













EHEDG Yearbook 2017/2018

European Hygienic Engineering & Design Group



EHEDG Yearbook 2017/2018

European Hygienic Engineering & Design Group



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Greeting from the President

Ludvig Josefsberg, e-mail: Ludvig.Josefsberg@tetrapak.com



Dear EHEDG Members and Friends of EHEDG,

Ladies and Gentlemen,

I am writing these introductory words to the Yearbook 2017-2018 just after the completion of the 5th biennial World Congress, this time held in November 2016 in Herning/ Denmark.

The congress was visited by over 300 delegates from 37 countries around the world and we are extremely satisfied with the feedback of the participants who much appreciated the program, the networking opportunities and the bulk expertise at site. 90 percent of the delegates considered the event as highly relevant for their day-to-day business, while more than 70 percent indicated to have found excellent networking opportunities with the EHEDG experts and other high-level attendees. Almost all of them said that they would like to attend a future EHEDG World Congress.

EHEDG is a non-profit trust founded in 1989 by a consortium of stakeholders of the European food industry and has since then spread its presence in more than 30 geographical sections and is today covering 55 countries in total, in and outside of Europe. Our plan up to 2020 is to expand with up to 20 new Regional Sections and thereby to contribute with our expertise and knowledge to an even larger part of the world's food industry.

EHEDG has during the last years gone through a major reorganization and facelift.

Since 2015 participation in the leadership team defined as the Executive Committee – ExCo - is only possible through appointment by an elected Foundation Board.

For the first time in 2014, all member companies and institutes were invited to cast a vote via the General Assembly. The next election for the term 2018 to 2020 will be held at the end of 2017 and we ask our members to make use of their voting rights.

We also took the opportunity to form an elected Advisory Board, with the main role to represent the member companies in defining the overall strategy of EHEDG. For the current election period 2015 to 2017, the Advisory Board consists of leading representatives of Endress + Hauser, GEA, Mondeléz, Nestlé, Tetra Pak and Sealed Air.

Finally, we took the opportunity to modernize the original EHEDG foundation act. Today the Foundation Board consists of, apart from myself as President, Patrick Wouters, as Vice President and Piet Steenaard as Treasurer and Secretary.

During the strategy work that led up to the new organization, also the mission and vision of EHEDG was revisited.

All of this can be found in the newly released document named "Statutes, Internal Rules and Code of Conduct" which was published in summer 2016.

Our mission is today expressed as follows: "EHEDG enables safe food production by providing guidance as an authority on hygienic engineering and design."

Furthermore, a clear vision and strategy was established respectively for our market, our product portfolio and our structure.

EHEDG has today definitely positioned itself as an authority within the area of safe food production. Our geographical sections are continuing to grow and our member companies and institutes did meanwhile exceed a total number of 400 during 2016. Approximately 50 of our member companies can be defined as the "BIG ONES", all of these globally operating in- and outside of Europe.

The food industry in Europe is the number one industrial employer with close to 15 percent of Europe's employment and also approximately 15 percent of manufacturing turnover. Furthermore, Europe is the second largest world exporter of food and the world's largest importer of food.

With such significance, it is without any doubt that a safe food production is on top of the agenda of all stakeholders of the food value chain, from the legislators and consumers and all the way back to the raw material producers and suppliers.

EHEDG has positioned itself in the center of this value chain with focus on hygienic engineering and design of food production equipment and facilities.

As such we are probably only a big fish in a very big pond, but definitely not alone. There are organizations in and outside of Europe that we liaise with and aspire to liaise with. One of our close partners since many years is 3-A Standards Inc. in the United States, with a similar mission as EHEDG.

But there are several other important stakeholders that must and should combine their respective knowledge in order to make the word a safer place to eat in. One is the Global Food Safety Initiative where major producers and retailers of food have joined forces. GFSI is the leading driver for food safety in this world. One of the key strategies defined by EHEDG is to establish a close cooperation with this initiative.

EHEDG has delivered great value to its stakeholders over the years, but there are still many challenges and opportunities ahead.

- We need to attract more members of the food manufacturing side for creating a better balanced perspective from the overall food industry, as well as to become more relevant to the large members, both equipment manufacturers and especially food producers.
- We need to intensify our product portfolio development, i.e. guidelines and proprietary training portfolio, and reshape our equipment certification model to take full ownership of the process.
- We need to improve our communication and establish a close association with global food safety initiatives in order to contribute with our knowledge in an effort to add technical depth into food safety management systems.

In conjunction with its World Congress 2016, EHEDG took the opportunity to relaunch its website ehedg.org or ehedg.com where much more of what EHEDG stands for can be found.

In conclusion I want to express my thanks to all our contributing members, as well as to supporters, for making EHEDG what it has become today. We count on your continued support to drive our mission and let us jointly make food safer to consume on the way to 2020.

There are plenty of opportunities to contribute in the further development of EHEDG by joining our Working Groups and other important initiatives. We need you!

Thank You

Ludvig Josefsberg EHEDG President



News from the Treasurer

Piet Steenaard, e-mail: steenaard@kpnmail.nl



Dear Readers of the EHEDG Yearbook,

2015 was a turbulent but successful year for EHEDG.

The general assembly elected the new President Ludvig Josefsberg and Vice President Patrick Wouters was re-elected. For myself it was an honor to be re-elected as the Treasurer after I took this important job in 2003 for the first time.

Ludvig, Patrick and I are enthusiastic to form the Foundation Board for the coming two years which is a big responsibility.

Having been granted the Dutch ANBI status (Institution for General Benefit), EHEDG has to be transparent. Therefore we publish our financial results on our website www.ehedg.org to share with all visitors of the page an overview of the financial situation of Stichting EHEDG, and the use of its funds. In the planning of 2016 we mentioned a number of important projects. The development of new tests for certification of open equipment and state-of-the-art training materials as well as the relaunch of our website are big steps forward. We are lucky to be in a position to be able to finance these costly projects.

In recent years, the organization was re-structured, including documenting all procedures on our financials. Bylaw 6 shows the financial rules in detail, offering now more clarity for our members. Every two years a delegation of our members form a Finance Auditing Committee. These audits and recommendations are informative and helpful to me and to the Executive Committee. The last audit took place in April 2016 and the next one will take place in 2018.

I am looking forward to meet all EHEDG friends again during our bi-annual World Congress 2018 in London and on occasion of our yearly Plenary Meetings with the Chairmen of the Working Groups and Regional Sections. The Exhibition Centre of MCH Messecenter Herning in Denmark was the place in 2016 were we organized our last EHEDG World Congress and our meetings. On these occasions, we share our passion and knowledge in hygienic design in an excellent networking atmosphere. EHEDG is an organization on voluntary basis and during these events we have the possibility to show our respect to all those hard workers and fine people who are all so dedicated to EHEDG. We also want to express our gratitude to our member companies who support all active experts to do their important work for EHEDG. Without the support of our company members and institutions we cannot bring people together to develop our guidelines. It is nice to know that our members support our vision and that we can discuss important issues with the Advisory Board, which is the elected body and the "voice" of our member companies. EHEDG is growing and more and more recognized as the global platform for hygienic design. It is an honor to be part of this.

Thank you all for your ongoing commitment.

Piet Steenaard Treasurer of EHEDG





News from the EHEDG Secretariat

Susanne Flenner, EHEDG Secretariat, e-mail: secretariat@ehedg.org



Dear Yearbook Reader,

Despite the attribute "European" in its name, the EHEDG community has grown again by a significant number of renowned companies and institutions from all over the world at the time you hold this Yearbook edition in your hands. It has been our pleasure to welcome all these new members and to connect them to the EHEDG expert network, and we look forward to involve more stakeholders in the future.

We are aiming to serve our members by sharing with them the bulk knowledge from our guidelines of which we have meanwhile published a series of almost 50 documents. The EHEDG training program is continuously further developed by building on the guideline knowledge and is offered in many languages and countries, and the courses will be soon complemented by additional e-learning material for further spreading the message of hygienic design as a prerequisite for a safe food production.

EHEDG testing and certification is granted to state-of-theart equipment fulfilling the requirements defined in our documents and based on our own test methods. More than 500 certificates issued to date by our authorized test institutes speak their own language and help the producers to decide for equipment which facilitates cleaning and thus makes food manufacturing safer to the benefit of the consumer.

Furthermore, we offer our members and interested stakeholders plenty of networking opportunities in numerous EHEDG events, of which we like to proudly mention our biannual World Congress as our flagship event, which we will hold next time 2018 in London, but also many seminars, workshops and conferences which are organized by our Regional Sections in more than 30 countries, thus helping to build up EHEDG knowledge communities all over the world. The true Hygienic Design expertise can be found in our Working Groups, of which more than 20 are currently active on a variety of topics from "A" like Air Handling to "Z" like Zoning of hygienic food factories and production lines. More than 400 experts are currently involved into this core competence field of EHEDG whom we like to sincerely thank for their outstanding contribution and their voluntary time spent on developing our documents in a dialogue of food producers, equipment manufacturers and academia.

With this package, EHEDG members have all prerequisites at hand to become knowledge leaders in hygienic design in their particular field of business, always with the aim of ensuring safe food by implementing advanced hygienic equipment, machinery and production processes.

If you like to learn more about the EHEDG structure and organization, please have a look at our Statutes, Internal Rules and Code of Conduct as well as at the standard procedures of our Sub-Committees Product Portfolio, Regional Development and Communication, which you will all find published on our website or which we can provide you upon request.

The Secretariat is closely involved into all EHEDG activities and is helping to convert the EHEDG mission into daily operational practice. We are your first contact point in EHEDG and will further help our members in making their commitment to our organization a real benefit. If you like to learn more about, you are welcome to contact us. There are many opportunities of getting involved.

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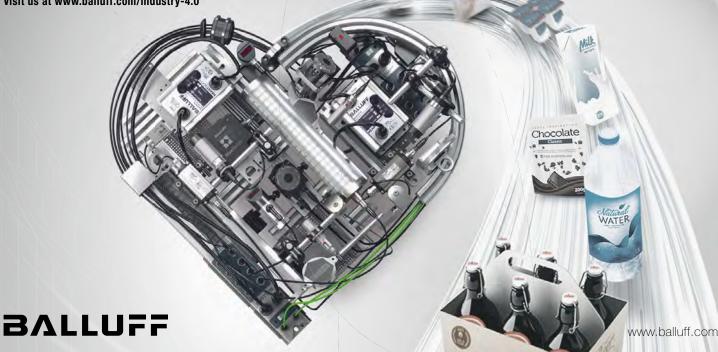
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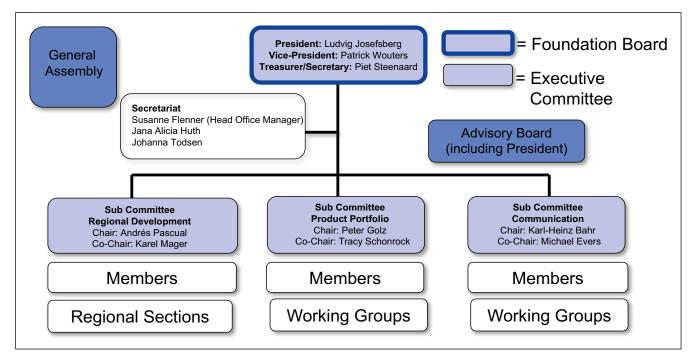
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EHEDG Presidency, Board and Committees

Status as of February 2017



For all details about the EHEDG organization, please see the Statutes and the accompanying Bylaws (available from the EHEDG Secretariat, E-mail: secretariat@ehedg.org).

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For individual positions, please see the organizational chart of EHEDG on page 12.

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- Companies for the manufacturing of food or of equipment for the production of food, pharmaceuticals and/or cosmetics
- Companies supplying engineering services
- Scientific and research organisations
- Health authorities

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Good reasons to become an EHEDG member

- EHEDG creates a central, internationally recognized source of excellence on hygienic engineering
- EHEDG provides networking on an international level, opportunities for the establishment of global contacts and are interlinking our Regional Sections
- EHEDG is a platform for an exchange of state-ofthe-art know-how and offer advancement in hygienic engineering knowledge
- EHEDG provides influence in setting global standards and rules and have impact on regulatory bodies
- EHEDG offers a legal basis by practically demonstrating how to follow existing requirements and standards
- EHEDG guidelines are referenced by international organisations and provide practical know-how
- EHEDG guidelines are created by gathering the expert know-how of our members who are equipment manufacturers of food and packaging machinery as well as food processing companies, research institutes and health authorities
- EHEDG follows up new trends and help to share, disseminate and canalize hygienic design expertise

- The EHEDG mission is extended to 'environmental issues' and aiming to support food safety and sustainability
- EHEDG evaluates hygienic design in relation to shelf-life
- EHEDG provides international, high-level training & education and our training material is developed by recognized experts in the field
- EHEDG provides equipment certification by EHEDGaccredited test institutes
- The EHEDG certification methods are continuously further developed and complemented by new test methods
- EHEDG provides reference publications like the EHEDG Yearbook and press articles in scientific journals and trade magazines
- EHEDG enhances the reputation of its member companies and helps them to become leaders in hygienic design and processing
- EHEDG provides an information and meeting platform on occasion of high-level international events, e. g. the EHEDG World Congress on Hygienic Engineering & Design which is held biannually in varying countries.

Benefits for Company and Institute Members:

- Full set of the EHEDG guidelines including future updates in all language versions for complimentary download from the EHEDG website by all staff members
- Free listing of active staff members (number depending on the company's contribution)
- Use of the EHEDG member logo under agreed conditions
- Publication of the company's logo and name in the EHEDG member lists and website interlinking
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The following institutes and organisations are authorised by EHEDG to test and certify equipment:

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DTU National Food Institute

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FRANCE

ACTALIA Sécurité des aliments

Centre d' Expertise Agroalimentaire, Dept. Research Boulevard 13 Juin 1944 14310 Villers Bocage Dr. Nicolas Rossi Phone: +33 2 31 25 43 00 E-Mail: n.rossi@actalia.eu www.actalia.eu

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NETHERLANDS

TÜV Rheinland Nederland B.V., (certification only)

Certification:

TÜV Rheinland Nederland B.V. P.O. Box 2220 6802 CE Arnhem Ms Angelique Verra-Woutersen Phone: +31 88 888 7813 E-mail: sales@nl.tuv.com

Certification Manager:

Ms C.C.M. van Houten

SPAIN

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Departamento de Calidad y Medio Ambiente Parque Tecnológico de Valencia c/Benjamin Franklin, n° 5-11 46980 Paterna (Valencia) Mr Rafael Soro Phone: +34 961 366 090 E-mail: rsoro@ainia.es www.ainia.es

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USA

The University of Tennessee

2510 River Drive Knoxville, TN 3799-4539 Mr Mark T. Morgan Phone: +1 865 974 74 99 E-mail: mark.morgan@utk.edu www.utk.edu

In addition to the certification organisations above, the following research institutes participate in the development of EHEDG test methods:

- Agence Francaise de Sécurité Sanitaire des Aliments, France
- Fraunhofer IVV Dresden, Germany
- Institut Nationale de la Recherche Agronomique, France
- Lund University, Department of Food Engineering, Sweden
- SIK Swedish Institute for Food Research
- Unilever Research Vlaardingen, The Netherlands
- University of Parma Food Sciences Department, Italy
- VTT Biotechnology and Food Research, Finland

For further information on EHEDG Test and Certification Institutes and web links please refer to www.ehedg.org.

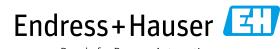


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People for Process Automation



EHEDG e-learning: new development to convey hygienic design knowledge

By Patrick Wouters, Cargill, Netherlands, e-mail: patrick_wouters@cargill.com

Hygienic engineering of food processing facilities, utilities, equipment and complete processes is getting more and more important to manage food safety by design. With an increased focus from legislative organisations and food certification scheme owners, it is crucial to have a good understanding of what is (minimally) required to produce safe foods and how this can be achieved. The European Hygienic Engineering & Design Group (EHEDG) has developed nearly 50 guideline documents on hygienic design and engineering related topics. Many of these guidelines have been translated into different languages, which is a great asset for those not able to read or understand the English language.

Learning concepts

EHEDG aims to clearly define and explain hygienic design requirements through its respective guideline documents. Reading a guideline document is an excellent way to obtain an understanding of the content. However, there are other approaches to learning that can help one get acquainted with new information, and depending on the type of person and their learning capabilities, there are different preferences when it comes to acquiring knowledge. One of these is to attend a training course in which a tutor explains the information, provides exercises, shows examples and illustrations of hygienic design, and shares his or her experience. These events also provide an opportunity to network and to have interactive discussions.

As EHEDG grows and increases the number of Regional Sections worldwide, there is a greater demand for training concepts other than just face-to-face classroom training courses. This is not only because it is expensive and unsustainable to fly hygienic design experts all over the globe, but also because today people's available time is limited and the required speed to obtain information is fast. Hence, there is a growing interest in virtual learning approaches that are available on demand and provide concise, interactive information. EHEDG has recognised this need and now is able to allocate the required funds and find enthusiastic volunteers to support the development of virtual learning opportunities.

Different roles and learning requirements

There are many different roles and jobs within various branches of the food industry that will require some level of understanding of hygienic design and engineering. For example:

- Engineering functions, civil, mechanical, electrical, process, installation, maintenance
- Food safety and quality assurance functions
- Operations functions (e.g., production management, supervisors and operators, cleaners)
- Marketing, sales, planning, logistics
- Auditors, inspectors, testers and certifiers

Not every role or function will require the same level of understanding and expertise in hygienic design and engineering, or require training using a similar style or materials. This is the reason there is the need to have different training offerings available that are targeted for the right audience and requirements. As a European non-profit organisation with a global reach, EHEDG is committed to play a role in this space.

EHEDG first e-learning module

Currently, the first EHEDG e-learning Module is under development and close to completion. The objective of this module is to explain hygienic design principles, reasons and benefits, with a run time of approximately 45 minutes. It contains some background information on food safety hazards managed by hygienic design. Moreover, it provides information about the EHEDG organisation. It provides interactive features to maintain the engagement of the learner throughout the module. At the end of the course, there will be an assessment to check the learner's understanding of the course content. The first version of the module will be in the English language and will be made available in other languages at a later date.

LMS

The e-learning module and other current and future training offerings will be hosted on the EHEDG website. A learning management system (LMS) will be made available as the host platform. This host platform not only will be the place where all learning concepts will be made available, but also where people can register for courses.

What next

EHEDG would like to learn from the experiences of the first module once it is launched to see if there is an interest to build more modules in the future. An evaluation tool will be made available to provide feedback. In the meantime, we welcome any other feedback and ideas, and of course, we welcome those who have an interest and the knowledge to help to develop new virtual training tools.

Other virtual or blended training concept developments are under discussion, including:

- Recorded training demonstrations and lectures on specific topics
- Live webinars with the opportunity to ask questions
- Online training, consisting of various live training webinars with specific tasks (homework) in between, which will need to be presented and explained by course attendees during additional webinars
- Other e-learning training modules

Contact:

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EHEDG e-learning, the welcome page of the first module which is under development.

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Hygienic design and sustainability: Ecodhybat project

By Rafael Soro Martorell, Irene Llorca and Alfredo Rodrigo, AINIA Technological Centre, Valencia, Spain, e-mail: rsoro@ainia.es

Hygienic processing is a *sine qua non* requirement for the food industry. Because of this, food producers devote a lot of time and resources to reach the required cleaning and disinfection level, among other preventive measures. Any surface in contact with food should be sanitised to reach an appropriate safe and hygienic standard.

Sanitation of food processing equipment also is a critical operation from an environmental point of view, since it is one of the most water -and energy-consuming operations as well as a wastewater generator. According to 2006 European Commission data, water consumption in the European food production sector represents 12 percent of total industrial water consumption, with sanitation cited as the main reason for water use in most food sectors.¹ On the other hand, water used for sanitation becomes wastewater, which contains food residues (organic load) and cleaning agents such as acid, alkali, detergents and disinfectants. The main pollutants found in wastewater are organic matter (e.g. chemical or biological oxygen demand [COD, BOD]), oils and fats, suspended solids, nitrate, chloride, phosphates, ammonium and nutrients as nitrogen and phosphorous. In general, the food and drink sector is considered one of the largest producers of wastewater.

Other environmental impacts that affect sanitation operations include the consumption of chemicals (e.g., alkali, acids and disinfection agents) or CO_2 emissions from fuel combustion gases (i.e., steam production). Thus, minimising the environmental impact of the cleaning and disinfection operations, while maintaining hygienic standards, is a major challenge for the food industry.

Hygienic design and environmental impact reduction

Research initiatives in the field of hygiene usually are focused on the hygienic effectiveness of sanitation products or techniques, but very few of them are focused on or even consider the economic and environmental variables. Studies based on life cycle analysis (LCA) methodology emphasises that cleaning processes are major contributors to the total environmental impact in food facilities.

The main objective of hygienic design is to reduce or eliminate the risk of equipment becoming a source of product contamination. It also often leads to environmental benefits, since easily cleanable equipment is likely to reduce water, energy and chemical use to reach the required hygienic level. Although a correlation between hygienic design and a reduction in the environmental impact during sanitation processes seems obvious, there is a lack of experimental and consistent data to support this conclusion or that provides a proven quantification of improvements considering the total life cycle of the equipment. There is a lack of experimental data demonstrating and quantifying the hygiene: environment relationship. With this in mind, the European Union (EU)-funded project Ecodhybat (LIFE12ENV/ES/001070) was launched, with the main objective of demonstrating that hygienic design of equipment is a cost-effective preventive approach to reduce both the consumption of water, energy, chemicals and wastewater and CO₂ emissions during sanitation.

Additionally, the project intends to demonstrate that hygienic design may be considered as a Best Available Technique (BAT) for the food and drink sector under the framework of the EU Industrial Emissions Directive 2010/75/EU.

Ecodhybat project

The Ecodhybat project (www.ecodhybat.com) was promoted and coordinated by AINIA, in partnership with the Spanish Association of Machinery Manufacturers (AMEC), Calidad Pascual (dairy industry) and Pescanova (seafood products). The project was co-financed by the LIFE programme of the EU.

The project has provided suitable experimental results at an industrial scale in two representative sectors: dairy and fish processing. The environmental impact (water, energy, cleaning products, wastewater and air emissions) generated by the sanitation of hygienically-designed equipment and surfaces has been compared to that of equipment with conventional designs. Conclusions can be extrapolated to other food sectors.

The project involved demonstration activities in four pilot production lines at industrial scale representative of EU dairy and fish processing industries and was comprised of three main phases:

• Preparatory activities:

a) hygienic and environmental diagnosis of processing lines, installations and equipment, and
b) methodology development to assess cleanability efficiency and quantify environmental impact of sanitation test.

- Implementation: Demonstration trials
- Evaluation: Environmental, hygienic and economic assessment

The following processing equipment and components were assessed, comparing the environmental impact of cleaning the hygienic version with that of the conventional design of the same or equivalent piece of equipment:

 Dairy plant (Calidad Pascual): Sterile tanks (30000 L), conveyor belts, tank cleaning devices (static spray ball vs rotary spray head), equipment for packaging disposal (Figure 1).

- Fish processing plant (Pescanova): Batter tank mixer (cover, shaft, level sensor, inlet, etc.), viscosity measuring system (inlet, lobe pump, piping, etc.), batter mix pumping system (centrifugal pump, piping, connections, etc.) (Figure 2).
- AINIA: Pressure sensors, centrifugal pump, valves, T connections, and load cells (Figure 3).



Figure 1. Assessing a sterile tank during trials at the dairy plant.

An assessment methodology consisting of a soiling procedure, cleaning method and evaluation protocol was developed in order to compare the environmental impact when cleaning hygienic and conventional equipment.

Industrial equipment to be evaluated was artificially soiled by using a soiling solution composed of a mixture of whole milk, fluorescein, ethanol and gluing additive (Figures 2 and 3). The relative percentage of each component and drying time varied, depending on whether the equipment to be evaluated was intended to be cleaned by means of open or closed systems.



Figure 2. Assessing a batter tank during trials at the fish processing plant.

Cleaning performance in both hygienically designed and conventionally designed equipment was determined by measuring the fluorescein concentration. The evolution of the fluorescein concentration over time allowed the determination of the point at which the equipment was 'cleaned,' followed by a comparison of the consumption of water and energy between them (Figure 4).



Figure 3. Assessing a centrifugal pump during trials at AINIA

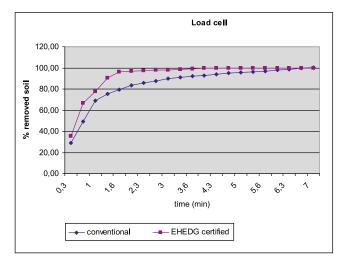


Figure 4. Results of load cells.

Results

Table 1 summarises the results obtained in terms of water savings during cleaning when comparing the hygienic version with the conventional one.

Table 1. Percentage of water savings.

Facility	Equipment	Water sav- ings (%)
Dairy	Sterile tank 30000 L (lid)	40
Dairy	Tank cleaning device (SSB vs. RSJ), tank 7000 L	42
Dairy	Eq. packaging disposal (interior)	75
Dairy	Eq. packaging disposal (exterior)	9
Dairy	Conveyor belt	37
Fish plant	Batter tank system	96
Fish plant	Viscosity measurement system	83
Fish plant	Batter mix pumping system	27
AINIA	Sensor	38
AINIA	Centrifugal pump	39
AINIA	T-piece	60
AINIA	Load cell	29

Considering the assessment method characteristics, the results obtained in terms of water savings are equivalent to time savings to achieve the same degree of cleanliness.

Conclusion

This study shows that hygienic design reduces environmental impacts related to sanitation of equipment and installations – from water, energy and chemical products, to wastewater and CO_2 emissions – and consequently, can positively contribute to a cost reduction in the industrial activity. Overall, a 48 percent water savings was obtained when cleaning the hygienically designed equipment.

Therefore, the Ecodhybat project has demonstrated and quantified the relationship between an improvement from the hygienic design point of view and the reduction in the environmental impacts when cleaning these equipment.

Results have been reviewed by the IPPC Bureau and, as a consequence, Hygienic Design has been included in the First Draft of the Best Available Techniques (BAT) Reference Document in the Food, Drink and Milk (FDM BREF, January 2017) as a Technique to consider in the determination of BAT across the FDM sector.

Reference

 European Commission. (2006). Reference Document on Best Available Techniques (BREF) in the Food, Drink and Milk Industries. Accessed at http://eippcb.jrc.ec.europa.eu/reference/ BREF/fdm_bref_0806.pdf.

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Mechanical energy balance in surface cleaning by pressurised water spray: a simplified model

Cleaning of open surfaces in the food industry, either manual or automatic, is usually performed by spraying pressurised water fans or jets onto surfaces. A simplified model for the analysis of mechanical energy input in this type of cleaning is presented. This model should determine the optimal cleaning parameters in each case. The proposed model can also be used for selecting the most appropriate detergent in each case and for assessing the cleanability of various materials and finishes.

By Enrique Orihuel, Ramón Bertó, Fernando Lorenzo and Celia López, Betelgeux, S.L., Ador (Valencia), Spain, e-mail: betelgeux@betelgeux.es, www.betelgeux.es

Cleaning procedures in the food industry always deal with removing undesired matter (soil) from surfaces. An extensive body of research exists on the topic of fouling mechanisms, either focused on building soil model systems or experimental techniques to characterise the physical factors involved in fouling and cleaning.¹⁻³ However, due to the high number of variables involved, it is difficult to find a comprehensive explanation of the process that also is practical for industry applications.

At a fundamental level, there is a consensus on which general factors influence cleaning processes, having as a starting conceptual point the four factors of Sinner's Circle or extensions of the circle as a six-variables dependent system.^{4,5} Sinner's Circle was proposed in 1959 by Herbert Sinner as a conceptual approach to the factors involved in cleaning processes, particularly in automatic laundry systems. It is represented as a circle divided into four sectors that represent the factors involved in cleaning: detergent, temperature, mechanical action and time (Figure 1A). This graph is intended to show that reduction of one factor requires compensation by increase of other factors. It is an intuitive and practical concept. However, because it is a schematic simplification of a very complex process, there are limitations and cases where the exchange of factors is not applicable.6

The most serious objection to Sinner's Circle is the lack of definition of the factors in quantifiable terms of physical magnitudes and the simultaneous use of intensive and extensive properties. The only factor that is clearly defined is time, although this factor in and of itself has no role in cleaning. The concept of interchangeability of Sinner factors can be reviewed considering cleaning as an energy balance.

In a cleaning process, a substance or mixture of substances is separated from the substrate to which it is adhered. It is therefore necessary to provide a certain amount of energy equal to or greater than the binding energy that holds the soil onto the substrate. This energy represents the sum of a complex set of energies associated with different soil-substrate interactions: chemical bonds, electrostatic forces, adsorption and other mechanisms that occur in the boundary layer.² In most cases, additional energy is required to overcome the forces of internal cohesion of soil and to disperse soil particles in order to prevent redeposition. In this study, the total amount of energy required to separate a certain soil from the unit area of a particular substrate is called the energy of surface descaling, expressed in units of energy per unit area (E_{SD}). E_{SD} is the sum of the different energies of adhesion and cohesion.

$$E_{SD} = \sum_{i}^{n} E_{i}$$
 [Equation 1]

For effective cleaning to occur, the energy for cleaning surfaces (E_{CS}) applied should be equal to or greater than E_{SD} . E_{CS} is compounded by three of Sinner's Circle factors: detergent, heat and mechanical action, which can be described analytically by Equation 2:

$$E_{CS} = E_H + E_M + E_O \qquad [Equation 2]$$

where E_{H} , E_{M} and E_{O} are thermal energy (heat), mechanical energy and chemical energy, respectively. E_H , E_M and E_O are supplied to the surface during the cleaning process, and their interrelation and comparison to Sinner's Circle factors are represented in Figure 1B. Equation 2 excludes time, because it is implicit in the other factors since energy is the result of the product of the power and the time during which it acts. The analytical development of the terms of heat energy (E_H) and chemical energy (E_O) in Eq. 2 is complex. The heat energy supplied is a function of many variables, among which are the coefficients of heat transfer between water and soil, water and substrate, and substrate and soil. Meanwhile, the chemical energy provided by the detergent is a function of a high number of variables, among which are the enthalpies of dissolution, reaction, adsorption, etc. In contrast, the theoretical approach to the mechanical energy (E_M) supplied can be relatively simple, which will be useful for optimising cleaning and for assessing the cleanability of different substrates.

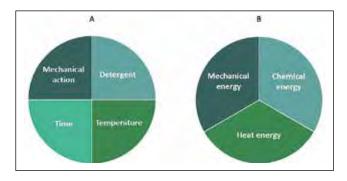


Figure 1. Sinner's Circle represented in the traditional way (A) and as an energy balance (B).

Mechanical energy in cleaning by spraying pressurised water

Most cleaning processes in the food industry involve projection of pressurised water as mechanical energy input, after or in combination with, application of detergent solutions. According to water pressure, water jets can be regarded as high pressure (> 50 bar), medium pressure (20 to 50 bar) or low pressure (< 20 bar). This operation is either performed manually by operators using nozzles to spray jets or fans of pressurised water, or in automated processes, where the nozzles for spraying water are stationary while the elements to be cleaned move (e.g., automatic cleaning of conveyor belts). Additionally, in the case of cleaning in circuits or enclosed systems, the mechanical energy is applied through water movement inside the circuit.

Usually cleaning is done in three successive stages: a) pressurised water spray (supply of E_M and, if hot water is used, E_H) to remove a portion of soil; b) application of a detergent solution in liquid form, foam or gel (E_Q); and c) final phase of pressurised water spray to remove the more strongly embedded soil (contribution of E_M and E_H if hot water is used). In every case, the mechanical energy input is achieved when fan or a jet of pressurised water hits on the soil adhering to the surface that must be cleaned. The supply of this type of energy input is analysed below.

Mechanical energy of a pressurised water fan

In the food industry, the mechanical energy required for cleaning is usually applied by projecting pressurised water as a flat fan (Figure 2). The water fan consists of small droplets and each of these micro-droplets transports a quantity of mechanical energy that partially contributes to the cleaning process. Although the system formed by the pressurised water impacting in the soil embedded in the substrate is extraordinarily complex, for practical purposes some simplifications can be made that lead to a simple model to use in the food industry.^{7,8}

The mechanical energy of water projected from the nozzle is the sum of its potential energy (E_p) and kinetic energy (E_k) :

$$E_M = E_p + E_k = mgh + \frac{1}{2}mv^2$$
 [Equation 3]

where *m* is the mass of water considered, *g* the gravitational acceleration, *h* the height of the nozzle and *v* the velocity of the water stream. For a specific time interval, Eq. 3 becomes:

$$E_M = Q\rho t g h + rac{1}{2} Q\rho t v^2$$
 [Equation 4]

where Q is the volume flow, q is density and t is time. Water velocity at the nozzle exit is a function of flow rate and nozzle section (S). Thus, substituting Q/S for v leads to:

$$E_M = Q\rho tgh + \frac{1}{2}\rho tQ^3 S^{-2} \qquad \text{[Equation 5]}$$

Dividing all components of Eq. 5 by time, the general expression of the mechanical power of the water coming out of the nozzle is obtained:

$$P_M = Q\rho g h + \frac{1}{2} \rho Q^3 S^{-2} \qquad \text{[Equation 6]}$$

 P_M is an important parameter because it is a measure of the mechanical energy input for a given system. The mechanical power available at the output of a nozzle through which water is projected is itself a function of the pressure at the inlet of the nozzle and the dimensions of the orifice. At higher input pressures, the flow will be greater. For a given input pressure, larger sections allow higher flow rates and therefore higher power. For practical purposes, it should be considered that the inlet pressure at the nozzle is lower – sometimes much lower – than the pressure provided by the pump as a result of significant pressure losses produced in pipes, valves and hoses.



Figure 2. Spraying of a water flat fan onto a surface.

The value of P_M can be easily measured in an industry by means of measuring the flow and knowing the equivalent orifice diameter of the nozzle, which is a parameter that the manufacturers of nozzles provide. For a given nozzle, the kinetic energy of water exiting the nozzle is proportional to the cube of the flow (Q). In Figure 3, $P_{\scriptscriptstyle M}$ values for a nozzle of 2.8 mm equivalent diameter are represented as a function of Q_{i} , considering the kinetic energy term only. Flow rate itself is determined by pump pressure, and higher pressures at the nozzle inlet are required for higher flow rates. For example, in order to reach a P_M value of 1,200 W, a flow rate of 27 L/min will be needed and the water pressure at the nozzle inlet must be approximately 35 bar. In contrast, a pressure value of 20 bar produces a flow rate of about 20 L/min, and the resultant power P_M is approximately 490 W. $P_{\scriptscriptstyle M}$ values are independent of the shape of the nozzle orifice, which determines the spray angle α.

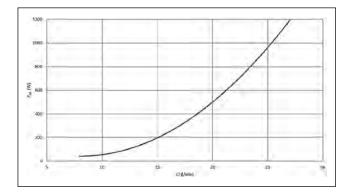


Figure 3. Mechanical power of the water fan $P_M(W)$ versus flow rate Q (*l*/min).

Useful mechanical power

Only part of the mechanical power that the water fan or jet carries when leaving the nozzle (Eq. 6) is actually utilised in the cleaning process. Once the water fan has exited the nozzle, it must cover a distance (d) until impacting on the surface to be cleaned (Figure 4). During their journey through the air, water droplets are slowed by friction with air, losing some of their kinetic energy. The greater the distance (d) between the nozzle and the surface, the greater the mechanical power lost by friction. In the food industry cleaning processes, these distances are generally short, typically under 1 m. With regard to the potential energy of the water fan, variations on the term of the potential power are negligible if water is horizontally projected.

Once the droplets impact on the layer of soil adhered to the surface, some of their power is used to overcome soil adhesion forces to the substrate and cohesion forces between soil layers. Remaining power is mostly lost when micro-droplets bounce from the surface, with variable rebound kinetic energy in a very complex phenomenon.⁹

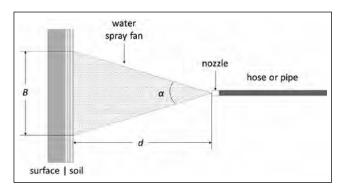


Figure 4. Water flat fan impacting on the soil embedded on the surface.

Estimation of power lost due to friction, rebounding, etc. and therefore not available for cleaning is very complex. However, for the sake of simplicity, an efficiency ratio (γ) can be defined as the ratio of the useful mechanical power available for the cleaning process (P_U) and the mechanical power at the output of the nozzle (P_M):

$$\gamma = \frac{P_U}{P_M}$$
 [Equation 7]

The efficiency ratio has values between 0 and 1, depending on how efficiently the mechanical power from the water fan at the exit of the nozzle is used in the cleaning. This depends on several factors, such as the aperture angle of the flat fan (α) and the angle of incidence of the fan on the surface to be cleaned.¹⁰

Evaluation of cleaning surface energy of a soil

The cleaning surface energy of a soil adhered to a substrate (E_{CS}) is defined as the total energy required to separate the soil from a particular given substrate surface and is expressed in units of energy per unit area (J m⁻²). As described above (Eq. 2), E_{CS} consists of three sources of energy: chemical, thermal and mechanical. In the simplest case, cleaning is performed without any type of detergent, the soil is non-water soluble, and water, surface and soil are at the same temperature. With these considerations, there is no contribution from chemical energy or thermal energy, so E_{CS} is equal to the useful mechanical energy required for removing the soil from the surface. If the mechanical energy input is realised by the impact of a water jet or fan on the soil, the cleaning surface energy can be expressed by Eq. 8:

$$E_{CS} = \gamma \frac{P_M}{A} t$$
 [Equation 8]

where *t* is the duration of impact of the water fan required for cleaning the soil, and A is the area over which the impact of droplets occurs.

When a water fan is projected perpendicularly on a surface at a distance (d) and moving with a velocity v, Eq. 8 is transformed to:

$$E_{CS} = \gamma \frac{P_M}{v B}$$
 [Equation 9]

Where B is the width of the water fan on impact and is a function of the distance (d) and spray angle (α) (Figure 4).

Therefore:

$$E_{CS} = \gamma \frac{P_M}{2 v d \tan \alpha/2}$$
 [Equation 10]

Equation 10 is useful for assessing the mechanical energy required to clean the unit surface of a substrate where a specific soil is embedded. Given the difficulty of knowing the value of γ efficiency ratio, in practice it is the ratio E_{CS}/γ that is evaluated. The E_{CS}/γ values quantified experimentally provide valuable information about the order of magnitude of mechanical energy to be applied to clean a certain soil on a particular substrate.

In our laboratory, E_{CS}/γ values have been quantified experimentally for different soils on AISI 304 stainless steel surfaces. This is part of an ongoing project aimed at establishing reference cleaning energy values for different

soils and surfaces and optimising the mechanical energy balance in cleaning processes. The results obtained experimentally provide estimated E_{CS}/γ values between 3,000 and 8,000 J m⁻² for soils such as ketchup, pork fat or buttermilk on stainless steel surfaces (data not published).

In comparison, other studies provide surface adhesion energy values between 1 and 20 J m⁻² for tomato paste on stainless steel.^{11,12} The discrepancy in order of magnitude can be explained by the different approach for calculating adhesion energy values. While Liu et al. measured apparent adhesive strength when removing soil from a surface by dragging a mechanical device over the soiled surface, our study focuses on the energy at the exit of the nozzle required to achieve a similar result.^{11,12}

In the food industry, both in automatic cleaning (e.g., cleaning or conveyor belts or crate washing) and manual cleaning in which the operator moves the water fan of pressurised water over the surface to be cleaned, it is very useful to know the values of E_{CS}/γ of most common soils, even if these values are an approximation. By estimating E_{CS}/γ values, the optimal parameters of cleaning operations can be determined and thus appropriate parameters such as nozzle type, pressure and flow of water, surface-nozzle relative velocity and distance between nozzle and surface can be chosen. Optimisation of cleaning processes in the food industry can lead to significant savings in consumption of energy, water and time.

Evaluation of detergent action and cleanability

The experimental quantification of the cleaning surface energy of soils in the food industry is also useful for the evaluation of different detergents and for determining the optimal conditions of application (dose, time, temperature). In cleaning processes, detergents are applied to reduce the amount of energy required for removing soil from a surface.

For similar cleaning conditions (velocity of displacement of water fan (ν), distance between nozzle and surface (d), angle between water fan and surface (α), and water temperature) experimental E_{CS}/γ values can be obtained in two cases: application of pressurised water on non-modified soil (E_{CSI}), and application of pressurised water after a detergent solution (in liquid, foam or gel form) has been applied to the soil at a certain dose (E_{CS2}). The difference between both values represents the chemical energy provided by the detergent per unit area (Eq. 11).

$$E_O = E_{CS1} - E_{CS2} \qquad [Equation 11]$$

The subscript 1 represents the mechanical energy required when only water is applied directly, while the subscript 2 represents the mechanical energy required when detergent has been previously applied. Under these conditions, experimental tests can be performed to quantitatively compare the cleaning performance of different detergents, as well as the efficacy of different application conditions (dose, time of contact, etc.). The heat energy factor also can be analysed in cleaning operations using a similar procedure. In this case, the energy requirement for cleaning can be evaluated in different tests in which the water temperature is changed while keeping the remaining factors unchanged. However, the situation is more complex in this case, since water simultaneously acts as a vehicle of mechanical energy and heat energy. Thus, mechanical energy and heat energy are interconnected. For example, if the mechanical power of the water fan is lowered by decreasing the flow using a smaller nozzle section, the amount of heat transported also will be reduced, even if the water temperature remains constant.

