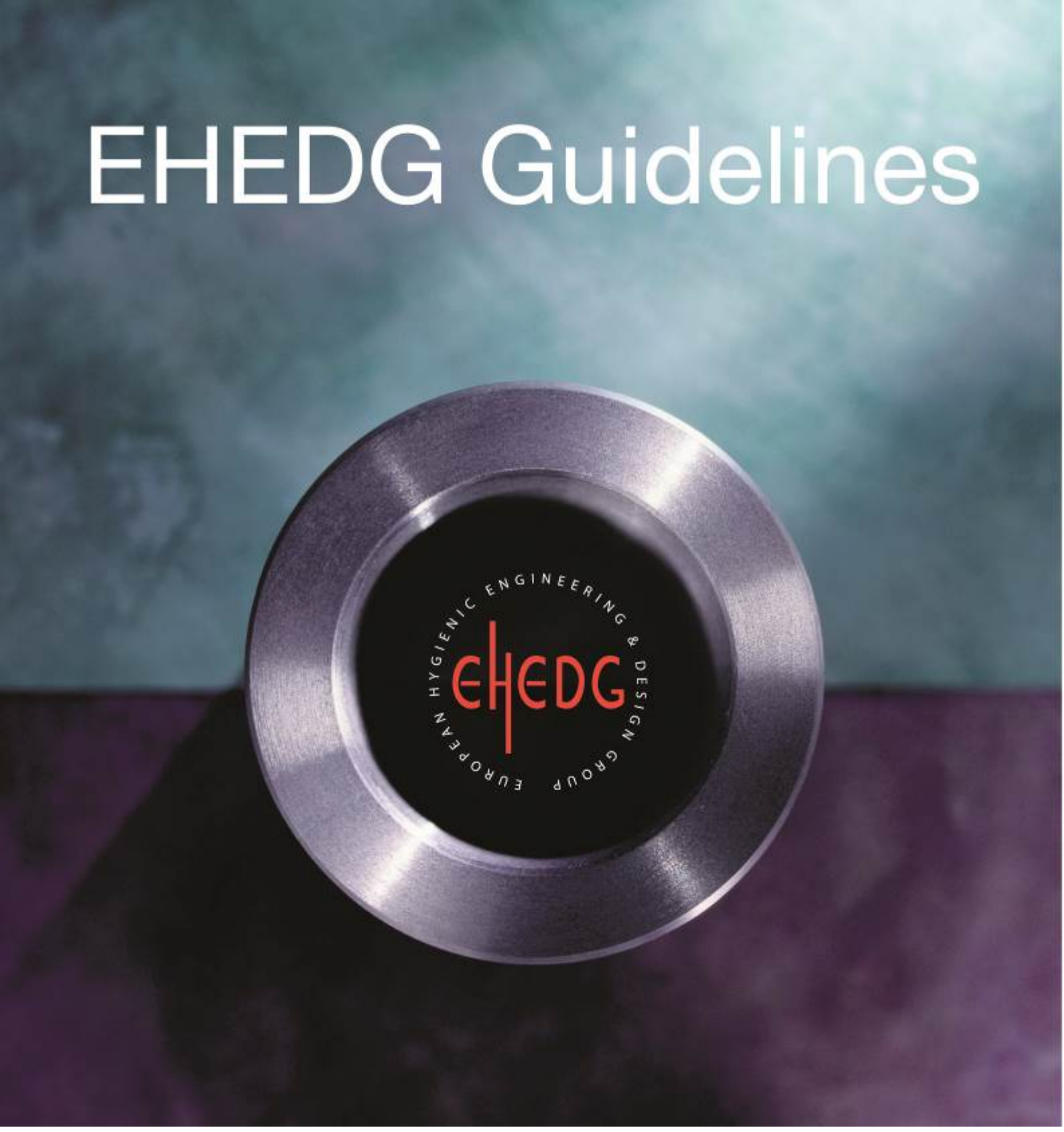
EHEDG Guidelines



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HYGIENIC DESIGN PRINCIPLES

Third edition, March 2018

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HYGIENIC DESIGN PRINCIPLES*

Third Edition, March 2018

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Summary

This document describes the principles for hygienic design of equipment and factories intended for food manufacturing. The fundamental reason for applying hygienic design principles is to prevent contamination of food products. Equipment and factories of poor hygienic design are difficult to clean.

