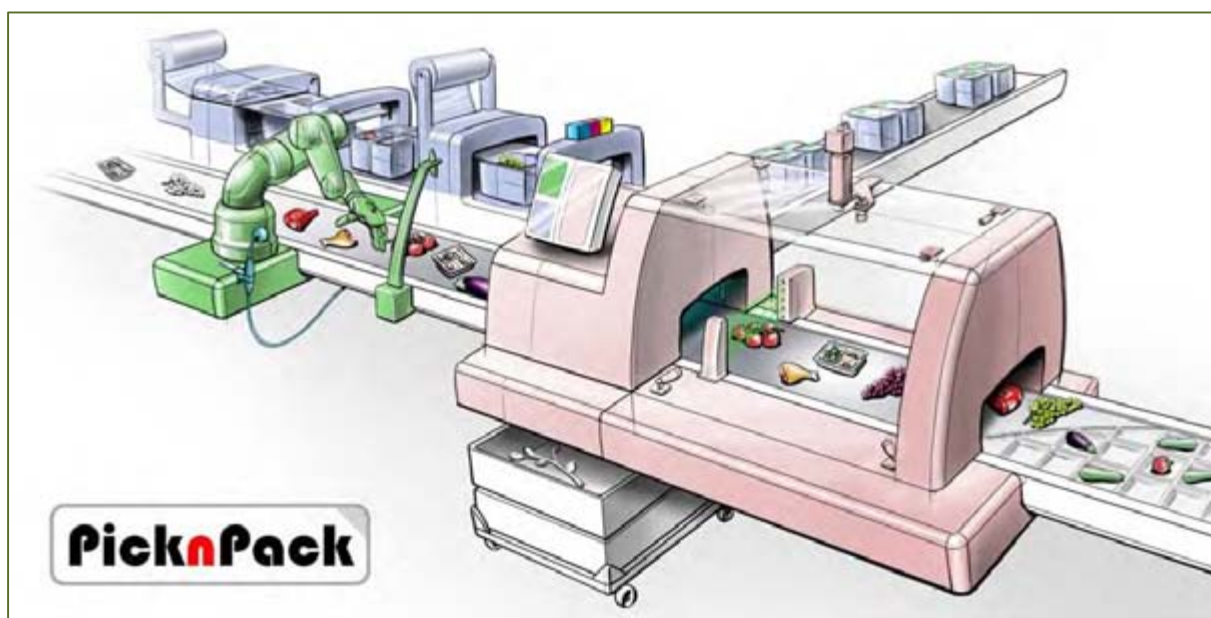


# D8.1 – Hygienic Design workshop and hygienic system requirements

Fraunhofer

3/26/2012



Flexible robotic systems for automated adaptive packaging of fresh and processed food products



The research leading to these results has received funding from the European Union Seventh Framework Programme under grant agreement n° 311987.

| Dissemination level |   |   |
|---------------------|---|---|
| <b>PU</b>           | Public  | X |
| <b>PR</b>           | Restricted to other programme participants (including the EC Services)        |   |
| <b>RE</b>           | Restricted to a group specified by the consortium (including the EC Services) |   |
| <b>CO</b>           | Confidential, only for members of the consortium (including the EC Services)  |   |

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## 1 Introduction

Hygienic design of equipment and facilities is one of the main tools that have food manufacturers to achieve their legal responsibility for ensuring product safety. Unsafe foodstuffs may not be placed on the market. Both food manufacturers and food equipment manufacturers should be aware of the importance of considering hygienic aspects in their operations.

## 2 Aim

The course gives knowledge and insight into the hygienic design of machinery, equipment and processes for the food industry in order to fulfill present legislation and standards with respect to hygienic food production and to satisfy the needs of purchaser and retailers. These includes minimal down time, cleaning costs, environmental impact and efficient cleaning, optimal product safety and constant product quality.

## 3 Methodology

The course is given from a practical point of view by different trainers. The fundamentals of the different subjects are given in a short and concise manner, continuously relating to practice by means of good/bad examples. The course gives tools to design equipment and machinery for the PicknPack-production line in a hygienic way. The participants will get handouts of the presentations.

The content of the course is based on EHEDG (European Hygienic Engineering and Design Group) guidelines and their training and education material.

## 4 Program

The workshop will be held on 26<sup>th</sup> April 2013 during the 2<sup>nd</sup> PicknPack Project meeting at AZTI-Tecnalia, Astondo bidea, 609 eraikina - 48160 Derio, Spain.

| Start |   | End   | Topic                          |
|-------|---|-------|--------------------------------|
| 9:00  | - | 9:15  | Welcome, introduction, program |
| 9:15  | - | 9:45  | Legal requirements             |
| 9:45  | - | 10:45 | Hazards in hygienic production |
| 10:45 | - | 11:00 | Coffee Break                   |
| 11:00 | - | 12:30 | Hygienic design criteria       |
| 12:30 | - | 13:30 | Lunch                          |
| 13:30 | - | 15:00 | Materials of construction      |
| 15:00 | - | 15:45 | Welding                        |
| 15:45 | - | 16:00 | Coffee break                   |
| 16:00 | - | 16:45 | Building / process layout      |
| 16:45 | - | 17:00 | Lubricants                     |
| 17:00 | - | 17:15 | Summary                        |

## 5 System Requirements

The hygienic system requirements have also been reported to the Deliverables D 5.1.

### 5.1 Hygienic Requirements from present Legislation and Standards

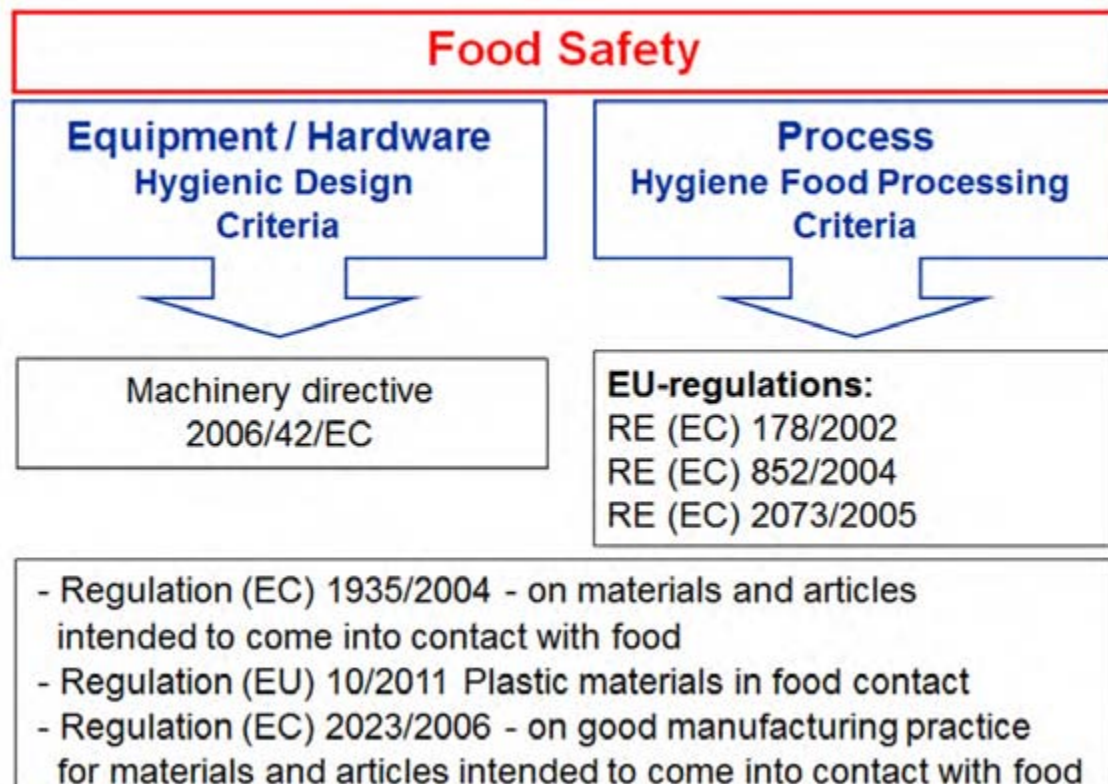


Figure 1: European food safety regulations

### 5.2 Hygienic Requirements – general

Definition: product contact surface

- Surfaces that intentionally or unintentionally come in contact with the product
- Surfaces from which product or condensate may drain, drop or be drawn back into the main product or product container

All articles, fittings and equipment with which food comes into contact are to:

- be effectively cleaned and, where necessary disinfected,
- be so constructed, of such materials, in good order, repair and condition, as to minimize any risk of food contamination.

Materials and equipment shall be selected so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- endanger human health,
- bring about an unacceptable change in the composition of the food,
- bring about a deterioration in the organoleptic characteristics thereof.

### 5.3 Hygienic Design Criteria - 8 Keys to hygienic Design

To fulfill the general hygienic requirements and to reduce / avoid product contaminations from

- Foreign bodies (stones, leaves, equipment & replacement parts, packaging, personnel)
- Chemical substances (lubricants, additives, cleaning & disinfection residues, incorrect process management),
- Microorganisms, pests (birds, insects, rodents),
- Allergens (yeasts and moulds, algae; bacteria; viruses)

the following equipment design criteria have to be followed:

- Smooth surfaces –hygienic welding
- No crevices (metal to metal contact)
- No protrusions
- No sharp corners
- No dead areas
- Accessible for cleaning and inspection
- Drainability
- Food grade of ancillary liquids

### 5.4 Packaging technology

Based on the product properties, the distribution and storage conditions and the shelf life of the product a hygienic or aseptic packaging process has to be developed.

Hygienic equipment

- Equipment that is easily cleanable

Aseptic equipment

- Hygienically designed equipment that is sterilizable and is impermeable to microorganisms to maintain its aseptic status.

Aseptic process

- A process using equipment and packaging material sterilized before use, and which, in running conditions, is protected against recontamination by microorganisms.
- Adequate decontamination of internal environment and/or packaging material has to be provided

Depending on the food product to be processed and the selected packaging technology the need of a hygienic zoning concept for the packaging line has to be discussed (Fig. 2).



| Zone | Hygienic requirements | Purpose of the area                       |
|------|-----------------------|---|
| B    | Basic                 | No handling of open and processed product |
| M    | Medium                | e.g. closed processing, protects zone H   |
| H    | High                  | e.g. open processing, clean room          |

Figure 2: Generic layout of hygiene zones in food factories and food processing machines



# Legal Requirements

# Content

- Codex Alimentarius
- Legal Requirements
  - European Legislation
    - EU Hygienic-Regulation
    - Directive 2006/42/EC on machinery
  - US-Legislation

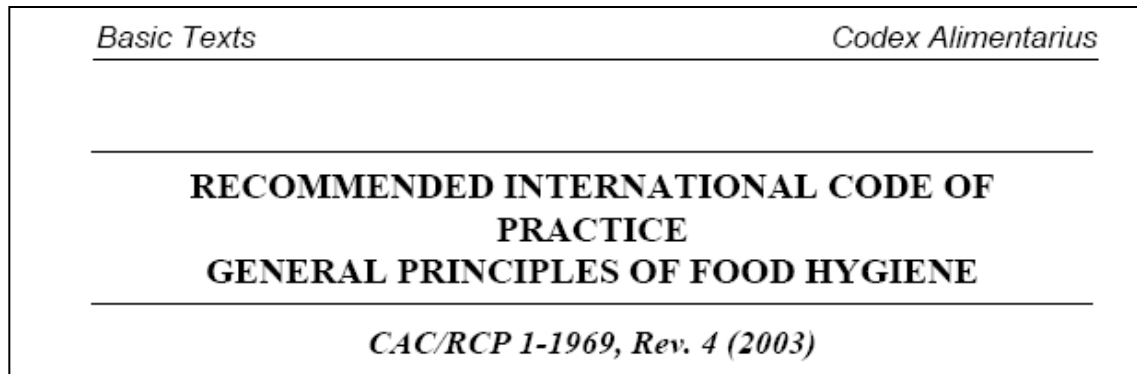


# Codex Alimentarius - Food Hygiene

## „Food safety”

*Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.*

Created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the joint FAO/WHO Food Standards Programme.



## Food Safety

### Equipment / Hardware Hygienic Design Criteria

### Process Hygiene Food Processing Criteria

Machinery directive  
2006/42/EC

#### **EU-regulations:**

RE (EC) 178/2002  
RE (EC) 852/2004  
RE (EC) 2073/2005

- Regulation (EC) 1935/2004 - on materials and articles intended to come into contact with food
- Regulation (EU) 10/2011 - on plastic materials in food contact
- Regulation (EC) 2023/2006 - on good manufacturing practice for materials and articles intended to come into contact with food

# Regulation (EC) 178/2002 laying down the general Principles and Requirements of Food Law

- Basic hygiene principles
- Food & feed business operator: legal responsibility for ensuring product safety
- Unsafe foodstuffs may not be placed on the market
- Traceability
- Consideration of long-term, cumulative effects

# Regulation (EC) 852/2004 on the Hygiene of Foodstuffs

- Primary production (Farm Level, Annex I) and further steps (Annex II)
- Analysis of potential food safety risks and determination of Critical Control Points (Hazard Analysis and Critical Control Points - HACCP)
- HACCP based on principles of Codex Alimentarius
- Control and documentation requirement during the whole production process
- Registration is mandatory for all food manufacturing establishments

# Regulation (EC) 852/2004 on the Hygiene of Foodstuffs

## Risk assessment - HACCP

- Conduct hazard analysis
- Determine critical control points (CCP's)
- Establish critical limit(s)
- Establish system to monitor CCP's
- Establish corrective action
- Establish verification procedure
- Establish documentation

# Regulation (EC) 852/2004 on the Hygiene of Foodstuffs

## Annex II (food business operators)

Surfaces (including surfaces of equipment) ... will require the use of smooth, washable, corrosion resistant and non-toxic materials, ...(Chapter II)

Articles, fitting and equipment must ....(Chapter V)

- Be effectively cleaned and, where necessary, disinfected
- Be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination
- Be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area

# Regulation (EC) 2073/2005 on microbiological Criteria for Foodstuffs

- Determining limits for safe food
- Process hygiene criteria during manufacturing
- Annex I: Food safety criteria for best before date for different food categories

# Directive (EC) 2006/42 Annex I 2.1. Food processing Machinery and Machinery for pharmaceutical and cosmetic Products

## Principles

Machinery intended to come into contact with

- Food, Cosmetics, Pharmaceuticals

must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

Machine parts / materials in contact with food can be cleaned before each use.

**Where this is not possible disposable parts must be used!**



# Requirements on Machine Conditions

All surfaces including their joining with product contact (exception: disposable parts) must

- Be smooth, without ridges or crevices
- Reduce projections, edges and recesses to a minimum
- Be easily cleaned and disinfected
- Inside surfaces must have curves of a radius sufficient to allow sufficient cleaning

## Design Requirements

It must be possible for liquids, gases and aerosols deriving from products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery.

Machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating.

Machinery must be designed and constructed in such a way that no ancillary substances, including the lubricants used, that are hazardous to health can come into contact with products.

# EU-Legislation

## Summary

All regulations and directives, except the machinery directive, arise from consumer protection and therefore from food law.

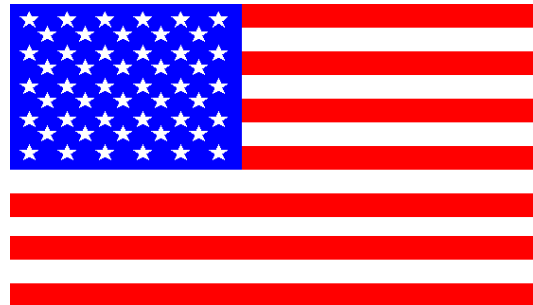
The basic principle is that everyone is self-responsible and has to perform risk assessment to assure food safety.

The framework of the legislation does not provide design details, but is supported and expanded by non-normative standards and EHEDG-guidelines.

Consider allergens

# Legal Requirements

## USA



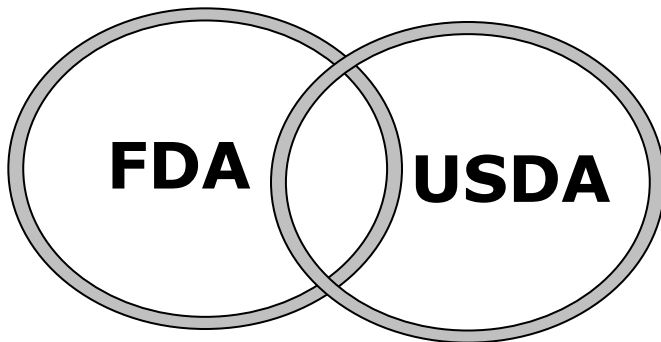
## Legal texts USA

### Food and Drug Administration (FDA):

Food code

### United States Department of Agriculture (USDA):

Legislation on machines processing agricultural products



Work jointly together with other local, federal and national organizations

# Food and Drug Administration (FDA)



- Monitors and regulates manufacturing and trading of pharmaceuticals, cosmetics and food
- Monitors by regular inspection (incl. NON-USA)
- No accreditation of machine components and equipment
- Demand for FDA-compliant materials according to 21CFR 174-178

# code of federal regulations

























National Archives and Records Administration

[http://www.access.gpo.gov/nara/cfr/waisidx\\_04/21cfr110\\_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr110_04.html)

## Title 21--Food and Drugs

### CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

#### PART 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

|   |   |         |   |
|---|---|---------|---|
|    |    | 110.3   | Definitions.  |
|    |    | 110.5   | Current good manufacturing practice.  |
|    |    | 110.10  | Personnel.  |
|    |    | 110.19  | Exclusions.   |
|    |    | 110.20  | Plant and grounds.  |
|   |   | 110.35  | Sanitary operations.  |
|  |  | 110.37  | Sanitary facilities and controls.   |
|  |  | 110.40  | Equipment and utensils.   |
|  |  | 110.80  | Processes and controls.   |
|  |  | 110.93  | Warehousing and distribution.   |
|  |  | 110.110 | Natural or unavoidable defects in food for human use that present no health hazard. |



# Hazards in Hygienic Processing



# Content

- Introduction
- Foreign bodies - Potential sources of contaminations
- Chemical contamination
- (Micro)biological contamination
  - Potentially pathogenic microorganisms (MO)
- Size of MO
- Growth of MO
- What MO need in order to multiply?
- What you should know about MO?
- Contamination routes

# Introduction

## What could happen to your business?

### **2008 Canadian listeriosis outbreak linked to a Maple Leaf Foods plant in Toronto (August 2008 to December 2008)**

- 22 people died and 57 injured
- recall cost \$20 million
- 4 separate class-action lawsuits in Ontario, Quebec, Saskatchewan and British Columbia (one claiming damages of \$350 million)
- Loss of image „Tragically, our products have been linked to illness and loss of life“ - Maple Leaf Foods CEO M. McCain

(Sources: <http://www.cnn.com/2008/HEALTH/08/24/listeria.outbreak/index.html> & [http://en.wikipedia.org/wiki/2008\\_Canadian\\_listeriosis\\_outbreak](http://en.wikipedia.org/wiki/2008_Canadian_listeriosis_outbreak))

# Introduction

## Contamination

- Introduction or occurrence of any biological or chemical agent foreign matter or other substance not intentionally added to product which may compromise product safety or suitability

## Types of contamination

- Foreign bodies
- Chemical
- (Micro)biological
- Allergenic

# Foreign Bodies - Potential Sources of Contamination

## Raw Materials / Contaminated goods

- stones, sand, leaves...
- equipment & replacement parts (washers, seals, screws...)
- packaging (film, containers, board, trimmings from packaging film)



Source: Soro, Almia

# Foreign Bodies - Potential Sources of Contamination

## Processing machines

- e.g. screws, gaskets, metals, plastics, glass

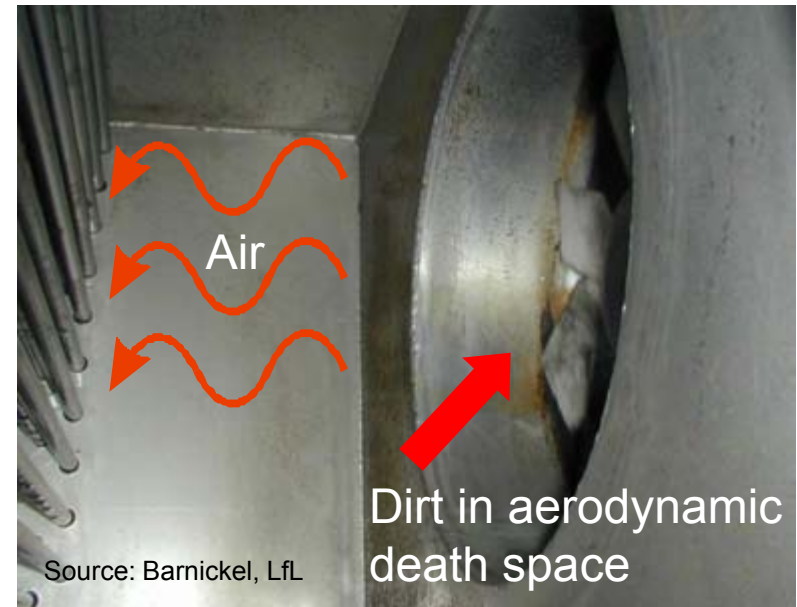


Source: Soro, Ainia

# Foreign Bodies - Potential Sources of Contamination

## Environment

- e.g. ceiling plaster, dust, fibres, broken glass...



# Foreign Bodies - Potential Sources of Contamination

## Personnel

- e.g. ties, rings, gloves, tools and mobile phones...



Mobile Phone

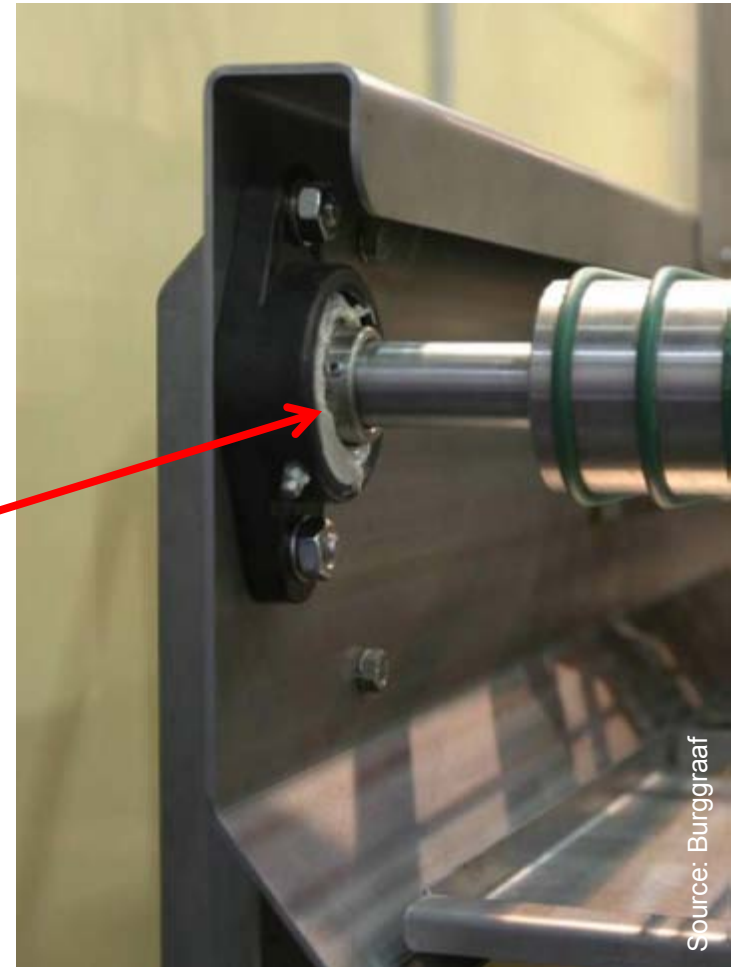
Source: Fraunhofer AVV



Source: Barnickel, LfL

# Chemical Contamination

- additives and lubricants
- cleaning and disinfection residues
- due to incorrect process management





# (Micro)biological Contamination

## Pests

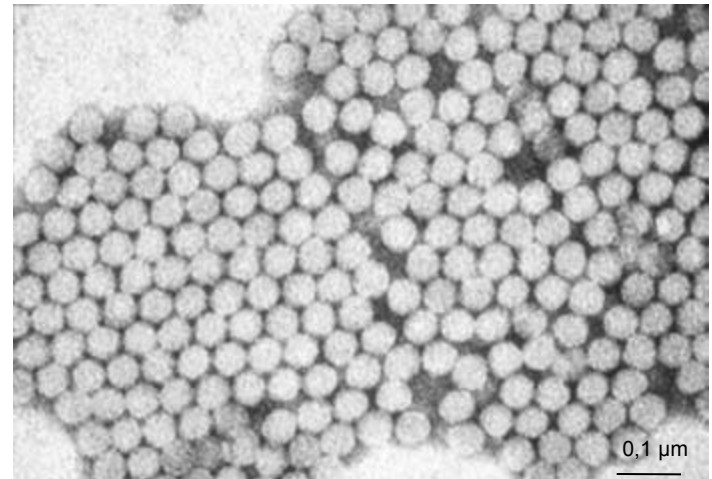
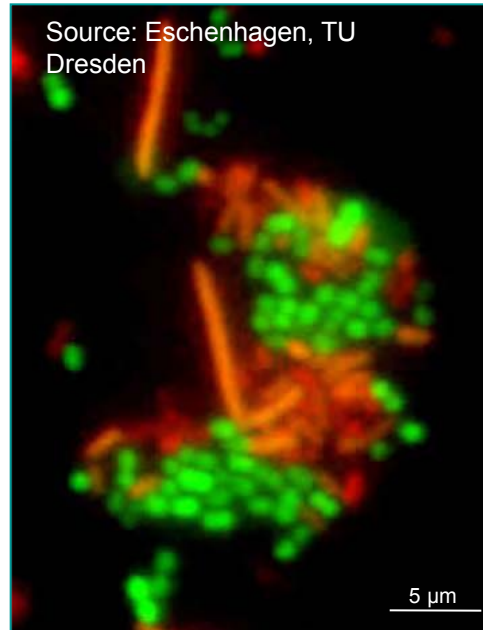
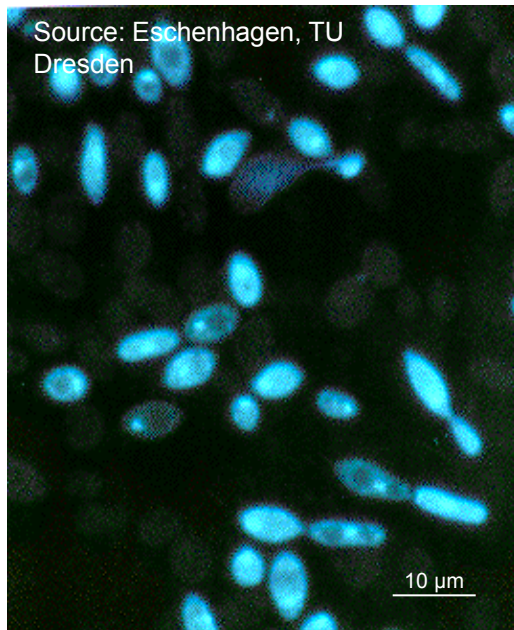
- bug tightness: max. tolerable pin hole size of 100  $\mu\text{m}$
- birds, insect, rodents, etc.



# (Micro)biological Contamination

## Microorganisms

- yeasts and moulds, algae; bacteria; viruses



<http://pathmicro.med.sc.edu/virol/hep-a5.jpg>

*Hepatitis A Virus*

*Saccharomyces cerevisiae*

red: *E. coli*, green: *Ent. faecalis*  
orange: *Salmonella typhimurium*

## Useful Microorganisms

- act on foods to produce desirable characteristics (odours, flavours, textures, microbiological stability...)



## Spoilage Microorganisms

- alter food
- produce undesirable characteristics



## Pathogenic Microorganisms

- affect individuals that have taken them causing food borne illness.
- They do not necessarily change the organoleptic characteristics of the food.



# Pathogenic Microorganisms

**Microorganisms** are one of the most important biological foodborne hazards, and are reported in more cases of foodborne illness than any other hazard

Examples:

*Listeria monocytogenes*

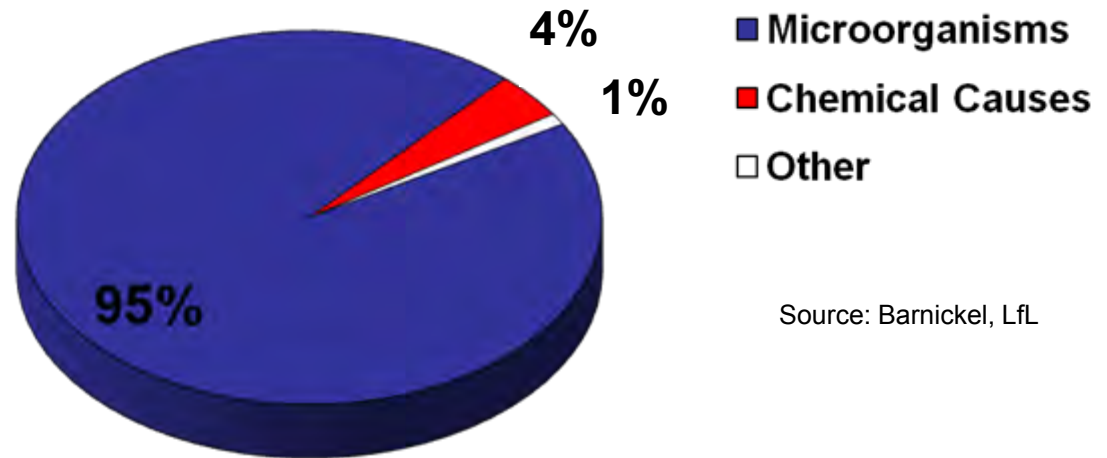
*Campylobacter*

*Salmonella*

*Clostridium botulinum*

*Escherichia coli*

*Vibrio cholerae*



Source: Barnickel, LfL

# Pathogenic Microorganisms (MO)

## Microbial toxins

- even when you kill them, some leave behind toxins (Endotoxins)
- heat-stable toxins (*Staphylococcus aureus*)
- other toxins, esp. moulds

# Size of MO

## Bacteria

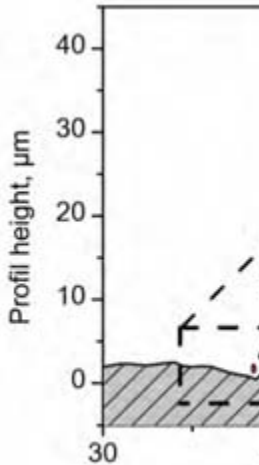
*Clostridium*

*Clostridium*

## Mould

*Aspergillus*

If you can't see and reach it, you can remove or sample it!

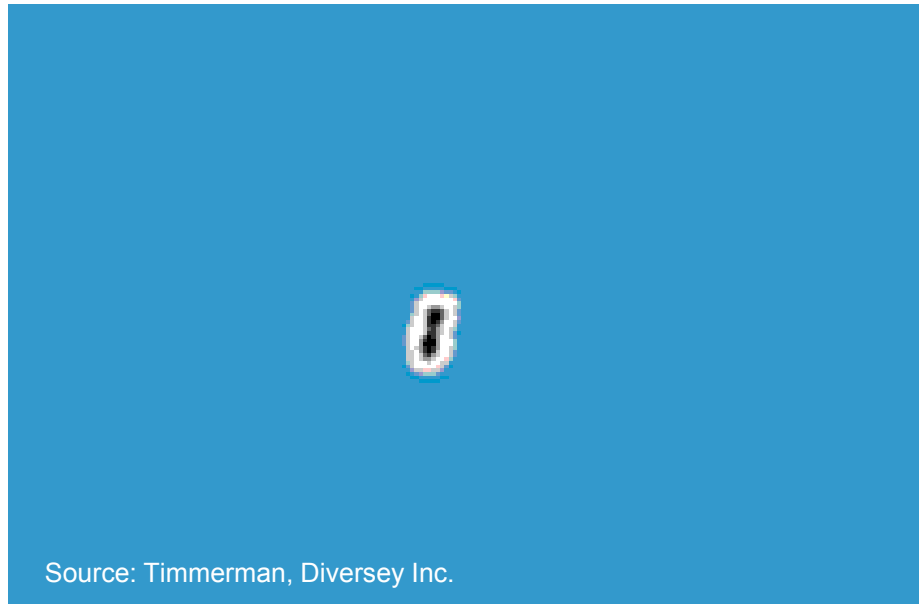


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anical polish.  
ts or damage.

Polymerforschung Dresden

## Growth of MO

- bacteria multiply by dividing and producing two identical new cells
- when conditions are just right, they can multiply very rapidly
- growth at: pH 0 to 13, most bacteria prefer a neutral environment (pH = 5-7)
- growth at salinity: 0 to saturated and hydrostatic pressure 0 to 1000 bar

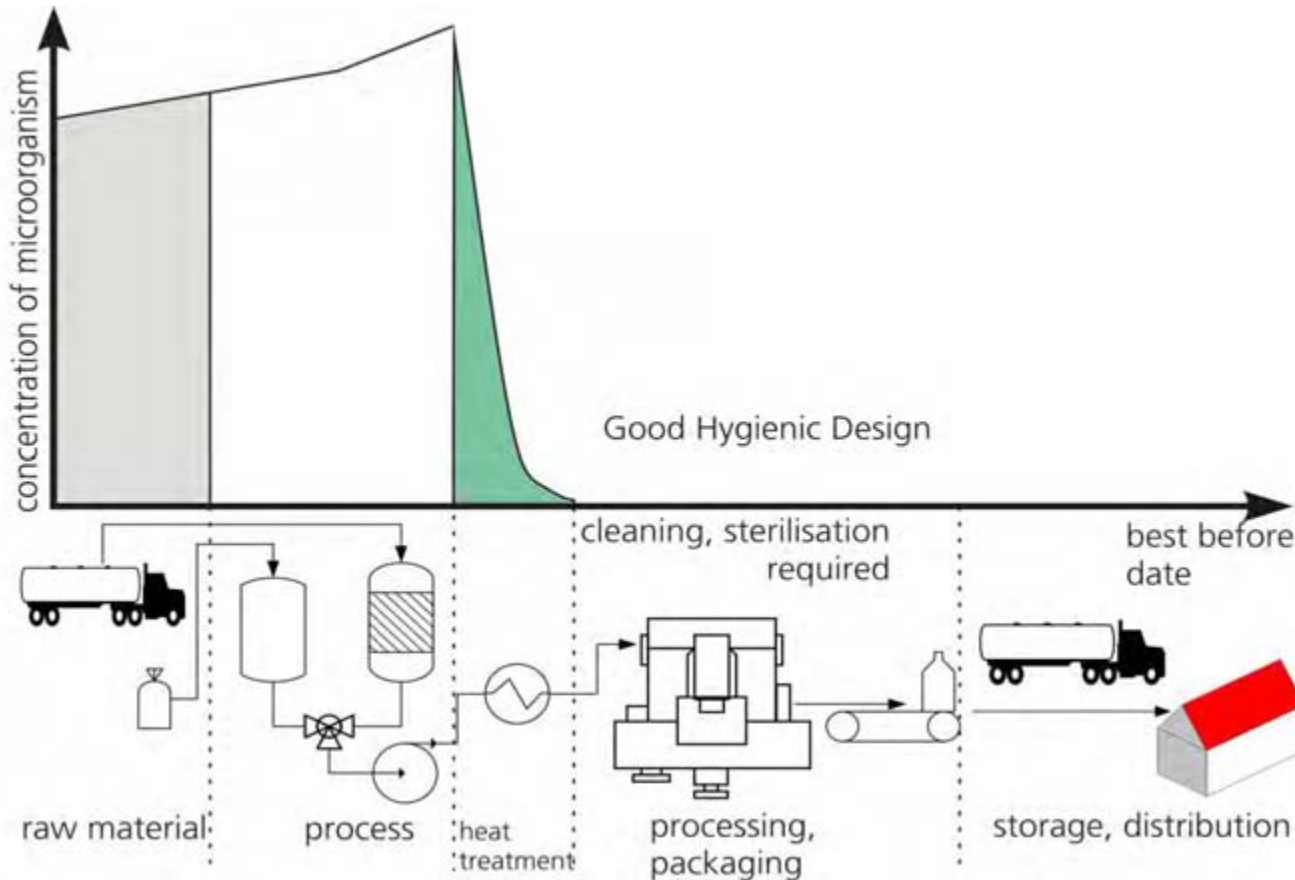


Source: Timmerman, Diversey Inc.

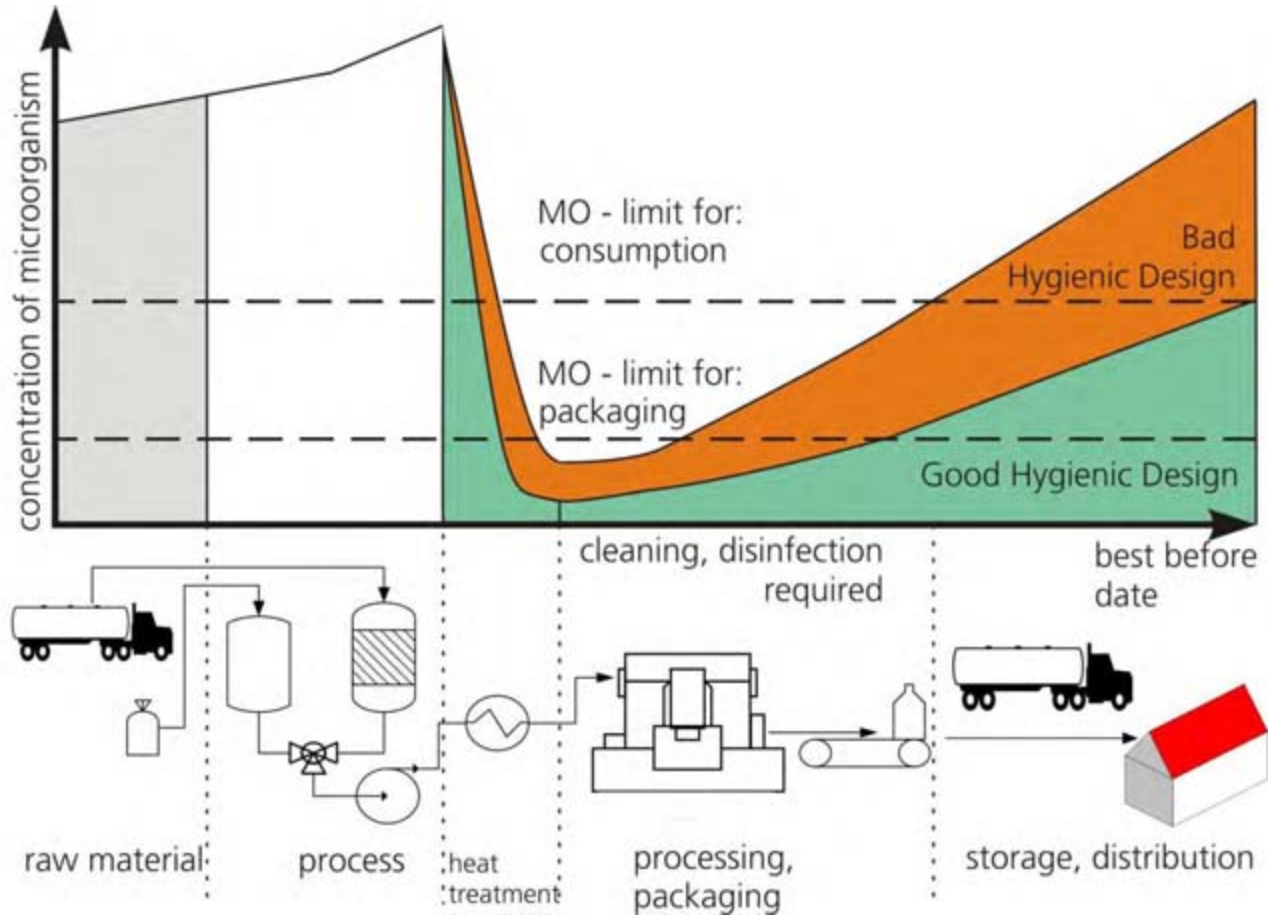
*Pseudomonas sp.*



# Growth of MO after Sterilisation without Recontamination after Heat Treatment



# Growth of MO after Pasteurisation



# What MO need in order to multiply?



# What MO need in order to multiply?

## Influence of temperature on growth rate

*Bacillus, Spores*



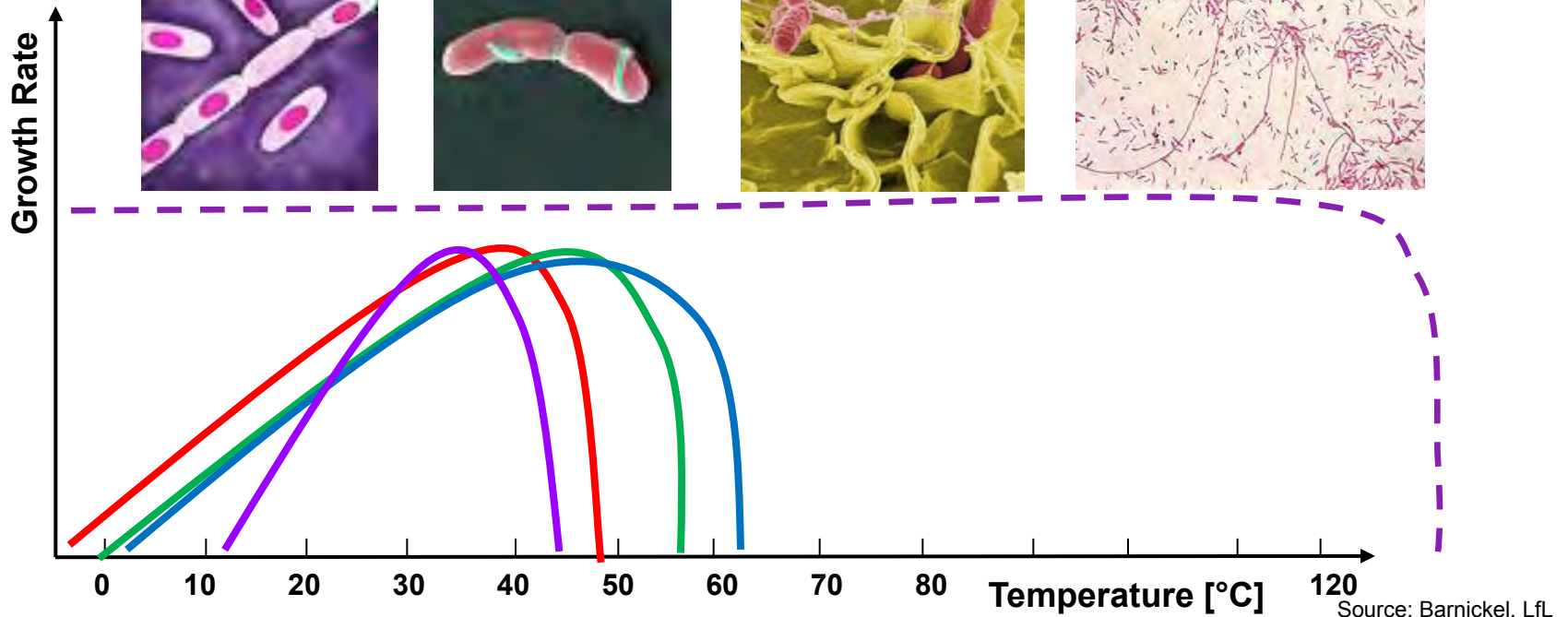
*Listeria monocytogenes*



*Salmonella*



*Legionella*



# What MO need in order to multiply?

## Food and water

Need food and water in order to grow and multiply. Each type of bacterium is specific in its needs.

