ASIFOOD

Co-funded by the
Erasmus+ Programme
of the European Union

Short Term Training Course (STTC)
"Safety and Quality in Innovative Food Production Systems"

20-26 May, 2018

Asian Institute of Technology, Thailand

Lecture 9 and 10 :

Hygienic Design and Sanitation (Part I and II)

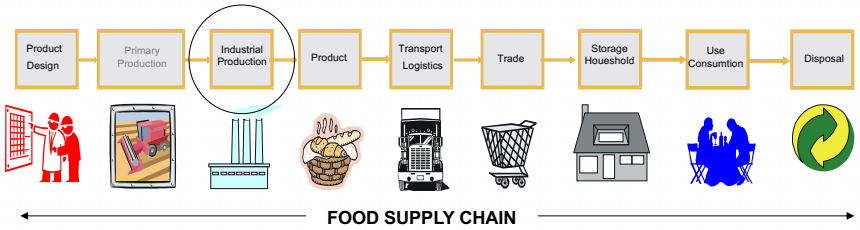
Hygienic Design and Sanititation

Gerhard Schleining

contents

- role of hygienic design within **food safety**
- standards – **guidelines**
- scope of **hygienic design**
- aspects of **building design**
- aspects of **equipment design**, **installation** und **integration**
- **sanitation**

FOOD SAFETY is a matter of the whole food supply chain



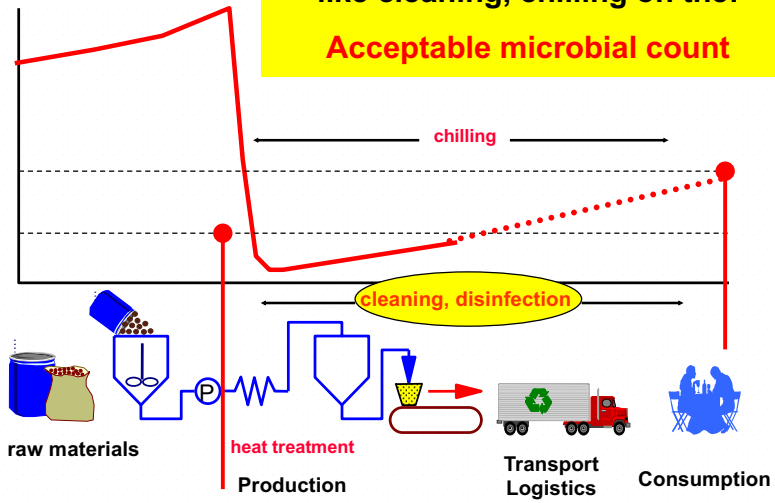
- biological
- chemical hazards
- physical

by

- HUMAN
- ENVIRONMENT
- EQUIPMENT

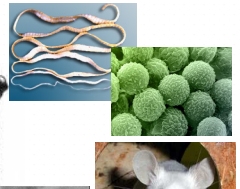
Influence of secondary processes like cleaning, chilling on the:

Acceptable microbial count

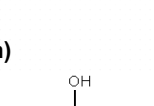


HAZARDS


Biological





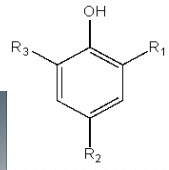


- parasites, vermints, pests, rodents
- microorganism
- Natural biological toxins (Mycotoxins)

Chemical

Residues of:

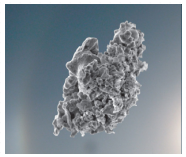
- pestizides, herbizides, fungizides, fertilizers, pharmaceuticals
- Processing contaminants (nitrosamins, fat oxidation, migration)
- Environmental contaminants: food allergens, heavy metals
- lubricants, cleaning agents and desinfectants, paintings



Physical

Foreign bodies:

- foreign food materials: last batch, seeds
- glass, wood, stones, hairs, debris (product)
- splitter of paintings, rust
- dust, paper



Quality

HYGIENE

Hygiene is the essential basis for the quality of a food product

Product Hygiene:

- Control of raw materials (supplier audits, acceptance tests)
- Control of intermediate and end products (shelf life)

Process Hygiene:

- **requirements to building and equipment**
- **cleaning, desinfection, pest control**
- Compliance of temperature-time-relations, storage conditions and **product flow** (cross contamination!!)
- **waste management**

Personal Hygiene:

- dress code, behaviour, if necessary adaption of sanitary rooms
- training !!!

preventive measures

- GMP
- HACCP
- ....
- **HYGIENIC DESIGN**
- ....
- preventive maintenance

PRODUCT QUALITY depends also on the design and quality of the used equipment

EQUIPMENT MANUFACTURER

equipment
design installation
cleanability functionality

EQUIPMENT QUALITY

FOOD MANUFACTURER

process product
design
safety capability

GMP/HACCP/...

processing
cleaning

PRODUCT QUALITY

EQUIPMENT MANUFACTURER

DIN EN ISO 14159
DIN EN 1672-2

Machinery Directive 2006/42/EC

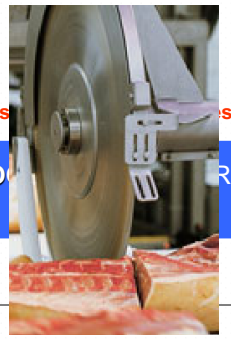
design equipment

HYGIENE

POTENTIAL CONFLICT

OPERATIONAL SAFETY

"hygiene package"



directive 95/63/EEC safety and health requirements for the use of equipment by workers

degree of details

REGULATIONS

- **Regulation 852/2004:** The layout, design, construction and size of food premises are to permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations…….
- **2006/42/EC** : Machinery Directive

STANDARDS

- **DIN EN ISO 14159:** Safety of machinery – Hygiene requirements for the design of machinery
- **DIN EN 1672-2:** Food processing machinery – Basic concepts – Hygienic Requirements

GUIDELINES

Interpretation must always be done in **relation to the local situation**:

- specific product requirements
- specific process requirements
- available equipment
- available staff
- environment

EHEDG-GUIDELINES

is a consortium of equipment manufacturers, food industries, research institutes and public health authorities, founded in 1989 with the aim to promote hygiene during the processing and packing of food products
(http://www.ehedg.org/)

- general design criteria, materials of construction
- closed equipment for liquid products
- open equipment (conveyor belts, mixer, etc.)
- technics: welding, passivation of stainless steel
- aspects: air, water, lubricants
- equipment: pumps, valves, pipes, couplings, sealings
- processes: thermal treatment (pasteurisation, sterilisation, chilling), dry products, packaging (materials), cleaning

EHEDG-TEST-METHODS

Procedures for evaluation, test and certification of equipment for authorisized test laboratories

- in-place cleanability, in-line pasteurisation, in-line steam sterilisability
- Bacteria tightness of equipment
- Bacteria impermeability of membran filters

certified eqipment is listed at: http://www.ehedg.org/certequip.htm

independent, not-for-profit corporation dedicated to advancing hygienic equipment design for the food, beverage, and pharmaceutical industries (founded 1920)
http://www.3-a.org

3A-STANDARDS

- 01-08 Storage Tanks 11/2001
- 02-10 Centrifugal and Positive Rotary Pumps 1/2006
- 04-04 Homogenizers and Reciprocating Pumps 11/1996
- 10-04 Filters Using Single Service Filter Media 11/2000
- 11-08 Plate-Type Heat Exchangers 1/2007
- 12-07 Tubular Heat Exchangers 11/2003
- 13-10 Farm Milk Cooling and Holding Tanks 11/2003
- 16-05 Product Evaporators and Vacuum Pans 8/1997
- ……

3A- ACCEPTED PRACTICES

- 603-07 Sanitary Construction, Installation, Testing, and Operation of High-Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems 11/2005
- 604-05 Supplying Air Under Pressure for Contact with Product or Product Contact Surfaces 11/2004
- 605-04 Permanently Installed Product and Solution Pipelines and Cleaning Systems 8/1994
- 606-05 Design, Fabrication, and Installation of Milking and Milk Handling Equipment 11/2002
- ……

check lists to evaluate equipment

- **Grocery Manufacturers Association** (GMA, http://www.gmabrands.com/)
- **American Meat Institute** (**AMI**, http://www.meatami.com/) based on design principles

