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HYGIENIC EQUIPMENT DESIGN CRITERIA*

(Second edition)

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1 Introduction

This document describes the criteria for the hygienic design of equipment intended for the processing of foods. Its fundamental objective is the prevention of the microbial contamination of food products. Such contamination may, of course, originate from the raw materials, but the product may also be contaminated with micro-organisms during processing and packaging. If equipment is of poor hygienic design, it will be difficult to clean. Residues (soil) may be retained in crevices and dead areas, allowing the micro-organisms which they harbour to survive and multiply. These may then cross-contaminate subsequent batches of product.

Although a primary objective of design remains that the equipment is able to fulfil its engineering function, sometimes the requirements of hygiene will conflict with this. In seeking an acceptable compromise it is imperative that food safety is never put at risk.

Upgrading an existing design to meet hygiene requirements can be prohibitively expensive and may be unsuccessful and so these are most effectively incorporated into the initial design stage. The long-term benefits of doing so are not only product safety but also the potential to increase the life expectancy of equipment, reduce maintenance and consequently lower operating costs.

This document was first published in 1993 with the intention to describe in more detail the hygienic requirements of the Machinery Directive (89/392/EEC superseded by 98/37/EC; *ref. 1*). Afterwards parts of it have been included in the standards EN 1672-2 and EN ISO 14159.

2 Objective and Scope

This document details the principal hygienic design criteria to be met by equipment for the processing of foods. It gives guidelines on how to design, construct and install such equipment so that it does not adversely affect food quality; especially safety. The guidelines apply to durable equipment used for batch and continuous, open and closed manufacturing operations.

The susceptibility of the product to microbial activity will determine the balance between normal engineering demands and those of hygiene. For example, dry products do not support the growth of micro-organisms and requirements will be more relaxed than for moist products. However, if the equipment is to be used for products destined for 'at-risk' consumer groups, the hygiene demands on design will be more stringent. Here the designer may need to consult appropriate authorities such that the right balance is achieved.

3 Normative references

The following documents contain provisions that, through reference, constitute provisions of this EHEDG Guideline. At the time this Guideline was prepared, the editions listed below were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent editions of the documents indicated below.

EN 1672-2:1997 Food processing machinery – Basic concepts – Part 2: Hygienic Requirements

EN ISO 14159:2002 (E) Safety of machinery – Hygiene requirements for the design of machinery

4 Definitions

The definitions in the EHEDG Glossary (see www.ehedg.org/glossary.pdf) apply to this guideline. The most relevant definitions specific to hygienic equipment design are:

Product contact surface

All equipment surfaces that intentionally or unintentionally (e.g. due to splashing) come in contact with the product, or from which product or condensate may drain, drop or be drawn back into the main product or product container, including surfaces (e.g. unsterilised packaging) that may indirectly cross-contaminate product contact surfaces or containers. A risk analysis can help to define areas of cross contamination.

Non-product contact surface

All other exposed surfaces.

Non-toxic construction materials

Materials which, under the conditions of intended use, do not release toxic substances.

Non-absorbent materials

Materials which, under the conditions of intended use, do not internally retain substances with which they come into contact.

Conditions of intended use (for the equipment)

All normal or reasonably anticipated operating conditions, including those of cleaning. These should set limits for variables such as time, temperature and concentration.

5 Materials of construction

Materials used in the construction of food machinery must fulfil certain specific requirements. Product-contact materials must be inert both to the product and to detergents and disinfectants under the conditions of intended use. They must also be corrosion resistant, non-toxic, mechanically stable, and their surface finish must not be adversely affected under the conditions of intended use. Non-product-contact materials shall be mechanically stable, smoothly finished and easily cleanable.

It is worthwhile maintaining an awareness of new developments in materials and products for the food industry and seeking the advice of materials suppliers where appropriate.

5.1 Non-toxicity

As the presence of toxic elements in the food is unacceptable, the designer has to take care that only non-toxic materials of construction are used in direct contact with the product. It is imperative to check legislative aspects – many countries have codes of practice and directives covering the composition of materials in contact with foodstuffs and it should be ensured that the use of a specific material is permitted under existing or pending legislation (*ref. 2*).