Most bacteria of concern prefer foods high in proteins and carbohydrates.

**Dried foods:** do not contain enough water (free water,  $a_w$ -value, water activity) to allow bacteria to grow, but are not necessarily free of bacteria or spores.

# What MO need in order to multiply?

## Effects of the water activity ( $a_w$ -value) on growth of MO

| $a_w$ -value | MO growth inhibited at lowest value (partial)           |
|--------------|---|
| 1 - 0,95     | spores of bacteria, some yeasts, gram-negative bacteria |
| 0,91 – 0,87  | most yeasts   |
| 0,87 – 0,80  | most moulds, <i>Staphylococcus aureus</i>               |
| < 0,5        | no growth of microorganisms                             |

### Examples



[www.carnation.co.uk](http://www.carnation.co.uk)



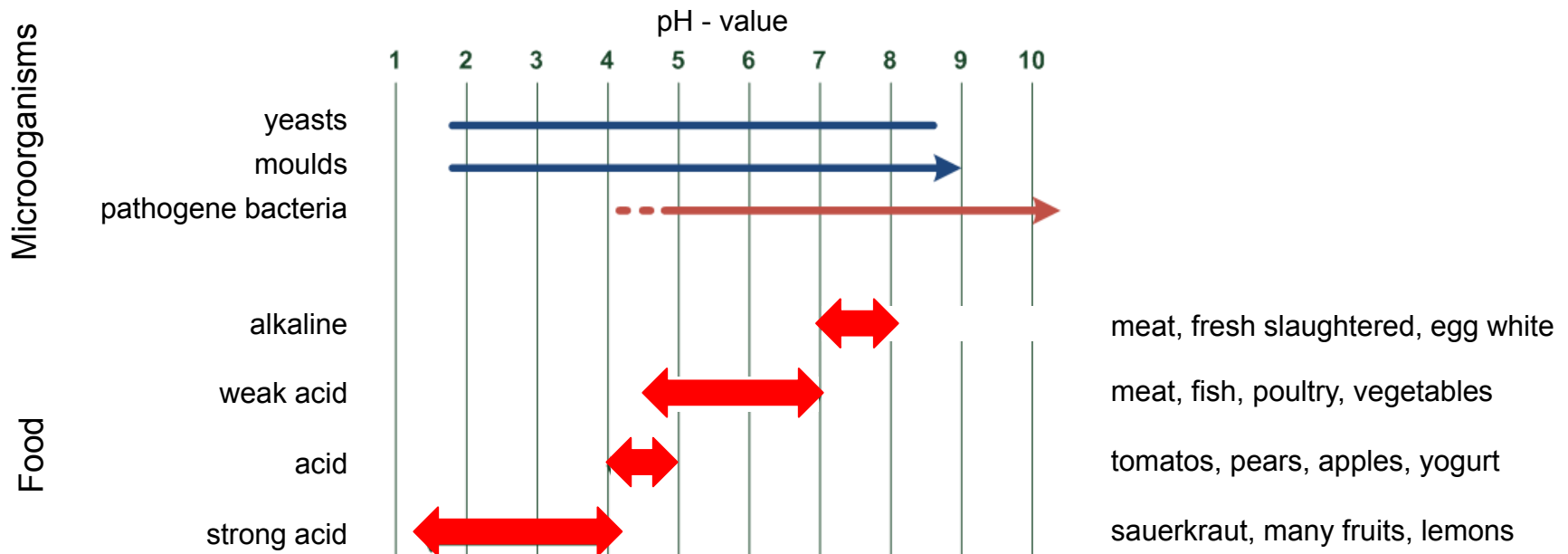
# What MO need in order to multiply?

## Oxygen and acidity

**Aerobic bacteria:** must have oxygen in order to grow → mainly of concern

**Anaerobic bacteria:** can not survive when oxygen is present

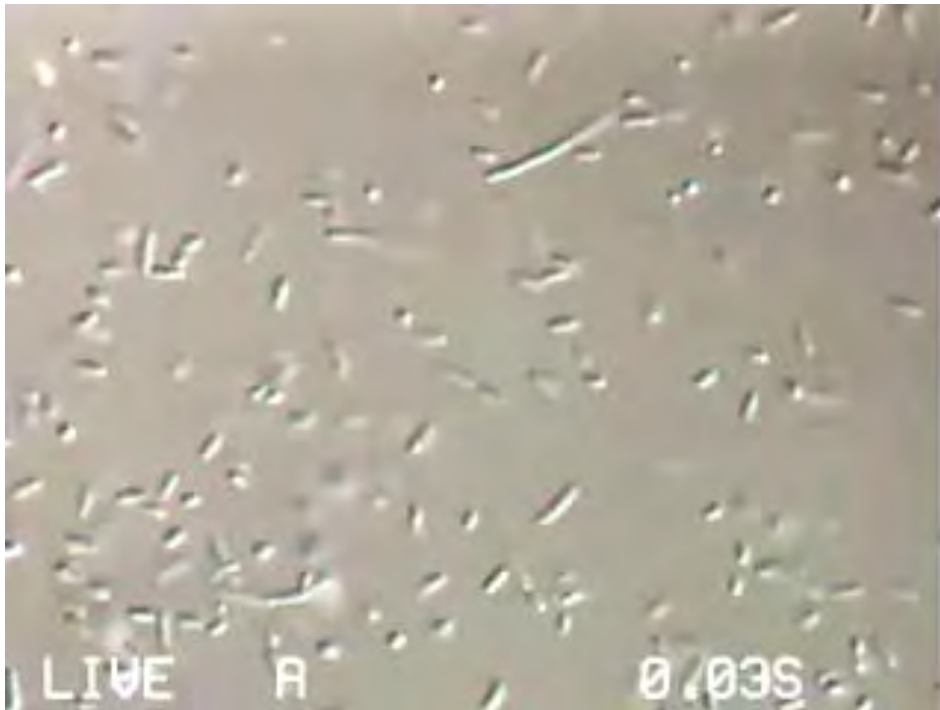
**Facultative anaerobic:** can grow with or without free oxygen



# What you should know about MO?

## Microorganisms...

- can swim in fluids or films (chemotaxis - they swim towards the food, up to 160mm/h)



Source: <http://www.youtube.com/watch?v=PZfsIGT5NIs>



# What you should know about MO?

## Microorganisms...

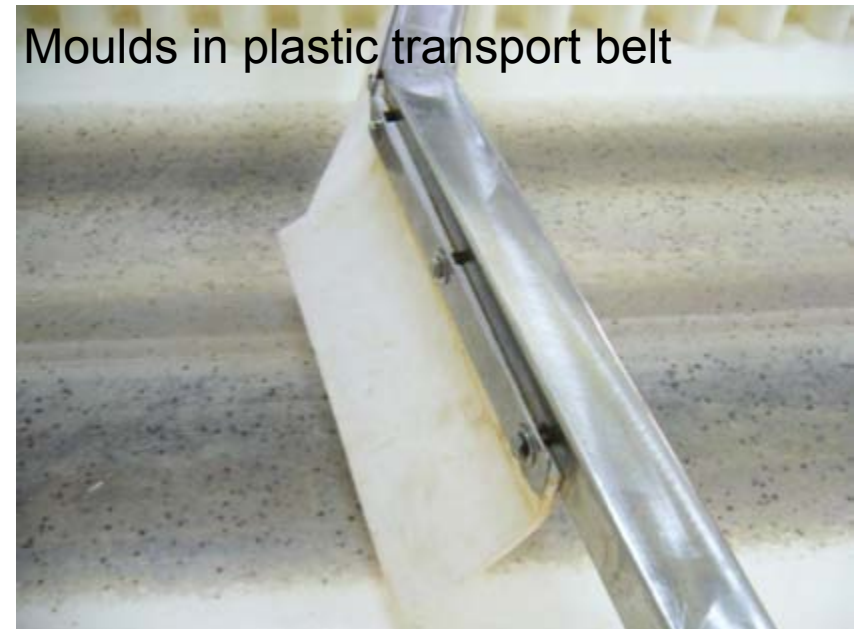
- form slime (biofilm) for protection & adhesion
- grow at interfaces, liquid or solid residues (fungi)
- are working together



# What you should know about MO?

## Microorganisms...

- surfaces are favored substrates to settle and to develop - resist flushing
- can penetrate plastic and can induce corrosion



# What you should know about MO?

## You can kill, reduce or inhibit growth by:

- sanitizers (e.g. citric acid, silver ions)
- physical treatments (e.g. heat, UV, drying)
- chemicals (e.g. chlorine, peracetic acid)
- but some have:
  - high tolerance against UV light and radioactive radiation
  - high resistance against biocides, especially in biofilms
- an important method is: keep environment as dry as possible

# Contamination Routes

## Wet floor – „Product contact“ surfaces?



# Contamination Routes

## Water-borne

- condensate / wet films
- stagnant water or liquid, drops
  - poor installations allowing backflow
  - non potable water



Drain opened



# Contamination Routes

## Water-borne

- Fresh water hose: residual water in tube, app. 2 month stagnant: 87 cfu/ml
- after 2 min. steaming:  $< 1$  cfu/ml



Source: Barnickel, LfL

# Contamination Routes

## Ancillary liquids

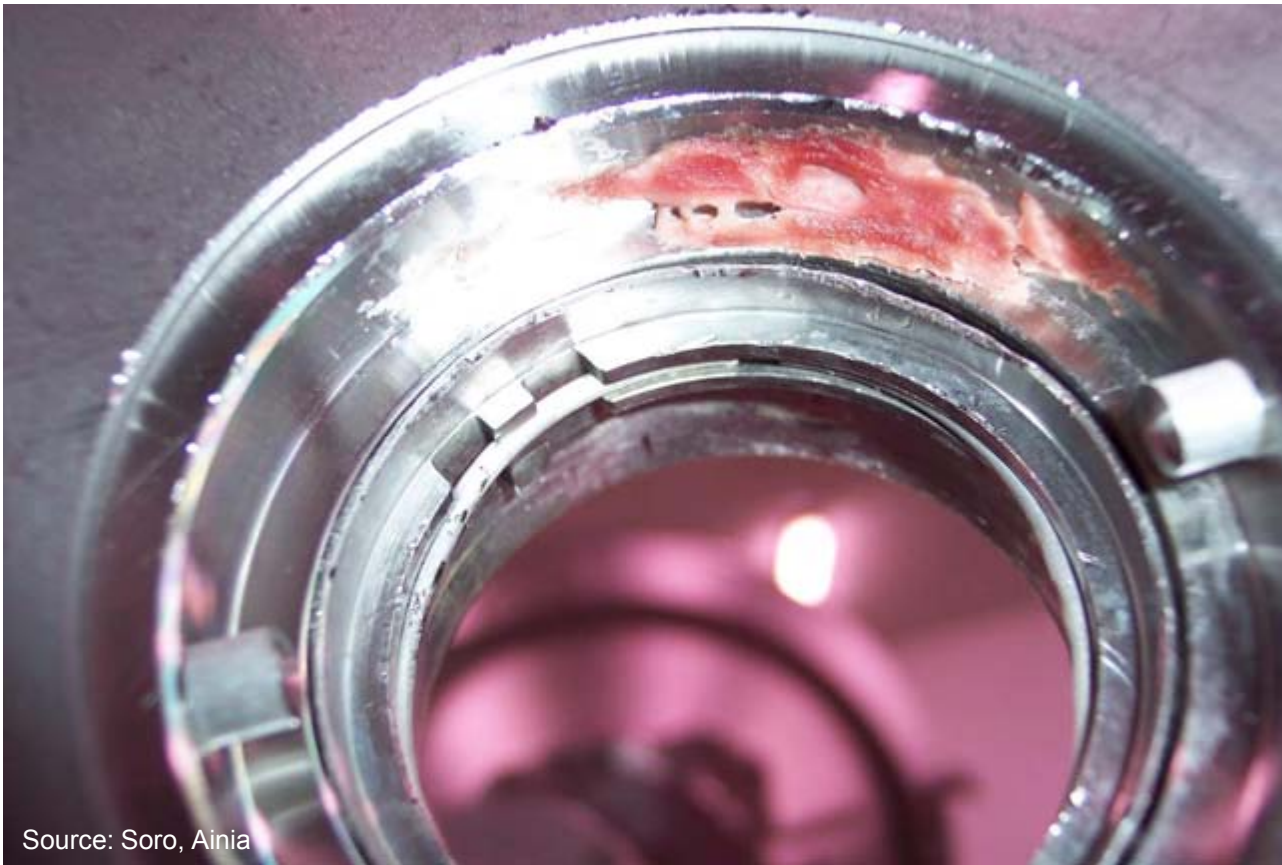
- lubricants, coolants, signal transfer liquids
- example of contaminated food grade grease



Source: Bowmer, Bel-Ray Company Inc.

# Contamination Routes

- product (meat) in a pipe connection after cleaning



Source: Soro, Ainia



# Contamination Routes

## Protection of Microorganisms by Soil

- Thermal Kill
- D-values\*\* (min) for Spores of *Bacillus subtilis* (\*\* D-value is the time taken to reduce numbers tenfold, or *by* 90%)

| Product              | $a_w$ | t (min) | Time Increase |
|----------------------|-------|---------|---------------|
| Physiological Saline | 1.00  | 0.23    | 1             |
| Fat & Protein        | 0.49  | 28.4    | X 128         |
| Fat                  | 0.50  | 25.0    | X 109         |
| Molasses             | 0.59  | 12.8    | X 56          |
| Protein              | 0.61  | 27.1    | X 118         |

After Unilever Vlaardingen: H.H. Oosterkamp

# Contamination Routes

## Airborne

- Microorganisms fly as passengers on dust particles/ aerosols  
(High pressure sprays!)
- passive transport on hairs, skin flakes, dust, etc.

# Contamination Routes

## Airborne - Problem high pressure cleaning



Source: Trainer Toolbox DVD 10

# Contamination Routes

## Airborne – Aerosol as transport vehicle

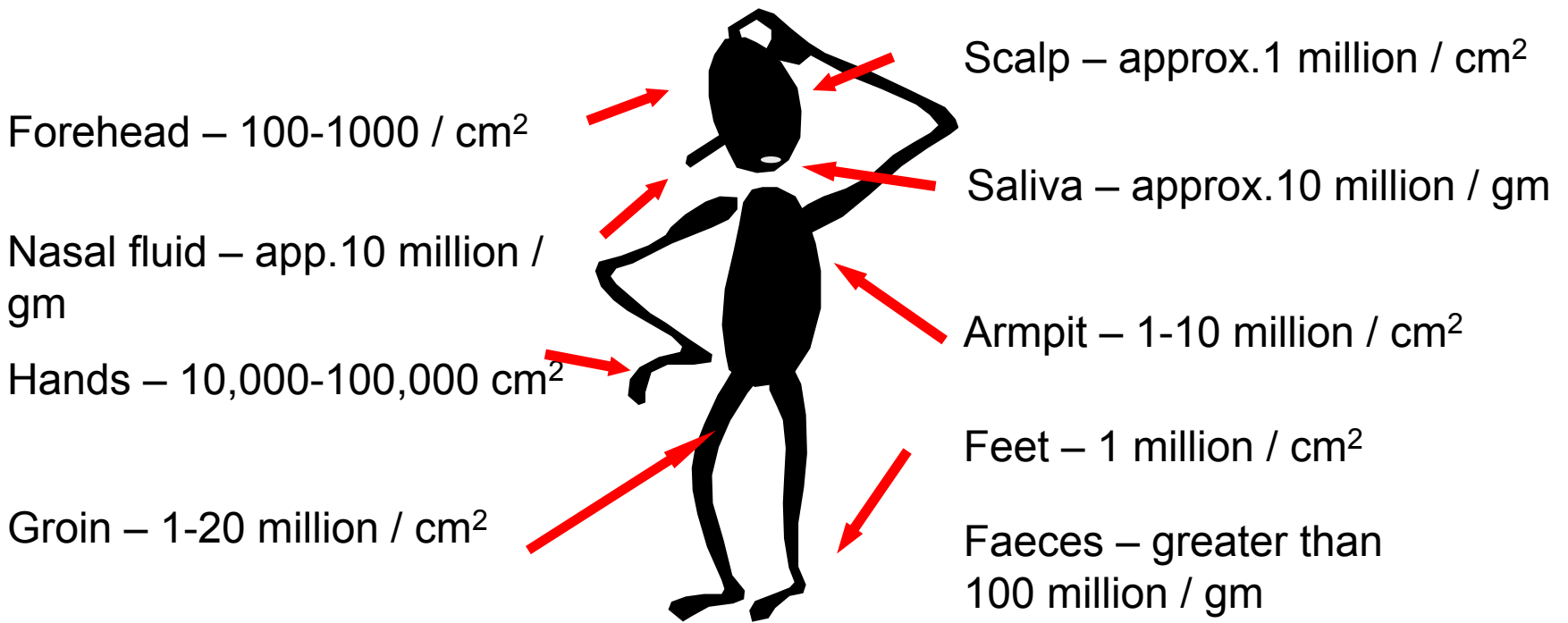
- e.g. steam



Source: Diversey Inc

# Contamination Routes

## Human error - Contamination source No.1



Air: Grade A: <1cfu/m<sup>3</sup>; Grade E: < 500cfu/m<sup>3</sup> (EC Guide to GMP, Revision Annex 1, 2003)

Potable water (22°C): 100 cfu/ml

# Contamination Routes

## Human error

Before Hand washing

After washing

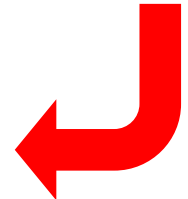
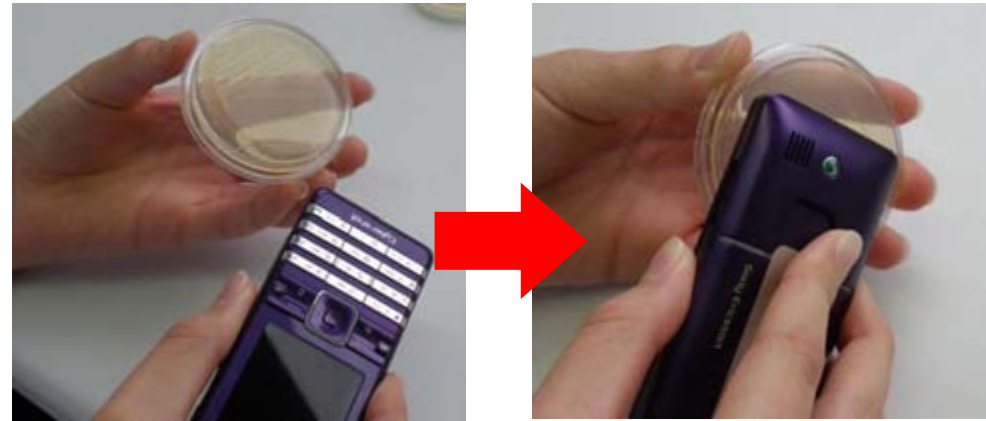
After desinfection



Source: Barnickel, LfL

# Hygienic Practices to avoid MO Input

- Training of personnel to use equipment as designed and to follow hygiene rules is essential
- No contact to hair
- No contact to mobile phone
- Don't put anything from the floor on the working place
- Minimize draft or aerosol
- Appropriate sanitary practice



Source: Barnickel LVFZ Kempten

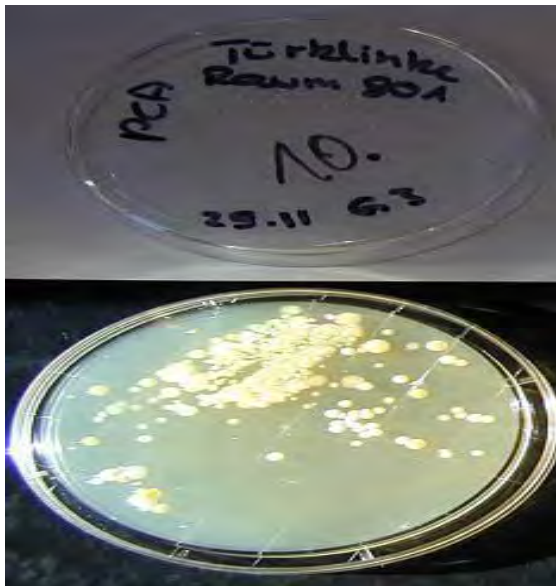
# Bacteria on a Spider



Source: Salker, Barnickel LVFZ 2010

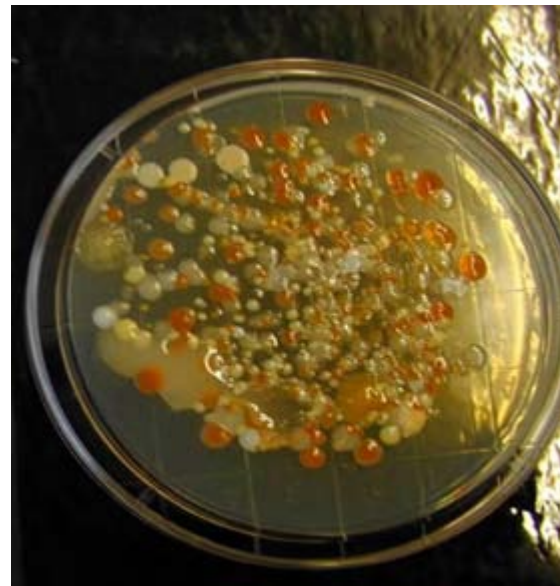


# Contact Plate Test Results



Door handle

Source: Barnickel, LfL

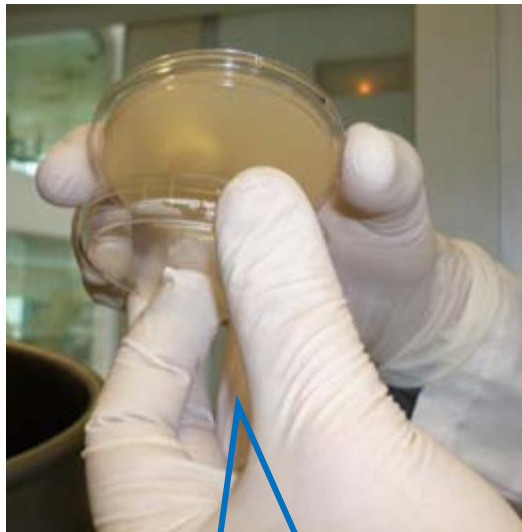


Desktop next to filler  
without cleaning



Contamination of floor  
water

# Detection of MO on Surfaces: Contact Plate Test



sterile agar plate with nutrient medium



collection of MO on test surface



incubation



counting of colonies

Source: Barnickel, LfL / Soro, AINIA



# Hygienic Design Criteria

# Content

- Hygienic design criteria for open equipment
  - Introduction
  - Welds,
  - Dismountable joints
  - Drainability,
  - Belts, Frameworks....
- Hygienic design criteria for closed equipment
  - Introduction
  - Seals, Welds, Pipe connections
  - Drainability
  - T-pieces

## Definition

### Open processes

- Product and product contact surfaces are exposed to the environment around the equipment.

### Closed processes

- Product and product contact surfaces are NOT exposed to the environment around the equipment during normal processing.

### Hygienic equipment class I

- Equipment that can be cleaned in-place and be freed from relevant microorganisms without dismantling.

### Hygienic equipment class II

- Equipment that is cleanable after dismantling and can be freed from relevant microorganisms after reassembly.

## Open process (GL: 8, 10, 13, 22)

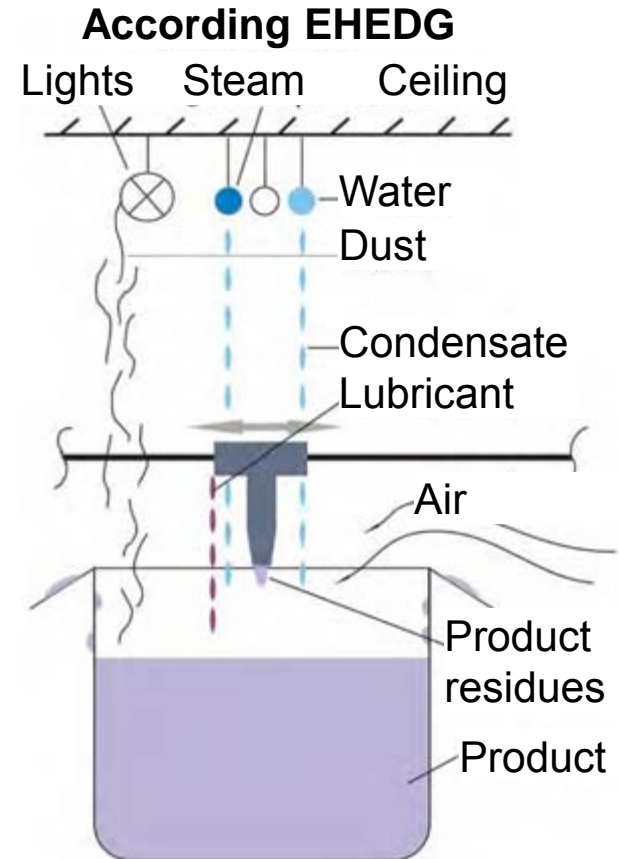
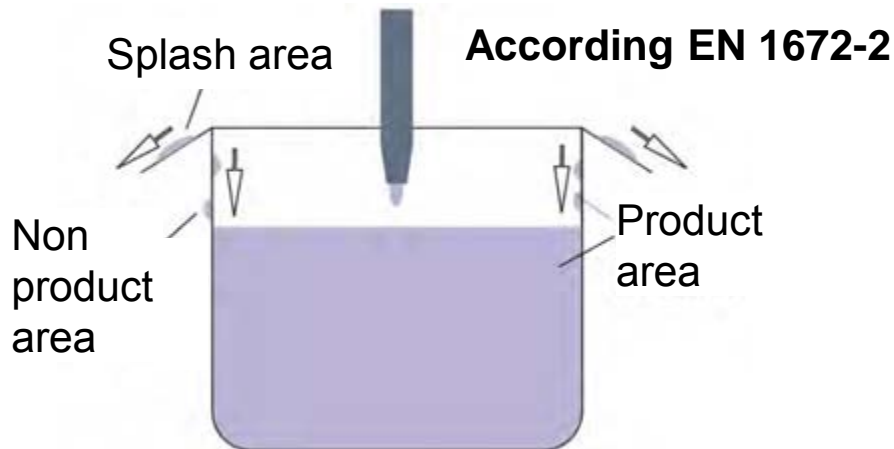
- product in (limited) contact with environment / surroundings
- often large product contact surfaces with complex geometries
- design of equipment plus environment must prevent any increase in soil and microbial concentration



# Definition of machine areas

## Product contact surfaces

The machinery surface which are exposed to the product (**direct**) and from which the product or other materials can drain, drip, diffuse or be drawn into (self returned) the product or product container (**indirect**).

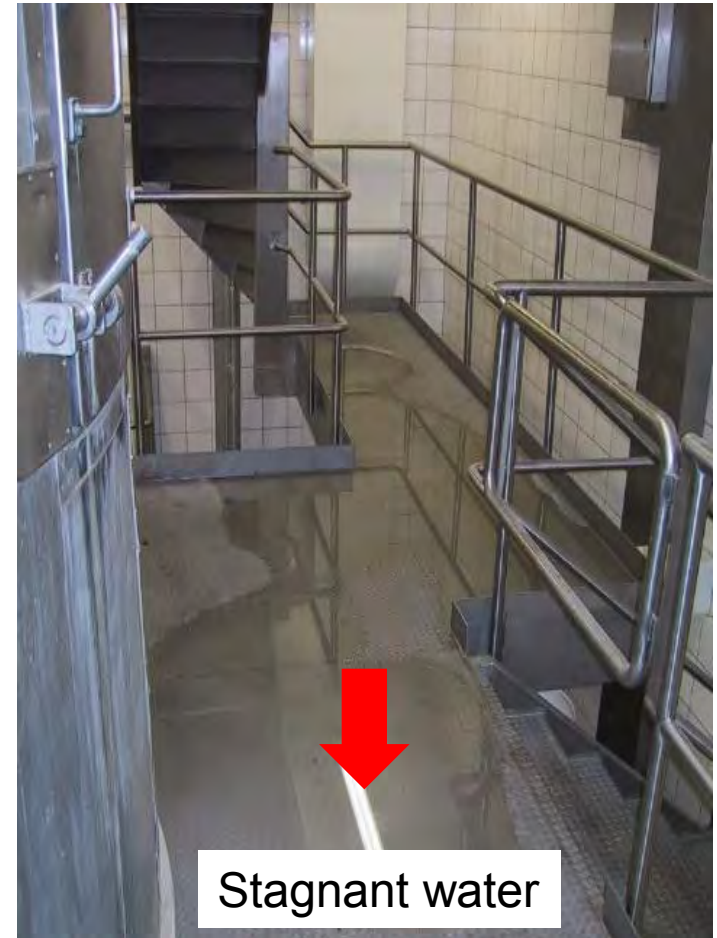


Source: Fraunhofer AVV

# Indirect product contact area



If possible: Keep it dry, high pressure cleaner?



Stagnant water








## General recommendations

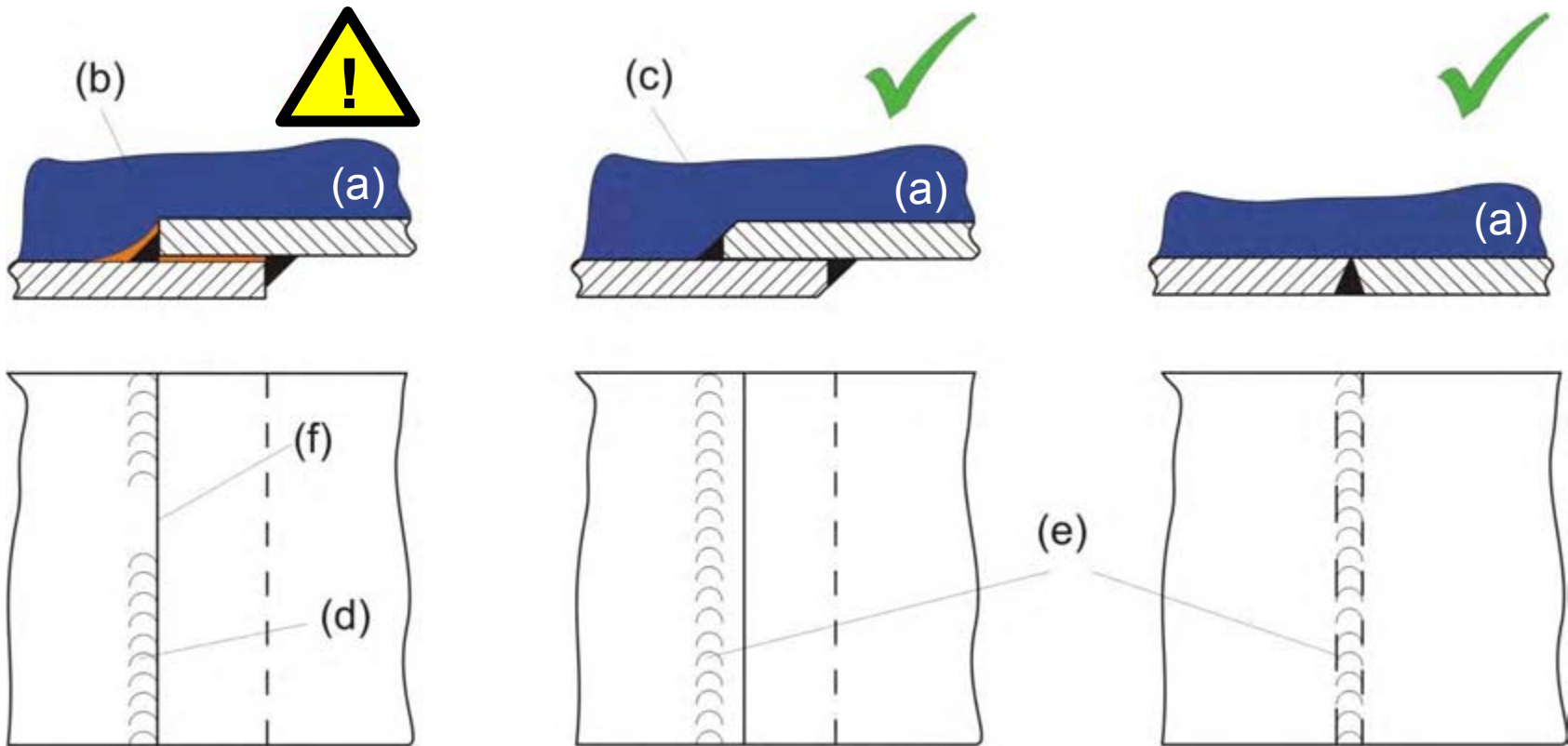
- Correct choice of materials of construction
  - Smooth surfaces – hygienic welding
  - No crevices (metal to metal contact)
  - No sharp edges and corners ( $r > 3\text{mm}$ )
  - No dead areas
  - Accessible for cleaning and inspection
  - Equipment must be fully self drainable
  - Cabinets slope away from product
- 
- make it close if possible
  - keep it covered



## Color code for EHEDG diagrams

|  |                                     |            |
|--|-------------------------------------|------------|
|   | Product or product area             | Dark Blue  |
|   | Water                               | Light Blue |
|   | Bacterial film or soil              | Orange     |
|   | Hygienic risk, poor hygienic design |            |
|  | Correct, easy cleanable design      |            |

# Welds

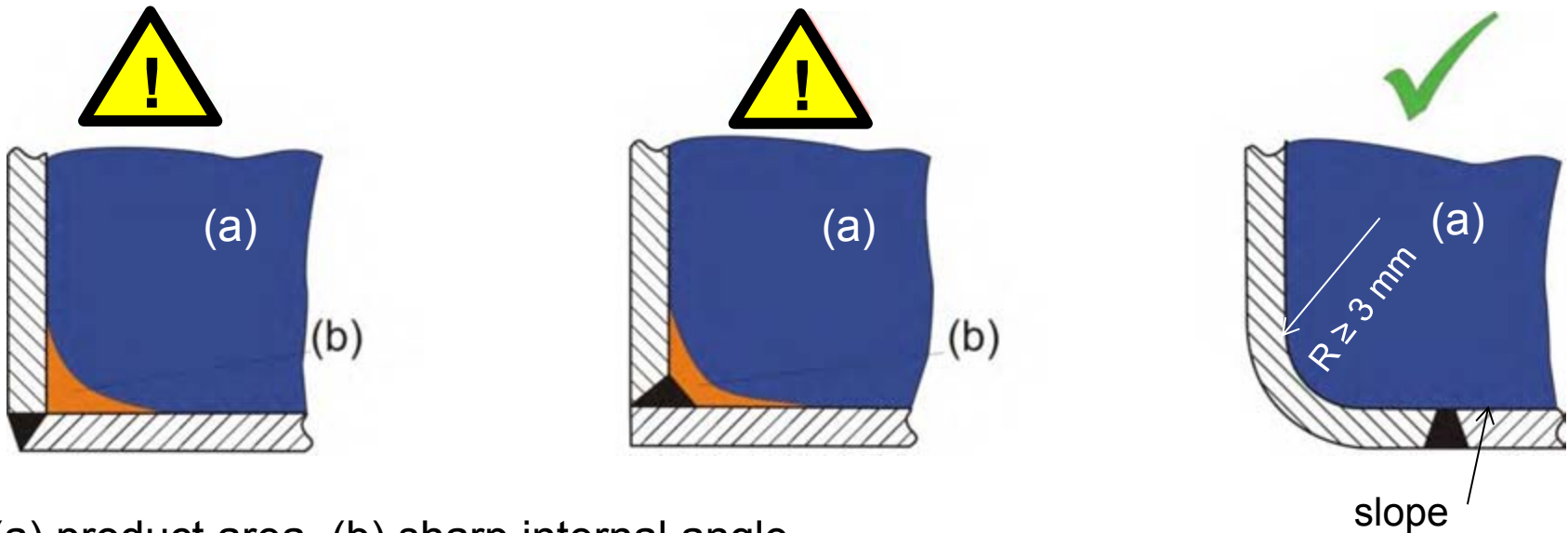


(a) product area, (b) step, (c) sloped edge, (d) intermittent welding, (e) continuous welding, (f) crevice due to metal-to-metal contact

# Welds

## Internal angles and corners must be effectively cleanable

- Sharp corners ( $\leq 90^\circ$ ) must be avoided
- Corners with angles smaller than  $135^\circ$  must be smooth and have a minimum radius of 3 mm. (preferably equal or larger than 6mm)



(a) product area, (b) sharp internal angle

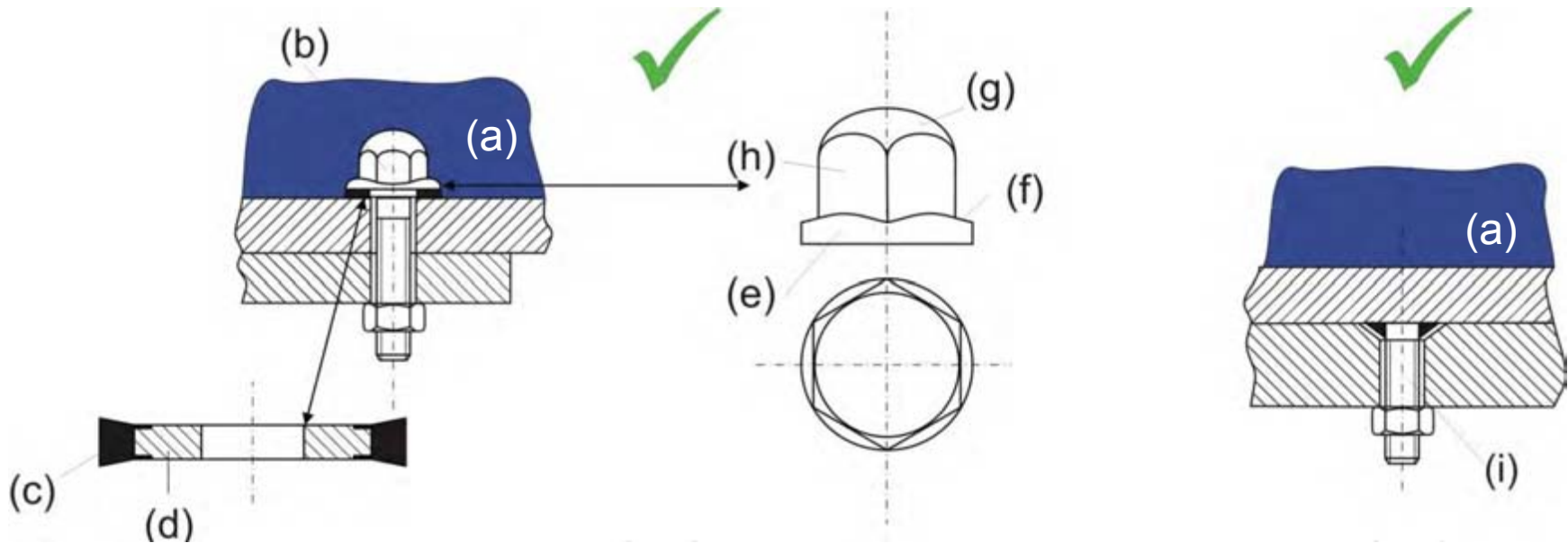
# Dismountable joints

- fully drainable
- fully sealed, avoid metal to metal contact (b)
- fixed compression
- fasteners on non-product-contact side



(a) product area, b) metal-to-metal contact, c) dead area, crevice

# Dismountable joints



(a) product area, (b) domed head, (c) elastomer, (d) metal, (e) circular collar  
 (f) sloped, (g) domed, (h) hexagon, (i) stud

# Drainability

- the exterior and interior of all equipment and pipework must be
  - self-draining or drainable
  - easily cleanable
- horizontal surfaces (upwards or downward facing) must be avoided
- surfaces should always slope away from product
- in case of external surfaces: slope away from the main product area
- Drainage of condensates should be considered when appropriate

