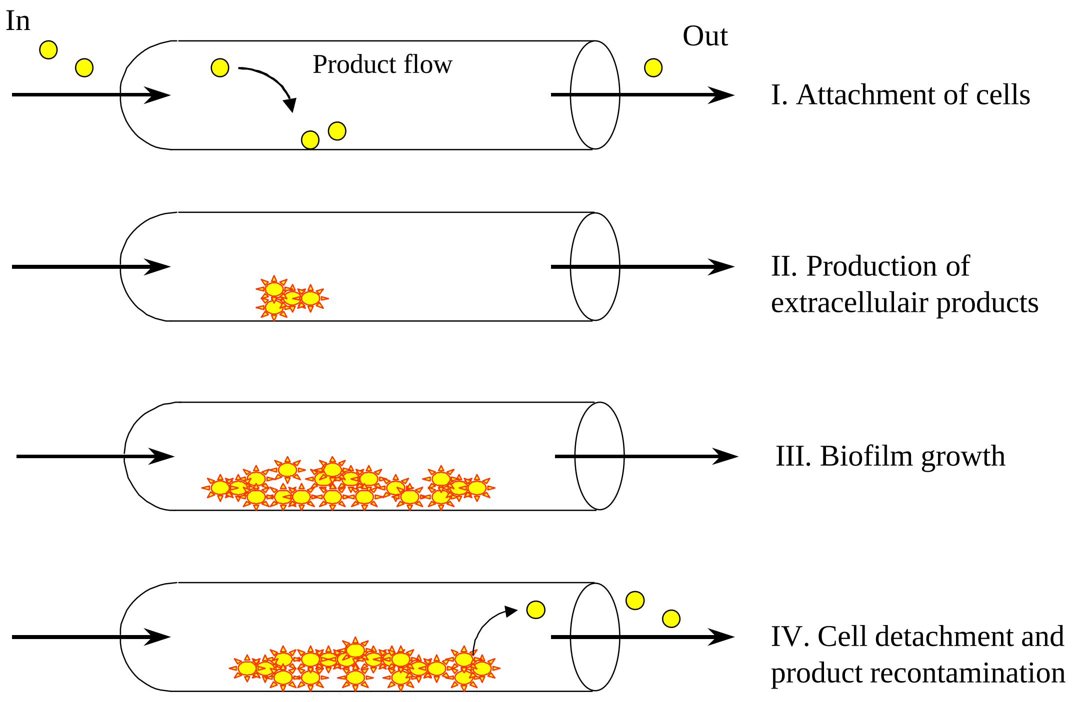


Figure 1.1 Factors involved in design of equipment.

Microbiological hazards:



Micro-organisms can attach to the wall of a pipeline. Production of extracellular products (like polysaccharides) causes an irreversible attachment. Subsequent growth and release of cells from the biofilm causes recontamination of the product.

