Hygienic equipment design and problematic areas in cleaning and disinfection of equipment surfaces

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The Legal Basis for Hygienic Design in EU

• Machinery directive

• 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

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

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 reduction of risks
EHEDG

- European Hygienic Engineering & Design Group (EHEDG)
  - A private consortium founded in 1989
  - [www.ehedg.org](http://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)
6. The microbiologically safe continuous flow thermal sterilisation of liquid foods (1993)
9. Welding stainless steel to meet hygienic requirements (1993)
10. Hygienic design of closed equipment for the processing of liquid food (2007)
12. The continuous or semi-continuous flow thermal treatment of particulate foods (1994)

Challenges in the hygienic design

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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

Non product area

Product area

Splash area

According EHEDG

Lights
Steam
Ceiling

Water
Dust
Condensate
Lubricant

Air

Product residues
Product

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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
Welds - Internal angles & corners must be cleanable

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

![Image](image)

(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

![Image](image)

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

Figure 4
*Hazard 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) slopeid, (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.

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Example of joints

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**Arrangement of ancillary equipment**

**Poor Design**

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

**Correct Design**

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

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Framework structures

Source: Soro, AINIA

Framework example

Source: Soro, AINIA
Framework example

Horizontal surfaces

Avoid product or liquid collection

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

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Horizontal surfaces

![Image showing horizontal surfaces with an incline plane made of one piece.]

Source: EHEDG Guideline No. 29

Accessibility

![Image showing accessibility with parts labeled: (a) condensate, (b) motor, (c) pump, (d) clearance, (e) valve.]

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

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**Accessibility**

**Poor Design**

**Correct Designs**

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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.
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**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 for drainability:

Poor Design (9.1)

Correct Design (9.2)

Poor Design (9.3)

(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.

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Example drawings of drainability in pumps:

Poor Design

Correct Design

Poor Design

Correct Design

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

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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.

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Drainability

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

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**Pipe drawings of POOR DESIGNS:**

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

Correct Designs

Poor Designs

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Poor drainability in tanks

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

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Self-drainable designs of tanks

(a) product area, (b) hinge

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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 constructed 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.