Finally, this conceptual approach is also useful for assessing the cleanability of different materials and/or different surface finishes. If there are differences in cleanability between two surfaces with the same embedded soil under similar cleaning conditions, this difference can be quantified by evaluating experimentally the corresponding values of E_{CS}/γ .

Conclusions

In this paper, a simplified model for evaluation of the energy requirements in cleaning processes has been presented. Several hydrodynamic factors are of importance for effective cleaning of hard surfaces related to the equipment used for application of pressurised water and the specific operating conditions. Only a fraction of the energy consumed during the cleaning process is available as useful energy that produces effective cleaning. The excess of energy results in increased cleaning costs due to inefficiency, as well as an increased negative impact on the sustainability of cleaning operations.

By estimating the energy requirements for cleaning common soils on food industry surfaces, the cleaning process can be optimised from the energy point of view, and the appropriate working conditions can be selected: pressure and flow of water, distance to surface and speed of displacement, water temperature, type of detergent, its dose and contact time, etc. Optimal setting of parameters also may provide indirect benefits that improve hygiene efficiency. For example, water pressure can be lowered in order to avoid formation of aerosols, which pose a significant hazard due to crosscontamination. Adherence to EHEDG hygienic design criteria can help to overcome this problem since requirements for high pressure cleaning are minimised.

The study of the energy balance in cleaning operations is thus essential to optimise these processes in a systematic and quantitative way, which will potentially lead to substantial savings in water and detergent consumption, time dedicated to cleaning, and overall costs of cleaning. Savings achieved in water use or energy consumption lead to more sustainable cleaning operations, contributing to enhanced sustainability of the food industry.

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Development of a software tool for virtual cleanability test

Three companies have been funded by the German government to jointly develop simulation software for the design of complex spray cleaning systems.

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Regular cleaning of machines and equipment parts is an essential process step to fulfil hygienic requirements in food, pharmaceutical, cosmetics and chemical production facilities. Drivers for food manufacturers, in particular, include tightened hygiene regulations, an increasing market for natural foods with extended shelf lives, and the trend towards flexible production with smaller batches, which means instituting more cleaning cycles per day or week. Achieving high standards of measurable cleanliness is also important for another reason. The presence of soils and chemical residues on equipment constitutes a hazard to the product, carrying with it the risk of major product recalls, foodborne illness outbreaks and damage to the product brand and company reputation.

At the same time, due to increasing efficiency requirements within food processing operations, there is a significant demand to shorten cleaning times in order to:

- decrease cycle times (e.g., parts cleaning), and/or
- increase the machine availability

In large-scale production facilities, equipment components often are cleaned in washing machines to remove auxiliary materials such as lubricants from upstream processes. The reduction of cycle times without losing cleaning effectiveness is directly related to increased efficiency of the line. One way to achieve these cost-saving efficiencies while maintaining the highest levels of cleanliness is to utilise fully automated spray cleaning systems. However, the design of these complex systems can pose a major challenge, primarily because they must be engineered to ensure that cleaning agents reach every targeted surface area with a specific level of intensity. This is important since the weakest link of the chain defines the overall cleaning time. An interactive software design tool that can simulate complex spraying systems has an excellent potential to assist food manufacturers with testing variations in advance of installation on the production line, which in turn provides a higher level of confidence that all surface areas are adequately and efficiently cleaned.

About the SIMKOR project

Three companies – Advitec GMBH, Innovations- und Simulationsservice Festenberg, and Fraunhofer IVV Dresden – are developing a software tool (SIMKOR) for the simulation of complex spray cleaning systems. The development project is funded by the German Federal Ministry of Education and Research. Such systems, created in a virtual engineering environment, will give users the opportunity to test different design variations via computer software and to compare and optimise them before physically building any setup or prototype. At present, there is no such option available in the world.

The project focuses on automated spray cleaning with a large number of nozzles using static and rotating tank cleaners with complex spray patterns. As shown in Figure 1, the considered zones of the impinging jet.

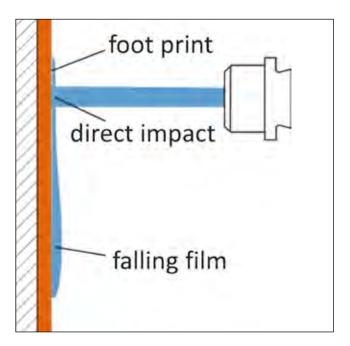


Figure 1. Considered zones of the impinging jet.

With regard to the quantification of the cleaning results, the new software tool is expected to close the methodical gap between expensive cleaning or spray shadow tests at the prototype level and the largely complex mesh-based computational fluid dynamics (CFD) simulation. Further, experts from research and industry believe that the state of the art regarding CFD expected in the medium term does not provide any practical use in this field.

Software features and timeline

In order to achieve a high level of acceptance, the software under development is based on standard computer-aided design (CAD) applications and their main exchange formats. The simulation will be interactive so that changes of the cleaning result due to modifications of the cleaning system (e.g., nozzle direction) will be shown immediately on the screen. In this way, complex cleaning systems can be designed and virtually optimised within a short time. The software will be designed with ease-of-use in mind, as well. In the case of industrial use, it will be important that design engineers without a deep knowledge of CFD are able to run the software reliably. Should the simulation show repeated instances of inadequate cleaning, the designer can investigate redesign of the equipment to achieve better cleaning results.

The conceptual design of the interfaces for the development environment is shown in Figure 2.

In the first step, the designer will open the assembly that is to be automatically cleaned in the CAD software and saves it in an exchange format. Then the designer will start the new simulation software by opening this file. The simulation software will permanently search for the latest version of the exchange file and will load it automatically. This will mean that not only can the cleaning system be optimised but also that the assembly can be redesigned to achieve better cleaning results.

After the file loads, the simulation software will show a user interface similar to the one from common CAD programmes where the designer can position a large number of nozzles via drag-and-drop out of a nozzle database. This database will be provided by the project team, and nozzle suppliers will have the opportunity to contribute portfolio information to this database.

The software user will be able to insert the nozzles in the simulation scene and optimise type, position, orientation and operating parameters with regard to the interactive cleaning result.

The SIMKOR software will be under development until June 2018. It is anticipated that the software tool will be made available for commercial use after that date.

Acknowledgment

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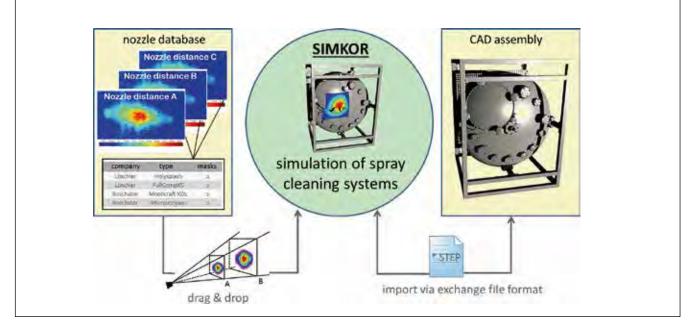


Figure 2. Interfaces between simulation, CAD software and nozzle database.



Self-optimising clean-in-place (SOCIP)

A multi-sensor approach for fouling level assessment in clean-in-place processes

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Clean-in-place (CIP) systems are largely used in the food industry for cleaning interior surfaces of equipment without disassembly. These processes currently utilise an excessive amount of resources and time, as they are based on an open loop (no feedback) control philosophy with process control dependent on conservative assumptions. This paper proposes a multisensor approach for CIP monitoring, including a vision and acoustic system and endowed with ultraviolet (UV) optical fluorescence imaging and ultrasonic acoustic sensors aimed at assessing fouling thickness within inner surfaces of vessels and pipework. An experimental campaign of CIP tests was carried out at laboratory scale. During the tests digital images and ultrasonic signal specimens were acquired and processed extracting relevant features from both sensing units. These features can then form the basis of inputs to an intelligent decision making support tool for the real-time assessment of fouling thickness towards the creation of a self-optimising clean-in-place (SOCIP) system.

In modern food manufacturing contexts, the standard procedure for cleaning equipment is CIP, which uses a mix of chemicals, heat and water applied over a set period of time without the requirement of dismantling. Usually CIP is a multi-stage process, typically starting with a pre-rinse, followed by a caustic wash and a rinse. A subsequent acid wash is optional and if applied is followed by another rinse. CIP may terminate with a disinfection or sanitising step that often involves a final rinse.¹

Existing CIP processes are time intensive and waste large amounts of energy, water, and chemicals.^{1,2} Furthermore, it is estimated that on average a food and beverage plant will spend 20 percent of each day on cleaning equipment, which represents significant downtime for a plant.² Monitoring of fouling can provide useful information on cleaning status and ensure efficient, effective operation of the equipment.

UV light detection methods are used for the detection of residual cells and soiling on industrial surfaces.^{3,4} The state of the art in thickness assessment techniques includes transient thermal probes developed to estimate the fouling thickness of heat exchangers.⁵

Pneumatic gauges for non-contact thickness measurement based on pressure profiles have been developed and implemented.⁶⁻⁸ However, these presented distortions in the measurement of soft deposits due to either the impinging jets or the suction streams.⁹

An application of a heat flux sensor aimed at monitoring local fouling of non-heated surfaces in commercial plants also has been utilised.¹⁰

Ultrasonic (US) measurement techniques transmit low power (<100 mW cm-2) high frequency (>20 KHz) mechanical waves through physical systems and are most commonly used in medical imaging and nondestructive testing. The techniques can be used to obtain information about the physical chemical structure of liquid materials and can identify any inhomogeneity's within fluid systems by how they scatter or reflect the waves.

Ultrasound techniques have been used to detect fouling in heat exchangers and pipe work.¹¹⁻¹⁵ Neural network classification has also been utilised for determining the presence of fouling in heat exchangers.¹⁶

This paper proposes a methodology for a multi-sensor monitoring system able to assess the fouling thickness within openable and non-openable components of CIP equipment, utilising a vision and ultrasonic sensing units respectively for tanks and pipework, as outlined in Figure 1. The output of these sensors will ultimately need to be correlated with the threshold of cleanliness to industrial standards.

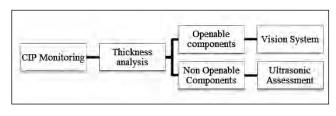


Figure 1. Framework for thickness assessment.

2. Materials and experimental procedures

In this section, a description of the experimental setup utilised for both the vision system and ultrasonic tests is reported, with the procedure adopted for this research illustrated in Figure 2.

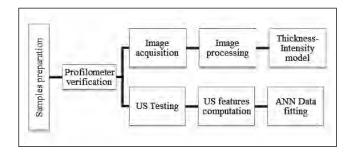


Figure 2. Thickness assessment procedures.

2.1. Samples preparation

For the experimental campaign of thickness assessment tests, chocolate spread was used as a fouling material, with the following characteristics (for 100 g of product): density = 1.26 g/mL, protein = 5.4 g, water = 0 g, fat = 30 g, viscosity = $28.1 \text{ Pa} \cdot \text{s}$ ($10 \text{ s} - 1, 25^{\circ}\text{C}$).

To produce repeatable samples, a series of eight close-wound stainless steel hand-coaters (RK Print Coat Instruments Ltd., UK) were used to apply a layer of chocolate spread on two different substrate materials: stainless steel for the vision system tests and transparent polymer for ultrasonic tests. The two substrates, used as part of sample material workshop preparation, allowed for expected data differences. Ultrasound will travel differently in stainless steel compared with transparent polymer; however, the substrate material effects are negated through subsequent signal processing techniques.

Table 1. Nominal and measured thickness values.

Test M	Nominal wet film depusit thickness (pm)	Measured average thickness (µm)
1	6	5.96
2	12	12.43
3	24	24.45
4	40	-40.25
5	50	50.14
6	60	60.36
7	80	80.04
8	100	99.69

The consistency between the sample thickness and the nominal value was verified using a CLI 2000 3D profilometer (Taylor Hobson, UK). Each sample was subject to a number of non-contact measurements, utilising the substrate as baseline and acquiring the average thickness. The nominal and measured thickness values are reported in Table 1.

2.2. Vision System setup

A darkroom box was designed and realised in order to allow a comprehensive and consistent experimental campaign of digital image acquisition of chocolate spread samples (Figure 3a/b).

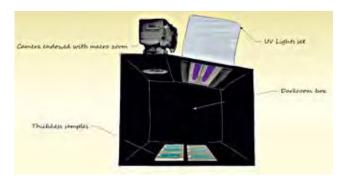


Figure 3a. Darkness box design for image acquisition tests.



Figure 3b. Darkroom Camera and UV light on top of darkroom box.

The darkroom box is insulated from external light sources and endowed with a set of two 18 W 370 nm fluorescent UV lights to allow the fluorescence of the chocolate layer.³

The image acquisition was carried out using a Nikon D3300 DSLR camera and a 10-20 mm wide angle Sigma zoom lens.

Nine different photographic configurations were used by varying the following parameters:

- ISO sensitivity = [1600, 3200, 6400]
- Shutter speed (s) = [1/10, 1/25, 1/50]

Other photographic parameters were kept constant:

- Focal length = 10 mm
- F-stop = F/5
- WB = auto

By combining the ISO sensitivity and the shutter speed values, replicates of nine digital images were acquired for each test, for a total number of 72 image instances.

2.3. Ultrasonic tests setup

This research utilises a pulse echo ultrasound setup (Figure 4).

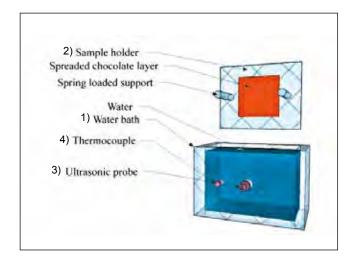


Figure 4a. Ultrasonic test setup.

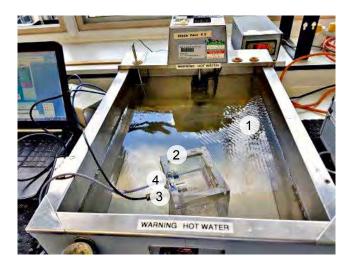


Figure 4b. Ultrasonic equipment used.

In this configuration a single ultrasound pulse is transmitted from a 2.25 MHz transducer (Imasonic IM series), reflected from the sample holder and received at the same transducer. An ultrasonic box (Lecoeur Electronique, France) controlled by a laptop is connected to the transducer and generates and receives the US signals. The propagation of ultrasound waves is temperature dependent so the temperature within the sample cell was recorded using a PRT1000 probe and data logger (PT-104, Pico Technology Ltd, UK).

The transducer was excited by a 200 v, 7 ns flat top pulse and the received signal was amplified by 15 dB. For all experiments the sample cell was filled with water. The sample holder was removed before each measurement and the thin layer was applied on it according to the procedure described in section 2.1.

Five repetitions were carried out for each sample to increase the tests reliability, for a total number of 40 ultrasonic tests, during which, the time of flight (μ m) and the received amplitude (%) data were acquired and recorded. The measurement is a reflected signal so scattering does not have undue impact. In any case, the measurement effectively occurs at a point contact where the curvature effect is negligible.

3. Data processing

In this section, the procedures for data processing are reported for both the vision system and the ultrasonic tests.

3.1. Vision System

The image processing procedure is illustrated in Figure 5, and it was applied to all 72 digital image instances.

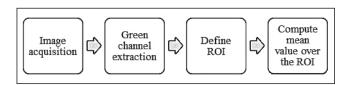


Figure 5. Image processing flowchart.

The acquired RGB image appears as a $6000 \times 4000 \times 3$ elements matrix, where the first two dimensions (6000×4000) represent the image resolution (24Mp), and the third dimension (3) represents the three colour channels: red, green and blue, respectively. An example of RGB image is reported in Figure 6 for Test 8.

In order to isolate the fluorescent layer of chocolate spread from the rest of the image, the green channel was extracted from the RGB image and reported in Figure 7. After this transformation, the green channel appears as a 6000 x 4000 px image in greyscale.

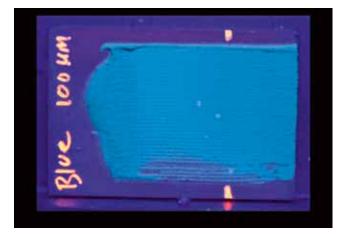


Figure 6. Test 8 (100 µm) RGB image (ISO 6400, S 1/10).

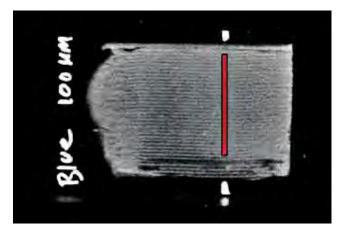


Figure 7. Green channel image and Rol, test 8 (ISO 6400, S1/10).

At this point, a manual selection of a region of interest (ROI) was carried out. The ROI is identified in correspondence of the area that was previously scanned with the 3D profilometer, with a width of $20px (\approx 1 \text{ mm})$ and highlighted in red in Figure 7.

The mean value of the pixel intensity was computed within the ROI for each image instance of each test for a total of 72 values. In this way, it was possible to construct a series of thickness-intensity curves (Figure 8). Nine curves (9 photographic conditions) of 9-points each (eight thickness samples plus the zero, assuming that thickness = $0 \rightarrow$ intensity = 0) were plotted.

The purpose of the image processing was to assess the thickness value given the pixel intensity; in this respect, a third-degree polynomial fitting was chosen to interpolate the data according to the following equation:

$$f(x) = \alpha x^3 + \beta x^2 + \gamma x + \delta$$

Where x is represented by the pixel intensity and f(x) is the computed thickness value. The best fit was determined to be a third-degree polynomial.¹⁷

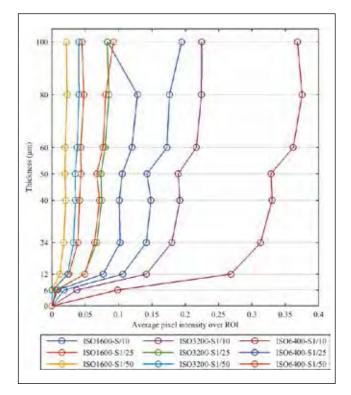


Figure 8. Intensity-thickness curves used for polynominal fitting.

The data fitting procedure was applied to all of the nine curves and the table of coefficients (α , β , γ , δ) is reported in Table 2 for all the photographic configurations. Outliers were removed from the curve fitting modelling.

3.2. Ultrasonic signal processing

US data were processed in order to compute the ultrasonic path length, which was calculated by multiplying the ultrasonic velocity through the water by the time of flight of the received signal.

The time of flight was recorded as the first zero crossing once the received signal is larger than the selected threshold value. To account for temperature effects the ultrasonic velocity is calculated using the Marczak Equation reported as:¹⁸

$$\begin{split} c &= 1.402385 \times 10^3 + 5.038813 \, T - 5.799136 \times 10^{-2} \, T^2 \\ &+ 3.287156 \times 10^{-4} \, T^3 \\ &- 1.398845 \times 10^{-6} \, T^4 \\ &+ 2.787860 \times 10^{-9} \, T^5 \end{split}$$

where T is the water temperature measured using the embedded thermocouple (°C).

The received signal amplitude is a function of attenuation through the propagating fluid and the percentage of reflected signal from the sample holder (with or without fouling layer). The percentage of reflected signal depends on the relative acoustic impedance (z) of the water and reflecting surface: $z = \rho c$, where c is the ultrasonic velocity and ρ the density of each material.¹⁹ A large acoustic impedance difference results in a larger proportion of the signal been reflected.

Table 2. Polynomial coefficients.

Configuration	α	β	γ	ð
ISO1600-S1/10	7.71E+04	-7143	254.6	1.846
ISO1600-S1/25	3.85E+06	-2.14E+05	3314	0.1667
ISO1600-S1/50	2.62E+07	-6.24E+05	4347	2.886
ISO3200-S1/10	2.63E+04	-5927	387.4	-0.535
ISO3200-S1/25	6.23E+05	-5.99E+04	1653	-1.16
ISO3200-S1/50	7.30E+06	-3.68E+05	5074	1.378
ISO6400-S1/10	5148	-1815	174.9	0.3628
ISO6400-81/25	2.42E+04	-2857	154.7	1.574
ISO6400-S1/50	2.05E+05	-1.48E+04	716.7	0.9556

Table 3. Two-element ultrasonic feature vector.

ID Test	US path length (mm)	Received amplitude (%)				
T 1.1	38.1941	33				
T 1.2	38.3098	34				
T 8.4	38.0093	10				
T 8.5	38.0043	11				

4. Neural network data fitting for thickness assessment

Ultrasonic features (i.e., US path and amplitude) were grouped in a two-element feature vector (partially reported in Table 3) and inputted to a neural network (NN) data fitting decision-making support system for thickness assessment.^{20,21}

Three-layer feed-forward neural networks were built with the following architecture:

- Input layer: Two nodes corresponding to the US feature vector (40 instances x 2 features)
- Hidden layer nodes (HLN): variable
- Target layer: One node corresponding to the nominal thickness value of each instance (40 instances x 1 thickness value)

Several NN configurations were considered, by varying the number of hidden layer nodes: 4, 8 and 16, and the training algorithm (i.e., Levenberg-Marquardt [LM]. Bayesian regularisation (BR) [23,24] and scaled conjugate gradient (SCG).²²⁻²⁵ Data division for NN learning was carried out randomly with the following percentages: 70 percent for training, 15 percent for validation and 15 percent for testing.²⁶

5. Results and discussion

In this section the results of the vision system and ultrasonic experimental tests are presented and discussed.

5.1. Vision System

Considering the polynomial fitting model computed for a given set of photographic conditions, it is possible to build a 3D mesh plot of the surface fouling within an openable component, where the x- and y-axes represent the image resolution, and the z-axis represents the computed fouling thickness (Figure 9). It should be noted that image acquisition and processing for fouling assessment is applied in a time-lapse context of fouling monitoring within openable components of CIP systems. In this way it is possible to have a real-time assessment of the fouling within the tank and its removal rate in order to adapt, during the cleaning process, the cleaning parameters such as time, detergent concentration, and potentially, water pressure and water spray direction.

5.2. Ultrasonic tests

The goodness of fit is shown in terms of the Pearson correlation coefficient R, defined as: $^{\rm 27}$

$$R = \frac{\sum_{i=1}^{n} (x_i - \overline{x})(y_i - \overline{y})}{\sqrt{\sum_{i=1}^{n} (x_i - \overline{x})^2 \sum_{i=1}^{n} (y_i - \overline{y})^2}}$$

where x is the target vector (nominal thickness values) and y is the estimated thickness value. The coefficients were calculated for all the stages of the NN fitting: training, validation, testing and a total one. A synoptic chart of the overall R coefficients versus hidden layer nodes and training algorithm is reported in Figure 10.

All of the NN configurations adopted yielded to a correlation coefficient higher than 0.9, which demonstrates good suitability of the US features in assessing the fouling thickness.

For this specific application, the best fit is given by LM-4HLN NN configuration, which corresponds to the Levenberg-Marquardt training algorithm with 4 hidden layer nodes. A detailed regression plot for this configuration is reported in Figure 11 including training, validation, testing and total regressions. The number of hidden layer nodes doesn't show a clear influence on results, whilst, on average, the most consistent training algorithm appears to be the BR.

6. Conclusions

For a comprehensive clean-in-place monitoring system, a broad study on the thickness assessment needs to be conducted. In this paper, two methodologies were proposed, one for openable components and another for non-openable components, respectively.

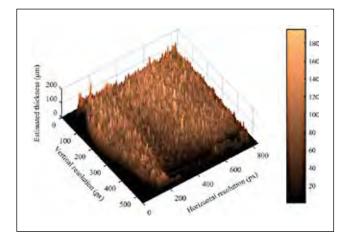


Figure 9. 3D mesh plot of thickness, Test 8 (ISO 6400, s 1/10).

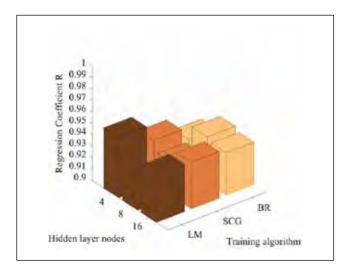


Figure 10. Data Fitting Results

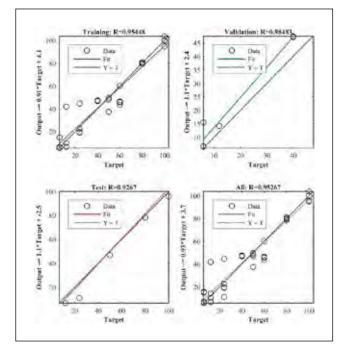


Figure 11. Regression plots for the LM-4HLN configuration.

A vision system endowed with UV light was set up to model the fouling thickness within tanks and vessels, and an ultrasonic intelligent system was used to assess the fouling thickness within pipework. A correlation between the fouling thickness and the pixel intensity was found, enabling realtime control of the fouling removal rate.

Ultrasonic tests results indicated that the technique was capable of determining the thickness of the fouling material in real-time with a similar level of sensitivity as the vision technique.

Future work will include the implementation involving a laboratory-scale CIP system featuring a range of typical process operating conditions and fouling materials. This work will combine the two sensor techniques demonstrated in the current work into a system capable of characterising the internal surface fouling conditions within different components simultaneously to deliver real-time data on cleaning performance.

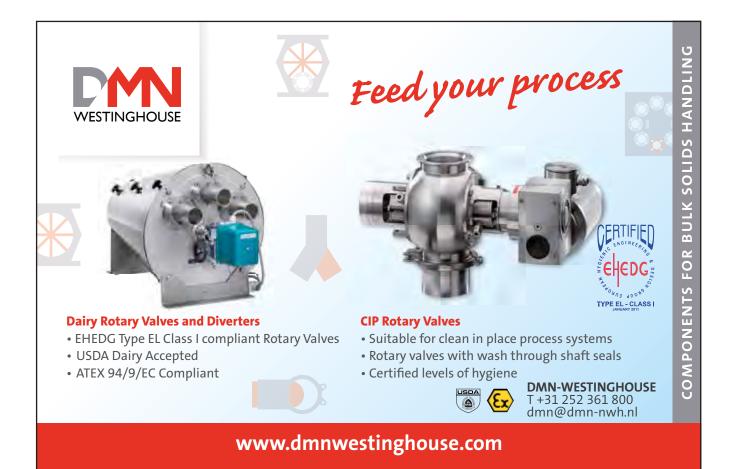
Moreover, further investigations need to be carried out on the correlation between the sensor monitoring system outputs and the adenosine triphosphate (ATP) swabbing technique. This standard is currently utilised within the food and drink industry to determine the cleanliness level. If the sensors are as sensitive as the ATP technique, this will enable the potential real-time monitoring of fouling removal that is suitable for industrial applications.

Acknowledgement

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Understanding the impact of stainless steel finishing methods on CIP effectiveness

By Giampaolo Betta¹, Matteo Cordioli², Matteo Mezzadri³, Fabrizio Nardini⁴

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The cleaning process is of great importance to ensure the safety and quality of finished products in food production plants. From the plant design point of view, the choice of food contact materials with different surface characteristics can influence the efficacy of the cleaning process, potentially reducing the time and cost of cleaning phase. The European Hygienic Engineering & Design Group (EHEDG) guidelines require that, to guarantee adequate cleanability, a product contact surface should have a maximum surface roughness (Ra) of 0.8 mm. As noted in EHEDG Doc. 8, cleanability strongly depends on the surface finishing technology because it can affect the surface topography¹.

In this article, a comparative evaluation study of clean-inplace (CIP) effectiveness on stainless steel surfaces is discussed. In this study, four different surfaces with the same nominal roughness and obtained by different finishing processes were subjected to cleanability testing according to a procedure based on the EHEDG Doc 2.² The objective of this work was to investigate whether a test based on the EHEDG Doc. 2 procedure is sensitive enough to show cleanability differences between various surfaces with the same macroscopic geometry and different topography at a microscale.



Figure 1. Stainless steel samples.

Materials and methods

Sample preparation

The test samples used in this study were four rectangular (60x1000 mm) stainless steel plates (AISI 304), each with a thickness of 8 mm (Figure 1). The geometry was designed to ensure a linearly distributed wall shear stress in the range 1-6 Pa, in order to increase the sensitivity of the method in the conditions representative of a real-world CIP system, as suggested by other researchers in the scientific literature.^{3,4}

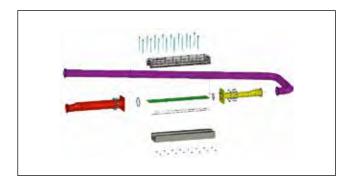


Figure 2. Sample disposition inside a CIP pilot plant.

In order to allow applicability of this method to a broad variety of materials and finishing processes, the geometry was designed to be easy to manufacture, treat and/or coat, with a size compatible with laboratory equipment and a weight suitable for single operator handling. Moreover, the geometry was optimised to reduce the consumption of microbiological laboratory materials, water and detergents. Finally, an incubating vessel was designed to ensure flat agar plates with constant thickness for easy and even automated agar inspection to make the EHEDG Doc. 2 procedure as practical and reliable as possible. The four samples were obtained from a cold rolled plate by:

- Spherical milling
- Insert milling
- Micro shot peening
- Electropolishing

Four replicates for each sample were tested.

Soiling and cleaning process

After the soiling phase with soured milk inoculated with 10⁵/10⁶ spores/mL of *Geobacillus stearothermophilus var. calidolactis*, the sample plates were dried inside a laminar flow hood to ensure reliable drying and avoid recontamination. After drying, the samples were inserted into the test section made up of two half-cylinders (test item is the green component in Figure 2) and then connected to a CIP test rig, as shown in Figure 2. The cleaning process was the same required by the EHEDG Doc. 2, with the following steps:

- Rinse with cold water
- Loop wash with cleaning solution at 63°C
- Rinse with cold water
- Final drainage

In this study, the cleaning step was carried out with only a 0.5 percent concentration of the mild detergent described in the EHEDG Doc. 2.

Detection of the residual soil

According to EHEDG Doc. 2, the rinse waters were examined to show the presence of free spores on the surface before and after the cleaning step. After incubation, the growing colonies must be between 3 and 300 spore/10 mL for the first rinsing and less than 1 spore/10 mL for the final rinsing.

After the CIP, the stainless steel plates were inserted into the specifically designed vessel and the vessel was filled with growth medium (MSHA) to ensure a constant thickness coating of the plates. The container was then incubated to promote the spore proliferation. After incubation, the agar slabs were extracted and submitted to image analysis to quantify the discoloured areas from purple to yellow.

Results

An example of agar slabs obtained after incubation of the sample plate is shown in Figure 3.

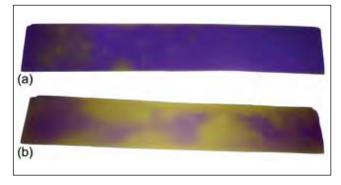


Figure 3. Example of agar slabs obtained from two samples: (a) insert milling and (b) spherical milling.

The results obtained from the various samples are reported in Table 1.

Table 1. percentage of yellow areas.

Samples	% of Dirty Surface
Spherical milling	69.8±10.8
Insert milling	37.8±10.4
Micro shot peening	80±15
Electropolished	6±2.9

Conclusions and future development

It is widely recognised that an electropolished surface is more hygienic than either machined or micro peened surfaces with the same Ra, and this is confirmed by the results shown in Table 1. This research shows that a cleanability test based on the EHEDG Doc. 2 procedure is able to distinguish different surface cleanability due to different surface topographies, even if the samples have the same Ra roughness. This method offers interesting opportunities for evaluation of the cleanability of surfaces obtained by innovative manufacturing, finishing and coating technologies.

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Creating optimal cleanable stainless steel surfaces

In the food industry, all food contact surfaces must be frequently and thoroughly cleaned. This is also valid for food contact surfaces made out of stainless steel. The efficiency of the cleaning process is related to the cleaning process itself, as well as to the hygienic characteristics of the surface being treated. However, those specific surface characteristics – in short, the 'cleanability' – often pose problems due to the traditional surface treatment methods that are applied after fabrication of the stainless steel components. But scientific research proves that there is an innovative alternative for those traditional methods: the SUBLIMOTION-process®.

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Hygiene demands permanent and special attention in the food industry because consumers expect high-quality products that are safe for consumption. Through its guidelines and other publications, the European Hygienic Engineering & Design Group (EHEDG) provides a number of hygienic design tools that help food producers meet these consumer expectations. One essential objective of hygienic design is to keep all food contact surfaces (and thus also the food) safeguarded from chemical and microbial contamination. Cleaning and disinfection is therefore essential.

The effectiveness of the cleaning and disinfection process not only depends on the technique and specifications of the process, but also on the characteristics of the surface being cleaned and disinfected. In particular, characteristics such as the roughness, topography, hydrophobicity and surface energy, each which have an impact on its suitability for getting rid of food and dirt (i.e., its cleanability).^{1,2} Moreover, as already stated in a previous version of the EHEDG Yearbook, for food processing machines that do not meet the 'easy to clean' requirements of the Machinery Directive 2006/42/EC and other relevant standards, conformity to the CE mark is not valid.³

The downsides of traditional stainless steel surface treatments

When stainless steel is processed (bent, cut, welded etc.) into parts and components that are destined to be used in food production facilities, several functional problems and deficiencies can appear, including:

- An unfinished, unclean surface that is visually not uniform.
- Surfaces with all kinds of contamination and imperfections generated during handling and fabrication such as the typical oxidation and discolourations in welding zones that are associated with the onset of corrosion, microscopic surface damage, grease spots, impurities, etc. (Figure 1).⁴ As a result, these surfaces do not possess good hygienic characteristics according to EHEDG guidelines Doc. 8. Hygienic Equipment Design Criteria, and Doc. 32. Materials of Construction for Equipment in Contact with Food.^{1.5} More specifically, the cleanability of those surfaces can and must be significantly improved.



Figure 1. A stainless steel component that shows the typical welding discolourations, imperfections, impurities and contamination generated during fabrication.

Traditional surface treatment processes that are used today to remove discolourations in welding zones, grease spots and similar contamination of stainless steel surfaces on an industrial scale include chemical pickling and passivation, electropolishing, mechanical grinding, brushing and polishing, and conventional bead blasting. All of these methods, however, leave the door open for further improvement with regard to environmental impact, safety of the process itself, and the resulting hygienic characteristics and cleanability of the food contact surfaces.

A mechanically polished surface, for example, can result in a surface with a low roughness but can also be damaged and contain micro-cavities, tears or laps, which lead to a reduction of its cleaning properties.^{6,7} Also, the remaining overall surface topography and quality strongly depend on the process parameters, such as belt speed, pressure, etc.⁸ When examining a stainless steel surface at the microscopic level after grinding and polishing, one can observe considerable amounts of remaining grease, oil and polishing paste residues on and within the surface. This contamination might affect the food products with which they come into contact, and in certain cases might quickly become the starting point for corrosion (e.g., definitely when the contamination comes from carbon steel). The widely applied bead blasting treatment, on the other hand, is known to result in ruptured surfaces (Figure 2).⁵ In addition, these types of treated surfaces possess a surface roughness that exceeds the maximum roughness values advised by EHEDG for large surface areas (i.e., R_a <0,8 µm).⁸

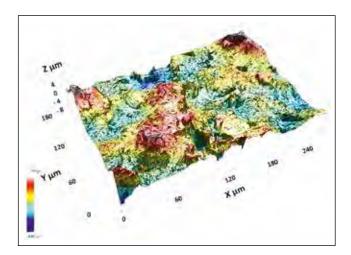


Figure 2. Microscopic 3D image of a standard 2B stainless steel surface treated with conventional glass bead blasting. The topography is very rough, with many alternating high peaks and valleys.

Chemically pickled and passivated stainless steel surfaces may, in some cases and strongly depending on the initial surface state before pickling, obtain an average surface roughness that falls below the advised 0,8 μ m. Even then, the disadvantage is that high peaks and deep valleys are created on the surface, which remain difficult to clean.⁸ This lack of thorough cleaning on the micro level, was shown in research conducted by Actalia, as discussed later in this article).¹²

Focusing on R_a values alone can lead to misjudgement of the cleanability of a surface and/or its susceptibility to accumulating contamination. Even surfaces with the same R_a values can have totally different topographies. For example, they can exhibit large differences in the number of peaks and valleys along the measured sample lengths (Figure 3).⁶

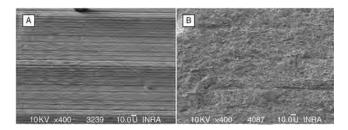


Figure 3. SEM observation of stainless steel characterised by similar Ra values (A: $R_a = 1.17 \ \mu m$, B: $R_a = 1.12 \ \mu m$) but with quite a different topography.⁹

As commonly known, and certainly within the EHEDG, cleanability strongly depends on the total surface topography, of which the R_a value is only one of many parameters.^{1,6} Every surface imperfection, from pits, holes and crevices to grooves and grain boundaries, makes removal of adherent bacteria more difficult (Figure 4).⁹

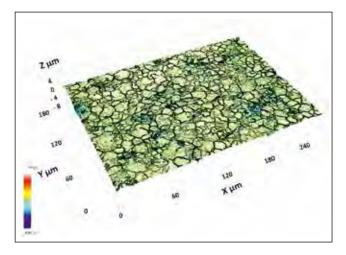


Figure 4. A standard 2B finished stainless steel surface shows, that although the surface possesses a low R_a value and gives the impression of being a smooth, ideal hygienic surface, there are deep micro-cavities, cracks and clear grain boundaries when examined under the microscope.

Figure 5 shows that these grain boundaries are optimal points of attachment for bacteria. So even standard 2B finished stainless steel shows there is still room for improvement in terms of hygienic characteristics.

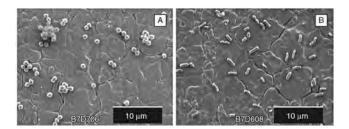


Figure 5. Adhesion of various microorganisms on stainless steel surfaces: adhesion of *Staphylococcus caprea* (A) and *Pseudomonas fluorescens* (B) under static condition on stainless steel with a 2B finish (horizontally immersed).⁹

One could say that one of the practical problems is that there is no explicit, straightforward legislation or regulation regarding surface roughness, topography and/or cleanability of stainless steel food contact surfaces. However, the European Union's Machinery Directive does state clearly that all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products must:

- be smooth and have neither ridges nor crevices that can harbour organic materials, and
- be easily cleaned and disinfected.¹⁰

To independently examine whether something is cleanable or not in a straightforward way, the EHEDG developed the standardised method for assessing the in-place cleanability of food processing equipment, which is outlined in EHEDG Doc. 2.¹¹

The SUBLIMOTION-process

Following extensive internal research and development at Phibo Industries to create a surface treatment process that results in optimal cleanable surfaces, an innovative alternative to traditional surface treatments is now available. The SUBLIMOTION-process is a monitored surface cleaning and conditioning process for stainless steel, based on a distinctive projection of a well-determined and specific colloidal suspension that removes contamination from the fabrication of the surfaces (Figure 6). This method results in a visually appealing and uniform finish, and reconditions the complete surface topography (including, amongst others, the roughness) and energy (Figure 7).



Figure 6. The same stainless steel component as shown in Figure 1, but now after treatment with the SUBLIMOTION-process. All contamination or impurities resulting from the fabrication are removed and at the same time the surface topography is reconditioned.

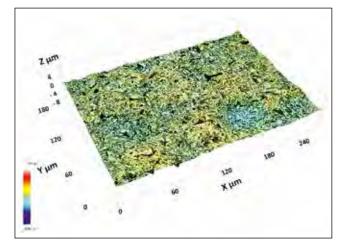


Figure 7. The SUBLIMOTION-process reconditions the surface topography, creating a surface with optimal cleanability.

Independently proven optimal cleanability

ACTALIA, an officially authorised test and certification institute, was employed to carry out the EHEDG cleanability test according to EHEDG Doc. 2 and to deliver EHEDG certificates in case of compliance.¹² In first instance, the institute conducted a scientific study inspired by EHEDG Doc. 2 with specifically adjusted parameters to compare

the cleanability of a stainless steel surface finished with the SUBLIMOTION-process to surfaces finished with traditional surface treatment methods. Having submitted all of these differently finished stainless steel surfaces to the cleanability test, the remaining contamination was compared. Testing showed that the stainless steel surface treated with the SUBLIMOTION-process showed no remaining contamination and was determined to be at least equally cleanable as an electropolished surface. This in contrast to the results of the reference pipe, the standard surface with 2B finishing and the surfaces treated with glass bead blasting and chemical pickling and passivation, as these last four types of surfaces all contained remaining contamination after completing the cleanability test.¹³

In the second phase of the study, ACTALIA verified the conformity of the SUBLIMOTION-process with Regulation (EC) 1935/2004 on materials and objects that come into contact with food and evaluated a tube of stainless steel with SUBLIMOTION-process finishing for compliance with the hygienic equipment design criteria of EHEDG according to the test method of EHEDG Doc. 2. The process also has been declared EHEDG Certified Type EL Class I for wet in-place cleaning of closed equipment, without dismantling.^{14,15}

As previously noted, these optimal characteristics regarding cleanability are very important for all the surfaces in the food industry in general and for both direct and indirect food contact surfaces in particular, as these characteristics lead to a reduced risk in microbiological contamination. As a consequence and according to EHEDG Guideline 35, this reduces the need for cleaning cycles, which enhances the efficiency of the food processing plant.¹⁶

Conclusion

The SUBLIMOTION-process is an alternative to conventional stainless steel surface treatment processes. Based on scientific research, testing has shown that the SUBLIMOTION-process conditions stainless steel surfaces in such a way that they possess better hygienic characteristics, which significantly improves cleanability after treatment (Figure 8).^{13,14} Moreover, the cleaning and conditioning of the surface is simultaneously realised in one single step.