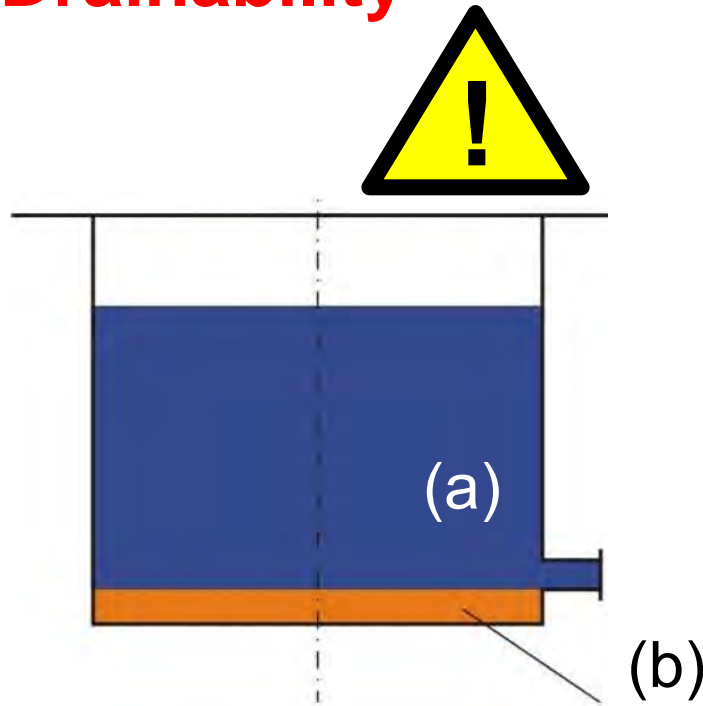
# Drainability of condensates



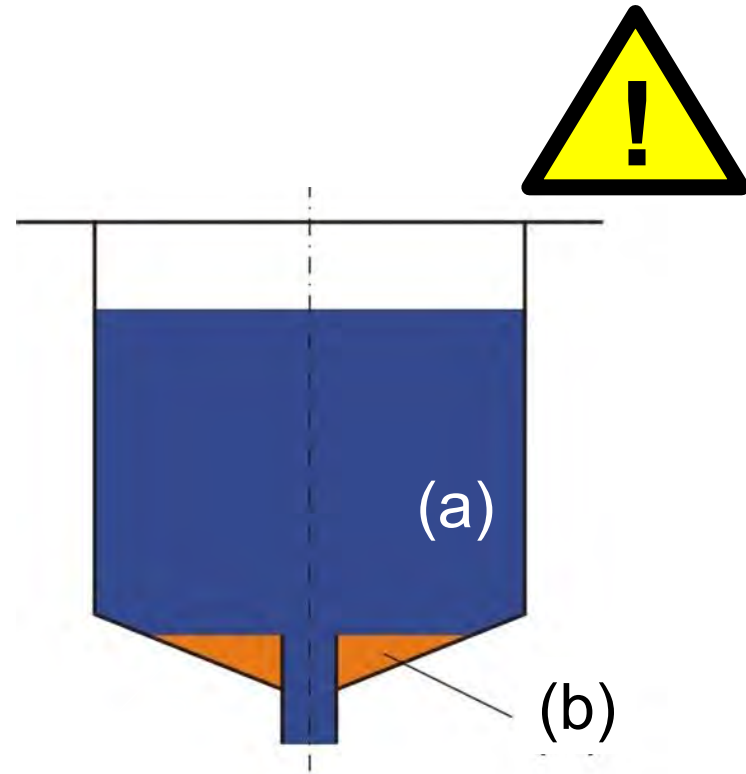
Source: Rafa Soro, AINIA



# Drainability

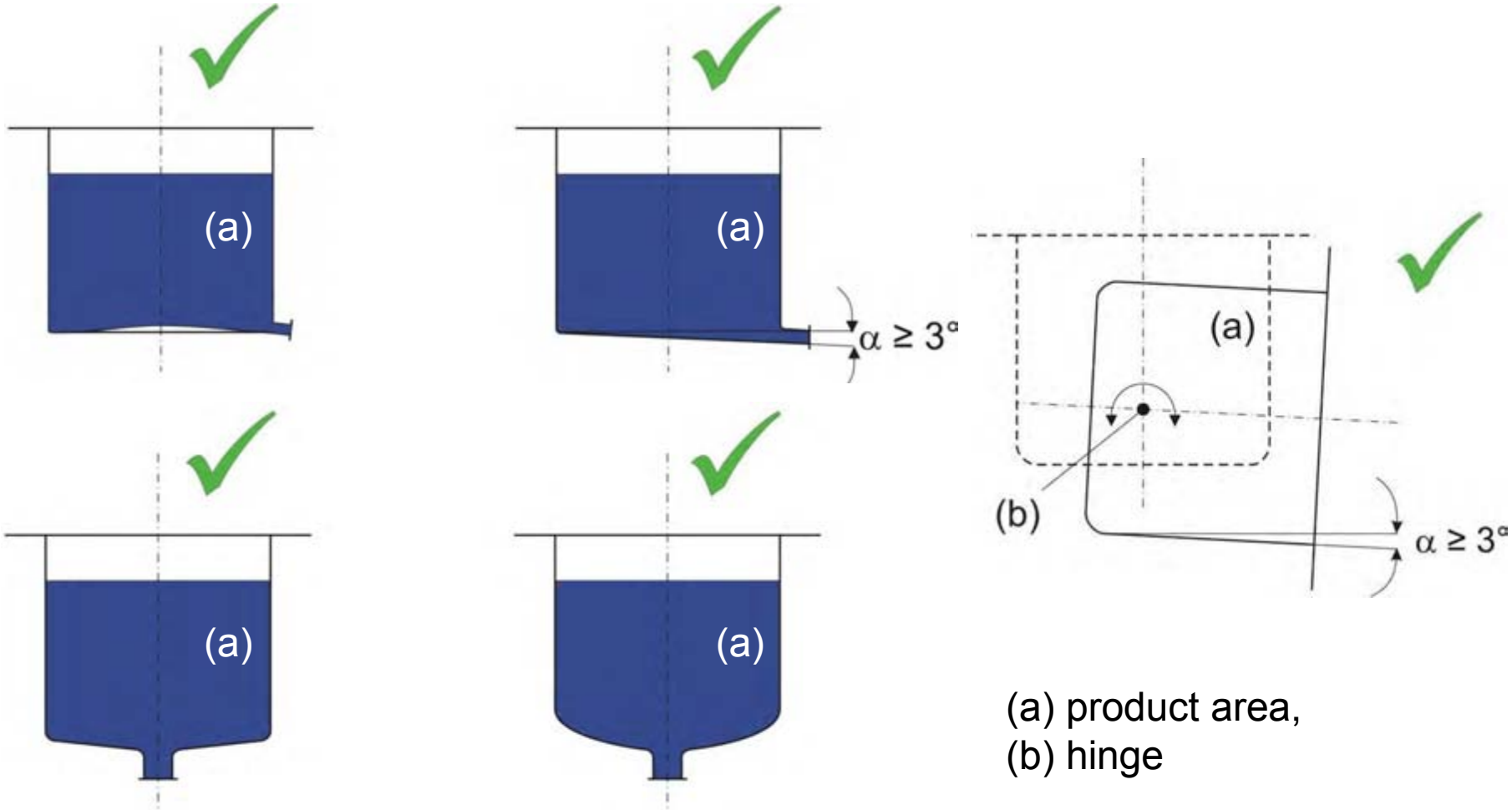


(a) product area, (b) residual soil



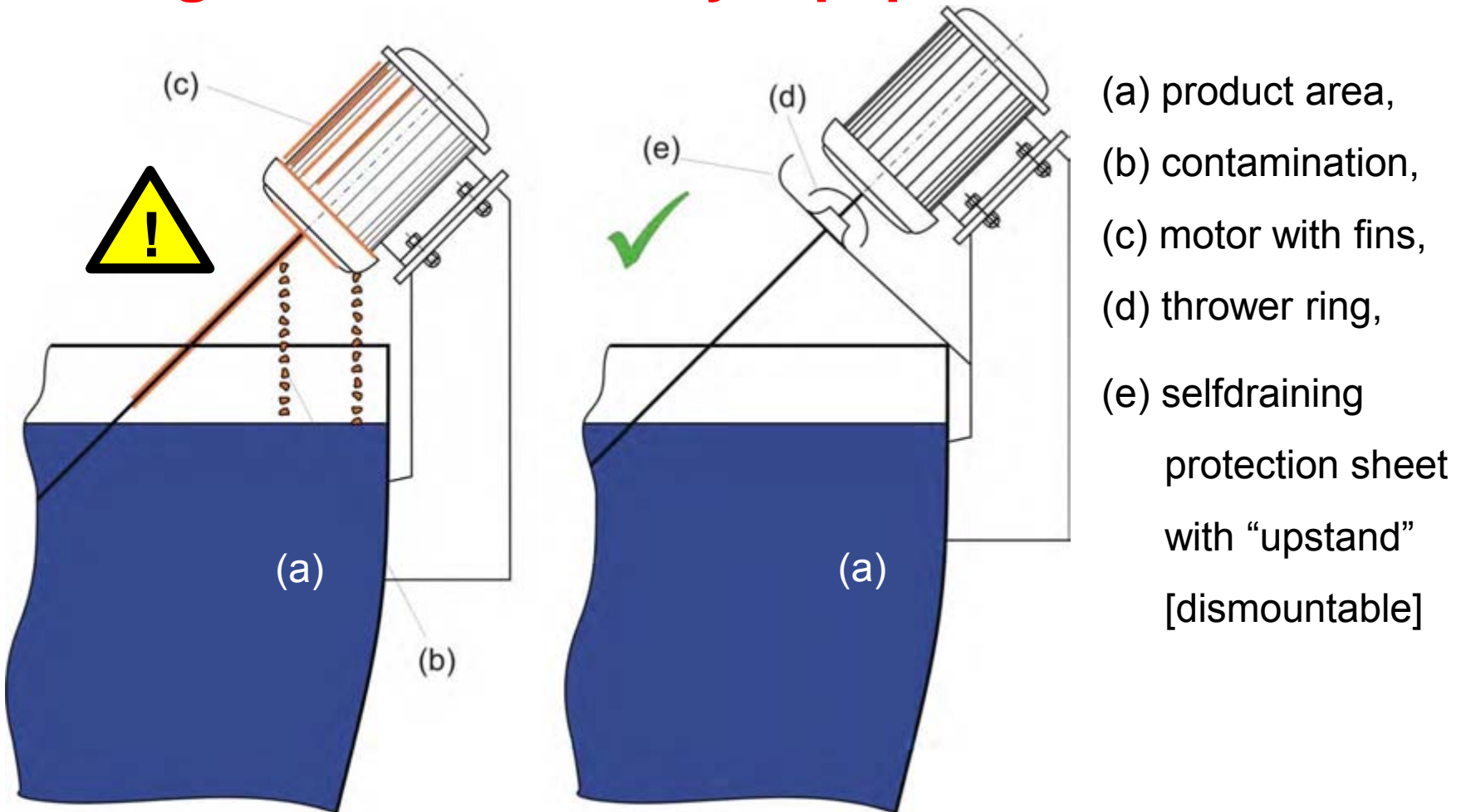
Tank for special purposes  
(e.g. brewery)

# Self-drainable designs



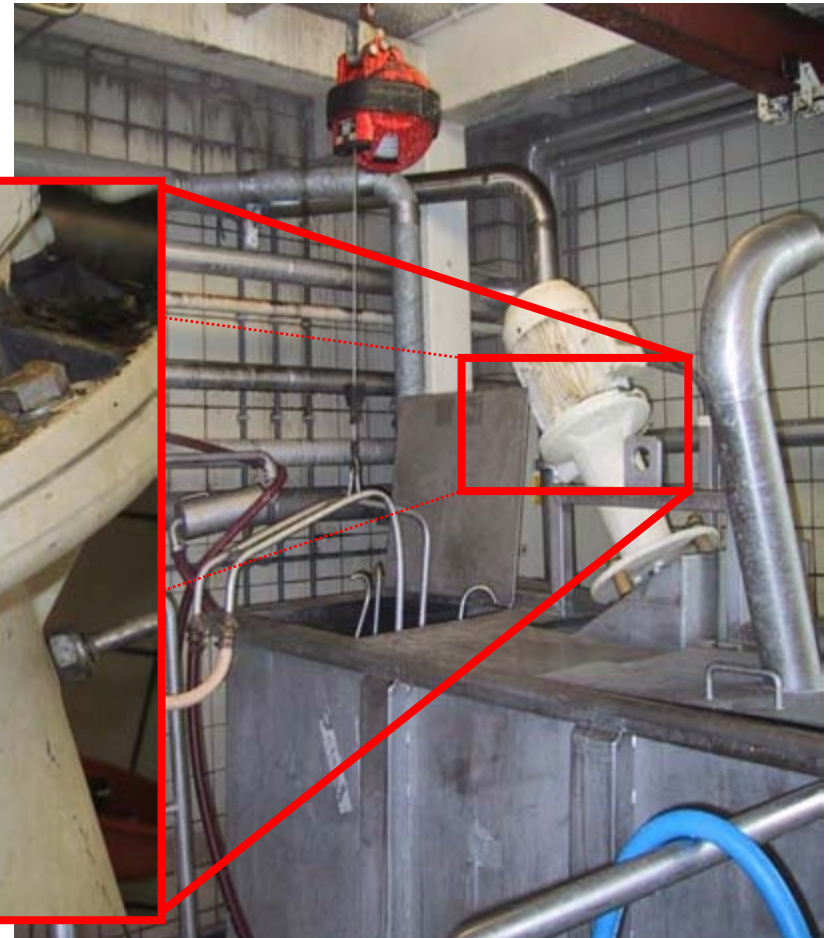
(a) product area,  
(b) hinge

# Arrangement of ancillary equipment



# Arrangement of ancillary equipment

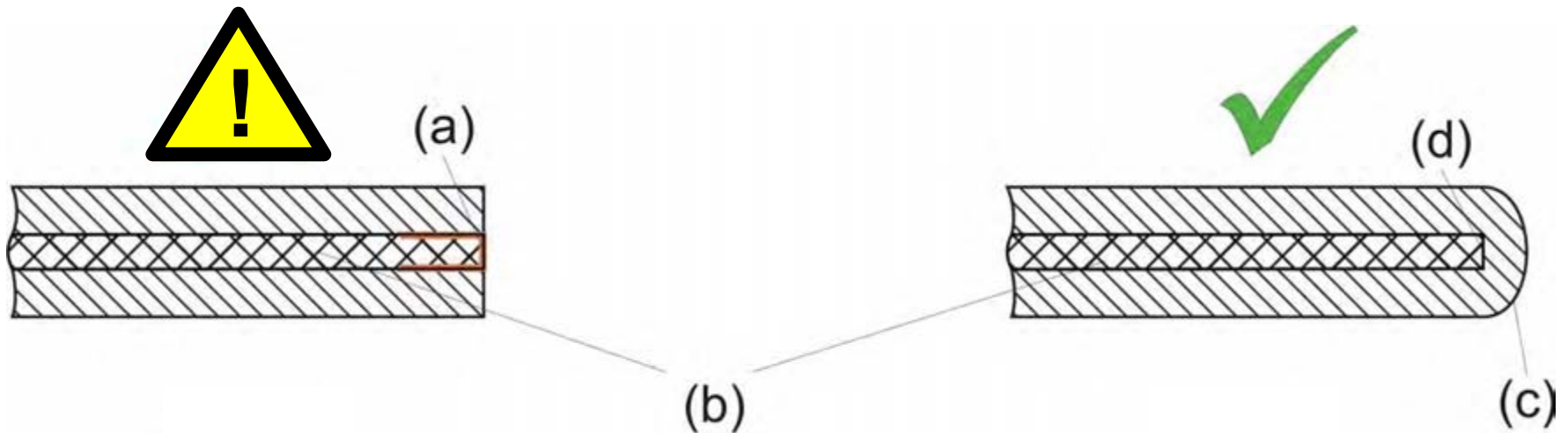
Physical hazards: e.g. Paint flakes



# Arrangement of ancillary equipment

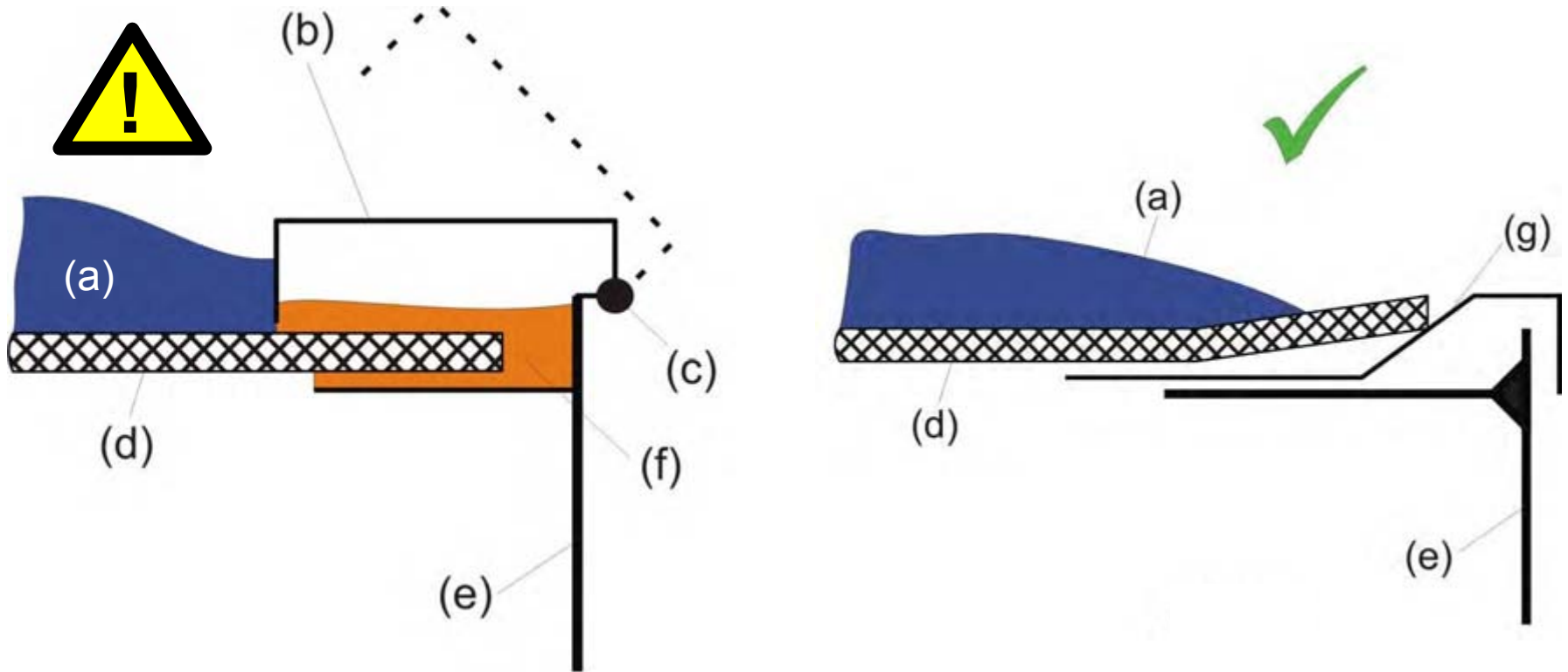


# Reinforcement of belts



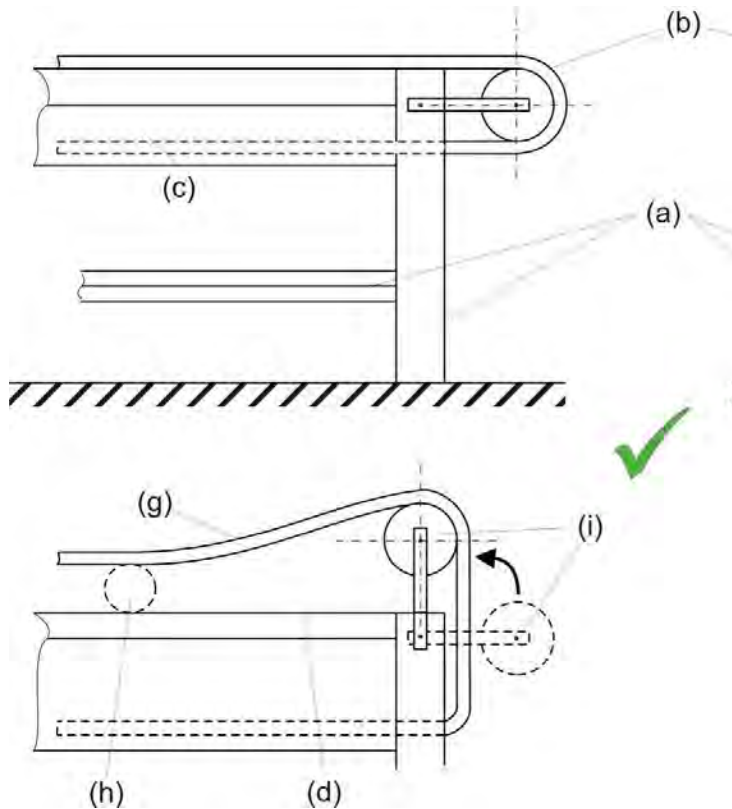
(a) open edge, (b) reinforcement, (c) rounded rim, (d) covered edge

# Sides of conveyor belts



(a) product area, (b) pivoted cover, (c) hinge, (d) belt, (e) frame, (f) dead area, (g) detachable cover

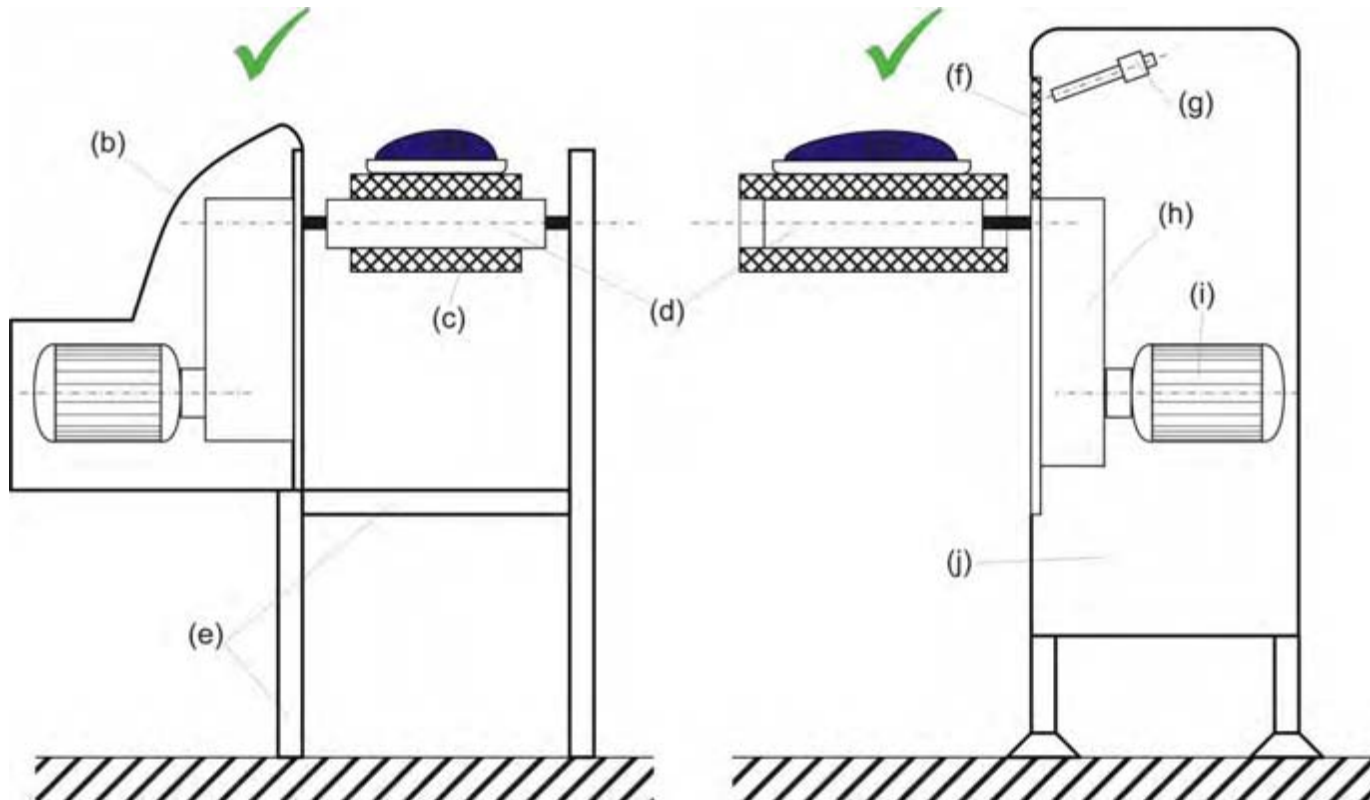
# Special belt design



(a) framework, (b) overhanging belt sides, (c) cladding, (d) stainless steel table, (e) roller, (f) belt, (g) released tension, (h) support roller, (i) swivel-mounted roller

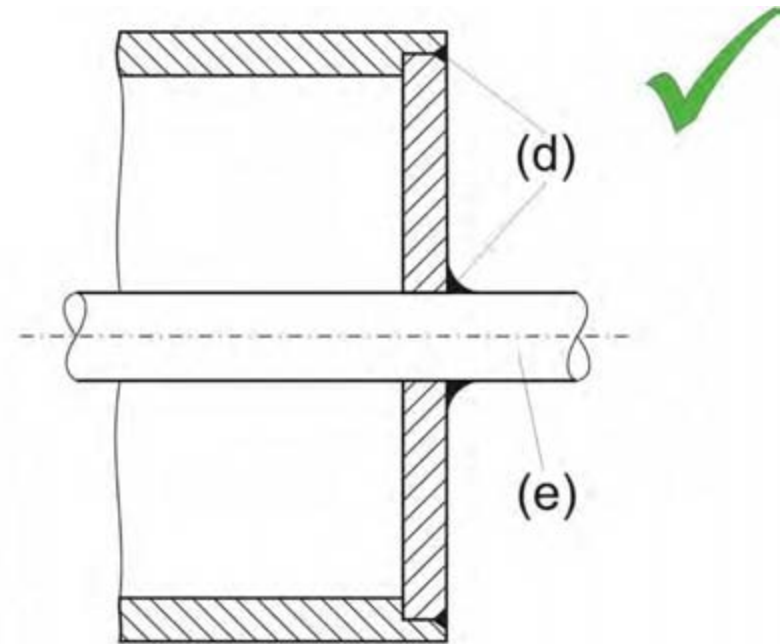
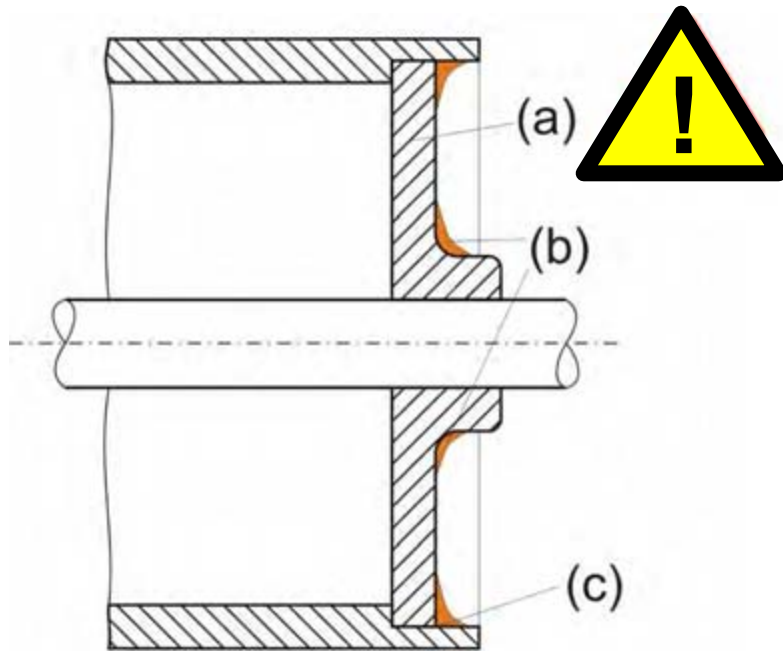


# Conveyor drive arrangements



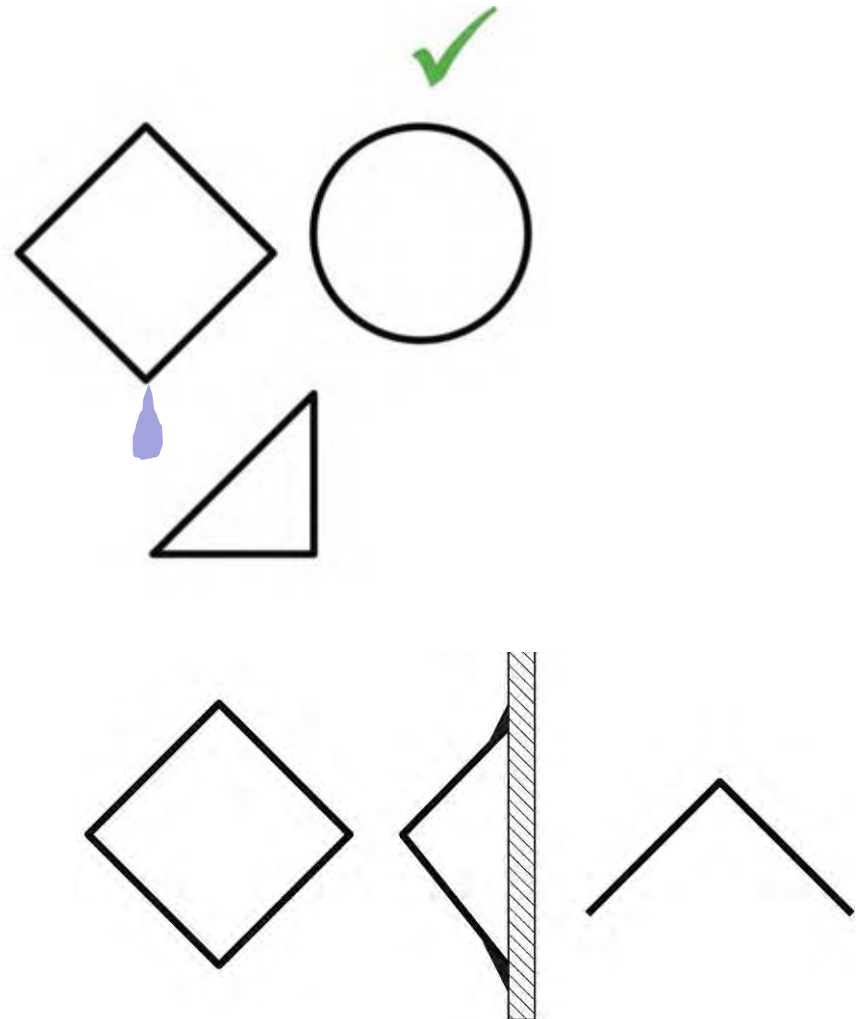
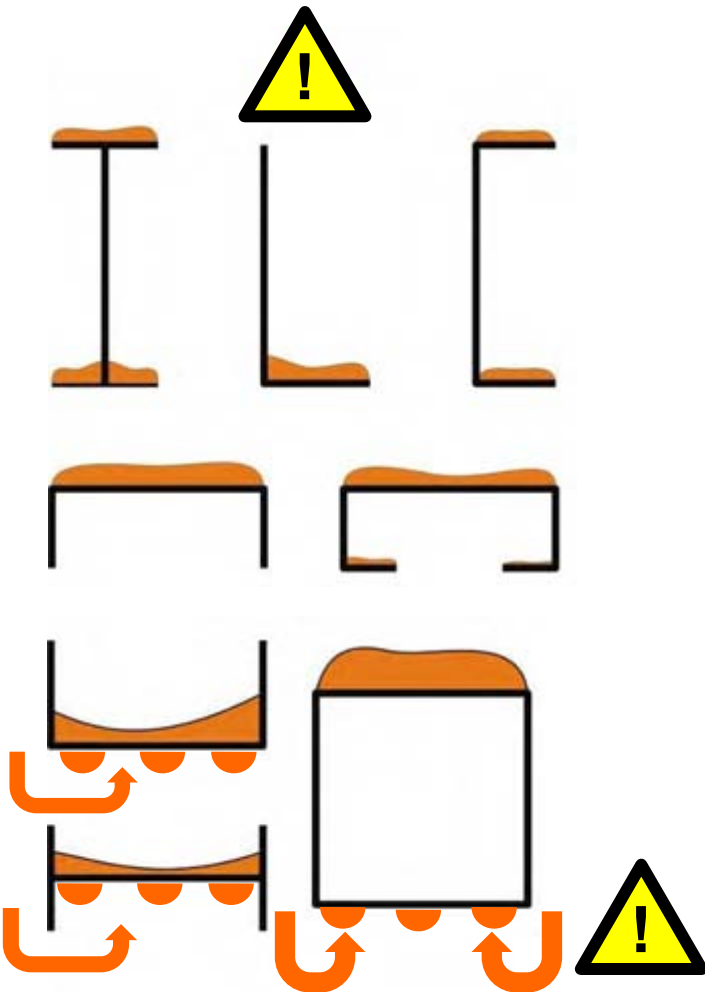
(a) product, (b) cover for motor and gear, (c) belt, (d) roller, (e) open framework, (f) sealed window, (g) sensor, (h) gear, (i) motor, (j) covered and sealed housing

# Design of rollers



(a) pressed-in roller end, (b) residues of soil and product, (c) crevice, (d) welds, (e) shaft

# Framework



# Framework

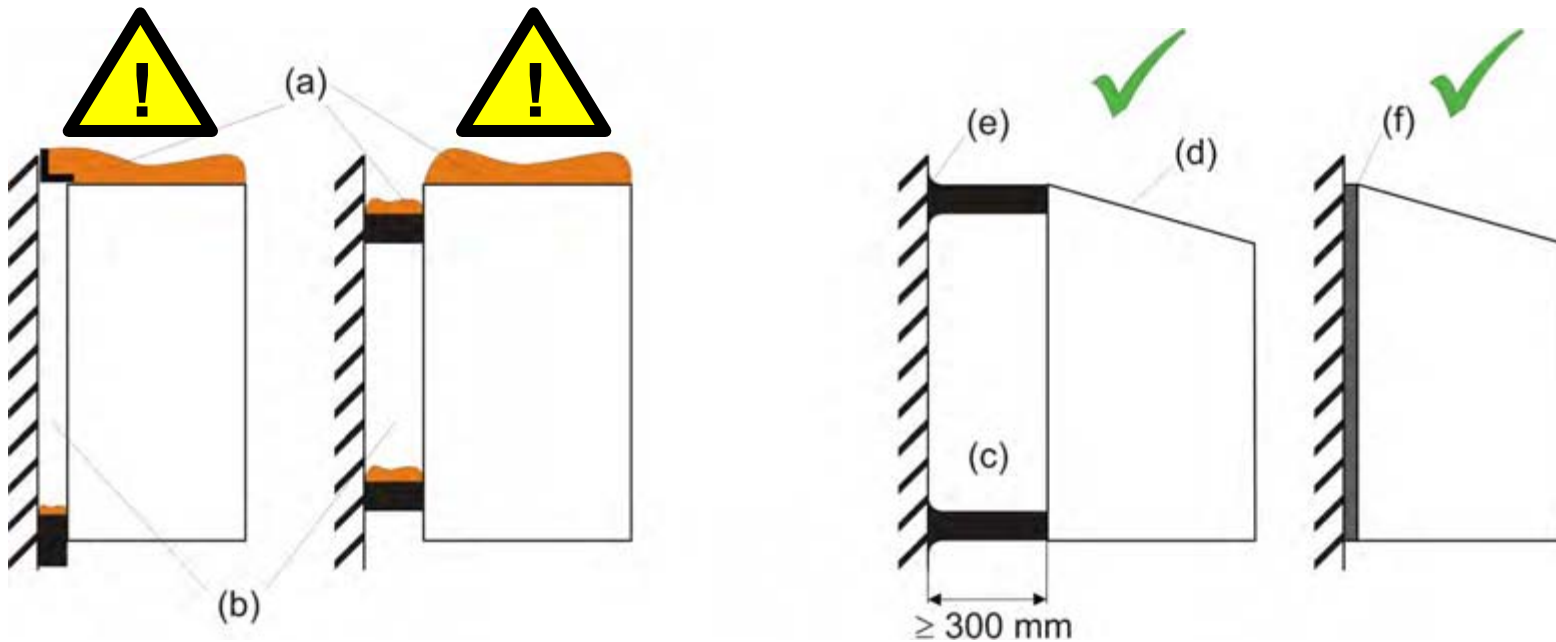


# Framework - Example



# Horizontal surfaces

- avoid product or liquid collection

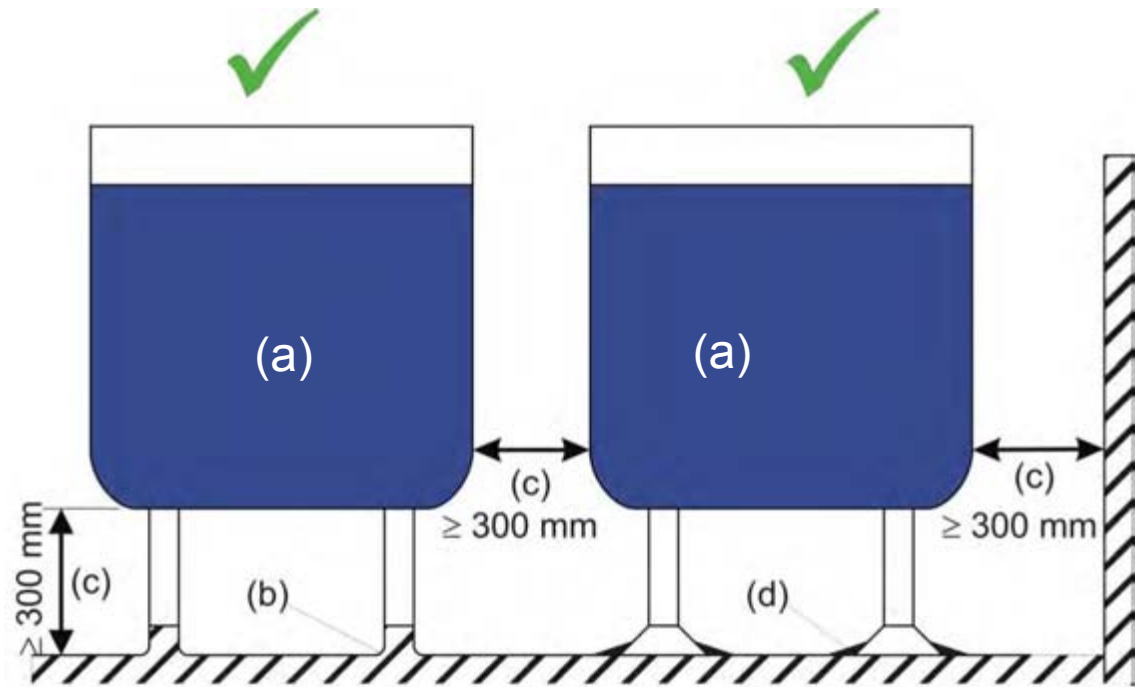


(a) residues of soil, (b) small clearance, (c) clearance, (d) slope, (e) radius, (f) sealing

# Horizontal surfaces



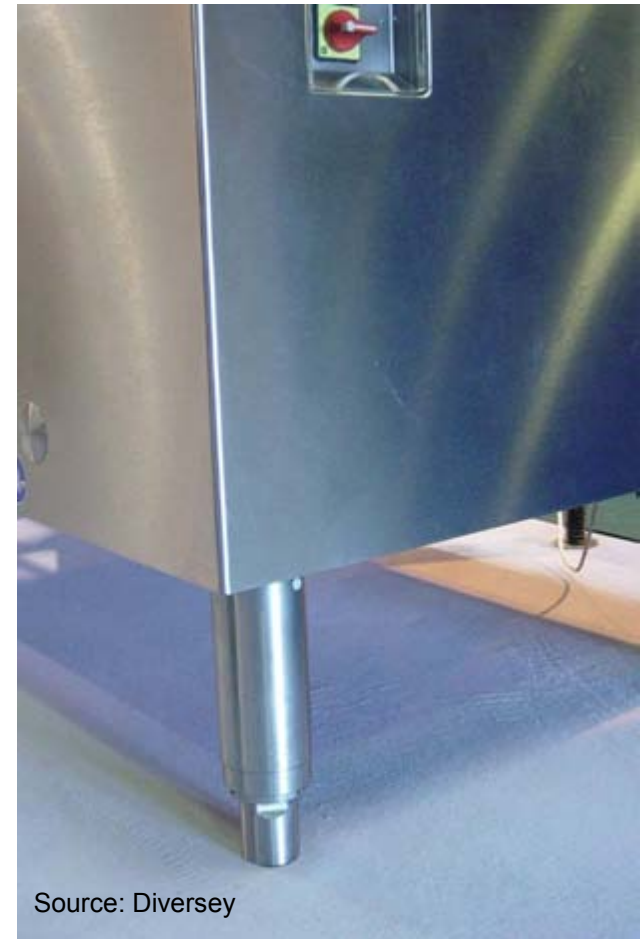
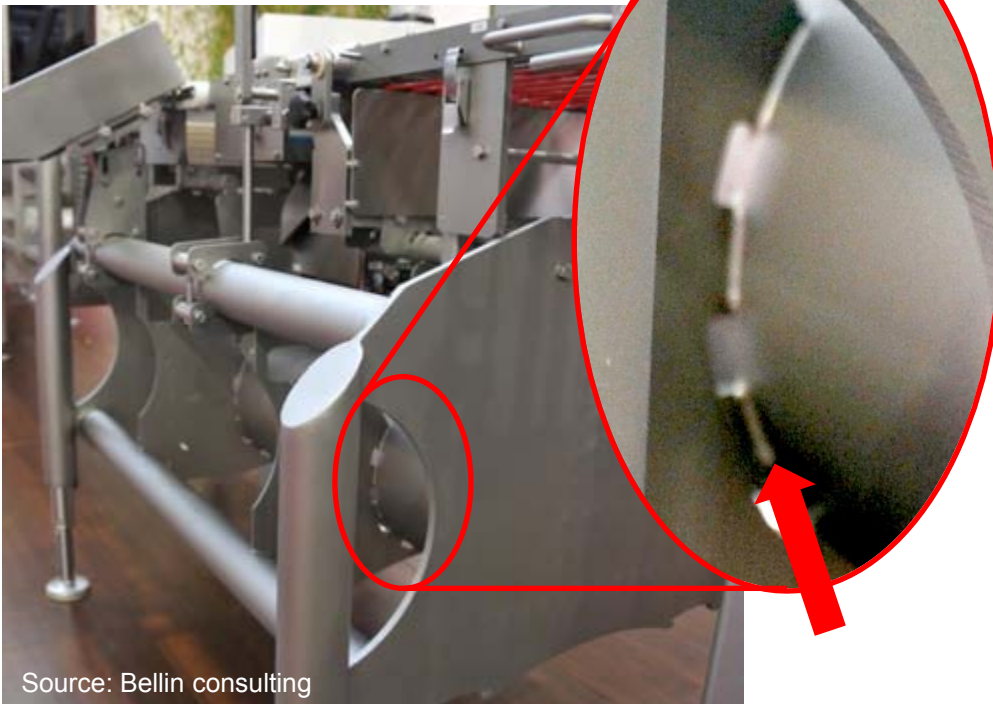
# Installations



(a) product area, (b) rounded pedestal, (c) clearance,  
 (d) sealed to the floor



# Installations



# Closed process

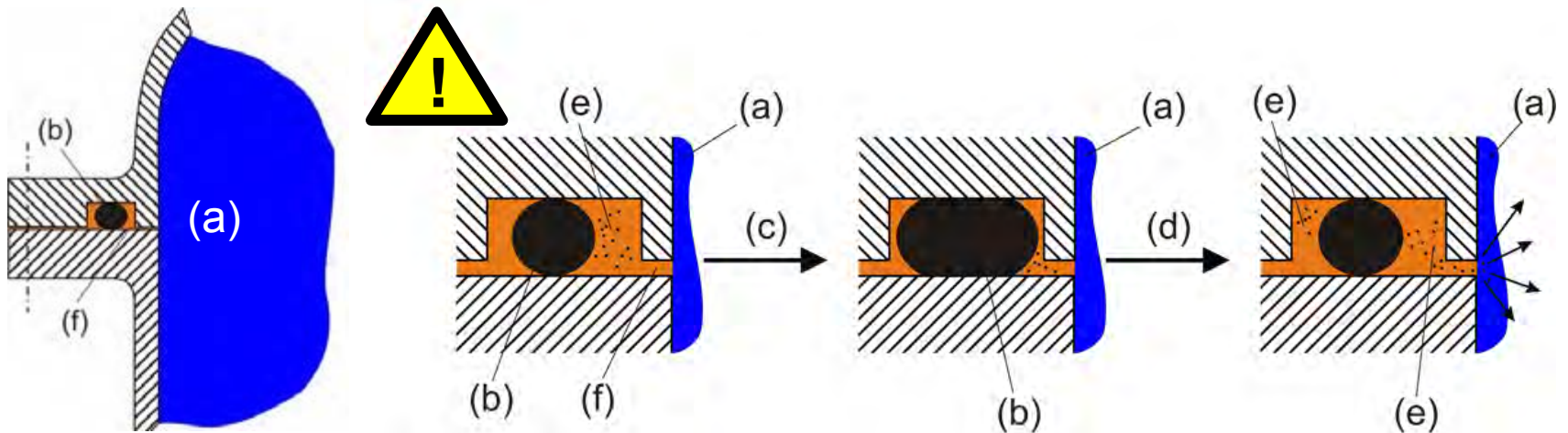


Source: Lorenzen, Tuchenhagen GmbH

# Seals

## Static seals

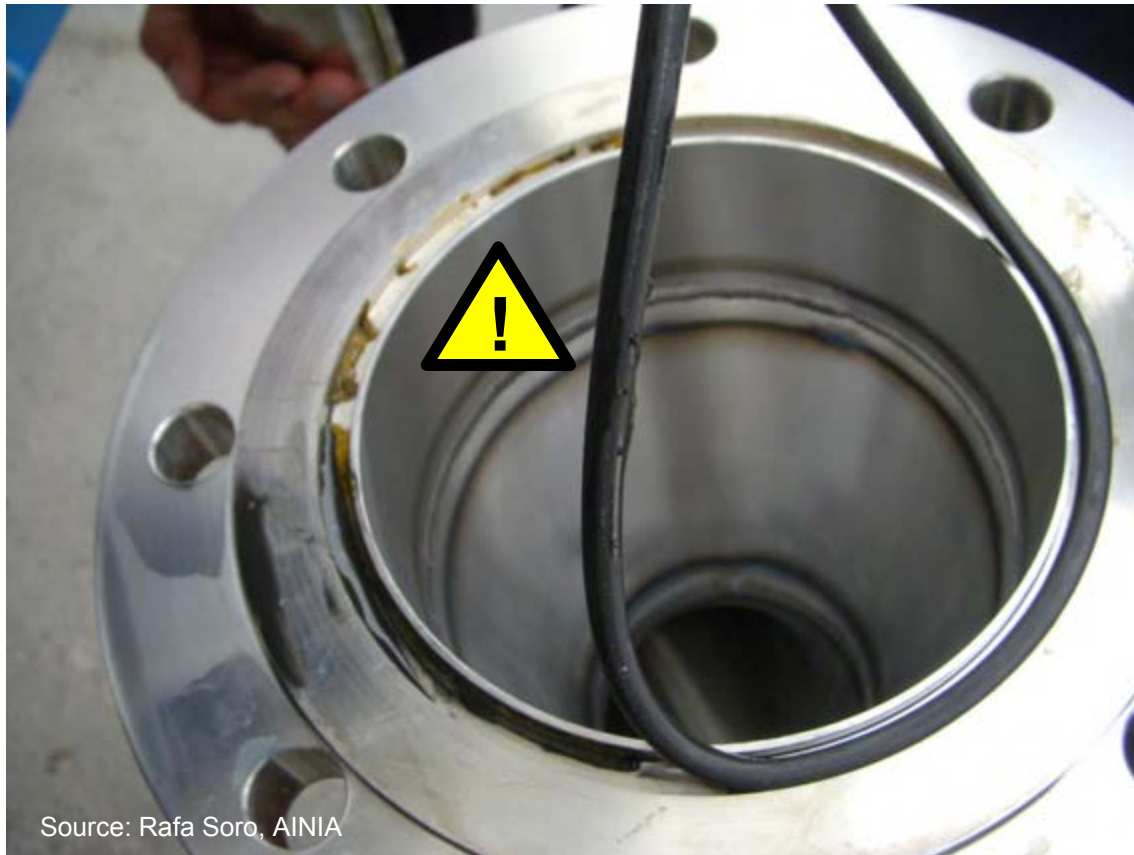
- no crevice on product side, surfaces must be precisely positioned
- O-rings in rectangular grooves have too much range of movement during strong temperature changes!