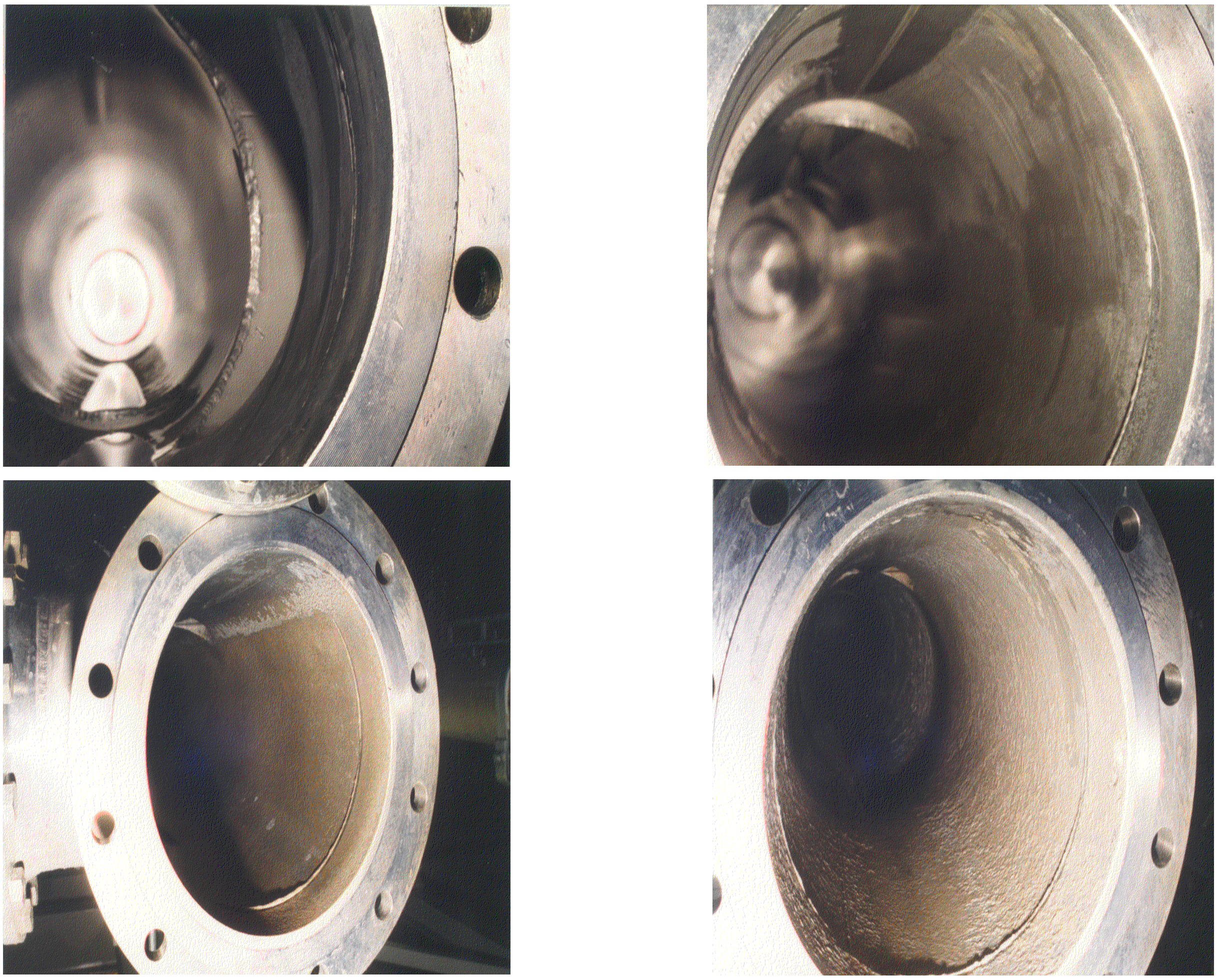


Figure 1.2 Growth of a biofilm inside a pipe.

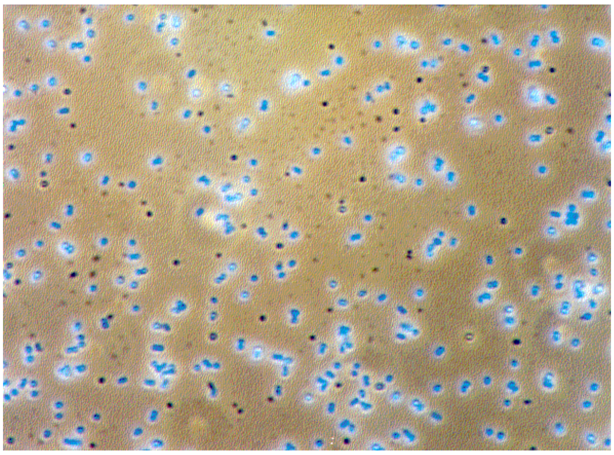


Figure 1.3 Close up of a biofilm.

When bacteria are present in biofilms they are more resistant to detergents and disinfectants and will thus survive a cleaning procedure. When bacteria are then released from a biofilm they can end up in the product causing recontamination. Apart from recontaminating the product, biofilms can cause several problems like corrosion or reduced heat transfer (when attached to heat exchangers). Therefore, factors that enhance the attachment of cells should be minimised.

Imagine that you are a bacterium and you want to survive in a fast flowing river. What would you do?

Right, you would like to hide somewhere, where you are protected from the force of the fast flowing liquid. That is exactly what bacterial cells are doing as well. They like to hide and attach in cracks and crevices on the surface of equipment or in slow flowing liquids like in stagnant areas. Prevention of cell attachment and biofilm growth therefore means using smooth and easily cleanable surface material and avoid dead ends or other places where bacteria can accumulate and grow to unacceptable numbers.