Figure 8. Large stainless steel container before and after treatment with the SUBLIMOTION-process.



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On-site refurbishment of used stainless steel vessels

Used tanks made of stainless steel often show traces of usage such as scratches and corrosion, which leads to tank surfaces that are out of specification and do not allow successful CIP cleaning as well as weaken reliability for save production. Reworking tank surfaces using a professional field service is one option to extend tank life.

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Stainless steel vessels

A typical production line in the food and beverage industry is comprised of various stainless steel vessels made from austenitic alloys such as 304, 316L, 316Ti or similar. The unlimited application of these vessels for extended periods of time in production operations is based on defined surface specification data. These specifications, especially those concerning vessel surface conditions and/or vessels that come into contact with product, are developed in accordance with the demands regarding optimal cleaning behaviour, longtime passive surface showing no corrosion etc. In addition to technical data, important specification criteria include specific roughness parameters (Ra/Rz), a clean and homogenous appearance of the surface (e.g., electropolished), and a surface free of any deviations and corrosion (Figure 1).



Figure 1. Surface roughness measurement in an electropolished stainless steel tank.

Surface deviations

Recurring evaluation procedures associated with assessing surface conditions, usually executed after clean-in-place (CIP) operations and shutdowns have been performed, sometimes show local surface deviations like scratches, coloured areas or corrosion (Figures 2 and 3). The quality assurance (QA) department has to decide whether the detected deviation is acceptable or not. In the cases in which the abnormality is not acceptable according to the defined internal production rules, the responsible persons have to follow pre-defined internal rules.



Figure 2. Scratches on a stainless steel tank surface.



Figure 3. Local corrosion on a stainless steel tank surface.

Deviations found on stainless steel vessel surfaces may be caused during maintenance operations when the agitator is disassembled or may result from corrosion due to the production environment. Further investigations into detected deviations of the stainless steel vessel often show that the scratches are not acceptable for food production. For this reason, it is necessary to find a quick and effective procedure to solve the problem and bring the vessel back into specification.

Passive layer – necessary passivation

The corrosion resistance of stainless steel rests on the formation of a very thin chromium oxide rich passive layer that only develops on metallic clean stainless steel surfaces. Scale layers, welding discolouration and tarnish, ferritic impurities (e.g., abrasion), and/or mechanical treatments (e.g., grinding, blasting, etc.) inhibit the formation of a closed and homogeneous passive layer.

Only fully controlled stainless steel surfaces and weld seams guarantee full corrosion resistance of the material. Therefore, it might be advisable to passivate the stainless steel surface after any kind of chemical or electrochemical surface treatment such as pickling or electropolishing.

The passivation solution supports the stainless steel surface to renew the chromium oxide layer quicker and even thicker. After such operations the surface is completely renewed and ready to use.

Quick and affordable solutions

It is possible to refurbish stainless steel tank surfaces with scratches and other deviations. Field-tested technical onsite operations provide the plant with options such as local mechanical grinding operations or professional local anodic cleaning and repassivation procedures with fully controlled chemicals. Experienced surface treatment workers can help to repair such local surface defects in a very short time (Figures 4 and 5). This local surface treatment minimises the shutdown time of the vessel and the connected systems. This improves productivity and leads to cost advantages since new purchase of equipment can be avoided.



Figure 4. Local refurbishment of scratches by mechanical grinding.

Stainless steel surfaces are regularly evaluated in compliance with the internal QA agreement, assessing them in production as well as how they are utilised in performing extra operations such as CIP, maintenance or extra cleaning. These aspects also are taken into consideration by the onsite mechanical grinding and anodic cleaning/repassivation service providers, which enables them to alter the surface condition to a very high condition.



Figure 5. Local refurbishment by electropolishing on-site.

The refurbishment of detected local deviations such as scratches or corrosion marks enables the user of the equipment to return quickly and safely to the original surface conditions and to continue the production process with equipment that meets the required specifications and needs.



Functional coatings for automation components in the food and beverage industry

Traditional coating materials are often not able to meet the ever-increasing demands of today's applications. In recent years, advances have been made using functional coatings, which will become a more important element of measures to comply with industry-specific requirements. Functional coatings (easy-to-clean, antifouling or antibacterial) offer considerable potential for this in the food and beverage industry.

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Figure 1. Functional coatings for automation components are becoming more important to the food and beverage industry.

A coating is a covering that is applied onto a surface of an object and appears as either a continuous or discontinuous film after application. Today, many objects that we come across in our daily lives have decorative or functional coatings such as refrigerators and cars. Likewise, aerospace products, marine and military applications all involve the widespread use of coated materials.1, The importance of functional coatings has increased significantly for market segments such as the food and beverage industry (Figure 1). The term "functional coating" describes systems that not only offer the classical properties of coating but that offer additional functionality.^{2,3} Functional coatings of interest to the food industry are, easy-to-clean, antifouling or antibacterial.4-6 Coatings can be differentiated not only by their functionality but also by the various coating processes used; e.g., chemical, mechanical, thermal or thermochemical processes. Functional coatings are usually thin films but also can be applied as multilayer systems. The differences are not clearly defined but are based on the coating process used. Each layer that is applied is intended to perform certain specific functions; therefore, the composition of coatings plays an important role in the overall performance of the various coating systems.

Types and application of functional coatings

Characteristics expected of functional coatings include durability, reproducibility, specific surface morphology, easy application, cost effectiveness and environmental friendliness.³ In addition to providing these properties, functional coatings often have to satisfy specific requirements as appropriate to the industry segment in question. Such requisites include resistance to abrasion, high resistance to corrosion or chemicals, and resistance to scratching and thermal effects.^{7,8} In addition, the capability to modify surfaces to achieve friction resistance or electrical conductivity also are desirable.

For applications in the food industry, the following functional coatings may be of interest: ^{4–7}

- Anti-fouling coatings
- Antibacterial coatings
- Chemically-resistant coatings
- Wear-resistant hard coatings
- Self-cleaning coatings (lotus effect)
- Easy-to-clean coatings

Anti-fouling coatings

Fouling, or biofouling, poses a problem in a wide range of applications, including food production, storage and primary packaging, due to microbial contamination.^{3,9–10} Fouling is the accumulation of organisms and other solid materials on surfaces. Bacteria attach themselves to the surface forming a biofilm, which is a gel matrix made up of different microorganisms. This biofilm can induce corrosion due to the bacterial production of sulphides and can lead to the accumulation of food residues, resulting in further growth due to proteins or other natural adhesives binding onto surfaces. The two major approaches to combat surface fouling are to prevent biofoulings from attaching or to degrade them.¹¹ For the food and beverage industry in which a non-biocidal approach is preferred, coatings with low surface energy can be used in order to avoid the adhesion of solid materials and organisms.

Antibacterial coatings

In the processing of food and the manufacture of food packaging material, hygiene is one of the most important requirements. Contamination by microbial growth has adverse consequences that may affect the health of consumers, or at minimum, can lead to a reduction in quality or even to complete spoilage. There is a wide variety of organic and non-organic biocides that are commercially available. Traditional techniques involve the design of coatings that release biocidal agents, including antibiotics and quaternary ammonium, into the surrounding environments. Most common coatings contain silver or copper colloids that penetrate the cell wall and inhibit the bacterium's metabolic system.¹¹ The mechanism preventing biofouling by antibacterial coatings is shown in Figure 2. These microcapsules also increase the longevity and efficiency of antimicrobial coatings.

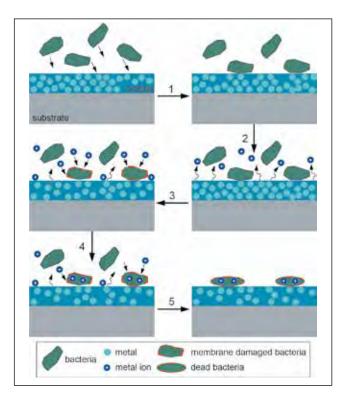


Figure 2. Mechanism preventing biofouling by antibacterial coating.

Self-cleaning coatings/easy -to-clean

Further potential applications of functional surfaces are coatings with a self-cleaning function meaning to have the ability to actively reduce harmful substances. Industrial applications are well known in household, fasade elements and automotive industry. For the food industry this does not mean that surfaces don't need to be cleaned anymore but to reduce the amount of time lost for cleaning and thus reduce cleaning costs as well as to improve overall productivity. In addition, less cleaning can contribute to long service life and robustness of automation components.

Self-cleaning coatings can be divided into two categories: hydrophobic and hydrophilic. Hydrophilic self-cleaning coatings are based on photosynthesis. When exposed to light, they are able to break down impurities. In contrast, the "lotus effect," in which water droplets can be seen on the surface, occurs in hydrophobic self-cleaning coatings with high water contact angles. Manual cleaning is unnecessary in this case and a water spray is sufficient to carry out the cleaning process (Figure 3). Self-cleaning coatings usually are superhydrophobic, because their contact angle is greater than 150°. Their special morphology prevents all kind of dirt from adhering, while their high hydrophobicity makes the surface water-repellent.¹² Hence, water rolls off the surface, carrying all contaminants with it. During the last few years, self- cleaning coatings using photocatalytic titanium oxide have attracted attention. Both hydrophilicity and photocatalysis occur simultaneously, although they are entirely different with regard to their underlying mechanisms.

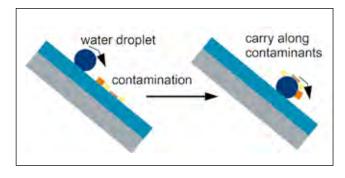


Figure 3. Schematic depicting the self-cleaning effect of a surface with hydrophobic coating.

The food processing environment

Hygienic and efficient automation technologies used are key aspects of a successful food production. The selection of materials used for both the plant engineering and the automation components installed plays an important role in the production of food. Requirements regarding the cleanability and durability of surfaces that come into contact with food products are critical factors. The application of functional coatings must comply with industry-specific requirements. In food processing there are different contamination sources and cross-contamination risks that must be prevented in order to ensure top product hygiene. Various types of stubborn residues, such as fat, protein, minerals or microorganisms that adhere to the surface of machinery and equipment, need to be removed. Proteinbased soils are highly critical, since they are not easily soluble and thus are typically difficult to remove even through hygienic design principles are applied.¹³. Faster cleaning process times and extended production cycles between cleans result in increased equipment availability and production efficiency.

One research approach at Festo is the design of new coated surfaces with features that enable automation components to be easily cleaned. Important requirements are as follows:

- Prevention of contamination
- Minimal adhesive effects for contaminantis
- Excellent resistance of coatings to cleaning agents, even when cleaned regularly with aggressive cleaning agents
- High corrosion protection for surfaces
- Stable surface characteristics when subjected to increased temperatures, steam and preliminary mechanical cleaning

The objectives are as follows:

- Improved efficiency for the customer; i.e., reduction of time, effort and costs of cleaning
- Improved environmental compatibility
- Chemical and physical resistance to occurring contaminations and cleaning processes used
- Good appearance of sensitive surfaces
- High-resistant and long-life automation components
- Nontoxic materials
- Freedom from toxic materials that can leach into products
- Product contact surface roughness of 0.8 microns or less

Material and analysis

In general, typical automation components requiring coating are cylinders, tubes, fittings and valves. The frequently used materials are aluminium, stainless steel and plastics such as polyamide (PA), polyurethane (PUR), polyethylene (PE), polycarbonate (PC), polypropylene (PP), polyvinylchloride (PVC), polymethyl methacrylate (PMMA) and polyetheretherketone (PEEK). The success of coating, such as anodizing, sol-gel, or physical or chemical vapour deposition (PVD/CVD), depends not only on the quality of the coating itself but on the characteristics of the surface material being coated. For all coating processes, workpieces are pretreated mechanically and/or chemically in order to achieve good adhesion of individual layers to the substrate surface. The success of functional coating processes is verified by various means, including surface characteristics analysis such as surface energy and contact angle measurement, elemental composition of the coating and coating thickness measurement (Figure 4a).

To ensure high reliability even in the cleaning phase, the requirements mentioned above must be verified separately. The resistance to chemical agents as a function of changes in pH, time and temperature is therefore examined.



Figure 4a/b. (a) Surface with hydrophobic coating (left) compared to a surface with hydrophilic properties (right); (b) chemical testing of easy-to-clean coating on a cylinder barrel.

In addition to this, coated products should be checked for ease of cleaning using optical and microscopical evaluation methods after the completion of a cleaning procedure, while the effects of mechanical treatments can be visualised using scanning electron microscopy (Figure 4b).

Conclusion

Overall, the design of functional coated automation components depends to a great extent on the requirements defined for the application in question. As the worldwide demands placed on functional coatings continue to increase, future generations of functional coatings that offer ease of application and long-term stability will be more cost-effective.

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Qualification of a 6-axis robot system for hygienic processes

In such fields as cleanroom technology for sterile pharmaceutical production, more and more processes are automated and placed into isolators to fulfil the requirements defined by Good Manufacturing Practice (GMP) guidelines. The most flexible automation solution is the usage of a 6-axis robot system. There are many industrial 6-axis robot systems on the market, but they are built primarily for handling operations such as in car manufacturing. Only a few robot systems are adapted to fulfil the GMP requirements regarding the defined cleanliness level for sterile manufacturing processes for particles and microbiological contamination.

The current GMP guidelines state that 'in clean areas, all surfaces should be smooth, imperious and unbroken to minimise the shredding or accumulation of particles or microorganisms and to permit repeated application of cleaning agents and disinfectants where used.' The manufacture of sterile products is subject to special requirements to minimise the risks of microbiological, particulate or pyrogen contamination. ISO 13408-6 states that the surface materials used should be evaluated with regard to the absorption and outgas behaviour of decontamination agents such as hydrogen peroxide.

Based on these requirements, a 6-axis robot system for pharmaceutical usage was modified and improved by applying principal hygienic design recommendations. For the Fraunhofer TESTED DEVICE[®] certification, the following parameters were tested: particle emission, hygienic design and cleanability as weak point assessments, material resistance against chemicals and microorganisms and material absorption/desorption characteristics with regards to hydrogen peroxide. This paper details the benefit of such a holistic qualification for a subsequent risk analysis. Whilst designed as an assessment for the pharmaceutical sector, the assessment techniques used may also be of interest to high hygiene applications in the food industry.

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For a wide range of hygienic production settings, requirements regarding contamination are exceptionally high. Especially for sterile pharmaceutical manufacturing, it is essential that machines and equipment do not contaminate the product either with particles or with microbes. To achieve this, machines and equipment are cleaned and disinfected at regular intervals.

A machine can be effectively decontaminated only if all surfaces can be reached by the cleaning and disinfection processes. To do this, the machine housing and all operating components and interfaces need to have an appropriate hygienic design. Materials must withstand the chemicals used and avoid the accumulation of particles onto the surface. GMP-A environments usually are under laminar airflow.¹⁶ It is advisable, that the equipment will not alter this laminar airflow pattern seriously in operation. The equipment must be suitable for complete decontamination using hydrogen peroxide. Therefore, it is advisable to use materials not only with an appropriate chemical resistance, but also with low adsorption of hydrogen peroxide during fumigation and subsequent desorption during aeration to speed up the aeration phase prior to the start of production. For a holistic approach regarding suitability testing of equipment for use in sterile pharmaceutical production premises, all mentioned

aspects need to be assessed. The individual tests performed for a holistic assessment of the 6-axis robot system VS050S2-AV6-R1 are described in detail in this paper.

Material and methods

Particle emission

If a material is subjected to mechanical stress due to friction from another material, material abrasion in the form of particle generation occurs. This also can be caused by sliding friction from bearings and joints from moving elements like robot systems. VDI 2083, part 9.2 describes a standardised method to obtain comparative information about particulate emission from various equipment.1 All the main parts of this guideline are implemented in ISO/ DIS 14644-14. All equipment to be classified is operated in an ISO Class 1 reference cleanroom according to ISO 14644-1 to eliminate measurement errors caused by potential foreign particles in the environmental air.² The laminar unidirectional airflow with a velocity of 0.45 m/s, which flows from the cleanroom ceiling to the raised floor in accordance with ISO specifications for a Class 1 cleanroom, ensures that particles generated during the test are transported downward

in a vertical direction toward the sampling probe installed downstream that detects the airborne particles (Figure 1). Using the principle of scattered light, a particle counter detects all particles with a diameter >0.2 µm and classifies the number of particles into predefined particle size channels according to their size. To take single events appropriately into account, the test is performed for a minimum of one hour with a defined representative set of operating parameters regarding speed, acceleration and payload (100 percent of maximum values regarding speed and acceleration, repeatability frequency f = 4 Hz; m = 1.6 kg). After assessing the data as described in VDI 2083 part 9.2, a result is obtained that gives an assessment of the tested equipment with regard to particulate emissions due to tribological stress. The final classification value obtained enables a direct comparison of equipment to be made and shows how much the system potentially contributes to particulate contamination of the cleanroom environment when subjected to tribological stress within the defined parameter set.



Figure 1. Probe head of a particle counter installed under a tribological element to detect emitted particles in an ISO1 environment according to ISO 14644-1.

Each sampling location is determined using existing knowledge and a manual scan for any detectable particle emission. As soon as a particle source is detected during the manual scan procedure, this location is marked and fully evaluated later (Figure 2).

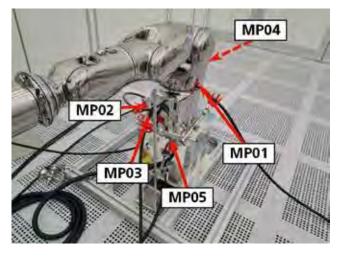


Figure 2. Examples of defined locations for the particle emission measurements.

Hygienic design

The hygienic design principles were investigated based on visual inspection and comparison with the requirements of existing hygienic design requirements defined in different standards. The surfaces of appropriately implemented machine components need to be durable and easy to clean and disinfect.³ They may not crack, chip, flake or corrode, as well as being resistant to friction and impermeable to the absorption of undesired substances. Materials for use in hygienic manufacturing environments must fulfil the following basic criteria: chemical resistance to all fluids that come into contact with it (product, including cleaning and disinfection media) and resistance to microbial metabolism/ microbial action.

The required chemical resistance can be evaluated on the basis of ISO 2812-1.⁴ Additionally, materials may not function as a food source for microorganisms. A suitable method for verifying microbial resistance is described in ISO 846.⁵ Material surfaces must be designed so that they are easy to clean.⁶ Metal food contact surfaces may not exceed a surface roughness of Ra = 0.8 μ m.⁷ To ensure excellent cleanability levels, this surface requirement also may be useful for components that do not come into contact with the product. However, it has been demonstrated that the cleanability of a material surface cannot be assessed by the Ra value alone.⁸

The geometric design of operating utilities significantly affects their suitability for use in clean manufacturing environments. If, for example, there are counter-drafts and eddies in an airflow, there is a risk that particles generated during operation of the system will not be extracted by the first airflow of the cleanroom. This may result in particles or microorganisms accumulating in indentations or crevices. Contamination that has accumulated in this way cannot be removed through cleaning. Dead legs, gaps and crevice where microorganisms can harbour and multiply must therefore be avoided.⁷

Counter-drafts or inaccessible areas may form if, for example, unsuitable screw heads have been selected for joining materials with screw connections, if the workmanship of weld seams is poor. If processes are carried out without due care and attention, the hygienic strategies developed in the design phase of an operating utility may be impaired. The hygienic design is evaluated based on European Hygienic Engineering & Design Group (EHEDG) Doc. 8 and ISO 16459.^{7.3}

Cleanability test

In order to obtain qualitative information about the cleanability of the robot system, the device is contaminated with a water-based fluorescing test contamination mixed with 0.2 g riboflavin in 1000-mL ultra-pure water, which is then allowed to dry onto the test piece. The surfaces are inspected under ultraviolet (UV) light before and after manual wipe cleaning with a pre-wetted polyester woven cleanroom wipe using ultrapure water. The use of the fluorescing pigment riboflavin enables areas that are difficult to clean to be clearly visualised, especially depressions, indentations, edges, and so on. However, measurable, quantifiable information cannot be obtained in this way; only qualitative

results are obtained. These results can later directly be used in a risk analysis. Details of the test are given in the VDMA information sheet 'Riboflavin test for low-germ and sterile process technologies.'⁹

Resistance against chemicals

There are several internationally recognised standards for assessing chemical resistance. Tests in accordance with the DIN EN ISO 2812-1 immersion process have proven especially useful in assessing the suitability of materials and surfaces for use in hygienic manufacturing environments.⁴ To compensate for the fact that future cleaning or disinfection agents are not known at this point, materials are tested with a representative spectrum of possible groups of chemicals. This approach permits a general assessment about the chemical resistance of materials to be made but not a specific assessment regarding defined cleaning or disinfection agents. The concept was developed by the industrial alliance CSM under the management of Fraunhofer IPA and is standardised in VDI 2083 Part 17 and VDI 2083 Part 18. 10,11 Based on the list of approved disinfectants of the Robert Koch Institute, the principal active component of each disinfectant was recorded and classified in 10 selected subgroups.¹² The resulting standard test assesses the chemical resistance to the following 10 representative reagents in dependence upon their anticipated maximum concentration on surfaces after cleaning and disinfection as a worst case, even after severe increase of the final concentration due to evaporation of the water content:

Room fumigation methods

- Formalin (37%)
- Hydrogen peroxide (30%)
- Peracetic acid (15%)

Alcohols

Isopropanol (100%)

Alkalis as constituents of alkaline cleaning agents

- Caustic soda (5%)
- Ammoniac (25%)

Acids as constituents of acid cleaning agents

- Sulfuric acid (5%t)
- Hydrochloric acid (5%)
- Phosphoric acid (30%)

Cleaning agents containing chlorides

Sodium hypochlorite (5%)

In accordance with the ISO 2812-1 immersion procedure, the entire material sample is placed in a receptacle filled with the chemical, which is then hermetically sealed. If a coating applied to a substrate requires testing, care is taken to ensure that all surfaces and edges of the carrier material are sealed with the coating concerned. In the modified spotting method according to VDI 2083-18, the test substance is placed in a glass vessel.¹¹ The test surface and a seal are placed over it and then clamped onto a device to create a hermetic seal. The test apparatus is then rotated 180° so that the test chemical is in contact with the surface of the sample.

The modification made to ISO 2812-4 requires a much larger volume of test chemical.¹² If only a droplet is applied, evaporation phenomena cannot be excluded. Test pieces are exposed to the respective reagents at room temperature for a period of one, three, six and 24 hours and subsequently examined to see if there any visible alterations. Using 10fold magnification, the test surface is visually assessed in conformity to ISO 4628-1 to -5 with regard to the following criteria: type of damage (alteration in degree of shine, discolouring or yellowing, swelling, softening or reduced scratch resistance); amount of damage (N-value); size of damage (S-value) and intensity of alteration (I-value).14 The analysis is carried out as follows: 'blistering, N2-S2" or "discolouring, I1.' The poorest value (N, S, I) obtained after 24 hours is taken for the comparative assessment. In the CSM procedure, the mean of all 10r 24-hour values from each of the previously mentioned chemicals gives the rating value, which is used for classification and comparison.

Resistance against microorganisms

The international test standard ISO 846 has proven useful in determining the biological resistance of materials to bacteria and fungi.⁵ Under the test conditions prescribed, test materials are assessed to find out if they are inert to fungi (Procedure A) and bacteria (Procedure C), or if microorganisms are able to interact with them. Test samples are incubated at 24°C and 95 percent relative humidity in accordance with the parameters stated in ISO 846 and visually evaluated after a period of four weeks. The numerical ISO assessment of both Procedure A and Procedure C enables classification according to a rating value based on a worst case of both procedures.

Hydrogen peroxide ab- and desorption characteristics

The following test set-up was chosen: Made entirely from polytetrafluoroethylene (PTFE), the emission chamber is constructed on the basis of the field and laboratory emission cell (FLEC) described in literature.¹⁵ The chamber is pressed onto the planar material sample with the aid of a stainless steel weight. The chamber has a diameter of 65 mm and a height of 5 mm. A 500-mL headspace bottle containing 100 mL of a stabilised 15-percent hydrogen peroxide solution kept at a temperature of 23°C serves as the vaporised hydrogen peroxide source. The solution is mixed constantly by an agitator rotating 500 times per minute. A stable balance is attained between the hydrogen peroxide in the solution and in the headspace of the bottle, thus providing a stable hydrogen peroxide concentration for the standardised test method for several days. The gas space is continuously rinsed with ultrapure air. The rinsing gas is introduced into the emission chamber in such a way so that it is in contact with the test material. A proportion

of the gas flow is constantly suctioned off and fed through a vaporised hydrogen peroxide measuring device (Dräger Polytron 7000 with LC hydrogen peroxide measuring probe and active pump, Dräger Safety AG & Co. KGaA, Lübeck) and the concentration of vaporised hydrogen peroxide measured in ppm(V). The remainder of the air flow is blown through an outlet just above the edge of the chamber (excess air). This eliminates the need for a hermetic seal between the chamber and the test sample. Possible alternatives to the Dräger Polytron 7000 measuring device include the Cavity Ring Down Spectrometer G1114 (Picarro Inc., Santa Clara) with a measuring range of 20 ppb to 100 ppm, or the enzyme-based measuring device AL2021 (AeroLaser GmbH, Garmisch-Partenkirchen, Germany) with a principal measuring range of 100 ppt to 3 ppm. The measuring range of the AL2021 can be adapted by carrying out appropriate dilution steps. All the connections between the vaporised hydrogen peroxide source, emission chamber and measuring device are made from perfluoroalkoxylalkane (PFA) which, like PTFE, does not absorb hydrogen peroxide. Thus, this excludes any influence on results by materials used in the construction of the test set-up. The complete apparatus as described in Figure 3 is situated inside a chemical extraction hood with a constant supply of fresh air.



Figure 3. Test set-up for the evaluation of hydrogen peroxide aband desorption characteristics.

Materials are exposed to vaporised hydrogen peroxide with a concentration of 50 ppm for a period of 60 min. The inflow of vapor phase hydrogen peroxide is then stopped and the curve of the desorption phase recorded, starting with the maximum concentration and continuing at least until the vaporised hydrogen peroxide concentration falls to 1/10 of the maximum value. The k-value serves as a simple index of the desorption kinetics. The value is defined as the time required for the vaporised hydrogen peroxide concentration measured at the end of fumigation to fall to 1/10 of the maximum concentration (Figure 4). The k-value of each test material is ascertained by triple determination.

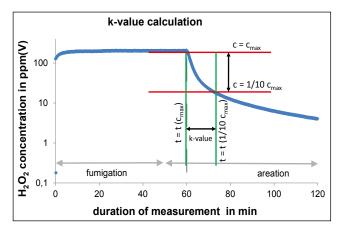


Figure 4. Definition of the k-value as a simple index of the desorption kinetics.

With a k-value below 15 min, the vaporised hydrogen peroxide desorption kinetics of a material are classified as 'fast' and a k-value between 15 and 60 min is classified as 'medium.' If the k-value exceeds 60 min, the vaporised hydrogen peroxide desorption of a material is classified as 'slow.' If the maximum end concentration measured is well below the anticipated maximum value, the material is classified as 'catalytic.'

Results

Particle emission

All recorded data lead to the following individual classification data as described in VDI 2083 part 9.2, is summarised in Figure 5. The overall classification is based on the worst value of all individual classification numbers.

		Axis 1							
Measuring point	MP01	MP02	MP03	MP04	MP05				
Air cleanliness class	2	1	1	2	1				
	Axis 2								
Measuring point	MP06	MP07	MP08	MP09	MP10				
Air cleanliness class	1	1	1	2	4				
		Axis 3							
Measuring point	MP11	MP12	MP13	MP14	MP15				
Air cleanliness class	1	5	2	1	4				
	Axis 4								
Measuring point	MP16	MP17	MP18	MP19	MP20	MP21			
Air cleanliness class	1	1	1	1	1	1			
		Axis 5							
Measuring point	MP22	MP23	MP24	MP25	MP26				
Air cleanliness class	1	1	1	4	1				
	Axi	s 6.1 (Flar	ige A)						
Measuring point	MP27	MP28	MP29	MP30					
Air cleanliness class	2	1	1	1					
	Axi	s 6.2 (Flar	ige N)						
Measuring point	MP31	MP32	MP33	MP34					
Air cleanliness class	1	1	2	1					

Figure 5. Overview of the results with corresponding classification number according to VDI 2083 part 9.2 based on particle emission testing. The overall classification is marked in red.

According to VDI 2083 part 9.2, the robot system is suitable for the usage in ISO 5/GMP A environments according ISO 14644-1 and EU-GMP guideline Annex 1.

Hygienic design

The GMP guideline Annex 1 for sterile pharmaceutical manufacturing states that none of the equipment used in manufacturing processes may represent a risk to the product.¹⁶ No food contact surface may interact with it as this would impair product quality and represent a further risk. In clean areas, all exposed surfaces must be smooth, impermeable and free of fissures, both to minimise particle and microorganism counts and to permit the repeated use of cleaning and disinfection agents. The GMP guideline states that manufacturing equipment must be in good condition, be completely cleanable and not represent a source of contamination to the product. Figures 6 to 8 illustrate selected design features regarding hygienic design principles.



Figure 6. Overall hygienic design of the assessed robot system.

The robot has been designed in compliance with the relevant recommendations regarding the hygienic design of manufacturing equipment is shown in Figure 6. There are no horizontal surfaces. All surfaces are smooth and rounded, enabling liquids to run off unhindered. Stagnant zones and inaccessible areas have been reduced to a minimum. All surfaces should have a gradient of \geq 3° to enable liquids to run off and prevent contamination from accumulating.

The shiny surface of the robot is smooth, impermeable and free of fissures. Its shine indicates a very low degree of surface roughness. The entire surface is easy to clean and disinfect. Designing robot axes from the point of view of hygiene is difficult because seals cannot impair axis maneuverability.

However, an area with two moving components is always hygienically critical. This problem was solved effectively by using shaft seals. The gap between the axes is wide enough to allow cleaning and disinfection agents to work effectively. The shaft seals fit tightly enough to prevent the entry of microorganisms and contamination.



Figure 7. Hygienic design of screw connections. (Left) Hygienically designed screws, and (right) installation lid.

Figure 7 shows that screws have been used only at the level of the robot arm to allow pneumatic hoses to be optionally connected for the grippers (option: signal line and valves) and on the electronics cover located at the foot of the robot. The cap screws with sealing rings comply with recommendations for the hygienic design of screw connections. Nevertheless, the number of screws used should be reduced to a minimum. Dead spaces can be avoided by using hex-head screws with rounded heads (cap screws) and thread seals.



Figure 8. Hygienic design of lids.

The joins and lids on the various robot components all have sealed covers to prevent the entry and accumulation of microorganisms and contamination into areas that are difficult to clean (Figure 8). The screw connection on the cover has also been sealed. Joins between the different materials are continuous and flat. This results in a surface that is relatively smooth and easy to clean.

It is not always possible to fully comply with guidelines on cleaning and disinfecting equipment without impairing its functionality. However, it is important to design areas as best as possible by complying with the recommendations made in the relevant guidelines. The assessment of the robot showed that most of the design concepts had been followed. The overall design of the robot series complies with recommendations on clean and hygienic manufacturing. Due to the abovementioned construction features of the robot and under consideration of the optimisation potential listed, the robot is declared suitable for use in clean and hygienic manufacturing areas. The assessment is based on the high level of ability to clean and disinfect the robot series and - with only a few exceptions - compliance with the conception and design recommendations of EHEDG Doc. 8 and ISO 14159.7.3 In principle, the robot is declared suitable for use in hygienic areas up to the highest cleanliness level of GMP Cleanliness Class A. However, this only applies for the tested operating utility when in a resting state; an overall assessment would need to be made after installation in a manufacturing environment.

Cleanability test

The following figures illustrate the results obtained from wipe cleaning. The initial state is always shown on the left and the cleaned state on the right.

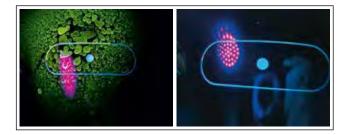


Figure 9. Cleanability test of Detail 1. (Left) Before wipe cleaning, and (right) after wipe cleaning.

Minimum amounts of residual fluorescence are visible on the silicon seal.

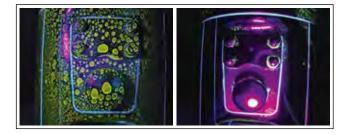


Figure 10. Cleanability test of Detail 2. (Left) Before wipe cleaning, and (right) after wipe cleaning.

Components mounted onto the surface restrict ease of cleaning. Residual fluorescence is clearly visible around the screws.

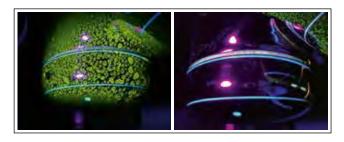


Figure 11. Cleanability test of Detail 4. (Left) Before wipe cleaning, and (right) after wipe cleaning.

The test shows that the fluorescing contamination has been nearly completely removed from the surface. Minimum amounts of residual fluorescence are visible on the dynamic seal.



Figure 12. Cleanability test of Detail 3. (Left) Before wipe cleaning, and (right) after wipe cleaning.

The test shows that the fluorescing contamination has been completely removed from the surface. No fluorescence is visible after cleaning with ultra-pure water.

Nearly all design features proved to have an excellent level of cleanability. Therefore, the robot system can be highly recommended for use in hygienic applications. However, wiping showed to be inefficient for some minor design features tested. Especially at the transition area closed by the dynamic seal, it is impossible to remove all traces of riboflavin. These design features, defined as not 100-percent cleanable, should be part of a risk analysis at a later time. Using different cleaning techniques (various wipes, spray cleaning, swabs, etc.), the hygienic risk from these features can be reduced to acceptable levels, even in high-risk areas such as sterile pharmaceutical manufacturing.

It is a known fact that not all the design requirements stated in the respective hygiene norms can be applied to every constructional component. By implementing recommendations as fully as possible, components can be built that are very easy to clean and thus highly suitable for hygienic applications. This is clearly demonstrated by the 6-axis robot system tested.

	a	b	C	d	e	f	g	h	i	j	k	1	m	n	0	p
	M	M	M	M	M	M	M	P	P	P	P	P	P	P	P	P
Formalin 37 %	NO	17	NO	NO	NO	NO	NO									
Ammoniac 25 %	NO	12	11	NO	15	NO	ND									
Hydrogen peroxide30 %	NO	NO	NO	NO												
Sulfuric acid 5 %	11	NO	13	NO	NO	NO	NO	NO	11	11	NO	NO	NO.	NO	NO	NO
Phosphoric acid 30 %	NO	NC	NO	NO	NO	NO	NO	NO	NO							
Peracetic acid 15 %	NO	13	13	13	M	13	NO	NO	15							
Hydrochloric acid 5 %	NG	12	13	14	15	14	13	NO	17	11	NO	NO	NO	NO	NO	NO
Isopropanol 100 %	NO	NO	NO	NO	NO	NO	ND	NO	NO	NO	NO	NO	NO	NO	NO	11
Sodium hydroxide 5 %	NO	NO	NO	NE	NO	NO	NO	ND	NO	NO	NO	NO	NO	NO	NO	N0
Sodium hypochloride 5 %	NO	12	NO	NO	H	NO	NO	NO	NO							
Total result	1					1										

Table 1. Results from the chemical resistance test after incubation with the mentioned chemical for 24 hours.

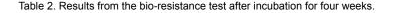
The assessed cleanability of the robot system is regarded as sufficient for a subsequent safe application of validated room or isolator decontamination methods, such as vaporised hydrogen peroxide. The riboflavin test showed that only a few areas are not fully cleanable by wiping. All other surfaces can be cleaned effectively using a validated wiping procedure. Provided a user risk assessment determines the cleaning efficacy of the critical areas are acceptable, the preceding cleaning process fulfils the requirement stated in ISO 13408-6 for a subsequent biodecontamination step.

Resistance against chemicals

Table 1 shows the results obtained from chemical resistance testing of all materials exposed to the environment, where 'M' is metals and 'P' is polymers.

All materials exposed to the surrounding environment demonstrated a very good to excellent chemical resistance against hydrogen peroxide and isopropanol used for decontamination in sterile manufacturing settings (very good to excellent chemical resistance results are marked in green).

Number	fungi	bacteria	Classification
1	1, very good	0. excellent	1. very good
2	2, good	0, excellent	2, good
3	2, good	1. very good	2, good
4	2, good	0, excellent	2, good
5	2, good	0. excellent	2, good
6	0, excellent	2, good	2, good
7	1, very good	1, very good	1, very good
8	2, good	0, excellent	2, good
9	0. excellent	0. excellent	0, excellent



Resistance against microorganisms

Table 2 shows the results obtained from the testing of all polymeric materials exposed to the environment to determine resistance against the action of microorganisms according to ISO 846.⁵

All materials exposed to the surrounding environment demonstrated a sufficient bio-resistance for sterile manufacturing settings (good bio-resistance is marked in yellow; very good to excellent bio resistance results is marked in green). A classification according ISO 846 of '2' or better can be regarded as sufficient for use in hygienic sensitive areas.

Hydrogen peroxide ab- and desorption characteristics

The results obtained from the evaluation of the Hydrogen peroxide ab- and desorption characteristics were as follows: All metals showed a k-value of 0-1 min. The k-value of the tested polymeric materials was between 0 and 9 min. Therefore, none of the tested materials exposed to the surrounding air showed a significant absorbance or later, a delayed desorption of hydrogen peroxide.

Conclusion

As illustrated in Figure 13 a holistic approach regarding a cleanroom suitability qualification of a 6-axis robot system for sterile pharmaceutical manufacturing requires the consideration of several parameters.

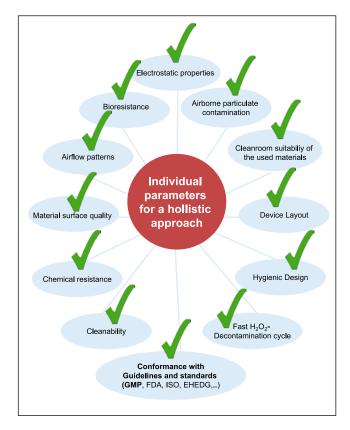


Figure 13. Holistic approach to a cleanroom suitability qualification of a 6-axis robot system for sterile pharmaceutical manufacturing.

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Designing a hygienic robot for the food processing line

Fast orientation, or fast picking, of raw materials is a complicated operation that is frequently done using non-hygienic equipment. A state-of-the-art robot designed to meet European Hygienic Engineering & Design Group guidelines allows complete hygienic control of the process line.

By Arnaud Derrien, Key Account Manager for Food Industry, STÄUBLI ROBOTICS, France, email: a.derrien@staubli.com

Robots are perfect employees. They always do what they are asked to do with stunning reliability. Their use improves process repeatability and can help manufacturing operations achieve the highest levels of performance and hygiene safety. Today, robots are increasingly integrated into sensitive processing zones. Common robot operations include raw food handling and process tool manipulation used for a range of tasks - from handling cheese to deboning hams and decorating cakes (Figures 1 and 2). Three types of robots are typically used in food factories: delta, 4-axis and 6-axis. In this article, robot technologies will be discussed from a microbiological standpoint to determine which technology is best fitted for bacteria control, and to show how European Hygienic Engineering & Design Group (EHEDG) hygienic guidelines have been used to improve the engineering of these technologies.



Figure 1. Robotic cheese handling in a hygienically sensitive area.

Is there a 'clean' shape for a robot?

The 'delta' robot architecture, introduced in the late 1980s, is a parallel-link technology in which the primary mechanical axes act on the robot faceplate in parallel rather than in series. Due to the reasonable level of precision and repeatability offered by this type of robot, its performance has appealed to a number of industries worldwide. The food industry first used this technology to manipulate packaged products, and thus the poor level of cleanability and presence of non-washable or unreachable parts, including connectors, were not obvious problems.

When the patent on this architecture came to an end, every line manufacturer developed their own robot. However, the designs were based on the same principles of performance and no basic questions were asked to determine whether delta robot architecture is suitable for use in production environments that process sensitive raw materials. Delta robot architecture means that not only are motors, transmission oils and retention zones mounted above the pick area, but the overhead mounting frame also is located above the food product. The question is, if a robot is engineered with hygiene in mind, can it be shaped like a delta?

EHEDG design principles refer to both open and closed equipment and may be used for designing easy-toclean robots as well. The EHEDG guidelines – specifically, Documents 2, 7, 8 and 10) have been used to assess robots from a microbiologically hygienic standpoint. Retention zones, corrosion-free components and non-washable parts have been checked for evidence of the presence and spread of bacteria. The findings showed a huge increase in the presence of microorganisms on the equipment, because these robots were originally designed for non-sensitive end-of-line environments. As today's robotic applications move further up the production line towards the food process area, adapting these technologies by integrating the EHEDG approach to cleanability and hygienic design is more important than ever before.