To complete this checklist, place an "X" in the appropriate box;
S = Satisfactory
M = Marginal
U = Unsatisfactory
The total score will automatically calculate and can be viewed on the Summary page

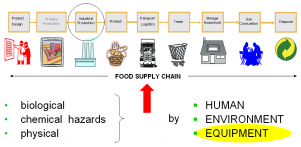
AMI Sanitary Design Checklist

Review Date: _____
Review Location: _____
Review Description: _____

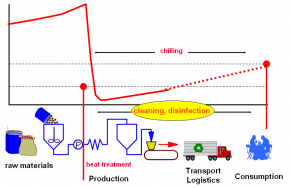
#	Description	Reference	S	M	U	NA	Comments	Points	Points Available
PRINCIPLE #1 - CLEANABLE TO A MICROBIOLOGICAL LEVEL									
1.1	Equipment is designed to be constructed & maintained in a cleanable condition to prevent the ingress, survival & multiplication of microorganisms (measured post installation).	NSF 5.1						-	20
1.2	All surfaces are cleanable as measured by <1 CFU per 25 square centimeters, <1 CFU per 10 ml when the item is rinsed, acceptable RLU (device specific) when measured by residual ATP, and/or negative for residual protein or carbohydrate when using swabs to detect residual protein or carbohydrate (measured post installation).	AMI						-	20
1.3	All surfaces are accessible for mechanical cleaning & treatment to prevent biofilms formation (measured post installation).	AMI						-	20
1.4	When requested, data are available to demonstrate that soiled equipment is cleanable (as defined above) by an individual using the cleaning protocol provided by the equipment supplier (measured post installation).	AMI						-	20

SUMMARY

- **food safety** is a matter of the **whole food supply chain**
- **hazards** arise from human and environment and also from **equipment**



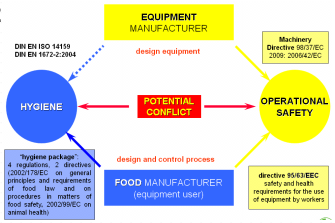
- secondary processes like cleaning effect the shelflife of products, if buildings and equipment is of poor design - **cleaning** will be difficult and **time** consumable



- **hygiene** is the essential basis for the **quality** of a food product
- **product quality** depends also on the **design** and **quality** of the used **equipment**

SUMMARY

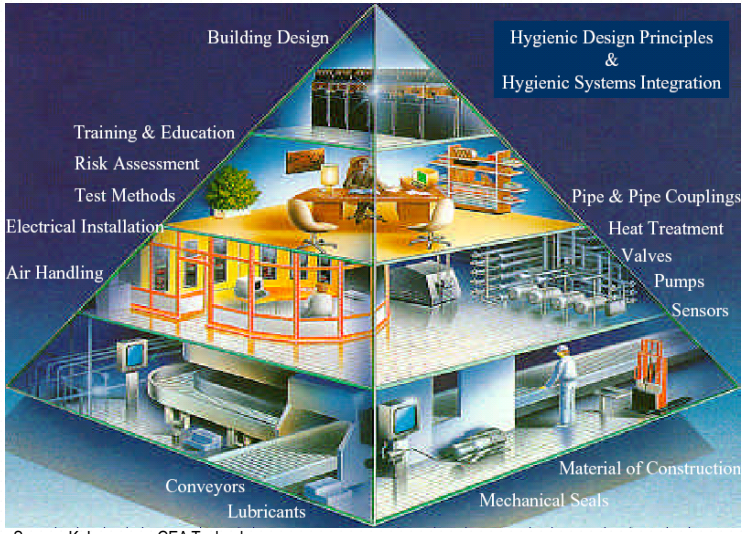
- **operational safety** requirements **conflict** with **hygienic** requirements in many cases



- interpretation of regulations and standards must always be done in **relation to the local situation** (specific product and process requirements, available equipment and staff, environment)

- **guidelines** (knowledge, experiences and sometimes **simple solutions**) are available

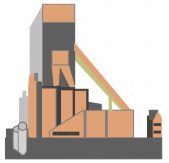
ASPECTS OF HYGIENIC DESIGN



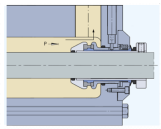
Source: K. Lorenzen, GEA Tuchenhagen

HYGIENIC DESIGN

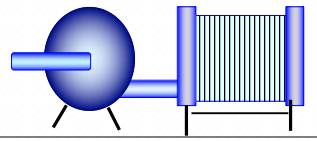
- **BUILDING DESIGN**
  - Plant Enclosure Related Aspects
  - Lay-Out Related Aspects
  - Air Related Aspects
  - Water Related Aspects
  - Zoning



- **EQUIPMENT DESIGN**



- **EQUIPMENT INSTALLATION AND INTEGRATION**

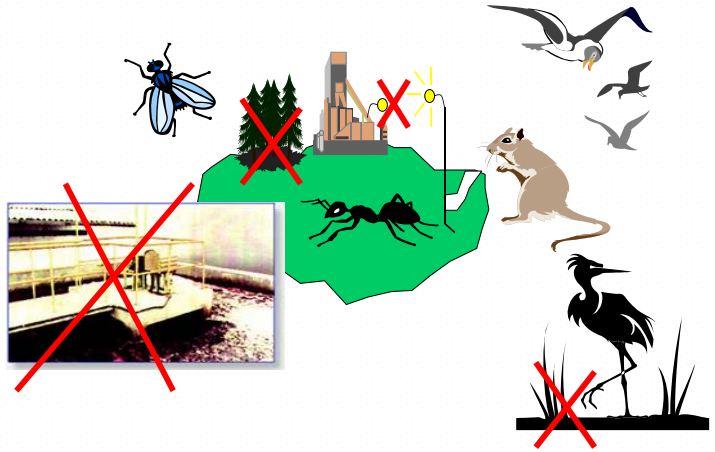


HYGIENIC DESIGN STRATEGIES

- avoid infestation by insects, birds, animals
- avoid contamination with foreign organisms and foreign materials
- avoid conditions which enhance the growth of micro-organism (accumulation of dust, surface/condensed water, product)
- improve cleanability

BUILDING DESIGN

PLANT ENCLOSURE RELATED ASPECTS



BUILDING DESIGN

LAY-OUT RELATED ASPECTS

- Placement of rooms (**Zoning**): separate **dry** and **wet** areas, short **product routing** without crossings
- **Interior building element surfaces** should be non-electrostatic, smooth, round corners and have good accessibility for cleaning

- No **metal panels**
  high heat transfer -> condesation
  -> expansion -> sealings

BUILDING DESIGN

LAY-OUT RELATED ASPECTS

- **Materials**
  should be resistant to food components, cleaning agents and disinfectants
  No **wood** and standard **glass** in open processing areas, but polymer material like polycarbonate or strengthened glass (standard glass with protective film)
  STAINLESS STEEL

AISI 304
- Normal applicable if no:
- No chlorides; otherwise risk of pit corrosion

AISI 316
- Better resistant to chlorides
- > 60 °C: stress corrosion

AISI 410
- Better resistant to stress corrosion

Alternatives
- AISI 409
- AISI 329
- Incoloy 825

MATERIALS

PLASTICS

Easy to clean:
- PC (polycarbonate)
- PE (polyethylene – h.d.)
- PP (polypropylene)
- PVC (polyvinylchloride)
- Acetal polymer

Remind
- PTFE (polytetrafluorethyleen)
  - Sometime porous
  - Soil sticking, more difficult to clean
  - Insufficient elasticity for permanent sealing

ELASTOMERS

Easy to clean:

- EPDM (ethylene-nitril-dieen-monomer)
  - Not resistant to oils and fats
- NR (nitril-rubber)
- NBR (nitril-butylene-rubber)
- Silicone-rubber
  - Special for higher temperatures (< 180 °C)
- Fluorelastomer (Viton)
  - Special for higher temperatures (< 180 °C)
  - < 1% Caustic soda

LAY-OUT RELATED ASPECTS

Drainage

- not in dry areas
- as far away as possible from processing equipment
- sufficient sloping
- ability to close during production
- water lock must be intact

LAY-OUT RELATED ASPECTS

Drainage

Sloped floor to prevent water collection (upfront cost): $1.2M

If not sloped, 22 employees x 1.25 h/day x 220 days required to drain the floor = **6 050 h/year**

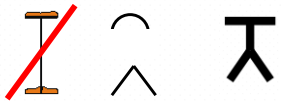
6 050 h/year x **$30/h** = **$181 500/year** to draw water to a drain

Payback Period of $1.2M divided by $181 500/year = **6.61 years**

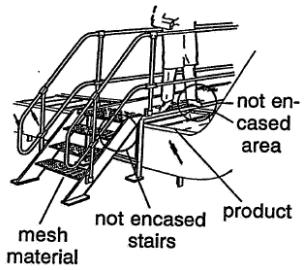
A properly sloped floor would have lasted much longer than this, with savings of $181 500 on manufacturing costs every year thereafter!