This document details the hygienic design principles that shall be followed when designing and constructing equipment and factories for manufacturing of foods. It gives guidance on design, construction and installation so that it does not adversely affect food safety and quality. These principles apply to open and closed manufacturing operations, surrounding facilities, all being cleaned either wet or dry.

This document is used as a basis for hygienic design evaluation within the EHEDG equipment certification program.

The content of this document covers functional requirements, intended use, materials of construction, hygienic design and construction and assessment methods.

Introduction

This document describes the principles for hygienic design of equipment and factories intended for food manufacturing. The fundamental reason for applying hygienic design principles is to prevent contamination of food products. Equipment and factories of poor hygienic design are difficult to clean. Residues (soil) may be retained in crevices and dead areas. Product residues allow micro-organisms present in the product to survive and multiply. Residues of cleaning and disinfection chemicals increase the risk of corrosion and may cross-contaminate subsequent batches of product. Additionally, contaminants, e.g. foreign matter, allergens, lubricants, detergents and disinfectants, might be carried with the product during processing and packaging.

The primary objective of equipment and factory design is to fulfil engineering functions. Sometimes the requirements of hygienic design conflict with the functionality. An acceptable compromise must never put the food safety at risk.

It is more effective to incorporate hygienic requirements into the initial design because upgrading an existing design can be prohibitively expensive and may fail. Benefits are not only product safety but also the potential of increasing the life expectancy of equipment, reducing maintenance measures, enhancing sustainability and lowering operating costs.

This document was first published in 1993 with the intention to describe in more detail the hygienic requirements of the European Machinery Directive (1). Subsequently extracts from it were included within the standards EN 1672-2 (2) and EN ISO 14159 (3). This revision has been prepared to take into account recent scientific advances, legislation and the enhancement of existing EHEDG Guidelines.

1 Objectives and Scope

This document details the hygienic design principles that shall be followed when designing and constructing equipment and factories for manufacturing of foods. It gives guidance on design, construction and installation so that it does not adversely affect food safety and quality. These principles apply to open and closed manufacturing operations, surrounding facilities, all being cleaned either wet or dry.

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2 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 1672-2:2005+A1:2009 Food processing machinery – Basic concepts – Part 2: Hygienic Requirements

ISO 14159:2002 Safety of machinery – Hygiene requirements for the design of machinery

3 Definitions and Terms

The definitions in the EHEDG Glossary (4) apply to this guideline. The most relevant definitions specific to hygienic design principles are:

Product contact surfaces (direct or indirect)
All surfaces that intentionally (direct) or unintentionally (indirect, e.g. due to splashing) come into contact with the product, or from which product, condensate or soil may drain, drop or be drawn back into the main product, packaging material or product container, including surfaces (e.g. unsterilized packaging) that may indirectly cross-contaminate product contact surfaces or containers. A risk analysis can help to define areas of cross contamination (e.g. all exposed surfaces of an open processing factory).

Non-product contact surface
All surfaces, which have no influence on the product (e.g. external surfaces of closed processing equipment or the internal area of an electrical cabinet installed in an open process area).

Non-toxic construction materials
Materials that, under the conditions of intended use, do not release any substance in amounts that would be harmful to the consumer.

Non-absorbent materials
Materials which, under the conditions of intended use, do not internally retain substances of which they come into contact.

Conditions of intended use (for the equipment)
All normal or reasonably anticipated operating conditions, including those of cleaning. These shall set limits for variables such as time, temperature and chemical concentration.

Hygienic equipment class I
Equipment that can be cleaned in-place and can 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.

