Legal Requirements

European Legislation
  – EU Hygienic-Regulation
  – Directive 2006/42/EC on machinery

Legislation of EU-Member-States

US-Legislation

EHEDG delivers guidance to understand and to follow

2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS

2.1.1. General
Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

The following requirements must be observed:

(a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be 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;

(b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:
— be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings,
— be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum,
— be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning;
(c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a ‘cleaning’ position);
(d) 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 in, areas that cannot be cleaned;
(e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.
Standards / Recommendations

European Hygienic Engineering and Design Group (EHEDG) (www.ehedg.org)
Guidelines, seminars and certification of equipment and components

3-A Sanitary Standards (www.3-a.org)
Guidelines and certification of equipment and components

NSF (www.nsf.org)
Certification of equipment and components
EHEDG Perspective on Hygienic Design

EHEDG Guidelines
EHEDG Training & Education Material

Doc. 32, Materials
Doc. 35, Welding
Doc. 16, Pipe couplings
Doc. 10 Hygienic design of closed equipment
Doc. 14 & 20, Valves

May 2010
Knuth Lorenzen, EHEDG President, 3-A Steering Committee, GEA TDS
Doc. 32, Materials of Construction

Surface characterization

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

Source: Manja Lukesch. Vergleichende Untersuchungen mit modernen optischen Messmethoden zur Bestimmung der Mikrotopographie von Oberflächen, IPF Dresden

May 2010
Size comparison

- Typical representation of a surface profile of Ra = 0.8 μm roughness achieved by 180-240 grit mechanical polish.
- No surface defects or damage.

Source: Andy Timperley, Timperley Consulting
Surface characterization

Topography respectively real topography

Rohr 50.80 × 1.65 mm, ID geschliffen in 3 Stufen: Korn 180/240/320, $Ra = 0.24 \mu m$

Rohr 50.80 × 1.65 mm, ID elektropoliert HE111 (Materialabtrag ca. 25 μm), $Ra = 0.18 \mu m$

May 2010
Doc. 35, Welding of Stainless Steel Tubing

Arithmetic estimation:

Product flow e.g. 30,000 l/h

Volume of pore app. 40,000 μm³ max. 40,000 germs

Within 20 min 120,000 germs per hour could contaminate the product (worst case calculation)

Theoretical maximum contamination level, 4 germs / litre

May 2010
Knuth Lorenzen, GEA, EHEDG President and 3-A Steering Committee
Doc.16, Design of pipe couplings

**EHEDG certified**

- Easy in-place cleanable
- Sterilisable in place
- Impervious to micro-organism
- Easy installation
- Reliable

**EHEDG Recommended Pipe Connection**

DIN 11864-2

**DIN 11864-1**

**Not recommended**

DIN 11851

May 2010
Doc. 10 Hygienic design of closed equipment for the processing of liquid food

STATE OF THE ART

Inline Access Unit

DEAD ENDS in pipe connections

May 2010

Knuth Lorenzen, GEA, EHEDG President and 3-A Steering Committee
Fluid motion in a dead space

Federal Institute of Milk Research, Kiel
Dr. Grasshoff

Knuth Lorenzen, GEA, EHEDG President and 3-A Steering Committee

May 2010
CIP operating time

Hygiene Installation
(State of the Art)

versus

the Common Way

Example 1: Dairy Installation with
4,500 Tuchenhagen Valves
and 5,000 m pipe line DN 80

CIP time per circuit (assumption)
5 Min. Pre rinse, 20 Min. caustic, 10 Min. Acid,
5 Min. Final rinse, 20 Min. Disinfection =
60 Min total CIP time
5,000 m = 60 Min. = 100 %

Total CIP time = 60 Min.
Total CIP circuits per day = 500

Example 2: Dairy Installation with
4,500 Γ- and T-shape Valves =
4,500 sockets = 360 m length of pipe
and 5,000 m pipe line = 5,360 m pipe line DN 80

efficiency to clean Γ- and T-shape valves versus
Tuchenhagen valves = 15 % (see graph Dr. Grasshoff)

5,360 m = 60 Min. = 100 % (5,000 m = 93 %, 360 m = 7 %)
5,000 m straight pipe will be cleaned in 55,8 Min.,
360 m Γ- and T-shape sockets will be cleaned in 28 Min.
(60 Min. divided by 0,15% = 400 Min. x 7% = 28 Min.)
Total CIP time = 83,8 Min.

