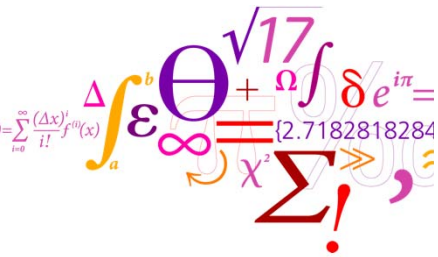
Hygienic Equipment Design and Problematic Areas in Cleaning and Disinfection of Equipment Surfaces

The Annual Veterinary Congress 2015
Helsinki Fair Center, Helsinki, Finland
December 4, 2015

Gun Wirtanen
DTU National Food Institute
Lyngby, Denmark
DTU Food
National Food Institute



The Legal Basis for Hygienic Design in EU

- **Machinery directive**
  - "Directive **2006/42/EC** of the European Parliament and of the council, on machinery"
- **Regulation no. 852/2004** of the European parliament "on the hygiene of foodstuffs" (replaced Dir. 93/43/EEC)
- **Harmonized standards EN 1672:2 + A1:2009**
  - Common hygiene requirements
  - Hygienic risk assessment
- Food contact materials
  - Regulations 1935/2004 and 2023/2006

CE marking

- Conformité Européenne (European Conformity)
- It is a declaration of conformity with relevant directive(s) and the corresponding harmonized standards
- Mandatory for all equipment sold in the EU (since 1993)
- The CE mark is not a guarantee for quality
- The CE mark signifies that minimum safety requirements are met

CE

Relevant Standards

DS/EN ISO 14159:2008 ***Safety of machinery – Hygiene requirements for the design of machinery***

- General hygiene demands for machinery
- Risk evaluation
- Design features for reduction of risks

Machinery in general

EN 1672:2 + A1:2009 ***Food processing machinery - Basic concepts - Part 2: Hygiene requirements***

- General hygiene requirements for food processing equipment
- Design features for reduction of risks

Food processing machinery specifically

EHEDG

- European Hygienic Engineering & Design Group (EHEDG)
  - A private consortium founded in 1989
  - www.ehedg.org
  - Members: food industries, equipment manufacturers, research institutes, public authorities
  - Products guidelines, training, expertise, certification and networking
  - List of EHEDG certified equipment is available online: http://www.ehedg.org/?nr=82&lang=en
- Promotes safe food by improving hygienic engineering and design in all aspects of food manufacturing
- Support European legislative work and cooperates with other organizations (e.g. 3-A)

Guidelines

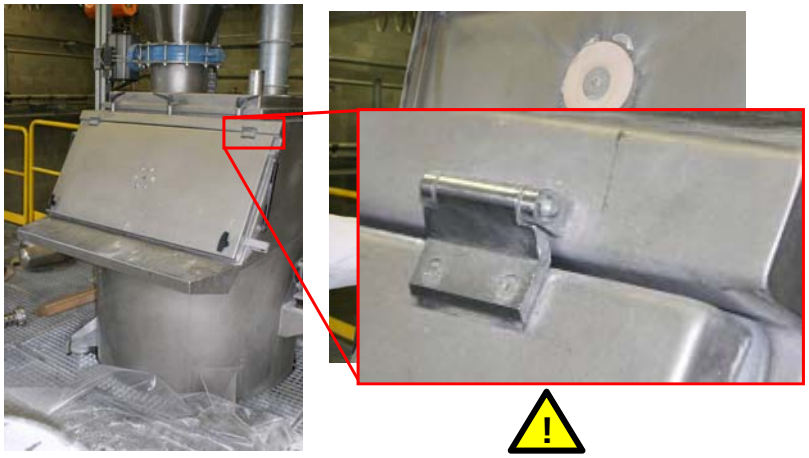
- Are produced **by recognised organisations** – thus they have validity
- They are **neither law text nor standards**
- Guidelines published by **EHEDG and 3-A** are good advice but not a legal requirement
- At the moment there are **42 Guidelines**

List of the EHEDG Guidelines (2015)