(a) product area, (b) elastomeric seal, (c) heating, (d) cooling, (e) micro-organisms  
 (f) gap

# Seals

## Static seals

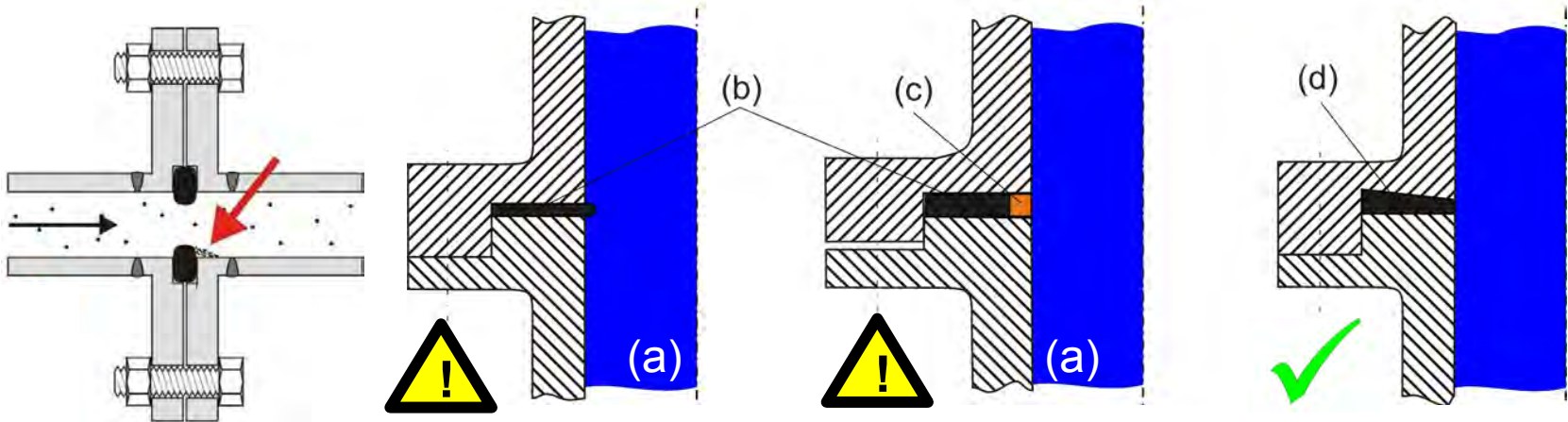


Source: Rafa Soro, AINIA

# Seals

## Static seal

- axial stop for controlled compression of the seal
- appropriate groove shape to avoid displacement and pinching
- shrink or expand with changes in temperature

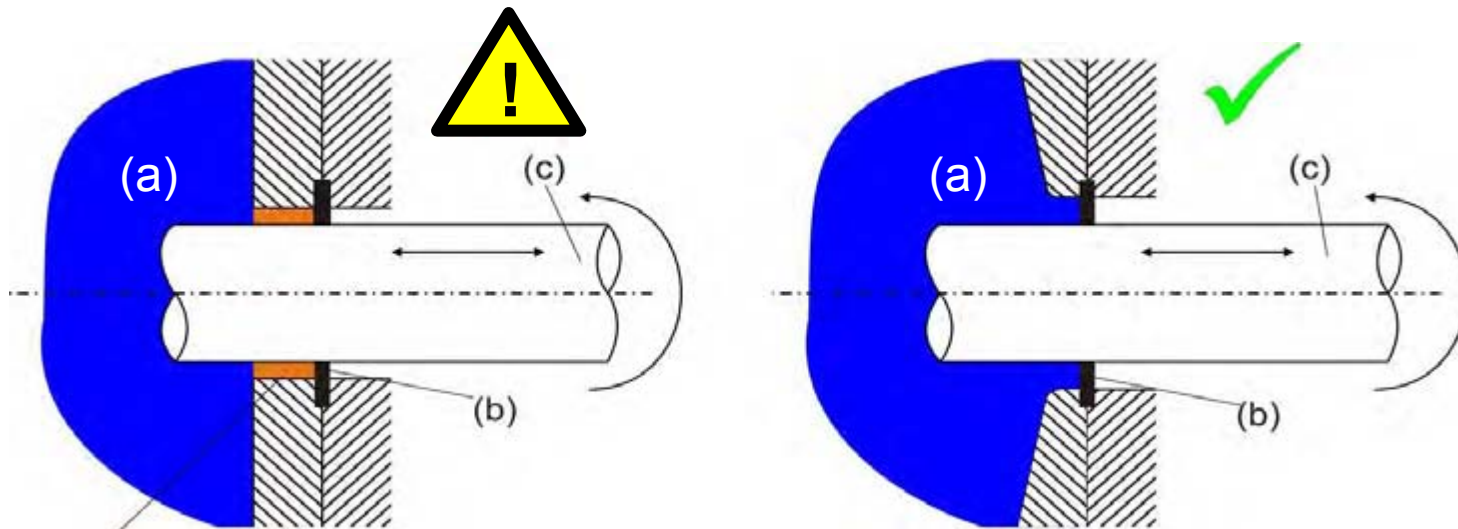


(a) product area, (b) elastomeric seal, (c) crevice, (d) sealing at the product area

# Seals

## Dynamic seal

- seals that slide into and out of the product
- springs in product (mechanical seals)
- annular crevices

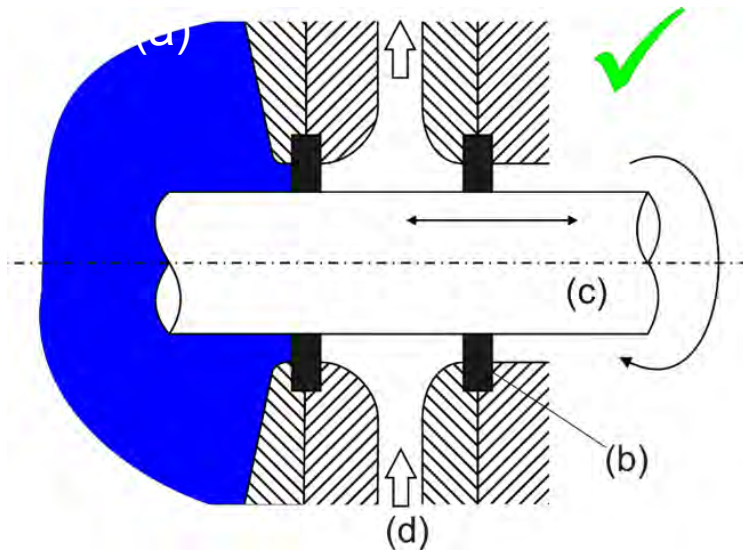


(a) product area, (b) dynamic seal, (c) reciprocating or rotating shaft, (d) gap

# Seals

## Dynamic seal

- membrane seals
- aseptic process: double seal and flushing of the barrier area



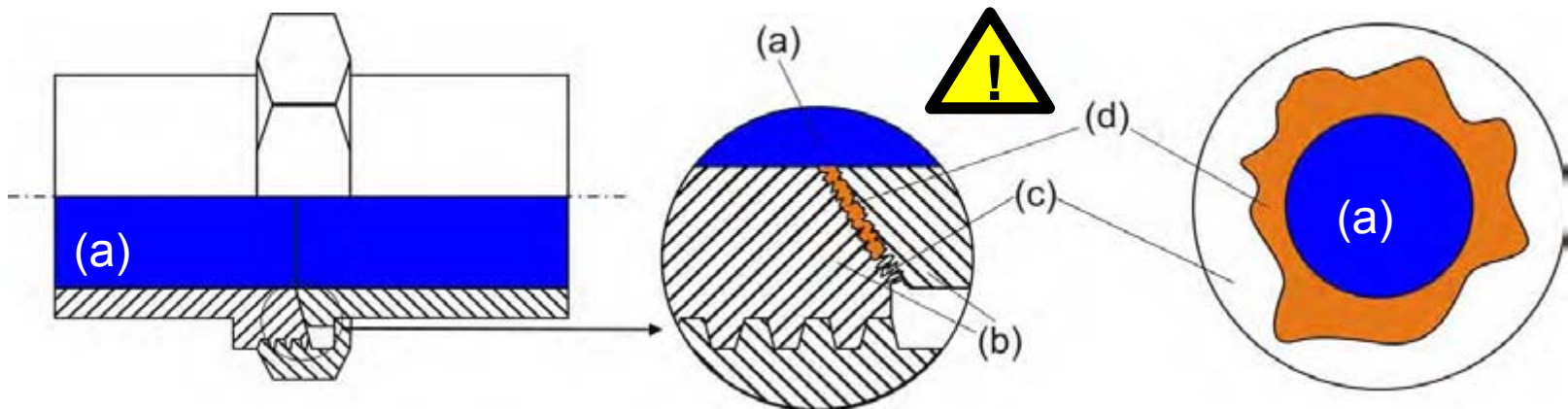
- (a) product area,
- (b) dynamic seal,
- (c) reciprocating or rotating shaft,
- (d) flushing chamber

- verification of flushing

# Pipe connection

## Requirements

- centering
- defined sealing pressure
- no crevice before sealing
- sealed by metal-polymer combination, **avoid metal to metal contact**



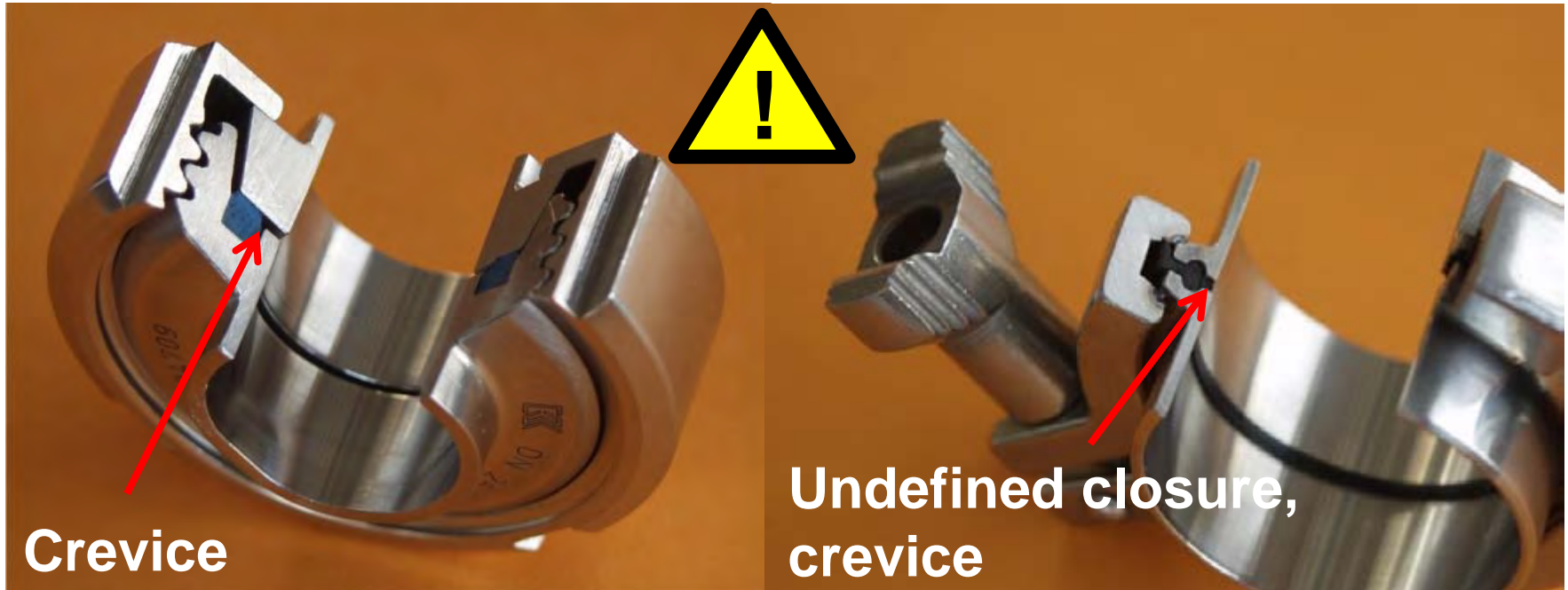
(a) product area, (b) metal coupling, (c) metal to metal contact area, (d) annular crevice



# Pipe connection

## DIN 11851

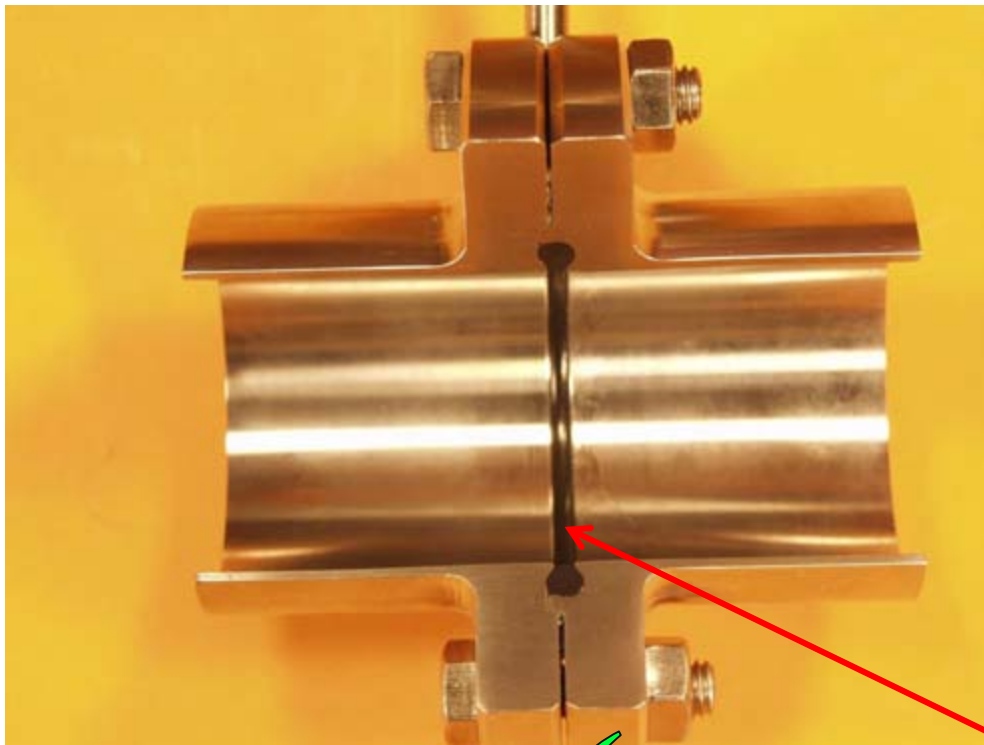
## Clamp ISO 2852



Source: Jürgen Hofmann

# Pipe connection

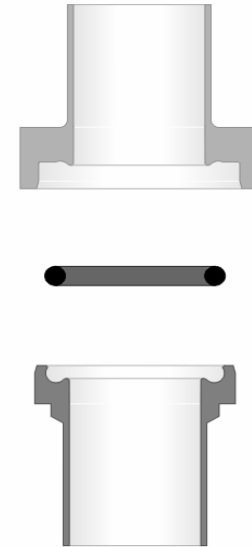
## DIN 11864-2 Form A, DIN 11853-2



Source: Jürgen Hofmann

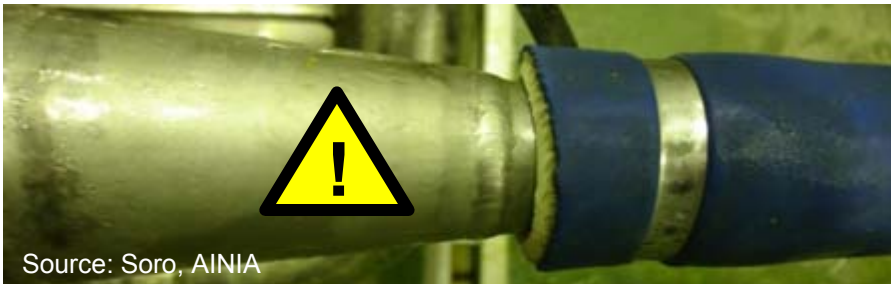
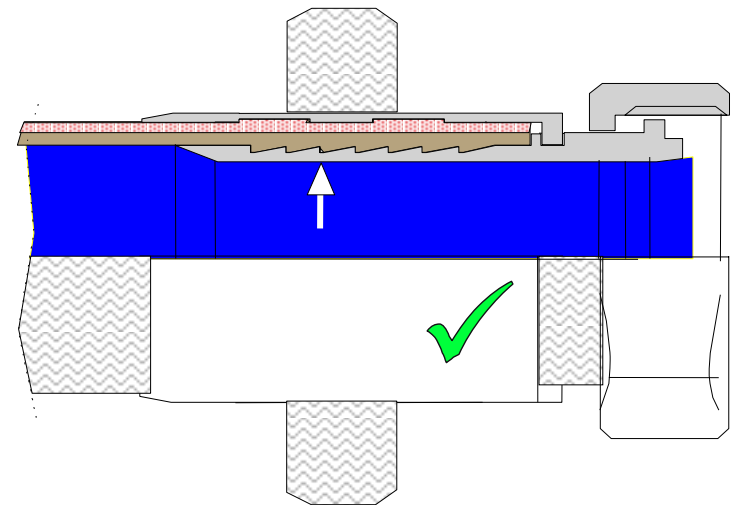
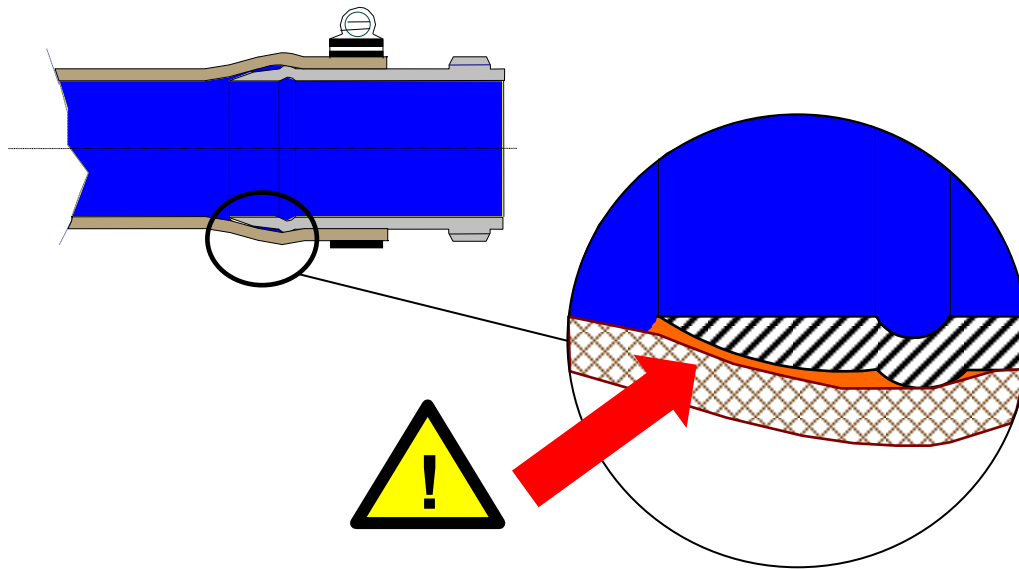


Centered sealing with defined compression



## Pipe connection

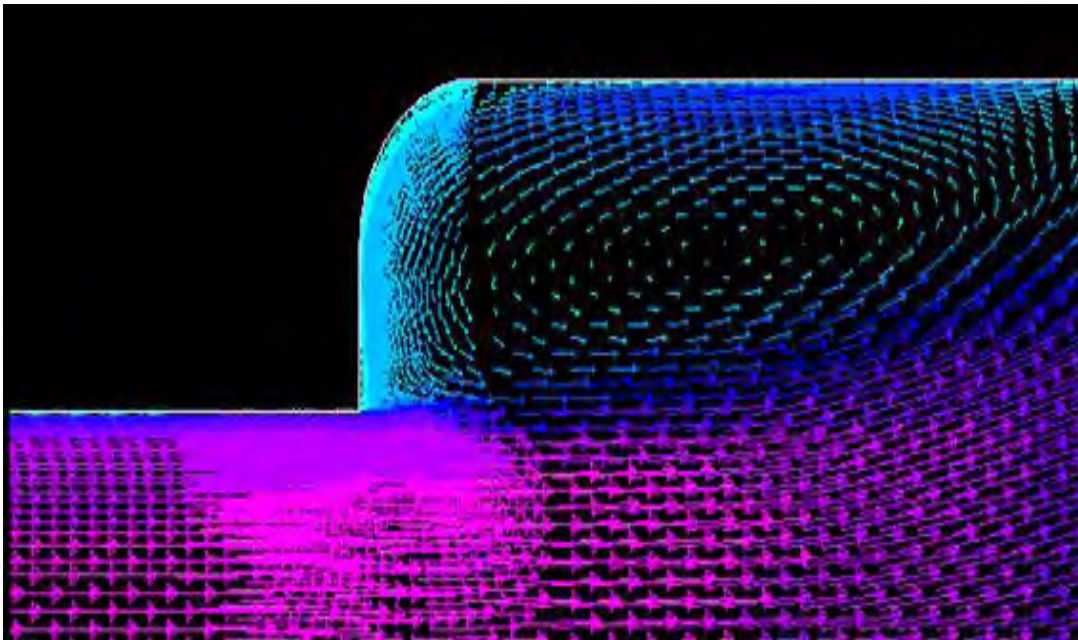
### Flexible Connections



Source: Soro, AINIA

# Pipe expansion

- cleaning requires mechanical energy input
- design has to be customized accordingly! – less flow disturbance



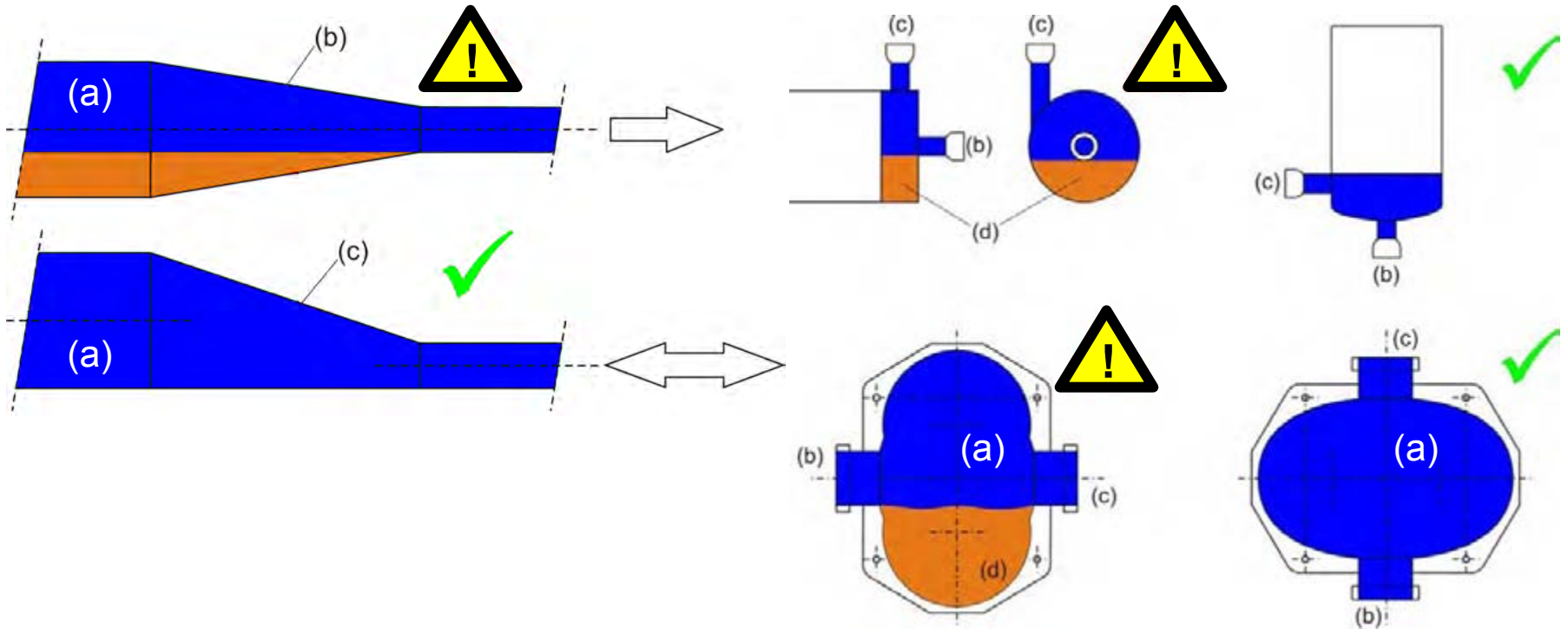
Water, 23 °C

Flow velocity:  $v=1,5$  m/s

Extent from  $\varnothing$  26mm to 38mm

Source: Inst. f. Chemische und Thermische Verfahrenstechnik, TU Braunschweig, 2009

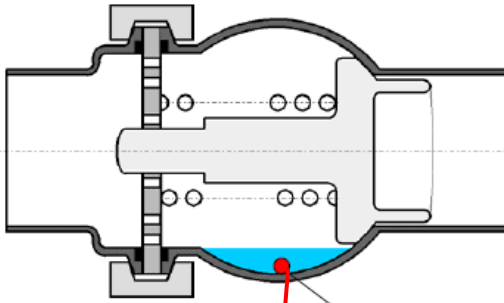
# Drainability



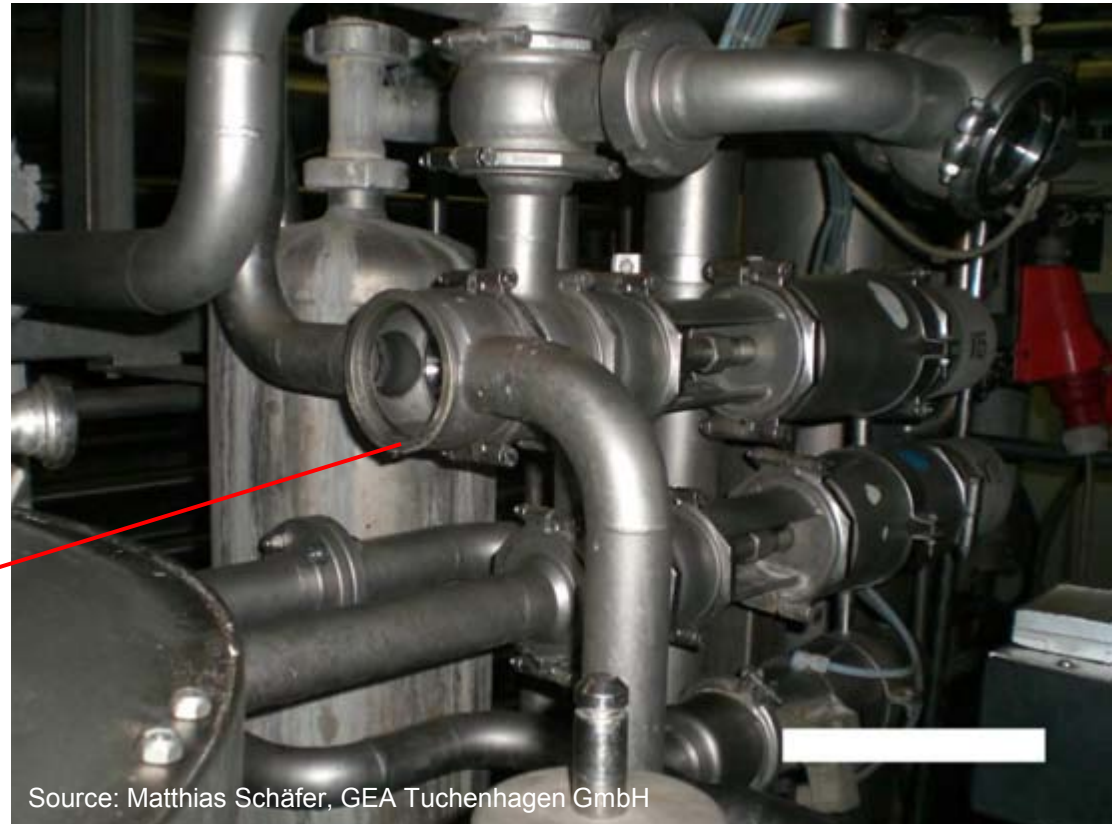
(a) product area, (b) concentric reducer,  
 (c) eccentric reducer, long version,

(a) product area, (b) inlet, (c) outlet,  
 (d) undrainable volume

# Drainability

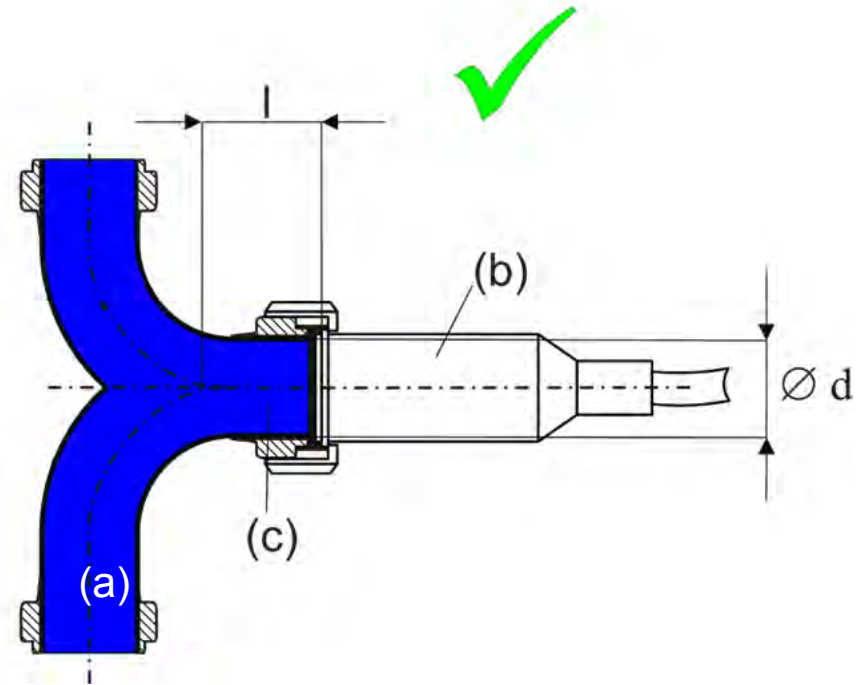
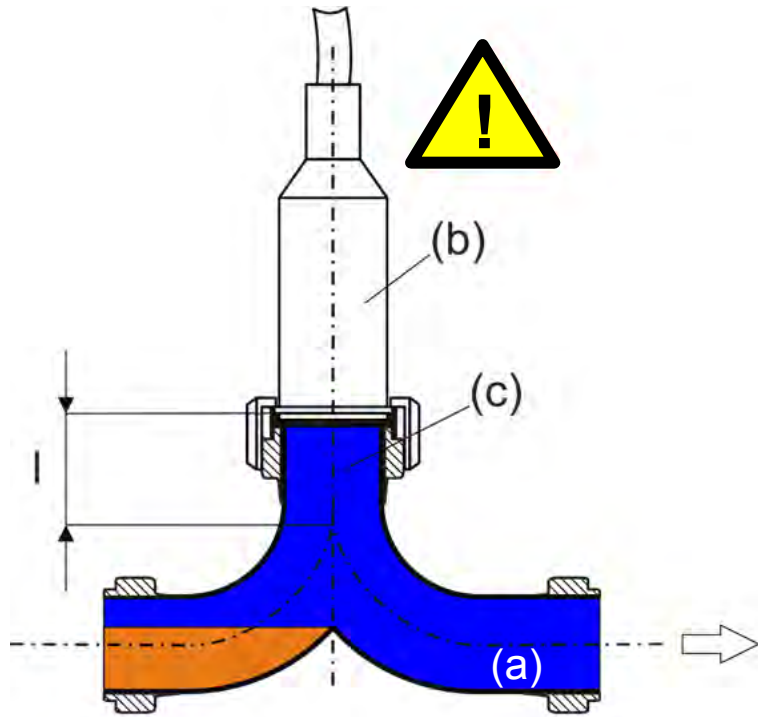


Sump area in a valve  
Not drainable in this  
position!



Source: Matthias Schäfer, GEA Tuchenhagen GmbH

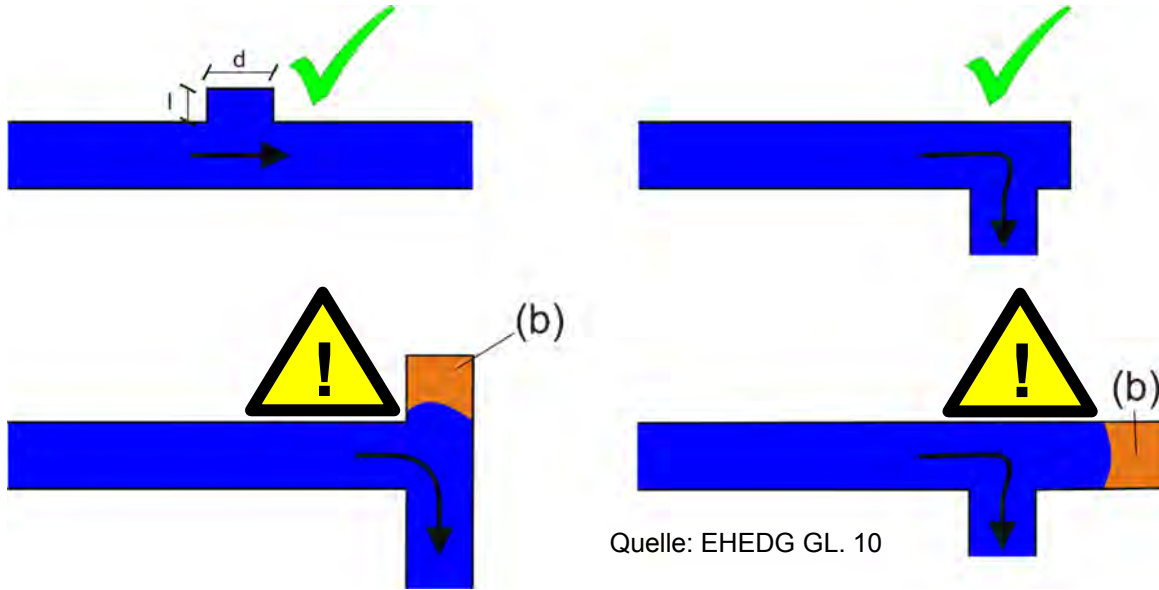
# Drainability



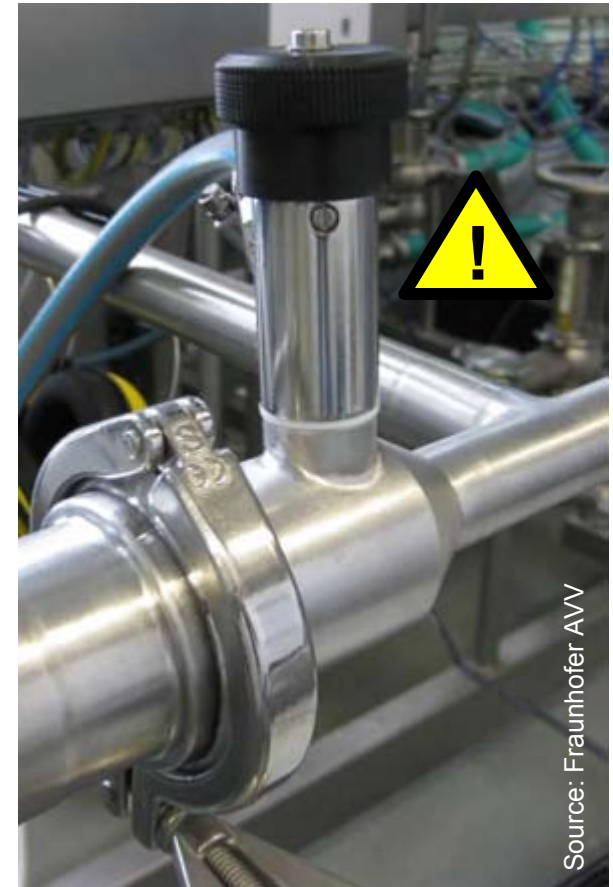
(a) product area, (b) sensor, (c) dead end

# T-pieces in CIP-cleaning

- avoid dead legs
- The configuration in pic. i) can be acceptable if the death leg is short ( $l/d < 1$ )



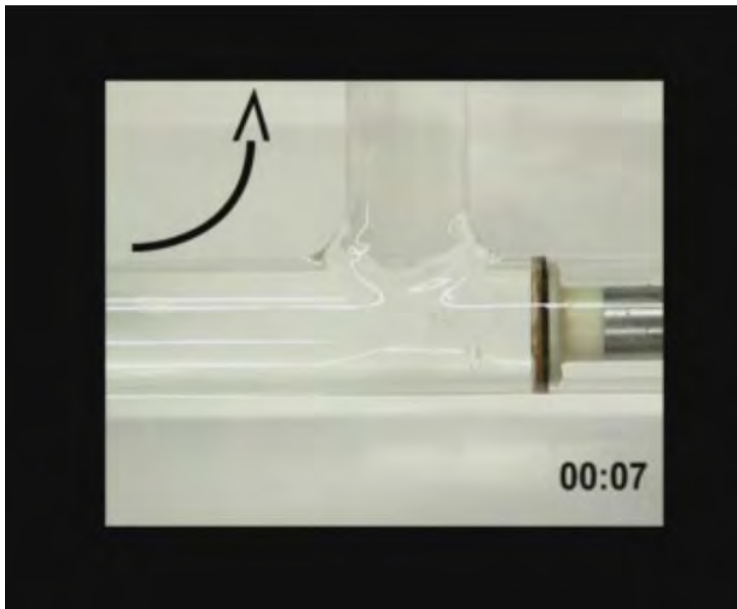
(b) dead leg with residual soil



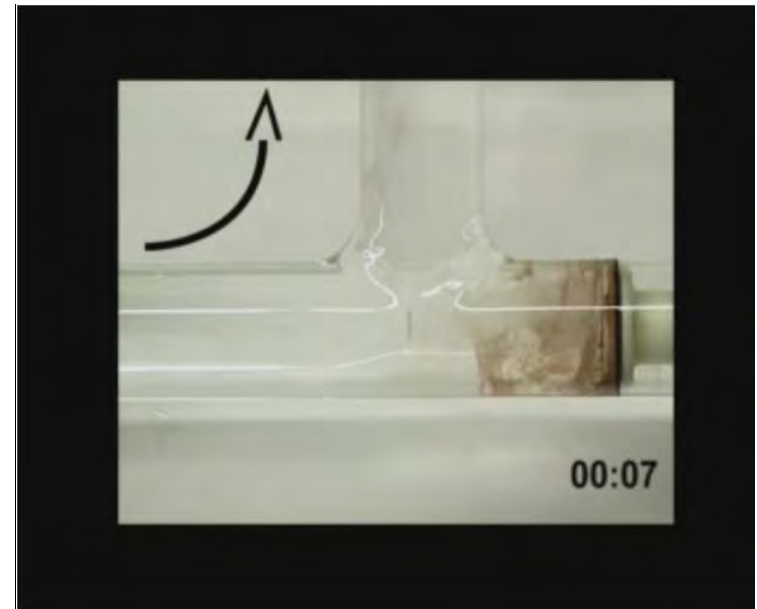
Source: Fraunhofer AVV



# T-pieces in CIP-cleaning



1.5 m/s  $D=50\text{mm}$ ;  $L/D=1.0$



1.5 m/s  $D=50\text{mm}$ ;  $L/D=1.5$



# Materials of Construction for Equipment in Contact with Food

# Content

- Introduction
- Regulations for the use of food contact materials
- Material of Construction - Austenitic stainless steels
  - Surface characterization - Roughness
  - Surface treatment
  - Influence of roughness on cleanability
  - Corrosion of stainless steel
- Material of Construction - Elastomers
- Material of Construction – Plastics
- Other materials

# Product contact surfaces

## Closed surfaces



Source: Lorenzen, Tuchenhagen GmbH

# Product contact surfaces

## Open surfaces



# Regulations for the use of food contact materials

## Directive 2006/42/EC

All surfaces in contact with foodstuffs, cosmetics or pharmaceutical products must:

- be smooth and have neither ridges nor crevices
- be easily cleaned and disinfected

The machinery must be so designed and constructed in such a way that these materials can be cleaned before each use.

**Where this is not possible disposable parts must be used.**

# Regulations of specific materials

- Directive 2002/72 plastic materials and articles intended to come into contact with foodstuffs
- Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food

## SUMMARY OF THE NATIONAL LEGISLATION

SANCO E6/MS(30/04/2010)

National legislation apply - : No national specific legislation

| Member States  | OTHER                               | Adhesives      | Ceramics       | Glass          | Enamel         | Metals Alloys | Cork | wood | Textile |
|----------------|-------------------------------------|----------------|----------------|----------------|----------------|---------------|------|------|---------|
| Austria        | -                                   | -              | +              | -              | +              | -             | -    | -    | -       |
| Belgium        | -                                   | -              | -              | +              | -              | +             | -    | -    | -       |
| Bulgaria       | -                                   | -              | -              | -              | -              | -             | -    | -    | -       |
| Cyprus         | -                                   | -              | -              | -              | -              | -             | -    | -    | -       |
| Czech Republic | -                                   | -              | +              | +              | +              | +             | +    | +    | -       |
| Denmark        | Mandatory registration <sup>1</sup> | -              | + <sup>2</sup> | +              | -              | -             | -    | -    | -       |
| Estonia        | -                                   | -              | -              | -              | -              | -             | -    | -    | -       |
| Finland        | -                                   | -              | -              | -              | -              | +             | -    | -    | -       |
| France         | -                                   | -              | +              | +              | +              | +             | -    | +    | -       |
| Germany        | -                                   | + <sup>3</sup> | + <sup>4</sup> | + <sup>4</sup> | + <sup>4</sup> | -             | -    | -    | -       |



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL  
Directorate E – Safety of the food chain  
E6 – Innovation and Sustainability

# Metals

## Product contact surfaces

### Stainless steel (austenitic)

|           |            |                   |
|-----------|------------|-------------------|
| EN 1.4301 | AISI 304   | X5CrNi18-10       |
| EN 1.4305 | AISI 303   | X8CrNiS18-9       |
| EN 1.4401 | AISI 316   | X5CrNiMo17-12-2   |
| EN 1.4404 | AISI 316L  | X2CrNiMo17-12-2   |
| EN 1.4435 | AISI 316L  | X2CrNiMo18-14-3   |
| EN 1.4541 | AISI 321   | X6CrNiTi18-10     |
| EN 1.4571 | AISI 316Ti | X6CrNiMoTi17-12-2 |



Source: Lorenzen, Tuchenhagen GmbH

- Currently there is no regulation regarding the use of different grades of stainless steel at European level.