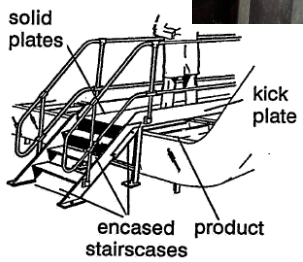
LAY-OUT RELATED ASPECTS

- **Framework:** open profiles, mounted with tight fit, no hollow bodies and horizontal surfaces, enclosed in concrete



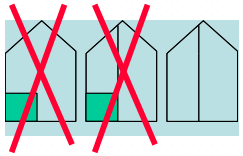
- **Platforms** and **walkways:** should be minimised, not above open processes





LAY-OUT RELATED ASPECTS

- avoid **false/dropped ceiling** constructions (control rooms)



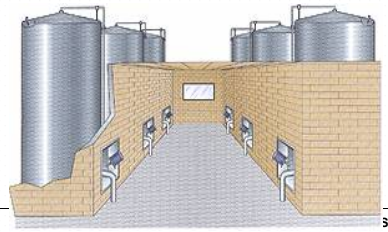
- **Windows**: not be able to open or insect screens (easily accessible, cleanable or replaceable),
- no or 45° sloped sills and ledges

LAY-OUT RELATED ASPECTS

- **Doors:** without any hollow body and seals (should be monitored regularly) ambient pressure difference should be preferred

- **Insulations** against noise or condensation: avoid as much as possible, no perforated or electrostatic materials, water tight and removable for inspection and cleaning

better: "**hot/cold room concept**"

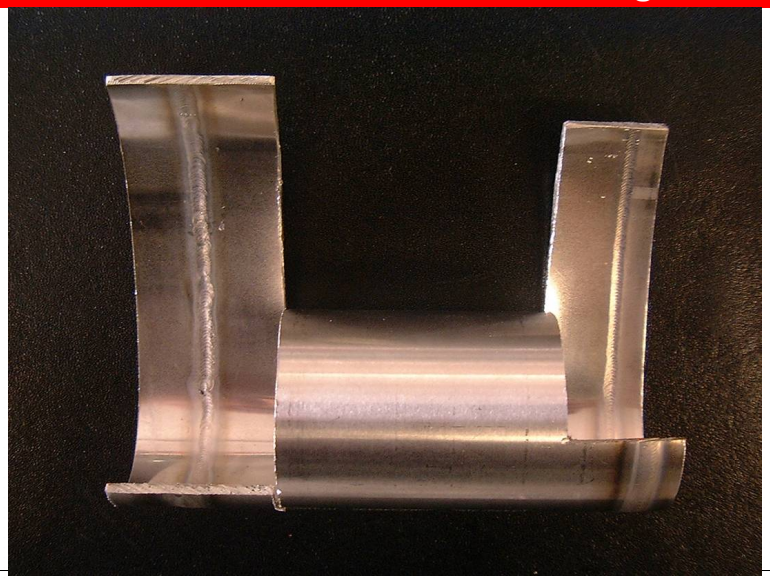


PIPING

PIPING

- in separate and accessible gangways and enter the process area through the ceiling
- open trays without horizontal ledges, crevices or gaps
- never be installed behind double ceilings and above open production lines
- as short as possible
- avoid "dead spaces": couplings, seals, valves, sensors !!!!!

RISK because of bad welding

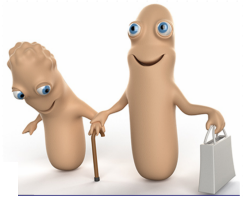


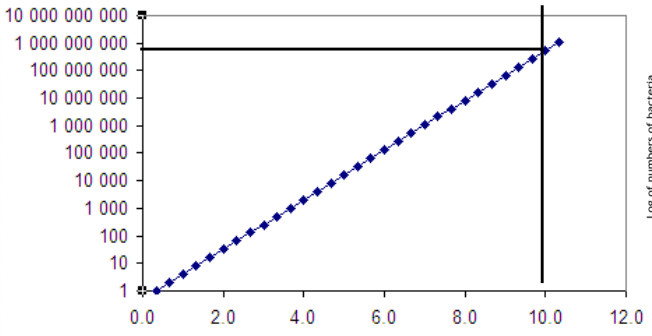
RISK because of bad welding

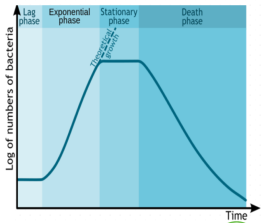
growths of microorganism

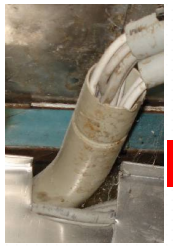
microorganism duplicate at optimum conditions every **20 min**

Listeria monocytogenes:
0.5 °C - 50 °C
pH 4.5 - 9.6
NaCl: up to 12 %
aw min 0.92



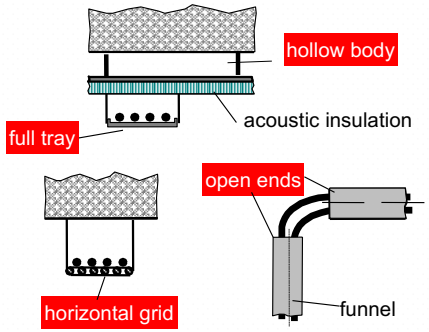






BUILDING DESIGN

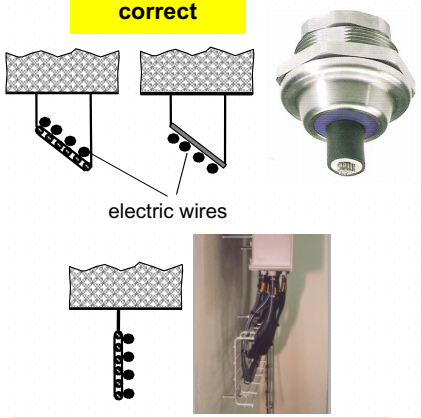
hygiene risk



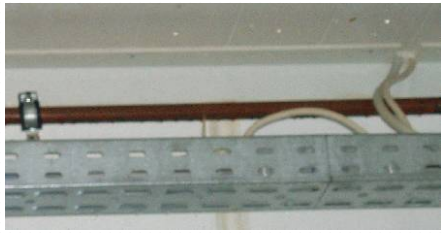
CABLE MOUNTING

avoid dust and condensations

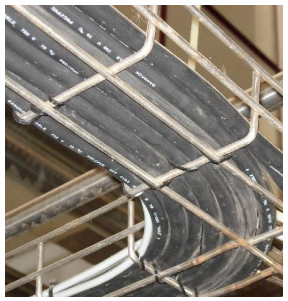
correct



CABLE MOUNTING





LIGHTING

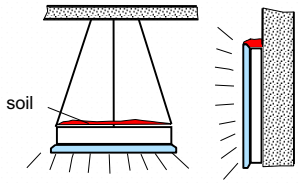
avoid contamination

- not close to doors (insects)
- not above open processes (foreign bodies)

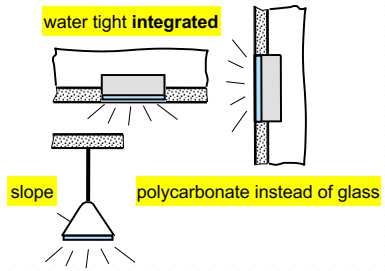
avoid dust and condensations

hygiene risk

horizontal surfaces



correct



AIR RELATED ASPECTS

avoid contamination with dust particles and micro-organisms

environmental air

- flow from higher care to low care hygiene areas
  from low to higher dust loaded areas
  USDA: minimum air change: 6/h,
  20-30/h when high load of dust or moisture
- light overpressure (~ >10%) with filterd air (~50 μ)
- dust extraction