1	Microbiologically safe continuous pasteurization of liquid food (1992)
2	A method for assessing the in-place cleanability of food processing equipment (2007)
3	Microbiologically safe aseptic packing of food products (1993)
4	A method for the assessment of in-line pasteurisation of food processing equipment (1993)
5	A method for the assessment of in-line sterilisability of food processing equipment (2004)
6	The microbiologically safe continuous flow thermal sterilisation of liquid foods (1993)
7	A method for the assessment of bacteria-tightness of food processing equipment (2004)
8	Hygienic equipment design criteria (2004)
9	Welding stainless steel to meet hygienic requirements (1993)
10	Hygienic design of closed equipment for the processing of liquid food (2007)
11	Hygienic packing of food products (1993)
12	The continuous or semi-continuous flow thermal treatment of particulate foods (1994)
13	Hygienic design of equipment for open processing (2004)
14	Hygienic design of valves for food processing (2004)
15	A method for the assessment of in-place cleanability of moderately sized food processing equipment (1997)

Challenges in the hygienic design

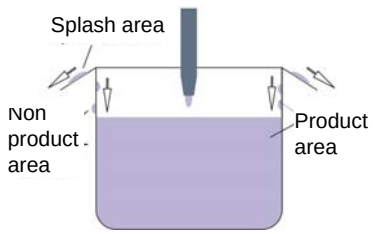
Challenges in the hygienic design



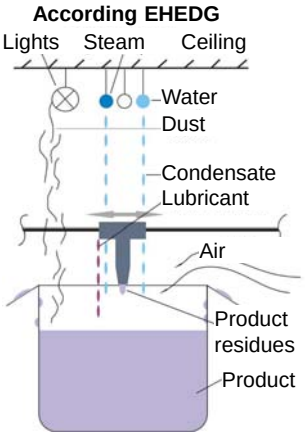
Definition - Product contact surfaces

Product contact surfaces = Surface exposed to the product (**direct**) and from which materials can drain, drip, diffuse or be drawn into (**self returned**) the product or product container (**indirect**).

According EN 1672-2



According EHEDG



Open process (GL: 8, 10 & 13)

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

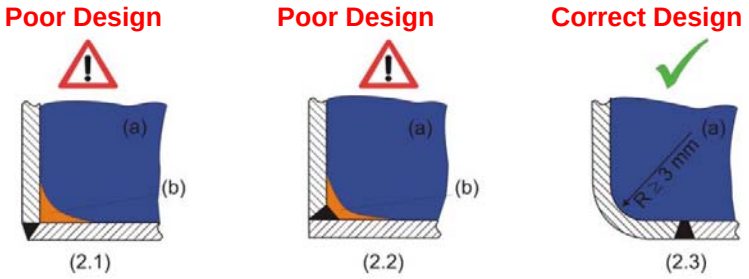
HYGIENIC DESIGN OF OPEN PROCESS EQUIPMENT AND SYSTEMS

In Guideline 13 factors affecting operation hygiene and cleanability are dealt with using the following pictures:

- welded joints (Fig. 1)
- corners (Fig. 2),
- dismountable & screw joints (Figs. 4-5)
- equipment rims (Fig. 8)
- drainability (Fig. 6)
- equipment covers (Fig. 10)
- shaft arrangements (Fig. 11)
- stirrer blade attachment (Fig. 13)
- equipment accessibility (Fig. 26)
- floor/wall fixing of equipment (Figs 24-25)
- product protection (Fig. 12)
- flange couplings (Fig. 14)
- foot bearings (Fig. 15)
- belt reinforcement (Fig. 16)
- conveyor belts (Figs 17-19)
- framework cladding (Fig. 21)
- framwork structures (Fig. 22)
- horizontal framwork (Fig. 23)
- walkway design (Fig. 27)

Welds - Internal angles & corners must be cleanable

- Sharp corners (≤90°) must be avoided
- Corners with angles smaller than 135° must be smooth and have a min. radius 3 mm (preferably equal or larger than 6mm)

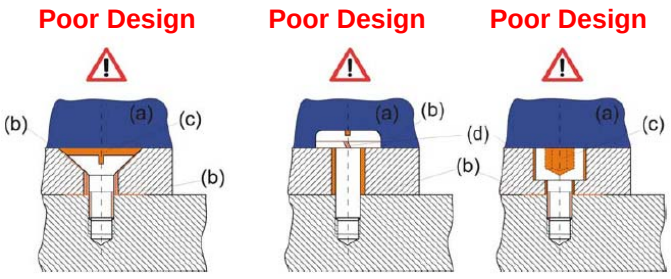


(a) product area, (b) sharp internal angle

Figure 2
Welded joints in corners. (2.1), (2.2) Welded seams in corners create uncleanable areas; (2.3) radiused corners and correctly welded seams in the plain area avoid any hygiene risk.