# Metals

## Non-product contact surfaces

### Stainless steel

### Aluminium

- e.g.: Hardcoat anodization, Anodization

### Mild steel – surface coated

- e.g.: Active primer and metallic top coat
- e.g.: Nickel plating

# Austenitic stainless steels

## Alloying components

- alloy of iron, carbon, chrome and nickel, at least 18% chrome and 8% nickel

## Properties

- malleable and weldable
- non magnetic
- high resistance to corrosion

## Operating range (food, drug, biotechnology)

- construction of apparatus and container
- piping and components

## General operating ranges

### Products with low chloride content

- AISI 304 or EN 1.4301 (Caution: Pitting)

### Products with chlorides, moderate temperature (<60°C)

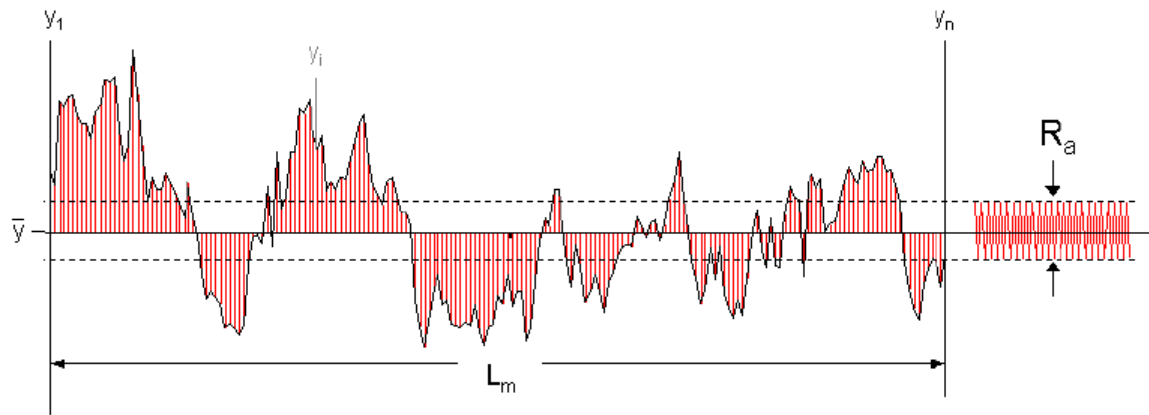
- AISI 316 or EN 1.4401 (Caution: Stress cracking corrosion)
- AISI 316L or EN 1.4404

### Products with chlorides, high temperature (60-150°C)

- AISI 410 or EN 1.4006 (no stress cracking corrosion)

# Surface characterization

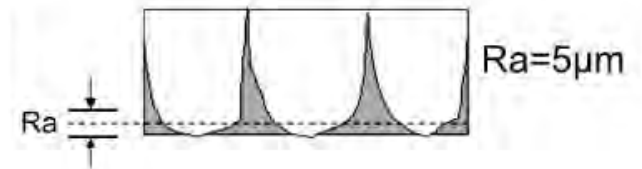
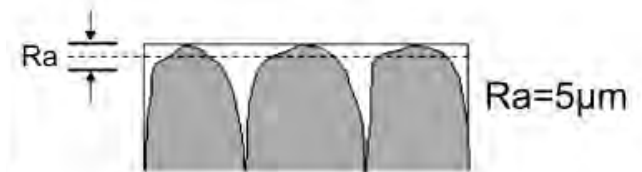
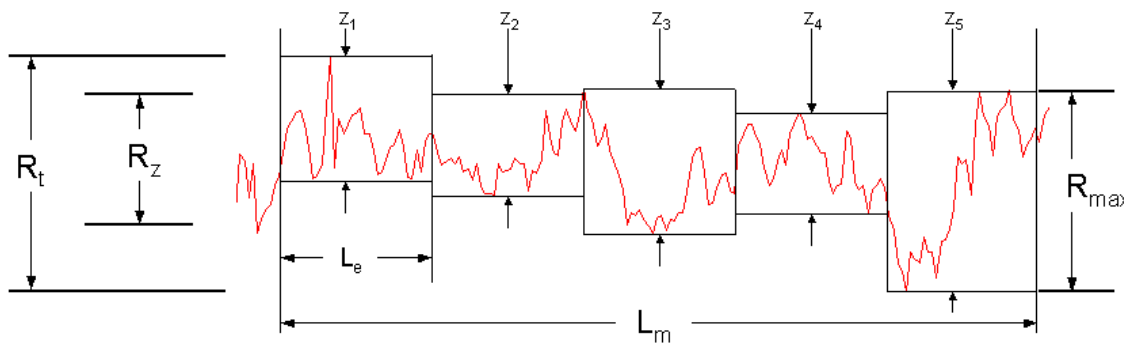
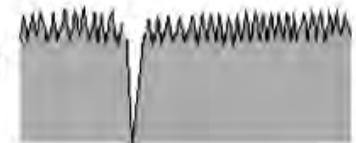
## Arithmetic average of roughness $R_a$ , Average distance $R_z$



$R_a = 2,4\mu\text{m}$



$R_a = 3\mu\text{m}$



Source: Alfredo Calvimontes, Topographic characterization of polymer materials at different length scales and the mechanistic understanding of wetting phenomena, PhD Thesis, TU Dresden

# Surface treatment - Electropolishing

## Definition

removing material from a metallic work piece (minimum 15  $\mu\text{m}$ ) by using DC and acid (mixture of phosphoric and sulphuric acid)

## Results

- Surface profile is smoothed in micrometre range
- Low surface roughness, inhomogeneous layers / structure will be removed
- Results a nonporous surface, which is free of cracks
- Excellent conditions for passivation and resistance to corrosion

# Surface treatment - Pickling

## Definition

- Acid is used to remove the surface impurities, such as scale, oxides, rust...

## Aim

- Preparation of stainless steel surface to achieve a tight passive layer

## Process

- Dipping into a pickle bath (nitric acid and hydrofluoric acid), using pickling paste
- Rinsing with water to remove acid completely

## Result

- Resulting surface roughness is coarser than from electropolishing

# Surface treatment - Passivation

## Definition

Formation of an oxide layer (passive layer), usually chromium oxide.

## Process

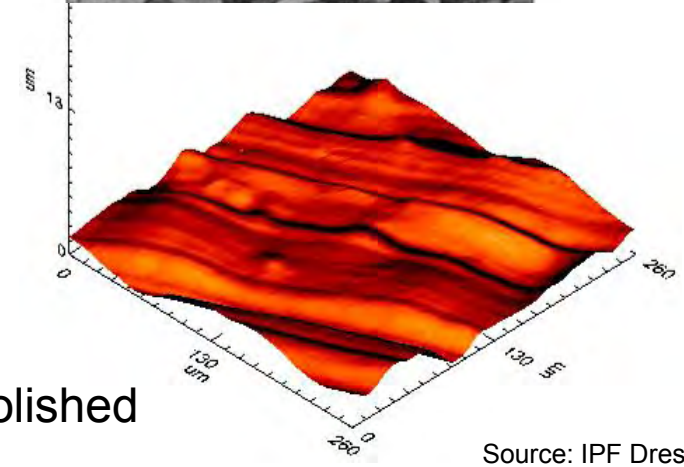
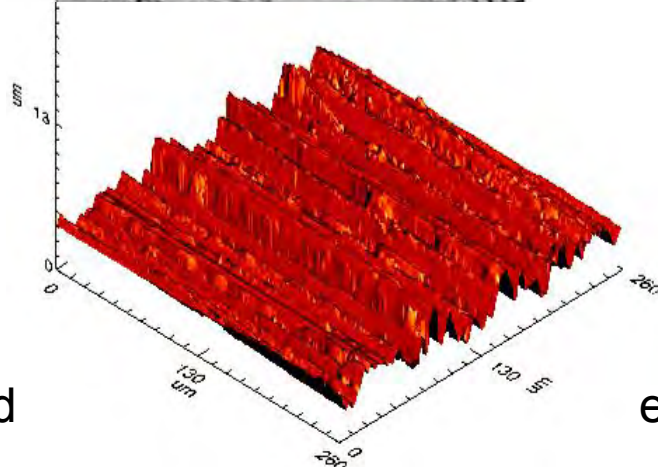
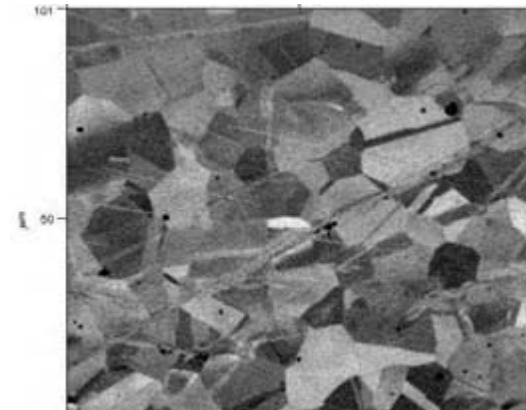
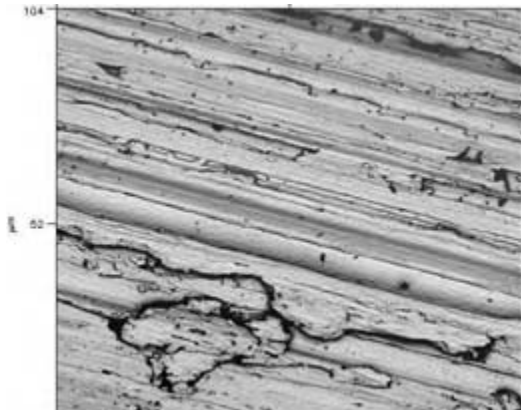
Treatment with an oxidizing acid (e.g. nitric acid, high concentration).

Passivation should be repeated at larger intervals.

# Surface treatment - Grinding

Ra = 1µm, K 150

Ra = 0,6µm



ground

electropolished

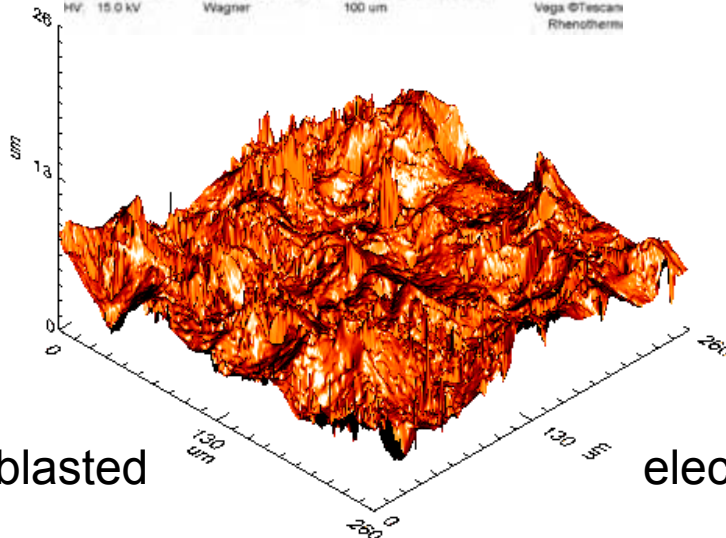
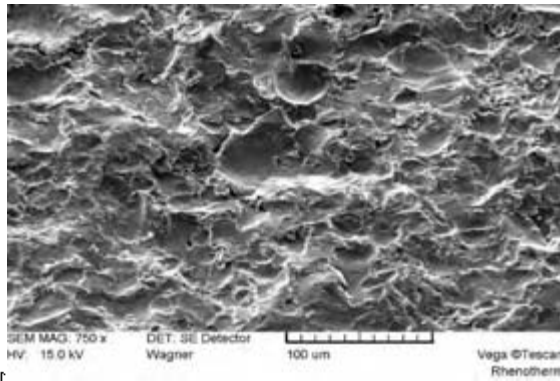
Source: IPF Dresden



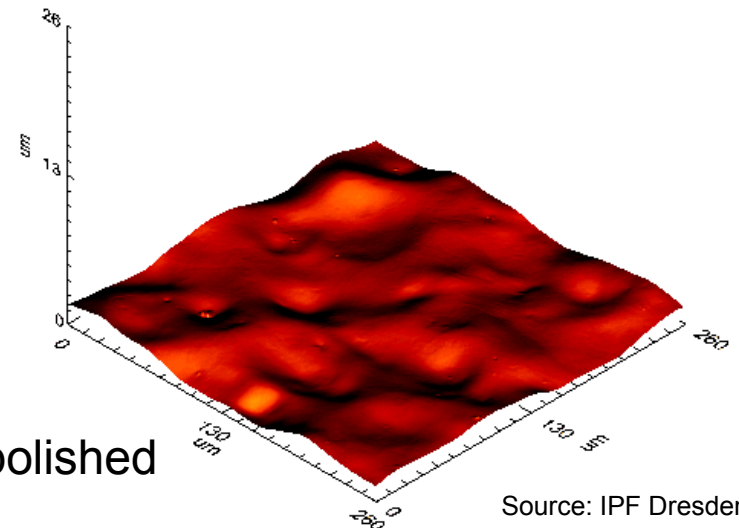
# Surface treatment - Bead blasting

Ra = 0,9µm

Ra = 0,4µm



bead-blasted

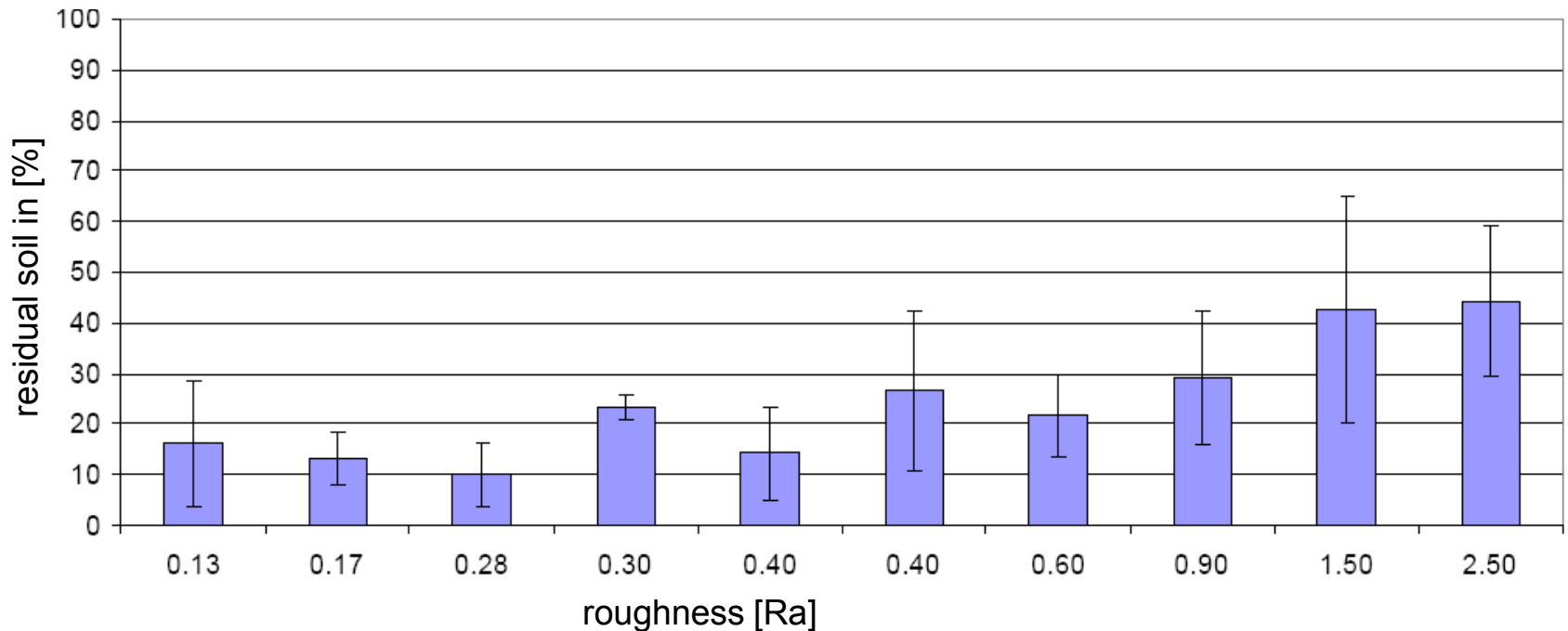


electropolished

Source: IPF Dresden

# Influence of roughness on cleanability

## Closed cleaning – EHEDG in-place cleanability test

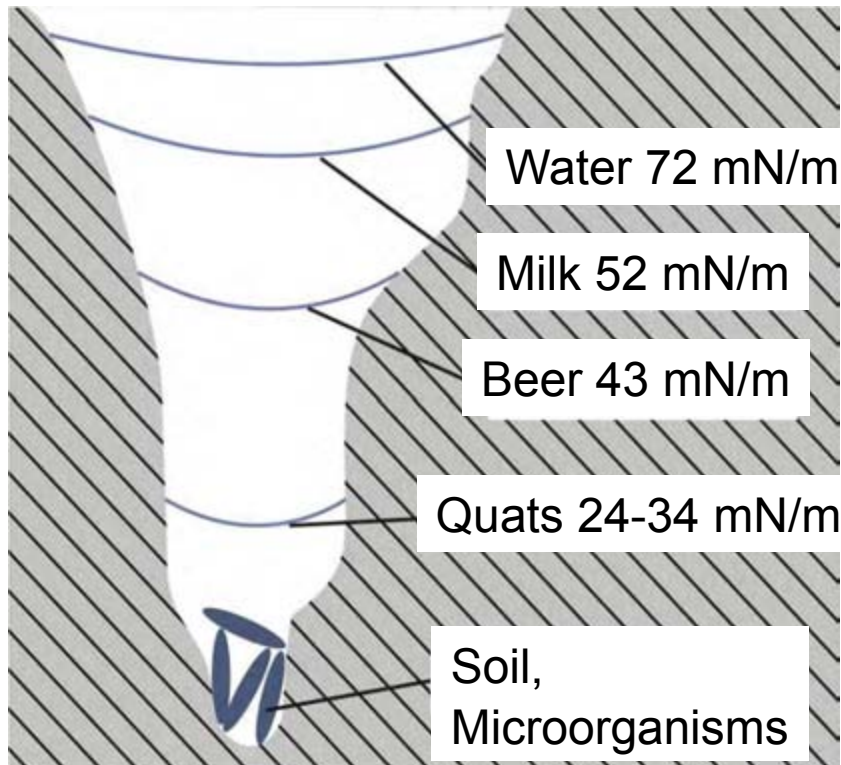


Influence of roughness tending to be low

Source: Bobe, AiF ZN210

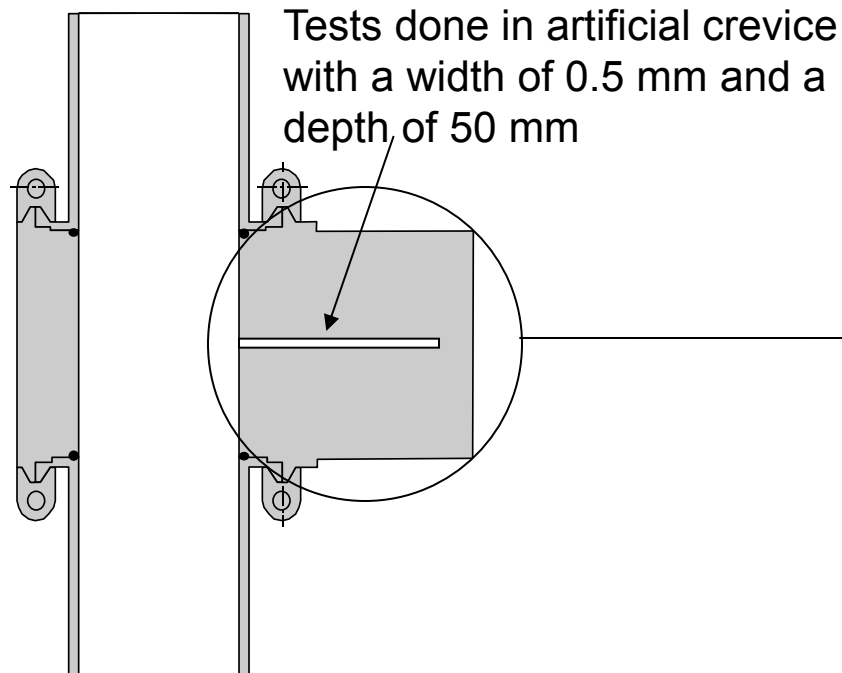
# Effects of crevices

## Growth of MO in welds - Penetration behaviour of liquids



# Protection of MO by soil and geometry

## Test unit for testing protection of microorganism by soil in crevices



GEA Tuchenhagen VARINLINE®  
Process Connection with artificial crevice

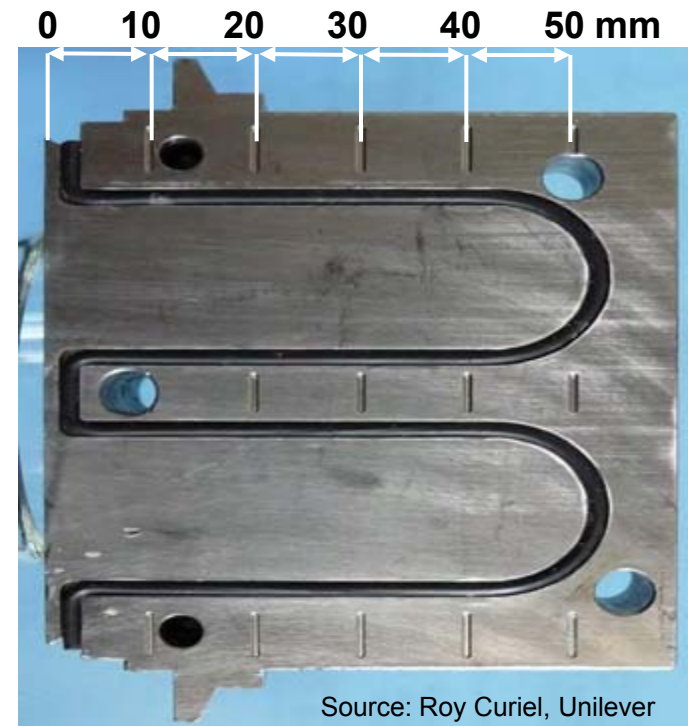
Internal part of test unit



# Protection of MO by soil and geometry: Against chemical disinfection

- Inactivation of *B. Subtilis* by Peracetic Acid in the presence of soil in crevices.
- In water a PAA concentration of 264 mg/kg will give 8 log reduction in 10 minutes

|                          |         | Log reduction |     |     |
|--------------------------|---------|---------------|-----|-----|
|                          |         | 10            | 30  | 30  |
| Contact time (min)       |         | 10            | 30  | 30  |
| PAA (mg/kg)              |         | 264           | 264 | 330 |
| DEPTH<br>crevice<br>(mm) | 0 - 10  | 0.7           | 0.9 | 1.0 |
|                          | 10 - 20 | 0.6           | 0.7 | 0.9 |
|                          | 20 - 30 | 0.4           | 0.6 | 0.8 |
|                          | 30 - 40 | 0.4           | 0.7 | 0.8 |
|                          | 40 - 50 | 0.5           | 0.7 | 0.9 |



# Corrosion

Localised corrosion (pitting) is most frequently encountered corrosion of stainless steel esp. in the presence of halides (chlorides).



Sources of chlorides in food industry:

**Supply Waters:** e.g. heating, cooling, or process fluids

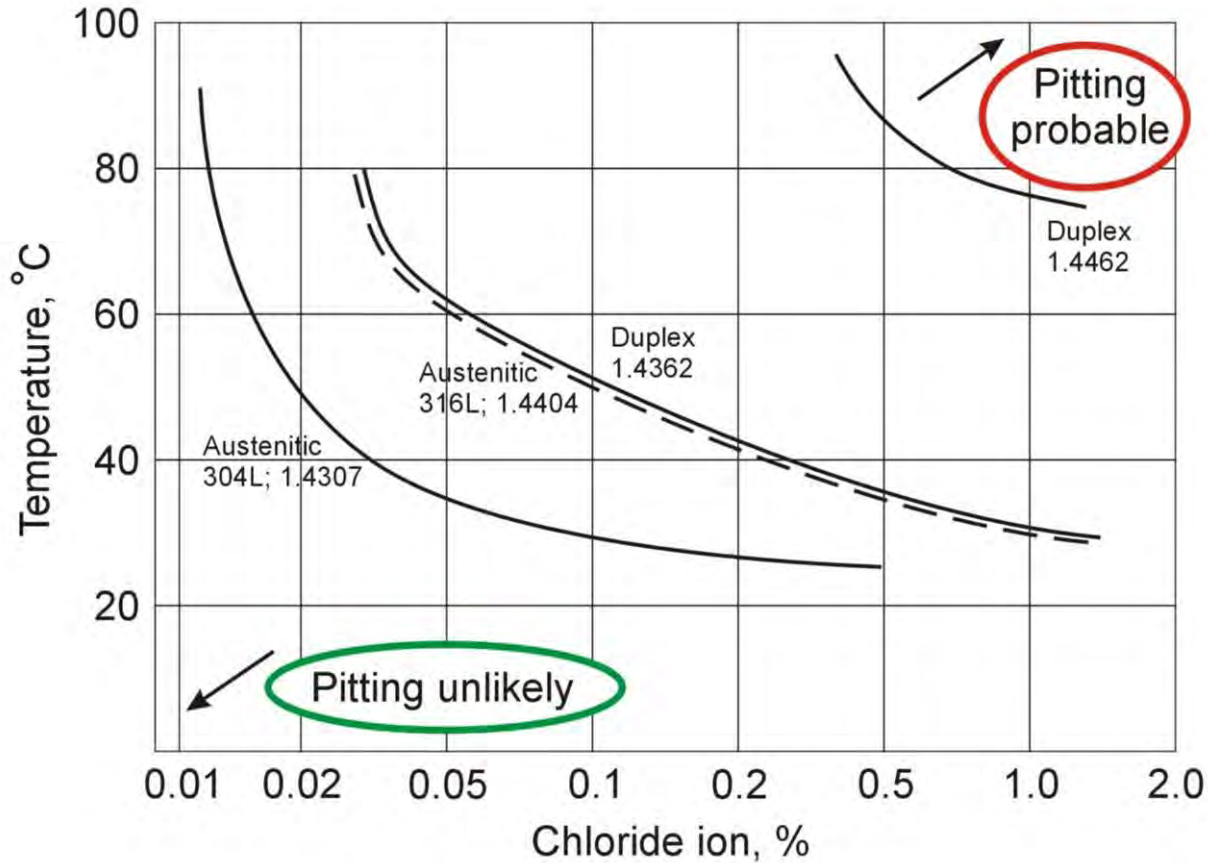
**Detergents and Sanitising Formulations:** Some are based on sodium hypochlorite or organic chlorine donors

**Brines:** widely used in food processing, mainly as refrigerants, but are sometimes essential to the preparation of foods (cheeses, meats or dry products)

**Products:** Many foods contain sodium chloride.

Source: Eric Partington, Nickel Institute, Brüssel

# Corrosion Resistance

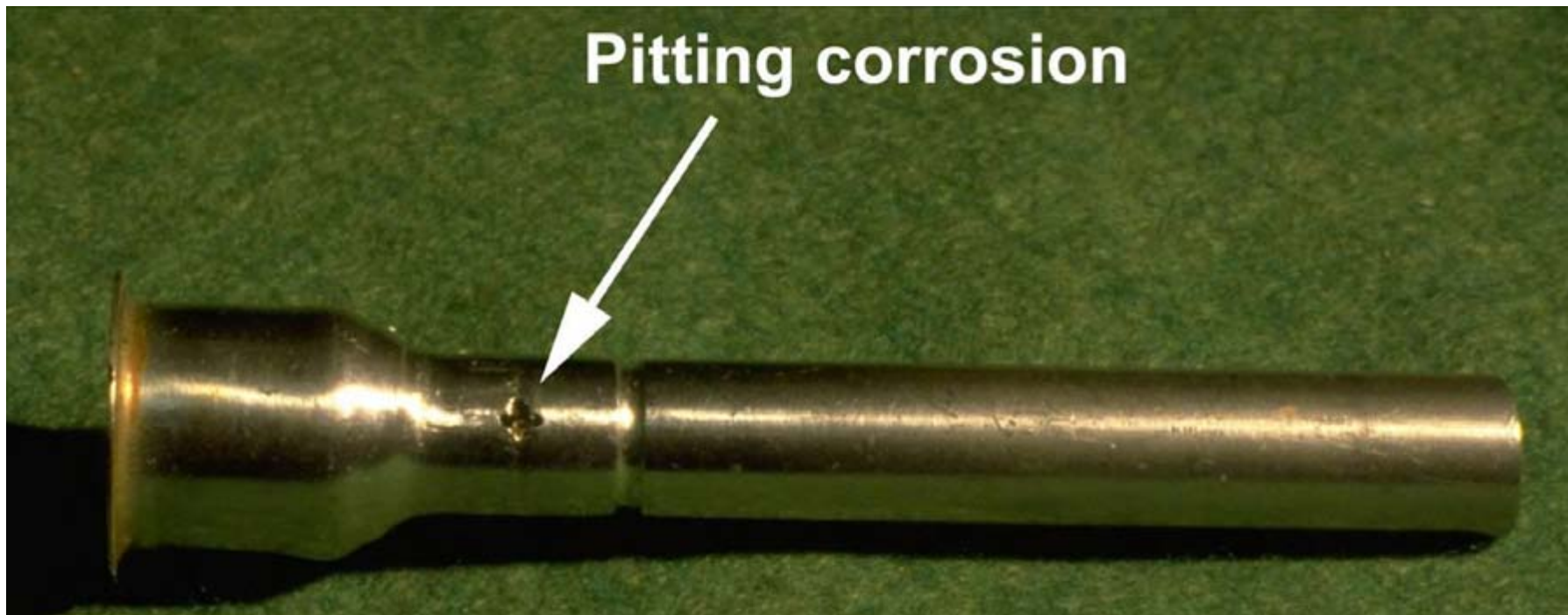


Source: Eric Partington, Nickel Institute, Brussels



# Types of corrosion

## Pitting corrosion



Source: Eric Partington, Nickel Institute, Brussels

# Types of corrosion

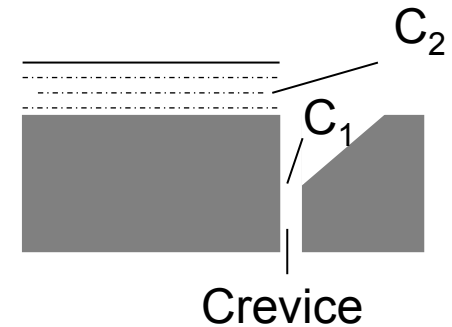
## Pitting corrosion



# Types of corrosion

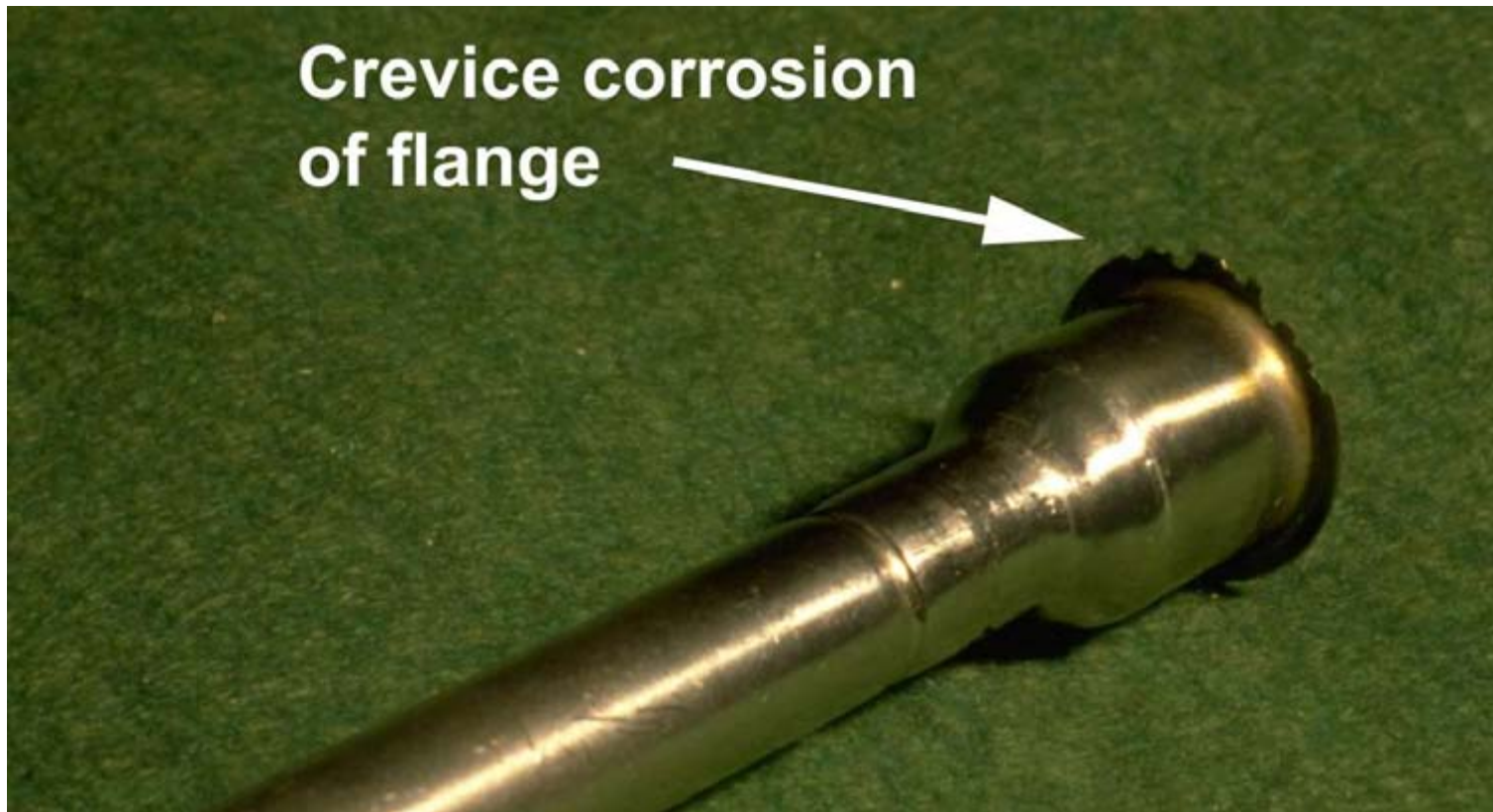
## Crevice corrosion

- requires presence of crevices
- may be constructive or operational (e.g. deposits)
- same mechanisms like pitting



# Types of corrosion

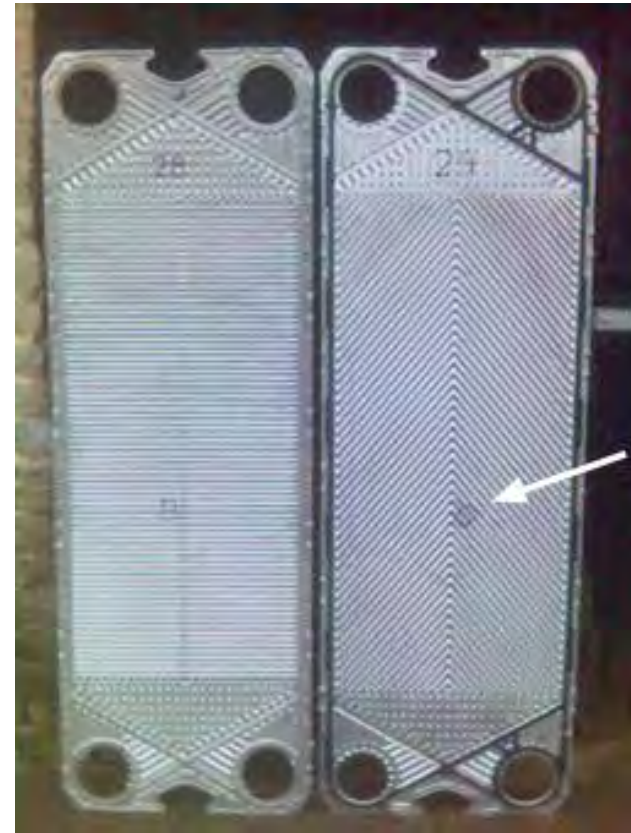
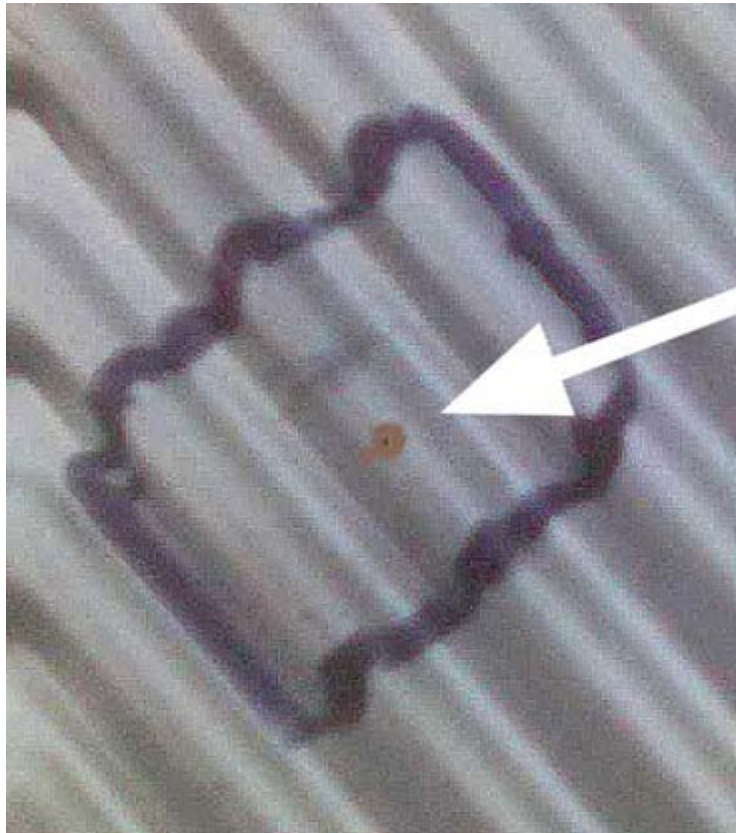
## Crevice corrosion



Source: Eric Partington, Nickel Institute, Brussels

# Types of corrosion

## Crevice corrosion



Source: Eric Partington, Nickel Institute, Brussels

# Types of corrosion

## Stress corrosion cracking

- requires simultaneous presence of 3 conditions:

- I. Surface is under tensile stress,
- II. Influence of a special medium (mostly chloride ions),
- III. Disposition of the material to stress corrosion cracking

- austenitic CrNi- and CrNiMo-steel is more sensitive to stress corrosion cracking than (austenitic-) ferritic steels



Static or dynamic tensile stress

# Types of corrosion

## Stress corrosion cracking



Source: Diversey

# Types of corrosion

## Galvanic corrosion



Contact different metals



Source: Diversey



# Elastomers

## Properties

- highly elastic → preferred material for seals, gaskets and hoses
- is composed of a number of ingredients including polymers, fillers and plasticisers → can be optimised by giving the desired physical properties

## Swelling and shrinkage

- may absorb process fluids and swell
- may shrink as ingredients in the compound are degraded, dissolved or leached out
- also shrink or expand with changes in temperature
- EPDM can absorb oil, grease and swell

# EPDM / NBR exposed to gearbox oil (GL 8)

## Change of EPDM

- Test parameters: gearbox oil, 70°C, 75h
  - Increase in mass:
    - 0h: ~1,5g
    - 75h: 2,67g
    - >1,1g oil absorbed
  - Increase in diameter
    - 0h: ~45mm
    - 75h: ~58mm
    - Factor ~1,3



- Olive oil: increase in mass and diameter is less compared to gear box oil

# Elastomers

| Elastomer type        | Nominal range °C | Hot water | Steam (150°C) | Ozone     | UV        |
|-----------------------|------------------|-----------|---------------|-----------|-----------|
| <b>NBR</b>            | 40 to +120       | Excellent | do not use    | good      | poor      |
| <b>HNBR</b>           | -30 to +140      | Excellent | good          | good      | good      |
| <b>EPDM</b>           | -50 to +150      | Excellent | Excellent     | Excellent | Excellent |
| <b>VMQ</b>            | -60 to +200      | Excellent | poor          | Excellent | Excellent |
| <b>FKM</b>            | -20 to +200      | good      | good          | Excellent | Excellent |
| <b>FFKM</b>           | -15 to +260      | Excellent | Excellent     | Excellent | Excellent |
| <b>Cl or Br Butyl</b> | -40 to +130      | Excellent | Excellent     | good      | Excellent |



Just examples, ask seal manufacturers for specified applications

Source: Eric Partington, Nickel Institute, Brussels

# Elastomers

## Properties

### Compression Set

- a measure of the inability of a material to recover to its original dimensions after deformation to a specified strain

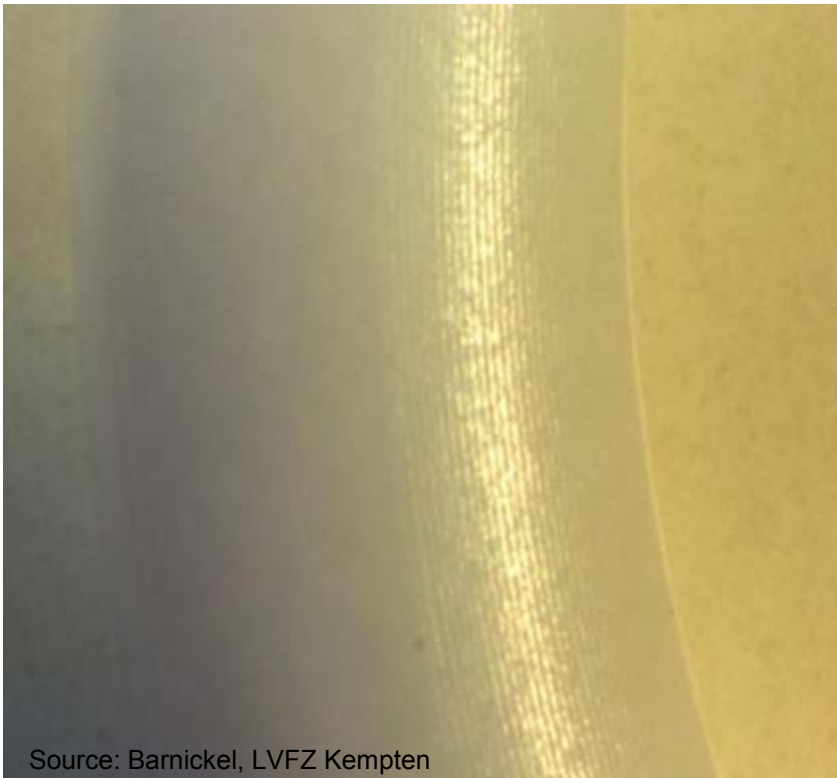
### Adhesion

- high temperatures also cause seal materials to adhere to the surfaces of their housing

