

Hygienic design, EHEDG and Hygienic Design Center at DTU

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Publication date: 2015

Document Version Publisher's PDF, also known as Version of record

Link back to DTU Orbit

Citation (APA): Wirtanen, G. L. (Author). (2015). Hygienic design, EHEDG and Hygienic Design Center at DTU. 2D/3D (physical products), DTU National Food Institute.

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DTU Hygienic Design, EHEDG &

Hygienic Design Center at DTU

Gun Wirtanen, Associate Professor

Technical University of Denmark Division: Production and Microbiology Research Group: Microbial Food Safety and Quality /1

guwi@food.dtu.dk

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Agenda

Introduction of the speaker

nal Food Institute, Technical University of Denmark

- Background to Hygienic Design
- European Hygienic Engineering & Design Group (EHEDG)
- Hygienic Design Center (HDC) at DTU and its activities

Gun Wirtanen - Curriculum Vitae

Associate Professor at DTU National Food Institute

- Lecturing in course 23521 (main lecturer) and similar level courses Lecturing in Hygienic Design Courses for industrial
- representatives (equipment manufacturers, food and biotech producers & food plant builders) at DTU Centre for Hygienic Design □ Lecturing in the EHEDG Advanced Course in Hygienic Design arranged e.g. at DTU Centre for Hygienic Design
- C Research projects in process hygiene
- □ Tutoring of student theses at BSc, MSc and PhD levels

External Lecturer in Process Hygiene at University of Helsinki, Finland

Biofilm formation, Surface Microbiology and Cleaning & Disinfection

Gun Wirtanen - Process Hygiene Activities · Project coordinator of the Specific Support Action project SAFOODNET (FP6-022808) 2006-2009, which focused on knowledge sharing of new methods, tools and applications inimproved hygiene management in the new EU

 Involved in coordinating Nordic projects P93156 "Sanitation of dairies" 1994-96, P96049 "Evaluation of cleaning agents and disinfectants for use in dairies: methods and

mechanisms" 1997-2000 & P00027 "DairyNet: Hygiene

· Published more than 350 publications on quality control of foods, food processing hygiene and cleanroom technology as peer-reviewed articles, invited book chapters, articles based on oral and poster presentations and articles in

Hygienic Design

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Control in dairies" 2001-04

technical journals nal Food Institute, Technical University of De

Gun Wirtanen – Curriculum Vitae cont.

Main jobs

- 2014-Associate Professor in Hygienic Design and Cleaning Operations at DTU National Food Institute
- 2010-2013 Senior Expert in Process Microbiology and Hygiene al VTT Expert Services Ltd.
- 1997-2009 Senior Research Scientist in Process Microbiology and Hygiene at VTT Biotechnology and Food Research, VTT Biotechnology and VTT
- □ 1988-1997 Research Scientist in Microbiology at VTT Food Research Laboratory and VTT Biotechnology and Food Research
- □ 1986-1988 Research Trainee in Microbiology at VTT Food Research Laboratory

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Introduction - Consequences of poor design and hygiene

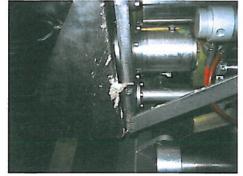
Why we are here ?

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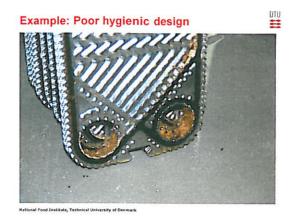
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Example: Poor hygienic design



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Overall consequences of poor hygiene

Reduced lifetime of process equipment

- · Increased cleaning & disinfection efforts
- · Costly repairs
- · Prolonged downtime of the process line

Product contamination

- · Bad reputation for brands or retailers
- · Single cases influence the whole food industry
- · Closing of factories
- · Law suits against leading staff

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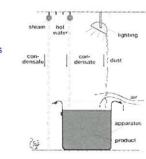
Five main routes of contamination



- Surfaces and tools
- Air

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-
- Water
- Pests



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Introduction - Good design does not guarantee good hygiene... but it helps

What we can do?