Dismountable joints

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

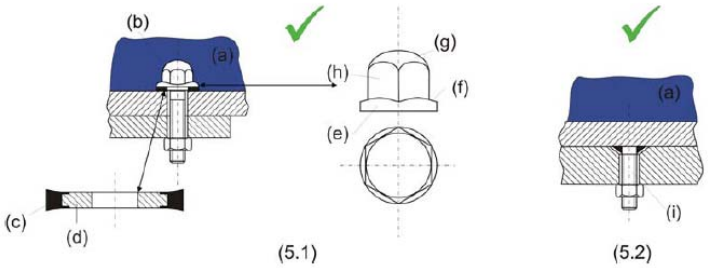


(a) product area, (b) metal-to-metal contact, (c) dead area, (d) crevice

Figure 4.
Hazards due to unhygienic design of screws exposed to product are caused by metal to metal contact, crevices, gaps and dead areas.

Dismountable joints

Correct Design **Correct Design**

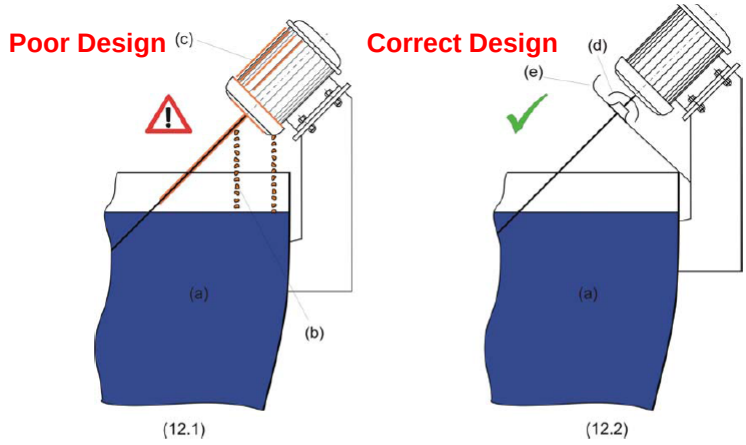


(a) product area, (b) domed head, (c) elastomer, (d) metal, (e) circular collar, (f) sloped, (g) domed, (h) hexagon, (i) stud

Figure 5
Hygienic design of screw joints. (5.1) The exposed domed head is easily cleanable and the metal backed gasket is used to seal the thread; (5.2) if applicable, any risk can be avoided by using a stud welded on the non product side.

Example of joints

Arrangement of ancillary equipment

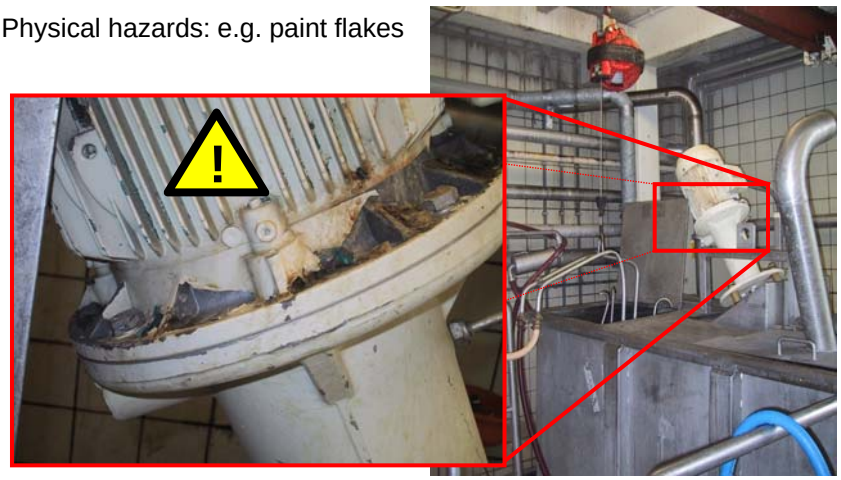


(a) product area, (b) contamination [condensate, lubricants], (c) motor with fins [dead areas], (d) thrower ring, (e) self-draining protection sheet with "upstand" [dismountable]