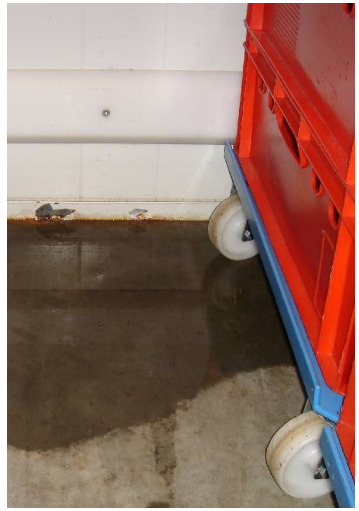
process and transport air

- inlet at a single location,
  > 3m above the ground level, >10m away from any exhaust discharge point

instrument air

- outlet away from open and dry products

WATER RELATED ASPECTS

WATER RELATED ASPECTS

WATER RELATED ASPECTS

specify, separate and monitor different water qualities

Water quality control

- process/product water
- utility water
- potable water
- specifications
- no connections

Legionella spp. (EHEDG Doc. 24 2004)

- right design and placing of equipment like cooling towers, evaporative condensers, domestic water systems, pressure jetting systems, can/bottle washing systems, emergency showers; fire sprinklers, fountains, garden hoses and sprinklers, spray humidifiers and air washers, machine tool cooling units, conveyor lubrication, …
- **avoid stagnant water (drainage), formation of aerosols**

ZONING

- means **keeping out** and keeping away of unwanted items
- specify areas and barriers
- requires knowledge about products and processes (what must be prevented)

glove box to **prevent emission** of unwanted contaminants (www.plas-labs.com)

ZONING

- must be logically and practically for all persons concerned
- must be economically
- rules must be followed by all -> **Training** is essential

Do not forget:

- cleaning utensils
- spare parts
- drainage
- fire protection
- waste collection
- air conditioning …..

ZONING CLASSIFICATION

- according **hygienic requirements**:

B (basic)	M (medium)	H (high)
no or closed production	temporary open production	open production

- and according **cleaning requirements**:

w (wet)	cw (controlled wet)	d (dry)

With different rules for installation, personnel behaviour, cleaning, etc.

example ZONING

cleaning requirements

hygienic requirements	wet	controlled wet	dry
	B_w courtyard, car park	B_{cw} office, store house	B_d dry store
	M_w bottle washing	M_{cw} closed filling	M_d milling
	H_w open filling	H_{cw} open filling	H_d powder filling

example ZONING

high care areas: barriers should be installed as close as possible to the product, e.g. integrated HEPA-Filter (pill press)

ZONING

BARRIERS

- Zones should be clear visible (by barriers for staff and products)
- walls, lines on the ground, drains (water lock!!), air filters, transfer windows
- access points for products, personnel, air, utilities
- traffic conditions
- drains, seals

are critical and must be systematically monitored !!!!!

- **Elevators can not be barriers** !!
  non-accessible spaces, air drafts
  If different hiegenic zones are accessable by stairs or elevators **air locks** must be installed

EQUIPMENT DESIGN

product contact surfaces
Surfaces which are exposed **intentionally** or **unintentionally** to the product and surfaces from which splashed product, condensate, liquids or material may drain, drop, diffuse or be drawn into the product or onto product contact surfaces or surfaces that come into contact with product contact surfaces of packaging materials.

***NOTE**: Product contact surfaces may contribute to cross-contamination, and must therefore be included in the hazard analysis.*

EQUIPMENT DESIGN

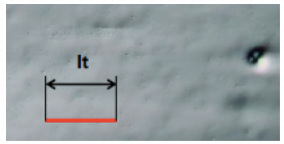
product contact surfaces must comply with the regulations set by the European Union and the United States (FDA). Food contact surfaces must be:

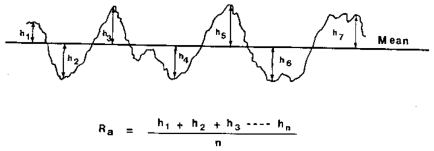
- non-reactive with the product, cleaning agents (migration, absorption)
- non-contaminating of the product
- noncorrosive
- non-toxic
- non-absorbent of any kind of liquid
- mechanically stable
- cleanable to ensure prevention of biofilm formation and harborage niches for microorganisms, allergen-containing residues or other chemical contaminants. Surfaces must be finished to a degree of surface roughness that is smooth enough to enable them to be easily cleaned and disinfected. The surface finish must be such that there are no cracks, pits or cavities where water or soil might remain which would give rise to potential contamination.

the **surface finish** (roughness Ra ≤ 0.8 µm) must not be affected under conditions of use (cold rolled steel has 0.2 ≤ Ra ≤ 0.5 µm and does not need to be polished)

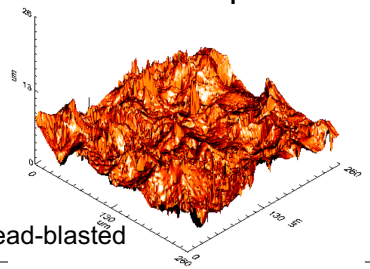
EQUIPMENT DESIGN

surface finish



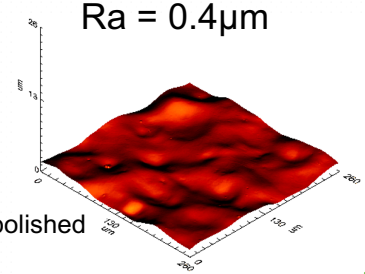


Ra = 0.9µm



bead-blasted

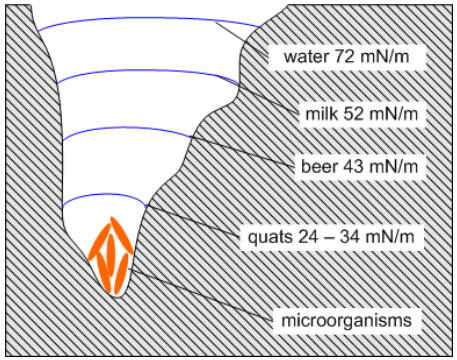
Ra = 0.4µm



electropolished

EQUIPMENT DESIGN

penetration depth in micro gaps

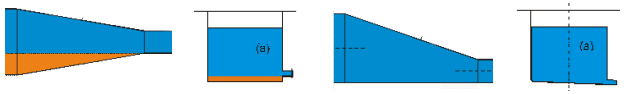


EQUIPMENT DESIGN

avoid accumulation of water / product

- **self draining**
  without dismantling

hygiene risk **correct**

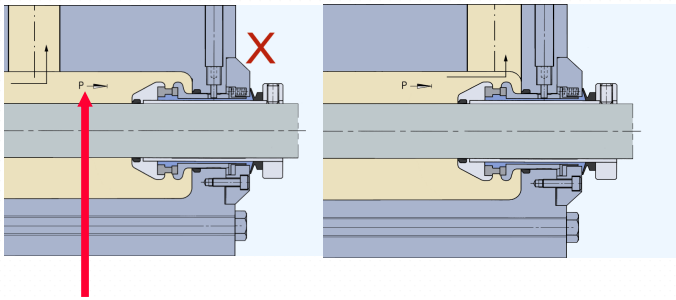


EQUIPMENT DESIGN

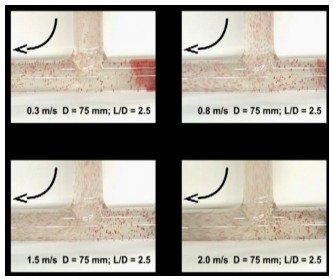
avoid accumulation of dust / water(condensate) / product

- no horizontal surfaces
- no ledges
- no hollow bodies
- no dead spaces ....