Hygienic equipment:

Hygienic equipment is equipment that can be cleaned in-place and freed from relevant micro-organisms without dismantling (Class I equipment) or equipment that is cleanable after dismantling and that can be freed from relevant micro-organisms by steam sterilisation or pasteurisation after reassembly (Class II equipment). The equipment is not bacteria-tight, so a small but acceptable increase in level of micro-organisms is possible.

Aseptic equipment:

Aseptic equipment: hygienic equipment that is, in addition, impermeable to micro-organisms.

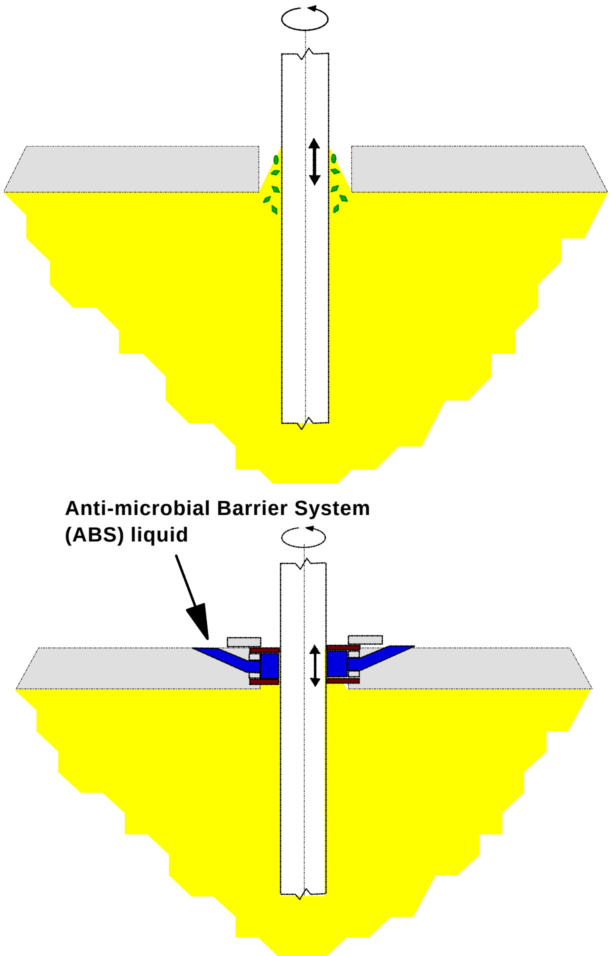


Figure 1.4 Hygienic and aseptic equipment.

1.2. *Organisations involved in Hygienic Design*

Although legislation is strict towards food hygiene they do not provide detailed information on how to achieve Hygienic Design. Therefore, to assist the industry on design of hygienic processing lines the 3-A organisation was founded in the US in 1927.

http://www.3-a.org/.

Since then a number of organisations were formed concerned with hygienic processing. In the US, apart from 3-A that has provided a number of guidelines for the dairy industry, there is the National Sanitation Foundation (NSF) that has focused on food service equipment.

http://www.nsf.org/

In Europe, the European federation of standardisation organisations (CEN) has produced standards on hygienic aspects of food processing machines resulting in for example: EN 1672: Food Processing machinery- Basic concepts.

http://www.cenorm.be/

Another European organisation is the EHEDG (European Equipment Design Group) that has developed a number of guidelines on hygienic design principles but also on test methods, which can be used to verify whether equipment complies with requirements for hygienic or aseptic operation of food plants (Lelieveld, 2000).

http://www.ehedg.org/

On an international level, an ISO committee has established a standard on hygienic requirements for the design of machinery (ISO 14159).

http://www.iso.ch/iso/en/isoonline.openerpage.

EHEDG, 3-A and NSF are currently working together to harmonise guidelines and standards on hygienic design. 3-A standards are regularly published in the journal Dairy, Food and Environmental Sanitation (http://www.foodprotection.org/Publications/DFES.html). (Holah, 2000). Summaries of EHEDG guidelines are published in Trends in Food Science & Technology (http://www.elsevier.com/locate/tifs).

1.3. Cleaning hygienic equipment - the basics

Microbial attachment and biofilm formation: a new problem for the food industry?

To prevent contamination of product apart from correct hygienic design of equipment and materials, cleaning procedures are equally important.