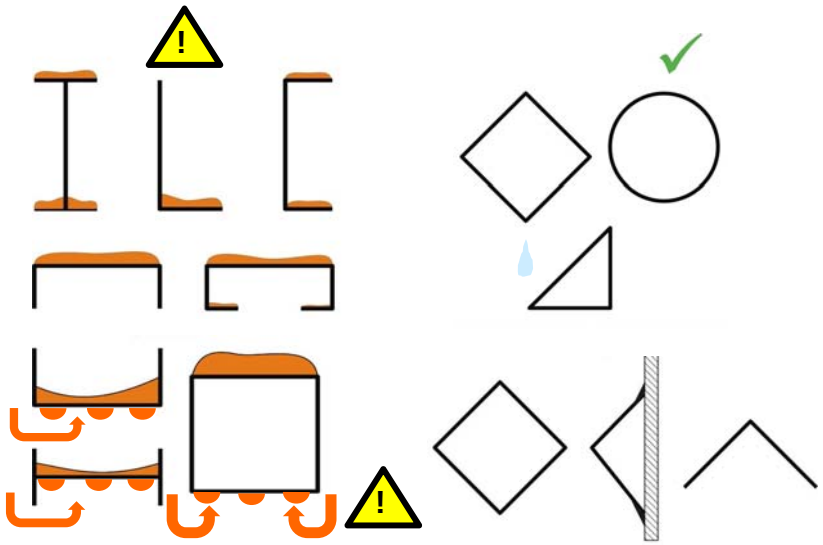
Figure 12
Protection of product. (12.1) Equipment mounted over any exposed product can contaminate it by soil, condensate or lubricants; (12.2) protection sheets, covers, and cowls must be arranged to protect the product.

Arrangement of ancillary equipment

Physical hazards: e.g. paint flakes



Framework structures



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Framework example

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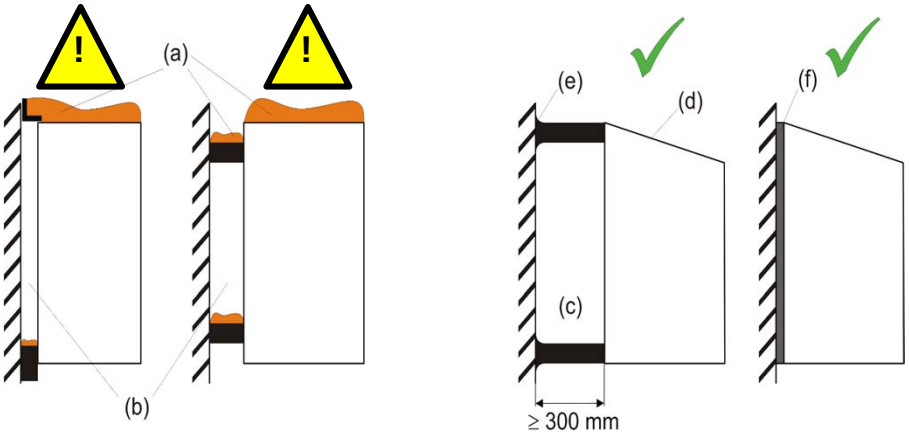
Framework example