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We need to know ...

- How to construct
- · What to avoid
- · What to buy
- · How to clean & disinfect
- · How to evaluate

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Good Hygienic Practise

- Hygiene must be included in all planning and production steps
- Design of premises and equipment
 –Location, roads, layout, design
- Maintenance and cleaning in processing facilities
 - -Procedures and monitoring
- Control of the production process
 - Raw materials, packaging, process water, air, intermediates, tools, pests, products

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How to construct ?

Materials must be...

- Inert to
 - Product
 - Detergents
- Disinfectants
- Non-toxic
- Smooth and crevice free

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How to construct ?

Design – accessible, cleanable & drainable

- Smooth surfaces
- No steps/misalignment
- · No metal-to-metal contact
- Crevice free
- Use rounded corners
- Accessible
- Cleanable
- Drainable
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What to avoid?

Contaminants can be of

microbiological sources

- · Bacteria, fungi, viruses, parasites, insects ...
- chemical sources
- Detergent, disinfectants, toxins, pesticides
- physical sources
- · Metal, rubber, plastic, glass ...
- Dirt, stones
- · Personal objects, jewelery, nails



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How to clean?

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Priorities to ensure high quality and safe products:

- 1. Remove soil (fat, protein, carbohydrates, salts & minerals)
- 2. Remove/kill microorganisms (cleaning/disinfection)
- 3. Avoid recontamination (rinsing/drying)

By combining proper design and effective cleaning & disinfection we should be able to obtain low microbial loads during processing

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Hayes, 1985

Introduction - Focus areas in hygienic design

Who and what is important?

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Focus areas - demands on equipment

Authorities' demands

- Cleanable and possible to disinfect to a certain (acceptable) level
- Contamination of food must be reduced
- Installations allowing cleaning of equipment and facilities

Producer's demands

Long processing time, good cleanability → fewer stops

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Focus areas - expertise

Material science

- Which steel, plastic and rubber types can be used
- Demands for surface characteristics
- Demands on process additives e.g. lubricants

Construction and design of equipment

- What is possible to construct
- Working environment

Fluid mechanics (closed equipment)

- Flow conditions in pipe systems and components

Water pressure (open equipment)

- Flow conditions in pipe systems and components nal Food Institute, Technical University of Denmarl

Focus areas - expertise

Microbiology

- Attachment and detachment
- Which microbes are present and which are critical
- **Chemical engineering**
 - Detergents and disinfection
 - Interaction between cleaning agent, soil and equipment

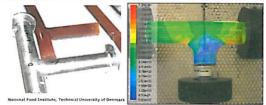
Food engineering

- Knowledge of the whole process (primary use)
- Equipment specification

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How to evaluate?

- · Visual and physical inspections
- Microbial culturing
- · In-use testing
- · Soiling test e.g. β-carotene, buttermilk with indicator organisms, uranine
- · Modeling tools (e.g. Computational Fluid Dynamics = CFD)



Relevant Harmonised 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

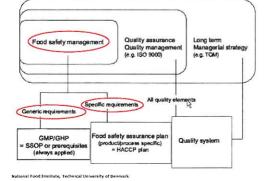
Design features for reduction of risks

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Food processing machinery specifically

Machinery in general

DTU Safety and quality assurance systems



- DTU

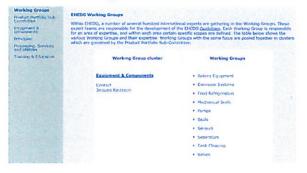
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European Hygienic Engineering & DTU **Design Group (EHEDG)**

- · A private consortium founded in 1989
- www.ehedg.org
- · Promotes safe food by improving hygienic engineering and design in all aspects of food manufacturing
- · The members can represent or be
 - Companies for the manufacturing of food and food equipment. pharmaceutical and cosmetic production
 - Companies supplying engineering services
 - Scientific and research organisations
 - Health authorities and associations and
 - Individual members
- · Activities: produce guidelines & training, provide expertise, carry out certification and networks
- · Supports European legislative work and cooperates with other organisations e.g. 3-A nal Food Institute, Tec
- The Guidelines are prepared DTI H in Working Groups and launched by EHEDG ExCo