Stainless steels are the logical choice for materials of construction for process plant in the food industry but, depending on the application, some polymeric materials may have advantages over stainless steel such as lower cost and weight or better chemical resistance. However, their non-

toxicity, and those of materials such as elastomers, lubricants, adhesives and signal transfer liquids, must be assured.

5.2 Stainless steel

Generally stainless steels offer excellent corrosion protection, and they are therefore widely used in the food industry. The range of stainless steels available is extensive and the selection of the most appropriate grade will depend on the corrosive properties (in terms not only of the chemical ions involved but also the pH and the temperature) of the process and of the cleaning and antimicrobial chemicals. However, the choice will also be influenced by the stresses to which the steel will be subjected and its machinability, formability, weldability, hardness and cost.

Where good resistance to general atmospheric corrosion is required, but the conditions of intended use will involve only solutions with a pH of between about 6.5 and 8, low levels of chlorides (say, up to 50mg/l [ppm]) and low temperatures (say, up to 25°C), the most common choice would be AISI-304, an austenitic 18%Cr/10%Ni stainless steel, or its low-carbon version AISI-304L (DIN 1.4307; EN X2CrNi18-9), which is more easily welded.

If both the level of chlorides and the temperature exceed approximately double these values, the material will require greater resistance to the crevice- and pitting-corrosion which may result from chlorides concentrating locally. The addition of molybdenum to AISI-304 (creating AISI-316) improves its corrosion-resistance and this grade of stainless steel is recommended for components such as valves, pump casings, rotors and shafts, while its low-carbon equivalent AISI-316L (DIN 1.4435; EN X2CrNiMo18-14-3) is recommended for pipework and vessels due to its enhanced weldability. Alternatively, titanium may be appropriate.

As temperatures approach 150°C, even AISI-316 stainless steels may suffer from stress-corrosion cracking where regions of high stress are exposed to high levels of chloride. Here AISI-410, AISI-409, AISI-329, or even Incoloy 825 (*ref. 3*) may be required for their high strength and/or high corrosion resistance, although they may be more costly.

AISI, DIN and EN designations of stainless steels commonly used in the food industry are given in Table 1.

Table 1. AISI, DIN and EN designations of stainless steels commonly used in the food industry

AISI	DIN/EN	Typical analyses					
		C%	Cr%	Ni%	Mo%	Ti%	N%
304L	eg: DIN 1.4307 (EN X2CrNi18-9)	< 0.03	18	9			
316L	eg: DIN 1.4435 (EN X2CrNiMo18-14-3)	< 0.03	18	14	3		
410	DIN 1.4006 (EN X12Cr13)	< 0.12	13	< 0.75			
409	DIN 1.4512 (EN X2CrTi12)	< 0.03	11.5			< 0.65	
329	DIN 1.4460 (EN X3CrNiMoN27-5-2)	< 0.05	27	5.5	1.7		< 0.20

A separate EHEDG Guideline on Materials of Construction is in preparation and full specifications for non-cast stainless steels are available from AISI (*ref. 4*) and EN/DIN (*ref. 5*) and for cast stainless steels from ACI (*ref. 6*).

5.3 Polymeric materials

When choosing polymeric materials the following criteria should be considered:

- Compliance with regulatory requirements and recommendations (*ref. 7, 8*)
- Compatibility with food stuffs and ingredients (chemical resistance to oil, fat, preservatives)
- Chemical resistance (cleaning and disinfectants)
- Temperature resistance in use (upper and lower use temperature)
- Steam resistance (CIP / SIP)
- Stress-crack resistance
- Hydrophobicity / reactivity of the surface
- Cleanability, effect of surface structure and smoothness, residue accumulation
- Adsorption / desorption
- Leaching
- Hardness
- Resilience
- Cold flow resistance
- Abrasion resistance
- Processing technology (injection moulding, melt-extrusion, transfer-moulding, paste-extrusion, welding, various coating technologies)

Polymers frequently used in hygienically designed equipment are:

- Acetal (Homo- and Co-Polymer) (POM)
- Fluoropolymers, e.g.:
 - Ethylene-Tetrafluoroethylene Copolymer (ETFE)
 - Perfluoroalkoxy Resin (PFA),
 - Polytetrafluoroethylene (PTFE, modified PTFE)
 - Polyvinylidene Fluoride (PVDF)
 - Fluorinated Ethylene Propylene Copolymers (FEP)
- Polycarbonate (PC)
- Polyetheretherketone (PEEK)
- Polyether Sulfone (PESU)
- High Density Polyethylene (HDPE)
- Polyphenylene Sulfone (PPSU)
- Polypropylene (PP)
- Polysulfone (PSU)
- Polyvinyl Chloride, unplasticised (PVC)

If considering the use of Polytetrafluoroethylene (PTFE), it must be taken into account that PTFE can be porous and difficult to clean. But certain grades of modified PTFE and fully fluorinated co-polymers such as PFA have been proven to meet EHEDG requirements for cleanability.