Source: Eric Partington, Nickel Institute, Brussels

# Unused sealings

PTFE



EPDM

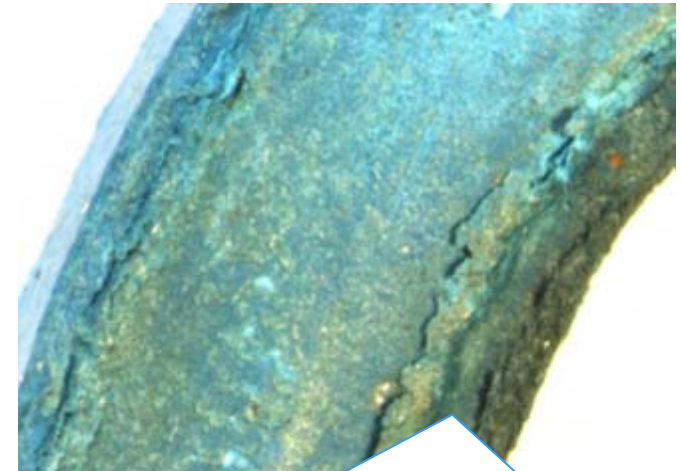


## Used EPDM sealings



Damage due to high compression

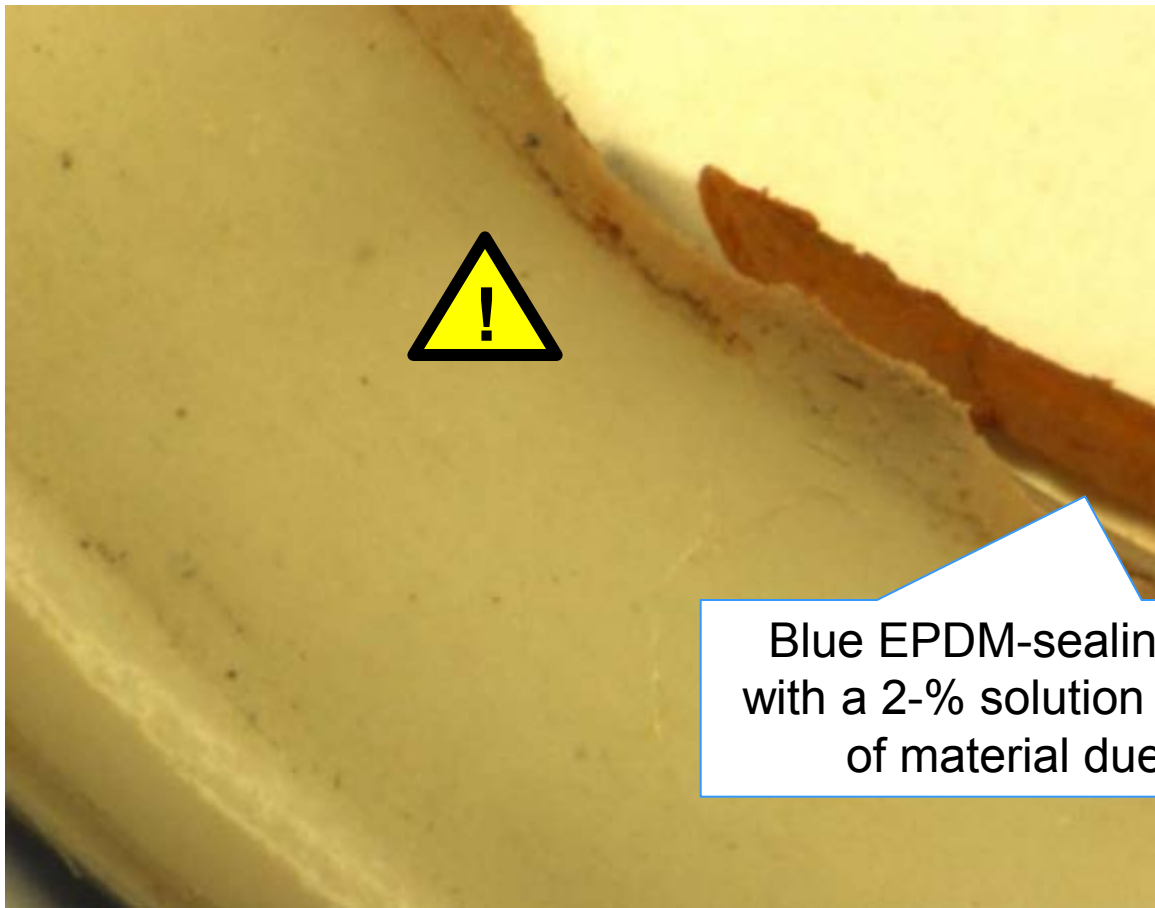
Sealing area was not in contact with product or cleaning fluid, influenced only by compression and heating



Brittle, cracked and porous EPDM-sealing, less softer on product contact areas

Source: Barnickel, LVFZ Kempten

## Used EPDM sealings



Blue EPDM-sealing, aged 6 month at 20 °C with a 2-% solution of sodium hydroxide, wear of material due to softener migration

Source: Barnickel, LVFZ Kempten


## Used EPDM sealings



Source: Barnickel, LVFZ Kempten



## Plastics

|   |                                 |                                    |
|---|---------------------------------|------------------------------------|
| PE  | (Polyethylene)                  | e.g. container                     |
| PP  | (Polypropylene)                 | e.g. components (potable water)    |
| PVDF  | (Polyvinyliden)                 | e.g. components (ultra pure water) |
| PTFE  | (Polytetrafluorethylene)        | e.g. components (coatings)         |
|  | 1. generation of PTFE is porous |                                    |
| PMMA  | (Polymethylmethacrylat)         | e.g. perspex                       |

- no general guidance on which plastic to use without consideration of the application

# Plastics

## Behaviour

### Ultraviolet light and ozone

- Exposure to ultra-violet radiation (such as from UV sterilising equipment or strong sunlight) or to ozone can result in embrittlement

### Hydrolysis

- many suffer from hydrolytic attack at elevated temperatures over extended periods of time (can lead to e.g. cracking, embrittlement or mechanical failure)

### Acidity

Many are pH-sensitive

- Polyvinylidene fluoride performs well in strongly acid environments
- Polyetheretherketone in strongly alkali environments - but not the other way round

Source: Eric Partington, Nickel Institute, Brüssel

# Plastics

## Behaviour

### Electrostatic charges

- many can collect an electrostatic charge when rubbed and this attracts dust and bacteria which will then adhere tenaciously
- anti-static agents must be food-approved

### Phase changes

- many undergo phase changes at specific temperatures

### Creep

- many polymers will behave in a plastic manner at low stresses → result in slow dimensional changes

# Plastics

## Behaviour

### Brittleness

- Plastic components may shatter under tensile, bending forces or under impact  
→ represent a hazard similar to glass

### Abrasion

- Polymers whose surfaces become abraded by solids or pastes may suffer from an increase in the accumulation of soils and biofilms and a reduction in cleanability

Source: Eric Partington, Nickel Institute, Brüssel

## Surface coatings

- Layer of a different material applied to a metal substrate

## Applications

- Anti-adhesive coatings (rollers, containers, screws, knives, guide rails)
- Potential for food contamination by flakes which have detached from the substrate
- Coating should be of contrasting color
- Colorant must be of food compatible material
- Consider sufficient adhesion to the substrate and durability over lifetime

## Materials used in Hygienic Design

- e.g. PTFE, FEP, PFA

# Ceramic materials

## Legislation

- Directive 84/500/EEC (some amendments, i.e. Directive 2005/31)

## Applications

- Bearings, mechanical seals, sensors, coatings etc.
- Excellent chemical, wear and high temperature resistance
- Brittleness may represent a hazard in some applications

## Materials used in Hygienic Design

- silicon carbide, aluminium oxide
- zirconia oxide, chrome oxide

# Glass

- Chemically stable
- Brittleness. Avoid in food contact surfaces that could suffer some impact.
- When used in the food industry in non food contact surfaces, impact resistance should be considered (i.e. as defined in NSF/ANSI 51 *Food Equipment Materials*).
- Recommendation for the food industry: have an internal written policy and documented controls in place for glass devices



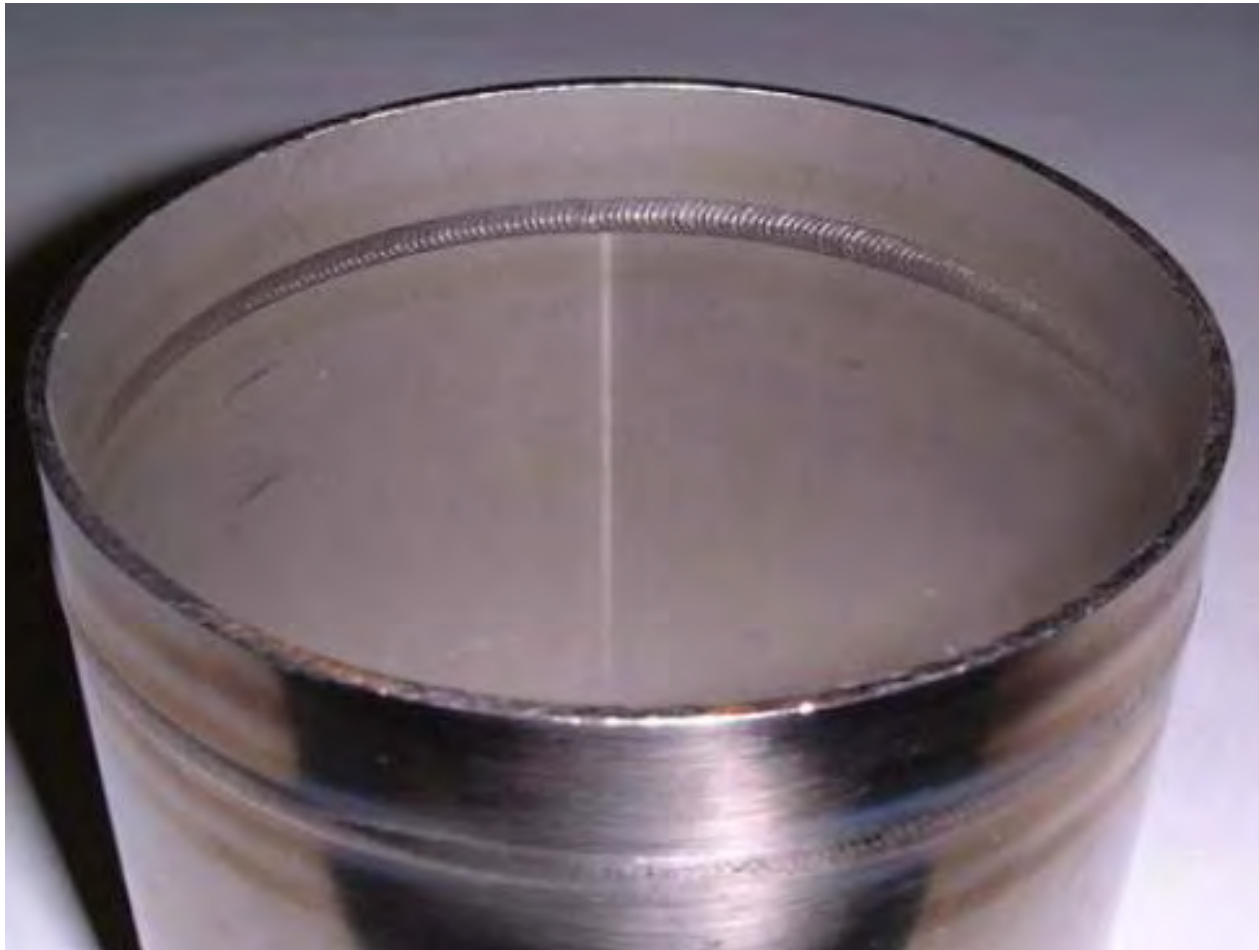
# Hygienic Welding Of Stainless Steel Tube Systems



# Content

- Introduction
- Welding technology
- Definition of an “ideal” hygienic weld
- Bad examples
- EHEDG welding guideline
- Practical tips to achieve better welds

# Introduction



# Introduction

Weld defects (e.g. cracks, porosities or oxidation) will cause

- increased adhesion of product
- potential for bacterial growth
- negative effects on cleanability
- potential for corrosion

A minimum microbial level in the process reduces the need for cleaning cycles  
→ enhancing efficiency of plants

The ideal “hygienic” weld is as easy to clean as the adjacent pipework

# Introduction

## Application area of welding

- if no detachable connections are necessary
- if geometry / material allows welding
- Results:
  - better cleanability
  - maintenance free in comparison with joints

# Welding technology



Source: Kopitzke, Arc Machines GmbH, Much




Source: Barnickel, LfL

Video

## Definition of an “ideal” hygienic weld

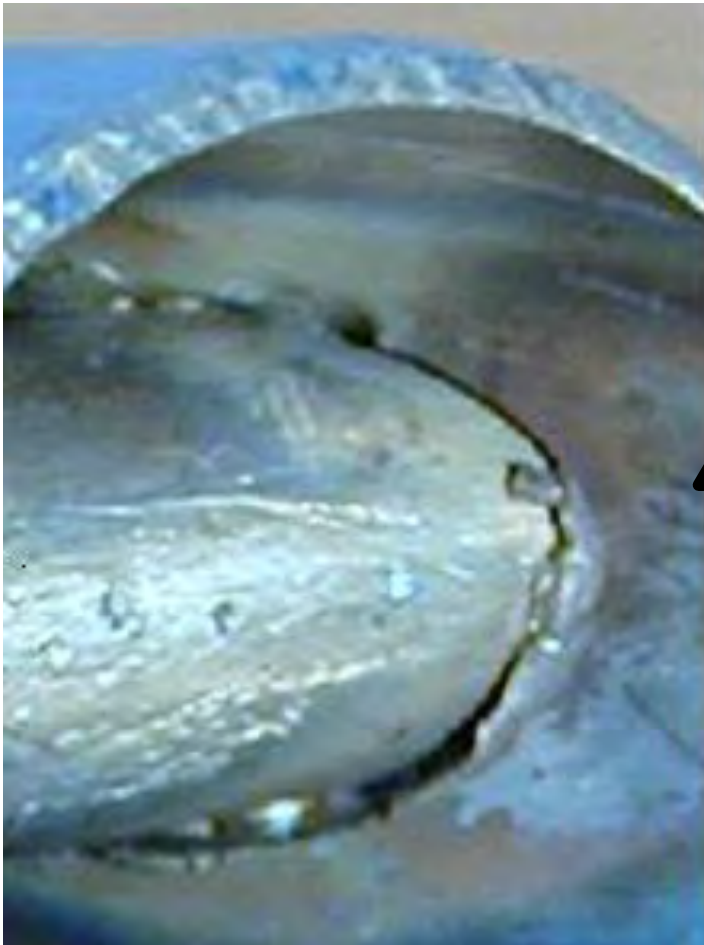
Although manual welding can achieve equally good individual results, but the required repeatability and consistency of the welds cannot be guaranteed with manual methods.



|                         |   |   |   |                                     |
|-------------------------|---|---|---|-------------------------------------|
| full penetration        | → |   | ← | no concavity                        |
| no cracks or pores      | → |   | ← | no convexity                        |
| no misalignment         | → |   | ← | no lack of fusion                   |
| no internal colouration | → |   | ← | minimal increased surface roughness |
| no inclusions           | → |   |   |                                     |
|                         |   | ↑ |   | no associated metallurgical changes |

Source: Kopitzke, Arc Machines GmbH, Much

# Bad examples



Source: Barnickel, LfL

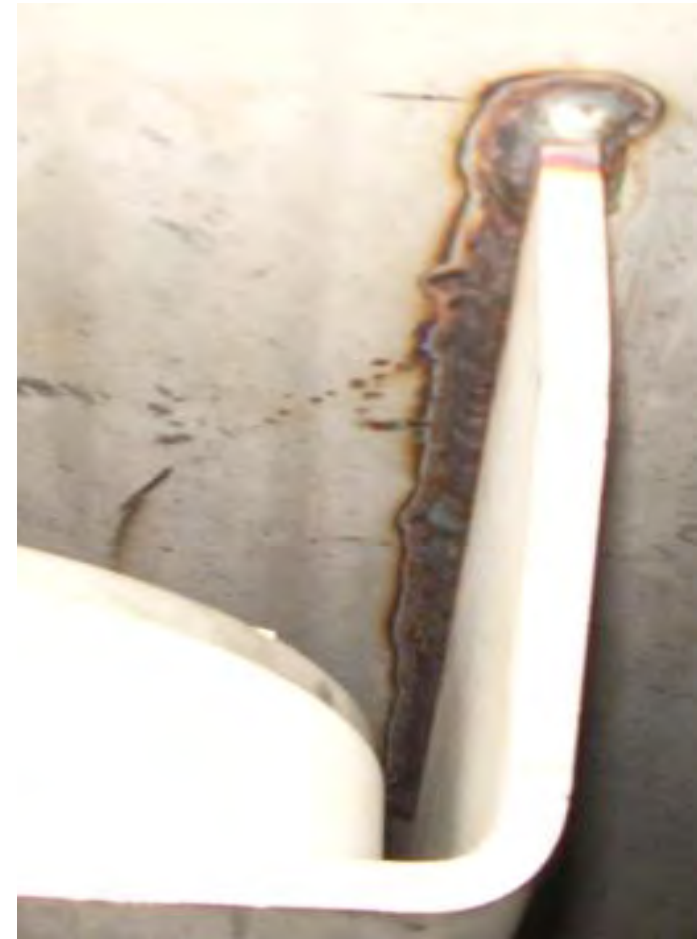


## Bad examples



Source: Barnickel, LfL

# Bad examples



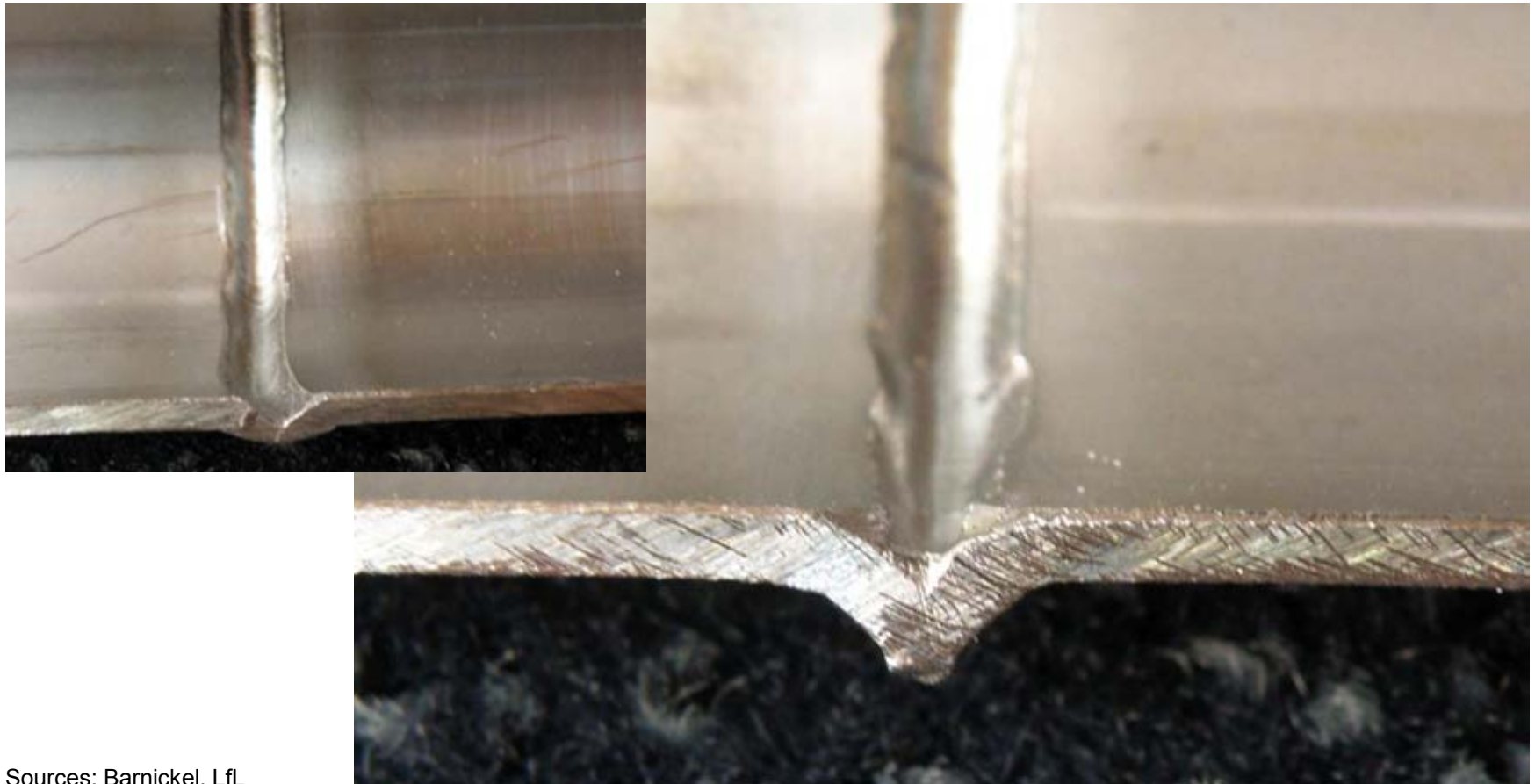
Source: Classen, DTI

# Bad examples



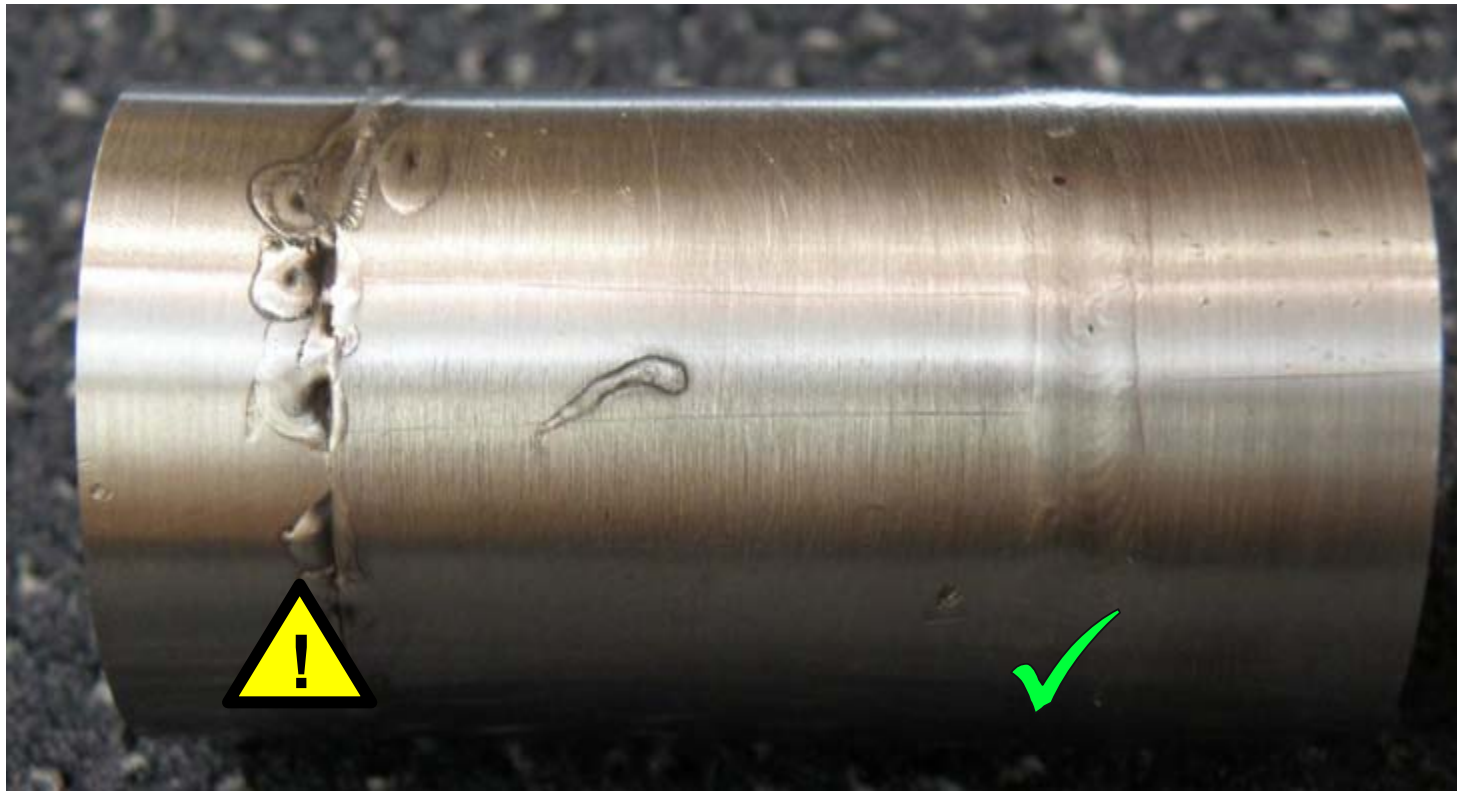
Source: Classen, DTI

# Bad examples



Sources: Barnickel, LfL

# Bad and good example



Sources: Barnickel, LfL

# EHEDG welding guideline

Document 35 defines the quantitative characteristics and geometrical values to assure hygienic acceptance of produced welds.

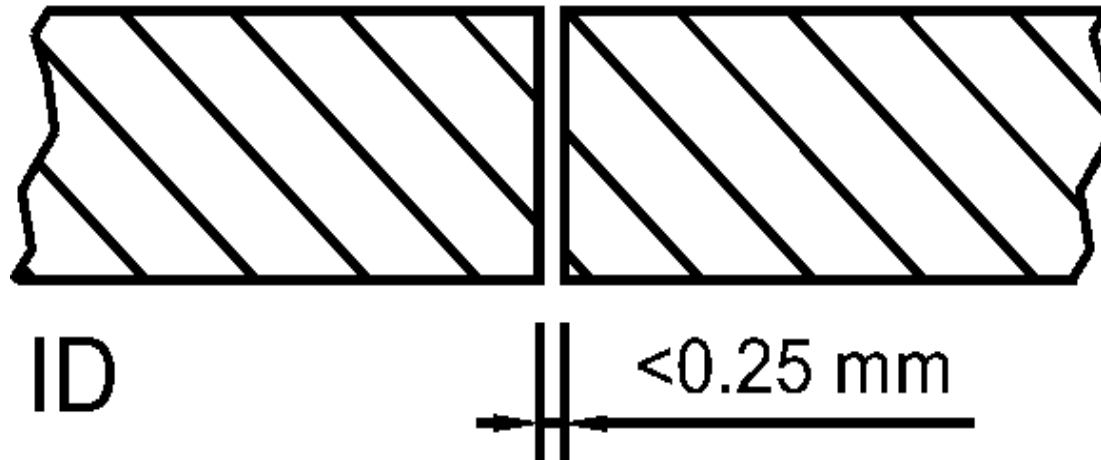
These parameters include:

- Gap before welding
- Misalignment
- OD concavity
- ID concavity
- Lack of penetration
- Convexity
- Weld bead width variation
- Weld bead meandering
- Cracks and cavities
- Arc strikes
- Inclusions
- Internal discolouration
- Tack welding

# EHEDG welding guideline

## Gap before welding

- less than 0.25 mm prior to welding is acceptable

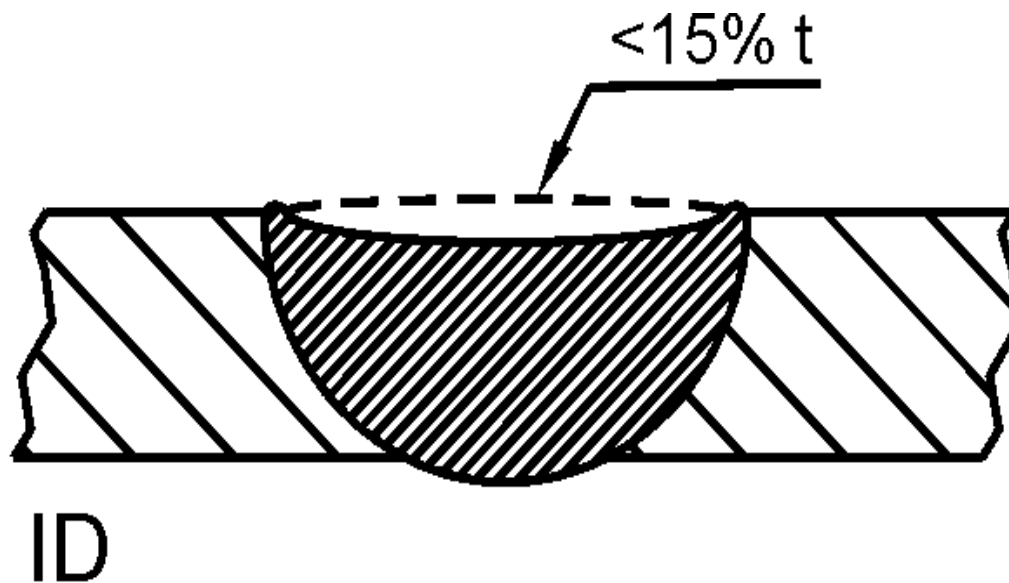


Source: Kopitzke, Arc Machines GmbH, Much

# EHEDG welding guideline

## OD concavity

- should be less than 15% of the wall thickness of the thinner tube



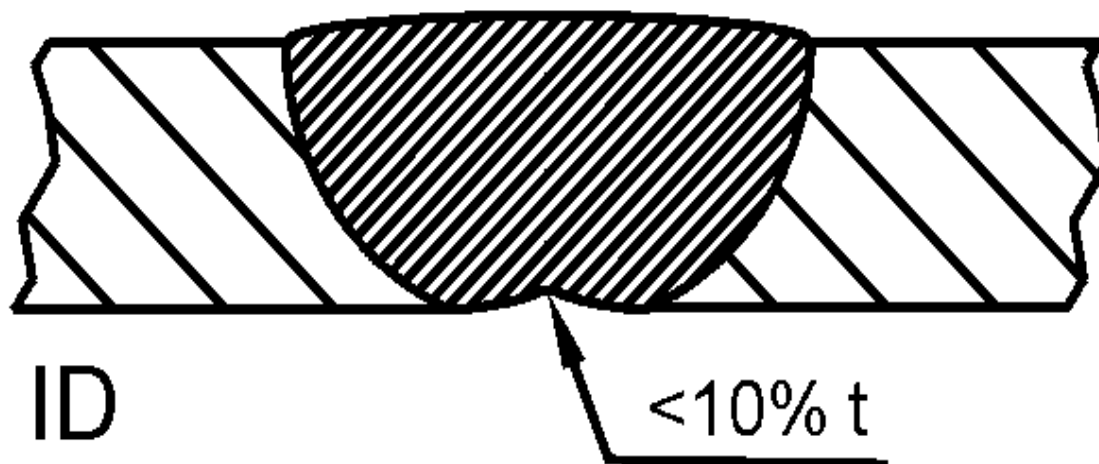
Source: Kopitzke, Arc Machines GmbH, Much



# EHEDG welding guideline

## ID concavity

- should be less than 10% of the wall thickness of the thinner tube

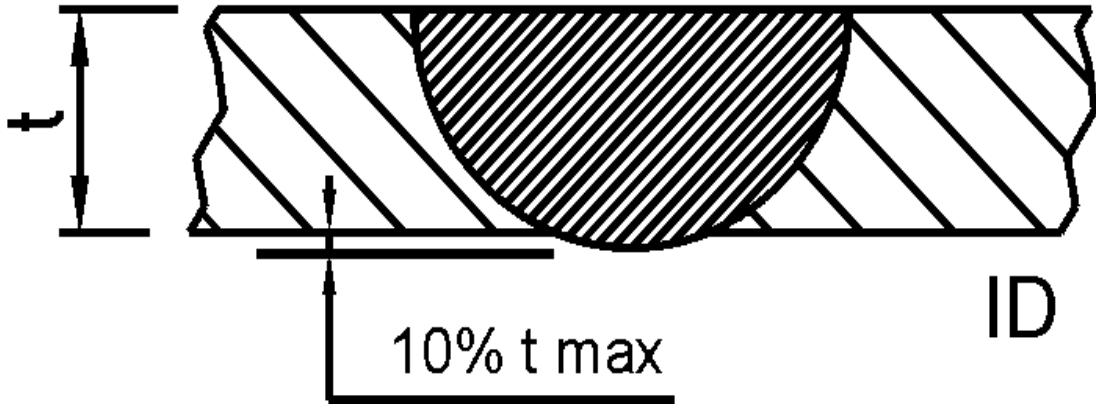


Source: Kopitzke, Arc Machines GmbH, Much

# EHEDG welding guideline

## Convexity

- should not be higher than 10% of the wall thickness of the thinner tube

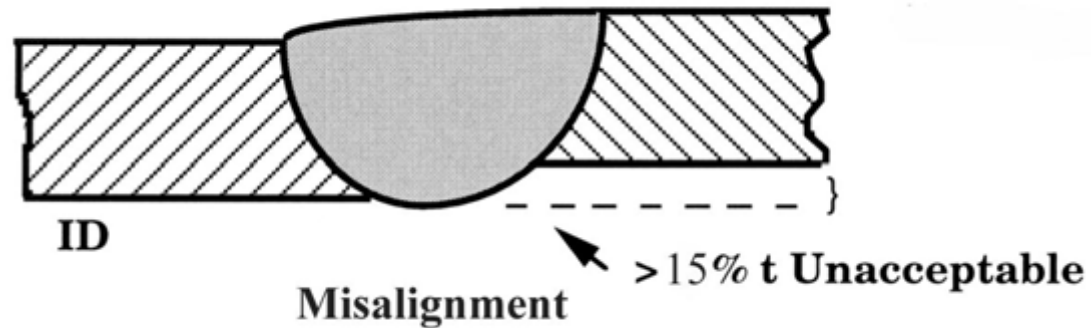
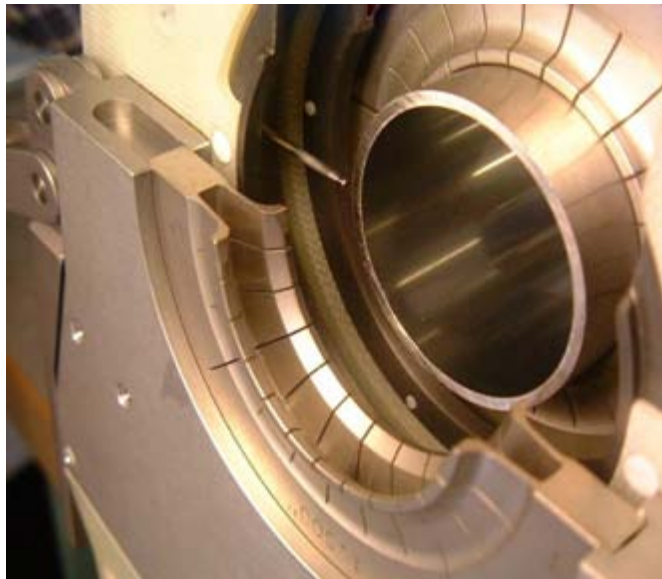


Source: Kopitzke, Arc Machines GmbH, Much

# EHEDG welding guideline

## Tube alignment

- Failure should be less than 15% of the wall thickness of the thinner tube



Source: Kopitzke, Arc Machines GmbH, Much

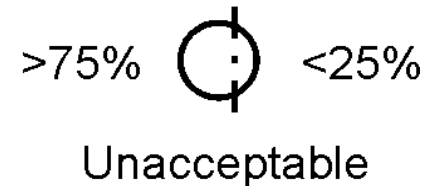
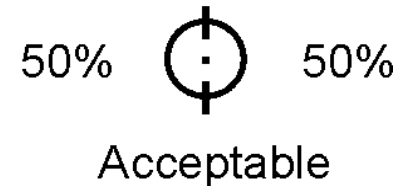
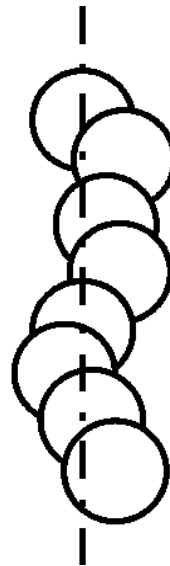
# EHEDG welding guideline

## Weld bead meandering

- the middle of the weld bead should not deviate more than 25% of the weld width from the ideal mid axis of the weld

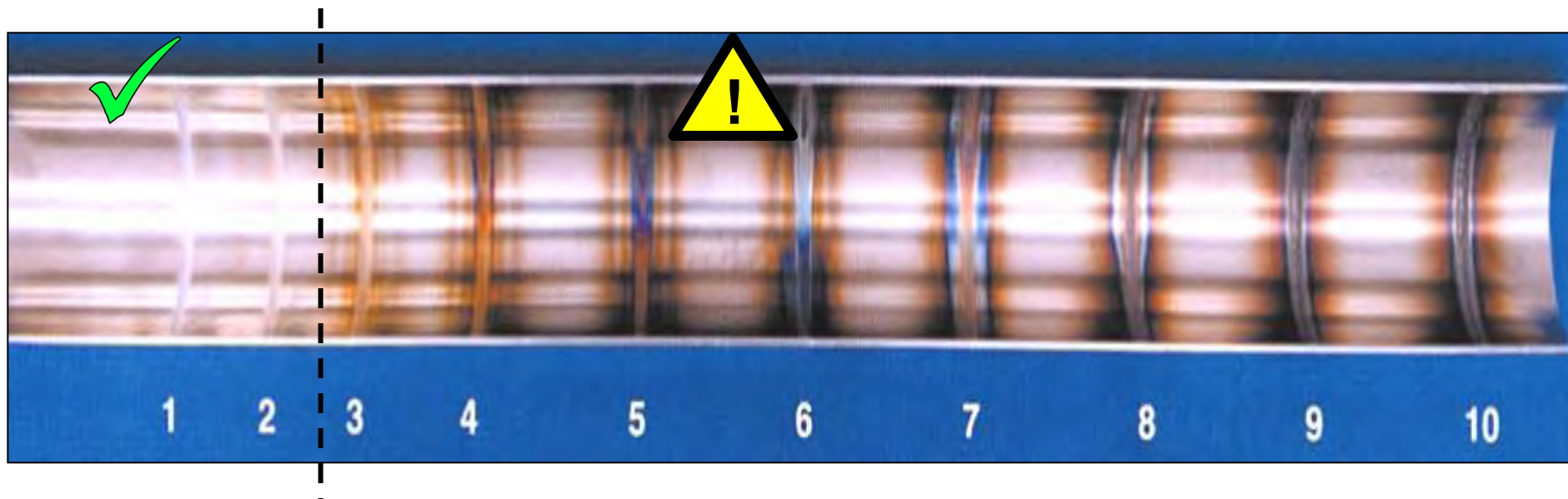


Straight, uniform weld bead



# EHEDG welding guideline

## Internal discolouration - Oxygen level in purge gas



No. 1 → 10 ppm

No. 3 → 50 ppm

No. 5 → 200 ppm

No. 7 → 1000 ppm

No. 9 → 12500 ppm

No. 2 → 25 ppm

No. 4 → 100 ppm

No. 6 → 500 ppm

No. 8 → 5000 ppm

No. 10 → 25000 ppm

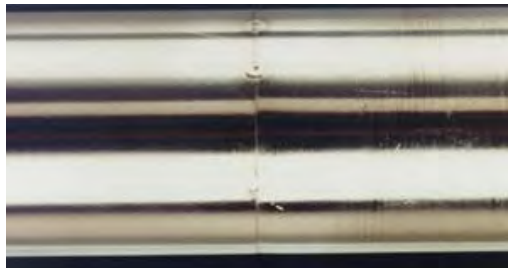
Source: Kопitzke, Arc Machines GmbH, Much

# EHDG welding guideline

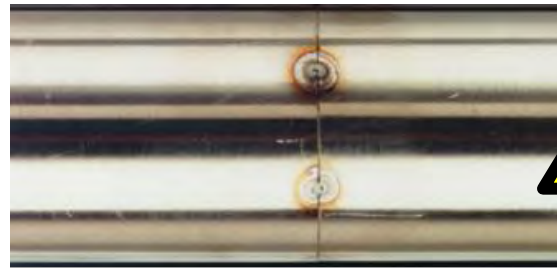
## Tack welding

should only be performed with minimal heat input, adequate external and internal purging and should not fully penetrate the tube walls.