The Guidelines are prepared in Working



List of the 43 EHEDG Guidelines (2015) 🗮

- opically safe continuous pastrunization of liquid food (1992) 1
- A method for assessing the in-place cleanability of food pr ent (2007)
- 3 Microbiologically safe asoptic packing of food products (1993)
- A method for the assessment of in line pasteurisation of food processing equipment (1993)
- 5 A method for the assessment of in-kine sterilisability of food processing equ
- The microbiologically sele continuous flow thermal sterilisation of Equid foods (1993) ent (2004

- A method for the assessment of builters tightness of food proceeding equipm
 Highenic volupment dosign criteria (2004)
 Weiding standers steet to meet trygemic resultements (1992)
 Highenic design of dosed equipment for the processing of liquid food (2007)
- packing of food products (1993) 11
- 12 The continuous or semi-continuous flow thermal treatment of particulate foods (1994)
- 13 Hygienic design of equipment for open processing (2004) 14 Hygienic design of volves for food processing (2004)
- 15 A method for the assessment of in place cleanability of moderately sized food processing equipr (1997) al Food Institute, Technical University of Denmark

List of the 43 EHEDG Guidelines (2015) 16 Hyglenic plue couplings (1997) 17 Hyplanic design of pumps, homogenizers and domoaning devices (2013) 18 Chemical Treatment of Stanless Steel Surfaces (2014) 19 A method for assessing the bacterial impermeability of hydro our membrane titters (2012) 20 Hygienic design and safe use of double-seat mixproof valves (2000) 21 Challenge tests for the evaluation of the hygienic characteristics of packing machines for liquid and semi-liquid products (2000) 22 General livgienic design criteria for the safe processing of dry particulate moterials (2014) 23 Production and use of food grade lubricance, Part 1 and 2 (2009) 24 The prevention and control of Leolonella spp. (incl leolonnaires disease) in food factories (2002) 25 Design of mechanical seals for hygienic and aseptic applications (2002) 26 Hygienic engineering of plants for the processing of dry particulate mater als (2003) 27 Safe storage and distribution of water in food factories (2004) 28 Safe and hygienic water treatment in food factories (2004) 29 Hygienic design of packing systems for solid foodstuffs (2004) 30 Guidelines on air handling in the food industry (2005) National Food Institute, Technical University of Denmark

List of the 43 EHEDG Guidelines (2015)

- 31 Hygrenic engineering of fluid bed and spray driver plants (2005)
- 32 Materials of construction for equipment in contact with food (2005)
- 33 Hygienic engineering of discharging systems for dry particulate materials (2005)
- 34
 Integration of hyperic and aseptic systems (2006)

 35
 Hyperic welding of statilies, steel table is in the feed processing industry (2006)
- 35 Hygenic wenning of stanless stear cost of the rens processing incluse y (2006) 36 Hygenic Engineering of Transfer Systems for Dry Particulate Materials (2007)
- 37 Hygiesic Design and Application of Sensors (2007)
- Hygenic Lengineering of Rotary Valves In Process Lines for Dry Particulate Materials (2007)
 Hyulenic Engineering of Rotary Valves In Process Lines for Dry Particulate Materials (2007)
- 39 Design Principles for Equipment and Process Areas for Aseptic Food Manufacturing (2009)
- 40 Hydenic Engineering of Valves in Process Lines for Dry Particulate Materials (2010)
- 41 Hygienic Engineering of Diverter Valves in Process Unea for Dry Particulate Materials (2011)
- 42 Disc Stack Centrifuges Design and Cleanablility (2013)
- 43 Hygienic Design of Belt Conveyors for the Food Industry (will be published soon)
- 44 Hyglenic Design Principles for Food Factories (2014)

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EHEDG Doc. 8: Hygienic equipment

- Guideline No. 8 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. It is intended to appraise qualified engineers who are designing equipment for food processing with the additional demands of hygienic engineering in order to ensure the microbiological safety of the end product.
- Upgrading an existing design to meet hygiene requirements can be expensive and may be unsuccessful.