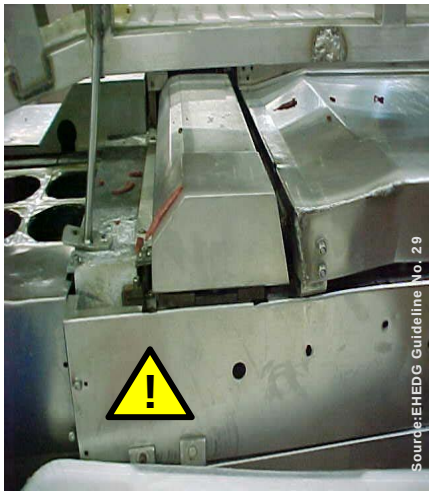
Horizontal surfaces

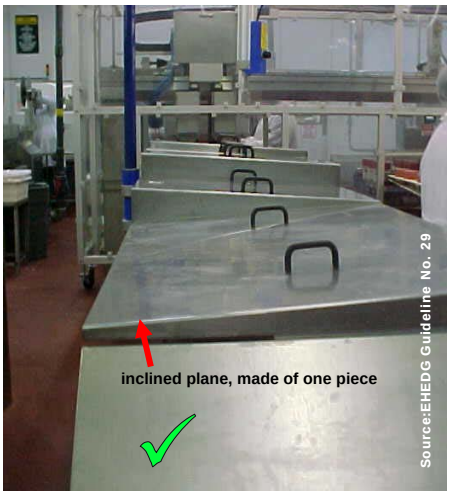
Avoid product or liquid collection



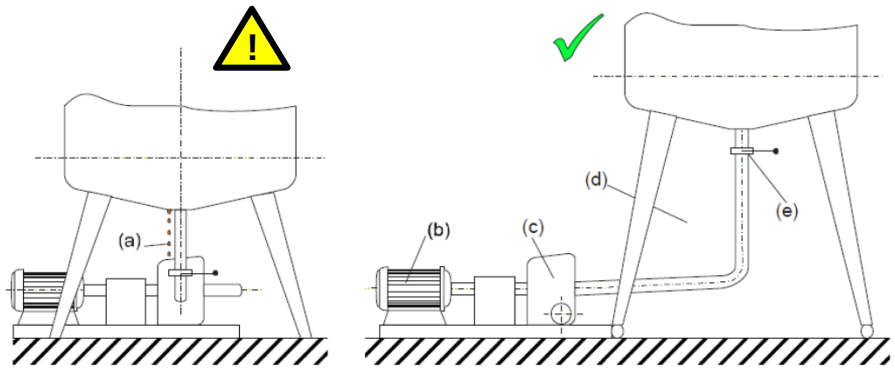
(a) soil residue, (b) narrow clearance, (c) clearance, (d) slope, (e) radius, (f) sealing

Horizontal surfaces





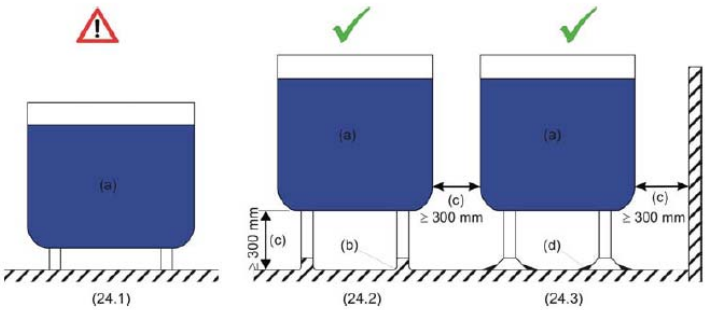
Accessibility



(a) condensate, (b) motor, (c) pump, (d) clearance, (e) valve

Accessibility

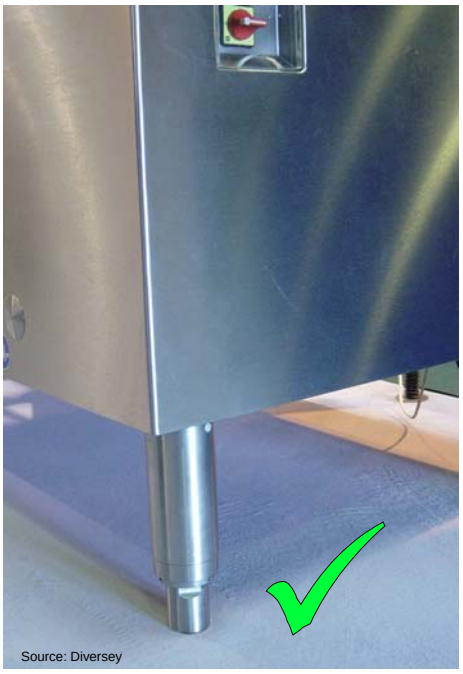
Poor Design **Correct Designs**



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

Figure 24
Equipment fixed to floors. (24.1) Underneath equipment with a small clearance to the floor, cleaning will be complicated; in addition, unradiused and improperly fixed feet, sharp corners and crevices at the fixing point cause hygiene risks; (24.2) feet properly fixed to rounded pedestals or (24.3) sealed to the floor with sufficient clearance characterise hygienic design.

Accessibility


Source: Diversey

Closed process (GL: 8 & 10)

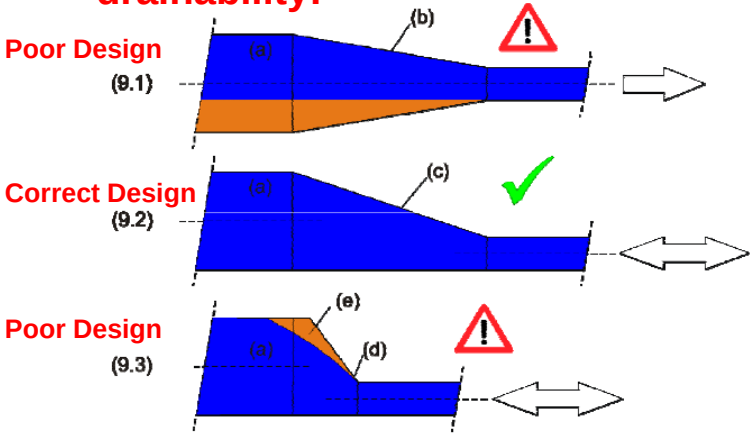
- product are **produced in tanks** and **moved with pipes** to the packaging machine
- the **product contact surfaces** should be easily **cleanable** using cleaning-in-place (**CIP**) **procedures**
- design of equipment must **prevent contamination**