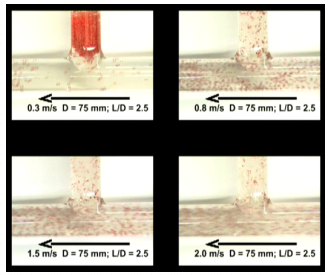
hygiene risk **correct**



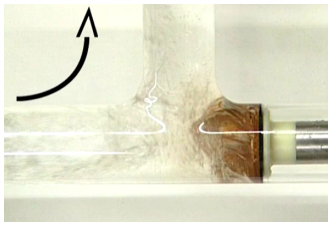
effect of flowrate on dead ends



VTS_25_1
VTS_06_1



VTS_01_1



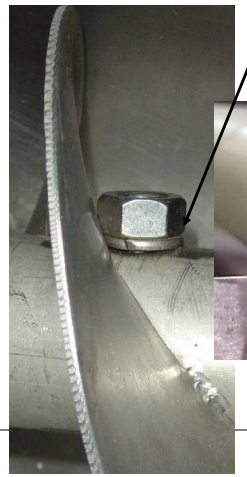
VTS_04_1

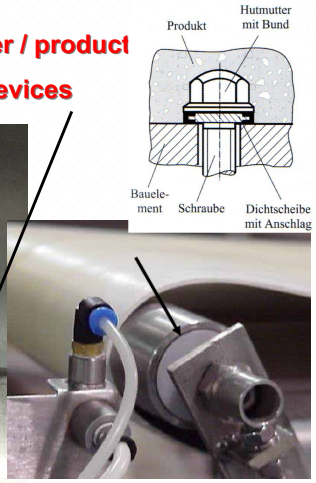
EQUIPMENT DESIGN

avoid accumulation of dust / water / product

- **avoid dead end**

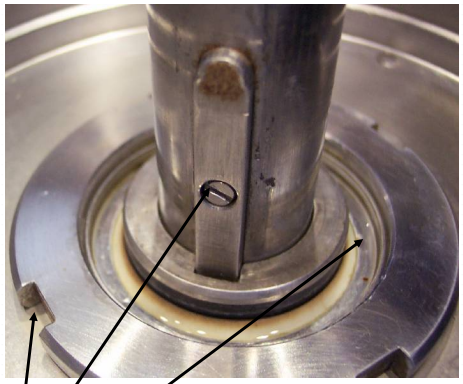
- **avoid crevices**





EQUIPMENT DESIGN

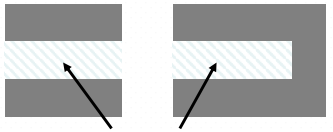
- **avoid crevices**



CONVEYOR BELTS

EHEDG Doc 13

- All surfaces should be accessable for cleaning
- Avoid cross contamination



- Covered edge

castors

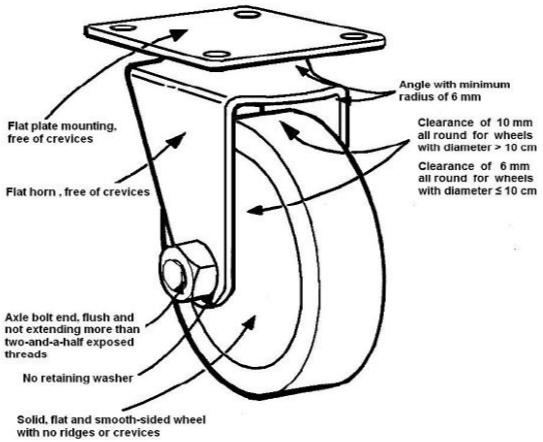
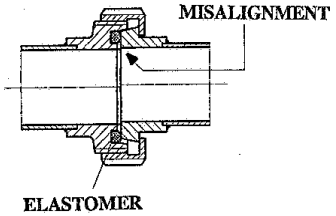


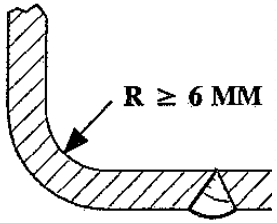
Figure 1: Hygiene design requirements that castors in the food industry must meet (APV Baker, 2001)

EQUIPMENT DESIGN, -INSTALLATION, -INTEGRATION

- **avoid misalignment**



- **no corners**

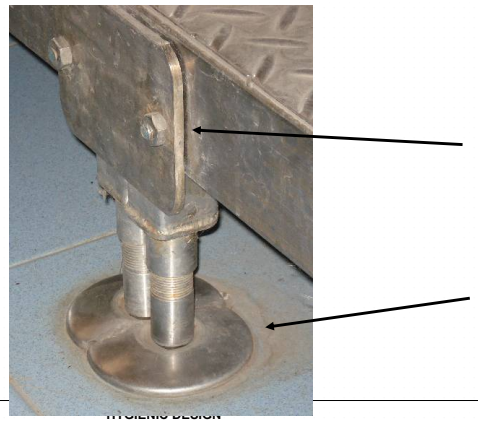


min ≥ 3mm

EQUIPMENT INSTALLATION/INTEGRATION

avoid accumulation of dust / water(condensate) / product

- **support structures** must be sealed to floor/wall/ceiling without any pockets or gaps



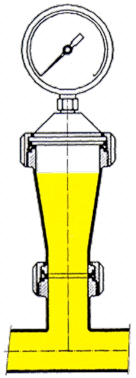
EQUIPMENT INSTALLATION/INTEGRATION

avoid accumulation of dust / water(condensate) / product

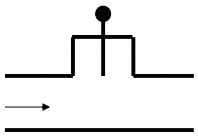
- **accessability**: > 0.3m above the floor and from walls, depending on size of cleaning tools

INSTALLATION OF SENSORS

- **avoid dead space**

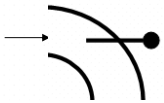


hygiene risk



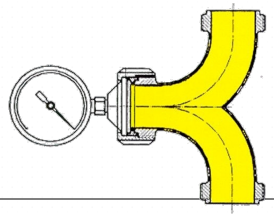
dead space

correct

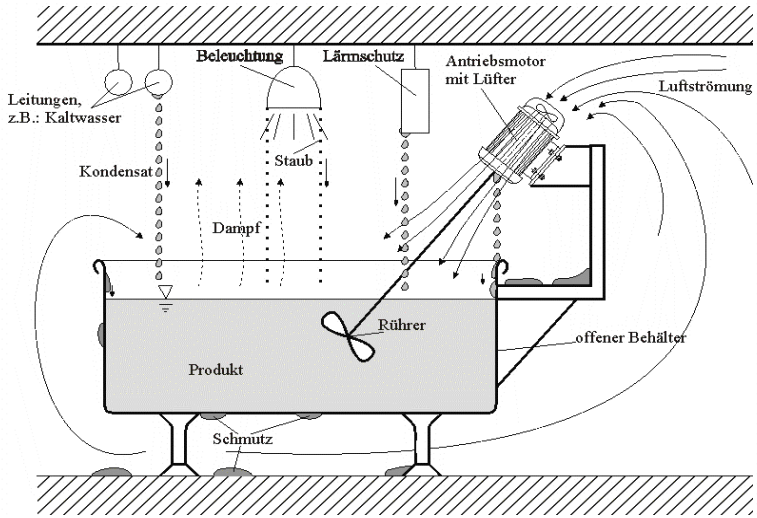


flow against sensor

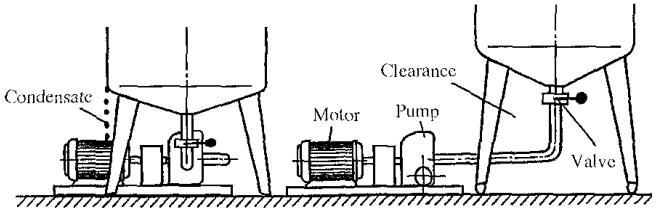
- sensor not cleanable
- measured value not relevant

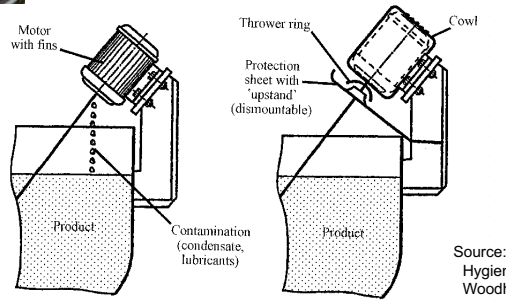


INSTALLATION, INTEGRATION



INSTALLATION, INTEGRATION



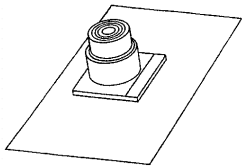


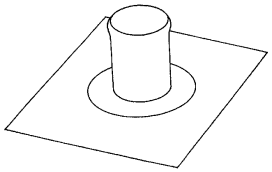
Source: Lelieveld H.L.M. et.al.: Hygiene in Food Processing Woodhead publishing Limited

