





# **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**



#### DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006

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.

9.6.2006 EN Official Journal of the European Union L 157/49

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



## Doc. 32, Materials of Construction Surface characterization

### Arithmetic average of roughness R<sub>a</sub>, Average distance R<sub>z</sub>





# **Size comparison**

BACTERIUM



- 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





 $Ra = 0.5 \ \mu m$ 



 $Ra = 0,5 \ \mu m$ 



 $Ra = 0.5 \ \mu m$ 

~ 1,2 - 4





## **Doc. 35, Welding of Stainless Steel Tubing**





# **Doc.16, Design of pipe couplings**

### **EHEDG** certified

EHEDG Recommended Pipe Connection DIN 11864-2









## **CIP** operating time

versus

Hygiene Installation (State of the Art)

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 %



the Common Way

Example 2: Dairy Installation with 4.500  $\Gamma$ - 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



Fig. 1. SRC valve with valve body combination 21. Valve body combinations 20 30 21 22 31 32

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  $\Gamma$ - 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  $\Gamma$ - 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.



We are talking about Hygienic Design – we mean much more



## Examples: Closed processes Sensors in pipelines









Annular dead zone



Dead section



# 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



ENGINEER

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# **Hygienic Design**



## Good material is not enough ..... Good design with good engineering is essential !



### **EHEDG Website**

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## **Guideline Downloads / Webshop**



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



### Webshop

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



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# **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-theart 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

<ul> <li>Contact EHEDG authorised</li> </ul>
Institutes for design evaluations
and equipment classification.
** If necessary other special

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.

Certificate Type*	EL CLASS I	EL ASEPTIC	EL CLASS II	E	D
Cleaning	wet		dry		
procedure	CIP cle cleaning witho	eaning, out dismantling	cleaning with dismantiing	automatic or manual cleaning	
Equipment	closed /	closed	closed /	closed	open
used for	open		open		
processes					
Fulfilled	8, (9, 10, 13,	8, (9, 10, 16,	8, 9, 10, 13,	8, 9, 22, 26,	8, 9, 22, 26,
requirements	16, 32, 35) **	32, 35) **	32, 35 **	32 **	32 **
according					
EHEDG doc					
Test method	cleanability	cleanability	none	none	none
	(doc 2 or	(doc 2 / doc			
	doc 15) /	15) +			
	open	sterilisability			
	process	(doc 5) +			
	equipment	bacteria			
	without test	tightness			
		(doc 7)			

**NEW** EHEDG Certification Scheme



## **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









# **Other EHEDG Activities**

- Annual conference with workshop
- Training courses
- Training material

Website

www.ehedg.org



**Please contact us:** 

EHEDG Secretariat c/o VDMA Lyoner Strasse 18 60528 Frankfurt Germany

Susanne Flenner susanne.flenner@ehedg.org/ secretariat@ehedg.org Phone: +49 69 6603 1217 Juliane Honisch juliane.honisch@ehedg.org Phone: +49 69 6603 1430



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