4 Functional hygiene requirements

Hygienic food processing equipment and factories shall be easy to maintain in order to ensure they perform as expected to prevent food safety and quality issues. The equipment and factory shall also be easy to clean and protect the products from contamination. In the case of aseptic equipment, the equipment must be sterilisable and must prevent the ingress of microorganisms (i.e. it must be bacteria tight). It must be possible to monitor and control all the functions that are critical for food safety.

4.1 Cleanability (prerequisite for disinfection)

Cleanability is a very important hygiene requirement independent of the cleaning methods, e.g. automatic or manual (including clean-out-of place (COP)). Improperly or insufficiently cleaned equipment cannot be effectively disinfected.

Equipment and factories which are difficult to clean will require procedures which are more severe, using more aggressive chemicals as well as longer cleaning and decontamination cycles. Consequences are higher costs, reduced availability for production, reduced lifetime of the equipment and more effluent.

Although an item of equipment is designed in compliance with the design principles for cleanability, it may not be suitable for use with of all kinds of food (e.g. a pump used for liquids might be easy cleanable but used for liquids with particles might not be cleanable). Integrating hygienically designed equipment and factories is not a guarantee to achieve cleanliness to a pre-determined level (e.g. to an acceptable level, with respect to allergens and DNA limits). Depending on the food product (e.g. sticky or viscous products), the important cleaning parameters: time, temperature, chemistry and mechanical action, may need to be increased for successful cleaning. The intended use must be considered.

4.2 Prevention of ingress of microorganisms

Hygienic equipment and factories used for food production shall be designed to limit the ingress of microorganisms. Aseptic equipment must be impermeable to microorganisms.

4.3 Prevention of growth of microorganisms

Hygienic equipment and factories shall be designed to prevent any areas where micro-organisms can harbour and grow, e.g. dead areas, gaps and crevices. This is also important during production, where microorganisms can grow very rapidly under favourable conditions.

4.4 Prevention of ingress and infestation of pests

Hygienic equipment and factories shall be designed to prevent the ingress of pests, e.g. insects, birds, into the production area. Also, the equipment shall be designed to avoid any areas where pests can harbour and multiply, e.g. not completely closed enclosures.

4.5 Prevention of foreign particulate contamination

Hygienic equipment and factories shall be designed to prevent wear and breakage of parts to avoid foreign particulates entering the food. Hygienic Design includes provisions to prevent ingress of foreign particulates, and the ability to detect and remove them.

Main aspects are:

- Materials of construction selected to resist cracking, chipping, flaking and abrasion.
- Elimination of all fasteners which may loosen and fall into product or open containers.
- Use of hygienic shielding over open product and open containers.
- Functional openings into the main product are sealed or provided with hygienically designed covers or caps.
- Implementation of an effective preventative maintenance program (e.g. replacement of gaskets and seals).
- Good manufacturing practice to clean and inspect all new equipment before delivery.

4.6 Prevention of chemical contamination

Hygienic equipment shall be designed to prevent contamination from cleaning chemicals, lubricants, signal transfer liquids, thermal heating and cooling fluids, etc.

4.7 Compatibility with other requirements

A design with excellent hygienic characteristics but lacking the ability to perform its requirements on ATEX, EU Machinery Directive (Operator Safety) (1), high pressure directives, industrial standards, etc. is of no use; hence a designer may have to make a compromise.

5 Materials of construction

5.1 General

Materials used in the construction of food machinery and factories must fulfil certain specific requirements. Under the condition of intended use these materials must be:

- inert to the product,
- inert to detergents and disinfectants,
- corrosion resistant,
- non-toxic,
- non-tainting,
- mechanically stable,

and their surface finish must not be adversely affected.

The presence of toxic elements in food is unacceptable. The designer must ensure that materials, under the intended conditions of use, in direct or indirect contact with the food do not release any substances in amounts that would be harmful to the consumer. 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 must be ensured that the use of a specific material is permitted under existing or pending legislation (5). Traceability is one of the basic requirements in this legislation.