INSTRUMENTATION

hygiene risk

correct

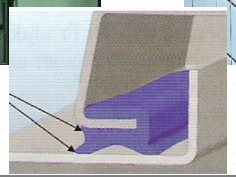




INSTRUMENTATION

hygiene risk

correct



SUMMARY

- if buildings and equipment is of poor design - **cleaning** will be difficult and **time** consumable
- **operational** requirements **conflict** with **hygienic** requirements in many cases
- knowledge, experiences and sometimes **simple solutions** are available, but need to be transferred to equipment manufacturers and to food producers
- **main issues** of hygienic design are to:
  - avoid contamination by foreign organisms and materials
  - avoid conditions which enhance the growth of micro-organism
  - improve cleanability
- **risks** by poor hygienic design are caused by :
  - wrong placement of equipment and utility installations
  - horizontal surfaces, hollow bodies
  - dead spaces, bad drainage
  - insufficient cleanability/accessability
  - use of non-resistant materials, etc.
- The **concept** of zoning is well known in the pharmaceutical industry and should be used more frequently in the food industry

SUMMARY

- **product contact surfaces** must be inert to product and cleaning agents, surface finish (roughness Ra ≤ 0.8 µm) must not be affected under conditions of use
- equipment should be **selfdraining**
- no **horizontal surfaces, hollow bodies, crevices, dead spaces** to avoid accumulation of **dust / water(condensate) / product**
- corners should have a **radius ≥ 6mm**
- **support structures** must be sealed
- **accessability** > 0.3m

special care must be taken to:

- **insulation**
- **installation of sensors** (dead space)
- **instrumentation**

Sanitation

- **definitions**
- **cleaning**
- **microbial destruction**
- **cleaning methods**
- **sampling**

Gerhard Schleining

SOME DEFINITIONS

"Cleaning": Removal of soil (food residues, dirt, grease or any other objectionable matter in an **incorrect location**)

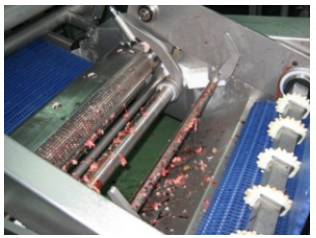
"clean": free of visible soil

"Disinfection": Reduction of the number of microorganisms to an acceptable level by chemical agents and/or physical methods

"Disinfectant": chemical agent that is used **after cleaning** for killing a certain proportion/type of micro-organisms **remaining on the surface**

WHAT IS SOIL?

- **Food** and **non-food** material (dirt, dust, organic material, allergens!) in an **incorrect location**, like fat deposit on a cutting board, lubricant on a conveyor belt, ….
- **water** soluble – no problem: inorganic salts, sugar (caramelised), starches, minerals, …
- soluble in **acidic** solutions (inorganic materials): calcium carbonate, metal (Fe, Zn) oxids, water- and milkstone (precipitated by heat)
- soluble in **alcaline** solutions (organic materials): fats (polymerised), proteins (polymerised, denatured)

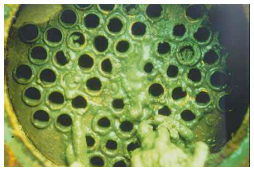


WHAT IS FOULING?

Fouling is the undesired deposition of material on surfaces

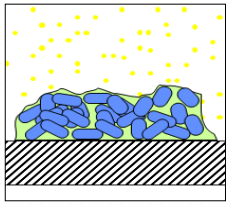
- Inorganic fouling („Scaling“: precipitation of inorganic crystals)

- Organic fouling (deposition of fat, oil, protein etc.)
- Biofouling (deposition and growth of microorganisms on surfaces) – particles which can multiply on the expense of nutrients



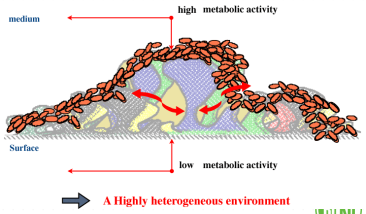
In non-sterile systems, biofilms cannot be avoided

BIOFILMS



- layer of microcolonies of bacteria associated with an inert surface attached by a matrix of **complex polysaccharid-like** material (glue) in which other debris including nutrients and other microorganisms (also viruses) may be trapped

- **first stage: electrostatic attraction (reversible)**
  second stage: exudation of extracellular polysaccharids
- unique environment established resistent to sanitizing agents (-1000x), heat more effective than chemical (watersoluble) sanitizers, teflon easier to clean than stainless steel

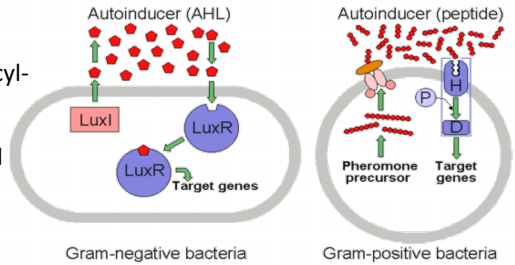


- new microorganisms attach themselfes with the aid of filaments and tendrils
- can behave like a tough plastic
- for cleaning the most important task is the detachment from the surface to be cleaned

Emergent properties in biofilms: Communication

Chemical signaling

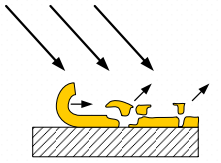
- In Gram-negative bacteria: Acyl-Homoserin-Lactone (AHL)
- In Gram-positive bacteria and fungi: small peptides



HanS-Curt Flemming, Univ. of Duisburg Essen, Biofilm Center

GENERAL PROCESS OF SOIL REMOVAL

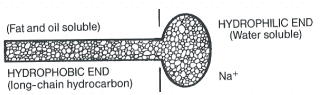
1. SEPARATION OF SOIL FROM SURFACE

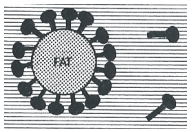


- **Mechanical**: **low** pressure water, steam, air, scrubbing
- **Thermal** energy: phase transition (melting)
- Change of **chemical nature**: reaction with alcali, acid

erosion -> detachment

- **Surfactants**: reduce surface tension, enhance wetting and emulsify fat



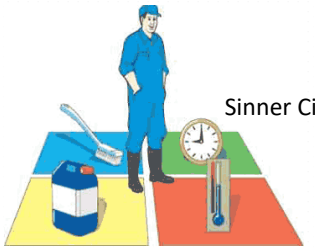


2. DISPERSION IN CLEANING SOLUTION

3. PREVENTION OF REDEPOSITION

MAIN INFLUENCES ON CLEANING

1. **contact time**
2. **mechanical energy**
3. **concentration of cleaning agent**
4. **temperature, pH**

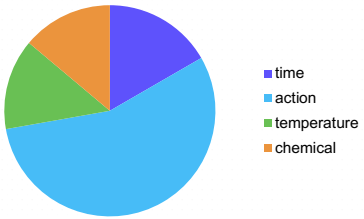


Sinner Circle

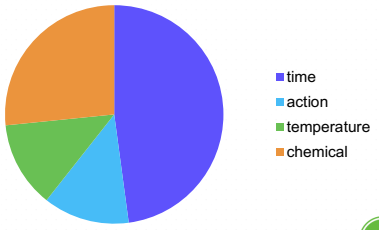
for each soil and surface, the best practice to clean has to be determined ⇒ right combination

⇒ right combination

mechanical cleaning



foam cleaning



MAIN INFLUENCES ON CLEANING

mechanical energy

Manual cleaning with brushes, scrapers, sponges:
abrasion, contamination!!