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EHEDG Doc. 8: Hygienic equipment design criteria, 2004

- Hygienic design is most effectively incorporated into the initial stage. The long term benefits of doing so are not only product safety but also the potential to increase life expectancy of equipment, reduce maintenance and 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.
- Parts of The Machinery Directive were subsequently incorporated in the standards EN1672-2 and EN ISO 14159. (16 pages)

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HYGIENIC DESIGN OF CLOSED

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:

- 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)

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- pipe joints (Fig. 1)

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- 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)

HEDG offers two main types of equipment certificat • Type EL for Equipment cleaned with Liquids • Type ED for Equipment Dry cleaned only

Overview of Equipment Certification Options

TYPE EL: (Equipment cleaned with Liquids)

- centrifugal and lobe pumps (Fig. 11) - dead legs (Figs 13-14)

General Information about EHEDG Certification

The criteria for certification include: a design review according to the EHEDG guidelines and testing according to EHEDG test methods (where appropriate).

- pump by-pass arrangements (Fig. 17)

HYGIENIC DESIGN OF OPEN

In Guideline 13 factors affecting operation hygiene and cleanability are dealt with using the following pictures:

- corners (Fig. 2),
- screw joints (Figs 4 & 5)
- welded joints (Fig. 1)
- dismountable joints (Fig. 3)
- equipment rims (Figs. 8-9)
- drainability (Fig. 6)
- equipment covers (Fig. 10)
- shaft arrangements (Fig. 11)
- stirrer blade attachment (Fig. 13)
 equipment accessibility (Fig. 26)
- equipment fixed to floor/walls (Figs 24-25)
- Kelicital Ford Tablinda Technical University of Desmark
- product protection (Fig. 12)
 flange couplings (Fig. 14)
 - foot bearings (Fig. 15)
 - belt reinforcement (Fig. 16)
 - conveyor belts (Figs 17-19)
 framwork structures (Fig. 22)
 - horizontal framwork (Fig. 23)
 - framework cladding (Fig. 21)
 walkway design (Fig. 27)
- E. Class J Class G and Class

TYPE ED: (Equipment Dry cleaned only)

ED Class I Closed equipment dry cleaned only without dismantling
 ED Class II Closed or open equipment dismantled for dry cleaning only

Each of the certification TYPES have subcategories (Classes) as shown below

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Certificale Type*	EL CLASS I	EL ASEPTIC CLASS I	EL CLASS LAUX	EL GLASS N	EL ASEPTIC CLASS	
Cleaning procedure	wet					
		raning without dismanif			h dismanifing	
Processes Fulfilled requirements according EHEDG dod	closed 8 (9 -0 16.32 35;**	claveo 11 (9. 12 16. 22 35. 39) ~	open 8 (9 12 22 26,**	closed * open 8. r/i 10, 12, 32, 36 ; **	closed 8 19 10 16 32 35 391 **	
	CERTIFIED	CERTIFIED	CERTIFIED	CERTIFIED	CERTIFIED	
	EHEDG	ELEDG	енерс	EHEDG	енерс	

Certilicate Type"	EL CLASS I	EL ASEPTIC CLASS I	EL CLASS I AUX	EL CLASS II	EL ABEPTIC CLASS
Design evaluation and Princosi area ^{res}	pres mode the separate	ared standle the sequelational	tenu culcule on the squarvert	en av sous or public on ave sous or public	ared trade the propriet
	Apaghnost Rail (1971) - Misintecam etamoration	magness Ravisos Bisteriospi pratinanço	Headmens Rai-Eader) Microscom Beaminution - Bitanaibirty	inighnesi Ravadu'i michanigot, isamisidari aclassitory	нартных Ra / гани - тислинация внатизация / агоннация
EMED& Test partmath	cloverability visit Zi	cleanability stoc 2++ eleminability (stoc 8++ bacterior systemass julce 71	~~	none	theninget-ity (dat 5. Builder is hydroes (dim 7)
Equipment Examples	lalan paé érhetnanat pre tagalar tagar periodos	Jope Inc mjorandol IAp punys yrfit starate hantonical beat Enline yddael, Aprylwy	buarlary equipment blo yanat benant machina by ethy feet graf tyre unit	thering channel briter desing parts, tarts mounted reliat verve correspon stead verves phone hostone	Othermal By discretifing and intertimple and partness type in pressure result value with double seal