Figure 2. Fully automated ham deboning equipment integrating EHEDG guidelines.

The HE project – developing a clean and consistent robot for sensitive environments

In recent years, a cooperative study between EHEDG, ECOLAB (Minneapolis, MN) and STÄUBLI ROBOTICS, called the Humid Environment (HE) Project, was undertaken with the goal of making technological strides in fast picking technology. The project brought together dairy manufacturers, freezing and thermoforming equipment manufacturers and robot manufacturers familiar with EHEDG guidelines and specifications. This 10-year cooperation resulted in the development of a consistent, high-performance and cleanable robot designed for sensitive food industries.

The primary goal of the project was to remove the oil, motors and condensation buildup from being sited above the product. During operation a robot can heat up to 70° C, especially when connected to fast-moving equipment. In sensitive environments operating in temperatures between 4° C and 10° C, condensation, oil expansion and cooling off occur within a few minutes. The hotspot created by the robot is most apparent when the robot reaches the end of the production cycle.

The ideal conditions for bacterial growth inside the robot include medium temperatures between 15° C and 40° C; water presence and activity; vapor condensation drawn from the environment directly inside the robot (including bacteria); neutral pH; and most significantly, lack of access for cleaning the inner parts of the equipment (Figure 3). The problem is the same for electrical control boxes: With uncontrolled air pressurisation, bacteria and corrosion will develop within a few weeks (Figure 4). Pressurisation of the arm and electrical boxes is the best solution during and after production periods (Figure 5).



Figure 3. As the robot operates, it heats up to 60 to 70°C. When reducing its speed, or when static, it cools down quickly, producing condensation, and drawing the environment (air, humidity and bacteria) into the robot.



Figure 4. Bacteria spreading in non-pressurised equipment.



Figure 5. Pressure in the arm avoids condensation and crosscontamination in the robot during and after production.

Study considerations

The research and development team studied a number of issues to find solutions to advance the hygienic design and suitability of robots used in food production environments. Among the top challenges considered were hidden retention zones, number of equipment components involved, and unsuitable materials.

What is a water retention area (or retention zone)?

A retention zone is the cumulative area of the robot plus the skeleton frame (or structure) that holds the robot upon the product. A water retention area is a place on the equipment where water can stay for extended time periods. The direct impact of such areas is to provide the ideal conditions for bacterial growth. Two types of water retention areas are identified: external surfaces of the equipment itself, and "hidden water retention areas" which are all the surfaces not directly accessible for washing and drying, such as the female threads of screws, dead end ball joints, etc. The external areas are easy to remove in the conception of the equipment itself. Hidden water retention zones need a specific focus to be sure that the complete mechanical installation does not create dead ends that give bacteria a chance to grow and spread.

Hidden water retention areas. One focus area in the study involves the link between the retention zone, the volume of the robot and the workspace. In general, the floor surface of a robot is around 4 to 6 m^2 , regardless of the working surface of the robot (and even for surfaces around 1/4 m^2). The overall volume of each robot cell is about 10 m^3 . The retention zone acting upon the sensitive handling area located directly above the product is nearly 2 m^2 . To support a delta robot, a frame with four substantial feet must be fixed into the floor, destroying the floor surface and allowing bacteria into non-accessible areas (Figure 6).



Figure 6. Parallel architecture robots are well known for the high risk of the retention zone (around 2 m^2), which houses critical mechanical parts such as motors and oils directly above the product.

The less equipment there is, the better. The number of peripheral stainless steel pieces of equipment connected to this type of robot also have an impact on the design of these technologies. These include larger supports, longer conveyors, reinforced structures with hollow construction, etc. In short, the fewer pieces of production equipment attached to the robot means less structures in which bacteria potentially can harbour or may prove difficult to clean.

Non-tolerated materials. The third consideration concerns the presence of unsuitable materials, such as carbon or elastomers, to fix the different suction pipes feeding the gripper. Delta robots were not designed for the routing of flexible pipes and so these are almost always attached ad hoc to the moving arms. Cable ties, even detectable ones, often fall onto the products and the friction between these moving carbon arms and cable ties causes particle emission above the food.

The problem is the same for dielectric exchanges between foaming solutions; for example, water and the various metals used in the arm construction. Corrosion honeycombing, which provides small niches and crevices where bacteria easily grow and survive, will appear as soon as detergents are used on equipment composed of at least two different metals, caused by electrolysis action (Figures 7 and 8). Avoiding this problem is the best way to prevent bacteria from adhering to the surface and to increase the longevity of the equipment.

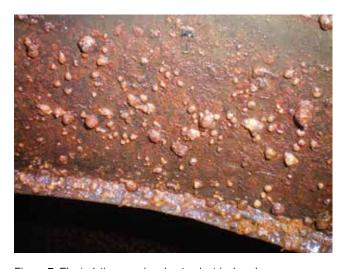


Figure 7. Electrolytic corrosion due to electrical exchanges between two different types of metal, enhanced by the presence of detergent solutions.



Figure 8. Protected robot against electrical exchanges by physical separation between stainless steel screws and aluminum based structure.



Figure 9. Design avoiding retention zone and extra components for grippers.

Development of a surface cleaning treatment for robots

While the main mechanical benefit of stainless steel is its resistance to rust, this metal presents particular challenges for machining and drilling, as well as being trickier to assemble. Some tests were made with robots designed from stainless steel, but they were not successful and the conclusion was that stainless steel is not suitable for a dynamic robot. The best compromise is a specific aluminum (light, rigid and mechanically approved for robotics). But even specific aluminum designed for salt-saturated ambiance can quickly corrode in a raw food production environment, which is why it is important to design the robot such that retention zones and extra components for grippers are avoided (Figure 9).

The HE Project led to the development of both a specific surface treatment and a 6-axis robot. A mix of specific aluminum, metal treatment and co-development of a surface resistance to detergents and sterilisation solutions. This treatment has now been in use for many years and allows, in many cases, the robot to be washed with the same chemical solution as the rest of the line. Some applications allow the robot to clean itself (as a clean-in-place [CIP] procedure) by manipulating the detergent foaming spray nozzle around the gripper, robot and ancillary equipment (Figure 11).



Figure 10. The 6-axis robot co-developed with ECOLAB for compatibility with detergent and sterilising solutions, including foam.

A CIP robot?

Self-washable equipment is ideal to eliminate human mistakes and ensure the cleaning of difficult-to-reach parts (Figure 10). As the robot is fundamentally a moving device, the HE concept was developed to allow for self-washing, which is used more frequently in sensitive industries such as dairy and meat processing.



Figure 11. A washable robot can, nearly always, self wash using the basis of a CIP procedure.

Focusing on common-sense solutions



Figure 12. Fastest picking or decorating robot based on EHEDG recommendations, eliminating fixing screws in front of the product to produce smooth, sloped and opened surfaces.

The main concern is the structure of the equipment itself: Common sense dictates that mounting the robot on the side of the production line will remove the main problems – oil, condensation, and other contaminants – from above the sensitive handling area (Figure 12). Secondly, a vertical frame, fixed on a single mount and sometimes onto the conveyor itself, eliminates the need for a stainless steel structure to affix the robot. This means that the overall retention zones above the products have been divided by 10. Again, the retention zone of a parallel architecture robot is around 1m². The retention zone of the skeleton frame (structure) to hold the robot above the product also is around 1m². This includes the stainless steel frames, screws, etc. For example, on a two-robot cell, the total length of the production line is divided by 2.2 and the retention zone above the product is significantly reduced. The tool, mounted to the wrist of the robot, can be cleaned since all of the pneumatic and electric connections are inside the arm. And, of course, this arm is pressurised to avoid the entrance of airborne contamination.

Ultimately, the cooperative study showed that 'HE grade' can be considered a general definition and shape used in the design and engineering of both 4-axis and 6-axis robots. To achieve enhanced hygienic features, parallel (or delta) architecture robot design is recommended, and any robots used in sensitive food production areas should be covered to prevent possible contamination.

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The hygienic storage and application of cleaning solutions

Cleaning and disinfection chemicals are required to be stored, transferred, dosed, applied and rinsed from surfaces. These five elements form the core of most cleaning and disinfection processes and each one needs to be risk assessed so that any hazards to the food product can be identified and controlled.

Gary Featherstone, Darren Saunders and John Holah, Holchem Laboratories Ltd, Bury, United Kingdom e-mail: info@holchem.co.uk

Chemical storage

As soon as a delivery of chemicals to a site occurs, provisions should be in place to ensure that the chemicals not only are stored in a safe and secure environment but are located where the risk of cross-contamination from external sources is eliminated or reduced and controlled. For example, chemical containers and packaging can become contaminated when they are stored in uncovered external areas, which exposes them to the elements. The risk is that these might be transferred into production areas without undergoing a decontamination procedure, consequently exposing food products to an avoidable hazard.

The ideal storage solution for chemicals is in a bunded bulk tank that is external to factory areas and that is kept well away from production processes and personnel contact (Figure 1a). From this central point, it is possible to provide consistent chemical concentrations to all of the dispense points in the factory, thereby ensuring a uniform use of chemicals across all cleaning processes. Another benefit of buying chemicals in bulk is that the unit cost per kilogram or litre is usually a lot cheaper than smaller pack sizes. However, the downsides to bulk storage of chemicals are the capital cost of tanks, pumps, pipework, bunding, and other accessories and the need for enough space to locate the facilities. Trace heating and lagging of the bulk tank system will be required for many of the chemicals stored in bulk tanks, particularly caustic-based products. Security and access to the bulk tanks also need to be considered, as does the need for bunding.



Figure 1. A range of external chemical storage devices, including bulk tanks (1a), IBC on a spillage container with a greater volume than the IBC (1b), and a smaller, leak-proof, external storage unit (1c).

If a chemical user wants to enjoy the price benefits of bulk chemicals but does not wish to invest in the infrastructure, it is possible to use intermediate bulk containers (IBCs) and locate them on ready-made bund stands (Figure 1b). Although this is a popular choice, the process may still need investment in pumps and pipework or require manual filling of containers direct from the IBC. Additional thought must be given to chlorinated products because chlorine levels can depreciate very quickly, especially when kept in direct sunlight. Other external storage solutions include designated areas that are locked, covered, cool, ventilated and not exposed to the elements. These storage areas vary in size, can be purpose-built or bought as an off-the-shelf item, storing everything from 1-litre containers all the way up to 1,000-litre IBCs (Figure 1c).

Internal cleaning chemical stores should be kept entirely separate from food and packaging stores. They should be:

- sound, dry, well ventilated, frost-proof, have ease of access and have sufficient light to enable the operator to read the label;
- designed so that drainage from this area is contained in the event of a hazardous spill (i.e., chemical containers should be stored on top of larger collection vessels and there should be no access to drains);
- secure (lockable), with controlled access;
- able to protect the products from extremes of temperature, sunlight and rain (e.g., some products will be susceptible to freezing);
- designed such that there is a consideration of the chemical compatibility of the construction materials.

Storage zones should be allocated for storage of specific chemical products such that incompatible chemicals are stored at gangway width (e.g., 3 m) apart.¹ Incompatible chemicals include:

- oxidising (Class 5.1) and corrosive (Class 8) chemicals
- flammable (Class 3) and corrosive (Class 8) chemicals

Chemical transfer

Transfer of chemicals from the storage area to the dosing point can be completed via the use of specialist pumps and stainless steel pipework, use of trolleys, or typically, by manual handling. While the latter should be avoided or reduced wherever possible, it is often the most sensible and practical option. The most hygienic option is for the storage of chemicals outside the food manufacturing area and the transfer of diluted product directly to the point of use (Figure 2). All other options require chemical containers to be taken into food processing areas, requiring decontamination procedures for the outer surfaces of the container, particularly in high hygiene zones. The handling of only diluted chemicals by the cleaning operatives also has health and safety benefits.

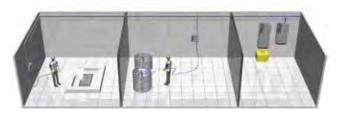


Figure 2. Centralised chemical dosing, application and rinsing system that keeps concentrated cleaning chemicals outside of food processing areas.

Although the majority of chemical products can be centrally stored and pumped to single or multiple dosing points, it is strongly advised that this approach is not used for chlorinated products. Chlorinated products can cause corrosion of stainless steel, which is the material of choice for transferring chemicals in food and beverage processing environments. Although plastic pipework can be used, specialist advice from a pipework manufacturer should be sought before installation.

Chemical dosing and chemical application

Effective and accurate dosing of chemicals is vital for ensuring that a cleaning and disinfection process delivers the desired result. The use of reliable dosing equipment helps to ensure that these processes are consistent, chemicals are used safely and effectively, and costs are controlled.

Chemicals can be applied to a surface in several ways, including:

- Soaking an item in a sink or container
- Manual application using a bucket and wipe/brush/pad/ mop, etc.
- Clean-in-place
- Semi-automated systems, such as utensil and tray washers
- Use of foam/gel
- Spraying
- Fogging

Chemical dosing and application systems are wide ranging and are either wall mounted or mobile equipment (Figures 3 and 4)

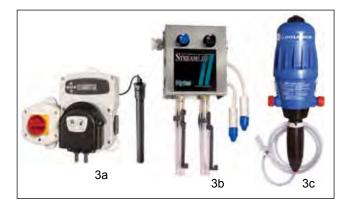


Figure 3. A range of wall-mounted diaphragm (3a), venturi (3b) and water-driven (3c) chemical dilution equipment.

When assessing equipment suitability for use in food and beverage processing areas, the following should be considered and any potential hazards identified:

- will there be direct contact with food equipment?
- Or, will contact be indirect via:
 the operative's hands when using the equipment
 or the applied chemical or rinse water itself?
- Is there potential for introducing foreign bodies (fixings, fasteners, ties, etc.) into the processing area?
- Is there a potential for the equipment to rust; both internally from the chemicals used and externally from unavoidable cleaning sprays?
- Does equipment need to be waterproof (electrics/ electronics)?
- Is equipment robust, and where required, consistent and accurate for use?
- Is equipment susceptible to leaks (e.g., materials of construction used to make seals, pipework, pumps, tanks, etc.)? If susceptible to leaks, is the equipment handling neat or diluted chemicals?
- Is the equipment to be used in high hygiene areas? If so, does the equipment provide harbourage for pathogenic microorganisms? If not, is it cleanable?
- If the equipment is to be used in high hygiene areas and is mobile, can it be identified as such (so that it cannot be used in lower hygiene zones)?

Dependent on the hazards identified, does the equipment meet the appropriate requirements such that the hazard is eliminated or minimised? This includes meeting the standards and criteria found in the following documents:

- EN 1672-2 1672-2:2005+A1:2009: Food processing machinery. Basic concepts. Hygiene requirements
- EN ISO 14159:2008: Safety of machinery. Hygiene requirements for the design of machinery
- EHEDG Guideline Document No. 8 Hygienic Equipment Design Criteria (2004)
- EHEDG Guideline Document No. 13 Hygienic Design of Equipment for Open Processing (2004)

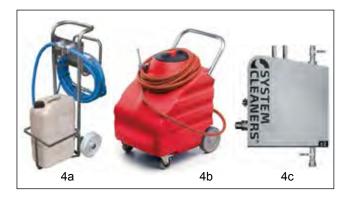


Figure 4. A range of mobile water (4a) and compressed air driven (4b) chemical application units and a wall mounted satellite application unit (4c) allowing detergent foaming, rinsing and disinfectant application.

Rinsing

Rinse guns are vital tools as they ensure quick removal of debris and chemical residues from surfaces and can access areas that manual methods cannot (niches, crevices, etc.). There are three main types of pressure systems used for rinsing in the food industry:

- High pressure (pumped system) 50 to 70 bar; delivering 10 to 15 L of water per min
- Medium pressure (pumped system) 15 to 25 bar; delivering 20 to 40 L of water per min
- Low pressure (mains water supply or pumped system)
 2 to 15 bar; delivering 10 to 50 L of water per min

While still used in the low-risk food manufacturing sector, such as in abattoirs, cutting and boning plants, and poultry factories, the use of high pressure rinse guns in the food industry has been virtually eliminated in high risk/high care food processing sectors in the United Kingdom and high hygiene areas internationally due to the significantly increased risk of cross-contamination. A disadvantage of a high pressure system is that it causes atomisation since water droplets are a lot smaller in comparison to those generated by low and medium pressure systems. After impact on a surface, these contaminated water droplets are dispersed into the local atmosphere and will remain there for several hours before descending onto already cleaned surfaces or product, thereby leading to crosscontamination.

Because water droplets generated from low and medium pressure systems are a lot larger, the risk of atomisation is significantly reduced. However, it does not matter what pressure is used for the cleaning process, overspray will always occur and contaminate nearby surfaces. Therefore, cleaning methods should be designed such that operatives are aware of this happening and procedures are put in place to ensure that the risk is reduced.

Other ways to help reduce aerosol generation include restricting flow rates with orifice plates on water inlets; changing nozzle sizes; reducing rinse times; and introducing more physical energy in the form of scrubbing with brushes or scouring pads. Another disadvantage of using high pressure is that the cleaning force and heat transfer from hot water is lost after approximately 20 cm (8 inches) and water becomes more of a mist rather than a jet. A medium pressure system will deliver an effective cleaning force and heat transfer of up to at least 10 times that figure, depending on its set up.

Two other major challenges arise from the rinsing process: damage to electrical components and hose management. Improved machinery design, higher dust and water ingress protection for electrical components, locating electrics far from the areas to be cleaned, and covering items such as control panels and motors before wet cleaning all can help to reduce the possibility of electrical damage.^{2,3}

Hose management is a continuous challenge in all food and beverage processing environments, particularly in those deemed high care and high risk. As hoses come into constant contact with the floor, the risk of crosscontamination to operative or processing equipment is high. The placing of centralised or decentralised chemical satellite stations and the installation of hose reels, together with the hose length leading from such points, should be carefully chosen to minimise the chance of hoses having to be led over production lines to clean adjacent lines. Training and supervision in good cleaning practices are also vital tools in preventing this from occurring, particularly for hoses attached to mobile chemical application units.



Figure 5. A range of wall hanging hose stands and wall hanging and mobile hose reels.

There are numerous reel, hanger and trolley options for hoses and each has its advantages and disadvantages (Figure 5). For example, an automatic retractable hose will ensure that the hose is kept off the floor at the end of its use, but during the retraction stage the hose will generate droplet splashes that may contaminate nearby surfaces and personnel. Although a manual retractable system can be controlled and the hose retracted at a much slower pace, there is still the risk of droplet generation. Overhead hose reel systems should be avoided wherever possible.

Regardless of whether the reel, hanger or trolley option is chosen, if the hose hasn't been cleaned and disinfected before storage it will act as a source of contamination. One of the best options is to not utilise reels, hangers or trollies but rather, to store the hoses after each use in a designated container holding a disinfectant solution. This ensures that any microbial contamination is significantly reduced before the next use. If this option isn't viable and the use of reels, hangers and trollies is unavoidable, the key step is to undertake a risk assessment and determine the best option for that particular environment.

It is also important to ensure that hoses and guns are routinely inspected and repaired or replaced. Any frayed hoses could provide a microbiological and a foreign body hazard and any holes could cause water or chemical to be sprayed onto surfaces or personnel.

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Air filter classification goes global: ISO 16890 will replace EN 779

Air filtration is the key technology that can supply air of the required cleanliness to hygiene production areas and ensure sufficient air quality for processes, products and human beings. With the introduction of new International Standard Organization (ISO) standards, the testing and classification of air filters is globally harmonised.

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For the manufacturing, testing, classification, installation and operation of air filters in general and in the food industry in particular, various standards and guidelines are of major importance. The European Committee for Standardisation (CEN) EN 779 has been the most important standard in Europe for testing and classification of coarse and fine dust filters intended to be used in air handling and ventilation units.

In the framework of ISO/TC142, the new test standard ISO 16890 for filter testing and assessment of coarse and fine dust filters was established. It replaced EN 779 by the end of 2016, with a transition period of 18 months. This new method for the evaluation of air filter elements represents a paradigm shift in the entire industry. In the future, filter efficiencies will be determined with regard to the particulate matter (PM) size fractions PM₁, PM_{2,5} and PM₁₀, which are also used as evaluation parameters by the World Health Organization (WHO) and environmental authorities. Based on these benchmarks, users will be able to more precisely select filters according to their individual requirements.

Limited informative value of EN 779

The main criticism of classification according to EN 779 was its distance from reality. Under this standard, the efficiency of an air filter was assessed as an average over a charge of a synthetic laboratory dust called ASHRAE dust. However, this applied exclusively to the particle size 0.4 µm. In reality, filters are exposed to a much broader range of particle sizes. For this reason, data obtained in the laboratory had only very limited value in terms of the actual performance of an air filter in a filter system.

As a result of the limited scope of EN 779 a filter could, for example, reach the average efficiency for 0.4 μ m particles required for an F7 rigid air filter, even if it had a low initial efficiency. If it captured an appropriate amount of dust, this loading caused a sharp rise in efficiency. In practice, however, this same filter behaved differently under normal operating conditions. Its efficiency would tend to remain constant or even slightly decrease during loading with atmospheric dust. As an example, in Figure 1 the evaluation of the fractional efficiency to 0.4 μ m particles is plotted as a function of the dust loading of an F7 rigid air filter in a V-bank design. It compares the loading behaviour against atmospheric aerosol and ASHRAE dust. One filter was operated for 2000 h at a flow rate of 3400 m³/h as a first filter stage with ambient air (light blue curve). After 2000 h of operation the pressure drop of this filter increased initially from 110 Pa to 178 Pa and the filter weight increased by 228 g. The fractional efficiency dropped during the first few hours of operation approximately 5 percent points and then rose very slowly, almost reaching back to the initial fractional efficiency towards the end of the curve. The dark blue curve represents the plotted results, which are gained during an EN 779 test. As shown, it is obvious that the behaviour of ASHRAE dust is completely different. With ASHRAE dust the efficiency strongly increases from the very beginning of the dust loading. The example shown in Figure 1 represents a typical behaviour of a filter element and a rise in efficiency that is not typically seen when loading a filter with ambient dust, no matter whether it is a pocket or rigid filter or whether micro-glass or syntheticorganic filter media are used.

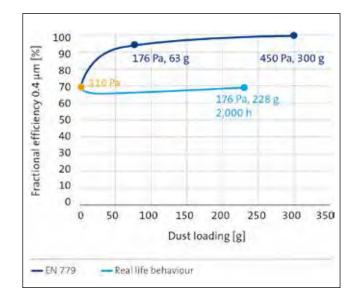


Figure 1. Fractional efficiency to 0.4 μm particles as a function of dust loading of an F7 rigid air filter.

The initial efficiency can be seen as the best case and hence, the new ISO standard evaluates the separation efficiency of a filter without dust loading in the laboratory.

Complete spectrum with ISO 16890

With the introduction of the new ISO 16890 standard, actual operating conditions will be more effectively taken into account. Instead of considering only the particle size 0.4 μ m, as previously, a broad range between 0.3 and 10 μ m will be used to determine separation efficiencies for particulate matter size fractions PM₁₀, PM_{2.5} and PM₁ (Figure 2). For example, in the future an air filter will be rated as ISO ePM10 80%. In other words, it separates 80 percent of PM₁₀ particles. The "e" stands for efficiency, and in combination with the particulate matter size fraction, the term ISO ePM₁₀ describes the variable for the efficiency.

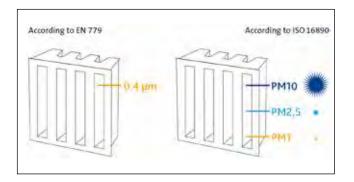


Figure 2. Consideration of particle sizes according to EN779 and ISO16890.

ISO 16890 filter testing procedure

The testing procedure of the new ISO 16890 standard begins by measuring the fractional efficiency curve of an air filter in the particle size range 0.3 to 10 µm. The filter is then subjected to an isopropanol vapour atmosphere to assess the extent to which particle collection is based on electrostatic mechanisms, after which the fractional efficiency curve is measured again. From the mean values of both fractional efficiency curves, the efficiencies for ePM₁ are calculated for the particle size range of up to 1 µm, ePM_{2.5} for the particle size range of up to 2.5 µm and ePM₁₀ for the particle size range of up to 10 µm. In addition, the minimal efficiencies ePM_{1, min} and ePM_{2.5, min} are calculated from the fractional efficiency curve that was measured after exposure to the isopropanol vapour treatment.

Based on these efficiency values, filters are divided into four groups. A prerequisite for each group is that a filter captures at least 50 percent of the appropriate particle size range. For example, if a filter captures more than 50 percent of PM₁ particles, it will be grouped as an ISO ePM₁ filter. The respective efficiency is then reported and rounded downwards in increments of 5 percentage points. So in the future, we will refer to this as an ISO ePM1 55% filter. As a result, classifications in the strict sense of the previous EN 779 or ASHRAE 52.2 will no longer exist. Alongside fine dust filters, the new ISO standard also evaluates coarse dust filters as ISO coarse: that is, filters that capture less than 50 percent PM₁₀.

Group Classification to ISO 16890

GROUP CLASSIFICATION TO ISO 16890		
ISO ePM1	ePM _{1,min} ≥ 50%	
ISO ePM2,5	ePM _{2,5,min} ≥ 50 %	
ISO ePM10	ePM10 ≥ 50 %	
ISO coarse	ePM10 < 50%	

Figure 3. Group classification to ISO16890.

The category in which filters are rated according to the new standard depends on their qualities and are individually determined in each case. Hence, there will be no direct one-to-one translation of the former EN 779 filter classes into the new ISO 16890 rating system. However, it is foreseeable that most currently commercially available F7 filters will be rated according to the new ISO standard between ISO ePM2,5 65% and 75% (Figures 3 and 4). In many general building ventilation application areas, however, PM₁₀ is the relevant particle size. The target here is an efficiency of at least 80 to 90 percent. This can be expected of most of today's F7 filters, but also can be achieved by some M6 filters.

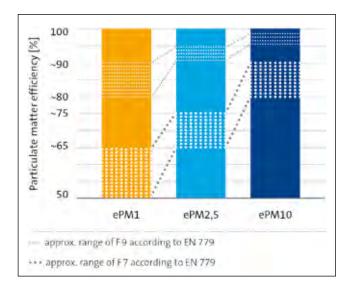


Figure 4. Approximate efficiency ranges of F7 and F9 filters when comparing EN 779 and ISO 16890.

Comparing the standards

Table 1 illustrates the differences that users can expect to see between applications of the EN 779 and ISO 16890 standards. These changes may be experienced in the form of measurement efficiencies, filter evaluation, filter performance, application, and filter characteristics.

Table 1. A comparison of EN 779 and ISO 16890standards. What has changed for users?

EN 779 – UP TO NOW	ISO 16890 – FUTURE	
MEASUREMENT EFFICI	ENCIES	
Determining of average efficiency / arrestance after loading with synthetic test dust in at least five individual steps.	 Measuring fractional efficiencies when new	
Average of several measurements at 0.4 µm	 Calculating average fractional efficiencies, Calculating efficiency ePMx 	
Distant from reality	Equivalent to real performance	
FILTER EVALUATION		
Only particle size 0.4 µm	Particle size spectrum from 0.3 – 10 µm	
FILTER PERFORMANCE		
Distinction according to filter classes rather than particle filtration performance	Filter performance is determined according to particulate matter fractions PM_{10} , $PM_{2,5}$ and PM_1	
No detailed info about particle size	Detailed info about various particle sizes	
APPLICATION		
No classification of particulate matter fractions for specific conditions of use	Specific application conditions are taken into account (e.g., general air conditioning versus medium-risk hygiene areas)	
Filters chosen without regard to application	Application is taken into account when choosing a filter	
FILTER CHARACTERISTICS Taken into account:		
1. Average gravimetric arrestance	1. Efficiency based on PM_{10} , $PM_{2,5}$ and PM_1	
2. Average efficiency (based on 0,4 μm particles)	2. Dust-holding capacity for synthetic test dust (ISO A2 / AC Fine)	
3. Minimum efficiency (F7 to F9)	3. Initial gravimetric arrestance	
4. Dust-holding capacity for synthetic test dust (ASHRAE)	4. Др	
5. Др		
CLASS DIVISION		
Filter classes	Four ISO groups	
G2 to F9	• ISO ePM ₁	
	• ISO <i>e</i> PM _{2,5}	
	• ISO ePM ₁₀	
	ISO coarse	

Hygienic considerations for building ventilation

The consequences deriving from the change in air filter testing and classification are not yet fully known. In each single case the relevant or critical particle size range has to be defined. The filtration efficiencies of the selected filter types depend on the quality of the air to be filtered and the target to be achieved. However, WHO recommendations also have to be met. Looking at the different particle size ranges of hygienic relevant dust types, it becomes obvious that pathogenic organisms such as Legionella or Pseudomonas range in particle size from 0.5 to 20 µm (Figure 5). Therefore, it is more reasonable to consider a high filtration efficiency for particle size ranges up to 10 μ m (ePM₁₀), rather than a lower filtration efficiency for particle size ranges up to 2.5 µm (PM_{2.5}). From a hygienic point of view, PM₁ is not relevant. Therefore, a feasible recommendation for the selection of appropriate filter types in a two-stage filter system could be in the following ranges:

Stage 1:	ePM10 > 50%	(comparable to F7)

In total: ePM10 > 90% (better > 99%) (comparable to F9)

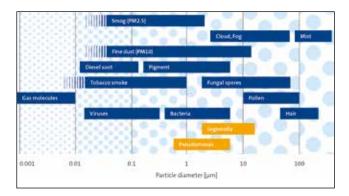


Figure 5. Approximate particle size ranges of different respirable fine dust types.

Summary and outlook

The ISO 16890 test standard has been published at the end of 2016. In Europe, there will be a transitional period of 18 months, during which both standards will be valid in parallel. The previous EN 779 standard will be withdrawn by the middle of 2018.

For many years the WHO and environmental authorities have been using particle sizes to evaluate air quality. Industry is now following their lead. With the introduction of the new ISO 16890 test standard, filter efficiency will be determined on the basis of particulate classes PM_1 , $PM_{2,5}$ and PM_{10} . In the future, this will ensure that filters are evaluated on the basis of their actual performance, which will help users to select filters in a more targeted manner than was previously possible.

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Hygienic design, taking a mixer for baby formula as an example

Scientific studies show that the most nutritious food for a baby is mother's milk. Nutritionists recommend that this natural form of nutrition should continue if possible for longer than six months when feeding infants. However, there is high demand for commercially produced baby foods in both developed and developing countries.

By Dipl.-Ing. Stefan Ruberg, amixon GmbH, Germany, e-mail: sales@amixon.com, www.amixon.com

All over the world, parents expect that the convenience foods with which they feed their infants will promote healthy development. Newborns have no intestinal flora, which develop in the first years of life. In this important phase of life, food must be pure and adapted to the specific nutritional needs of the very young. Baby formula, which may be given in the first six months of life and is strongly aligned with breast milk, differs from follow-on milk in its composition. Once the baby is older than six months, one can begin to transition the infant to follow-on food.

Of course, all foods formulated for consumption by infants must meet both nutritional and stringent food safety requirements. These demands are met only if the raw material components are prepared in quality-controlled systems. As such, modern mixing plants are gastight and dust-tight to protect both the mixtures and personnel from environmental contaminants.

In the case of an end-of-the-line mixing facility, the processing equipment is arranged one below the other (Figure 1). The finished mixture flows from the mixer via the collecting container and packaging machine directly into the end consumer packaging. End-of-the-line systems generally are used for a single product family, such as allergenic, non-allergenic, milk protein-free or -containing, Halal or Kosher. In amixon® mixers, cleaning downtime and the number of manual actions are reduced due to the highly sophisticated designed inspection doors and gaskets manufactured according to OmgaSeal® design (Figure 2). Since no dust escapes, the system stays clean and can be maintained easily. The mixer presented here, within an endof-the-line mixing facility, achieves optimum mixing gualities with a minimum input of energy and short mixing times, ensuring that the particle structure of the raw materials is maintained.

Each filling line has its own mixer. The batch sizes generally range from 300 to 1000 kg. The method of production requires the mixer to have very specific characteristics, including mixing efficiency, short mixing times, fast and complete emptying capability, and exemplary cleanability. The new KoneSlid® mixing system (Figure 5) was developed to fulfil these characteristics.

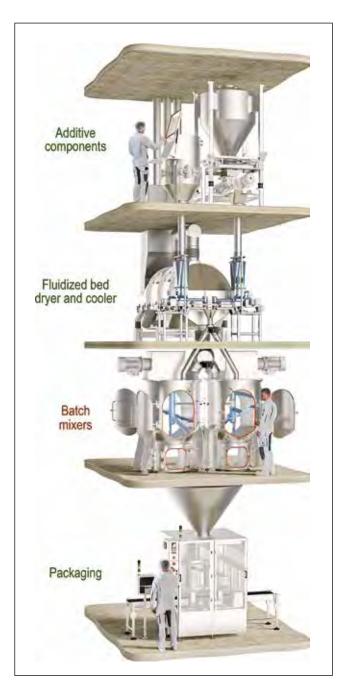


Figure 1. The continuously produced product stream is homogenized in two batch mixers reciprocally. Small amounts of trace elements, vitamins or bacterial cultures are fed by means of less-in-weight feeders. The packaging machine is supplied continuously.

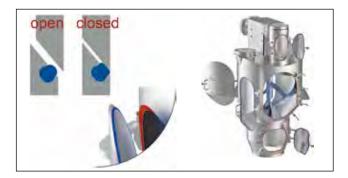


Figure 2. The mixer is equipped with four inspection doors. The doors are cut out with 4000 bar compressed water from the mixing chamber. The cut is made at a constant inclination. In the sloping soffit, the O-ring seals are tight to the product.

At low rotational speeds the KoneSlid mixer mixes precisely and the mixing time is very short. In addition, the mixing process is gentle. Practical application tests confirm that sensitive agglomerates from the spray tower, the fluidised bed granulation and the vacuum freeze drying are preserved. If necessary, the mixer can be manufactured vacuum-tight, which means the atmospheric oxygen can be removed from the porosity of the powder mixture during mixing by creating a vacuum. Saturation is achieved by injecting nitrogen or carbon dioxide. Emptying takes place without segregation in just a few seconds. Free-flowing goods usually flow out completely, so that the potential for cross-contamination is excluded (Figure 3).

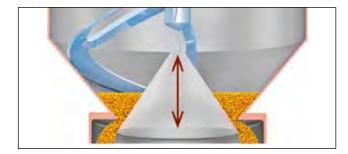


Figure 3. The KoneSlid mixer discharges itself within a few seconds. Free-flowing goods normally flow out completely.

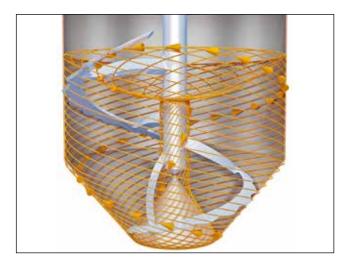


Figure 4. The KoneSlid mixing principle operates independently of the degree of filling. This can vary from approximately 10 to 100 percent.

The filling degrees can vary from about 10 percent to 100 percent (Figure 4). In the case of food products liable to dust explosion, type approval Ex II 1D (for zone 20) is available. As an option, the mixer can be manufactured in either a pressure shock-resistant or pressure-resistant version.

The upper part of the mixing chamber is similar to a roof. This offers advantages in the case of wet cleaning. Water droplets can flow easily downward inside the mixer. The drying will be improved.

Large inspection doors offer easy access for manual dry cleaning. The doors are produced using the CleverCut® method. The O-ring in the groove seals is very close to the product and practically free of dead space. The design is permanently gastight, dust-proof and waterproof. The inspection doors are opened by manually actuating the KwickKlamp® closures. Electromechanical safety interlocks only allow the inspection doors to be opened when the system is disconnected from the power supply.



Figure 5. KoneSlid mixer with two large inspection doors.

Another method of preparing dehydrated food, especially when semi-finished products need to be produced in large quantities and over long periods of time, is continuous mixing. amixon continuous mixers utilise the continuous "vessel rearrangement" principle (Figure 6). All of the recipe components are dosed into the mixer under gravimetrical control. The finished mixture is discharged continuously. What is special, however, is the following: When a mixing machine that usually operates continuously is started up, the initially discharged product flow does not conform to the recipe, because the flow rates of the individual dosing devices must first be calibrated to one another after starting. Because the amixon continuous mixer also is a precision batch mixer, the calibration phase of the dosing devices can be corrected up to 100 percent. The procedure at the start of production is as follows: The discharge valve of the mixer is closed. All gravimetric working dosing components are started simultaneously with small mass flow and tune themselves automatically in relation to one another. The level of the mixing container fills up continuously, starting up the mixer when it reaches half-capacity. Tuning is completed once the mixer is filled to about half of its capacity. The discharge device opens slowly once the mixer is filled at approximately 80 percent of cubic capacity. This is kept constant. The dosing flows are increased up to the maximum mass flow while maintaining a constant synchronisation. All dosing devices gradually slow down the mass flow and then switch off and close at the same time. The mixer discharges the mixture continuously until it is completely empty. Freeflowing goods flow out completely. Hence, every gram of the product components used becomes a saleable product. The mixer can compensate smaller, briefly occurring dosing fluctuations and empty free-flowing goods almost entirely without leaving residues. Large CleverCut inspection doors enable ergonomic inspection and cleaning.



Figure 6. The amixon continuous mixer with four gravimetric dosing systems. The mixer rests on load cells. Filling and discharge nozzles are provided with flexible collars. The mixer's sealing valve is controlled so that the filling level in the mixer remains constant.

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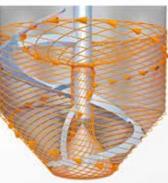
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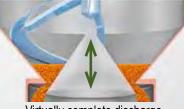
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Minimising belt-related risk factors in food production by constructing for cleanliness

Many of the factors that lead to hygiene risks during conveyance and on-belt processing are addressed by new belt designs. A homogeneous non-fabric positive-drive belt with minimal surface disruption can cut down on issues arising from frayed fabric edges, fabric saturation, dirt and residue buildup, and cleaning problems such as secondary splash contamination.

By Richard Duijn, Head of Homogeneous Belts, Ammeraal Beltech, The Netherlands, e-mail: rduijn@ammeraalbeltech.com

One of the goals in food production is cleanliness, but the mechanical requirements involved in conveying food materials during production often creates difficulties in maintaining that goal. Fabric belts, for instance, can absorb trace amounts of the organic material they are transporting, leading to bacterial growth and equipment failure. They also can contribute to physical contamination due to fabric fray, most often at the edges. In fact, it is largely for these reasons that fabric belts are not the belts of choice for many applications in the food industry.

Certain homogeneous belts, on the other hand, may not present issues regarding permeability or edge-fraying, but can still host unwanted dirt and residue build-up due to the sheer volume of right-angle ridges that many drive designs entail. A typical lateral positive-drive belt with a width of 600 mm will have more than 24 meters of raised 90° edges per meter of belt, creating more than 24 meters where dirt and residue can easily accumulate (Figure 1 and Figure 2). In addition, the sprocket designs of such belts also can be problematic, producing still more hard-to-reach right-angled edges.



Figure 1. Underside of a traditional positive-drive conveyor belt with lateral teeth design.

Cleaning such belts requires additional cleaning energy and if delivered with high pressure water to dislodge contaminants, may redistribute the dirt and residue via a splash effect across previously uncontaminated areas (cross-contamination). This occurs not only on the belt but in the surrounding production space. Despite this, the use of homogeneous positive-drive belts is becoming more common in the food industry. In general, they do a good job of conveying products reliably, have a lower water and energy consumption during cleaning, and pose little need for maintenance. Tracking is ensured through the interaction of the sprocket-wheel and the teeth, and the homogeneous material is sturdy enough to withstand the strains of demanding applications. The team of Ammeraal Beltech developers set out to address hygiene challenges by utilising the EHEDG Guideline Doc. 43: Hygienic Design of Belt Conveyors for the Food Industry while ensuring that these positive-drive performance advantages are maintained.

The greatest challenge was to minimise right angles of the underside teeth, which was accomplished in two ways.

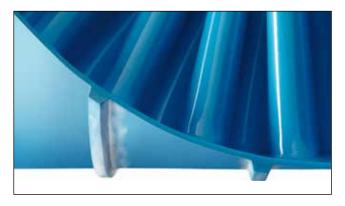


Figure 2. Underside right angles and corners are vulnerable for dirt accumulation and are difficult to reach and clean.

First, the lateral design was replaced with a limited lug pattern, so that the belt no longer had raised features running all the way across it. Instead, a few strategically placed lugs (positioned along the slider strips to maximise tracking efficiency) interacted with an equally less complex sprocket wheel. As a result, the belt now had very few raised edges, and the sprocket wheel had wider gaps, making it easier to clean.

The second design decision was to soften or "round" all the lug angles, so that even the minimal raised area was less likely to cause problems (Figure 3). Curving the lugs and the juncture of lug and belt meant that the whole belt could now be wiped clean with little effort and significantly reduced splash transference; in fact, the cleaning could even take place while the belt was in motion (i.e. clean-in-place [CIP]).





Figure 3. Alternative rounded lug design for teeth.

At the same time, the curvature of the lugs translated into curvatures in the sprocket wheel, making that part of the belt system easier to clean (Figure 4).



Figure 4. Accompanying sprocket for the lug design features rounded edges that also facilitate cleaning.