Floor scrub

Metal detectable plastic scraper

Low pressure, high temperature spray units

Hot water wash

High pressure hot water cleaning
High pressure water guns
Steam guns
High pressure steam
High pressure, low volume

fogging ⇒ mold, legionella, listeria

Foam or slurry (less air) cleaning: cleaning compound+water+air, visible

MAIN INFLUENCES ON CLEANING

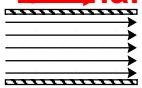
mechanical energy

Wall shear stress depends on velocity and viscosity

$$\tau = \eta \frac{du}{dy}$$

u … local flow velocity
η … dynamic viscosity
y … distance from the wall

laminar

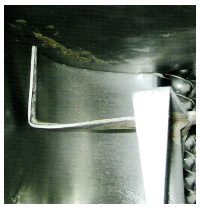


turbulent

MAIN INFLUENCES ON CLEANING

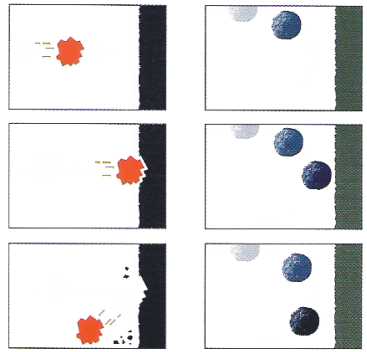
mechanical energy

before



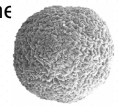
after

ECOLAB: micro-spheres are projected (0.5-5 bar) at an angle of 40 degrees, the particles have an erasing effect and safeguards the treated surfaces



conventional aggregate

ExaStrip principle



ExaHDO® micro-sphere
diameter 40 microns

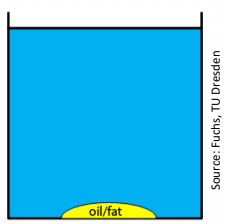
CLEANING SUBSTANCES

	alkaline	acidic	surfactants in aqueous or alcoholic solution	complex forming
properties	solvent and dispersive, e.g. **organic** soils like fat and protein, Ca!, Mg!, affect passive layer of stainless steel	dissolving of **inorganic** deposits	**emulsifying** fat, improves **wetting**	preventing of heat and alkali related precipitation in **hard water**, **emulsify** fat
example	caustic soda (NaOH)	nitric acid (HNO_3)	sodium lauryl sulfate (anionic surfactant)	sodium carbonate, phosphates

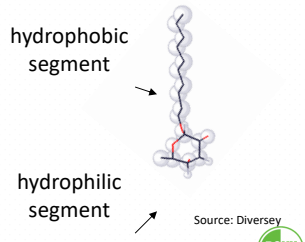
SOLVENTS: dissolving and diluting (water, alcohols, glycol ethers, …)

SURFACTANTS (SURFace ACTive AgeNTS)

- help in wetting the surface and the soils
- can be used in both, acidic or alkaline formulations
- consist of hydrophilic and hydrophobic section
- surfactants enclose the lipoid particle and form a micelle



Source: Fuchs, TU Dresden



Source: Diversey

ENZYMES

- break up organic soils into smaller, more soluble pieces
- most common types for detergents: proteases (for proteins), amylases (for starch), lipases (for fats)
- biodegradable
- e.g. cleaning of surfaces and pre cleaning of medical instruments
- Enzymes are **allergenic** (avoid aerosols, protect skin)

Be sure to use the right concentration: Use Test Strips

- weak: only bacteriostatically instead of bactericidally, resistant ones won't be killed
- strong: insolubility, high costs, damage equipment, residues in product (rubbery layer)

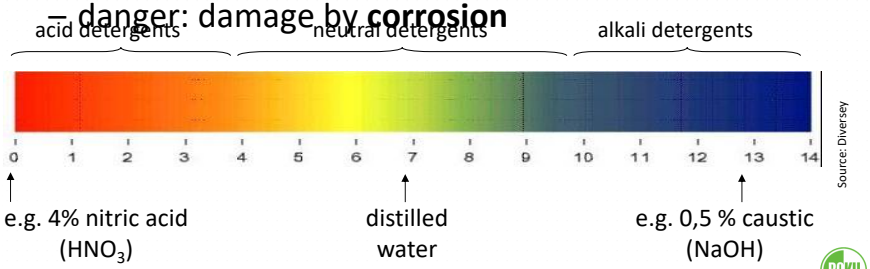
more must be better

temperature

normally the higher the more efficient

- but ⇒
  - in some processes (e.g. dairy products): > 80°C ⇒ **protein coagulation**
  - high **energy** without extra benefit
  - danger: damage by **corrosion**

pH



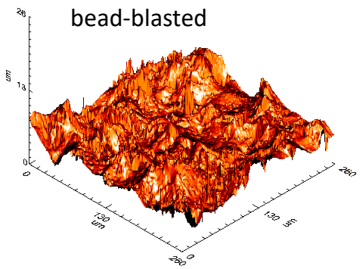
ADDITIONAL INFLUENCES ON CLEANING

cleaning object: design, kind of material, roughness

surface finish

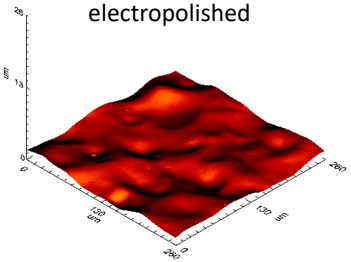
Ra = 0.9µm

bead-blasted



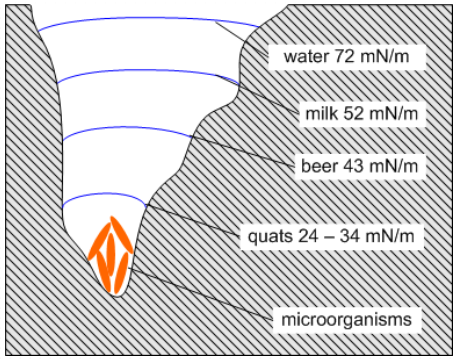
Ra = 0.4µm

electropolished

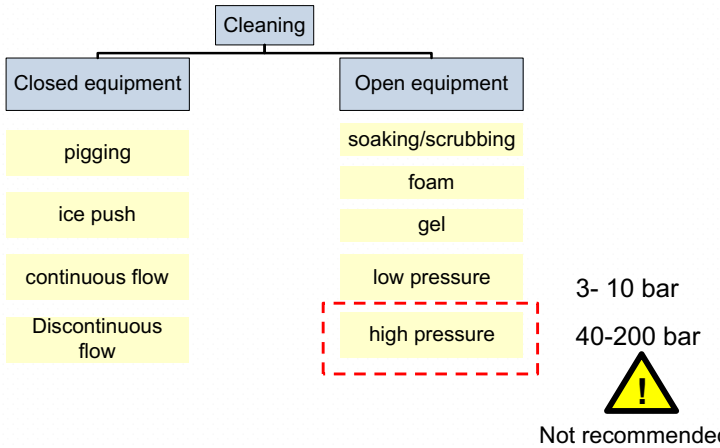


ADDITIONAL INFLUENCES ON CLEANING

Low surface tension increase penetration depth in micro gaps



CLEANING METHODS



CLOSED EQUIPMENT: CIP CLEANING

- Controlled flow rate
- Sequence of cleaning solutions and water

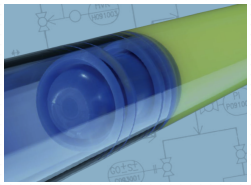
Example dairy

- **Pre rinsing** (°C should be optimized (above melting temperatures of fatty deposits, below denaturation temperature of proteins)
- **NaOH** with complexing, dispersant and anti-foam agent (0.5-2%, 70-85°C)
- Intermediate **rinsing**
- **nitric acid** (0.5-2 %, 40-60 °C)
- post **rinsing**

Source: Lorenzen, Tuchenhagen GmbH

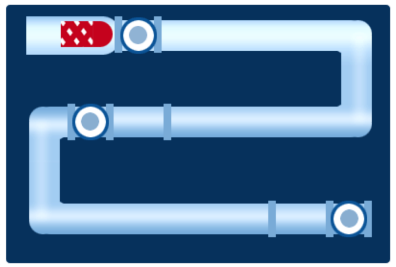
- exterior cleaning of the facility - foam cleaning