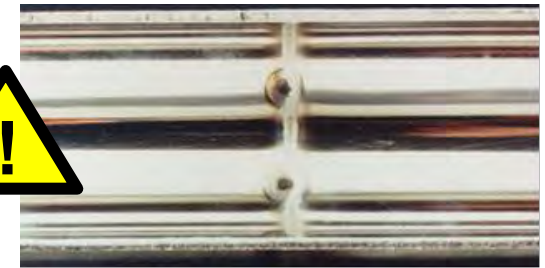
Tacks must be smaller than the weld bead and completely remelted by it, so that tacks are not visible after the welding process



Acceptable tacks



Unacceptable tacks



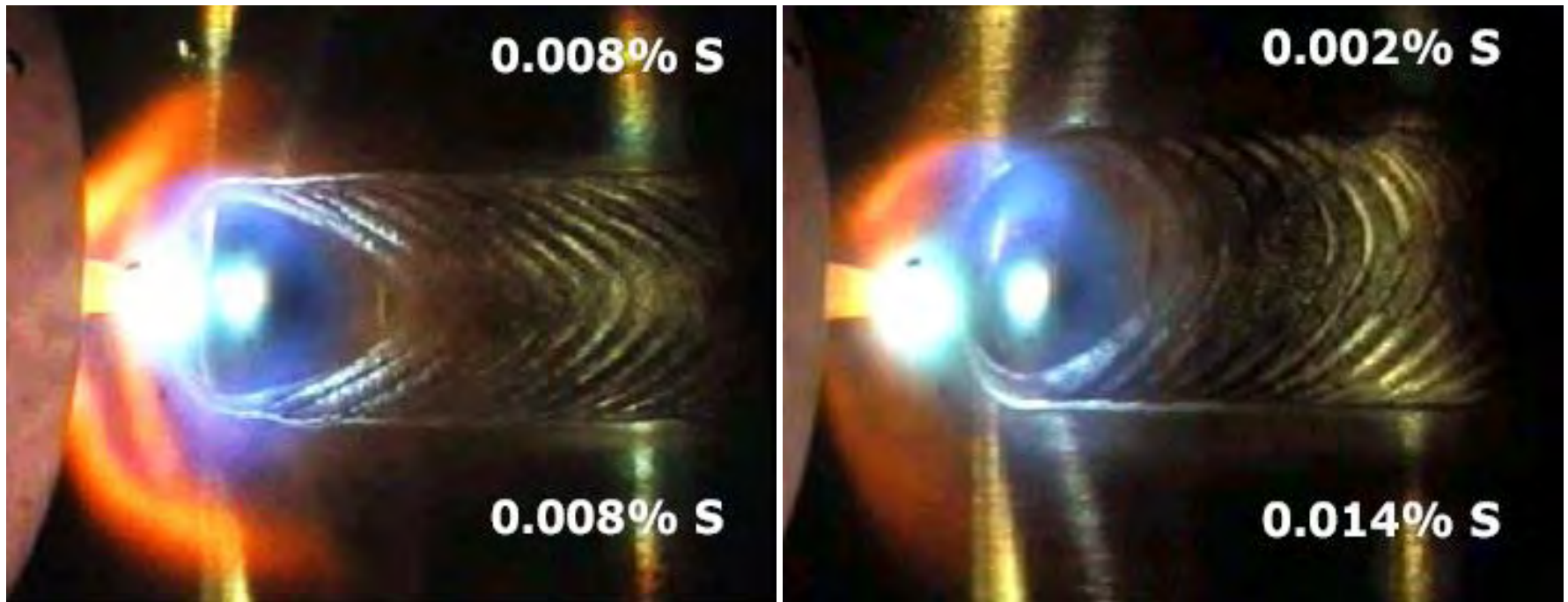
Unacceptable tacks  
after welding

Source: Kopitzke, Arc Machines GmbH, Much

# EHEDG welding guideline

## Arc wandering

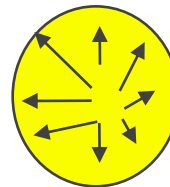
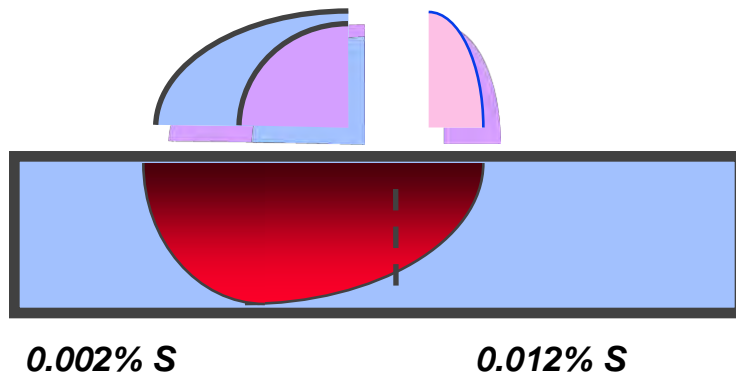
- Sulphur content inside the material is an important criteria for a hygienic weld



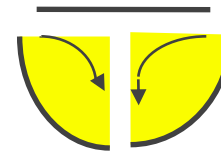
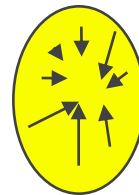
Source: Kopitzke, Arc Machines GmbH, Much

# EHEDG welding guideline

## Arc wandering



Low Sulphur  
0.001 - 0.008 %



Medium to high Sulphur  
0.008-0.030 %

Weld puddle profile

Source: Kopitzke, Arc Machines GmbH, Much



Video

## Conclusions

- if possible, orbital welding is to be preferred
- welds should be inspected
- no pickling or grinding before optical inspection
- properly welded joints are preferable to gasketed couplings
- Guideline Doc. 9, 35



# Factory siting, layout and building design

# Introduction

## Protect your product comprehensively!

- Even a hygienically designed machine is no guarantee for a safe production without an effective barrier to the environment
- A good building layout and master concept, also called master plan, for the design of a food processing facility is necessary to avoid:
  - Attraction, entry and nesting of pests
  - Accumulation of water, soil and dust
  - Microbiological and allergenic contaminations
- Building layout should facilitate cleaning and disinfection activities

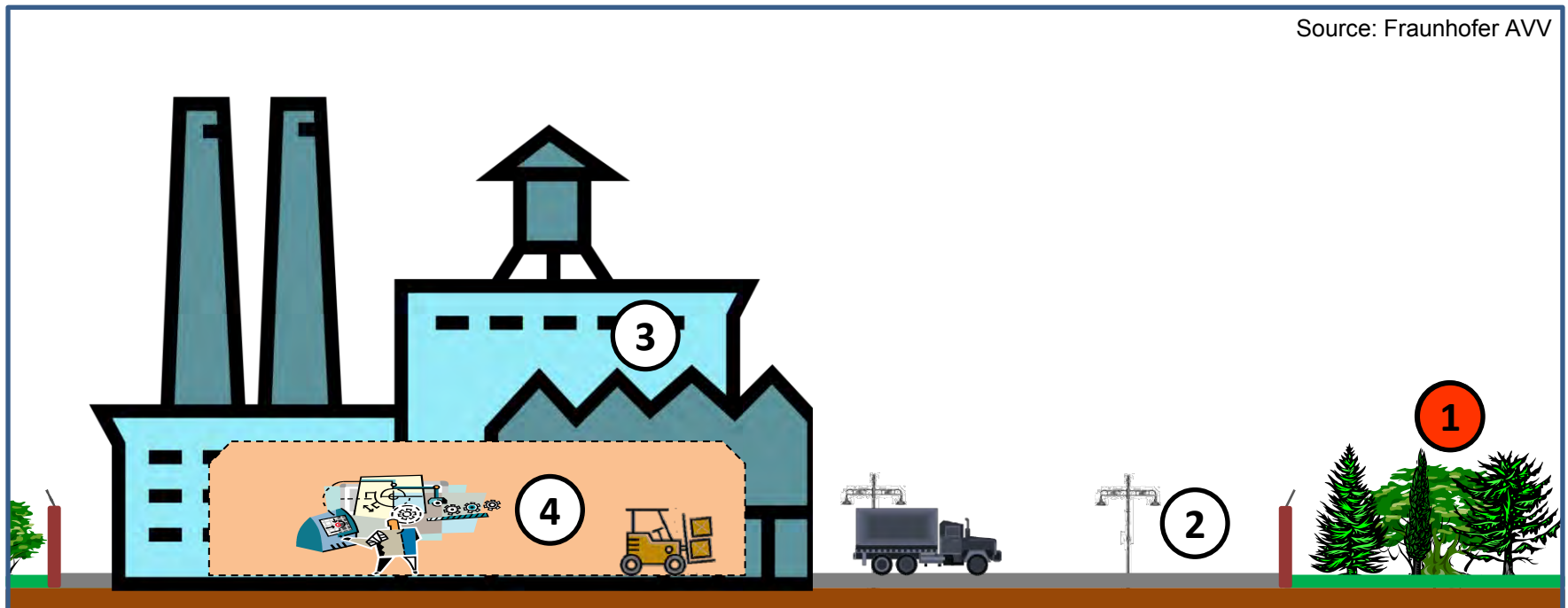
# Zones for factory planning

1 Environment

2 Factory site

3 Building envelope

4 Production areas



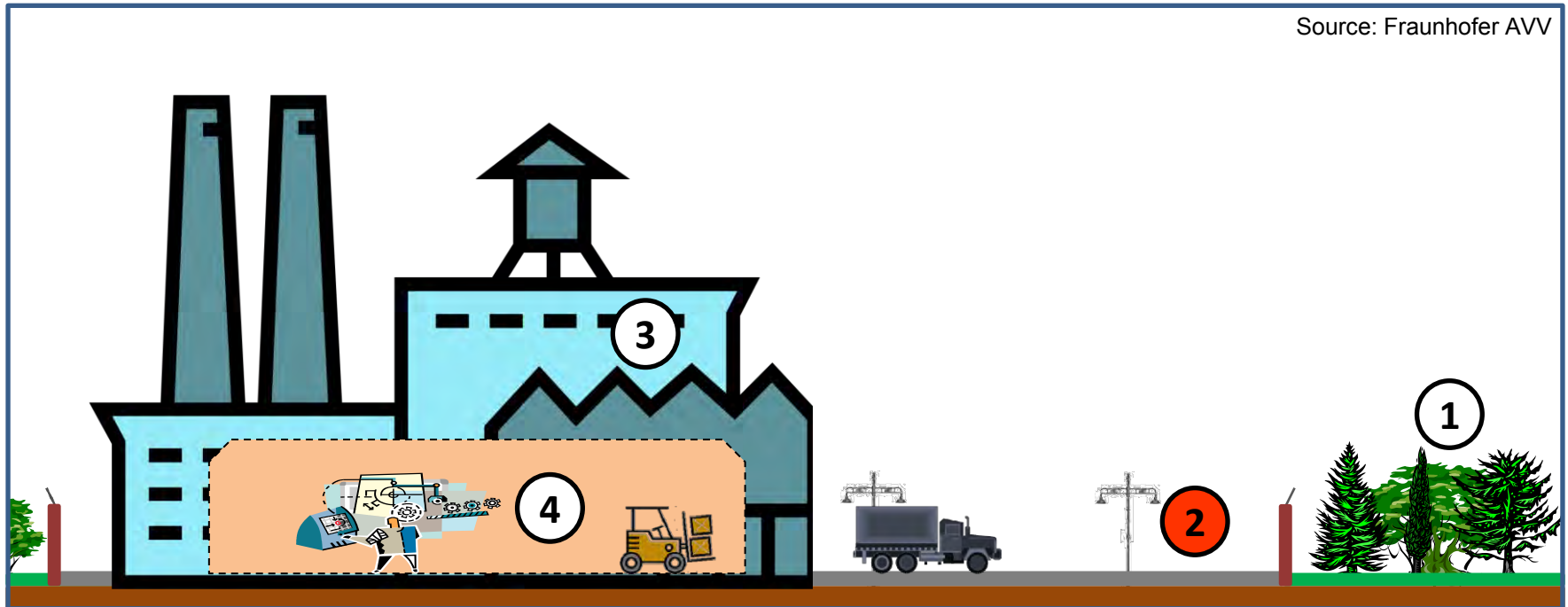
# Environment

- Legal requirements
- Climatic conditions
- Landscape
  - Local flora and fauna
  - Higher humidity close to water
  - Breeding place for insects and pests
- Economic use
  - Infrastructure
  - Local emissions
  - Quality of groundwater
  - Adequate distance to dumps, farms, chemical plants



# Zones for factory planning

## 2 Factory site



# Factory site

## Ground and facilities

- Checking of soil quality and soil support capability
  - Precluding chemical or biological contamination
  - Cracking due to sagging foundations
- Prevention of hiding places for animals
- Covered waste collection unit

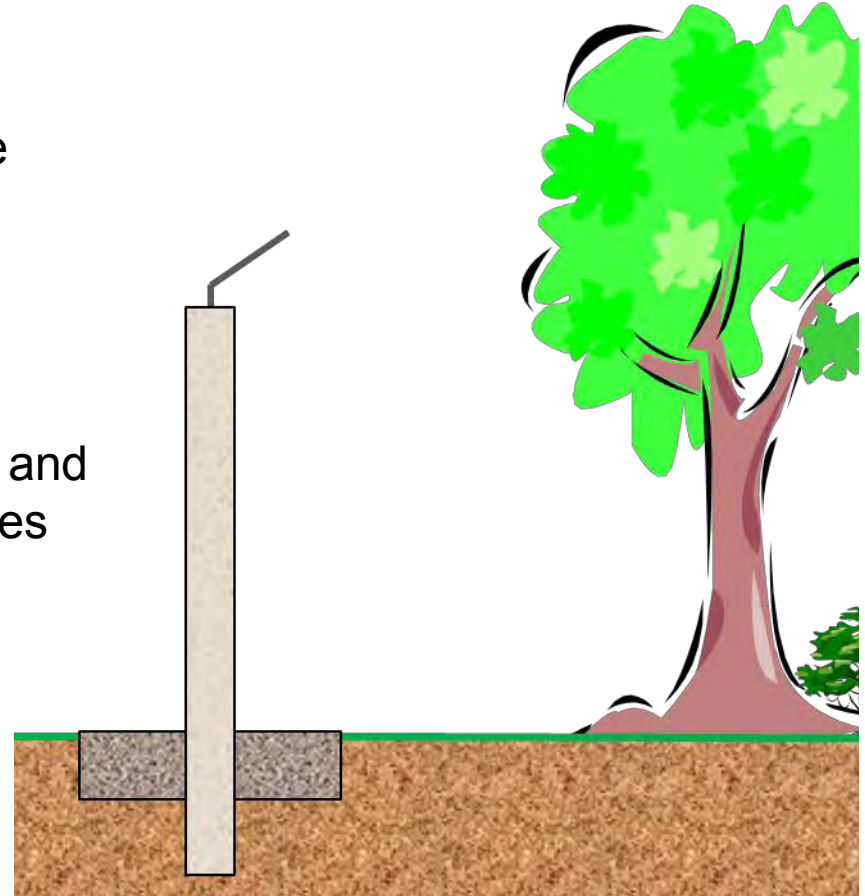


# Factory site

## Perimeter fence

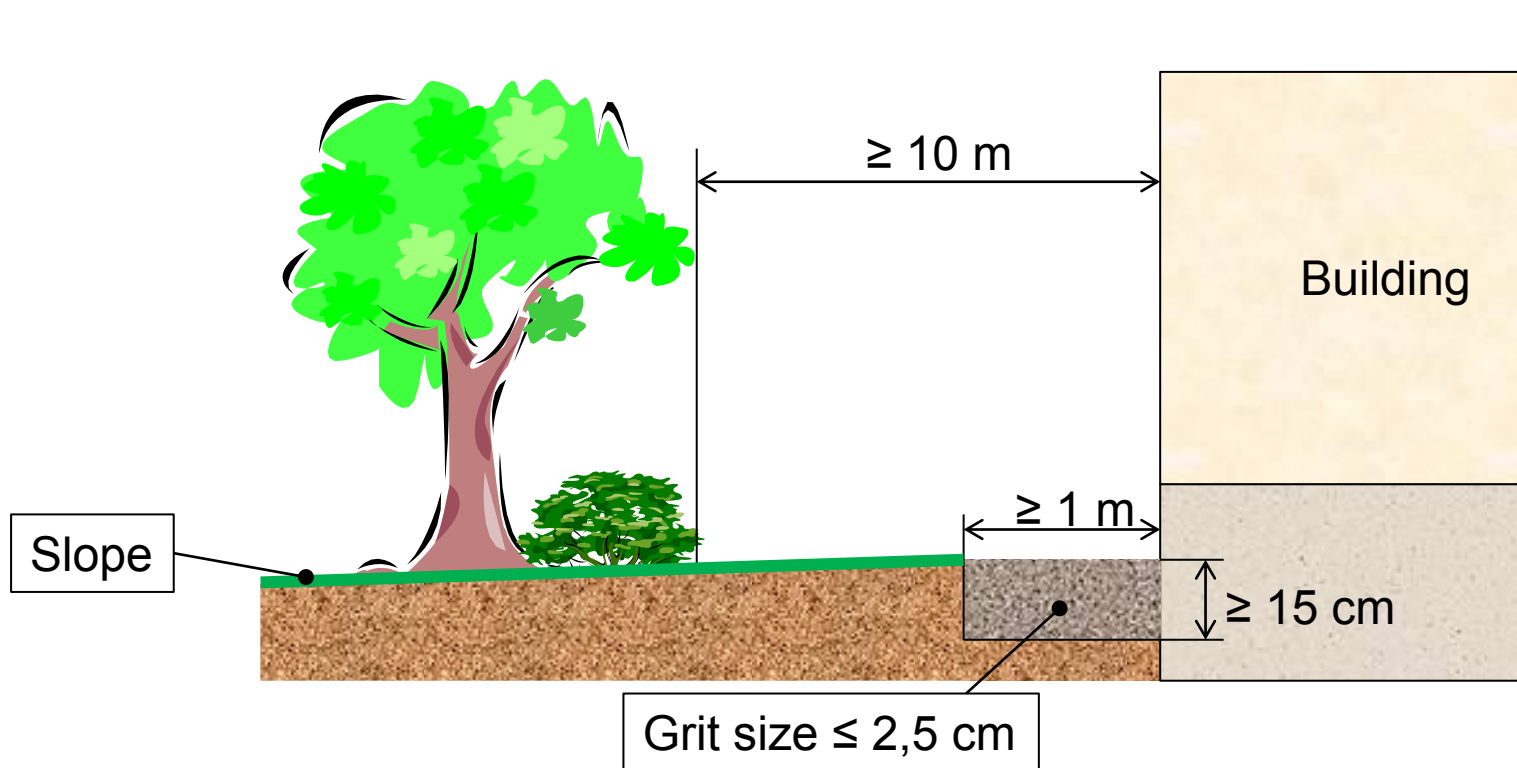
- Uninterrupted with a managed entrance
- Unplanted stripe inside and outside (e.g. coarse gravel)
- High enough
- Deep enough
- Smooth enough
- Distance to trees and bushes (climbing support)

} Prevent entry of climbing, jumping and burrowing creatures



# Factory site

## Distance to buildings



Source: Fraunhofer AVV (acc. to Hauser 2008)

## Factory site

### Areas for roads, walk and parking

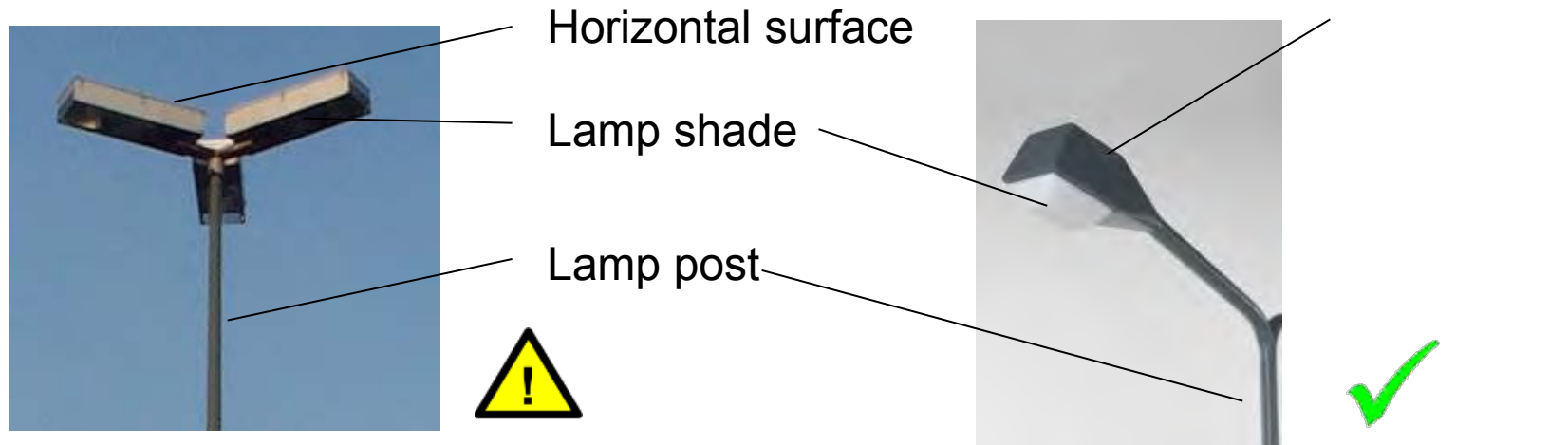
- Stable and cleanable materials
- Minimize or eliminate joints (e.g. use concrete, tarmac or similar materials)
- Periodic maintenance (remove pest plants and close gaps)



# Factory site

## External light sources

- On poles or standards (not at buildings)
- Lamp design: Avoid possibility of accumulation, perching on lamps
- Avoid high-UV amenity lighting



## Factory site

### Sufficient draining of the premises

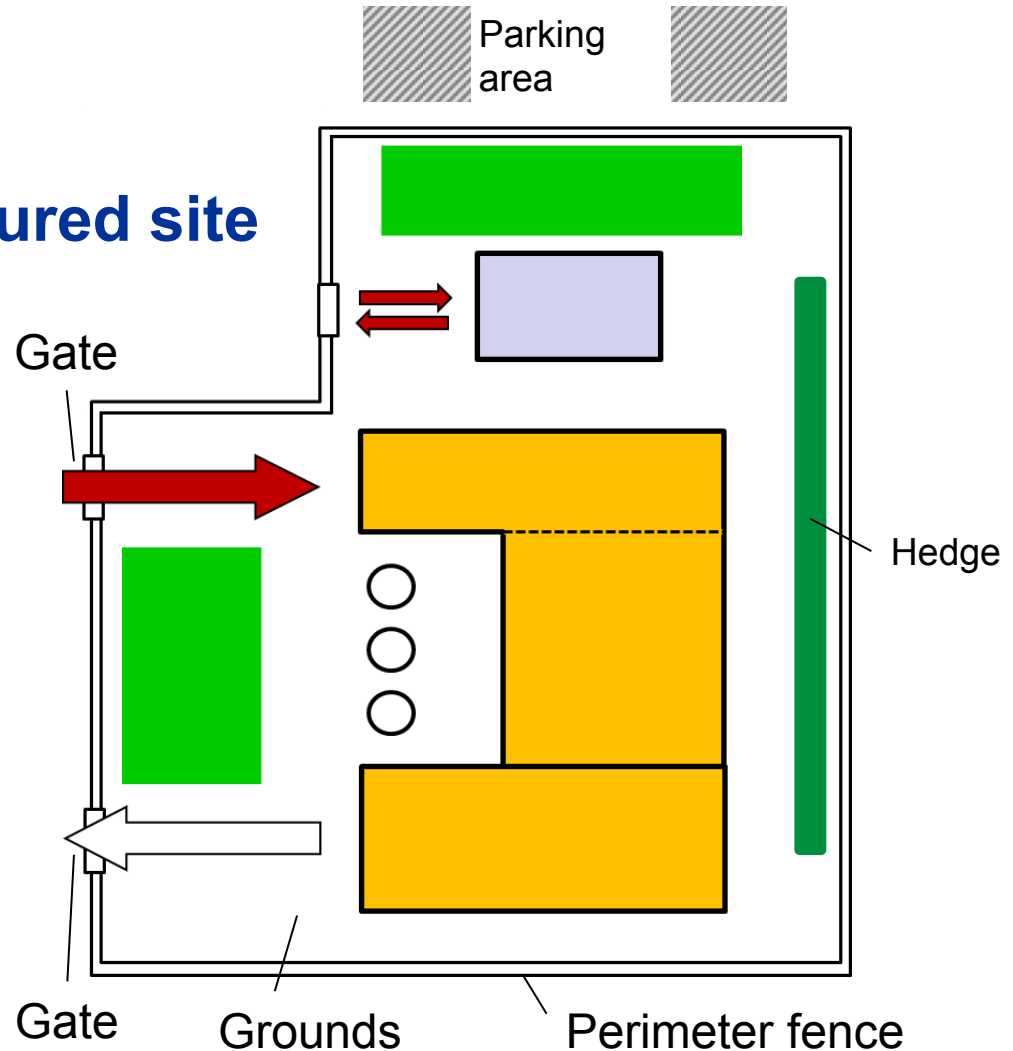
- As possible: plane surfaces
- Inclined away from buildings
- Qualified surface drainage system
- At every local minimum on the site must be a drain

→ Fast removal of water out of the premises

# Factory site

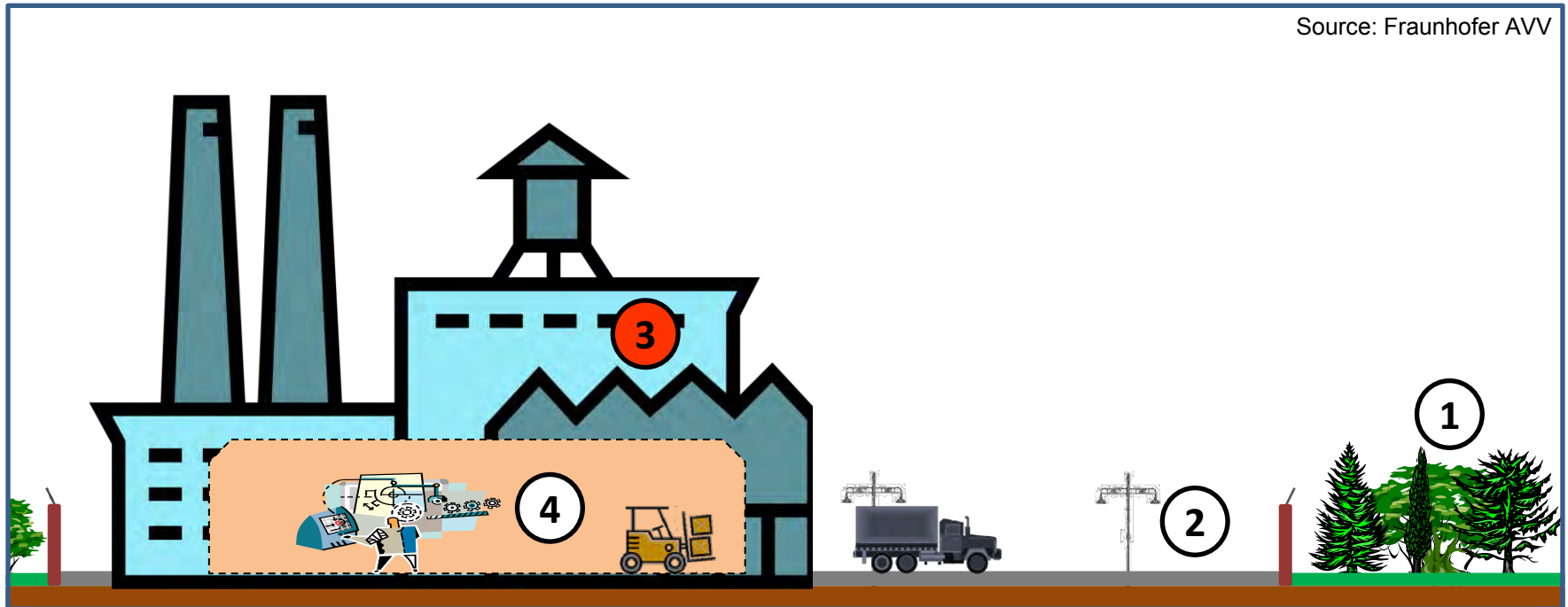
## Simple model of a structured site

- Location and arrangement of buildings have to be accurately projected
- Routes for employees, products, production equipment, products, disposal...
- Barrier to environment
- prevent possibility of contamination from laboratories inside the factory



# Zones for factory planning

## 3 Building envelope



# Building envelope

## Protection against animals, pests and microbial contamination

- Prevention of hiding places for animals
- Building envelope impenetrable to living invaders
- Self closing openings/ doors/ windows/ apertures (protected by fine screens if open) / Pest-tight openings
- No light sources above entrances
- Avoid stairs for personnel next to loading bays
- All opening screened with stainless steel mesh  $< 1\text{mm} \times 1\text{mm}$



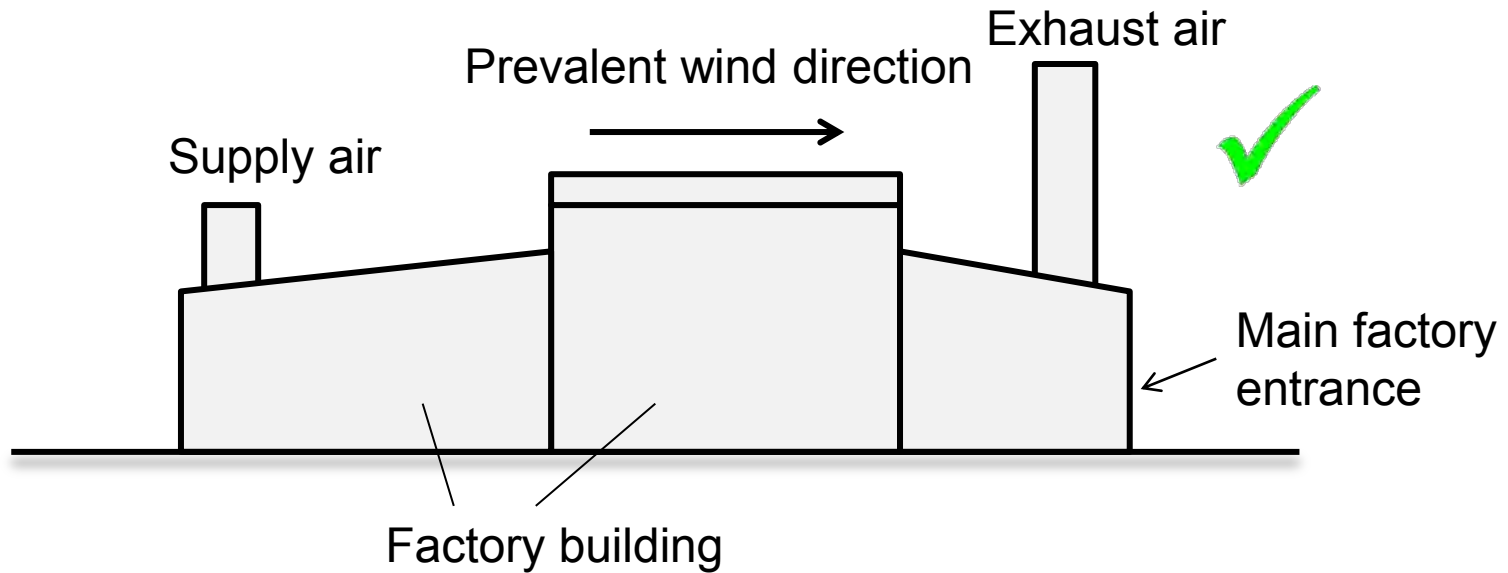


Source: Roland Cocker, Cocker Consulting

# Building envelope

## Placement of air supply systems

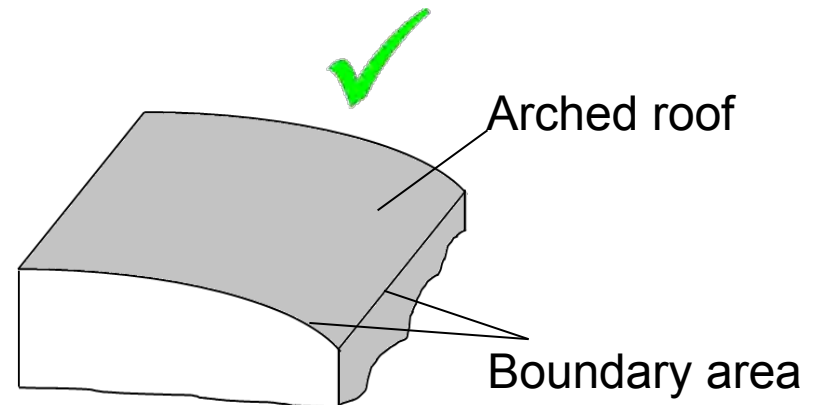
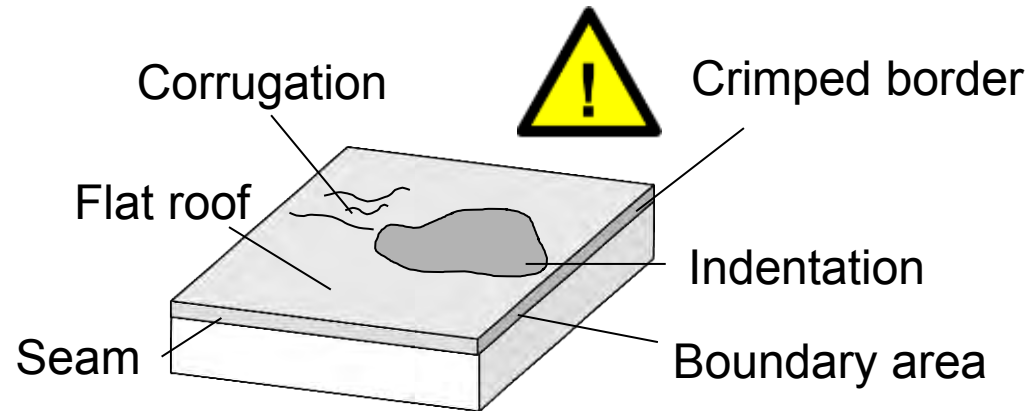
- Prevention of cross-contaminations



# Building envelope

## Roof

- Pest-tight, water proof
- Sloped ( $\geq 3^\circ$ ) and self draining
- As possible: Consist of a single membrane
- Avoid internal roof drains
- No Ventilation devices that discharge food particles onto the roof (Birds and pests could feel attracted!)
- Spaces between roof and upper side of suspended ceilings should be accessible

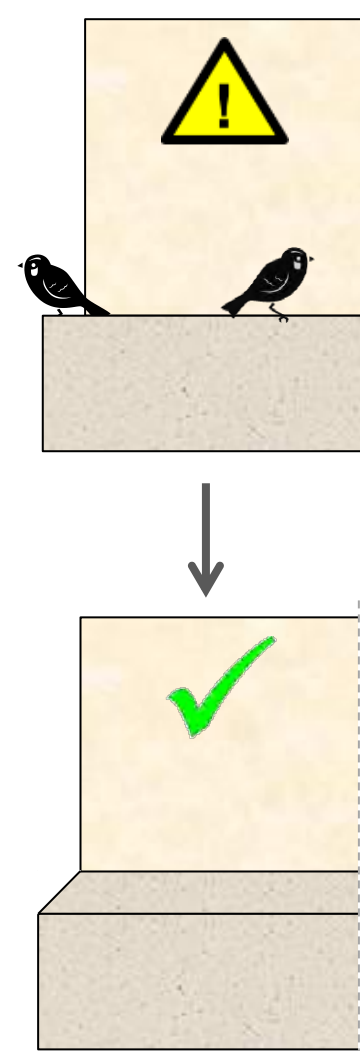
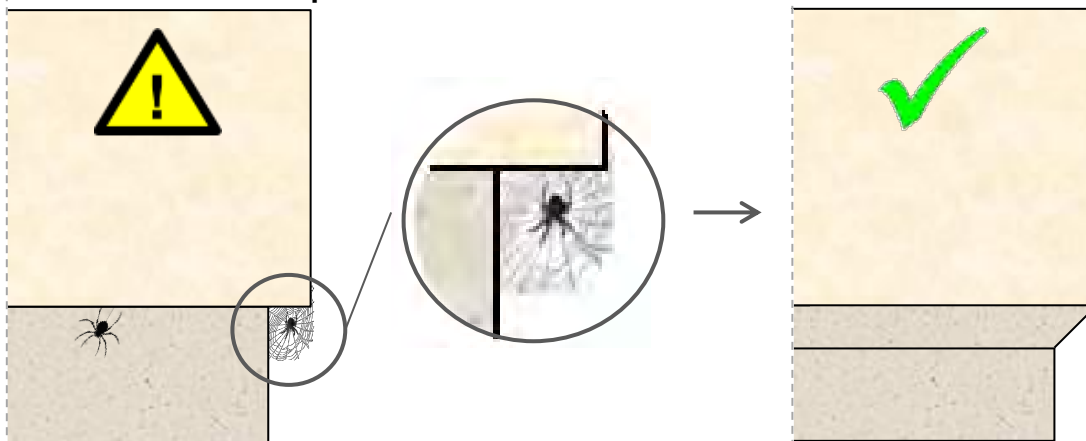


Source: Fraunhofer AVV (acc. to Hauser 2008)

# Building envelope

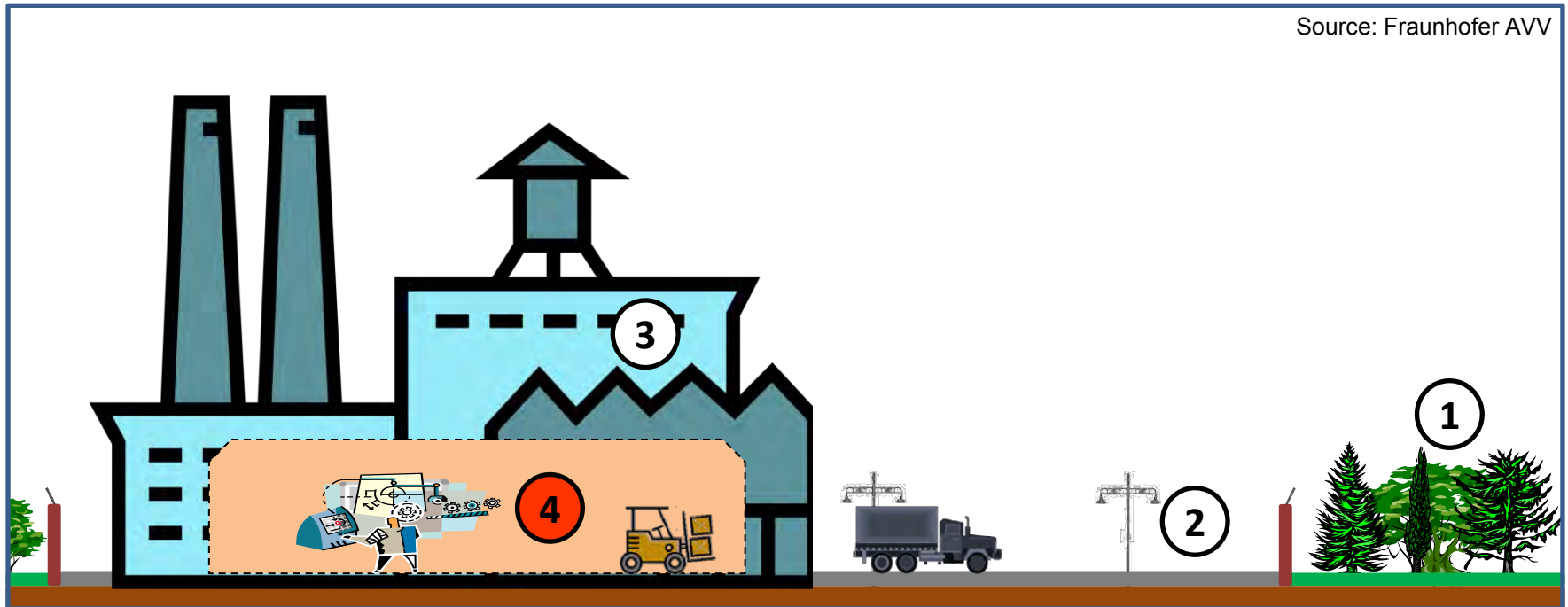
## Wall exteriors

- Smooth surfaces
- All gaps sealed
- No horizontal surfaces (gradients  $\geq 45^\circ$ )
- No windows next to product area
- As few as possible entrances



# Zones for factory planning

## 4 | Production rooms

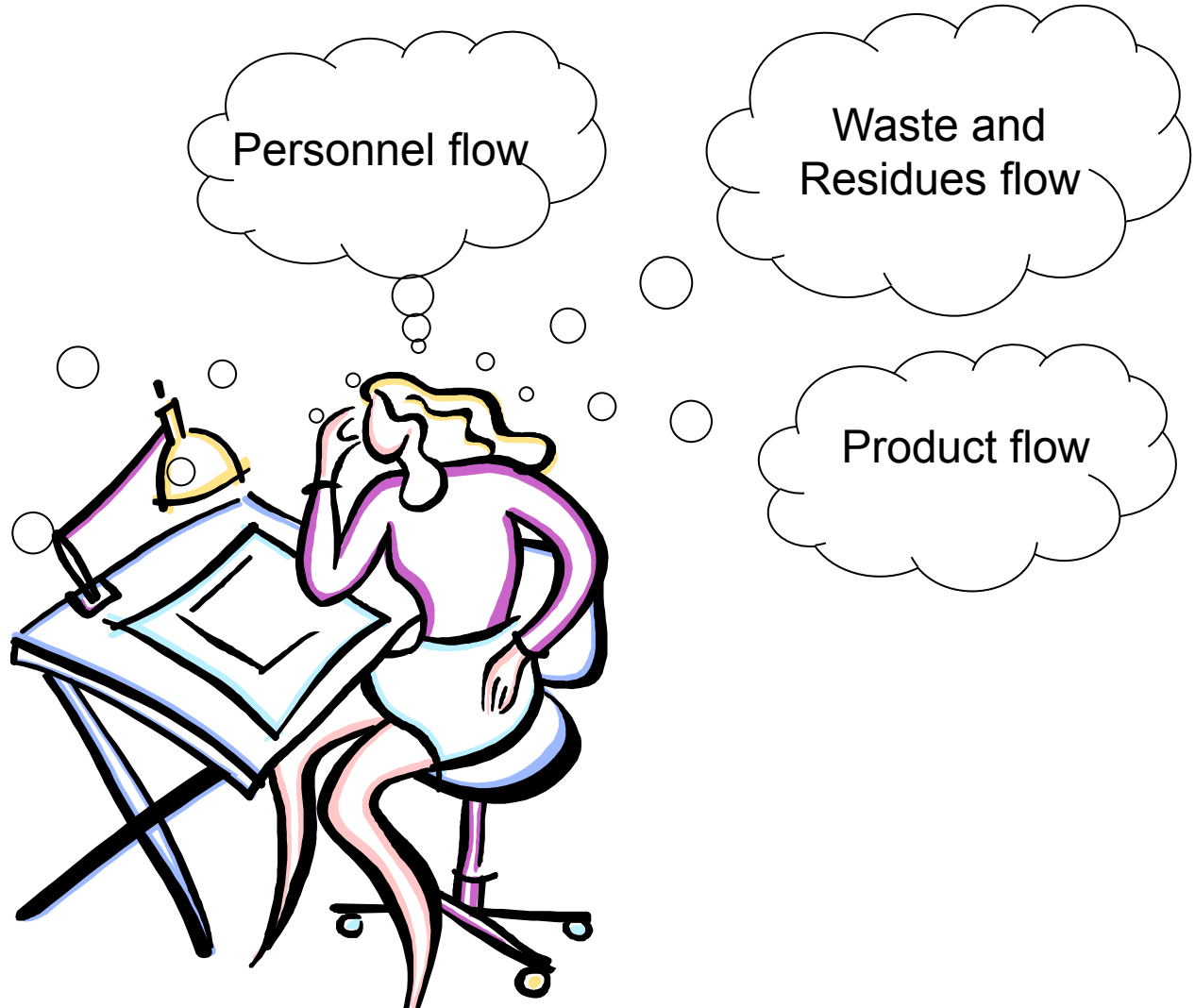


# Main Flows

## Layout

Others: packaging, traffic

Services: gases, utility water, air



# Product flow

- Segregation of zones with different hygienic standards
- Routes as short and straight as possible,
- Minimise product traffic
- Product flowing from basic to high hygiene
- Prevent cross contamination between product and
  - Raw material
  - Secondary packaging material
  - Residues
  - Cleaning chemicals / non-food chemicals



# Zoning

## What's the meaning of zoning?

- Set of procedures, practices and physical barriers aiming to prevent product (cross) contamination
- Part of a total hygiene concept



# Zoning

## Zoning may involve

- Equipment, tools and other working devices of restricted use within designated areas (e.g. Color code)

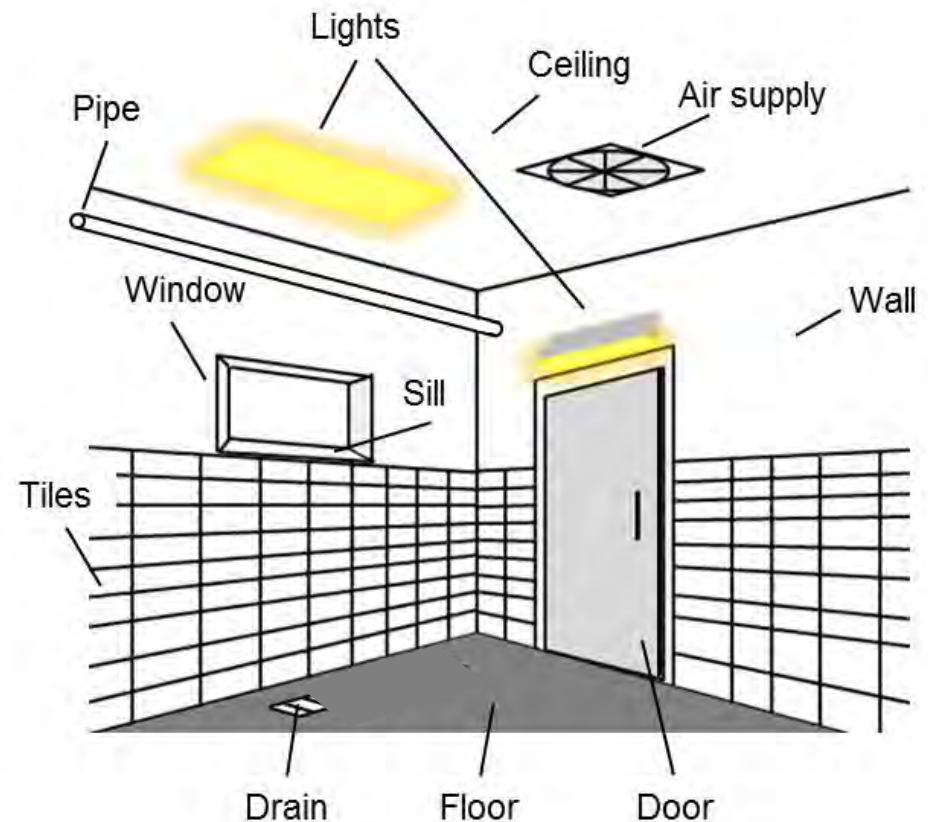


- Make provision for local storage as appropriate
- Internal hygiene policy: requirements of each area (clothing, hands cleaning and disinfection for accessing certain areas, etc.)