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

If product-contact or non-product contact materials are coated the coating shall be resistant to the conditions of intended use.

Further and detailed information about materials of construction is published in EHEDG Guideline no. 32 (6).

5.2 Metals

There is a wide range of metals available to construct equipment applicable for either product or non-product contact. Their selection is influenced by the values of stress the metal is subjected to and its corrosion resistance, machinability, formability, weldability, hardness and cost. The final choice depends on the intended use.

Stainless steels are the logical preference for metallic materials of construction used for wet cleaned process plants but the specific alloy depends on the application.

The use of other metals (e.g. mild steel and anodised aluminium) may be appropriate in a dry environment (7).

5.3 Polymeric materials

5.3.1 Plastics

Some plastics may have advantages over stainless steel such as lower cost and weight, wear resistance or better chemical resistance. However, their use is governed by legislation (e.g. EU (8), FDA (9)) and the main criteria to be considered are:

- suitable for the intended use, particularly the temperature ranges and resistance to abrasion,
- stress-cracking resistance and brittleness,
- hydrophobicity / reactivity of the surface,
- thermal expansion coefficient,
- cleanability, effect of surface topography and roughness, residue accumulation influenced by the manufacturing technology.

If considering the use of sintered plastic materials (e.g. some types of PTFE or some types of PEEK), it must be taken into account that they can be porous and difficult to clean.

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

5.3.2 Elastomers

The same parameters as listed in the 'Plastics' section above apply for the selection of an elastomer. There is currently no specific regulation of elastomers in the EU (no single instrument of EU 1935/2004 (5)). Alternatively, compliance with FDA regulations can be covered through Food Contact Notification (FCN) certificates as well as conformity statements to 21 CFR 177.2600 or other national regulations.

In addition, elastomers require,

- resilience,
- resistance to aging,
- low thermal expansion coefficients.

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

5.4 Other materials

Other materials such as glass, enamel or ceramic are used for construction of equipment. EU legislation exists only for ceramics covering the migration of lead and cadmium in food contact (10).
For cleanability requirements these materials shall be non-porous.

The use of wood with its known limitations (porosity, durability) could result in microbiological and foreign matter contamination risks. These limitations shall be taken into account with respect to food safety and the conditions of intended use.

5.5 Adhesives and sealants

Adhesives and sealants shall comply with local regulations (EU; USA: FDA; etc.) and used within the recommendations of the supplier of these compounds.

This is required to ensure that the adhesive does not lead to localised corrosion attack of the equipment or release harmful substances under the conditions of intended use in amounts that would make the product

unfit for consumption. All bonds must be continuous, crevice free and mechanically sound, so that the adhesive does not separate from the base material to which it is bonded.

The use of sealants (e.g. RTV-room temperature vulcanisation) are not recommended as a substitute for hygienic gaskets.

5.6 Lubricants

Equipment shall be designed such that lubricants do not come into contact with products. Where contact may be incidental, lubricants shall conform to the NSF (USA) or InS Services Ltd. (UK) Non-Food Compounds Registration Program (H1 classification), which is based on meeting regulatory requirements including FDA 21 CFR for appropriate use, ingredients and labelling (11). Additionally, certification to ISO 21469 for manufacturing is advisable. Further guidance on production and use of lubricants is available in EHEDG document No. 23 Part 1 and 2 (12).

These documents specify which components are allowed in oils and greases used for lubricating purposes, as protective anti-rust films, as release agents 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 Signal transfer liquids

Liquids used for signal transfer shall be non-toxic. These may come into contact with the process fluids if the barrier between them fails.

5.8 Thermal insulation materials

The insulation material must not contain chlorine when in contact with stainless steel. Ingress of water could lead to the accumulation of chloride on the adjacent surfaces, resulting in pitting corrosion and eventual failure. Ingress of water may also result in loss of insulation performance and promotion of microbiological contamination.