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Certificate Type'	ED CLANK I	ED CLASS 8		
Clearing procedure	67			
	clearsing wishout discountling	cleaning with dismanilung		
Precessors	closert	count / com		
Futfilled requirements, according PHLDG (Inc.	8 29 22 26 32 38 **	# (9 22 28 12 25) ¹⁴		
Design evanation and relevant arra ^{res}	алац такж Ви намосног помрляева, Ra' сала с неколькора, аканеталск	area stude of salacte on the edupment reaghters Rainaction / Andrescopic examination / accessibility		
EHEDG Test methods	CERTIFIED	ICERTIFIED		
Figurpoine of Brancpiers	EHEDG	EHEDG house and		
	TYPE ED CLASSI	TYPE ED CLASS 9		

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History of Center for Hygiejnisk Design (HDC) at **DTU National Food Institute**

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Contact: Br. Roy Bette Set +44 1256 842015

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Confuct: Mark Y. M Instance and Hand, Free Scores & Tacks ENEDI Authorized Te

- 09/2011 EHEDG approves that the HDC at DTU can be the new EHEDG Test Center in Denmark
- 2012-13 IPU & DTU National Food Institute cooperate in building up the centre
- 11/2013 DTU HDC is officially opened
- > 04/2014 Accreditation of DTU HDC is approved by DANAK according to ISO 17025, which is valid until April 2018
- > 05/2014 according to EHEDG statutes HDC must be witnessed by an EHEDG test expert in the first commercial trials, this was done in week 20 (2014) with an expert from Munich.

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DTU Center for Hygienic Design (HDC) DTU Center for Hygienic Design (HDC), is the only EHEDG

authorized test center in The Nordic countries, where equipment manufacturers can have their equipment tested and certified for cleanability and design according to European Hygienic Engineering & Design Group (EHEDG) Guidelines.

The other EHEDG test centers are located in Germany, England, France, USA, Netherlands and Spain.

The HDC is accredited by DANAK and it is strategically located at the DTU National Food Institute. 2 DANAK

HDC collaborates with industry and there are links between: Development, Design, Consulting, Testing, Certification, Research, Training and Education.

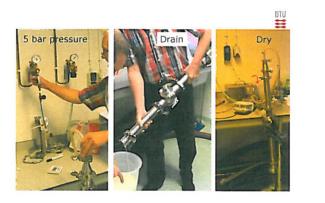
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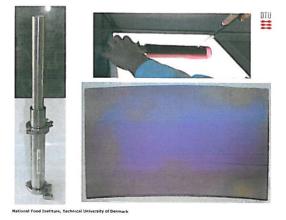




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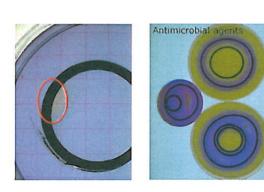
Changes in colour in the reference pipe Agar from a pump rotor

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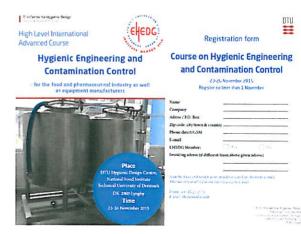
Activities at DTU HDC

- Festing based on EHEDG GL Doc 2 of closed processes, which is a part of the certification procedure
- Certification of process equipment
- Evaluation of hygienic design in food and biotech processes from autumn 2016
- Consulting equipment manufacturers and food producers
- >Training and education in hygienic design
- Development of test method(s) for certification of open process equipment