Polymeric materials – like other materials of construction such as glass, steel and enamel – must be selected based on the conditions of intended use.

Certain polymers, particularly Fluoropolymers, can be applied as a coating material (thin layers from 50 µm to about 1.2 mm) on many metallic substrates to improve their chemical resistance or other surface related properties. Technologies to apply the coatings depend on the geometry of the component and it is advisable to discuss options with the raw material supplier and manufacturer. It is suggested that a food compliance statement be requested from the raw material manufacturer.

For further information and details on the temperature and chemical resistance of the various polymers listed above and the parts made thereof, please refer to the specific product data sheets and/or contact your part supplier or the polymer manufacturer directly.

5.4 Elastomers

The same parameters as listed in the ‘polymeric materials’ section above will apply for the selection of an elastomer. When it comes to finished parts then identification and traceability become important issues that need to be addressed. Compliance with FDA regulations can be covered through Food Contact Notification (FCN) certificates as well as conformity statements to 21 CFR 177.2600, for example.

The elastomer types that can be used in the food industry for seals, gaskets and joint rings are:

- Ethylene Propylene Diene Monomer (EPDM) *
- Fluoroelastomer (FKM)**
- Hydrogenated Nitrile Butyl Rubber (HNBR)
- Natural Rubber (NR)
- Nitrile/Butyl Rubber (NBR)
- Silicone Rubber (VMQ)**
- Perfluoroelastomer (FFKM)***

* EPDM is not oil and fat resistant

** also for temperature applications up to 180 °C

*** also for high temperature applications up to and above 300°C

For further information and details on the suitability of the various elastomers listed above and the parts made thereof, please refer to the specific product data sheets and/or contact your part supplier or the elastomer manufacturer directly.

5.5 Adhesives

Adhesives used should always comply with the FDA regulations and with the recommendations of the supplier of the equipment for which those gaskets are used. This is required to ensure that the adhesive will not lead to localised corrosion attack of the stainless steel of the equipment or release toxic components under the conditions of intended use. All bonds must be continuous and mechanically sound, so that the adhesive does not separate from the base materials to which it is bonded.

5.6 Lubricants

Equipment should be designed such that lubricants do not come into contact with products. Where contact may be incidental lubricants should conform to the NSF Non-Food Compounds Registration Program. This supersedes the USDA product approval and listing program, which is based on meeting regulatory requirements including FDA 21 CFR for appropriate use, ingredients and labelling (*ref. 9*). Further guidance on production and use of lubricants is available in EHEDG document No.23 (*ref. 10*).

These documents specify which components are allowed in oils and greases used for lubricating purposes, as protective anti-rust film, as release agent on gaskets and seals of tank closures, and as a lubricant for machine parts and equipment in locations where there is exposure of the lubricated parts to food or food ingredients.

5.7 Thermal insulation materials

Thermal insulation of equipment must be carried out in such a way that the insulation material cannot be wetted by ingress of water from the outside environment (e.g. hosing down, condensation on cold surfaces). The insulation material may not contain chloride. Ingress of water may otherwise lead to a build up of chloride on the stainless steel surfaces, resulting in stress corrosion cracking or pitting corrosion. Ingress of water may also result in loss of insulation performance.

5.8 Signal transfer liquids

Liquids used for signal transfer may come into contact with the process fluids if the barrier between them fails. Therefore these liquids must be food grade.

6 Functional requirements

Hygienic food processing equipment should be easy to maintain to ensure it will perform as expected to prevent microbiological problems. Therefore, the equipment must be easy to clean and protect the products from contamination. In the case of aseptic equipment, the equipment must be pasteurisable or sterilisable (depending on the application) and must prevent the ingress of micro-organisms (i.e. it must be bacteria tight). It must be possible to monitor and control all of its functions which are critical from a microbiological safety point of view.