The resulting belt, the Soliflex Pro, is designed specifically to reduce hygiene risks. As this new belt took shape, the construction teams continued to find new ways of further decreasing surface disruption. High-frequency welding was used to join lug and belt surfaces, and even the raised injection mould pattern was eliminated.

In the end, the goal was achieved. The new belt had no rightangle disruptions, and had a total edge-length of just over 4.5 meters on a 600-mm belt, roughly one-sixth of what a common lateral positive-drive belt would have presented (Table 1). Tests and real-time application use have further demonstrated the belt's effectiveness, as well as the effectiveness of designing first and foremost for hygiene.

Table 1. The difference between a traditional lateralteeth design and a lug teeth design is a 81.2 percentreduction in 90° angled edges that can trap dirt.

	Meters to be cleaned (600 mm width)
Traditional lateral teeth design	24
Lug teeth design	4.5



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Magnetically-geared motors: Taking the "open design" principle to the next level

Due to its hygienic design and the absence of lubricants, a magnetic gearbox is well-suited for applications in the food industry. Through the inherent overload protection, a magnetic gearbox is recommended for applications in which personal safety must be guaranteed.

By Dr. Stefan Vonderschmidt and Andreas Vonderschmidt, GEORGII KOBOLD GmbH & Co. KG, Germany, e-mail: stefan.vonderschmidt@georgii-kobold.de

Open design in the food industry

The food industry places high demands on drive technology. On the one hand, machines in the food industry often must be cleaned with aggressive cleaning agents; on the other, no contaminants are allowed to come in contact with the food. Recent foodborne illness outbreaks show how such contamination incidents quickly develop into highly publicised food scandals — with corresponding costs to the manufacturer economically and negative impact on the brand image.

Conventional gearmotors are often housed in special enclosures so that they can easily be cleaned and to provide additional safeguards against food contamination by the lubricants in the gearbox. Design for easier cleaning is difficult to achieve with such motors. For a good design, as many components as possible should be eliminated from the system. An initial approach in this case is to have a hygienic design in which the motor is manufactured without any edges to prevent buildup of contaminants and to make it simple to thoroughly clean. Another element is also necessary for a consistent implementation of the design concept: conventional gearboxes must be safeguarded against leakage, either through construction or through regular maintenance and service. Magnetic gearboxes from GEORGII KOBOLD, for example, are lubricant-free, so an oil sump is unnecessary.

A gearbox with an easy access design built into the system so that the machine operator can reach into the danger area is another useful advantage of a magnetic gearbox. Magnetic gearboxes have an inherent overload protection due to their mechanically-decoupled shafts. The torque of the magnetic drive can be adjusted such that there is no risk of injury from accidental or deliberate engagement of the moving components.

Magnetically-geared motors

Magnetically-geared motors are made up of three main components (Figure 2). These are an outer magnetic wheel with many magnetic poles, a modulator consisting of magnetically soft iron segments, and an inner magnetic wheel with fewer magnetic poles.¹ While the functionality of the magnetic gearbox is analogous to a planetary gearbox, its operation principle is most similar to an electric motor assembly. If the outer magnetic wheel is physically cut free, a spatially-fixed, high-pole magnetic field will form. The modulator changes this multi-pole field when it is introduced. As the modulator rotates, a low-pole, rotary field is generated. Analogous to a synchronous motor, this synchronously drives the inner magnetic wheel. Figure 1 shows such a magnetic gearbox with an integrated electric motor in hygienic design.

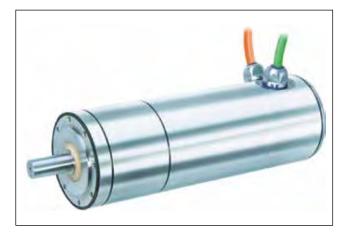


Figure 1. Highly-integrated, magnetically-geared motor in hygienic design.

Adjustable slip torque for consequent open design

When a machine operator must reach into a moving part of a machine, his personal safety is of paramount importance. Due to the fact, magnetic gearboxes can transmit only a limited torque, an open design is possible. If this maximum torque is exceeded, the magnetic gearbox will slip, similar to a torque-limiting clutch. Because of this inherent overload protection, magnetic gearboxes are recommended for safety-critical applications. The maximum transmittable torque can be adjusted in the design and construction of the magnetic gearbox. One way to adjust the torque is to adjust the air gap between the magnet wheels, for example.



Figure 2. Structure of a magnetic gearbox.

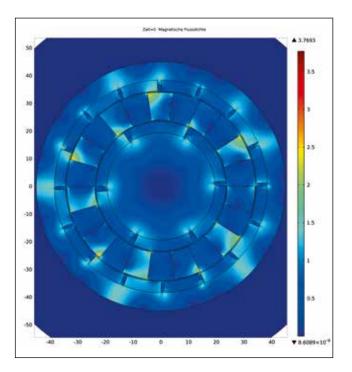


Figure 3. Magnetic flux density of a magnetic gear.

Figure 3 shows a simulation of a magnetic gearbox. Figure 4 shows the maximum transmittable torque for the air gap width ranging from 0.1 mm to 1 mm. As shown, the air gap has a major impact on the transmittable torque. By adjusting the air gap, it is possible to accurately adjust the slipping torque of a magnetic gearbox. In practice, it is possible to accurately adjust the torque to within \pm 0.1 Nm.

Summary

A magnetic gearbox enabling easy access design that solves various problems in the food processing industry has been presented. On the one hand, the gearbox is easy to clean thanks to hygienic design. Depending on the cleaners used, housings can be manufactured in stainless steel or anodised aluminum. The magnetic gearbox requires no lubricant, which provides additional safeguards to protect the food. In applications in which an operator can or must reach into the moving part of the system, the transmission can be designed so that it assumes the functionality of a torque-limiting clutch, also making additional safeguards unnecessary. With these three advantages, a magnetic gearbox significantly simplifies the open design of systems in the food technology sector.

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 Vonderschmidt, A. (2015). Lubricant-free magnetic gearboxes offer a hygienic alternative. European Hygienic Engineering Design Group. *EHEDG Yearbook 2015/2016, pp. 116-118.*

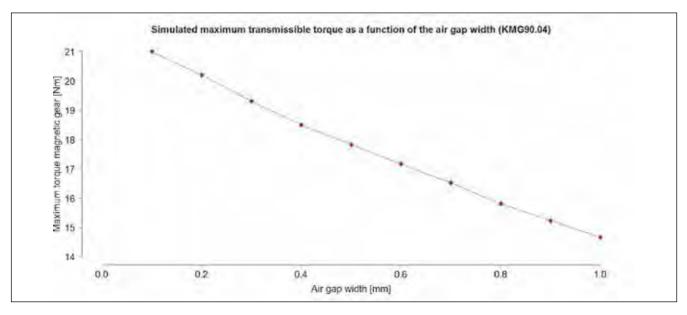


Figure 4. Torque of a magnetic gearbox as a function of the air gap width.



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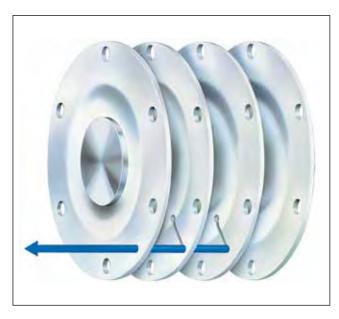
Versatile series offers maximum operative and food safety and durability for applications such as flavour metering or filtration aid additions in the food and beverage industry

By Kazim Konus, Product Manager for the Ecodos Product Family, Lewa GmbH, Germany, e-mail: kazim.konus@lewa.de

Securing consistent taste and uniform quality is of the highest importance to producers in the food industry. Brewing beer requires special care because the ingredients - prized flavouring agents derived from normal beer in the case of non-alcoholic beers - must be added at just the right time and in the predefined amounts. This is done to ensure that non-alcoholic beers have the typical taste and flavour of a beer that contains alcohol. Lewa GmbH's diaphragm metering pumps for low-pressure applications of < 20 bar, in a hygienic design, were developed specifically for these types of highly complex food processing procedures. The reliability and metering accuracy of ± 1 percent enable these pumps to meet all requirements for this hygienic process. The technology also is suited for sensitive applications due to the gentle, low-shear fluid pumping typical of diaphragm metering pumps.

diaphragms, a monitoring diaphragm and a pressureresistant safety diaphragm – and integrated diaphragm rupture monitoring. As a result, the system is more durable, hermetically sealed and leak-detectable (Figure 1). Due to its hygienic design, possible damage of the diaphragm is indicated in the second layer via the installed rupture monitoring instrument, such as a pressure gauge or a pressure switch (with an electrical signal for the customer control system). In this way, the operator is immediately informed about a diaphragm rupture so corrective measures can be taken to prevent product contamination by foreign bodies or microorganisms.

Easy to clean with clearance space optimisation



4- layer sandwich diaphragm ensures safety

Figure 1. The 4-layer diaphragm design makes the system durable, impact-resistant, hermetically sealed and leak-detectable.

High-quality individual components ensure that pumps operate with maximum reliability, require minimal maintenance, and lead to extremely low lifecycle costs. The regular service life of a diaphragm is approximately 16,000 operating hours, which corresponds to two years of continuous operation. A major contributing factor for this longevity is the 4-layer diaphragm design – two operating



Figure 2. The dead space-optimised design of the pump head offers minimum flow resistance and allows the pump to remain sterile.

For applications in the food industry, all pressurised, wetted materials are US Food and Drug Administration (FDA)compliant, conform to US Pharmacopeia (USP) class VI, and are designed in accordance with the European Hygienic Engineering and Design Group (EHEDG) guidelines. The pump head is made of polypropylene (PP) or electropolished stainless steel with a surface roughness of < 0.5 μ m in the hygienic type. This ensures that surfaces that come in contact with the product are easier to clean. Insert rings made of different materials are available for the stainless steel pump head valve seats. The valves themselves are selected for both chemical and process compatibility with the fluid.

The ideal choice for most requirements specified by EHEDG is DIN 1.4435 stainless steel, AISI grade 316L. The pump heads made of this material are designed to withstand pressures of up to 20 bar and processing temperatures of 80°C (for SIP operations, this temperature can be exceeded for short periods.). As the more cost-effective alternative, PP is ideal for use when temperature and pressure requirements are not too high. The geometry of the pump head is designed so that residue from process media is reduced to a minimum. This also makes it possible to easily clean-in-place (CIP) and sterilisation-in-place (SIP) the device onsite. The pump head's dead space-optimised design keeps the amount of process fluid in the working area low. Additionally, the rinsing, draining and drying processes can be carried out easily (Figure 2).

Multiplex capability opens up additional areas of application



Figure 3. Multiplex pumps are ideal for recipe metering and mixing tasks.

International Electrotechnical Commission (IEC) motors from major manufacturers, which can be installed vertically to save space, are used exclusively as drives. Springcam drive units are used in smaller models while variable eccentric drives are used for higher performance. Depending on the size of each pump head, 0.4 to 1,500 L/h can be pumped using a single-drive unit. To ensure that no oil from the drive unit leaks when replacing the pump head, the drive unit is sealed off from the drive unit housing. Combining multiple pump heads with a power train opens up even more areas of application. These multiplex pumps are ideal for recipe metering and for mixing tasks (Figure 3). Each pump head can be precisely adjusted to recipe-specific amounts.

Metering accuracy of ±1 percent

The metered flow can be adjusted using the stroke length and the frequency of a variable frequency inverter. Costly optimisation and parameterisation efforts are not necessary because contactors and pumps are shipped after being tested for functionality. Metering is extremely accurate at ± 1 percent of precision. Different requirement profiles supplied by the customer can be implemented and the turndown ratio can be expanded over 1:50 when using a servomotor and an intelligent control system during activation.

Examples of use: Flavour metering and adding filtration aids



Figure 4. The ingredients in non-alcoholic beer have to be added precisely and at just the right time.

The ingredients in non-alcoholic beer have to be added precisely and at just the right time (Figure 4). For this reason, flavouring agents that will be added are stored in a vessel equipped with an agitator, cleaning ball and two level switches. A strainer in the low pressure metering pump suction line keeps out solids that hinder proper operation of the pump valve. This strainer ensures the pump's process valve can be closed properly. In this process, the flow rate that will be metered is continuously adjusted to the amount of beer by an electromagnetic flow meter and a control loop. A contactor protects the pump from possible overpressure on the discharge side. The entire system is operated via programmable logic controller (PLC); however, it also works in manual mode. Low-pressure metering pumps are used to add filtration aids during the filtration of beer, wine, fruit juices and other beverages. This makes it possible to perform tasks such as metering diatomaceous suspensions in the precoat filtration process, which separates yeast and macromolecular proteins. In this process, the pumps are in continuous operation and requirements related to hygiene are particularly stringent. The filtration process starts with the precoating of the filter plates. Here, an evenly distributed diatomaceous suspension is introduced into the water flow or directly into the product. A steady flow of suspension must be continuously added from this point on. This causes the filter cake to grow steadily and as a result, enlarges the filter surface. Valves specifically designed for suspensions with special valve seats were selected in accordance with the process requirements. The pump connections use a setup such as pipe couplings (DIN 11864) or other hygienic design screw fittings. The pump's hermetic seal with the corresponding system connection prevents the product from being contaminated.

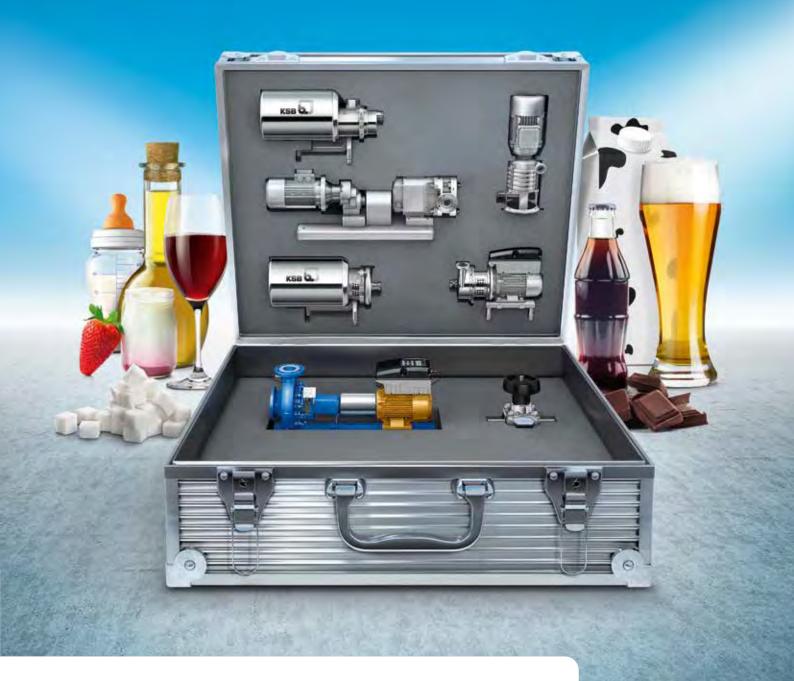
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The New Benchmark of Efficient Hygienic Design

Diaphragm valves are a key component of hygienic system design and play an important role in everything from manufacturing efficiency to product quality and utility demand. Cast and forged body diaphragm valves are the standard options, both of which introduce their own unique benefits. They also share a number of common weaknesses, including weight, efficiency, ease of installation, carbon footprint, and arguably the most critical, thermal mass. Recognising these challenges and identifying the need for a solution, Bürkert has developed hydroformed tube body diaphragm valves.

By John van Loon, Bürkert Fluid Control Systems, Germany, e-mail: info@burkert.com

Alternative to forged and cast valve bodies

Traditional forged body diaphragm valves consume energy, using high amounts of costly-to-raise clean steam. They also diminish available production time while heating and cooling slowly in clean-in-place/sterilisation-in-place (CIP/ SIP) cycles. This is also true for cast bodies, even though they are lower in mass than forged body diaphragm valves. With the introduction of a new hydroformed tube body diaphragm valve, Bürkert presents an alternative to forged and cast valve bodies (Figure 1). The tube valve bodies manufactured with hydroforming technology are of high stability and fitting surface quality, are constructed with 316L stainless steel, and are cleanability certified in accordance with the European Hygienic Engineering and Design Group (EHEDG). It is manufactured from high-quality stainless steel tube like other plant or system lines. This enables hygienic tube-to-tube welding of virtually identical materials, through which a uniformly high quality of weld seams is ensured. Compared with cast bodies, neither cavities nor other defects occur in the manufacturing process, which means the risk of contamination is minimised.



Figure 1. The new hydroformed tube valve body. Photo © Werner Bennek/Bürkert

By processing the tubes in combination with hydroforming technology, it is possible to manufacture variants that are 75 percent lighter than forged housings. By reducing the material used to make the tube, the manufacturing plant's energy requirement and the heat-up or cooling phase duration is reduced during the cleaning or sterilisation processes (Figures 2 and 3). Thus, energy costs are lowered and downtimes are reduced. Moreover, the same housings enable reduced installation costs because supports are eliminated. In addition, the lightweight design of the housing has a positive effect from an ecological perspective. Due to the low mass, the user benefits by reduced energy costs and a lowered CO_2 footprint during operation. The manufacturing process is also designed to be more environmentally-friendly. When manufacturing a DN 25 cast valve body, almost 7000 g of CO_2 are released; the value for the new Bürkert tube valve body is just over 2000 g.

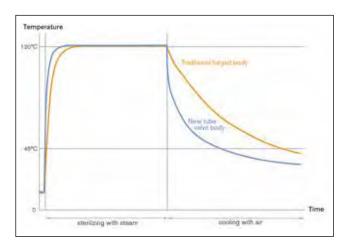


Figure 2. The hydroformed tube body diaphragm valve is lighter than forged housings, which can result in shortened heat-ups and quicker cool downs in SIP/CIP cycles. This figure shows SIP temperature curves in comparison.

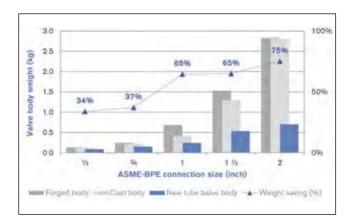


Figure 3. The tube valve body has a lighter thermal mass (up to 75 percent) than traditional forged or cast body alternatives and therefore saves energy.



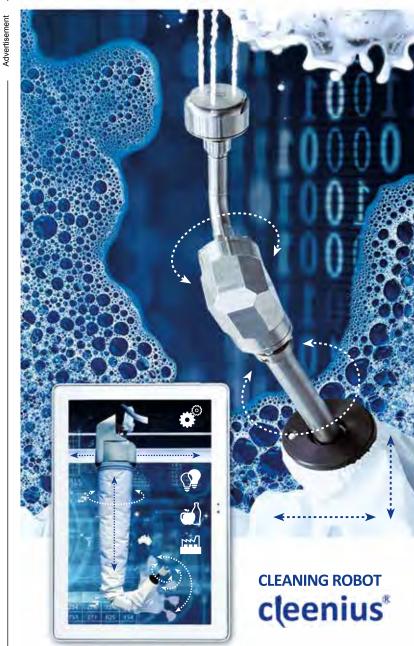
Requirements in the target industries

In the hydroforming process, an ordinary stainless steel tube of pharmaceutical quality is filled with a water-oil emulsion and then charged with a high inner pressure. In this process, the tube is formed into a valve body, and simultaneously joined to a flange. Afterwards, the flange and tube are connected via laser welding to ensure the cleanability of the body. A special annealing process to increase resistance and release stress follows. In the final step, precision surfaces of the highest quality are generated. The result is a product in which a food medium only comes into contact with a pharmaceutical-compatible tube and diaphragm.

Target applications of the tube valve body are in the pharmaceutical, bio-pharmaceutical, cosmetics, and food and beverage industries. From a technical, economic, and ecological perspective, the valve bodies satisfy the current requirements and regulations of these markets. For example, they fulfill the globally established American Society of Engineers Bioprocessing Equipment (ASME-PBE) standard regarding dimensions and tolerances, as well as both the EHEDG and 3-A Sanitary Standards requirements regarding hygienic design. For the market introduction the tube valve bodies are available in the welding connection sizes 1/2" to 2" according to ASME BPE, DIN and ISO and with the Bürkert diaphragm valve types 2031, 2103 and 3233.



Figure 4. The new tube valve body in combination with Bürkert's diaphragm valve actuators.



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Hygienic design as an asset for better engineering

By Pascal Bär, Product Manager Flow Components, GEA, Michele Madureri, Head of Configuration Engineering Homogenization, GEA, Thomas Veer, Head of Process Technology – Dairy & Beverage, GEA, e-mail: pr@gea.com

The consequent consideration of hygienic design criteria, interlinked with the awareness about process requirements, leads to a better understanding on what the most suitable equipment in terms of cost-efficiency ratio for a process might be. GEA utilises hygienic design as an asset for better engineering, not just during the equipment development phase, but also as a tool to identify the most suitable equipment for a specific process.

Hygienic classes for process valves – a useful tool

Every process chain is only as strong as its weakest link. With respect to hygiene standards, even comparatively small components such as valves play a critical role. To enable companies working with food and beverage processing to easily find the right valves for each individual process, GEA has developed a classification of process valves into three hygiene classes: Hygienic, UltraClean, and Aseptic (Figure 1). The system primarily takes microbial contamination risks and detection possibilities at process valves into consideration, as well as factors such as shelf life, maintenance requirements and long-term hygiene risks. This classification system is oriented to recommendations prepared by the Federation of German Machinery and Plant Manufacturers (VDMA) for applications of hygienic filling machines for liquid and viscous products (No. 2/2000, 2nd edition, 2006).

The hygiene classes ideally serve as orientation and as the basis of discussion for plant engineering specialists and plant operators. They should be interpreted as a recommendation and not as a limitation.

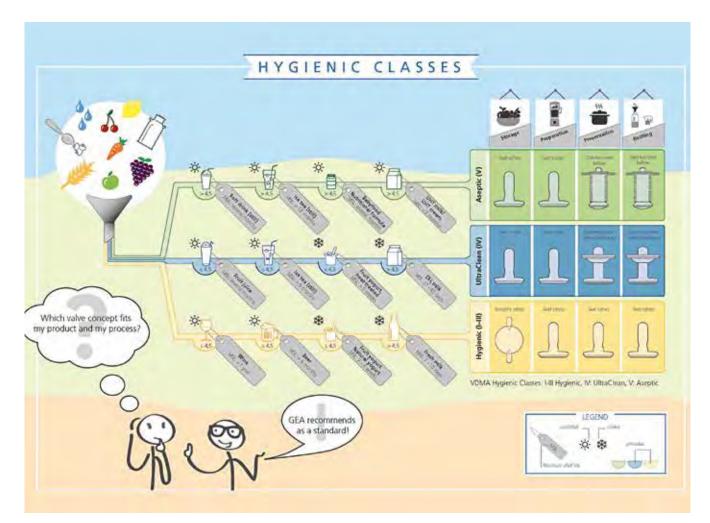


Figure 1. Hygienic, UltraClean and Aseptic: The three hygiene classes for process valves.

Hygienic. To fulfil the basic requirement of Machinery Directive 2006/42/EC, system design of process valves must, as well as all other food processing equipment, exclude any risk to personal health or safety. The materials used must be cleaned before every use, and the surfaces in contact with food may not provide cavities such as dents or edges in which microorganisms can lodge. The reason for this requirement is the mandatory prerequisite to produce food safely, in consistent quality and with appropriate shelf life. Process valves within the Hygienic class are used in various food and beverage industry applications in which requirements for reducing pathogen burden or maintaining the shelf life of sensitive products are essential, such as in brewery, dairy, beverage, and food production plants.

UltraClean. Valve components classified as UltraClean are characterised by greater safety protection from contamination by the environment (atmosphere) and thus grant microbial stability of the product over the entire process. The same design specification for Hygienic class valves used with foods also applies to UltraClean components. The enhanced safety of UltraClean valves is mainly achieved by protecting the valve stem from the atmosphere, either by steam or by a hermetic sealing diaphragm. Generally speaking, products qualifying for UltraClean technology can allow repeated heat treatment as long as the final product quality falls within an acceptable range. For more sensitive products that cannot pass through thermal treatment more than once, aseptic processes and components may be more suitable.

Unlike the general assignment of stem diaphragm valves as pure aseptic valves, GEA primarily classifies not just its own valves as UltraClean but the technology of stem diaphragm valves in general, and assigns these to the associated processes (e.g., fruit juice and lactic-acid products). The various materials used in a stem diaphragm valve require a separable connection between the membrane and the shaft. At precisely this contact interface between the synthetic material and the metal, the different coefficients of expansion can cause product carryover to occur. The frequency of temperature and load changes, as well as the type of cleaning, influence the lifetime of the membrane. In the long term run, such membranes - regardless of their manufacturers - are therefore not as stable as metal bellows. In addition, membrane defects cannot always be detected from the outside, which can give rise to extra costs in troubleshooting.

This classification system does not, however, categorically preclude the application of these valves in other areas. As a result, the stem diaphragm valve can provide added value for classical hygienic applications or for aseptic uses.

Aseptic. In contrast to the other two hygienic classes, hermetic sealing of the product area against the environment (atmosphere) is mandatory with aseptic components. With this requirement and the demand for outside detection of failures, contamination risks are lower than with components from other classes. With a bellows valve, a metal bellows is inseparably bonded to the valve stem by a special welding process, meaning that microbes



VALUE INNOVATORS BY NATURE





cannot enter the piping network (prevention of the elevator effect). The bellows is inert, temperature-resistant, and longlasting, which assures aseptic characteristics throughout many years. This simplifies inspection and maintenance and enhances process reliability. If leakage should occur, detection from outside is reliably possible, which minimises follow-on costs. Aseptic processes are used for highquality products and/or long shelf-life requirements, with production for specific consumer groups, such as UHT milk products, medical nutrition and baby food.

The application matters. As with all investments, it pays off to consider the total cost of ownership. In the same manner risks for the product and the process, investments, cleaning costs and time, maintenance and spare parts costs, and any required troubleshooting play important roles. Valves are just one part of a complete food production process. For all other food equipment, hygienic design has exactly the same importance, including decanters and homogenisers.

Cleanable high-pressure homogenisers

High-pressure homogenisers are designed to downsize dispersed particles in product to micrometers or even nanometers. This process creates a stable dispersion in a finished product, or provides a starting point for further production processes. Hygiene is paramount.

GEA has developed a liquid-end compression block providing unique hygienic features specifically designed for baby food, viscous condiments, dressings (e.g., mayonnaise), and probiotic foods containing fibers and solid parts (Figure 2). The innovative mechanics of the compression block, designed according to the strictest hygiene regulations, allows the product to flow continuously, reducing shear stress passages and facilitating fluid feed into the homogenising valve. The patented compression head has optimised technical features to improve hygienic design and cleanability: reduction of dead spaces, absence of springs and spacers, and improved flushing of gaskets. This design results in better cleanability characteristics and the economical use of clean-in-place (CIP) media and water.

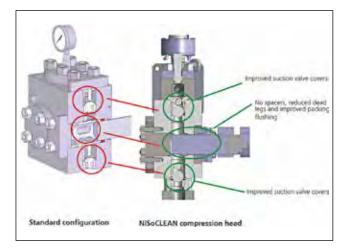


Figure 2. GEA designed concept for high-pressure homogenisers.

Hygienically designed decanters

The currently available "ecoforce" decanter range is designed to be used wherever products are sensitive to microbes, such as in the dairy industry. Typical applications include the production of base material for processed cheese, the raw material for quark bars or baker's cheese, the recovery of cheese fines and for producing lactose and casein.

All decanter components, including the scroll, bowl wall, feed system and solids discharge, are designed to exclude or minimise dead space. This prevents germ nests due to product residues in the production and cleaning processes. All seals and grooves are designed to be flushed. The stainless steel surfaces in contact with the product are polished to Ra < 0.8 μ m, allowing all surfaces that come into contact with the product to be cleaned without leaving residue. Spray nozzles for the solids, and rotor and liquid areas are welded to the decanter hood, ensuring defined CIP capability and reproducible cleaning for the entire decanter.

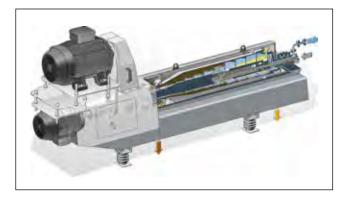


Figure 3. The decanter gearbox is located outside the product room to ensure easy-to-clean outer surfaces.

These decanters include an industry innovation: gentle product processing, with a hermetic feed consisting of a rotating feed tube with direct transfer to a box distributor. In contrast to conventional distributors with hole or slit geometry, the box distributor has smooth walls to minimise shear in the feed zone. As a consequence, the product is brought into the separation chamber with defined and gentle acceleration, thus improving product quality (Figure 3). All necessary electrical control devices (e.g., lubrication oil unit, cooling water control unit) have been removed from the decanter frame into an external utility cabinet. This ensures smooth and easy-to-clean outer decanter surfaces.

Hygienic design as a mindset and not just as a guideline to follow

Knowing the application and considering hygiene design criteria to maximise food safety doesn't end with process valves, but must be considered for all types of food equipment, including homogenisers and decanters. Equipment and processes designed with hygiene in mind offer the benefits of greater food safety and process reliability in the long run.



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Hygienic aspects of water treatment systems

To achieve top-quality beverage or food production it is frequently necessary to start with water of potable quality. Thus, the selection of the best possible water treatment process available is mandatory for those applications in which water quality is of the highest concern. Implementing a water treatment system that minimises the use of chemicals has become more widely accepted. To realise this aim, it is necessary to comply with the appropriate hygiene requirements throughout the entire treatment system, from the raw water source to the point of use.

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Every drink made in the brewing and beverage production sector begins with a main ingredient: water. In any beveragemaking process, the composition of the product water plays a vitally important role in achieivng the final product quality. After all, water accounts for more than 90 percent of the final product, which is why the microbiological quality of product water is always a particular focus in the production process. To minimise microbiological contamination in the product water, chemical disinfectants often are used. However, there are potential problems in using these chemicals, including the possible formation of disinfectant by-products that can be entrained into the product. The downside of these byproducts is that they alter the product characteristics, and in some cases, are suspected of being carcinogenic (i.e., bromate).

The Hydronomic water treatment system from Krones AG, with a possible combination of ultrafiltration (UF) and directly linked-up reverse osmosis (RO) operates in most cases without any disinfectant chemicals. Water treatment without chemical disinfectants means there is no disinfection of the piping system and product water, no active "protection" to avoid biofouling in the pipes, and no microbial stabilisation of water reserves. In other words, if the technology promotes a "no-disinfectants process," it is necessary to purposefully implement hygienic design of the equipment in the water treatment plant to minimise the presence of microbes before they can enter the treatment system. Hygienic design elements may include:

- Use of hygienic components, such as pumps, leakproof valves, connections, and weld seams analogous to their use in the product area
- Ensure hygienic design all along the path of the water and in the construction of the requisite components without any dead spaces to enable effortless cleaning
- Easy-clean stainless steel construction with appropriate surface qualities in conformity with the European Hygienic Engineering & Design (EHEDG) and Good Manufacturing Practices (GMP) guidelines
- Option for weld seams (preferred choice) where this makes sense; otherwise, use hygienic (leak-proof) connections in conformity with DIN11864 (I, II, III) (Figure 1).

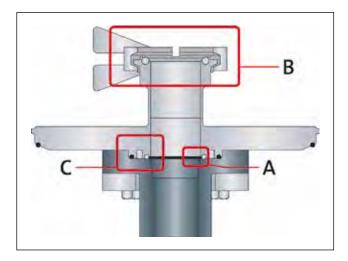


Figure 1. Description A, B, C: Leak-proof connection (retentate>< filtrate) at the ultrafiltration module

- Fittings are replaced via automatically bended pipes, and tees by necked-out designs, so that the number of actual weld seams is minimised
- Stainless steel pressure vessels manufactured inhouse are used throughout for the membrane modules

These elements of hygienic design are instrumental in establishing the preconditions for automatic cleaning of all wetted surfaces, and for sanitising them with water at a temperature of 85°C. This is a route towards operating a production process without chemical disinfectants.

Hot-water sanitisation

To implement this concept by using membrane technology such as UF, facilities can install a closed-cycle process with a variable system throughput and an online backwashing function. Every part of the system, including the interconnecting pipes, should be hygienically designed according to design criteria for hygiene-compliant machines, and must be dependably suitable for cleaning in place (CIP) and sterilisation in place (SIP) (Figure 2). In addition, the use of a hot-water sanitisation routine at about 85°C is useful. Thermal sanitisation reduces microorganisms by several powers of 10 (log rate). Water temperatures below 60°C encourage microbial growth, which increases the risk of infection. Temperatures above 75°C, with appropriate contact times, by contrast, will kill beverage-spoiling microbes. The use of leak-proof valve technology, especially in doubleseal valves, guarantees immixture-free separation of the media involved (Figure 3). All seals and connections are hygienically designed to the extent possible in conformity with DIN 11864. All of the system's pipes are technically curved, also to the extent possible, with any remaining welding realised exclusively by orbital welding. Any right-angled fittings are substituted by necked-out design. All system components, including the piping, can be cleaned entirely by using the dedicated CIP system of the water treatment plant. To reach the desired temperature of 85°C for the hot water sensitisation (in defined steps of 1°C per minute), the use of automatically regulated heat exchangers is the best option. All system components are sanitised with hot water at 85°C, and finally cooled down to a defined temperature, again at a rate of 1°C per minute. This procedure of heating and active cooling, if repeated on several occasions, enables a simulated Tyndallisation process.

By properly combining all of these measures, it is possible to guarantee maximised microbiological safety without the use of chemical disinfectants in water treatment systems.



Figure 2. Impeccable hygiene is not only important for interior surfaces but for the system's exterior as well, including the tubular frame and stainless steel construction.



Figure 3. The use of leak-proof valve technology, especially double-seal valves, that are manufactured in-house guarantees immixture-free separation of the media involved.



Hygienic double seal valve design

A cost-efficient and technically sophisticated design alternative.

By Steffen Donauer, Pentair Südmo GmbH, Riesbürg, Germany, e-mail: Steffen.Donauer@Pentair.com, www.foodandbeverage.pentair.com

In the food and beverage industry, hygienic double seal valves are primarily used in clean-in-place (CIP) and water distribution systems (Figure 1). However, some plant operators also use these valves directly in production processes for various end-products. Double seal valves are thus ideal for a wide range of applications.



Figure 1. The Pentair Südmo Double Seal Valve SD Economic is an example of hygienic double seal valves used in the food industry.

The purpose of double seal valves in the hygienic process is to reliably separate two incompatible media, such as cleaning fluid and product. This is ensured by two separate seals, between which an open air space enables any potential leaks to be detected and removed. The following article explains the qualities of the set-up and function of a double seal valve, and its advantages over other valve types.

Optimum seat seal arrangement: radial top – axial bottom

In double seal valves separation without mixing is significantly influenced by the design and arrangement of both seat seals. A radial seal to the top and an axial seal to the bottom line is ideal. If the permissible operating pressure is exceeded in the bottom line, for example due to thermal expansion of an enclosed medium, this can result in a movement of the valve disc. With an optimum seal concept, the bottom axial seal opens first, whilst the radial seal continues to seal the top line. The pressure in the bottom line is relieved and leakage gets diverted to the outlets. The mix-proof barrier remains intact and prevents contamination of the medium in the upper line (Figure 2a/b).



Figure 2a. Seat seal arrangement: radial top – axial bottom (closed).



Figure 2b. Seat seal arrangement: radial top – axial bottom (open).

A further advantage of the seat seal described is that even if the permissible operating pressure is exceeded in the upper line and the radial seal is broken as a result, leaks are securely diverted outwards. In this case, the difference is that the increased pressure does not move the disc, but rather, pushes it further into the seat. A metal limit stop prevents damage to the axial seal and allows it to continue to function as a seal.

Problematic seat seal arrangement: axial top – radial bottom or axial top – axial bottom

Other seal arrangements can cause problems. If, for example, the permissible operating pressure is exceeded in the bottom line in the arrangement with the axial seal top and radial seal bottom, a break in the top line seal results. If the top line is filled, this results in an uncontrolled drain via the outlets as a leak (Figure 3a/b).



Figure 3a. Seat seal arrangement: axial top – radial bottom (closed).



Figure 3b. Seat seal arrangement: axial top - radial bottom (open).

A seal arrangement with two axial seals is more problematic, since moving the seal disc causes both seals to lift from the seat at the same time (Figure 4a/b). In this case, both lines are connected with each other such that mixing of the media can no longer be excluded. This seat seal arrangement has a further weakness: Due to the manufacturing tolerances of the valve disc and housing, it is not possible to clearly determine on which of the two seals the full closing force of the actuator stands. This may reduce the pressure tightness of either of the two seals.



Figure 4a. Seat seal arrangement: axial top – axial bottom (closed).

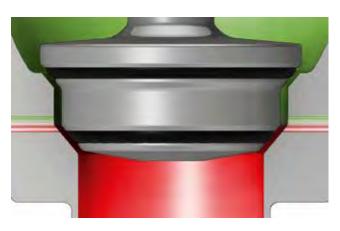


Figure 4b. Seat seal arrangement: axial top – axial bottom (open).

Other design-related features of the double seal valve

On the double seal valve the leakage chamber gets connected or disconnected to the atmosphere via two outlet valves attached to the side. The pneumatic actuators of the outlet valves are coupled directly to the main actuator via a compressed air hose so that a pulse controls all three actuators. This significantly minimises the implementation and control effort.

It is also possible to flush the leakage chamber via an external additional pipe connection. By performing cleaning tests with riboflavin, it has been proven in practice that an 180° offset arrangement of the flush valves benefits optimum cleaning, because this avoids uneven flow velocities in the leakage chamber (Figure 5).



Figure 5. (Left) Mix-proof separation of two media. (Right) Upper line and lower line connected.

Alternatively, the leakage chamber can be sterilised with steam. In combination with a sterile chamber at the spindle of the disc, the possible negative influence of the "elevator effect" can be prevented such that the valve also is suited for sensitive media with high hygienic requirements. The elevator effect means that a part of the valve disc comes into contact with the external atmosphere due to the lifting movement and product contamination due to carryover from the valve stem cannot be ruled out.

The outlet valves are designed such that the dead space between the closed valve disc and the inside of the valve are minimal. This ensures that this area also is cleaned in the open valve position. Thus, external flushing of the leakage chamber can often be eliminated.

Double seal valves compared to other valve types that separate without mixing

In addition to double seal valves, there are numerous other valve types that separate two incompatible media from each other without mixing. The choice of the suitable valve type depends on various factors, such as process reliability, cleanability and price. No universal recommendation can be made. The following explanations can help to better understand the advantages and disadvantages of double seal valves compared to other valve types.

Double seal valve vs. double seat valve

Double seal valves are a low-cost alternative to balanced and/or liftable double seat valves. Balancing, which is not provided by the design, demands less reliability during pressure increases above the permissible operating range. Cleaning the leak outlet by cycling the valve disc without breaking the mix-proof barrier is not possible with double seal valves. It is only possible to cycle the flush valves when cleaning in the open valve position. However, this involves greater implementation and control effort. Furthermore, there are no noticeable differences in terms of the conformities common for the branch, ease of maintenance and process parameters.

Double seal valves vs. leakage butterfly valves

Leakage butterfly valves are a low-cost alternative to double seal valves, but cannot be recommended as process valves for the distribution of products due to their specific design. Cleaning the leakage chamber requires external flushing, which significantly increases the implementation and control effort. For this reason, leakage butterfly valves are almost exclusively used in the CIP sector. Furthermore, the advantages of double seal valves lie specifically in their lower switching loss, better suitability for matrix constructions (valve manifolds) and easier cleanability. In some markets and industries, butterfly valves have been removed from the production process in favour of seat valves in recent years because they are more difficult to clean.

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The key to quality

Meeting hygienic security specifications with automated orbital welding equipment

By Press Department Polysoude S.A.S., e-mail: communication@polysoude.com

The design of production lines and equipment for processing, filling and packaging food, chemical and pharmaceutical products must exclude any contamination. The installations consist mainly of thin-walled pipes with less than 3.5 mm wall thickness, constructed with commonly used materials such as stainless steel or nickel-base alloys like AISI 304, AISI 316 and 904L. Installation critical zones include connections between pipes and joints between pipes and bends or other components. Consequently, reducing the potential for contamination means reducing the number of these connections to a strict minimum.

Welded joints are generally assumed to be the origin of a wide variety of imperfections, including geometry (concavity or convexity, regularity of the weld), surface (roughness, porosity, cracks), material composition (metallurgical and structural changes, colourisation), and fusion (lack of fusion, burn through, crevasses), to name a few. In general, a certain number of weld imperfections exclude the obtained joints from being acceptable. However, for practical and economic reasons, 'perfect' welded joints are impossible to realise. To overcome this, obligatory limits have been specified for all acceptable weld imperfections.

To get satisfactory results, welding operations must be preceded by an extensive planning process, which begins with the conception of the installation. A manual welder needs free access to the tubes to be joined. Very narrow distances between tubes or other obstacles make the welder's work difficult or even impossible. As such, the pipe material has to be chosen with regard to sufficient weldability. Notably, the sulphur content of the alloys is limited between a minimum and a maximum. In addition, the sulphur content of the parts to be welded must not differ too much, and therefore it is strongly recommended parts are manufactured using alloys that are created at the same temperature.