The right cleaning order would be to first remove product and soil residues before disinfectants can be applied to kill the micro-organisms. When bacteria are protected by a layer of soil, they are less vulnerable for disinfectants and are also protected from destruction by heat.

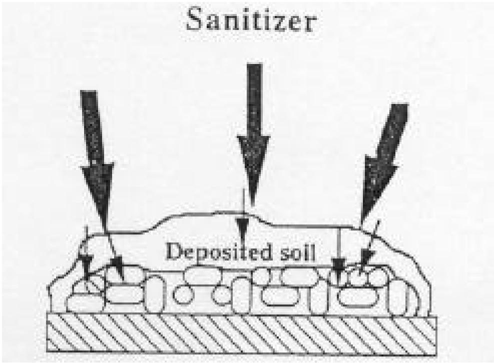


Figure 1.5 Wrong use of sanitizer: the deposited soil shields the biofilm from it. *Food Technology* 48 (7). 107-114

Even when saturated steam is used for inactivation, the water activity in the soil remains low causing an increase in D-values. This means that longer heating times are necessary to reduce the number of bacteria. Therefore, removal of micro-organisms is more efficient when equipment is first cleaned to remove soil and than disinfected to remove micro-organisms:

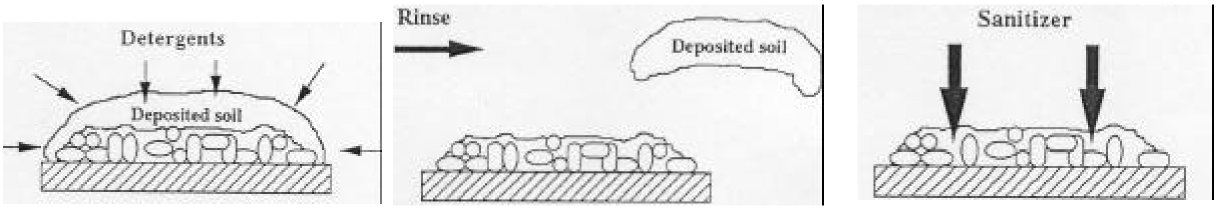


Figure 1.6 Use of detergent to remove soil deposit, followed by rinsing and biofilm removal.

1.3.1. Cleaning

Sinner circle: cleaning efficiency depends on a right combination of time, mechanical cleaning (brushing, high pressure), chemicals (acids, bases) and physical cleaning (temperature, surface tension).

For example, in a Cleaning In Place (CIP) procedure a chemical cleaning agent is pumped at elevated temperatures through pipelines for a certain period of time. Effective cleaning requires a velocity of cleaning liquid of 1.5 m/s (Lelieveld, 2000).

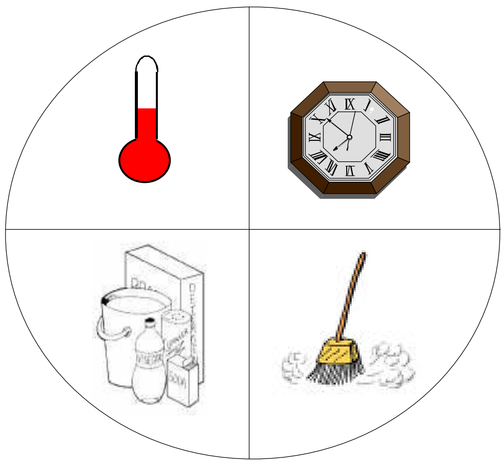


Figure 1.7 The sinner circle.

There are different types of cleaning agents:

Alkaline cleaning agents. Usually contain 60-80% NaOH, which is applied on heavy fouling like fats and proteins on stainless steel, rubber and glass

Acidic cleaning agents. Used to remove protein and calcium residues. Applied for removal of e.g. milkstone (Ca aggregates).

Neutral cleaning agents. Usually surface tensions active compounds in water like quaternary ammonium compounds (quats).

1.3.2. Disinfection methods

A. Heat / Steam

Heat resistance of micro-organisms depends on the type of micro-organism (can it form spores for example that are more resistant towards heat treatment), pH and presence of buffers, NaCl etc.