6.1 Cleanability and decontamination

Cleanliness is a very important issue. Equipment which is difficult to clean will need procedures which are more severe, require more aggressive chemicals and longer cleaning and decontamination cycles. Results will be higher cost, reduced availability for production, reduced lifetime of the equipment, and more effluent.

6.2 Prevention of ingress of micro-organisms

Ingress of micro-organisms into products must be avoided in general. Usually, it is desirable to limit the number of micro-organisms in food products as much as possible to meet requirements of public health and required shelf life.

Equipment intended for aseptic processes must additionally be impermeable to micro-organisms.

6.3 Prevention of growth of micro-organisms

Under favourable conditions micro-organisms grow very rapidly. Consequently any areas, e.g. dead areas, gaps and crevices, where micro-organisms can harbour must be avoided.

6.4 Compatibility with other requirements

A design with excellent hygienic characteristics but lacking the ability to perform its functional duties is of no use; hence a designer may have to compromise. Such action, however, will have to be compensated by more intensive cleaning and decontamination procedures and these must be documented so that the users are aware of the nature of the compromise. The cleanability of the equipment, including the CIP where appropriate, must be demonstrated.

6.5 Validation of the hygienic design of equipment

Irrespective of the amount of know-how and experience with hygienic design which is applied when designing and fabricating, practice has shown that inspection, testing and validation of the resulting design to check if the requirements are met is very important. In critical cases it may be necessary to check the hygiene level as part of the maintenance procedures. The designer has to make sure that relevant areas are accessible for inspection and/or validation.

7 Hygienic design and construction

In the design, fabrication and installation of equipment the following basic criteria must be taken into consideration:

7.1 Surfaces and geometry

Surfaces must be cleanable and must not present a toxicological hazard by leaching of components into the food. All product contact surfaces must be resistant to the product, and to all detergents and disinfectants under the full range of operating conditions (the intended conditions of use). Product contact surfaces must be made of non-absorbent materials and must satisfy the roughness requirements as specified under section 7.2 below.

Product contact surfaces must be free of imperfections such as crevices, therefore:

- Avoid direct metal to metal joints other than welding (metal to metal contact may harbour soil and micro-organisms). In the case of equipment intended for aseptic processing, the hazard also exists that metal to metal seals will not prevent the ingress of bacteria.
- Avoid steps due to misalignment in equipment and pipe connections.
- If seals or gaskets are used, their design must be such that no crevice exists where soil residues may be trapped and bacteria can accumulate and multiply.
- Unless deformed to obtain a flush static seal at the product side, the use of O-rings in contact with the product must be avoided in hygienic equipment and piping systems (*ref. 11*). For appropriate O-ring design, see EHEDG document No. 16 (*ref. 12*).
- Eliminate the contact of product with screw threads.
- Corners should preferably have a radius equal to or larger than 6 mm; the minimum radius is 3 mm. Sharp corners ($\leq 90^\circ$) must be avoided.

If used as a sealing point, corners must be as sharp as possible to form a tight seal at the point closest to the product/seal interface. In this situation a small break edge or radius of 0.2 mm may be required to prevent damage to elastomeric seals during thermal cycling.

If for technical and functional reasons any of these criteria cannot be met the loss of cleanability must be compensated in some way, the effectiveness of which must be demonstrated by testing.

All surfaces in contact with product must be either easily accessible for visual inspection and manual cleaning, or it must be demonstrated that routine cleaning completely removes all soil. If cleaning in-place (CIP) techniques are used, it must be demonstrated that the results achieved without dismantling, are satisfactory (see section 7.8 “Testing the hygienic characteristics of equipment”).

7.2 Surface finish / surface roughness

Product contact surfaces should have a finish of an acceptable Ra value and be free from imperfections such as pits, folds and crevices (for definition of Ra, see ISO 4287:1997). Large areas of product contact surface should have a surface finish of 0.8 μm Ra, or better, although the cleanability strongly depends on the applied surface finishing technology, as this can affect the surface topography.

It should be noted that cold-rolled steel has a roughness of Ra = 0.2 to 0.5 μm and therefore usually does not need to be polished in order to meet surface roughness requirements, provided the product contact surfaces are free from pits, folds and crevices when in the final fabricated form.