Other concerns associated with ensuring that pipes are suitable include very tight tolerances of geometry and wall thickness, as well as the quality of the pipe end preparation. If machined on-site, the burr-free rectangular preparation without chamfer only can be obtained if proper facing machines are used. Finally, the pipes have to be positioned in a manner that avoids misalignment and gaps between the pipe extremities (Figure 1).



Figure 1. Installation in a food and beverage plant with an orbital welding head. The workpieces must be properly positioned to avoid misalignment.

Automated orbital TIG welding technology is strongly recommended

Recommendations, standards and regulations on surface finishes that will come into contact with food, beverages or medicines define the required quality of stainless steel welded connections. In addition to conforming to both European and American laws, the most important stipulations are specified in the European Hygienic Engineering & Design Group (EHEDG) Guideline Docs. 9 and 35, which address stainless steel welding.^{1,2} These guidelines state that an essential prerequisite to successfully welded joints is the control of the welding process at all stages and, although manual welding is not expressly excluded, automated welding is preferred for its repeatability and consistency. In both the standards of the US Food and Drug Administration (FDA) and in the book "Hygiene in Food Processing," which has a focus on hygienic equipment design, the use of automatic orbital TIG welding for pipework is strongly recommended.3

A well-trained manual welder can, of course, produce quality welds; however, an automated orbital welding machine guarantees constant results together with sustained consistency. Automated orbital welding delivers smooth weld seams that allow adequate cleaning. The seam roots end flush with the internal pipe wall and the minimised and controlled heat input causes the lowest level of oxidation, which, if really necessary, can be removed by etching.

Independent of the chosen welding method – manual or automated welding – adequate equipment and consumables must be made available. Top-class welding gear leads to first-rate results. In manual welding, the craftsmanship of the welder is another important factor, but in automated welding as well, only a well-trained operator who is proficient in his or her tasks will get the desired results in a reliable way. Tungsten electrode products from well-known brands should be preferred. If closed orbital welding heads are the tools of choice, customer-specific prepared electrodes can be purchased. The adequate length and shape of the electrodes enable the operator to change them whenever necessary without worry about machining small pieces, dust release, or similar challenges while working on-site.

Meticulous attention must be paid to the inert gas, which can be supplied by cylinders or a central gas tank. The purity of the inert gas in the cylinder or tank may meet the specifications, but any contamination from tubes, hoses, valves, connections from the distribution system also needs to be reliably excluded (Figure 2). Furthermore, if the devices are subject to changing temperatures, unwanted humidity can be generated.

Poor shielding gas quality is discovered in most cases during the welding process or through an external visual inspection. However, insufficient inerting inside the pipes to be welded is very difficult or impossible to detect, especially when the roots are not accessible. To ensure sufficient root protection, the oxygen content of the outstreaming backing gas has to be monitored, since welding can only be executed if the required low values are reached.



Figure 2. The hygienic, aseptic, sterile and particle-free design of the weld seam surface is smooth and clean, enabling thorough cleaning because product residue cannot adhere and bacteria cannot settle. These are properties that typically are met by using automated TIG orbital welding.

Orbital TIG welding – when quality is the primary concern

When high quality welds are required, orbital TIG welding is the recommended technology for tube-to-tube or tube-tobend welding applications. Fusion welding without additional filler wire is a stable, reliable process that can be used on steel, stainless steel, titanium, nickel, aluminium and their alloys. In the course of the development of appropriate welding parameters, a provisional welding instruction (pWPS) can be created, its final transformation to a weld procedure specification (WPS), a so-called welding program, guarantees the constantly high-quality weld level through automation. The welding cycle can be repeated as often as necessary, always leading to the same result. Once memorised, the welding parameters can be checked at any moment and compiled into a printable protocol for consistent traceability.

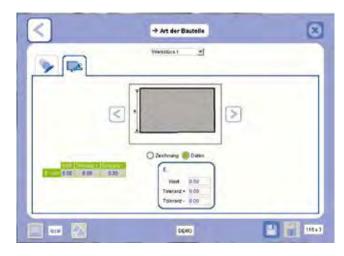


Figure 3. A guaranteed reproducible welding result, which displays the mechanical parameters for tube-end preparation as documented by a state-of-the-art system.

Enhanced efficiency of automatic equipment is achieved due to its precise programming facility. Unlike power sources of the previous generation, the latest units allow the operator to find matching weld programs by means of a touchscreen or personal computer (Figure 3). The operator inputs fundamental data relating to the size and material of the tubes to be joined. The system consults its built-in database to find similar applications, or suggests weld parameters determined by progressive calculation. The proposed welding procedure can be optimised by an expert help menu.

State-of-the-art orbital welding equipment is designed for real-time monitoring of the key weld parameters; a complete weld protocol can be generated and stored or output as a printed document.



Figure 4. Orbital welding equipment on stainless steel tube.

Fusion welds are carried out using portable inverter power sources, combined with closed orbital welding heads (Figure 4). These closed chamber welding heads are especially designed to meet the requirements of hygienic applications (Figure 5). The weld zone is completely covered by the shielding gas inside the closed chamber of the welding head (Figure 6). Thus, all welds are oxidationfree, complying with hygiene requirements.



Figure 5. High-quality welding results – work on tubes and fittings is carried out primarily using closed welding heads.

Conclusion

There are many benefits to using automated orbital TIG welding for pipework joints, especially when the manufacturer requires hygienic application on the production line. The required quality level, in accordance with the common stipulations for all TIG welding processes on steels, titanium and alloys, is constant and reliable. Automated orbital TIG welding has a positive impact on quality, because it creates the smooth weld seams required for comprehensive cleaning, together with a weld seam sealed flush with internal pipe walls, which are essential factors for the bacteria-free production of drinks, food and pharmaceuticals.



Figure 6. Orbital welding equipment on stainless steel tube with backing gas for the oxidation-free welds.

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Zero defects in orbital TIG welding

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Level measurement of highly sensitive and delicate products

The food and pharmaceutical industries are placing ever higher demands on level measurement systems in terms of hygiene and cleaning capabilities. The design and fit of all devices is therefore becoming particularly significant. They are required to be flush, crevice-free and made from approved materials. Radar level transmitters with a new 80 GHz technology not only meet these hygiene requirements but also offer further advantages to the industrial sectors.

By Jürgen Skowaisa, Product Manager Radar at VEGA Grieshaber KG, Germany, e-mail: j.skowaisa@vega.com, www.vega.com

Level sensors serve both to measure the tank contents and to prevent overfilling. Radar filling level measuring instruments are ideal for such applications, because they measure without product contact and thus meet hygiene requirements. However, some difficulties – at least from a level measurement point of view – are caused by agitators or cooling coils, because they can create interfering reflections to a non-contact level device.

In the past, sensors often had to be adapted to internal installations by means of suppression or mapping of unwanted signals. The new radar level sensor for liquids is developed for this kind of application. It operates at the high frequency of 80 GHz (26 GHz frequency was previously the norm).

The front-flush encapsulated antenna is designed to be easy to clean and insensitive to the extreme conditions of sterilisation in place (SIP) and cleaning in place (CIP) processes.

A high measurement accuracy is achieved, even in high tanks with installations and agitators, due to tighter focusing. The focusing of a radar measuring instrument depends on the transmission frequency and the effective surface area of its antenna. Without changing the size of the antenna, this higher frequency enables precise focusing. At an antenna size of approximately 80 milimetres, the beam angle is only three degrees, whereas a sensor with a 26 GHz transmission frequency and the same sized antenna has a beam angle of 10 degrees. Or in other words, also with smaller antennae, a reasonable beam angle is possible (Figure 1).



Figure 1. The smallest antenna of the radar level sensor for liquids is no bigger than a 1 euro coin, which makes it adequate for installation in small tanks.

The narrower beam angle delivers a much better and consistent level measurement in applications that were previously a great challenge (Figure 2).

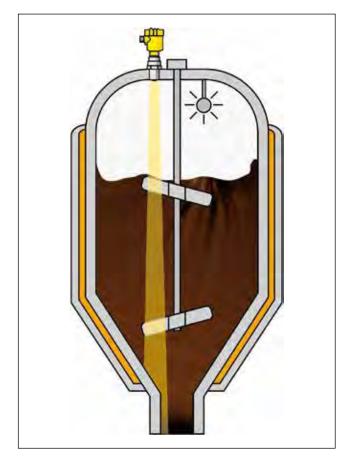


Figure 2. In the new radar level sensor the radiation angle is three degrees only. The sensor can therefore measure the filling level reliably, even in tanks with agitators.

Adapts to changing media

Typically used in the food industry are small filling tanks, measuring about one metre in height and 60 centimetres in diameter, that supply filling heads on the production lines. Products can range from jam and peanut butter, to chocolate spread.

Another typical feature is that these media differ in viscosity and temperature, and have varying densities dependent on conditions inside the tanks such as agitation, condensation, foaming and splashing. The flavours and fragrance industry also uses small tanks with many internal installations. These require cleaning several times daily when changing batches, so a flexible filling level measurement is essential – one that can measure independently of process parameters such as temperature, pressure and the liquid density, and that is adaptable to changing conditions (Figure 3).



Figure 3. The new radar level sensor is available with antenna systems in different sizes and hygienic fittings.

But the advantages of a radar level sensor also can be seen in another aspect. There is a clear trend towards small batches in the food and pharmaceutical industries, so tanks and equipment are becoming increasingly smaller. In the past, the radar measuring technique often met with difficulties in these areas and problems were mainly caused by physical issues. These included the blocking distance of the sensor (that is the distance between the sensor connection and the liquid surface), the large size and the design of the antennas, and the measuring uncertainty with media, such as cooking oil with poor reflection properties.

This is where 80 GHz provides benefits. The tight focusing of the sensor not only proves effective for installations such as agitators, but also allows the use of small process connections. This is because the three times higher transmission frequency to existing devices enables three times smaller antenna sizes, which still achieve a similar signal focusing. Therefore, smaller process connections with an antenna size of only 20 millimetres, or three-quarter inch, are possible (Figures 1 and 3).

Unaffected by buildup

An interesting example is the manufacture of processed cheese, in which different types of cheese are combined and melted in a mixing tank. The challenge: the cheese sticks to the walls and is scraped off. Even with this heavy buildup, the radar level sensor is able to measure safely and reliably. And, despite the much shorter wavelength and the high transmission frequency, the sensor is not affected by deposits or condensation forming on the antenna. This is achieved by optimisation of the sensitivity in the near range of the sensor. A distance-dependent dynamic adaptation reduces the influence of interference directly before the antenna system, and at the same time, enables very high signal sensitivity over longer distances. This is also true because the sensor has a flush and an encapsulated antenna system integrated into the process connection. With the previous 26 GHz transmission frequencies, it was often difficult to measure media with poor reflective properties, such as cooking oils, with high accuracy when the level was near to the tank bottom. With 80 GHz it becomes easier. In media with low dielectric factors, part of the radar signal penetrates the medium and it is reflected back by the tank bottom beneath. Therefore two signals are received: The actual liquid level and also the tank bottom. If the dielectric factor of the medium is very low, and the signals of the tank bottom (e.g., a flat metal bottom) are greater, the radar will go prematurely to zero, even though there is still a liquid level in the tank. Penetrating signals are damped more strongly in the medium with 80 GHz than with 26 GHz sensors. The reflection from the bottom of the tank is less, which results in a better measurement down to the bottom of the tank than is possible with previous sensors.

Since the antenna system is integrated into the process connection, no antenna protrudes into the tank. It is also possible to measure very close to the process connection. Therefore, the volume of the tank is utilised efficiently and creates higher process flexibility.

New sensor generation

Although the radar level sensor belongs to a new sensor generation for liquids, the user still expects the performance of a proven device. In 2014, VEGA launched a high-frequency level sensor for bulk solids onto the market. This instrument also operates with the same high frequency band and has since been installed in more than 10,000 applications worldwide. It functions well in silos and in applications with many installations, which in turn create many interference signals. The most important electronic components and technologies of this instrument have been adopted in the new liquids radar level sensor for good reliability. However, the difference is that the radar level sensor operates with a wider bandwidth of four GHz, to create a clearer separation of individual echo signals in liquid-level applications.

The operation of the devices follow a familiar routine, because the new radar level sensor is also integrated into VEGA's instrument platform. The display and adjustment module serves as usual, for both the operation of the sensors and local display of the measured values. A computer or special software is not required. This display and operating module can be inserted into and removed from the sensor at any time without interrupting the power supply.

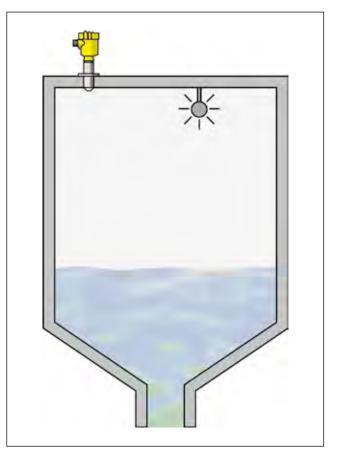


Figure 4. Aroma tanks are cleaned several times a day when changing batches. The radar level sensor adapts to the changing conditions and measures the filling level reliably, independent of process changes such as temperature and pressure.

Later installation without re-acceptance

As such small process fitting sizes can be used, the radar level sensor is easy to install onto existing connections, which is of particular interest in the food industry where plants and processes are acceptance tested and any subsequent engineering alterations are only possible by utilising considerable resources. One example is the manufacture of polyvinyl acetate – also known as the gum base of chewing gum. This takes place in a reaction vessel with a four-level agitator. The reaction of the different basic materials starts when these are mixed by the agitator.

Simple installation is also a plus. The sensor can be installed through existing process connections, which in itself used to cause great interference reflections in the near range. This type of installation repeatedly led to problems because the relatively small echoes of the product's surface could not be measured optimally due to interfering noise from the valve in the near range. The device now works more precisely through a valve because the sensor has a tighter signal focusing, which means it gets a stronger signal from the product and the interference from the ball valve are almost nonexistent. Threaded versions can be adapted with appropriate adapters (e.g., to clamp connections). Crevice-free process fittings, where polytetrafluoroethylene (PTFE) is the only wetted material for use in the aseptic area, are available. These will meet 3-A Sanitary Standard, US Food and Drug Administration (FDA) and European Hygienic Engineering and Design Group (EHEDG) requirements. The sensor also has approvals for use in hazardous areas.

Application in bioreactors

Some pharmaceutical companies use bioreactor vessels to cultivate particular cells or microorganisms required for the production of enzymes, proteins and antibodies. The very high level of hygiene required means the vessels and all associated parts must be easy to clean, because even the slightest contamination with other organisms can lead to an aborted production run.

These reactors are mainly "batch-fed," in which they are completely filled at the start and not emptied again until the process is completed. The pressure and level in the reactor have to be monitored continuously during process in order to obtain a high-quality yield (Figure 5).

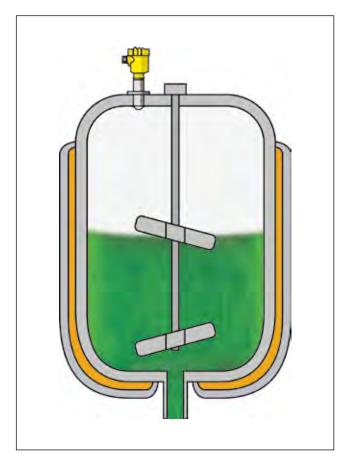


Figure 5. Radar level sensor for continuous level measurement in the bioreactor.

Application in storage tanks for liquids

Many different liquids with widely varying properties are required in the pharmaceutical production. Products have to be stored and held ready for subsequent processing at all stages. These are used as catalysts for the decomposition of compounds and stored in a wide variety of concentrations. Some of these products are acids.

For smooth production and optimal storage, reliable level measurement and point level detection of raw materials, intermediates and finished products are absolutely necessary (Figure 6).



Figure 6. Non-contact level measurement with radar in storage tanks for liquid raw materials, intermediates and finished products.

Conclusion

The new high frequency of 80 GHz enables new fields of application for the use of radar technology in the pharmaceutical and food sectors. The small process connections can be optimally adapted to the new radar sensors, also on small production facilities, where a 26 GHz sensor is too big to mount. Special process connections, designed for the demands of these industry branches, are easy to clean and fulfil high hygienic requirements.



The development of stainless steel production technology and its impact on hygiene

By Krzysztof Kaczmarczyk, ATT INOX DRAIN, e-mail kaczmarczyk@att.eu, Poland

It was only at the turn of the 18th century that serious discussion began on the topic of hygiene and bacteriology. It was in the 19th century that the foundations of our current knowledge on the subject were laid. However, at a time when food was produced locally on small farms and its processing was limited to the seasonal pasteurisation of produce, no one thought of introducing hygienic standards for food production. It was only with the development of industrial food production that the real efforts for safety in food processing began.

Undoubtedly, one material that has aided in this process is stainless steel, and the products made from it are able to meet the highest hygienic standards. It should be remembered, though, that the material itself does not provide an absolute guarantee of hygiene. The growth of microbes and bacteria can take place in any area in which organic residues from the food production process collect.

The use of hygienic materials is only half the battle in assuring food safety on the production line; the other crucial element is the way in which the individual elements are constructed from this material. To achieve a satisfactory product quality that meets the highest hygienic standards, it is essential to implement best practices in hygiene starting as early as the design stage. An awareness of the hygiene requirements of the machinery among the engineering staff permits the elimination of impromptu solutions at the construction stage, which may not meet the hygiene standards that have been set.

Today, as quality and hygiene requirements for food processing plants continue to grow, it is wise for equipment manufacturers to invest in a research and development (R&D) department. The R&D team keeps track of the market in terms of the demands of the end customer, modifies existing products and introduces new ones, and supports the work of the sales and design departments.

In addition, stainless steel equipment manufacturers can raise the hygienic quality of their components by working closely with food processors to identify troublespots in the production process itself. An analysis of these processes and the creation of production management systems make it possible to create a flexible production process that can be adapted so that the final product meets the highest standards of quality. By fully engaging the production personnel who have working knowledge of the food product characteristics and process protocols, potential trouble areas can be identified at every stage of production. In turn, this analysis helps the equipment manufacturer design and engineer components that meet the hygienic needs of the food plant.

An asset for manufacturers of stainless steel equipment and components has been the development of laboratory techniques for the study of stainless steel. These studies have resulted in the accumulation of very precise knowledge about the chemical composition, malleability characteristics and mechanical properties of the material. This knowledge enables the equipment manufacturer to select the appropriate type of material and machining technology for a given product. The near universal automation of stainless steel machining processes, such as CNC cutting and shaping machines and automated welding systems, is another advancement that helps to create smoother and therefore more hygienic surfaces. This combination of detailed knowledge of the material being used, the automation of its production, and appropriately selected design technologies means that a final product can be achieved that meets the highest standards of quality and hygiene.

Among relevant examples of technologies that have a positive impact on the manufacturing of stainless steel equipment elements are:

 Pressing elements of the body, trap, and other components means that the number of welded joints can be reduced, thus limiting areas where bacteria can collect. Figure 1 illustrates the smooth surface of a pressed body.



Figure 1. Pressed body. The arrow points to the smooth bottom surface of a pressed drain body, where absence of welds has eliminated a typical hygiene troublespot.

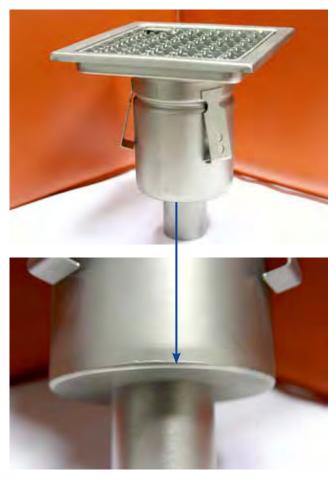


Figure 2. Welded body. The arrow points to the bottom of the drain body, which when produced through automated processes rather than manually, reduces surface irregularities as shown here.

- Eliminating manual welding and replacing it with automated processes reduces irregularities and raises hygiene standards (Figure 2).
- Automation of the pickling and passivation process of stainless steel products is intended to reduce the harmful effects of machining and welding on the passivation layer.
- Abrasive machining of sharp edges eliminates areas where contamination can collect (Figure 3).



Figure 3. A stainless steel mesh grating during the vibro-abrasive process using ceramic mouldings material.

The growth in the number of food processing companies has spurred industry equipment suppliers to consistently raise the quality of the products they sell to guarantee safe and hygienic final food products. One conclusion is clear: It is not the material nor the technology nor good design alone, but rather a combination of the three that results in functional and hygienic equipment. It bears repeating that the technological process consists of many components, all of which need to be continuously developed and monitored, and the combination of all these components results in a product of the highest hygienic standards.



Self-cleaning and flow in drainage systems

In food production sites, the floor drains are the interface between hygienic production areas and a contaminated sewer system. Certain product features in drainage systems, such as opensided gratings, large filter baskets and removable water traps, are to a high extent self-cleaning, and consequently, they can contribute to a high level of hygiene.

By Palle Madsbjerg, BLÜCHER Export Manager, Denmark, email: pm@blucher.dk, www.blucher.com

Fast removal of solid waste

For hygiene and safety reasons it is important to remove solid waste from the floor in food processing areas. In most cases, it is flushed into a drainage channel or point drain. To secure easy access to the drainage of these particles, there should not be any barriers to flushing through solid waste. This can be ensured by installing gratings with open sides, as opposed to traditional gratings with frames around the sides (Figure 1). The latter tends to hold back the waste, which remains on the floor around the drainage. It is important to note that channels are more difficult to clean than point drains, and should be used only where necessary when designing a hygienic drainage layout.



Figure 1. Gratings with open sides allow easy access of solid waste into the drainage system. The frame of some gratings holds back solid waste on the floor.

From the perspective of hygiene and cost-efficient cleaning, solid waste should be manually removed from floors and placed into waste recepticles. However, some solid waste will always be rinsed to drain and drainage systems should be designed so that solid waste is removed manually from one spot only: the filter basket. Flushing the channel to make solid waste in the channel move towards the filter basket is not a good solution, nor is removing the gratings to take out deposited solid waste. Such actions take time and are not very hygienic processes in and of themselves.

The first challenge in improving self-cleaning of drainage channels – a decidedly more hygienic approach – is to ensure that solid waste is transported to the lowest point of the channel, since this will hold an adequate volume of water to flush the solid waste towards the channel outlet. To ensure this, a U-shaped channel is described in the European Hygienic Engineering & Design Group (EHEDG) Guideline

Doc. 44, Drains. Due to its steep sides, this channel shape makes the solid material slide towards the bottom where the water is flowing (Figure 2).

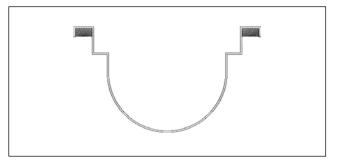


Figure 2. U-shaped channel – EHEDG DOC.44, Figure. 8.7.17.

The second challenge is to ensure a sufficient level of water to lift solid waste with a density lower than water away from the bottom of the channel so that it floats in the water and is more easily transported towards the outlet.



Figure 3. Channel flow testing.

The bottom of a U-shaped channel is rather flat and requires a significant volume of water to lift waste to a certain level. Consequently, if the steep sides of a U-shaped channel can be combined with a V-shaped bottom, then it will take a smaller water volume to create the necessary water level for lifting the solid waste (Figures 3 and 4).

With an increasing focus within the food industry on reducing water consumption, the demands on drainage systems are changing. This should be kept in mind when designing production facilities for the future. If this is not taken into consideration there is a risk that money saved on water consumption will instead be spent on increased cleaning costs. Thus, the expected benefit of the investments in water saving will not be achieved.



Figure 4.U-shaped channel with V-shaped bottom.

Water on the floor

Research shows here is a higher risk of water pooling on the floor in areas with large amounts of solid waste due to restricted flow in the drainage system. In many cases, the reason is limitation of flow through the filter basket. It has become apparent that the amount of solid waste to be expected is often underestimated by decision makers, and often there will not be any plan for emptying filter baskets during the day. Furthermore, flow is often calculated based on an empty filter basket, whereas a full filter basket will restrict the flow dramatically. For this reason, it is good to use an oversized filter basket rather than a smaller one (Figure 5). A filter unit that can be installed in the drainage channels is commercially available. It can be inserted in target areas where the amount of solid waste is very high, and it leaves space in the outlet filter basket for waste from other areas.



Figure 5. A 7-litre filter basket that is filled halfway allows full flow. A channel filter can hold back waste before it enters the channel.

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Typically, the flow capacity in drainage is determined based on the capacity of the water trap, and as mentioned, sometimes the restrictions of flow are actually in other areas. But to secure sufficient flow through the water trap it is important to ascertain that the flow stated by the supplier is in accordance with comparable figures. Therefore the requirements in EHEDG Guideline Doc. 44 for hygiene in buildings using flow tests defined in EN 1253 can serve as an appropriate guideline for utilising a water trap with a documented and comparable flow indication.

Safe and hygienic barrier between sewer system and hygienic area

Traditionally, water traps in drainage systems have been either P-shaped types or welded in as an integral part of the drain. From a plumbing point of view, this is considered an acceptable solution. From a hygienic point of view, however, the presence of contaminated water that cannot be removed from nearby hygienic processing areas is problematic. In some facilities, there have been attempts to solve this by filling the traps with disinfectant, which is not a recommended solution when one considers the higher costs and reduced efficiency. Therefore, water traps that can be removed from the drain bowl and/or drain bowls that can be emptied have become the standard.

All drain points with removable water traps also can be used as cleaning and rodding points, which saves time and money if piping has clogged.



Figure 6. Removable water trap complying with EN 1253.

Removable water traps as we know them today were developed in Denmark in the 1970s. This design offers the advantage of ensuring that the water trap will not run dry even if a sealing ring is leaking. Consequently removable water traps are considered a safer solution than the bell-type water traps. In addition, tests in accordance with EN 1253 standards show good self-cleaning capabilities for these water traps, which translates to less maintenance work for the building owner while maintaining a high level of hygiene (Figure 6).

Even with the promise of reduced water consumption used in cleaning processes in the food production plant, it is important to use products designed for this specific environment. For drainage systems, self-cleaning functionality and an easy-toclean design are essential in enabling the industry to reach its target of saving water while optimising hygiene.



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Traceability of rubber parts for food contact

Rubber parts, such as gaskets, bellows and diaphragms, are widely used in the food and pharmaceutical manufacturing industry. It is paramount to customer food safety that all food contact materials fulfil meaningful requirements. The question is, what are meaningful requirements when it comes to the traceability of rubber parts?

By Anders G. Christensen, Sales and R&D Director, AVK GUMMI A/S, Denmark. e-mail: avk@avkgummi.dk

Traceability is important to ensure the right quality of equipment during design and installation and for backtracking in the event of a failure. Applying a product traceability process to the raw materials used for making parts for food processing equipment can be very complex because the materials are often manufactured by second- or third-tier suppliers. Rubber as a food contact material (FCM) is even more complex, since such formulations vary from one rubber manufacturer to another.

To ensure food compliance, a number of regulatory instruments exist, including US Food and Drug Administration 117.2600, 3-A Sanitary Standards (18-03) and European Commission No. 1935/2004. Such regulatory requirements need to be taken into consideration when building a traceability hierarchy.

Given these challenges and mandates, how can a traceability system be designed that covers the rubber materials used for gaskets, diaphragms, bellows, and so on? A simple representation of the supply chain in question is as follows:

- Tier 0: Food manufacturer
- Tier 1: Plant or process line supplier
- Tier 2: Valve, pump or flowmeter supplier
- Tier 3: Gasket, diaphragm or liner supplier
- Tier 4: Rubber compound supplier
- Tier 5: Suppliers of ingredients for rubber compounds

Needless to say, if a food manufacturer has more than one supplier, and if this repeats upstream, the challenge of tracing rubber compounds increases dramatically. Clearly, it is valuable to reduce the complexity of the supply chain as much as possible, not only in relation to the number of competing suppliers but also in relation to the number of tiers. For example, if a gasket manufacturer also develops and produces the rubber compounds, the traceability process is simplified because the manufacturer takes responsibility for the entire supply chain back to the qualification of the ingredients.

Traceability from rubber ingredients to gasket manufacturing

As a rubber compound and moulded rubber parts manufacturer, AVK GUMMI covers the supply chain from tiers 3 to 5. For the FCM process flow, the following 15-point product quality plan developed and used by AVK GUMMI can be applied by the rubber parts supplier to ensure traceability: **1. Receipt of rubber ingredients.** Ingredients for rubber compounds are qualified and sourced from approved suppliers according to specifications. Raw materials are selected to comply with a generic certificate (Figure 1).

2. Receiving inspection. The first three deliveries are inspected and controlled in the quality laboratory. The deliveries are released based on a certificate and a sampling plan for additional testing.

3. Rubber ingredients stock. Barcode registration and labelling is done. Ingredients are stored according to DIN 7716.

4. Weighing of rubber ingredients for mixing. This involves automatic double-check weighing and automatic dispensing of rubber ingredients directly into the mixer.

5. Mixing of rubber compound. For every mixing batch, a charge number is generated. An automated mixing process is developed for the specific recipe. All process data are automatically stored.

6. Inspection of rubber compound. Every batch is inspected and released based on rheological properties. A batch label showing all basic data is generated following the batch downstream to final inspection.

7. Rubber compound stock. Rubber compounds are stored according to DIN 7716. The shelf life depends on the formulation.

8. Vulcanization of rubber parts (e.g., gaskets). For vulcanization of the parts, the mould and machine are matched and process variables set automatically for the specific rubber part. Process data are automatically stored. The production order is matched with a part number, a compound batch number, etc.

9. Operator's inspection of rubber parts. Rubber parts and process parameters are inspected by the operator against an item-specific inspection plan. Data is stored for 20 years as with all other FCM documentation.

10. Post curing. FCM parts are post cured for removal of undesired vulcanization decomposition products. Partspecific post cure programmes are set automatically, and data is recorded and stored automatically.

11. Post cure inspection. Inspection of recorded post curing data is conducted.

12. Cleaning of rubber parts. Excess rubber from the split lines in the moulding process is removed in an automated process.

13. Final inspection. The rubber part is inspected against a specific final inspection plan. The results are registered in a final inspection report, including reference to upstream inspections.

14. Stock of finished goods. Rubber parts are packed and labelled according to customer requirements and stored in accordance with ISO 2230.

15. Packing and shipment.

	are in compliance with the following regulations:		
GMP	Good Manufacturing Process in accordance with 2023/2006 EC		
REACH	In accordance with regulation EC 1907/2008, Candidate List of Substances of Very High Concern (12.01.2017) Substances Istati n Annex XV (14.08.2014) Substances listed in Annex XVII (08.05.2014)		
RoHS + RoHS 2	In accordance with the Directive 2002/95/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 JANUARY 2003 and Directive 2011/85/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 JUNE 2011		
Bisphenols	Do not contain Bisphenols as described in 1895/2005/EEC. BPA, BADGE, BFDGE, NOGE		
Phthalates	Do not contain phthalates		
Latex	Do not contain latex		
ODS	Do not contain Ozone Depleting Substances, In accordance with the Regulation EC 1005/2009 OF EUROPEAN PARLAMENT AND OF THE COUNCL OF 16 SEPTEMBER 2009 and Regulation EC 2037/2000 OF EUROPEAN PARLAMENT AND OF THE COUNCIL OF 29 JUNE 2000.		
ADI free	Do not contain any substances originating from humans or animals.		
Hazardous Materials	Do not contain any hazardous substances as described in the Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships, 2009		
Conflict Materials	In accordance with US Law: 'Dodd Frank Wall Street Reform & Consumer Protection Act', sec 1502, of 21.07.2010.		
Yours sincerely, AVK GUMMI A/S Henrik Pedersen R&D Manager	Anders G. Christensen Sales and R&D Director		

Figure 1. Generic certificate.

For Medico parts, the process flow is further reinforced, including double control throughout the entire process, quality assurance release and extended data storage time.

Change control

Over time, a rubber compound may need to be adjusted for various reasons. For instance, an ingredient may have been modified or discontinued. While this may seem a minor issue to some, the impact may be severe if it is not addressed properly. In some cases, a simple substitution may be possible. In others, a reformulation may be necessary in order to maintain satisfactory mechanical, chemical or thermal properties. In such a situation, it is important to involve customers and regulators to validate the updated rubber compound. Depending on how critical the change, such validation programmes may last for months, if not years. Therefore, it is of great importance to initiate the dialogue in good time. A successful validation is only completed through renewed approvals from customers and regulators.

Original spare parts

For the food manufacturer it is essential to have confidence that the process equipment remains unchanged compared with the original specification. Since most rubber parts undergo wear and tear over time and are subject to replacement, they are often part of the preventive maintenance plan.

Standardised rubber parts, such as O-rings, clamp sealings and even unauthorised copies of special parts, are available through wholesalers. While some of these may claim to meet certain criteria (e.g., FDA), the quality is often doubtful, and the traceability has been lost. While it may seem tempting to purchase cheap spare parts on the Internet, the savings will not only lead to loss of traceability but also to an increased risk of product contamination and reduced efficiency due to unintended downtime and less cleanability. Using original spare parts is the obvious solution to maintaining a high-quality food process line with good traceability.

Damage analysis and preventive actions

Rubber parts become worn over time. Sometimes this happens unexpectedly, either because the material selection was wrong for the application or because an error has occurred during manufacturing of the part.

In these cases, it is critical to find a quick and durable solution. A close dialogue between the end user and the rubber part manufacturer is very helpful, although it may be difficult to uncover the actual circumstances under which the part has failed. During such an investigation, a complete mapping of the actual manufacturing process takes place. If an error has occurred, the potential root causes will be investigated, and preventive and corrective actions will be identified and anchored in the design or process FMEA.

Consequently, manufacturing instructions are updated. Inspection of the failed part, supported by information about the conditions under which it has been used, will lead to a more qualified rubber material or suggestions for optimising the working conditions. Although failures are always unwanted, very often an investigation and dialogue into failures create opportunities for improvements to be implemented.

Three steps to ensuring traceability of rubber parts

The answer to the question, "How can a traceability system be designed that covers the rubber materials used for gaskets, diaphragms, bellows, etc.? As discussed here, the first step is to use original parts. The second step is to request date marking on rubber parts (Figure 2). If this is not possible, tracking to delivery notes is necessary (Figure 3). And the final step is to work with rubber part manufacturers who can provide satisfactory process flow traceability. This can be validated through audits, either by the customer or a third party.



Figure 2. Rubber gasket with date marking.



Figure 3. Wedge with delivery note.

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Decontamination of food industry cleaning brushware – a matter of hygienic design

The importance of using hygienically designed cleaning equipment is recognised by both the Food Safety System Certification (FSSC 22000) and the British Retail Consortium (BRC). Both of these organisations' current food safety standards state that '(Cleaning) tools and equipment shall be of hygienic design...,' but what impact do these requirement have on the food industry?^{1,2}

By Debra Smith, Vikan (UK) Ltd., United Kingdom, e-mail: dsmith@vikan.com

Thanks to organisations such as the European Hygienic Engineering & Design Group (EHEDG), many food manufacturers already appreciate the benefits of using hygienically designed production equipment. Equipment and components designed with hygiene in mind are quicker and easier to clean, which minimises the risk of microbiolgical, chemical and physical contamination, as well as pest infestation. This in turn maximises food safety and quality, reduces the risk of expensive product rejection or recall, and minimises food waste. However, when it comes to the equipment used to clean the food production environment and production equipment, the need for good hygienic design of the cleaning tools is often not considered appropriately.

Typically, cleaning equipment is used over large surface areas and therefore is capable of collecting (and subsequently spreading) contamination. There may be an expectation that any contamination collected by the cleaning equipment is subsequently removed as part of the cleaning process. However, unpublished data from Campden BRI, used to establish guidance on effective microbiological sampling of food processing areas, showed that 47 percent of the cleaning equipment sampled was positive for *Listeria monocytogenes*.³ This observation gave rise to the concept of cleaning equipment as a major 'collection' point for the isolation of pathogens.

Whether this observation was due to poor hygienic practices or to the poor hygienic design of the cleaning equipment (or both) is unknown. However, investigations conducted by Vikan indicate that much of the cleaning equipment currently used in the food industry is of poor hygienic design, which increases the risk of contamination from this source. It is clear that the ability to clean the cleaning equipment itself is critical to ensuring food safety and quality, and that the application of good hygienic design criteria will help in this regard.

Current food industry cleaning equipment decontamination practices

Traditionally, food industry cleaning equipment used in wet environments is decontaminated at the end of the production day – or more frequently if required – through immersion in warm soapy water, by use of a hose, and/or by manual cleaning. These actions are followed by the application of a chemical disinfectant, or by loading it into an onsite cleaning system, like a tray washer, before being hung up or placed in an oven to dry. During the day, cleaning equipment may also be placed in a 'sanitiser bath.' The sanitisers used in these baths tend to be a combined detergent-disinfectant chemical that is perceived to help remove soiling and disinfect the equipment simultaneously. However, there can be issues with sanitiser baths. This includes the potential for organic soiling on the cleaning equipment to quickly reduce the efficacy of the disinfectant component of the sanitiser, and act as a protective barrier to the microorganisms present. Consequently, if the sanitiser solution is not changed at an appropriate frequency, it can became a 'soup' of food debris and microbes that can increase the risk of crosscontamination from the cleaning equipment.

In some dry goods industries, brushes are not wet cleaned at all, for fear that the moisture introduced by the cleaning may not be completely removed by drying, subsequently leading to microbial growth and increasing the risk of cross-contamination. Instead brushes are used until they are deemed 'unfit for purpose' and then thrown away and replaced. In some high risk dry goods environments, like baby formula manufacture, brushes are used once and thrown away rather than risk the possibility of crosscontamination. This is an expensive and wasteful practice but it has been deemed the best way to ensure food safety for this critical consumer group.

A few food manufacturers also use an autoclave to subject the equipment to a thermal disinfection step following cleaning. More recently, some manufacturers are using industrial dishwashers or washing machines to effect both cleaning and a thermal disinfection step into the decontamination process.

Some of these cleaning practices are employed to maximise the cleaning of equipment with poor hygienic design, particularly with regard to the presence of crevices, which can harbour food debris (including allergens), water, and microbes. This may be the driver behind the relevant FSSC 22000 and BRC audit requirements, but how does the food industry ensure compliance with these requirements?

Hygienic design criteria

Currently, there are only two groups within Europe that provide hygienic design criteria relevant for application to cleaning equipment and they are as follows,

The European Hygienic Engineering & Design Group (EHEDG)

Founded in 1989, EHEDG is a consortium of equipment manufacturers, food industries, research institutes and public health authorities that aims to promote hygiene during the processing and packing 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 Guideline Document 8: *Hygienic Equipment Design Criteria*, and Document 32: *Materials of Construction for Equipment in Contact with Food* provide some hygienic equipment design criteria that can be applied to the manufacture of food industry cleaning equipment, including,^{4,5}

- free of crevices and contamination traps; e.g., use of smooth welds, absence of small holes, recesses, and sharp internal angles
- a smooth surface finish ($R_a < 0.8 \mu m$)
- easy to clean (and dry); e.g., quick and easy to dismantle/re-assemble, or of one-piece construction, or with easy access to all areas for cleaning and disinfection
- made of food safe materials; e.g., no wood or glass, non-toxic
- well constructed; e.g., durable, no foamed materials, not painted or coated
- non-absorbent
- appropriately temperature and chemical resistant.

The European Brushware Federation (FEIBP)

The FEIBP provide further criteria specific to brushware and other manual cleaning equipment. In 1995, the group established a Professional Hygiene Brush Working Group to formulate a FEIBP charter defining criteria for professional hygiene brushware (PHB).⁶

EHEDG and FEIBP guidance assist food manufacturers in selecting appropriately designed cleaning equipment for use in production, but there is a general lack of awareness with regard to the hygienic design of manual cleaning equipment that remains to be fully addressed.

Hygienic design of food industry brushware

The hygienic design of brushware poses a particular challenge. The most commonly used construction method for brushes and brooms involves the drilling of holes into a solid plastic block and then stapling tightly packed bristles into the holes. This creates possible dirt traps, both within the holes and between the bristles. The bristles themselves also present a foreign body risk. Other brushware manufacturing techniques do exist, such as fused filament and resin set, but investigations conducted by Vikan show that all have hygienic design issues. The hygienic design of equipment can be assessed in a number of different ways, including visual inspection, use of an ultraviolet (UV)-sensitive lotion, and use of a commercial washer disinfector soil. Often, simple visual inspection by eye or using magnification, combined with the guidance from EHEDG and FEIBP and common sense, can identify hygienic design issues.

Figures 1a and 1b show the surface finish of a fused filament food industry cleaning brush where the numerous 'creases' in the surface provide ideal harbourage for contamination and will prove difficult to clean.



Figure 1a. Surface of a fused filament cleaning brush shows numerous creases that can provide harbourage for contamination.



Figure 1b. A magnified view of the fused filament cleaning brush showing its difficult-to-clean surface finish.

UV lotion typically is used to help visualise difficult-toclean areas of the hand following handwashing. The lotion is applied to and thoroughly rubbed all over the hands, which are then washed and dried using a prescribed handwashing method. The hands are then viewed under a UV lamp, which reveals any 'contamination' remaining on them to demonstrate areas where it is particularly difficult to remove or has been missed by the handwashing. Vikan have applied the principles of this test to investigate the hygienic design of food industry drainage systems and cleaning brushware.^{7,8}

Figures 2a and 2b show a traditional drilled and stapled brush that has been 'contaminated' using a UV-sensitive lotion and decontaminated by vigorous dunking in warm, soapy water. Figure 2a clearly shows UV lotion trapped between the brush block and the bristles in the drilled holes. Figure 2b shows a vertical cross-section of one of the drilled holes that reveals residual UV lotion lining the hole within the brush block.