CLOSED EQUIPMENT: PIG CLEANING SYSTEM



cleaning and **product recovery**

http://www.wls.be/images/files/Chemical%20industry.pdf

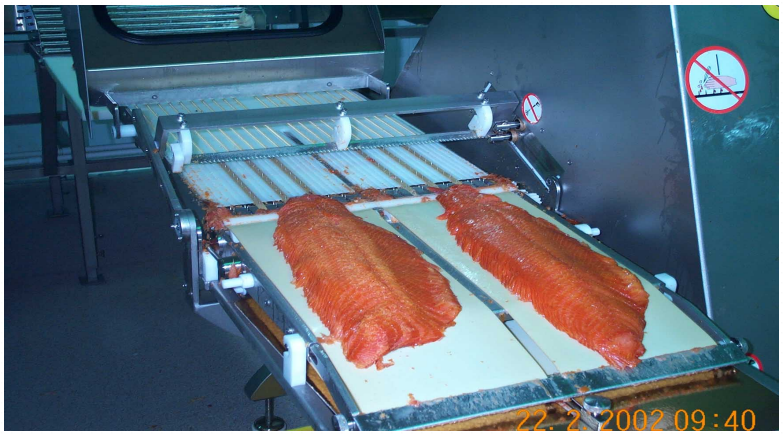


http://www.cleaningwork.co.kr/Eng/clean/pig.html

OPEN EQUIPMENT: SOAKING AND SCRUBBING

Step 1 – Remove all products
Step 2 – Dry clean area
Step 3 – Wet area
Step 4 – Clean and scrub area
Step 5 – Rinse
Step 6 – Disinfect

1 REMOVE FINISHED PRODUCTS



2 DRY CLEANING

Remove garbage, food debris & other waste

3 WET AREA

3 APPLY DETERGENT

4 SCRUBBING

- protein, oil etc. can be difficult to remove, especially if the surface has **dried out** or been exposed to **heat**
- all surfaces need to be scrubbed including corners, **underneath tables** etc.
- use **color coding system** for cleaning **brushes & pads**

5 RINSING

low pressure !!

PLANT CLEANING: Final rinse order

Avoid Cross contamination

6 DISINFECTION

If cleaning was incomplete, disinfectant will not be able to reach bacteria

FOAM CLEANING

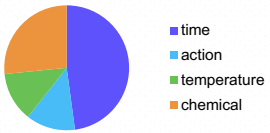
advantages

- can reach even places difficult to clean
- low chemical consumption (90-95% air),
- fewer aerosols, lower impact compared to high pressure cleaning

disadvantages

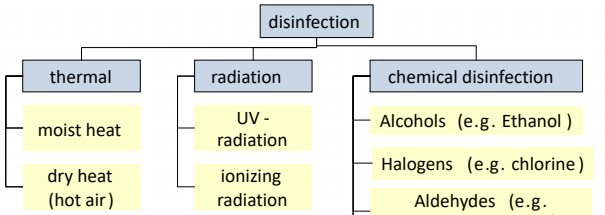
- contact time (10-20 min) of foam is much longer than of liquid cleaner
- not able to solve very hard deposits without mechanical energy
- costs of equipment
- there might be problems if the systems are not maintained and operated properly (especially for chlorine-containing foam)

foam cleaning



CONVENTIONAL DISINFECTION METHODS

MICROBIAL DESTRUCTION



- **TDT** (thermal death time): time required to sterilize **completely** a suspension of bacterial cells or spores at a given temperature,
- **D value**: minutes required to destroy **90%** of the cells at a given temperature

Both depend on **kind** (spores survive >1h at 100ºC) and **number of cells,** nature and flow rate of **medium**

RADIATION

- Damage DNA -> cannot devide
- **UV-C** (250-260 nm): no/few undesirable by-products, distance/shadow/dust !!, **no resistances possible**, mold spores and viruses need higher radiation, damage to plastics, operator protection necessary, used for conveyor belts
- **electron beam**: shortest penetration (7.5 cm)
- **gamma rays**: penetration >1m
- **x-rays**: penetration < 10cm

CHEMICAL DISINFECTION 21-38ºC

- **Sterilants**: destroy all forms of microorganisms: ethylene oxid, glutaraldehyd, peroxyacetic acid
- **Disinfectants**: reduce microorganisms but not necessarely spores to levels considered as safe

  oxidative **biocides**: peracetic acid, chlorine dioxide, ozone, anionic sulfonic acid, quaternary ammonium compounds, phenolics, formaldehyde, ….

Lack **penetration ability** (cracks, crevices,…)

Biocide	Mode of action	Target
HRAs (Halogen-releasing agents)	Halogenation/oxidation	Nucleic acid, proteins
QACs (Quaternary ammonium compounds)	Electrostatic interaction	Cell surface, enzymes, proteins
Peroxygens	Oxidation	Lipids, proteins, DNA
Alcohols	Protein denaturation	Plasma membrane
Aldehydes	Alkylation reaction	Cell wall
(bis)Phenols	Penetration/Partition phospholipids bilayer	Phospholipid bilayer
Biguanides	Electrostatic interaction	cytoplasmic membrane of bacteria, plasma membrane of yeasts

target areas

- **cell membrane** & its outer layers
- damage to **enzymes** and important metabolic processes
- affects **synthesis of proteins**
- inhibition of **DNA** synthesis & breakage of DNA strands

"EMERGING" DISINFECTION METHODS

MICROBIAL DESTRUCTION

PULSED LIGHT

- >8 power to ten of vegetative cells, 10^6 of spores on **packaging materials** or in beverages
- 10-1000 on rough **surfaces** like meat

HIGH HYDROSTATIC PRESSURE

- effects molecular structure of chemical compounds necessary for metabolism
- does not destroy structure (applied from all sides)

Tools

- never use **floor** brooms, brushes, pads also on **tables**
- never use tools used for cleaning garbage barrels on packing tables
- never use the same tools to clean floor drains on any **food contact surface**
- never use tools in raw product areas and afterwards in finished product areas
- **clean & sanitize** all tools every day, after plant is cleaned
- **store** tools properly

CLEANING VALIDATION

validation of cleaning procedures is a very efficient strategy (FDA)

- to remove sufficiently residues of **products** and **cleaning agents**
- and to **control potential contaminants**

cleaning procedures must always be developed under consideration of the **product requirements**

important issues are:

- validation procedure
- acceptance criteria, acceptance limits
- sampling

Acceptance criteria – Acceptance limits

Residual Products

- (UV) visual cleanliness of all equipment parts
- TOC (Total Organic Carbon) for organic residues
- Protein: ELISA or BCA (Bicin Choninic Acid) Cu^{++} -> Cu^{+} by peptid bounds

Residual Cleaning Agents

- pH and conductivity for residual NaOH
- TOC for organic residues
- Surface tension or main components of detergents

Process Hygiene

- CFU of surface sampling agar plates
- residual Endotoxin (LAL - Limulus Amebocyte Lysate)
- Differentiation of micro-organisms may be required

limits can be based on historical data and on process evaluations.

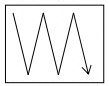
acceptance limits for micro-organisms on product contact surfaces depend on the surroundings, and may not be higher than the acceptance limits of the respective room class. Limits can be based on historical data and on process evaluations.

Sampling

- sampling is most important for the representative validity of the results
- contaminate will not be **uniformly distributed** and will not be **worn off** the surface uniformly

DIRECT SURFACE SAMPLING (swabs, contact plates)

- for flat surface areas and cracks, crevices, gaskets, seals
- recovery effectiveness and reproducibility depend on: swabbed material, sampling solvent, concentration range of residues, the swab pattern and sequence



INDIRECT RINSE SAMPLES

- for large surface areas, especially inaccessible areas of equipment that cannot be routinely disassembled
- do not necessarily correlate with residues on the equipment surface

SUMMARY on CLEANING

- Cleaning performance depends on many factors (kind of soil, material, time, temperature, pH, concentration, **physical force**)
- **Biofilms** are difficult to remove and are a permanent source of recontamination

CLEANING:

1. Separation of soil from surface (mechanical, chemical, surfactants)
2. Dispersion in cleaning solution
3. Removal of dispersed solution

DISINFECTION:

- Microbes can be destroyed by: heat, chemicals, radiation, pulsed light, high pressure
- **require a clean surface to be effective**

SUMMARY on CLEANING

CLEANING METHODS

- fogging supports growths of mold, legionella, listeria, ……

VALIDATION:

- to be sure to clean and sanitize **sufficiently** (according to acceptable limits for your product) and not too excessively (environmental pollution, time, costs) a **validation of cleaning procedures** should be carried out
- place and method of **sampling** is crucial for the validity of the results