A roughness of Ra >0.8 μm is acceptable if test results have shown that the required cleanability is achieved because of other design features, or procedures such as a high flow rate of the cleaning agent. Specifically, in the case of polymeric surfaces, the hydrophobicity, wettability and reactivity may enhance cleanability (*ref. 13*).

The relation between the treatment of stainless steel and the resultant surface topography is indicated in Table 2. It is the topography which governs the cleanability. Pits, folds, crevices, surface ruptures and irregularities which have been peened over can all leave regions inaccessible to cleaning agents.

Table 2. Examples of surface treatments of stainless steel and resulting surface topography

Surface treatment	Approx. Ra values (μm)	Typical features of the technique
Hot rolling	> 4	Unbroken surface
Cold rolling	0.2 - 0.5	Smooth unbroken surface
Glass bead blasting	< 1.2	Surface rupturing
Ceramic blasting	< 1.2	Surface rupturing
Micropeening	< 1	Deformed (peened) surface irregularities
Descaling	0.6 – 1.3	Crevices depending on initial surface
Pickling	0.5 – 1.0	High peaks, deep valleys
Electropolishing		Rounds off peaks without necessarily improving Ra
Mechanical polishing with aluminium oxide or silicon carbide		Surface topography highly dependent on process parameters, such as belt speed and pressure.
Abrasive grit number		
500	0.1 – 0.25	
320	0.15 – 0.4	
240	0.2 – 0.5	
180	\leq 0.6	
120	\leq 1.1	
60	\leq 3.5	

Non-product contact surfaces must be smooth enough to ensure that cleaning is easy.

7.3 Drainability and lay-out

The exterior and interior of all equipment and pipework must be self-draining or drainable and easily cleanable. Horizontal surfaces must be avoided; instead surfaces should always slope to one side. In

the case of external surfaces, this should result in any liquid flowing away from the main product area.

7.4 Installation

The risk of condensation on equipment, pipe work and the internal surfaces of the building should be avoided wherever possible. If unavoidable, the design should be such that condensate is diverted away from the product.

Equipment and support structures must be sealed to the supporting surface (floor, walls, columns, ceiling) in such a way that no pockets or gaps exist. Any clearance between equipment and the civil construction (floors, walls and ceiling) shall be adequate for cleaning and inspection (*ref. 14*).

7.5 Welding

Permanent metal to metal product contact joints must be continuously welded and free of imperfections.

During welding, protection of both the torch side and the opposite side of the weld by an inert gas may be required. If carried out properly, the need for post welding treatments (grinding, polishing) will be minimised. For pipework, the preferred method is automatic orbital welding, which is capable of producing consistently high quality welds.

Welds on the non-product contact side must be continuous; they must be smooth enough to allow proper cleaning.

Detailed recommendations on welding to meet hygienic requirements are given in EHEDG document No. 9 (*ref. 15*).

7.6 Supports

Supports for piping or equipment must be fabricated and installed such that no water or soils can remain on the surface or within the supports. The possible adverse galvanic reactions between dissimilar materials should be taken into consideration.

7.7 Insulation

Options available for insulation of equipment and pipework are:

- Sealed cladding
Insulation materials should be clad with stainless steel, which must be fully welded, so that no ingress of air or moisture is possible, as this may encourage microbial growth and hence increase the risk of microbial contamination or corrosion of the cladding if the insulation materials release chlorides.
- Vacuum
Pipework can be insulated by evacuation of air in the shell of double walled pipe. This is a very effective way of preventing any of the problems listed.

7.8 Testing the hygienic characteristics of equipment

A series of EHEDG test methods for assessing the hygienic characteristics of equipment has been published.

- A method for assessing the in-place cleanability of food processing equipment, EHEDG Doc. 2 (*ref. 16*)
- A method for the assessment of in-line pasteurisation of food processing equipment, EHEDG Doc. 4 (*ref. 17*)
- A method for the assessment of in-line sterilisability of food processing equipment, EHEDG Doc. 5 (*ref. 18*)
- A method for the assessment of bacteria tightness of food processing equipment, EHEDG Doc. 7 (*ref. 19*)
- A method for the assessment of in-place cleanability of moderately-sized food processing equipment, EHEDG Doc. 15 (*ref. 20*)

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