Figure 2a. Drilled and stapled brush after cleaning. UV lotion trapped between the brush block and the bristles.

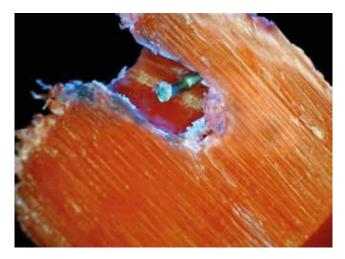


Figure 2b. Vertical cross-section of a drilled hole containing residual UV lotion after brush cleaning.

Alternative methods of fixing bristles using resin have been employed as a way of eliminating or sealing drilled holes, but even these have hygienic design issues. Figure 3 shows a resin set brush following investigation using UV lotion. Residual, contamination can clearly be seen trapped within the loop formed by the brush bristles.

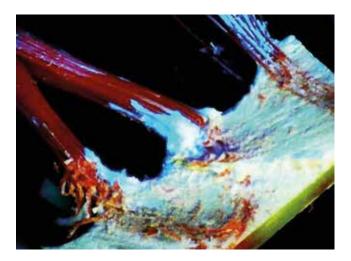


Figure 3. Image of a UV lotion 'contaminated' resin set bristle bundle after cleaning.

Drilled and stapled resin set brushware were investigated using a commercial washer disinfector soil. This red, protein-based soil is used by the United Kingdom National Health Service to validate the decontamination of surgical equipment by industrial dishwashers. The dry powder soil is reconstituted using a set volume of water to form a thick solution that is applied to the object under investigation. The 'contaminated' object is then allowed to dry for a period of 2 hours at room temperature before being placed into an industrial dishwasher and cleaned. Cleaning validation is assessed visually through observation of any remaining soil. Figure 4 shows how the red soil has penetrated between the bristles where the resin fails to seal between them, thus creating a narrow channel that has not been possible to clean during the dishwashing process.



Figure 4. 'Contamination' (red) trapped between the bristles of a drilled and stapled resin set brush following decontamination using an industrial dishwasher. Channel depth is approximately 8 mm.

Additionally, with regard to materials of construction and food safety, some of the resins used in the manufacture of resin set brushes fail to meet all of the European Union (EU) food contact regulations.^{9,10} Cleaning equipment manufacturers should, on request, provide documentation that demonstrate

appropriate compliance to these regulations, including Declarations of Compliance and migration test reports. Further information on how to ensure cleaning tools are food safe and compliant with legislation has been published in *International Food Hygiene*.¹¹

Most recently a new food industry brushware option has been developed in line with EHEDG hygienic design principles to optimise hygienic design. These Ultra Safe Technology (UST) brushes have a fully moulded construction that eliminates the need for drilled holes, staples and resin, thus minimising the risk of contamination from trapped food, microbes and moisture (Figures 5a and 5b).



Figure 5a. Vertical cross-section through a UST brush to show its fully moulded construction.



Figure 5b. The unique bristle pattern for the UST hand scrub brush, along with the fully moulded construction, minimises the possible risk of trapped contamination in accordance with EHEDG hygienic design principles.

To aid cleanability UST brushes have a smooth surface finish ($R_a < 0.8 \ \mu m$) with no acute internal angles and utilise a new way of individually securing each bristle, which minimises the risk of foreign body contamination. They also have unique bristle patterns designed to improve functionality and cleanability, and are made entirely from European Union (EU) and US Food and Drug Administration (FDA) approved food-safe materials.¹²

Conclusion

Raising awareness of the role of cleaning equipment as a source and vector of contamination, and determining how this can be minimised through good hygienic practice and good hygienic design, should be a priority for all those involved in food safety, from legislators, auditors and trainers, to food manufacturers and cleaning equipment manufacturers.

As part of FSSC 22000, the guidance in ISO/TS 22002-1:2009 and BRC v7 highlights this need but fails to supply relevant information to help the food industry comply with this requirement. The hygienic design criteria provided by EHEDG and FEIBP do provide some assistance in this regard, but there is a need to develop specific guidance and training with regard to the hygienic design of cleaning equipment in support of the food industry.

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International Hygienic Study Award 2016

EHEDG World Congress in Herning hosted award ceremony

Dr. Peter Golz, VDMA, Frankfurt, Germany, phone: +49 69 6693-1656, e-mail: peter.golz@vdma.org



The international Hygienic Study Award 2016 was presented on occasion of the EHEDG World Congress in Herning. With this award, its conceptual sponsors – VDMA, EHEDG, Fraunhofer IVV and IVLV – express their appreciation for an outstanding scientific work in hygienic design and hygienic processing. The 2016 prizes were awarded to young research fellows from Braunschweig, Dresden and Vienna and the Hygienic Study Award 2016 was sponsored both by EHEDG and VDMA.



Dr. Marc Mauermann (right) and the proud winners of the Hygienic Study Award 2016 at the awards ceremony in Herning. Middle: 1st winner Dr. Christiane Boxler, University of Braunschweig left: 3rd winner Ellen Angerbauer, University of Vienna. Missing on the picture: 2nd Winner Sebastian Kricke (Source: EHEDG)

Winner of the 1st prize: Christiane Boxler, University of Braunschweig

Fouling by milk constituents and cleaning of modified surfaces

Abstract: This work seeks to identify and quantify the influence of surface energetic and topographic properties on the fouling and cleaning of milk constituents. The surfaces were characterized according to their surface free energy, roughness, topography, zeta potential and chemical composition. To obtain insight into fouling and cleaning patterns and mechanisms, experiments were carried out in three different test facilities: batch vessel, flow cell and plate heat exchanger (PHE). Wherein the thermal fouling resistance was monitored and the amount, composition and structure of the deposits as well as the protein content in the cleaning solution were determined.

The main surface property influencing the interactions at deposit/surface interface was the polar contribution to surface free energy, particularly the electron donor component (γ -). Crystallization and particulate fouling were more pronounced than protein fouling in the fouling experiments under flow conditions.

The removal patterns as well as the thermal data and cleaning profiles were dependent on the surface properties. On high γ - surfaces, the soil was almost completely removed and the highest cleaning rate as well as the fastest reduction of the thermal resistance could be measured. Optimum γ - values for minimal fouling and maximal cleaning effort were suggested.

Winner of 2nd prize: Sebastian Kricke, Univerisity of Dresden

Validation of a process model for jet cleaning

Abstract: At the Technical University of Dresden a process model for cleaning prediction for jet cleaning was developed The aim of this work was to make a new statement on the validity of the process model for jet cleaning using an accurate parameterization of the soil specific removal model based on an optimized measurement data acquisition and a corrected evaluation.

Winner of 3rd prize: Ellen Angerbauer, University of Vienna

Training on Hygienic Design in the Catering Sector

Abstract: This thesis aimed to provide guidance for employees to increase the hygienic level in catering businesses. It focuses on the hygienic design of open equipment and the processing environment. Within the framework of this thesis a handbook, PowerPoint slides and an interactive e-learning course have been developed. The e-learning course (2 ECTS) includes the handbook as well as the PowerPoint slides and interactive tasks. It has been made available on the training platform of the ISEKI – Food Association (https://moodle.iseki-food.net/) where it can be used by all registered members.



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The Regional Sections are the local extensions of the EHEDG and are created to promote hygienic manufacturing of food through regional activities. EHEDG has established Regional Sections in various countries in Europe and overseas. These groups organise local meetings, courses and workshops.

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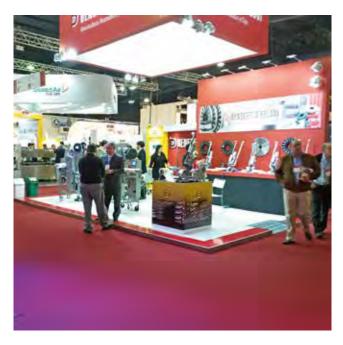
New Regional Section

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In 2014, the Instituto Nacional de Technologia Industrial (INTI) was introduced to the European Hygienic Engineering and Design Group (EHEDG) through its Hygienic Equipment Design for the Food Industry training programme, conducted by AINIA's professional staff. Following the training, INTI started the process to represent EHEDG in Argentina.

The EHEDG Regional Section Argentina was officially established in Belgrade at the EHEDG Plenary Meeting in October 2015. Formal activities began in 2016. EHEDG Argentina has focused on actions to spread information and make EHEDG known in Argentina.

In order to achieve this goal, INTI participated in South America's most important food machinery fair, TecnoFidta, an event that attracts more than 10,000 delegates. In 2016, the fair was held in September in Buenos Aires.



EHEDG Argentina attended TecnoFidta 2016 in Buenos Aires, held in September 2016.



(From left): EHEDG Argentina's Daniel Bono, regional EHEDG office, Guillermo Rubino, chair, and Melina Gaspoz, treasurer, at TecnoFidta 2016.

EHEDG Argentina also visited several dairy machinery companies where information about EHEDG, the benefits of membership and the global reach of the organisation were presented.

INTI is an institution that is represented in every province in Argentina. To take advantage of this, we are in the process of developing an intra-institutional information distribution plan focused on EHEDG topics. The idea is to reach as many companies as possible that represent the related sectors in Argentina. In addition, INTI's Technological Surveillance Bulletin, which is distributed to the nation's dairy industry machinery companies, features a new section that promotes EHEDG news and information.

At present, EHEDG Argentina has one associate company member and we have received interest from a great number of companies across industry sectors.

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Created in 2012 as a non-profit organisation in accordance with Belgian law, the EHEDG Regional Section Belgium consists of five members with the following functions:

Chairman	Hein Timmer- man	EHEDG Board Member, Contact person for Association University of Ghent
Vice- chairman	Johan Roels	Dutch-speaking part of Belgium Contact person for all 'solid material handling' activities Contact person for all fair organisers
Vice- chairman	Laurent Paul	Wallonia and German-speaking part of Belgium
Treasurer	Noël Hutse- baut	Contact person for France Contact person for Flanders' Food (Flemish government invest)
		Contact person for "Agoria," representing the technological industry in Belgium
Secretary	Frank Moer- man	Contact person for Association Catholic University of Leuven
		Contact person for "ie-net," the organisation of all Flemish engineers

The number of individual EHEDG members in Belgium has increased to 42 in 2016, up from 39 in 2015. The number of company/institute members is now eight, doubling from four in 2015).

For several years, EHEDG Belgium has maintained successful and strong relationships with many Belgian companies, universities and organisations representing the country's technological industry, resulting in many activities and seminars. Regional Section members are asked to give support on 'hygiene' related issues, specifically in the field of hygienic design of food processing equipment, factories and utilities, cleaning and disinfection, and maintenance. EHEDG Belgium works together with publishers of local food technology magazines (e.g., *Food Process, Food Industry, Maintenance Magazine*), allowing us to publish the latest developments in the field of hygienic engineering and design.

In March 2015, a four-lecture hygienic engineering and design seminar titled ,'Solid Material Handling' was held at Solids 2015, a trade fair organised at the Antwerp Expo, attracting an audience of 20 participants. In April 2015, EHEDG Belgium actively participated in the organisation of Quality Days 2015 in Waregem. About 220 people heard an EHEDG presentation about the hygienic design of floors and drains. In September 2015, nearly 160 people attended a one-day workshop entitled 'Hygiene for Food' that was organised in Antwerp by EHEDG Belgium, Flanders' Food and Agoria. A total of 17 exhibitors were present.



The discussion panel at the one-day seminar 'Hygiene for Food' 2015 in Antwerp.



Nearly 160 participants attended the one-day seminar 'Hygiene for Food' in Antwerp.

In October 2015, about 55 people (80 percent students) attended a three-lecture seminar, 'Pest Management in the Food Industry,' held in Leuven (Group T - Association KU Leuven). In February 2015, the Belgian division of JBT FoodTech, a manufacturer of sterilisers and filling machines, kindly received 25 participants for a company visit that was set up by EHEDG Belgium and ie-net. The latter is an organisation representing all Flemish engineers. Also in 2015, one three-day hygienic engineering and design course was offered in the Dutch language in Roeselare/ Flanders, and two three-day courses titled 'Conception hygiénique' were offered in the French language in both Gosselies/Wallonia and Villeneuve-d'Asg/Lille in North of France. In addition, EHEDG Belgium board members gave presentations at conferences in the United States and France.

In February 2016, 25 participants visited DuPont Biosciences in Bruges, where the company manufactures industrial enzymes by means of fermentation processes. The activity was jointly organised by EHEDG Belgium and ie-net. Another company visit was organised in November 2016 with Flanders-based Ardo, the largest producer of frozen vegetables and fruit in Europe with a total of 21 factories. Three-day courses on hygienic engineering and design were organised in Antwerp/Flanders (Dutch) and Gosselies/ Wallonia (French). EHEDG Belgium board members also gave presentations at conferences in The Netherlands, Slovenia, Macedonia, France and Denmark. EHEDG guidelines in Dutch and French can be purchased from EHEDG The Netherlands (www.ehedg.nl) and EHEDG France (www.ehedg.fr), respectively.

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EHEDG Brazil

New Regional Section

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The EHEDG Regional Section Brazil was officially established in Belgrade, at the EHEDG Plenary Meeting in October 2015. EHEDG Brazil is hosted by the Instituto de Technologia de Alimentos (ITAL), a well-known institution operating under the auspices of the São Paulo state government. The mission of ITAL is to promote research, development, innovation, technological assistance, training, and technical and scientific knowledge dissemination for the agribusiness sector in order to benefit society.

Activities during the first year

The first seminar on hygienic design was held at ITAL on 10 November 2015 and attracted more than 120 attendees from Brazilian food companies and food equipment manufacturers.



Hygienic design seminar held at ITAL, November 2015.

The first EHEDG Advanced Course on Hygienic Design took place in August 2016 at ITAL. A few days after the announcement, the course was fully booked, demonstrating the importance of this subject to Brazilian companies. The course featured the participation and expertise of Knuth Lorenzen, chairman of the EHEDG Working Group Training and Education, and was very well evaluated by the participants. All training materials were translated to Brazilian Portuguese.



EHEDG Advanced Course on Hygienic Design, held at ITAL in August 2016.

FISPAL is an international fair on process, packaging and logistics for food and beverage companies held annually in São Paulo in June. Rafael Soro from AINIA, Spain, was invited to speak at FISPAL by EHEDG Brazil. His presentation, "Hygienic Design as a Strategy for Cost Reduction," given at the Food Safety Seminar was well-received by the audience.



Rafael Soro speaks at the Food Safety Seminar held at FISPAL in São Paulo, June 2016.

Translation activities

EHEDG Guidelines Docs. 8, 10, 18, 22, 23 (parts 1 and 2), 24, 27, 39 45 and glossaries have been translated into the Portuguese language, as well as content appearing on the website and selected training materials.

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EHEDG China

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On 14 December 2015, after two years of negotiation, the China Institute of Food Science and Technology (CIFST) and the European Hygienic Engineering and Design Group (EHEDG) signed a cooperative agreement in Frankfurt that officially formed the EHEDG Regional Section China.

The EHEDG China section leadership includes:

- Chairman Dean Wang Xichang, College of Food Science and Technology, Shanghai Ocean University
- Deputy Chairman Dean Wang Shouwei, China Meat Research Center
- Treasurer Mrs. Shao Wei, Secretary-General, China Institute of Food Science and Technology
- Secretary Mrs. Chen Li, Division Leader, ACO Drainage Technology (Shanghai) Co., Ltd.

During the signing of the agreement, EHEDG International and EHEDG China agreed on the direction of the group's local work for 2016, including joint advocacy of EHEDG philosophy, organising EHEDG training courses, and actively identifying new members.



Signing EHEDG by-laws at VDMA in Frankfurt, December 2015.

As part of those activities, CIFST's sponsored 2016 International Food Safety Conference held in April 2016 featured EHEDG Past President Knuth Lorenzen as a keynote speaker. More than 500 representatives of the food industry in China benefitted from his introduction to the history and mission of EHEDG, which provided delegates a comprehensive understanding of the concept of hygienic engineering and its important role in assuring food safety.



EHEDG Past President Knuth Lorenzen gave a keynote at the CFIST 2016 International Forum on Food Safety in China.

On 29 April 2016, EHEDG China held its first meeting at the CIFST headquarters, led by Regional Section Chairman Dean Wang Xichang, Deputy Chairman Dean Wangshou Wei, and Secretary-General Shao Wei. Representatives of 10 companies participated in the meeting. Ms. Zhang Hui, health engineering specialist with Unilever, The Netherlands, was invited to speak to the group about EHEDG training courses. Participants expressed their views and made constructive suggestions, giving their full support to the local work to be carried out. In addition, EHEDG China Chairman Dean Wang Xichang introduced the Regional Section's current organisational structure and the upcoming training and meeting schedules. He announced that the EHEDG Advanced Course on Hygienic Design would be held from 15-17 November 2016, and would be directed toward college students, food and food-related businesses and research and development staff members. In terms of training, he also noted that further development of constructive proposals from the meeting would include development of university-level platforms and a professional engineering design team of experts working together to promote health. The culture of Chinese hygienic design and engineering health trainers will be of particular importance.



The first EHEDG China member meeting in April 2016.

EHEDG China has received strong support from headquarters and the regional section is constantly growing. EHEDG China will uphold the concept of EHEDG, with an open and welcoming attitude towards those who wish to join and assist people with lofty ideals. The section is committed to to continuously promoting health education and training in engineering and design work, as well as to introducing the hygienic engineering and design concept to China to help enhance the overall level of China's food safety.

For more information and if interested in the activities of EHEDG China, please contact:

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EHEDG Croatia

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The EHEDG Regional Section Croatia was officially established at the EHEDG Plenary Meeting on 11 October 2013 in Prague. EHEDG Croatia is a part of the Croatian Society of Food Technologists, Biotechnologists and Nutritionists.

Activities of EHEDG Croatia

EHEDG Croatia continuously works on different activities, including translation of guidelines and other EHEDG materials, achieving recognition at the local level, and establishing and maintaining local networking. The Regional Section also strives to build a numerous and well-balanced membership and promotes EHEDG through information days at the national level. The group has participated in many external events, such as national scientific and expert conferences. Currently, the number of EHEDG company/ institute members is three. In cooperation with EHEDG Regional Section Macedonia, EHEDG Croatia Chair Helga Medic participated in the NUTRICON Conference in Skopye, Macedonia, giving a lecture on EHEDG. In May 2016, a lecture titled "Hygienic Design in the Food Industry" was presented to an audience of more than 120 participants from food and beverage companies, state and local government bodies and academia at the National Expert Conference of Food Safety and Quality in Opatija. Lectures on hygienic design also were introduced at the University of Zagreb, Faculty of Food Technology and Biotechnology.

EHEDG Croatia organised two EHEDG information days in Opatija and Osijek, as well as a meeting with the representatives of the Croatian Food Agency, which has become a member of EHEDG.

The meeting of EHEDG Regional Sections Croatia, Macedonia and Serbia was held in September 2016, in Ohrid/Macedonia, to improve cooperation among the Regional Sections and plan future joint activities.



(Center) Chair of EHEDG Croatia HelgaMedic at the second EHEDG Info Day 2016 in Osijek, Croatia.

EHEDG Croatia future activities

In June 2017, EHEDG Croatia will organise a seminar on hygienic engineering and design together with EHEDG Macedonia and Serbia, in Zagreb. It will be held at the University of Zagreb, Faculty of Food Technology and Biotechnology in Croatia. The seminar will help increase the recognition of EHEDG activities and guidelines in Croatia. Food processors and research institutions representatives also will be introduced to EHEDG membership benefits and training opportunities. EHEDG Croatia will continue to translate guidelines and publish articles about EHEDG in national journals.

Translation activities

EHEDG Croatia translated the following EHEDG Guidelines into the Croatian language: Docs. 1, 2, 3, 8, 10, 13, 17, 18, 19, 22, 23 and 39. Translation of Doc. 44 and EHEDG website content is in progress.

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EHEDG Czech Republic

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The EHEDG Regional Section Czech Republic was founded in November 2012. Members of the section continue to work on popularising the EHEDG know-how in the Czech Republic.

EHEDG Czech Republic is taking a new, customised approach to disseminating information about hygienic engineering and design in cooperation with local and national universities, while having only provided lectures to academic institutions in the past. The aim of the group's current approach is to educate teachers at each university, helping them to develop their own study materials using information from EHEDG guidelines and books. Faculty from universities were invited to a first-time workshop to kick off this project. The EHEDG Czech Republic members believe that hygienic design topics will become accepted as a part of education at universities in a short time. Czech Technical University in Prague has already developed its own materials and lectures that include technical content and information about hygienic standards and other requirements.

Although food producers in the region have not yet been successfully targeted for EHEDG membership, EHEDG Czech Republic is working diligently to inform stakeholders about EHEDG guidelines and legislative requirements for food industry machinery. EHEDG Croatia has provided presentations at selected dairy industry conferences that received very good feedback from a dairy industry association and some dairy factories.

Legislation concerning machinery for the food industry (Directive 42/2006 EC) has not been effectively implemented in the Czech Republic. The need for adhering to this legislation is a message EHEDG Czech Republic plans to deliver to the Ministry of Agriculture. The group believes that state oversight agencies for food manufacturers are the correct executive bodies to disseminate basic information about hygienic engineering and design requirements for food industry machinery and production line areas and facilities.

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EHEDG Denmark

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The challenge for EHEDG Regional Section Denmark this year has been the planning of the EHEDG World Congress 2016 in Herning, Denmark. The program for the Congress has been widely promoted and reported. Among its activities, EHEDG Denmark arranged two company tours in conjunction with the Congress. Offered the day after the Congress, these tours were planned so that delegates could get an extra professional benefit before returning back home. On one tour, visitors were welcomed by Danish Crown in Horsens and Blücher A/S in Videbæk, and the second tour visited DSS Tetrapak A/S in Silkeborg and Arla Foods in Tavlov.

The EHEDG World Congress program was developed as a joint effort between the Danish chapter and Karel Mager, Co-Chair of the EHEDG Sub-Committee Regional Development. The program was well received by the 315 delegates to the Congress, a record high attendance tally. EHEDG's organising partner MCH did great job handling all of the logistics in connection with the Congress. Many thanks to MCH for all the professional support to make the 2016 EHEDG World Congress a success.



Congress audience

Activities

On 16 September 2015, EHEDG Denmark organised a joint seminar with EHEDG Nordic under the theme, 'Total Cost of Ownership, Sustainability and Cost Benefit,' held at Technical University of Denmark (DTU) in Lyngby. There were 29 attendees and the meeting was intended to promote the 2016 EHEDG World Congress and knowledge of EHEDG. A visit to the test center at DTU was included. The event also marked the opening of cooperation with EHEDG Nordic, which resulted in a later joint seminar organised by both Regional Sections in Lund.

In December 2016, a meeting for existing and potential EHEDG members was held to set the 2017 strategic activities of EHEDG Denmark and to support the awareness of EHEDG in connection with the Congress.

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EHEDG France

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The French Regional Section, EHEDG France, has 101 members, including 77 industrial companies of which 17 are in the food sector, 48 are in equipment manufacturing, and 12 are in hygiene products and services. The Regional Section organised and participated in several major events in 2015 and 2016, including the following described below.

EHEDG training courses

EHEDG France organised two training courses in the past two years. The first was held in October 2015 at INRA, Villeneuve d'Ascq, North, and the second was presented in April 2016 at ACTALIA, Viller Bocage, Normandy, which attracted a total of 27 professionals. The courses were conducted by two EHEDG authorised trainers: Olivier Rondouin and Hein Timmerman.



EHEDG trainig course at INRA, Villeneuve, d'Ascq, October 2015.

Presence at the CFIA 2016

From 8-10 March 2016, EHEDG France participated in the CFIA in Rennes, the first tradeshow of food industry suppliers in France. This was an excellent occasion to meet many people from the food industry at the stand and to present conference sessions via the CFIA Web TV studio.



EHEDG exhibition stand at the CFIA.



Roundtable presented by EHEDG France via CFIA Web TV in March 2016.

Food Factory 2016

EHEDG was a partner of the 8th International Conference on the Food Factory of the Future, which was held in Laval from 19-21 October 2016. The scientific program included a half-day session on the "Safe Food Factory," featuring three presentations by EHEDG experts: "The role of factory design in pathogen control," by John Holah (Holchem Laboratories Ltd., United Kingdom); "The future of food industry brushware – a matter of hygienic design," by Debra Smith (Vikan A/S, Denmark); and "Hygienic design and cleaning/disinfection of belt conveyors for the food industry," by Frank Moerman (Catholic University of Leuven, Belgium).



Dr. John Holah lectures at the EHEDG special session at Food Factory 2016 in October.

Parallel with scientific conferences, SME workshops were dedicated to hygienic design. Five original topics were presented, including:

- "Economic gains related to hygienic design," by Knuth Lorenzen, Past President, EHEDG
- "Hygienic design in the food powder industry," by Franck Deramond, APIA Technologie, France
- "Hygienic design of technical brushes," by Simon Lorrillière, CEO of Brosserie Brenet
- "Hygienic design of transport tanks for bulk foodstuffs," Anne Woerth, Mars Chocolat France
- "Prevention and removal of foreign bodies in food factories," by Olivier Rondouin, Doceor (Laval)



EHEDG workshop at CFIA in 2016.



Participants of an EHEDG workshop at CFIA in 2016.

The gala dinner was the occasion to celebrate the 10-year anniversary of EHEDG France with EHEDG president Ludvig Josefsberg.



A toast to the 10 years of EHEDG France.

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EHEDG Germany

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In Germany, EHEDG is well recognised as the most relevant source for information and organisation with regard to hygienic design. Many equipment manufacturers, food producers and institutes not only are members who benefit from its large network, but also are highly engaged in working groups, fairs, internal events, seminars and publications to promote EHEDG products and services and to represent EHEDG as an organisation. With 149 company/institute members and 150 individual members, EHEDG Germany makes up the largest regional section within the global EHEDG network.

EHEDG Testing and Certification Institute

The German EHEDG Testing and Certification Institute is located at Technische Universität Munich (TUM) in Weihenstephan. The institute is accredited by ISO 17025 for all three EHEDG Test Methods. Apart from the three people working directly in the department of EHEDG, valuable support is given by TUM's Department of Microbiology, which carries out all works related to the cultivation of microorganisms. The German EHEDG Testing and Certification Institute is the largest in terms of size and quantity of tests conducted among the organisation's authorised institutes. An annual workload of around 60 different pieces of equipment is tested each year. Based on the test results, equipment suppliers are in a position to certify their components according to EHEDG criteria or to improve the design of their equipment to be certified in future. The German testing institute has three sizes of different cleanability test rigs to test all kinds of equipment with a wide range of sizes mounted into pipelines. For the testing of aseptic applications, there are two similar test rigs available. The need for certification with regard to innovations in design of equipment used in open processes is increasing, and the newly introduced Type EL Class I AUX is well accepted by the industry.

General Assembly

In 2016, the General Assembly of EHEDG Germany was hosted for the first time by a member company. Due to the outstanding success of this event, the section will continue with this format. The invitation was given by Freudenberg Process Seals GmbH & Co. KG in Weinheim. The meeting started with a dinner gathering in the "Woinemer craft brewery" of Weinheim and included a visit of the manufacturing site and a tasting of a selection of different beers. The next day, various topics were presented at Freudenberg's headquarters in Weinheim. The primary topics dealt with information about EHEDG activities, new guidelines and the development of the open surface cleaning test method. Mr. Leuze from Novonox showed how EHEDG requirements of the guidelines can be transferred to standardised components. Novonox is using the Freudenberg Hygienic Usit washer to provide easyto-clean screws and nuts, handles and knobs. In order to avoid damaging the smooth surfaces by mounting the screws Novonox also developed special fastening tools. This is a practical example showing how to bring hygienic design principles to life. The meeting ended with a visit of the production site of Freudenberg in Reichelsheim, where the members of EHEDG Germany had the chance to look at the production of elastomer parts for many different applications, as well as the production of the Hygienc Usit washers for hygienic and aseptic applications.



The EHEDG Germany General Assembly held on 1 June 2016 in Weinheim was well attended.

In 2017 the General Assembly will take place upon invitation of Endress + Hauser at their facilities near Basel.

Training and events

The three-day EHEDG Advanced Hygienic Design Course takes place in Weihenstephan each spring. Approximately 50 people participated in the training, which featured several workshops and the opportunity to exchange knowledge with experts and colleagues. The highlight for delegates was the workshop in the pilot plant where a real hygienic design qualification of equipment and machinery was carried out. The other highlight was the dinner in the ski lodge with a barbeque meal.



The pilot plant workshop during the spring Advanced Hygienic Design Course was a highlight for attendees.

In addition, EHEDG Germany offers several one- and two-day training courses on hygienic design at different locations in Germany. With the support of the University of Applied Science of Hannover, the regional section was able to organise a course for more than 25 people this year. At the University of Applied Science of Sigmaringen, we offer a cleaning-in-place (CIP) seminar for pipelines and tanks.

Other organisations, like TÜV, VDMA and various publishers, help promoting the topic of hygienic design by supporting several seminars, workshops and other events. EHEDG member companies also help disseminate this knowledge through in-house trainings and sales events for their customers.

The Drinktec Fair 2017 in Munich will be the next important event in Germany. EHEDG will be represented by an amazing booth that will present the newest developments in hygienic design.

Publications

The main task of the regional group is the translation of the EHEDG guidelines. EHEDG Germany already has translated and published several existing guidelines into the German language, but as a larger number of guidelines will be updated in the near future, only the revised and new guidelines need to be translated now.

The Regional Section's company members publish information about EHEDG in various journals, including articles on certification topics and solutions for adequate hygienic design. The latest information about EHEDG and its activities is regularly published by media partner "Lebensmittel¬technik," which is a popular journal for the food and mechanical engineering industry. Each year, the journal features a special EHEDG edition that includes a list of EHEDG-certified equipment. With a print volume of 11,000 copies, the journal is distributed at trade fairs and at many EHEDG events and seminars.



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EHEDG India

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Though relatively new, the EHEDG Regional Section India has participated in a number of conferences, symposia and workshops to bring awareness about the principles of Hygienic Engineering and Design to local academic institutes and professionals. The Regional Section members, led by EHEDG India chair Dr. Vish Prakash, have participated in national and international seminars, sharing EHEDG's mission and message with hundreds of participants across India and the world. These include seminars and conferences in China, Sri Lanka, Vietnam and the South Asian Association for Regional Cooperation (SAARC) countries along the Indian Ocean Rim. EHEDG India members also have communicated EHEDG messages nationally through various educational platforms and via media outlets such as television and radio programs. Dr. Prakash also serves as chair of NuFFooDS Magazine, in which he has published several articles about Hygienic Engineering and Design that have been distributed to a broad, global audience.

Dr. Prakash has taken the initiative to share with the Food Safety Organizations the concept and benefits of hygienic engineering and design, especially among small- and medium-scale industries in the national economy. India's economy represents a \$230 billion (USD) market, with an overall net potential of between 30-40% of its agriproduce moving into the value chain in the food sector. As such, the hygienic engineering and design sector has a tremendous opportunity in India and other developing countries to provide both the scientific and economic benefits of thoroughly cleanable equipments and facilities for design.

Workshop support and partnering

2015 EHEDG workshop in Mumbai, India

In March 2015, EHEDG India supported the success of the EHEDG workshop held prior to the Global Nutraceuticals Summit 2015 in Mumbai. The workshop attracted 115 participants and was a great success, featuring faculty from Europe that included then-President of EHEDG, Mr. Knuth Lorenzen, and EHEDG Asia Coordinator, Mr. Karel Mager. EHEDG was invited to present a full session in the Nutra Summit, and Mr. Lorenzen and Mr. Mager were the guests of honour at the inaugural and EHEDG sessions, respectively.

2016 Nestle Company workshop in Pune, India

In partnership with EHEDG India, Nestle Company organised a workshop on the importance of hygienic engineering and design held on 26 August 2016 in the Alfa Laval campus in Pune, India. The workshop was inaugurated by Dr. Prakash who gave inaugural about EHEDG to foster awareness and highlight the importance of hygienic engineering and design in manufacturing companies such as Nestle, from procurement of equipment to raw material handling and all the way to the point of consumption, including equipment at the consumer level. Another important issue discussed was the role of EHEDG in bringing in reliability to system operation in the food safety network, especially with regard to equipment manufacturing and food processing systems in tropical countries. The talk was well received by participants and a detailed discussion followed.

2016 Alfa Laval Group workshop in Pune, India

Alfa Laval also organised a workshop at Pune in partnership with EHEDG on 25 September 2016. An EHEDG representative gave input as to how the dairy industry in India was transformed into a exemplar sector, implementing several principles of hygienic design in equipment procurement, processing and installation. EHEDG India was very ably represented by Mr. A. Subramani of Abbott Laboratories, India, who gave an in-depth talk that put the spotlight on EHEDG and was well received by workshop participants. He emphasised the issues that need to be addressed in the field of hygienic engineering and design with regard to the food chain and processing operations, especially clean-in-place (CIP) interfaces and integrating equipment with affordable solutions. By means of this important partnership workshop EHEDG India brought in the importance of implementing CIP among the various processing lines in the country.



Group photo at Adia Laval workshop conducted on 26th Aug 2016 in partnership with EXEDG - India Region

Alfa Laval Workshop with EHEDG partnership, Pune, India 2016.

EHEDG workshop in India in 2017

Dr. Wani Abbas, EHEDG India Region Secretary, initially planned to hold a food science and technology conference in India during Fall 2016, but has postponed the event to 2017. He plans to organise an EHEDG industry training workshop one day prior to the conference. As the dates and location are finalised by organisers, the information will be uploaded to the EHEDG website following approval by EHEDG India and EHEDG International leaders.

EHEDG India outreach

The various communication materials, yearbooks, newsletters and other important information from EHEDG was widely circulated by EHEDG India members among Indian industries to raise awareness of hygienic engineering and design in the manufacturing and food processing sectors. This will be continued with more vigour in 2017.

EHEDG India also plans to form a Regional Section council with the participation of esteemed members, which includes six active professionals from the fruit and vegetable, spice, milk and dairy products, flour milling, nutri foods and other major food processing industries.

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EHEDG Italy

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The Italian food and agriculture industries, along with related supply and distribution chains, represent the largest economic sector in the country. About 60 percent of total turnover is achieved in the Italian regions of Lombardy, Emilia Romagna, Veneto and Piedmont, making this area the most important 'food valley' in Europe.

Within this area, the Province of Parma distinguishes itself in that 23 percent of all employees in the food industry of the entire region Emilia Romagna work in that province.

The province of Parma is home to historically consolidated food production enterprises, such as Prosciutto di Parma PDO, Formaggio Parmigiano Reggiano PDO and tomato products. Currently, Parma is the site of many well-known food and food equipment manufacturing groups.

Parma also is home to the European Agency for Food Safety Authority (EFSA), and as such, is frequently the site for working group meetings, seminars and conferences involving top European experts.

Since 2007, Parma also is the site of the EHEDG Regional Section Italy.

Members and working groups

As of October 2016, EHEDG Italy membership totals 60 individuals from approximately 25 companies. Many Regional Section members actively work in EHEDG Working Groups and/or as volunteer translators for EHEDG guidelines and other documents.

Translation

Thanks to the voluntary work of several EHEDG Italy members, EHEDG Docs. 2, 3, 8, 10, 13, 14, 17, 18, 20, 32, and 34 are available in the Italian language. Other documents are under revision. A frequently updated list of translated documents is available at the EHEDG Guidelines Webshop.

EHEDG Italy events

EHEDG Italy hosted the EHEDG World Congress, 30-31 October 2014 in Parma, in conjunction with the CibusTec exhibition. In October 2016, EHEDG Italy organised a oneday conference in Parma, also in conjunction with ClbusTec. EHEDG Italy frequently participates in various congresses, seminars and conference offering presentations on hygienic design and engineering.



EHEDG seminar in Parma October 2016.

Training

As a member of the EHEDG Working Group Training and Education and EHEDG Authorised Trainer, Dr. Giampaolo Betta, chairman of EHEDG Italy, organises various training courses, as well as the EHEDG Advanced Course on Hygienic Design. The next edition of the EHEDG Advanced Course on Hygienic Design will take place in Parma in April 2017.

Testing and certification

A new laboratory is under development in Parma with the coordination of EHEDG Italy. The ISO 17025 accredited laboratory will be available for commercial testing in 2017.

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EHEDG Macedonia

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EHEDG in-country roundtables

In 2015 and 2016, EHEDG Regional Section Macedonia organised two roundtables in Skopje and in Kumanovo. These events were organised in cooperation with the Macedonian Association of Chambers of Commerce, the Macedonian Academy for Science and Arts, and the Municipality of Kumanovo. The roundtables covered the necessity for improving manufacturing capacities in the Republic of Macedonia by introducing new technologies with hygienic design in food production processes. EHEDG's scope of work and activities also were presented.

EHEDG info, promotion days and seminars

In 2015 and 2016, EHEDG Macedonia held four seminars in four cities, two in Ohrid, one in Tetovo and one in Struga. The Regional Section also hosted four EHEDG Info days during the past two years, in Veles and in Skopje in 2015, and in Sveti Nikole and in Tetovo in 2016.

These events were organised in cooperation with the Agency for Support of Entrepreneurship in Macedonia, Enterprise Support Agency (ESA) in Tetovo, and by two new EHEDG members, the Technical-Technology Faculty and the Municipality of Karposh. Companies and institute representatives who attended these events had the opportunity to hear more about benefits of membership in EHEDG, as well as opportunities to build networks, create partnerships and learn the latest about the field of hygienic engineering and design, and in food quality and safety. Participants also were invited to attend the EHEDG World Congress 2016 in Denmark.

Hygienic Design Festival

EHEDG Macedonia members were heavily involved in organising the Hygienic Design Festival, a conference held in Ohrid, Republic of Macedonia from 27-29 May 2015. More than 100 delegate from 14 countries worldwide, including representatives from food companies, academia, research centres, institutes, and Macedonia's National Food Safety Agency, were present. Then-EHEDG President-elect, Mr. Ludvig Josefsberg, gave a presentation titled, "New Strategy and Structure of EHEDG." The event was covered by many national electronic media outlets. The future cooperation between EHEDG and the National Food Safety Agency was discussed at this conference.



EHEDG President Ludvig Josefsberg fields questions during an interview with the Macedonian press, May 2015 in Ohrid.

EHEDG representation at fairs

In 2015, EHEDG Macedonia was present at two fairs: TEHNOMA, and ITF-AGROFOOD, at the Skopje Fair. Both fairs drew visitors from various companies who were interested in learning more about EHEDG's objectives, goals, scope of work, training, certification and membership.

B-FoST 2016 Congress

The 1st Black Sea Association of Food Science and Technology (B-FoST) took place in Ohrid, Macedonia from 22-24th September 2016. The congress attracted more than 200 people from 36 countries worldwide. There was a special Hygienic Engineering and Design Session chaired by Prof. Dr Mark Shamtsyan and Mr. Hein Timmerman, which was organised by members of EHEDG Macedonia.

EHEDG training

An EHEDG training course was organized in conjunction with the B-FoST congress with four participants from Macedonia, two from Serbia, and one from Romania. The trainers were Prof. Dr Vladimir Kakurinov, Prof. Dr. Mark Shamtsyan, Mr. Hein Timmerman and Mr. Huub Lelieveld. All participants expressed their satisfaction regarding the lecturers and course materials.



EHEDG training in Ohrid, Macedonia.

EHEDG Regional Sections meeting

The chairs of three Regional Sections – EHEDG Macedonia, Serbia and Croatia – held meetings during NUTRICON 2015 and B-FoST Congress 2016. The topics discussed included each section's activities of the previous year and forthcoming activities, as well as opportunities for organising joint EHEDG trainings in these countries and activities for increasing membership in EHEDG.



Chairs of Regional Sections EHEDG Macedonia, Croatia and Serbia held meetings in 2015 and 2016.

Translations

In 2015/16, EHEDG Macedonia translated five EHEDG guidelines into the Macedonian language. These were EHEDG Docs. 17, 18, 22, 31, 44, and the EHEDG Glossary.

Upcoming activities in 2017

- Exhibition participation
- Roundtables / info days / seminars
- NUTRICON 2017 Conference
- Translation of EHEDG guidelines

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EHEDG Mexico

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EHEDG Mexico is celebrating five years of the Regional Section's active presence in México. Supporting organisations, including SOMEICCA A.C. and LEFIX y Asociados, have assisted EHEDG Mexico with organising multiple international events, conferences and workshops, including one in Colombia for the very first time. In addition, hygienic design research projects have been conducted with students at the Facultad de Química, Universidad Nacional Autonoma de Mexico (UNAM). Plans for 2017 and 2018 include programming events such as the First Latin American and Caribbean Festival for Hygienic Design, as well as collaboration with national and international authorities to better disseminate information about EHEDG guidelines, training and education.