HYGIENIC DESIGN OF CLOSED PROCESS EQUIPMENT AND SYSTEMS

In Guideline 10 drawings on: 1) how to avoid crevices, shadow zones and stagnant product areas, 2) how to connect and position equipment in a process line to ensure unhampered draining and cleaning-in- place *etc*. & 3) how to prevent leakages in processes and thus also product contamination:

- pipe joints (Fig. 1)
- metal-to-metal seal (Fig. 2),
- O-ring seals (Figs 3-4)
- flange connection (Fig. 5)
- heating of sealing (Fig. 6)
- dynamic seal (Fig. 7)
- double shaft-seal (Fig. 8)
- pipe transitions (Fig. 9)
- dead legs (Figs 13-14)
- centrifugal and lobe pumps (Fig. 11)
- pump by-pass arrangements (Fig. 17)
- swept tee (Fig. 10)
- flow diversion (Fig. 16)
- poor probe mounting (Fig. 12)
- temperature probes (Fig. 15)
- screw connections (Fig. 20)
- vessel lid mounting (Fig. 19)
- metal plate welding (Fig. 18)
- vessel insulation (Fig. 21)

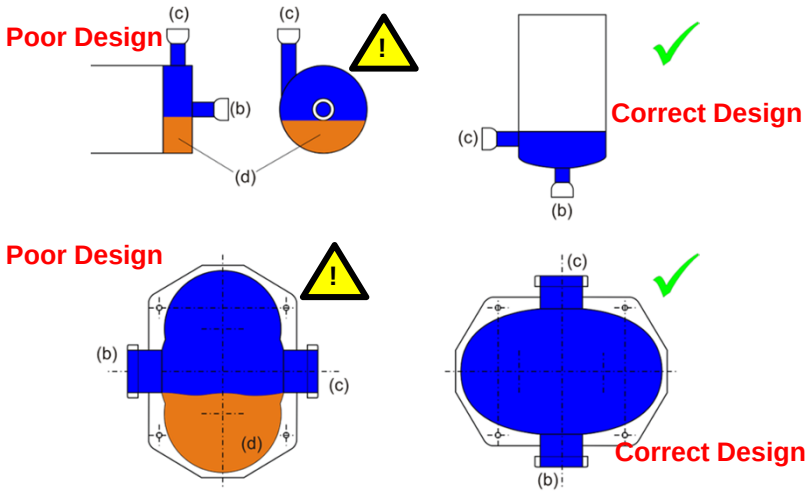
Example drawings of pipe transitions drainability:



(a) product area, (b) concentric reducer, (c) eccentric reducer, long version, (d) eccentric reducer, short version, (e) potential shadow zone

Figure 9 — Transition of pipe diameters.

Example drawings of drainability in pumps:

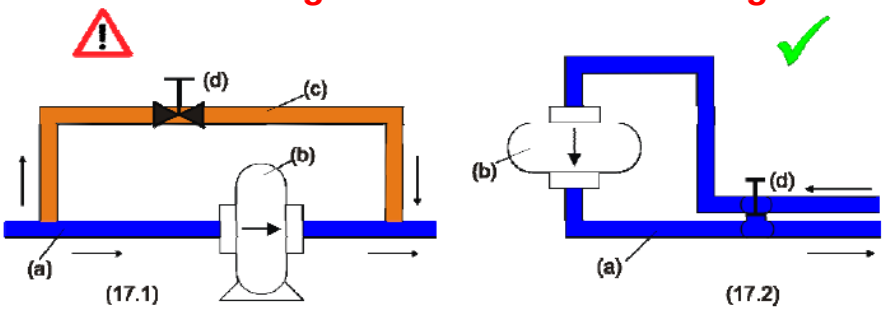


(a) product area, (b) inlet, (c) outlet, (d) undrainable volume

Examples drawings of pump by-pass arrangements

Poor Design

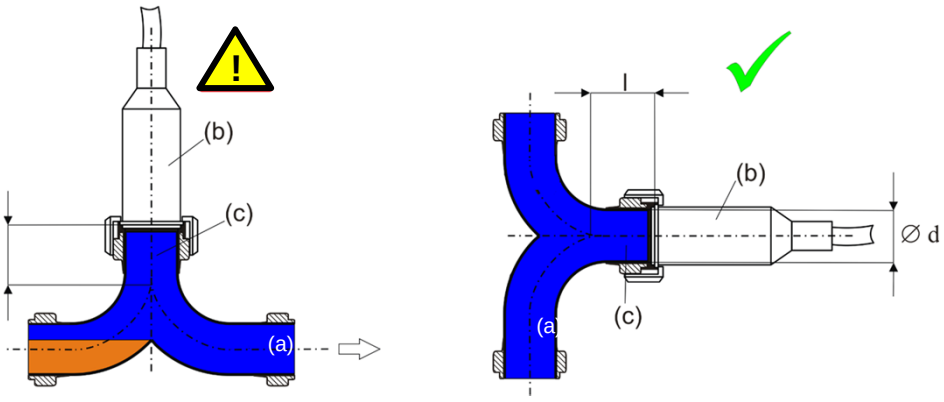
Correct Design



(a) product area, (b) positive displacement pump, (c) bypass, (d) valve

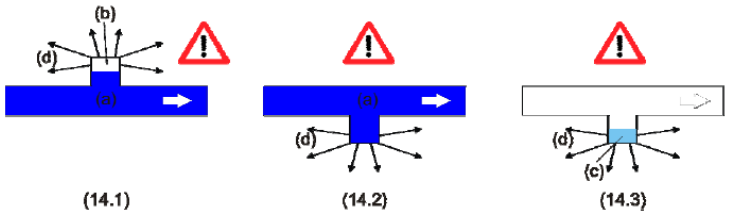
Figure 17 — Arrangements for positive displacement pumps with pressure relief valve or bypass.

Drainability



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

Pipe drawings of POOR DESIGNS:



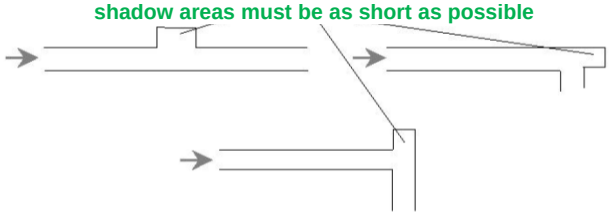
(a) product area, (b) air bubble, (c) condensate, (d) heat radiation; arrows represent heat loss

Figure 14 — The adverse influence of dead areas on the decontamination of process lines.

(14.1) and 14.2) decontamination with liquids;

(14.3) decontamination with steam.

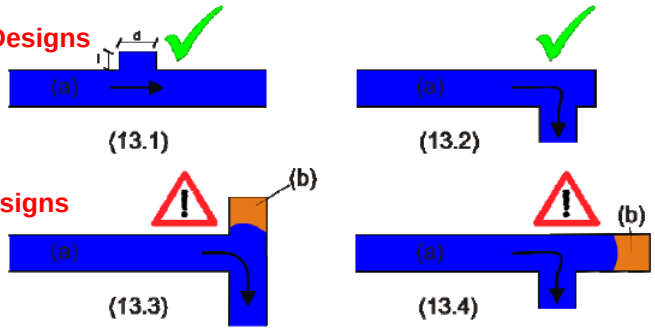
shadow areas must be as short as possible



Examples of pipe drawings e.g. T-pieces in CIP cleaning (dead legs => l/d < 1)

Correct Designs

Poor Designs

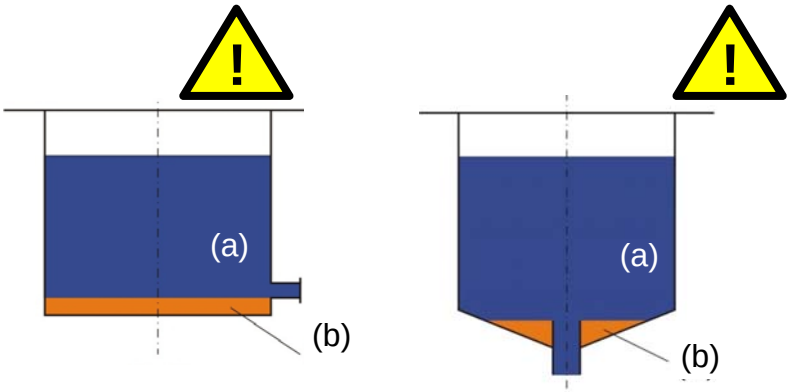


(a) product area, (b) dead leg with residual soil

Figure 13 — Position of dead legs with reference to the flow of product and cleaning liquids.