Because of the Γ- and T-shape valves, there is a surplus
length of the pipe of 7%, and a surplus cleaning time of
23,8 Min. which results to 40% more CIP time and less
production time.

Knuth Lorenzen, GEA, EHEDG President and 3-A Steering Committee
Mix-matched housing combination

Risk of remaining soil

We are talking about Hygienic Design – we mean much more
Examples: Closed processes
Sensors in pipelines

Hygienically
Annular dead zone
Dead section

Knuth Lorenzen, GEA, EHEDG President and 3-A Steering Committee
LIVELY
DEAD
AREAS

EASY TO AVOID!!

May 2010
Knuth Lorenzen, GEA, EHEDG President and 3-A Steering Committee
Doc. 14, Valves
Metallic stops – put into practice
- Doc. 14, Figure 3, 4

• Defined deformation of the seal
• FEM calculations allow for optimal design of the seal
• No stroke variation
• Long lifetime of the seals

Knuth Lorenzen, GEA Tuchenhagen DS, EHEDG President, 3-A Steering Committee
Hygienic Design

Prevention of stagnating product

Hygienic equipment + Hygienic application = HYGIENIC DESIGN

Technology

Good Engineering

Good material is not enough ……
Good design with good engineering is essential!
EHEDG Website

The European Hygienic Engineering & Design Group (EHEDG) is a consortium of equipment manufacturers, food industries, research institutes as well as public authorities and was founded in 1986 with the aim to promote hygiene during the processing and packaging of food products. The principal goal of EHEDG is the promotion of safe food by improving hygienic engineering and design in all aspects of food manufacture.

EHEDG actively supports European legislation, which requires that handling, preparation, processing and packaging of food is done hygienically using hygienic machinery and in hygienic premises (EC Directive 90/270, EN 1672-2 and EN ISO 14159).

Download the EHEDG brochure.

Please have a look at the EHEDG Introduction movie (turn on the sound). Duration: 4:15 min.

May 2010

Knuth Lorenzen, GEA, EHEDG President and 3-A Steering Committee
Guideline Downloads / Webshop

All published EHEDG guidelines are listed below and this section is regularly updated and complemented by new documents in various language versions. The search function can be used to look for keywords mentioned in the guideline titles and contents (full-text search).

Further information about individual guideline contents opens up when clicking onto a selected title. EHEDG Company and Institute Members have to be logged in to download complete documents of their choice in a PDF version. Individual EHEDG Members (receiving a 30% discounted rate) and Non-Members can order guidelines by following the link in the guideline description or visit the Webshop directly (for further information also see EHEDG Guidelines).

NOTE: Reproduction or further distribution of EHEDG guidelines is strictly prohibited! All documents downloaded or purchased are intended to be exclusively used by the EHEDG Member or the guideline customer.
Subgroup Download Section

Welcome to EHEDG
The European Hygienic Engineering & Design Group

Knuth Lorenzen, GEA, EHEDG President and 3-A Steering Committee
EHEDG Tasks and Objectives

• To fill existing gaps of practical guidelines and education
• Continuation of voluntary work
• Discussion and further development of Hygienic Design issues
• Preparation of scientific and technical guidelines on all aspects of state-of-the-art hygienic design requirements and in accordance to EU legislation
• Development of test methods to identify and eliminate HACCPs of equipment used in food production
• Offer lectures, seminars and workshops on Hygienic Design
• Strengthen the participation in standardisation bodies like CEN, ISO, DIN, JIS, 3-A and NSF etc.
• Strengthen the cooperation with the EU, i.e. food contact material directive, BAT, traceability and other EU-Projects)
• Improve PR activities to disseminate Hygienic Design know-how
Test Methods