6 Hygienic design and construction

6.1 General

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

6.2 Surfaces and geometry

Direct and indirect product contact surfaces must be easy to clean, non-absorbent and not present a toxicological hazard by leaching of substances into foodstuffs. All 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).

All easy to clean surfaces must be smooth and free of imperfections (e.g. crevices and cracks) to prevent harbouring of microorganisms and other residues, therefore:

— Avoid surface microstructures (topography or defects) which cannot be easily cleaned (e.g. pores, sharp peaks, deep valleys, crevices and cracks).
The surface finish affects the time needed for cleaning.
For stainless steel surfaces an Ra-value of equal or less than 0.8 µm achieved by mechanical polishing or machining is recommended. Allowance for higher Ra values may be justified for special equipment types or special functional requirements as referenced in other EHEDG guidelines.

— Direct metal-to-metal joints shall not be used other than welding (metal-to-metal contact surfaces may harbour soil, liquids and could corrode).

  - If equipment is to be EHEDG certified, metal-to-metal joints are only permitted in Type EL Class II and Type ED Class I and II.

— Avoid steps due to misalignment of equipment and pipe connections.

— Static seals shall be front-flush in the installed condition. The use of O-rings in contact with product shall be limited to static connections unless stated otherwise in other EHEDG documents for special applications, e.g. in mechanical seals. (13).
  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.
  For appropriate seal and O-ring design, see EHEDG document No. 16 (14) and the upcoming Guideline on Elastomeric Seals. Crevice free design and easy cleanability shall be demonstrated by testing.

— Eliminate exposed screw threads, metal-to-metal joints of fasteners, pockets (e.g. in cap head screws and pop rivets), crevices in hinges, etc.

— All internal angles of 135° or less shall have a minimum radius of 3 mm. Sharp corners (≤ 90°) must be avoided.

— Where a gasket or membrane is used to separate the product area from a potential dead space, visual leak detection must be provided and positioned on the lowest possible point.
  For special type of equipment, e.g. for sensors, the visual leak detect requirement may be replaced by sensor detection and failure alarm of the equipment in case of moisture ingress.

— Hollow structures (“hollow body”) created by welding shall be constructed to avoid the risk of microbiological contamination by e.g. cracks in the welding seam.

If for technical and/or functional reasons any of these criteria cannot be met, the deterioration of cleanability must be compensated by other means of which efficiency 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 7 Hygienic Design Assessments).

6.3 Welding

Permanent metal-to-metal joints which are in contact with the product must be continuously welded and free of imperfections. Welds on the non-product contact side must also be continuous. All welds must be sufficiently smooth and located such as to allow proper cleaning.

Detailed recommendations on welding to meet hygienic requirements are given in EHEDG documents No. 9 (15) and No. 35 (16).

6.4 Drainability

The exterior and interior of all equipment and pipework must be self-draining (e.g. sloping pipework) or drainable (e.g. opening a valve or gas purging). For self-draining horizontal surfaces must be avoided; instead surfaces shall always slope to one side with a minimum angle of 3°. In the case of external surfaces, any liquid must be directed away from the main product area.

6.5 Insulation

Options available for insulation of equipment and pipework are:

— Sealed cladding
  Insulation materials shall be constructed from corrosion resistant materials and fully sealed so that no ingress of air or moisture is possible in order to avoid microbial growth.
  The fabrication environment for applying a sealed cladding must be controlled to avoid excessive

humidity in the finished construction. Moisture trapped in the enclosed surfaces increases the risk of corrosion of the cladding and the equipment.

— Vacuum
Pipework and vessels can be insulated by evacuation of air in the outer shell or jacket. This is a very effective way of preventing any of the problems listed above.

6.6 Installation, supports and layout

The risk of condensation from equipment, pipe work and the internal surfaces of the building dropping onto product contact surfaces shall be avoided. Measures must be taken during design, layout and installation such that condensate is diverted away from the product contact surface.