# Production rooms

## Overview production room surfaces

- 3 main classes of walls / surfaces
  - Floors
  - Vertical walls
  - Ceilings
- Openings
  - Windows, doors, stairways
- Installations
  - Light sources, pipes, wires, air boards, (HD-plants)



Source: Fraunhofer AVV (acc. to Hauser 2008)

# Production rooms

## Floors: Hygienic design criteria

- impermeable
- resistant to expected loads, chemicals
- without cracks;
- with cleanable joints (material + dimensions);
- self draining
- easy to clean
- the subfloor must be strong enough for the installation
- good wet grip



Source: Hermanek, ACO Industries k.s.

# Production rooms

## Floors: Drainage

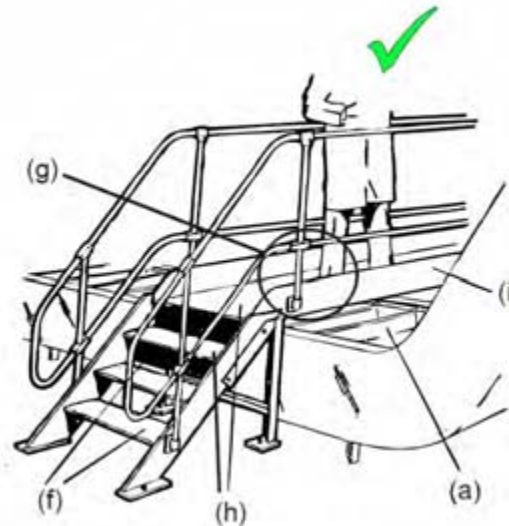
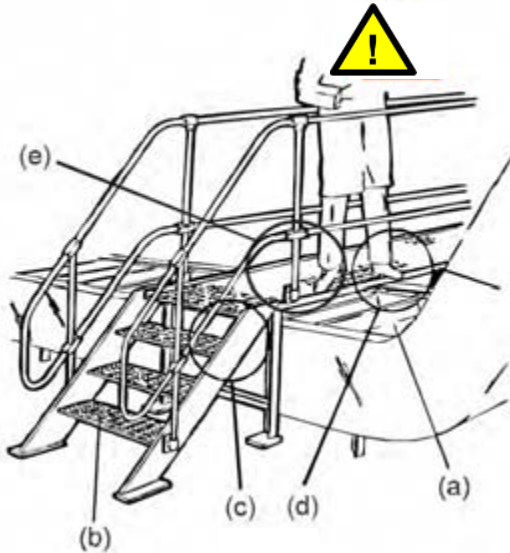
- To avoid stagnant water:
  - Inclined floor (slope  $\geq 2\%$ )
  - Covered discharge gutters
  - Central drainage channel, lateral drainage channel, central drainage points
  - Hygienic designed sink trap
- For cleanability:
  - Floor finish
  - Connection to vertical walls (wall socket design)



# Production rooms

## Floors: Walkways

- Avoid walkways over exposed product stream/lines
- Covering the product line OR walkways in hygienic design
- the stair must be in accordance with local regulation about people safety



Source: EHEDG GL Doc. 11

Source: EHEDG GL Doc. 26

# Production rooms

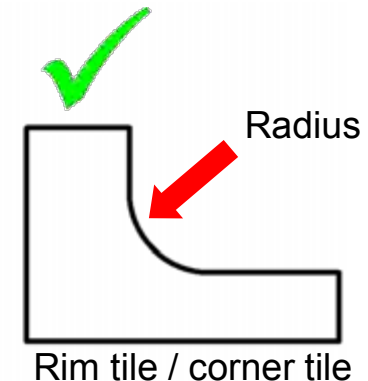
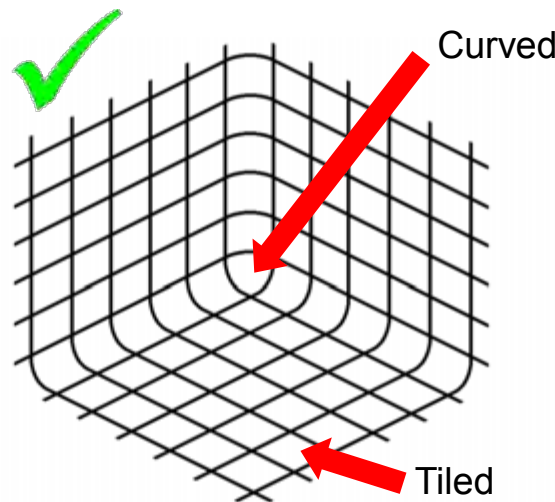
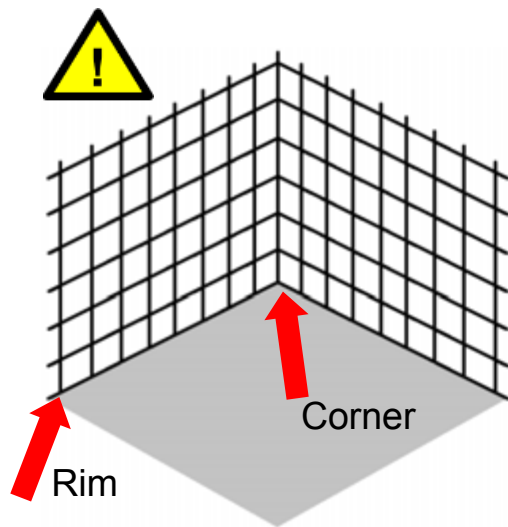
## Vertical walls

- Material (hard, flat, smooth, washable)
- Covers / cladding (wall tiles, plates, panels)
- No ledges / no protrusions
- Wall socket design for easy cleanability
  
- Openings: windows, doors, stairways
- Sealed openings for services through the wall (pipes, ...)
  
- Installations: equipment placed near the wall needs enough distance to the wall → accessible for cleaning (e.g. electrical cabinets, boards)

# Production rooms

## Vertical walls: Design

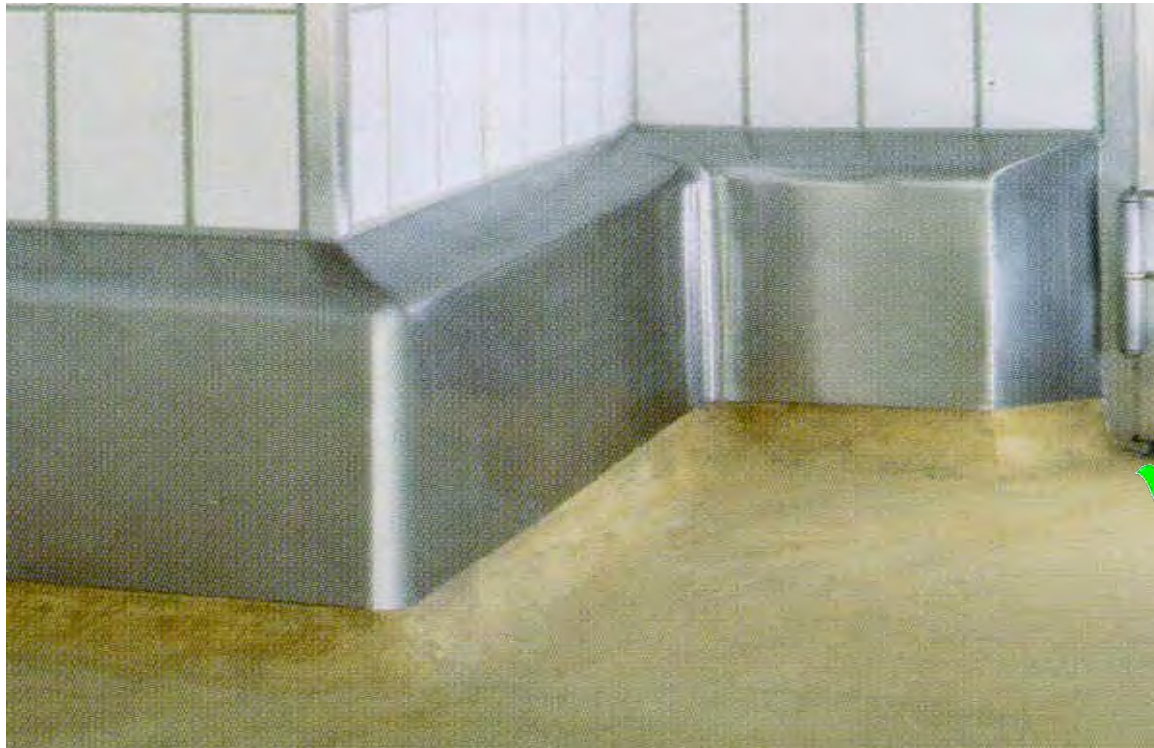
- Edge protection strips (metal or plastic)
- Impact protection at lower part of the wall
- Wall socket: rounded tiles with a suggested minimum radius of 75mm



Source: Fraunhofer AVV (acc. to Hauser 2008)

# Production rooms

## Vertical walls: Protection



Source: R. Soro, Ainia



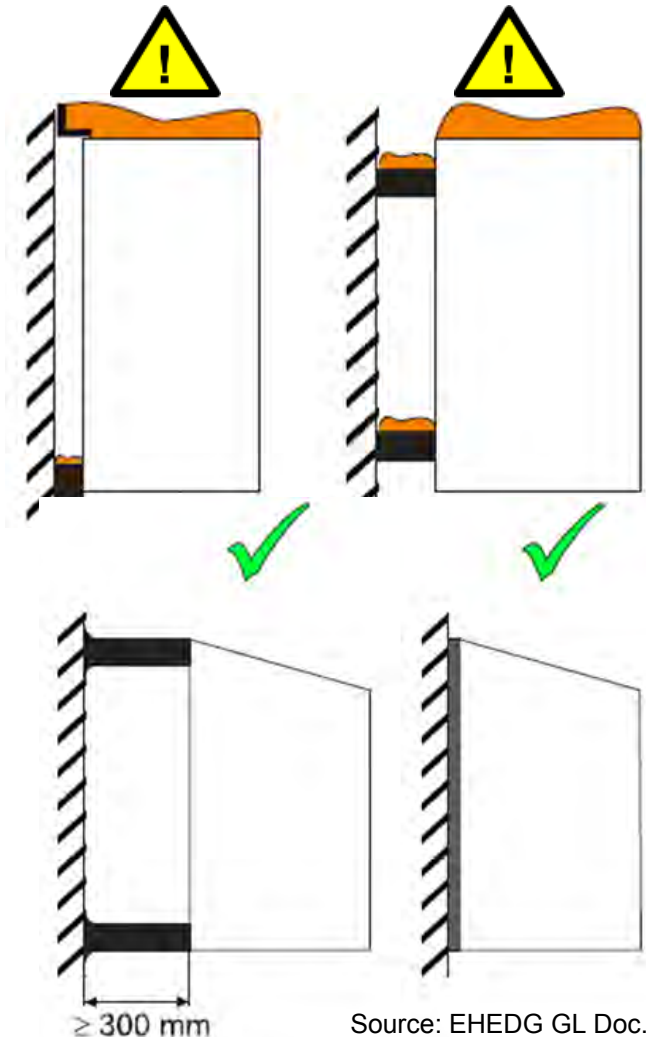
# Production rooms

## Vertical walls: Openings

- e.g. windows / doors / wall breakthroughs
- Eliminate if not needed!
- Impermeable to pests (e.g. screened permanently closed)

## Vertical walls: Installations

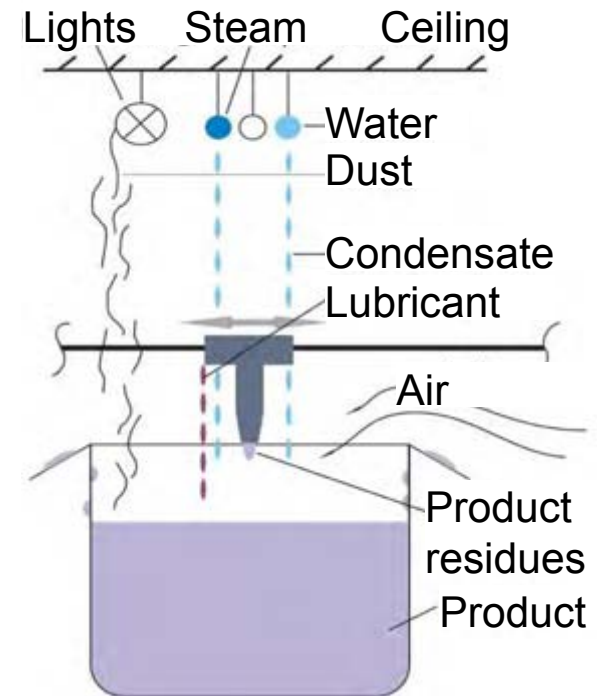
- e.g. electrical cabinet
- No horizontal surfaces
- Sealed to the wall or enough space for easy cleaning accessibility

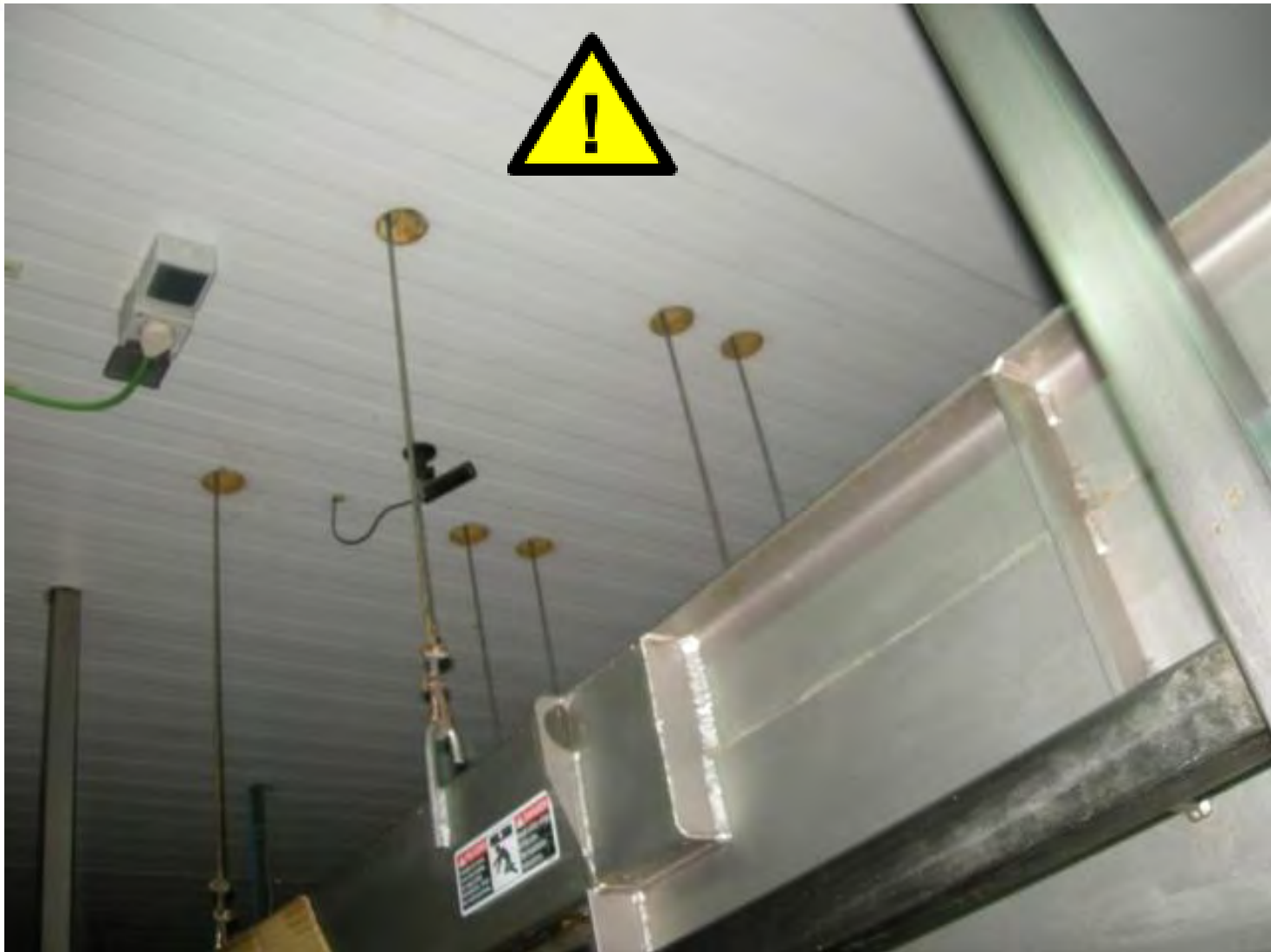


# Production rooms

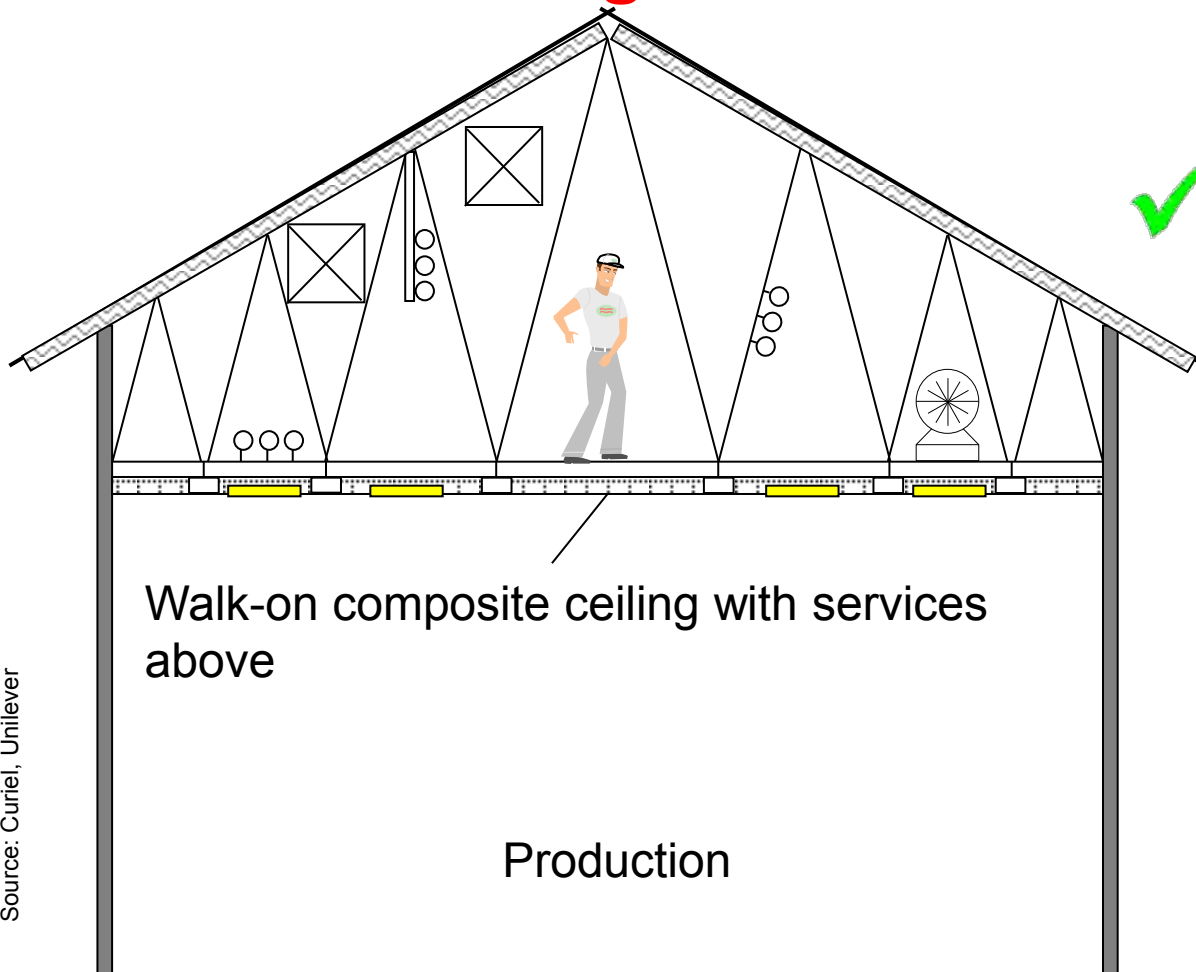
## Ceilings

- Suspended ceiling not sealed from the room only acceptable in areas with basic or medium hygienic requirements
- Covers, cladding (glazed tiling, plates)
- Openings: stairways, elevators, conveyor belt  
→ Sealing systems required!
- Installations: pipes, wires, light sources, air ventilation  
→ Falling contaminants





# Walk-on Ceilings



Typical walk-on ceiling

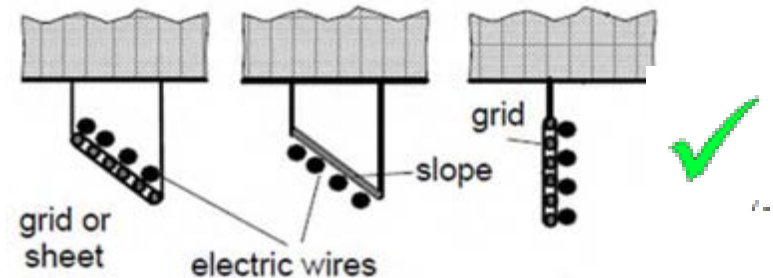
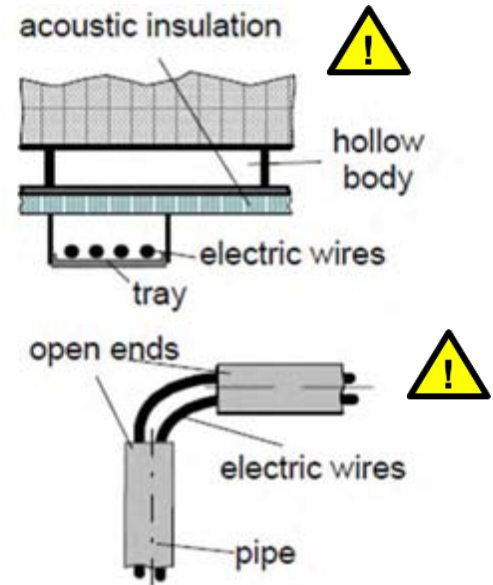


Source: Curiel, Unilever

# Production rooms

## Ceilings: Electrical installations

- Not acceptable
  - Open pipes for fixing
  - Horizontal surfaces
  - Clusters of electric wires
- Hygienic design
  - minimise cableing in process areas
  - Closed pipes with sealed outlet
  - Inclined stainless steel grid
  - Distanced parallel electric wires

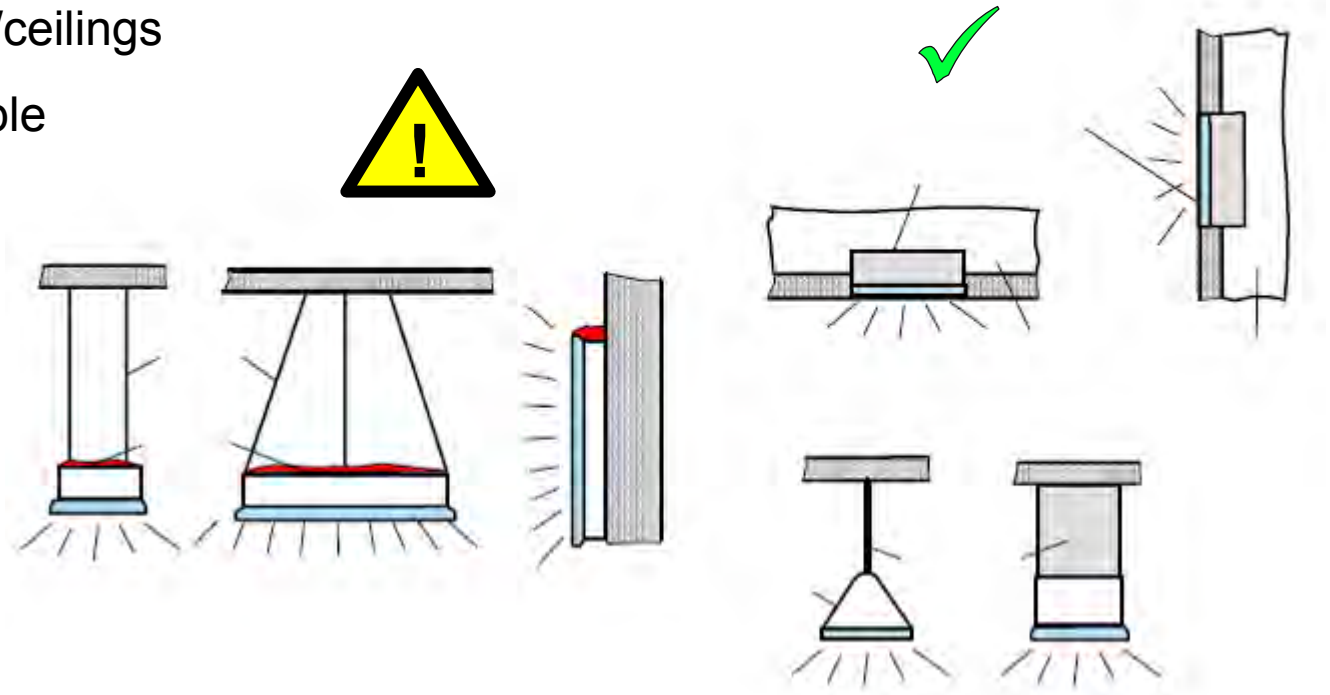


Source: EHEDG GL Doc. 26

# Production rooms

## Ceilings: Installation of light sources

- Avoid soil deposition and glass fragments
- Integrate in walls/ceilings
- Relocate if possible
- Seal up

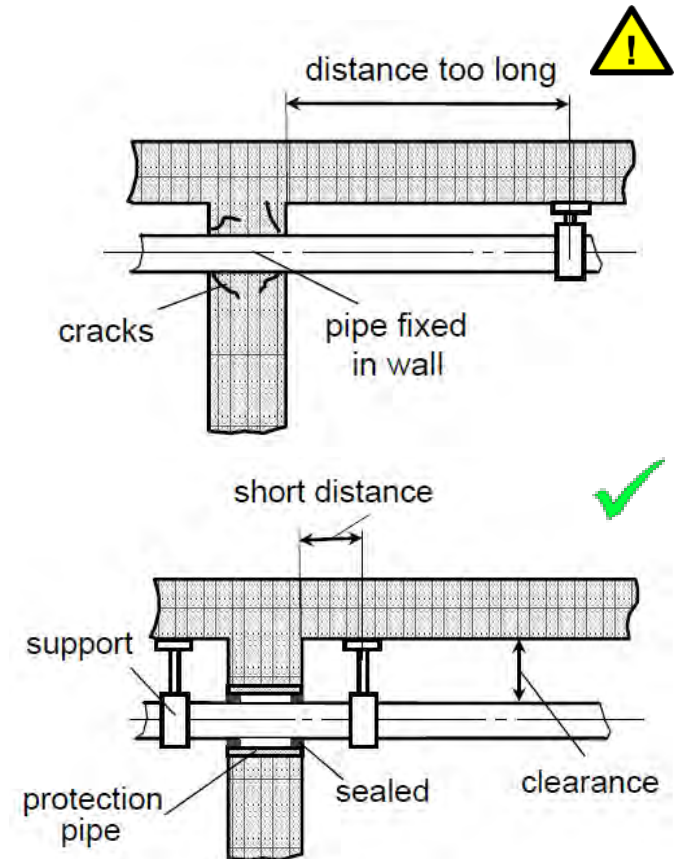


Source: EHEDG GL Doc. 26

# Production rooms

## Pipe mounting through a wall

- Not acceptable
  - Forces = cracks in the wall
  - Short distance to ceiling
- Hygienic design
  - Sealed protection pipe
  - One support near each wall side
  - Distanced to ceiling = accessible for easy cleaning



Source: EHEDG GL Doc. 26

# Production rooms

## Ventilation

- Adequate ventilation should be provided to prevent condensation or excessive dust.
- Natural ventilation should be avoided
- Best option: controlled combination of supply and extraction systems
- Air flow must go from high hygiene to basic hygiene zones
- The system must ensure the number of air changes recommended depending on the hygienic requirements of the area.



# Production rooms

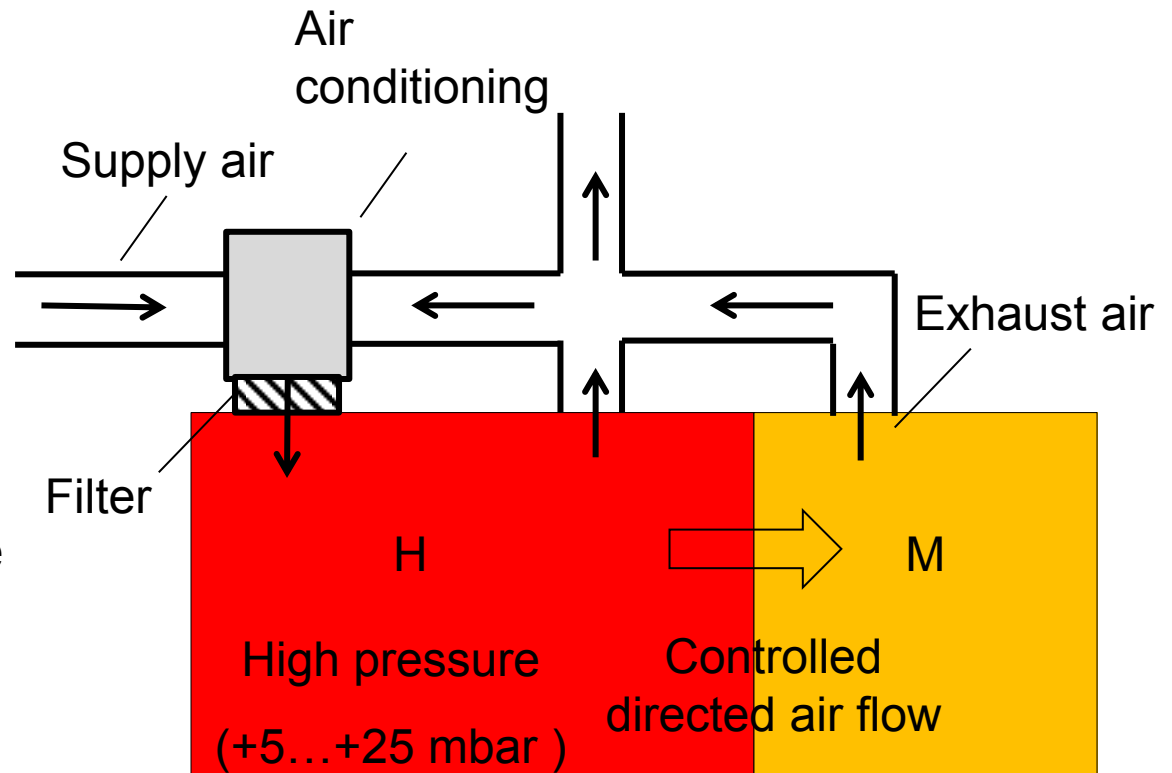
## Ventilation

- Air must be filtered
- A moderate over pressure (25 pascal) is recommended in production areas to prevent contaminants from entering.
- Air should be kept as dry as possible to avoid microorganism growth
- Ventilation for a clean and free of contaminants air will be achieved through the combination of filtration, temperature and humidity control and pressure gradient.

# Production rooms

## Controlled directed air circulation (one way)

- Air supply system
- Decontamination of air
- Prevent the transfer of air-transported particles into the H-Zone



Source: Fraunhofer AVV (acc. to Hauser 2008)

# Production rooms

## Movement of personnel / traffic

- Controlled movement / access control
- Protective clothing
- Routine hygiene trained personnel
  
- Well organized infrastructure, so that personnel can keep / follow hygienic rules
  - e.g. switch for washing basin handled with knee or by motion sensors
  - Doors opened by motion sensors
  - Changing rooms and ergonomically designed disinfection equipment
  - Effective locks

# Summary

## Hygienic design rules for building layout

- Remote from farms, dumps, effluents, airborne particle sources
- No entry / no encouragement for vectors
- Zoning philosophy: multiple barriers = „boxes within boxes“
- Control all mass flows (necessary and unwanted)
- Export potential hazards from the high care zone
- Select qualified raw materials
- Stop accumulation of moisture / water
- Minimize / eliminate horizontal surfaces



# Food Grade Lubricants in Food Production

# Content

- Food grade registrations
- Storage and handling of food grade lubricants
- Lubricant hazards in the food production plant
- The importance of Best Manufacturing Practice
- Switching to food grade lubricants
- Reasons for bearing failure
- Summary
- EHEDG Guideline Document 23

## Lubricant registrations

- FDA (U.S. Food and Drug Administration)
  - List of allowed ingredients
- NSF International (formerly the National Sanitation Foundation)
  - List of lubricants: [www.nsfwhitebook.org](http://www.nsfwhitebook.org)
  - certifies lubricants and manufacturers of lubricants according to ISO 21469
- INS (Europe)



# Food grade registrations

## Food safety is ensured by:

- only using FDA listed ingredients
- only using ingredients from correct section (lubricants- CFR, Title 21, section 178.3570)
  - up to the maximum percentage stated (%v/v)
- Only using lubricants accepted for H1 registration



# Food grade registrations

- H1 – Product can come into incidental contact with food
- H2 – Absolutely no contact with food
- 3H – Proprietary Substances.
  - Release agents, food processing products, potentially part of the ingredients of the food
- HT1 – Heat transfer fluids that have incidental contact

# Food grade registrations conformance

- Packaging must show approval mark
- Packaging must show registration number
- Packaging must show classification
- Reference number covers formulation and labels
- All changes require re registration

# H1 Product availability

## H1 Registered Products

- bearing greases, track treatment
- chain lubricants
- gearbox fluids (enclosed and open)
- assembly and anti-seize compounds
- hydraulic & compressor fluids
- airline lubricants
- penetrating fluids
- can seamer lubricants
- sugar dissolving solutions
- release agents
- general purpose sprays and lubricants



# Storage and handling of food grade lubricants

## Storage

- separate stores for food grade lubricants
- clean and dry warehouse
- store drums on their side

## Handling

- do not use wood or dirty steel parts to dispense grease
- use clean metal scoop
- do not leave containers open after use
- use dedicated containers for storage and lubrication transfer



Source: Bowmer, Bel-Ray Company Inc.

# Lubricant hazards in the food production plant

## Packaging

- labels correct
- sealed, no damage



## Storage

- damaged packaging leaking
- contamination
- mixing food and non food grade products
- correct labeling



Source: Bel-Ray Company Inc.

# Lubricant hazards in the food production plant

## In use

- leakage from open lube points and bearings
- contact between sliding surfaces and food produce
- contamination
- spillage
- over lubrication
- non food grade lubricants mixed with food grade lubes



Source: Bel-Ray Company Inc.

# The importance of Best Manufacturing Practice

## Have clear procedures including:

- Lubrication Management System
- factory survey
- correct lubricant
- lubrication frequency
- monitoring
- sampling and testing
- record keeping for audit purposes
- lubrication training



Source: Bel-Ray Company Inc.

# The importance of Best Manufacturing Practice

## Completing lubrication tasks:

- use dedicated transfer containers
- always use clean tools
- cover areas prone to contamination
- use drip trays where possible
- use correct amount of lubricant
- clean up any spills
- identify and label critical control points to comply with HACCP regulations
- dispose of soiled wipes correctly
- complete job sheet and record actions



Source: Bel-Ray Company Inc.



# Lubricant cleanliness

## A clean lubricant will:

- last longer in the component
- ensure longer lasting parts
- will keep components clean
- lower your costs



Source: Bel-Ray Company Inc.

# Switching to food grade lubricants

## Oil Products

- drain the system
- change filters
- flush with food grade product
- check / change filters
- fill with food grade product
- seek assistance from your supplier

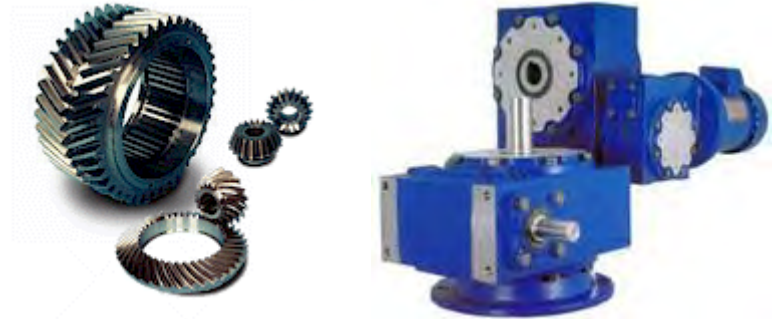
## Grease Products

- check compatibility
- clean bearing out
- 1/3 to 1/2 fill product with food grade grease
- purge any grease lines with food grade product
- seek assistance from your supplier

# Switching to food grade lubricants

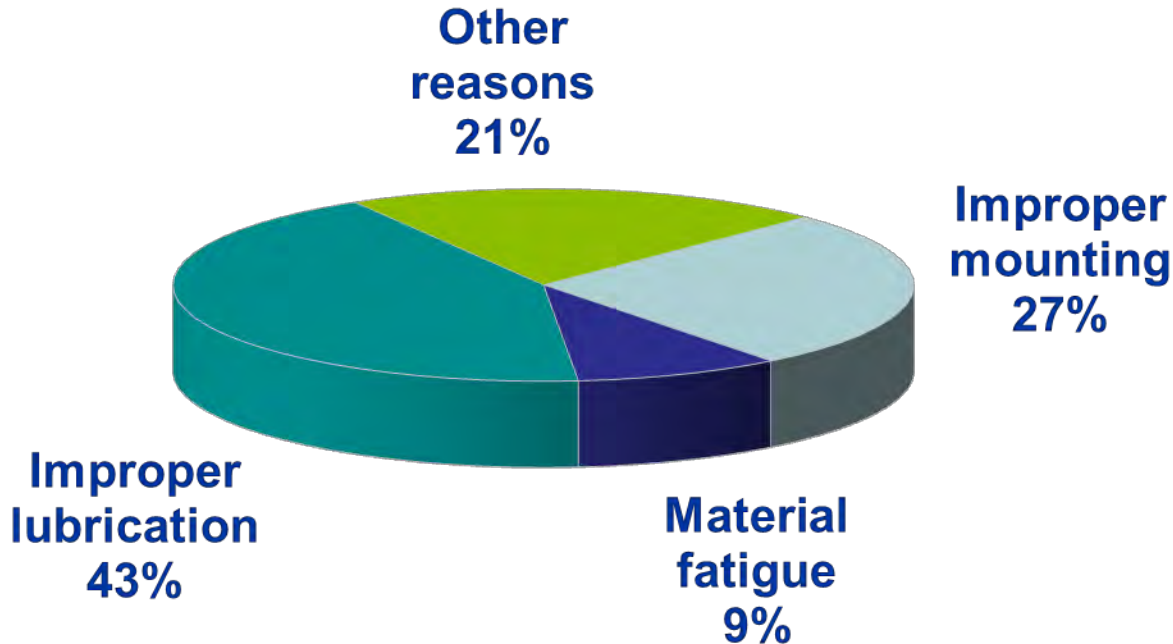
## Gear Oil Products

- drain the system
- change filters
- flush with food grade product
- check / change filters
- fill with food grade product
- run the gearbox
- sample analysis
- seek assistance from your supplier



Source: Bel-Ray Company Inc.

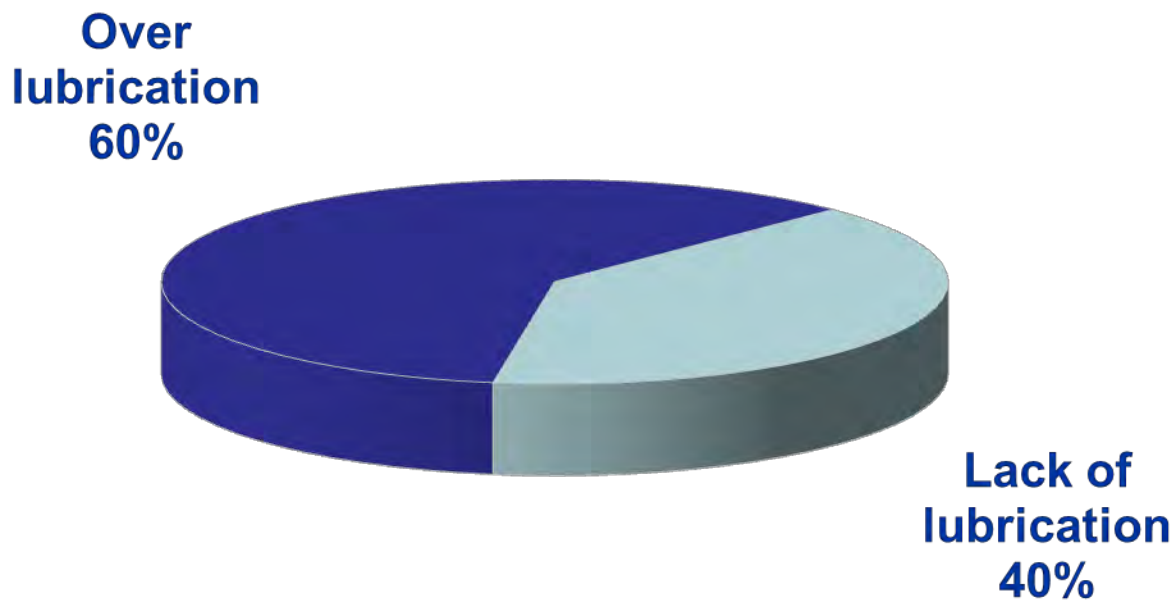
# Reasons for bearing failure



## Avoid high pressure cleaning

- water can enter the the lubrication system
- damage of sealing → spillage of oil

## Breakdown of “improper lubrication” section



## Potential failures due to over lubrication

- Standard grease gun can develop 200 bar
  - High pressure grease guns can develop >400 bar
- RISK: OVERLUBRICATION

Potentially resulting in drag of the bearing causing:

- increased power demand
- ball/roller skid
- increased friction
- excessive heat
- excessive race wear
- degradation of the lubricant

# Correct application of a lubricant

## Little & often!

### Precision bearings

- Typically fill 1/3 to 1/2 of vacant area in bearing.
- High speed bearings require approx. 1/3 fill.

### Plain bearings

- Typically fill until clean grease shows.

# Application

## Deterioration of Lubricants during operation



Bad cleaning example



Major cause of food contamination



# Application

## Potential lubricant contamination



Bearing as high risk lubrication point



Open lubrication: Contamination risk

## Summary

- use only food grade lubricant
- NSF H1 registered
- identify lubrication point
- avoid contamination
- avoid high pressure cleaning
- be alert to any spillage

# EHEDG Guideline Document 23

- guideline for using food grade lubricants
- covers all items presented today
- in depth guide to potential hazards and solutions for the safe use of food grade lubricants
- available at [www.ehedg.org](http://www.ehedg.org)