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- 2 d basic course in hygienic design (HD) on equipment once a year at DTU in Danish/Swedish/English September 22-23, 2015: c Design Course - Equ ent Mar
- The basic course can be tailored (1 d or 2 d) for food producers and food building designers in Danish/Swedish/English and held in the premises of the client: - Basic Hygienic Design Course - Food Manufacturer - Basic Hygienic Design Course - Designing Buildings & Cleanrooms
- 2 d course "Inspection Procedures in Food/Biotech Process Design" held at DTU by Dr. Roland Cocker in English March 8-9, 2016
- 4 d Advanced course in hygienic design (with exam) is held at DTU once a year in English November 23-26, 2015
- More information at the home page: www.hdc.food.dtu.dk National Food Institute, Technical University of Denmark



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ay 1	Monday 23/11	Tuesday 24/11	Day 2
100 - 10.30	Registration and coffee/tea	66.15-08.30	Registration and collection
30 - 11.15	larmulaction and participant presentation	06,30 - 09.15	Certification procedure including EHEDG test procedure for closed equipment
13- 12.00	Legisl requirements	09.15 - 10.00	Fond microbiology
200 - 13.15	Tunch broak	10.00 - 10.30	Collee/ten break
15-14/10	Scientific background to EHEDG decoments	10.30 - 18.15	Section and at microbiology
1.09 14.45	Hygienic design of open process equipment	11 15 - 12.00	Equiptoent material stainless steel and polymers
45-15,30	Hygienic design of closed process equipment	12:00 - 13:15	Lunch break
.30 - 16.00	Confire/Ina break	13.15 - 14.00	Welding stainless steel
	Summary of the day and participant expectations	14.00 - 15.30	Common demonstration an hygicalc design
30 -	Daney	15.30 - 16.00	Coffeertee break
		fe.00 - 17,30	Group work 1 - 3: Hygienic design of varians: process items, surface hyperse and FHUDG test procedure for closed equipment
		19.30 -	Dianet

Day 3	Wednesday 25/11	Thursday 26/11	Day 4	
di6.15- (86.76)	Topost sition and collectes	06.15-08.30	Registration and coffee hea	
44.30 - 08.35	Static seals and couplings	08.30 - 09.13	Generating & Distalection - Cleaning Procedures in Oren and Glowed Protestest	
N1.91 - 71.99	Huid dynamics	09.15 - 16.00	Cleaning and disinfection - Cleaning agents & disinfectants	
10,89 - 10,39	Cation les break	10.00 - 10.30	Codec-tea beak	
16.50 - 11.15	Lidnes	10.30 - 11.15	Froadgrade habricants	
13.35 - 12.00	Pumps (dynamic seals) and case study on pumps	11.15-12.00	Exam (aids afforced)	
12.09 - 13.15	Lanch break	12.00 - 13.15	Lunch break.	
13.15 14.00	Heat treatment (heat transfer)	13.15 - 14.00	integration, installation and maintenance	
14.00 15.30	Group work 2 - 3: Hypienic design of various process items, surface hypiene and UHEDG test.	14.00 14.45	Building and process layout	
15.30 16.00	procedure for closed equipment	14.45 - 15.30	Concluding ressorks, course certificates and course evaluation by participants	
	Group work 3 & Housen's design of various	15.50 - In.00	Collins in break with sandwiches	
16.80 - 1730	process lienes, surface hypiene and EHEDG test procedure for chosed equipment	16,00 - 16.45	Ban to Copenhagen and thereafter to the hotel for those who are staying until Friday	

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	CONTRACTOR OF STREET	
09,00 - 09,30	Registration and Coffee / 7.00	
09.00 · 00.99	Ann of the Course and Presentation of Participuos	
10.00 - 10.45	Knowledge Requirements for Laspe, tors & Approach	
10.45 - 11.59	Legil Aspects & Client Documentation	
\$1.30 · J2.30	Lauch break	
12.50 - 13.15	Documentation of Inspection	
13.15 14.00	Prese painties Needed in the Impection	
14.00 - 14.30	Coller i Jeal mai	
11.30 - 15.15	Presequisites continuing	
15-15-15-00	Discurson	ł
19.00 - 22.00	Dianer in Lyneter	c,

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