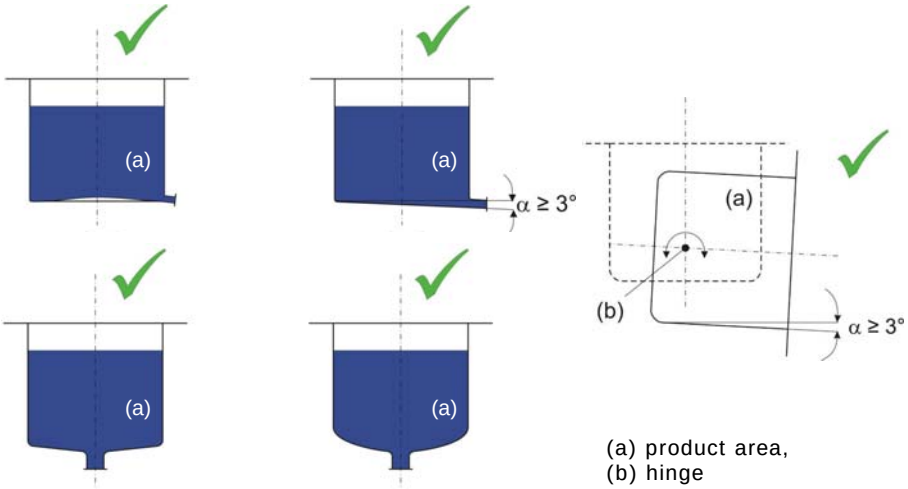
Short dead legs (13.1, 13.2) will be cleanable, long ones not (13.3, 13.4). Dead leg position in (13.4) is better than in (13.3) due to the direction of the flow.

Poor drainability in tanks



(a) product area, (b) residual soil
Right tank: tank for special purposes (e.g. brewery)

Self-drainable designs of tanks



(a) product area,
(b) hinge

Details in Hygienic Design:

- **Materials** must be durable in the process temperature interval, should not affect the odour and taste of the product produced, be corrosion resistant, be wear and tear proof as well as be **easily cleanable.**
- The **surface structure of the material** must be **smooth:** the surface profile properties e.g. shape, height and roughness can be measured.
- **Joints** shall be **shallow and polished** to the same roughness as the surrounding surfaces.
- **Suitable materials in the gaskets** shall be used since **metal/metal** joints are **not tight.**

Details in Hygienic Design:

- **Fastners** with e.g. nuts, bolts, screws and rivets shall be **avoided in product contact areas.** Alternative fastening methods should be used.
- Pipes and equipment should be **self draining.**
- **Dead spaces** should be **avoided.**
- **Internal angels and corners** should be **aradiused** to facilitate cleaning.
- **Bearings and shaft seals** shall be mounted **outside the production area** to avoid contamination.
- **Instrumentation** should be **hygienic.**
- **Surfaces** shall be construced **to avoid accumulation of dust**.

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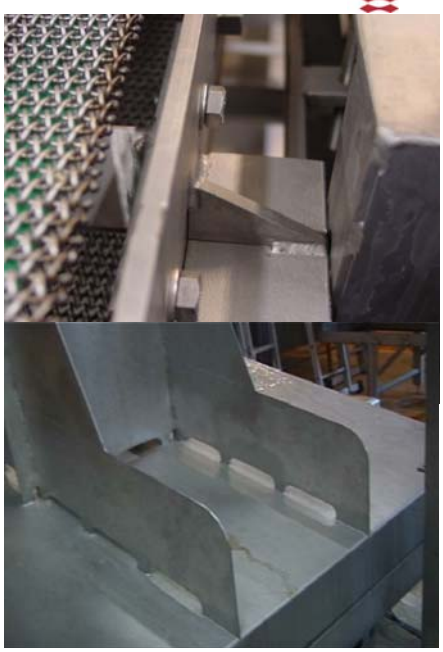
In Summary
Equipment shall be:

- Accessible
- Cleanable
- Drainable



SUMMARY

- Hygiene aspects should be in focus when designing both food processing equipment and food processing layout - saving money and time
- Legislation do not contain any detailed instructions for hygienic design. There are guidelines and standards available e.g. by European Hygienic Engineering & Design Group (EHEDG), by 3-A SSI, by NSF, by ISO & by BRC.
- Wrongly designed constructions are the major reason for poor hygiene in equipment.
- More attention should be paid to hygienic design when purchasing equipment.