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. The number and area of floor contact points shall be minimized. Distances between equipment and the civil construction (floors, walls and ceiling) shall be adequate for cleaning and inspection (17) (18).

Supports for piping or equipment must be fabricated and installed such that no stagnant water or soil can remain on the surface or within the supports. The possible adverse galvanic reactions between dissimilar materials shall be taken into consideration. Additionally, supports shall be sealed to avoid build-up of residues and moisture.

When service lines, brackets, etc. are attached to hollow supports care must be taken that the support is not penetrated allowing moisture to enter the hollow structure.

The layout of process lines shall be arranged such that the risk of cross-contamination is minimized (18).

6.7 Integration of equipment

Integration of equipment including provision of services and utilities shall also comply with hygienic design principles (18) (19).

7 Hygienic Design Assessments

7.1 EHEDG testing and certification scheme

A series of EHEDG test methods for assessing the hygienic and aseptic characteristics of equipment have been published:

— A method for assessing the in-place cleanability of food processing equipment, EHEDG Doc. 2 (20)

— A method for the assessment of in-line sterilisability of food processing equipment, EHEDG Doc. 5 (21)

— A method for the assessment of bacteria tightness of food processing equipment, EHEDG Doc. 7 (22)

Equipment complying with the hygienic design criteria and the applicable test methods can be certified with respect to the appropriate class type. Details are available on www.ehedg.org.

7.2 Qualification stages for equipment

Complying with EHEDG hygienic design principles may support qualification in terms of user requirements specifications (URS) and applicable legislation.

8 References

(1) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)

(2) EN 1672-2:2005+A1:2009 Food processing machinery – Basic concepts – Part 2: Hygienic Requirements

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

(4) EHEDG Glossary, www.ehedg.org/glossary.pdf

(5) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

(6) EHEDG Document*) No. 32 (2005). Materials of construction for equipment in contact with food.

(7) EHEDG Document*) No. 22 (2014). General hygienic design criteria for the safe processing of dry particulate materials

(8) Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

(9) Code of Federal Regulations, Title 21, (21 CFR) Part 170-199, Food and Drugs Administration

(10) Commission Directive 2005/31/EC of 29 April 2005 amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs

(11) NSF White Book Listing of Non-food Compounds (www.nsf.org/usda)

(12) EHEDG Document*) No. 23 (2009). Production and use of food-grade lubricants, Part 1 and 2

(13) Lelieveld, H.L.M., (1990) Processing Equipment and Hygienic Design. In: Microbiological and Environmental Health Issues Relevant to the Food and Catering Industries. Symposium Proceedings, Campden & Chorleywood Food Research Association Group, Chipping Campden, 6-8 February 1990

(14) EHEDG Document*) No. 16 (1997). Hygienic pipe couplings. Also as an extended abstract in *Trends in Food Science & Technology* 8(3): 88-92

(15) EHEDG Document*) No. 9. (1993). Welding stainless steel to meet hygienic requirements. Also as an extended abstract in *Trends in Food Science & Technology* 4(9): 306-310

(16) EHEDG Document*) No. 35 (2006). Hygienic welding of stainless steel tubing in the food processing industry.

(17) EHEDG Document*) No.13 (2004). Hygienic design of equipment for open processing.

(18) EHEDG Document*) No. 44 (2014). Hygienic Design Principles for Food Factories.

(19) EHEDG Document*) No. 34 (2006). Integration of hygienic and aseptic systems.

(20) EHEDG Document*) No. 2, Third Edition (2004, updated June 2007). A method for the assessment of in-place cleanability of food processing equipment.

(21) EHEDG Document*) No. 5, Second Edition (2004). A method for the assessment of in-line steam sterilisability of food processing equipment.

(22) EHEDG Document*) No. 7, Second Edition (2004). A method for the assessment of bacteria tightness of food processing equipment.

*) Order information for all EHEDG documents can be obtained from the website www.ehedg.org

(2017) Updated editions expected to be published later on.