B. UV-disinfection

Penetration of UV light is limited; therefore this technique can only be applied on sterilisation of air, surfaces and clear fluids (like water)

C. Disinfection agents

There are different types of disinfectants that work against different micro-organisms:

- Oxidising agents: Halogenic substances ($NaHClO_3$, Halamid etc), Water peroxide, peracitic acids, ozone.
- Alcohols: ethanol, propanol etc.
- Aldehydes: formaline, glutar aldehyde etc.
- Phenols and derivates: lysol, hexachlorophene etc.
- Quaternary ammonium compounds (quats).
- Ampholytes.

Table: working spectrum of active compounds of disinfectants

	Halogenics	Peroxide	Peracitic acid	Alcohols	Aldehydes	Phenols	Quats	Ampholytes
Gram +	++	++	++	++	++	++	++	++
Gram -	++	++	++	++	++	++	+	++
Mycobact.	++	++	?	++	++	++	-	?
Pseudomonas	++	?	++	?	?	?	+/-	+/-
Yeasts	++	++	++	++	++	++	++	+
Moulds	+	++	++	++	+	+	+	+
Bacterial spores	+	+	++	-	+/-	-	-	-
Viruses	++	++	?	+	+	-	+	?

++ very good

\+ reasonably

+/- variable

-- not working

? unknown

1.4. Contents of this course

1.4.1. Contents of the next chapters

Chapter 2: Hygienic design of Surfaces

Explains how to obtain smooth and cleanable surfaces.

Subjects: welding, corrosion, surface roughness etc.

Chapter 3: Hygienic design of closed systems

Avoiding stagnant areas and other places where bacteria can accumulate and grow. Subjects: sensors, valves, pipe couplings, pumps and drainability of apparatus

Chapter 4: Hygienic design of open systems

How to avoid contact between product and the environment

Subjects: condensations, design of floors, drains, air filtration, zoning/layout, personnel and pests

Chapter 5: Background on Hygienic Design (HD)

How to prevent contamination with other hazards than microbiological ones. Subjects: toxicity coatings, lubricants, residuals cleaning agents, glass etc.

Chapter 6: Machinery

Design of heating and packaging equipment

Subjects: pasteurisers, sterilisers, hygienic and aseptic packaging

1.5. Further reading

1. H.L.M. Lelieveld (2000). Hygienic design of factories and equipment. In: Lund, B.M., Baird-Parker, T.C. and Gould, G.W. Microbiological safety and quality of food 2. Aspen Publishers Inc. Gaithersburg, 1656-1690

2. Holah, J. (2000). Food Processing equipment design and cleanability F-FE 377A/00 Teagasc: Ireland, 47 p.

3. Anonymous (1993). Welding stainless steel to meet hygienic requirements, SHE 9, Hygienic Processing Working Party, Unilever

4. Anonymous (1994). Hygienic plant engineering requirements, SHE 8, Hygienic Processing Working Party, Unilever

5. ISO 14159. Safety of machinery-Hygiene requirements for the design of machinery

6. EN 1672 (1997). Food processing machinery-Basic concepts-Part 2: Hygiene requirements

EHEDG guidelines:

7. Document 8: Curiel, G.J., Hauser, G., Peschel, P. et al. (1993). Hygiene equipment design criteria. Trends in Food Science & Technology 4(7), 225-229

8. Document 9: Eastwood, C.A., Woodall, D.L., Timperley, E.A. et al. (1993). Welding stainless steel to meet hygienic requirements. Trends in Food Science & Technology 4(9), 306-310

9. Document 10: Curiel, G.J., Hauser, G. Peschel, P. et al. (1993). Hygienic design of closed equipment for processing of liquid food. Trends in Food Science & Technology 4(11), 375-379

10. Document 13: Curiel, G.J., Hauser, G. and Timperley, E.A. (1995). Hygienic design of equipment for open processing. Trends in Food Science & Technology 6(9), 305-310

11. Document 14: Abram, I., Baumbach, F., Curiel, G.J. et al. (1994). Hygienic requirements on valves for food processing. Trends in Food Science & Technology 5(5), 169-171

12. Document 16: Baumbach, F., Dubois, J.P., Grell, W. et al. (1997). Hygienic pipe couplings. Trends in Food Science & Technology 8(3), 88-92

13. Document 18: Maller, R.R. (1998). Passivation of stainless steel. Trends in Food Science & Technology 9, 28-32