- A method for the Assessment of in-place cleanability of food processing equipment, Doc. 2

- A method for the Assessment of in-line pasteurization of food processing equipment, Doc. 4

- A method for the Assessment of in-line sterilisability of food processing equipment, Doc. 5

- A method for the Assessment of bacteria tightness of food processing equipment, Doc. 7
Certification of Equipment

In compliance with the hygienic equipment designs criteria (Doc. 8) and the confirmation of „successfully“ conducted cleanability test

**NEW** EHEDG Certification Scheme

<table>
<thead>
<tr>
<th>Certificate Type*</th>
<th>EL CLASS I</th>
<th>EL ASEP TIC</th>
<th>EL CLASS II</th>
<th>ED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning procedure</td>
<td>wet</td>
<td>dry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIP cleaning, cleaning without dismantling</td>
<td></td>
<td>dry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>automatic or manual cleaning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment used for processes</td>
<td>closed / open</td>
<td>closed</td>
<td>closed / open</td>
<td>closed / open</td>
</tr>
<tr>
<td>Fullfilled requirements according EHEDG doc</td>
<td>8, (9, 10, 13, 10, 32, 30) **</td>
<td>8, (9, 10, 13, 32, 30) **</td>
<td>8, 9, 10, 13, 32, 30 **</td>
<td>8, 9, 22, 29, 32 **</td>
</tr>
<tr>
<td>Test method</td>
<td>cleanability (doc 2 or doc 15) / open process equipment without test</td>
<td>cleanability (doc 2 / doc 15) + sterilizability (doc 5) + bacteria tightness (doc 7)</td>
<td>none</td>
<td>none</td>
</tr>
</tbody>
</table>

* Contact EHEDG authorised Institutes for design evaluations and equipment classification. ** If necessary, other special guidelines, e.g. doc 25 about mechanical seals, could be used to get more clearness about essential requirements to get an easy to clean design.
Test Institutes for EHEDG-Certification

The EHEDG authorise the use of the certification logo on equipment or components which corresponds to the relevant EHEDG guidelines. The following institutes are accredited to test and authorised to certify:

**TU München**
Forschungszentrum Weihenstephan für Brau- und Lebensmittelqualität
Dr. F. Jacob
Alte Akademie 3
D-85354 Freising
Germany
Tel. +49 8161 71 3331
Fax +49 8161 71 4181

**Danish Technological Institute**
Mr. H. Classen
Holbergsvej 10
DK-6000 Kolding
Denmark
Tel. +45 7220 1943
Fax +45 7220 1919
Test Institutes for EHEDG-Certification

CCFRA Technology Ltd
Mr. A. Timperley
Chipping Campden
Glos, GL55 6LD
U.K.
Tel. +44 1386 842000
Fax +44 1386 842100

TNO Certification B.V.
Mr. M. Keiser
P.O. Box 541
NL-7300 AM Apeldoorn
Netherlands
Tel. +31 55 549 34 68
Fax +31 55 549 32 88

Purdue University
Dr. M. Morgan
745 Agriculture Mall Drive
West Lafayette, Indiana 47907-2009
USA
Tel. +1 765 494 1180
Fax. +1 765 494 7953
Certificate of Compliance with the Hygienic Equipment Design Criteria of the EHEDG; Document No. 8, 1993

CCFRA Technology Ltd hereby declares that the product

Product

from

Company name

has been evaluated for compliance with the hygienic design criteria of the EHEDG by:

CCFRA Technology Ltd

and, in our opinion, justifies the use of the EHEDG Certification logo type EL as demonstrated by:

Report **

Signed __________________________  Date __________

Testing Officer

Signed __________________________  Date __________

Head of Department

CCFRA Technology Ltd, Chippenham, Wiltshire, UK.

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May 2010

Knuth Lorenzen, GEA EHEDG President & 3-A Steering Committee
Other EHEDG Activities

- Annual conference with workshop
- Training courses
- Training material

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www.ehedg.org
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May 2010
Thank you for your attention.