CUCCAL International Congresses, 2015 and 2016

EHEDG had a strong presence at the CUCCAL International Congress, both in 2015 and 2016. CUCCAL 8 was held in October 2015 at Mérida, Yucatán, and CUCCAL 9 was held in September 2016 in Guadalajara, Jalisco. Key sessions at CUCCAL 8 were presented by EHEDG Past President Knuth Lorenzen, who along with EHEDG Mexico Chair Marco A. León Félix, provided instruction for the organisation's Advanced Hygienic Design Course (AHDC) at both congresses. Esmeralda Paz Lemus, an EHEDG Authorised Trainer candidate and member of EHEDG Mexico, assisted with instruction for the AHDC at CUCCAL 9. The 32 course attendees included representatives of the Mexican food industry, including Coca Cola, FEMSA, Hershey's, SESAJAL and America Alimentos, among others. Other attendees included professionals and scientists from Costa Rica, LAICA Group, from academia and research centres (USB, IT de Tlajomulco, UT de Tecamachalco, CIATEJ), from food equipment manufacturers (GEA México, Haskell), and from food industry suppliers (Ecolab Costa Rica, ACCO USA).

Both of the congresses were partially sponsored by EHEDG, which provided materials and delivered EHEDG Yearbooks to the student winners of the INOCUITON, a national competition for food science, technology and engineering. The 400 attendees of CUCCAL 8 and 9, hailed from Costa Rica, Cuba, Germany, Mexico and the United States.



CUCCAL 9 Congress in Guadalajara, September 2016.



Advanced Hygienic Design Course, in Guadalajara, CIATEJ 2016.

EHEDG conferences, technical sessions, short courses and research

Conferences and technical sessions for the food industry and food equipment manufacturers based on EHEDG presentation material, were held in several Mexican cities, including México City, Monterrey, Guadalajara, Mérida, Culiacán, Mazatlán, Hermosillo, Mexicali, Los Mochis and Puebla, among others. It is important to note that EHEDG Mexico's main objective is to promote EHEDG guidelines among Mexican authorities. During the Regional Section's last conference in México City, representatives from SENASICA, the Mexican food safety authority overseeing agriculture, production and meat and meat products, were present. In 2015, EHEDG Mexico also had the opportunity to present information about EHEDG at ANDINAPAK, which was a first in Colombia.

The EHEDG Basic Hygienic Design Course, was taught once in 2015 and again in 2016 in Guadalajara and México City, respectively. As a consequence, EHEDG memberships in Mexico grew, with the addition of three new companies (SESAJAL, Grupo Idea and Q-pumps). According to the course evaluations, the 18 attendees were more than satisfied; however, materials are being improved for 2017 courses, which may be held in Monterrey, México City and/ or Mazatlán.

A research project supported by EHEDG Mexico, "Evaluation of Hygienic Conditions in Food Processing Machinery," has been completed. Fish (El Mar Congelado) and meat (Choribi) companies allowed food chemistry student Xiomara Villarreal of the Chemistry Faculty at UNAM to run an evaluation of selected equipment according to EHEDG Docs. 8 and 2, and against a cleaning evaluation procedure. Results will be submitted to the *Journal of Hygienic Design* for publication.

In 2017, the very first Latin American and Caribbean Hygienic Festival (LACHDFest) will be organised in México City. EHEDG Mexico's goals are to increase knowledge about EHEDG guidelines among the nation's food industry and food machinery manufacturers, as well as to promote awareness of the organisation's hygienic design training, education and certification processes. Regional Section representatives will be present from Argentina, Brazil and Uruguay. Other workshops and conferences about hygienic design and featuring EHEDG International speakers and national and international authorities also are under consideration.



EHEDG Mexico City Conference, December 2016.

External meetings and tradeshows

EHEDG Mexico was present at the Food Technology Summit (FTS) in 2015 and 2016, at Expopack 2015 and at Expobotanas 2015, where the Regional Section shared exhibit stands with LEFIX y Asociados. FTS is one of the most important events for food manufacturers in Mexico and Latin America, and Expopack is aimed at food machinery manufacturers. By exhibiting at both of these events, EHEDG Mexico was able to successfully reach both main target sectors. During 2017, a follow-up programme for 48 interested companies and 14 individuals is being organised to increase EHEDG membership and hygienic design awareness.

In 2017, EHEDG Mexico plans to again be present at Food Technology Summit, Expocarnes and Expolactea. It is important to note that it will be the very first time that EHEDG will be present at Expocarnes, a large meat industry conference, as well as at Expolactea, the Latin American dairy industry's conference.

Contact

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EHEDG exhibit stand at the Food Technology Summit in Mexico City, 2016.

EHEDG Nordic Section (Finland, Norway and Sweden)

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Promoting EHEDG membership

One of the main goals of the EHEDG Regional Section Nordic is to increase awareness about EHEDG among food producers, academic institutes and food equipment manufacturers. To achieve this goal, the activities of EHEDG Nordic have been focused on participating in events aimed at promoting hygienic design in food manufacturing and increasing awareness of EHEDG's mission and activities.

We are also cooperating with EHEDG Denmark, an activity begun last year with the aim to organise and hold joint workshops and seminars. So far, EHEDG Nordic has experienced challenges in getting academia and institutes on board, but activities aimed at attracting new Regional Section members will continue during the years to come.

Activities within EHEDG Nordic

In 2016, EHEDG Nordic participated in Nordic Food Chain, a fair for food equipment industry and logistic industry held in Malmö, Sweden.



(From left): EHEDG Nordic Secretary Admira Mesic and Chair Stefan Åkesson share information about EHEDG at the Food Chain Nordic fair in 2016.

By participating in the fair, the aim was to create general awareness about EHEDG and to promote membership and interest in active participation of regional food producers, equipment manufacturers and other experts in EHEDG Nordic. In advance of the fair, the EHEDG leaflet and membership application form were translated into the Swedish language.

EHEDG Nordic also participated in a seminar held by "Mejeritekniskt Forum," a Nordic organisation for the dairy industry. The aim was to create awareness about EHEDG's mission and activities, with a focus on the guidelines and certification of equipment. Another focus was to promote EHEDG membership enrollment, especially by Nordic food producers.

By invitation, EHEDG Nordic also made a full-scale presentation about the EHEDG organisation and provided an overview of membership benefits at an internal seminar headed by one of the leading international suppliers of industrial robots.

Future goals

EHEDG Nordic is a small section within EHEDG, and thus one of the main goals is to promote membership and create awareness about EHEDG among Nordic food producers and academia. Another goal for 2017 and 2018 will be to set up hygienic engineering training courses.

Contact

For more information and if interested in the activities of EHEDG Nordic, please contact the chair:

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EHEDG Poland

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In 2015-2016, EHEDG Regional Section Poland's major activities have focused on the development of hygienic engineering and design training courses that are generally included only in university-level programs. The courses – Quality and Safety Systems in Food Production; Food Law; and Waste Utilisation in Food Production – have been offered at Poland's Gdansk University of Technology. These subjects also have been the focus of both BSc and MSc theses.

EHEDG Poland also has organised and participated in several meetings with leading food equipment manufacturers for the meat, dairy and packaging industries at the International Food Fair in Poznan, and its members have visited a number of private poultry and meat product producers. In 2016, a seminar entitled "Shall We Apply Computing Cloud to Food Engineering Systems? Impact of Food Industry 4.0," presented by EHEDG Poland chair Dr. T. Matuszek, was organised for a number of food equipment manufacturing company representatives. Two papers authored by Dr. Matusek also were prepared and accepted for publication in the Polish edition of the Food Industry Journal. The papers are titled "Data Needed for Equipment Design Regarding Hygienic Requirements" and "Contamination Risk in the Open Area of Food Engineering Processes."

EHEDG Poland translated several EHEDG guidelines into the Polish language, as well as other materials and website contents. Regarding the new website, the Regional Section is currently preparing additional content in the Polish language.

In the future, EHEDG Poland will continue to promote the use of hygienic design principles and management of processes, machinery and components, facilities and maintenance systems throughout Poland. The group plans to spread EHEDG know-how about the highest food production hygienic standards during workshops and seminars, as well as through university study courses. EHEDG Poland also is considering organising an interregional cooperation among several of the EHEDG regional sections in the near future.

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EHEDG Romania

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EHEDG Regional Section Romania was established in 2016, and the by-laws were signed in Herning/Denmark on occasion of the EHEDG World Congress, where EHEDG Romania was officially launched at the EHEDG Plenary Meeting on the pre-congress day of 1 November. The Regional Section Bylaws were signed by EHEDG President Ludvig Josefsberg, Piet Steenaard as the EHEDG Treasurer and Liviu Gaceu, PhD, EHEDG Romania Chair. Other members of EHEDG Romania are Mona Popa, PhD, Cristian Neacsu and Monica Talpau.

EHEDG Romania's activities, primary including communications, will be managed and organised at the Research and Development Institute of Transilvania University of Brasov (UNITBV). At EHEDG Romania's disposal is the Romanian Society for Information Technology in Food and Agriculture (ROSITA), a professional nongovernmental organisation focused on spreading knowledge in the food sector. ROSITA also publishes the Journal of EcoAgriTourism, a communication channel for professionals in working in the food industry. As the organiser of the biennial International BIOATLAS Conference on Food and Tourism, UNITBV also will support EHEDG Romania's mission by organising a series of workshops, seminars and training sessions. AGRILIFE is another important forum for spreading EHEDG knowledge, and is organised by the University of Agricultural Science and Veterinary Medicine of Bucharest.

Although 2017 marks its first year as an official EHEDG Regional Section, EHEDG Romania is already working to achieve recognition for the organisation and its mission on a national level by establishing and maintaining an excellent local networking base with a growing membership. EHEDG Romania has implemented several activities, including translation of several EHEDG guidelines and organising seminars on hygienic engineering and design in 2015 and 2016 throughout the country, including:

 Organising the 3rd North and East European Congress on Food (NEEFood), 21-25 May 2015, in Brasov, Romania



NEEFood Congress participants, May 2015.

- Organising an EHEDG workshop in Brasov, Romania, 20-21 May 2015
- Organising several hygienic design seminars in partnership or in conjunction with ACO, BASF, USAMV, Calvatis and UNITBV in 2016.
- Joint organisation with EHEDG Macedonia of the 1st Black Sea Association of Food Science and Technology (B-FoST) Congress, held in Ohrid, Macedonia from 22-24 September 2016. The congress featured a special Hygienic Engineering and Design session and a training course.
- Participated with EHEDG Macedonia, Germany, Spain, Serbia, Armenia, Bulgaria and Croatia in the development of a joint proposal titled "Hygienic Engineering and Design – New Food Safety Tool," which was submitted to the COST Open Call in April 2016.



Dr. Marc Mauermann, Fraunhofer IVV, Dresden, spoke at the ACO, BASF, USAMV and UNITBV seminar on 25 May 2016.



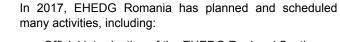
ACO and UNITBV seminar, 25 September 2016.



ACO, BASF, Calvatis and UNITBV seminar, held 27 October 2016 in Cluj Napoca, Romania.



Representatives of the Macedonian, German, Spanish, Serbian, Armenian, Romanian, Bulgarian and Croatian EHEDG Regional Sections who worked on the joint proposal to COST.



- Official introduction of the EHEDG Regional Section Romania, January 2017 at UNITBV
- EHEDG workshop, March 2017, UNITBV and ACO
- EHEDG workshop, June 2017, USAMV, AGRILIFE Conference
- Meetings to be held at ACO, BASF, Calvatis, USAMV, Mondelez International, and UNITBV
- Continued EHEDG guideline translations
- Development of new hygienic design curricula for students
- Publication of EHEDG articles in the Journal of EcoAgriTourism
- Continued development in cooperation with other EHEDG Regional Sections of joint project proposals and submissions to COST, ERASMUS+ and H2020 programmes

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EHEDG Romania and EHEDG Macedonia jointly organised the 1st B-FoST Congress in Ohrid, Macedonia, September 2016.

1" Black Sea Association of Food Science and Technology Congress



Participation at the EHEDG training course at B-FoST.

EHEDG Serbia

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Plenary meeting and seminar

The EHEDG Regional Section Serbia Plenary Meeting, held from 15-16 October 2015 in Belgrade, Serbia, attracted 62 delegates from 27 countries. EHEDG leaders discussed the future of the organisation's operational work in view of an ongoing geographical expansion and with respect to technical activity clusters. In addition, the EHEDG Subcommittee on Product Portfolio, Regional Development and Communication introduced its strategic planning for the coming years.

On the second day of the meeting, the agenda included eight expert lectures and lively discussions. The programme was aimed at giving the delegates, including the 60 representatives from Serbian industry, a deeper insight into typical EHEDG topics and goals.

Translation of EHEDG guidelines

The translation of EHEDG guidelines is an important task for EHEDG Serbia. In 2015 and 2016, Regional Section members have translated a total of 11 documents into the Serbian language.

Promoting EHEDG membership

A number of activities have been organised by EHEDG Serbia to disseminate information about EHEDG and its mission among professionals and scientists in the region. These include various lectures given on EHEDG-relevant topics at the Symposia Days of Serbian Microbiologists (April 2015); the Serbian Congress of Microbiologists in Belgrade (May 2016); and the 13th Serbian Congress for Nutrition in Belgrade (October 2016).

EHEDG Regional Sections meeting

During the 1st Black Sea Association of Food Science and Technology Congress (B-FoST) in September 2016, a meeting was organised between EHEDG Macedonia, Serbia and Croatia Regional Section chairs to discuss their individual group activities and achievements from the previous year. The meeting also provided a forum in which to plan forthcoming activities in 2017, opportunities for organising joint EHEDG training courses in these countries and discussing ways to increase membership in EHEDG.



EHEDG Executive Meeting, October 2015, Belgrade.



Participants of the EHEDG Plenary Meeting, October 2015, Belgrade.

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EHEDG Spain

Rafa Soro Martorell, AINIA Technological Centre, Valencia, Spain, e-mail: rsoro@ainia.es

The first EHEDG event in Spain occurred in 2001, when the 11th Annual EHEDG Congress was combined with a training workshop on hygienic engineering held in Valencia. The event was organised by AINIA and attracted more than 200 attendees. Four years later, in 2005, the Spanish Regional Section of EHEDG was created under the initiative of AINIA Technological Centre. In subsequent years, EHEDG Spain has carried out several activities to spread the requirements of hygienic design and information about EHEDG among Spanish companies. Seminars and advanced courses have been organised and held across Spain.

In 2012, the EHEDG World Congress on Hygienic Engineering and Design was held in Valencia, Spain, coorganised by EHEDG and AINIA. More than 250 delegates from more than 30 countries attended the Congress.

Dissemination activities have been organised to spread relevant information about EHEDG among Spanishspeaking professionals. Various communication channels have been used for this purpose (e.g., AINIA website, Tecnoalimentalia electronic bulletin, and Twitter).

The seventh and eighth editions of the EHEDG Advanced Course on Hygienic Design were held at AINIA in June 2015 and 2016, respectively. As on previous occasions, both food and equipment manufacturers were represented among delegates. The course, taught by EHEDG Authorised trainers, included case studies that were developed in a pilot plant.



Attendees of the EHEDG Advanced Course on Hygienic Design held at AINIA in 2016.

Representatives of EHEDG Spain have participated as speakers, giving lectures related to EHEDG and hygienic design at several events during 2015 and 2016:

Date	Event	Speaker
21/04/2015	BTA Fair (Barcelona)	Rafa Soro
22/04/2015	BTA Fair (Barcelona)	Irene Llorca, Andrés Pascual
28/05/2015	Pumps & Valves Fair (Bilbao)	Rafa Soro
06/10/2015	Seminar on Hygienic Design (Montevideo – Uruguay)	Huub Lelieveld, Rafa Soro
07/10/2015	Innova Congress (Montevideo – Uruguay)	Rafa Soro
10/11/2015	Seminar on Hygienic Design (Madrid)	Irene Lorca, Irene Lorca, Karel Mager, Andrés Pascual, Rafa Soro and sev- eral speakers from companies
17/11/2015	Seminar on Hygienic Design (AMEC - Bar- celona)	Irene Lorca Rafa Soro
04/05/2016	Seminar on Hygienic Design (SMC – Vitoria)	Irene Lorca Rafa Soro
07/06/2016	Veterinarians Association – Valencia	Rafa Soro
15/06/2016	Fispal Fair (Sao Paulo – Brasil)	Rafa Soro
07/07/2016	Seminar on Hygienic Design (AMEC – Barcelona)	Irene Lorca Rafa Soro
23/11/2016	Seminar on Hygienic Design (Valencia)	Irene Lorca, Rafa Soro and several speakers from companies

EHEDG Spain was present at the Barcelona Food Technologies (BTA) 2015 trade fair in Barcelona from 21-24 April 2015. This is the most important fair in Spain for equipment manufacturers, so it was a great opportunity to promote EHEDG. The Pumps & Valves Fair in Bilbao (May 2015), was another excellent opportunity to promote EHEDG activities.



The EHEDG booth at the BTA 2015 trade fair in Barcelona.

AINIA also has published several newsletters about EHEDG and hygienic design that have been distributed among much of the Spanish food industry and many food equipment manufacturers.

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EHEDG Switzerland

Dr.-Ing. Christoph Schill, Bühler AG, Switzerland, e-mail: Christoph.schill@buhlergroup.com

Upon ending his professional career in 2016, Dr. Rudolf Schmitt also handed over the presidential Chair of the EHEDG Regional Section Switzerland to Dr. Christoph Schill of Bühler AG. Dr. Schmitt was successfully heading EHEDG Switzerland since its establishment for eight years and built up a well-working Regional Section with 84 individual and 19 company members. The EHEDG Regional Committee has expressed its deepest thanks to Dr. Schmitt for his great support in all these years.

The major objective of EHEDG Switzerland is to promulgate knowledge about hygienic design throughout the Swiss food industry and academia. A seminar is organised every year, focusing in 2015 on the contents of EHEDG Doc. 44 on 'Hygienic Design Principles for Food Factories.' The overall seminar title, "Food Factory Design - An Advantage in Competition by Modern Plant Design," touched on several important topics. These included the general prerequisites of modern hygienic food factory design, hygienic installations of air handling systems and electrical wiring. The seminar also emphasised the impact of hygienic design on food safety, as well as personnel safety, including an overview of tripping hazards that can arise when retrofitting existing plants. The seminar was enriched by several networking opportunities, expert talks and discussions. With an attendance of about 30 high-level professionals, the seminar provided an excellent platform for sharing EHEDG's expert know-how with interested participants. The selected venue at Bühler AG supported the success of this seminar.

In 2016, the annual EHEDG Switzerland-organised seminar, titled "Hygiene Design – The Key to Success," took took place in Kirchberg on 24 November 2016. The seminar focused on the basics of hygienic design, risk assessment, and clean-in-place (CIP) methods and systems.

Some members of the EHEDG Regional Committee also gave several lectures on hygienic design at the HES-SO Valais and the Zurich Universitiy of Applied Sciences (ZHAW) in 2015. A major highlight in 2016 was the acceptance of EHEDG Doc. 45, "General Principles of Cleaning Validation in the Food Industry," by the EHEDG Executive Committee. This document was published in April 2016. Then-EHEDG Switzerland chair Dr. Rudolf Schmitt headed the Working Group "Cleaning Validation" and was primarily responsible for the realisation of this document. EHEDG Switzerland financially supported this work.

The 2016 General Assembly, held at HALAG AG, enabled the adoption of the EHEDG statutes regarding the EHEDG financial by-laws. As a result, the office of treasurer is now included in the statutes. Dr. Lars Fieseler was nominated as the first treasurer of EHEDG Switzerland.



Participants of the seminar Food Factory Design held in 2015 at Bühler AG.

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EHEDG Thailand

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EHEDG Thailand was officially established on 20 April 2009. The Regional Section was initiated between EHEDG and King Mongkut's Institute of Technology Ladkrabang (KMITL). At present, there is one institute member (KMITL) and seven company members (Betagro, Dhawath Technology Systems Co. Ltd., Grundfos (Thailand) Ltd., Innovative Engineering Group Ltd., Patkol PLC, Renox Stainless Steel Co. Ltd, and Solids Handling and Process Engineering Co. Ltd.). However, several industries are interested in membership and have attended the activities of EHEDG Thailand.

Training and seminar activities

There were several training courses, seminars and other activities in which EHEDG Thailand participated in 2015-2016. The first one was the EHEDG Thailand seminar entitled 'Hygienic Design of Closed Equipment Design for Processing Liquid Food,' held 14-15 September 2015 at KMITL.



Participants at the EHEDG Thailand seminar at KMITL in September 2015.

EHEDG Thailand also held several successful in-house trainings, at the National Food Institute (19-20 August 2015): at Charoen Pokphand Group (21-22 August 2015, 16-17 June 2016); and at Thai Union Group (21-22 August 2015, 16-17 June 2016).

In addition, members from EHEDG Thailand were invited to speak at several meetings in 2015-2016. One member made a presentation on the topic of hygienic design, food safety and food grade lubricants at a meeting organised by Klueber (Thailand) Co. Ltd. on 6 March 2015. EHEDG Thailand members also presented at the Technology Promotion Association of Thai-Japanese (TPA) on 27-28 August 2015 and 20-21 June 2016, and at Food Focus Thailand on 2 September 2016.

Mr. Takashi Hayashi, chair of EHEDG Japan, visited EHEDG Thailand three times in 2015-2016 in order to co-organise a joint seminar.



In-house training at the Charoen Pokphand Group in June 2016.



(From left): EHEDG Thailand members Dr. Navaphratta Nuank and Dr. Taweepol Suesut, KMITL were invited speakers for Food Focus Thailand seminar in September 2016.



EHEDG Thailand is helping to create a hygienic design course as a joint Erasmus + project with SEA-ABT.

EHEDG Thailand also has participated in the Erasmus+ Programme with the South East Asia Academy for Beverage Technology (SEA-ABT) to create an EHEDG hygienic design course for food and beverage industries. All of EHEDG Thailand's activities have been fruitful, and several national food manufacturers are interested in learning more about hygienic design and EHEDG guidelines.

Translation activities

EHEDG Guideline Docs. 1, 8, 10, 11, 13, 14, 16, 17, 20, 25, 33 and 37 have been translated and published in the Thai language. EHEDG Guideline Doc. 43 is now in the process of translation by EHEDG Thailand members.

Contact

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EHEDG TURKEY

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EHEDG Turkey was officially established at the 3rd Food Safety Congress, held from 3-4 May 2012 in Istanbul. The event was organised and hosted by the Turkish Food Safety Association (TFSA) with the participation of approximately 700 delegates from Turkey and abroad. Dr. Patrick Wouters (Cargill, EHEDG Vice President) and Mr. Dirk Nikoleiski (Mondelez International, EHEDG Executive Committee Member) were invited to lecture at the Hygienic Design Session of the Congress, which garnered a lot of interest in the topic of hygienic engineering and design.

On the second day of the Congress, TFSA President Dr. Samim Saner, Turkish committee members and EHEDG International representatives officially signed the Regional Section Bylaws.

Recent activities

EHEDG Turkey formed its Regional Committee and immediately started its activities in 2013. The first EHEDG Advanced Course on Hygienic Design was organised and held on 5-6 December 2013 in Istanbul, Turkey and coached by EHEDG international authorised trainers. Among the 51 course participants were EHEDG Turkey members Prof. Y. Onur Devres and Prof. Barbaros Ozer, who have since been considered as EHEDG Authorised Trainers.

The next year was very busy as well. On 7-8 May 2014, the Advanced Course on Hygienic Design training was presented in Turkish language for the first time and attracted 24 participants. EHEDG Turkey's second training course in 2014 was held from 17-18 December and attracted 26 participants.



EHEDG Advanced Course on Hygienic Design, May 2014.

An article about EHEDG and its activities was published in the second issue of Turkish Food Safety Magazine in 2014. The magazine is distributed to 5,000 food producers, food engineers, managers, equipment manufacturers and health authorities in Turkey.

In 2015, the 12th National Congress on Installation Engineering was held from 8-11 April in Izmir under the theme 'Hygienic Design in Food Processing.' Former EHEDG President Mr. Knuth Lorenzen, Prof. Devres and Prof. Ozer presented the special session on hygienic design. Their presentations, "Potential Savings in CIP of Food Production Plants Through Hygienic Design" (Lorenzen); 'Hygienic Design Criteria Pursuant to European Hygienic Design and Engineering Group' (Devres) and 'Hygienic Priorities in the Food Industry' (Ozer) were published in the official proceedings in the Turkish language.



Former EHEDG president Mr. Knuth Lorenzen lectures at the 12th National Congress on Installation Engineering, April 2015.

The International HVAC, Refrigeration, Pumps, Valves, Fittings, Water Treatment and Insulation Exhibition was held simultaneously with the Congress. Mr. Knuth Lorenzen also attended the exhibition and introduced EHEDG and its activities to various Turkish companies at the event.

Prof. Ozer also made a presentation entitled 'Importance of Hygienic Design in Food Processing Plants' at the 5th Food Safety Congress, held 7-8 May 2015 in Istanbul, to an audience of 600 delegates.



EHEDG Turkey member Prof. Ozer lectures on the importance of hygienic design in food processing plants,' in May 2015, Istanbul.

Prof. Devres joined the MAFEX Maghreb Food Exhibition in Casablanca, Morocco from 9-11 December 2015, presenting the topic 'Hygienic Design in Food Processing Plants.' He also presented 'Hygienic Design Criteria' as an introduction to the EHEDG organisation and the principles of hygienic design to various Turkish companies, including Apack Ltd., Kromel A.S., Bigtem A.S., and Cantek Refrigeration Systems A.S. Two training courses were held in 2016, one in April with 14 participants and the second one in November with a number of 20 participants.

EHEDG Turkey members Profs. Devres and Ozer published articles on hygienic design in Installation Engineers' Journal in September-November 2015 (No. 149, pp. 37-46) and in July-August 2016 (No. 154, pp. 79-86), respectively. The article, 'How to Do a Hygienic Design,' by Prof. Devres was published in Dunya Gida Journal in May 2016 (pp. 40-43).



Prof Onur Devres presenting an introduction on hygienic design criteria at various companies in Turkey.

Members

In 2015 and 2016, EHEDG Turkey welcomed five company members of the Regional Section: Betka Gida Sanayi ve Ticaret Ltd. Sti.; Bigtem Makine A.S.; Gemak Gida End. Mak. Tic. A.S.; Goztepe Makina Kalip Yedek Parca Imalat ve Tic. Ltd. Sti.; and Kromel Makina Sanayi ve Ticaret A.S.

Contact

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EHEDG UK and Ireland

Eric Partington, Nickel Institute, eric@effex.co.uk

After its establishment in 2014, the EHEDG Regional Section UK & Ireland is guided by a management committee comprised of 12 members:

- Eric Partington (Nickel Institute) is chairman
- Mariane Hodkinson (Campden BRI) and Craig Leadley (Campden BRI) form the Regional Section's secretariat
- Andy Buchan (ACO) and Sharon Kirby (Tonic Public Relations) coordinate all marketing and communications, such as press releases and newsletters
- Ray Tomsett (Wire Belt) and Rich Liddy (SMC Pneumatics) are in charge of the finances
- Deb Smith (Vikan) and Emma de-Alwis (Campden BRI) are the points of contact for companies that would like the Regional section to contribute to organised functions
- John Holah (Holchem) liaises with UK academia to offer hygienic design expertise to post-graduate university courses
- Doug Mills (Dixon Europe) and Ike Topselvi (ITT) answer technical enquiries

The communications team is constantly 'spreading the word' about EHEDG in the region. We take full advantage of social media through the EHEDG UK & Ireland LinkedIn page and by posting news on Twitter. EHEDG UK & Ireland uses an accredited data management company to send the Regional Section's *Hygiene Matters* e-newsletters to an extensive mailing list of companies. We offer editorials and features to trade journals such as Food Processing magazine and Baking Europe.

Our main achievements in 2016 included:

- Speaking at the Hygienic Design Food Processing Environments, a conference in February held in conjunction with the UK Institute of Food Science and Technology at Eastwood Park in Gloucestershire. The speakers were Andy Buchan, John Holah, Eric Partington and Deb Smith.
- Speaking at Food Matters, an exhibition held in April. Emma de-Alwis spoke on food safety challenges in the dry ingredient and snack food industry.
- Speaking at a meeting of the British Sandwich Association. The speaker was Mariane Hodgkinson.
- Speaking at the Packaging Hazards seminar held at Campden BRI in July. Again, the speaker was Mariane Hodgkinson.
- Speaking at the Process & Packaging Machinery Association Exhibition in September. Emma de-Alwis spoke on hygienic design.

- Speaking at Campden BRI's Contamination Control seminar. The speaker was Mariane Hodgkinson.
- Hosting an EHEDG stand at the Food Matters Live exhibition at the ExCeL Centre in London's Docklands in November.
- Speaking at Food and Drink Business Europe's Quality and Safety Seminar held at the National Motorcycle Museum at the end of November. Eric Partington gave a presentation titled 'Hygienic Engineering and Design – What Food Manufacturers Need To Know.'



EHEDG Regional Section UK & Ireland stand at the Food Matters Live exhibition in November 2016

Our plans for 2017 include holding a hygienic engineering conference in March in conjunction with the UK Institute of Food Science & Technology. EHEDG UK & Ireland also plans to take a stand at the Food Matters Live exhibition in the ExCeL Centre in November. And, of course, the Regional section is already preparing to host the EHEDG's World Congress 2018 at the ExCeL Centre in November of the following year.

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EHEDG Guidelines

EHEDG Guidelines can be ordered from the Webshop www.vdmashop.de/EHEDG by non-members and individual members. They are free for EHEDG Company and Institute Members while Individual EHEDG Members receive a 50 % discount.

Doc. 1. Microbiologically safe continuous pasteurisation of liquid foods

First edition, November 1992 (17 pages)

There are many reasons why, in practice pasteurised products sometimes present a microbiological health hazard. Due to distribution in residence time, not all products may reach the temperature required for pasteurisation or may do so for too short a time. Further there may be a risk of contamination with a non-pasteurised product, or the cooling medium. This document describes the requirements particularly for liquid foods without particulates.

> Languages available: Armenian, Croatian, Dutch, English, French, Macedonian, Russian, Spanish, Thai, Ukrainian

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

Third edition, June 2007 (16 pages)

The method is intended as a screening test for hygienic equipment design and is not indicative of the performance of industrial cleaning processes (which depend on the type of soil). See Doc 15 for a test procedure designed for moderately-sized equipment.

Languages available: Armenian, Croatian, Dutch, English, French, German, Italian, Macedonian, Russian, Serbian, Spanish

Doc. 3. Microbiologically safe aseptic packing of food products

First edition, January 1993 (15 pages)

This guideline stresses the need to identify the sources of micro-organisms that may contaminate food in the packaging process, and to determine which contamination rates are acceptably low. It clarifies the difference in risk of infection between aseptic processing and aseptic packing and recommends that aseptic packing machines be equipped with fillers that are easily cleanable, suitable for decontamination and bacteria-tight. Requirements for the machine interior include monitoring of critical decontamination parameters. See also Doc. 21 on challenge tests.

> Languages available: Armenian, Croatian, Dutch, English, French, Italian, Macedonian, Russian, Spanish, Ukrainian

Doc. 4. A method for the assessment of in-line pasteurisation of food processing equipment

First edition, February 1993 (12 pages) NOTE: Document was withdrawn in March 2016

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

Second edition, July 2004 (9 pages)

Food processing equipment may need to be sterilised before use, and it is important to ensure that the sterilisation method applied is effective. Thus, it is necessary to determine under which conditions equipment can be sterilised. This paper details the recommended procedure for assessing the suitability of an item of food processing equipment for in-line sterilisation. It is advisable to conduct in-place cleanability trials (ref. Doc.2) prior to this test in order to verify the hygienic design of the equipment.

> Languages available: Armenian, Chinese (Taiwan), Dutch, English, French, German, Macedonian, Russian, Spanish, Ukrainian

Doc. 6. The microbiologically safe continuous flow thermal sterilisation of liquid foods

First edition, April 1993 (26 pages)

Thermal sterilisation is aimed at eliminating the risk of food poisoning and, when used in conjunction with aseptic filling, at achieving extended product storage life under ambient conditions. Whereas pasteurisation destroys vegetative micro-organisms, sterilisation destroys both vegetative micro-organisms and relevant bacterial spores. This document presents guidelines on the microbiologically safe continuous sterilisation of liquid products. The technique of Ohmic heating was not considered in this paper but may be included in an update being prepared. See Doc. 1 for guidelines on continuous pasteurisation of liquid foods.

> Languages available: Armenian, Dutch, English, French, Macedonian, Russian, Spanish, Ukrainian

Doc. 7. A method for the assessment of bacteria tightness of food processing equipment

Second edition, July 2004 (10 pages)

This document details the test procedure for assessing whether an item of food processing equipment, intended for aseptic operation, is impermeable to micro-organisms. Small motile bacteria penetrate far more easily through microscopic passages than (non-motile) moulds and yeasts. The facultative anaerobic bacterium Serratia marcescens (CBS 291.93) is therefore used to test bacteria-tightness or the impermeability of equipment to micro-organisms. The method is suitable for equipment that is already known to be in-line steam sterilisable (see also Doc. 5).

> Languages available: Armenian, Dutch, English, French, German, Japanese, Macedonian, Russian, Spanish, Ukrainian

Doc. 8. Hygienic equipment design criteria

Second edition, April 2004 (16 pages)

This guideline 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 design 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 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 increased life expectancy of equipment, reduced maintenance and consequently lower operating costs.

This document, first published in 1993, describes in more detail the hygienic requirements of the Machinery Directive (98/37/EC ref.1). Parts of it have subsequently been incorporated in the standards EN1672-2 and EN ISO 14159.

Languages available: Armenian, Chinese (Taiwan), Croatian, Dutch, English, French, German, Italian, Japanese, Lithuanian, Macedonian, Portuguese (Brazil),Russian, Serbian, Spanish, Thai, Ukrainian

Doc. 9. Welding stainless steel to meet hygienic requirements

First edition, July 1993 (21 pages)

This document describes the techniques required to produce hygienically acceptable welds in thin walled (< 3 mm) stainless steel applications. The main objective was to convey the reasons and requirements for hygienic welding and to provide information on how this may best be achieved. This document is superseded by Doc 35, recently published. The working group will continue with a guideline on inspection of the quality of welds in food processing machinery.

Languages available: Dutch, English, French, Japanese, Macedonian, Spanish, Ukrainian

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

Second edition, May 2007 (22 pages)

Using the general criteria for the hygienic design of equipment identified in Doc 8, this paper illustrates the application of these criteria in the construction and fabrication of closed process equipment. Examples, with drawings, show how to avoid crevices, shadow zones and areas with stagnating product, and how to connect and position equipment in a process line to ensure unhampered draining and cleaning in-place. Attention is drawn to ways of preventing problems with joints, which might otherwise cause leakage or contamination of product.

> Languages available: Armenian, Croatian, Dutch, English, French, German, Italian, Lithuanian, Macedonian, Portuguese (Brazil), Russian, Serbian, Thai, Ukrainian

Doc. 11. Hygienic packing of food products

First edition, December 1993 (15 pages)

Products with a short shelf-life, or whose shelf life is extended by cold storage or in-pack heat treatments, do not have to conform to such strict microbiological requirements as aseptically packaged foods (Doc 3 discusses aseptic packing). This paper discusses the packing of food products that do not need aseptic packing but which nevertheless need to be protected against unacceptable microbial contamination. It describes guidelines for the hygienic design of packing machines, the handling of packing materials and the environment of the packing machines. See also Doc. 21.

> Languages available: Dutch, English, French, Macedonian, Russian, Spanish, Thai, Ukrainian

Doc. 12. The continuous or semicontinuous flow thermal treatment of particulate foods

First edition, March 1994 (28 pages)

Thermal sterilisation is a process aimed at eliminating the risk of food poisoning and, when used in conjunction with aseptic filling, it aims to extend product storage life under ambient conditions. This is achieved by the destruction of vegetative micro-organisms and relevant bacterial spores.

Liquid foods containing particulates are inherently more difficult to process than homogenous liquids due to heat transfer limitations in particulate-liquid mixtures and the additional problems of transport and handling. This paper presents guidelines on the design of continuous and semicontinuous plants for the heat treatment of particulate foods. Ohmic heating techniques are not covered. See also Doc. 1 on continuous pasteurisation and Doc. 6 on sterilisation of liquid products without particles.

> Languages available: Dutch, English, French, Japanese, Spanish, Ukrainian

Doc. 13. Hygienic design of equipment for open processing

Second edition, May 2004 (24 pages)

It is important that the plant design takes into account factors affecting the hygienic operation and cleanability of the plant. The risk of contamination of food products during open processing increases with the concentration of micro-organisms in the environment and their opportunity to grow in poorly designed equipment. This means that in open plants, environmental conditions, in addition to appropriate equipment design, have an important influence on hygienic operation. The type of product and the stage of the manufacturing process must also be taken into consideration.

This paper deals with the principal hygienic requirements for equipment for open processing and applies to many different types, including machines for the preparation of dairy products, alcoholic and non-alcoholic drinks, sweet oils, coffee products, cereals, vegetables, fruit, bakery products, meat and fish. It describes methods of construction and fabrication, giving examples as to how the principal criteria can be met. See also guidelines on hygienic design criteria Doc 8, hygienic welding Doc 9, and the hygienic design of equipment for closed processing Doc 10.

> Languages available: Second Edition, May 2004: Croatian, English, French, German, Italian, Japanese, Lithuanian, Macedonian, Russian, Serbian, Thai, Ukrainian

First Edition, 1996: Dutch

Doc. 14. Hygienic design of valves for food processing

Second edition, July 2004 (17 pages)

Valves are essential components of all food processing plants and the quality used strongly influences the microbiological safety of the food production process. These valves must therefore comply with strict hygienic requirements

The guidelines apply to all valves used in contact with food or food constituents that are to be processed hygienically or aseptically. Aside from general requirements with regard to materials, drainability, microbial impermeability and other aspects, additional requirements for specific valve types are also described. See also Doc. 20 on double-seat mixproof valves.

> Languages available: Dutch, English, French, Italian, Japanese, Macedonian, Russian, Spanish, Thai

Doc. 15. A method for the assessment of in-place cleanability of moderately sized food processing equipment

First edition, February 1997 (12 pages) NOTE: Document was withdrawn in March 2016

Doc. 16. Hygienic pipe couplings

First edition, September 1997 (21 pages)

This paper identifies and defines critical design parameters for welded pipe couplings: easily cleanable in-place; easily sterilisable in place; impervious to micro-organisms, reliable and easy to install.

Gaskets of various types were tested for reliability and hygienic aspects using EHEDG cleanability test methods and repeated sterilisation. The objective was to provide a reliable dismountable joint which is bacteria-tight at the product side under the conditions of processing, cleaning and sanitation.

> Languages available: Armenian, English, French, German, Japanese, Macedonian, Russian, Thai, Ukrainian

Doc. 17 Hygienic design of pumps, homogenisers and dampening devices

Third Edition, April 2013 (41 pages)

This updated guideline is meant to specify the technical requirements of pumps, homogenizers and dampening devices including their hygienic application in order to ensure a safe processing and production of food under hygienic conditions. The requirements described in the guideline apply to all pumps intended for the use in safe food processing, including centrifugal pumps, piston pumps, lobe rotor pumps, peristaltic pumps, diaphragm pumps, progressive cavity pumps, screw pumps as well as to homogenizers and dampening devices. The document includes a classification of pumps which is complemented by illustrations and pictures for a better understanding of the hygiene-related issues and potential problem areas (such as gaps and deadends) as well as of state-of-the-art hygienic design solutions. Special needs for CIP/SIP-capability, gentle product handling and easy maintenance have to be duly considered for pumps, homogenizers and dampening devices used in food processing. These demands, their implementation and related design principles are described in detail in EHEDG Doc. 17. Based on the EC-Machinery Directive 2006/42/ EC, the document specifies additional requirements to such equipment in order to fulfil good mechanical and hydraulic properties as well as thermal efficiency by following modern design practices and ensuring low-cost manufacture.

> Languages available: Third Edition, April 2013: Armenian, Croatian, Dutch English, French, German, Italian, Japanese, Macedonian, Russian

Second Edition, September 2004: French, Italian, Macedonian, Thai

Doc. 18. Chemical Treatment of Stainless Steel Surfaces

Second Edition, January 2014 (19 pages)

This guideline issued in January 2014 replaces Doc. 18 "Passivation of Stainless Steel" (1998) and includes new sections on pickling and electropolishing of stainless steels. Chemical surface treatments such as pickling, passivation and electropolishing can help to assure the successful functional and corrosion-resistant performance of stainless steels for product contact surfaces in the food and beverage industry. This document explains the general principles of those three processes above: Why they are necessary, when and how they should be applied, how they work and which chemicals are used.

> Languages available: Second Edition, January 2014: Croatian, English, Italian, Macedonian, Portuguese (Brazil), Russian, Serbian

First Edition, August 1998: Armenian, Dutch, French, German, Japanese, Macedonian, Russian, Spanish

Doc. 19. A method for assessing the bacterial impermeability of hydrophobic membrane filters

Second Edition, June 2012 (9 pages)

Research has shown that hydrophobic membrane filters, with a pore size of 0.22μ m, do not retain micro-organisms under all process conditions. Investigations were conducted into risk assessment of sterilising hydrophobic membrane filters, evaluating the performance of the filters under a range of operating conditions.

To validate the performance of sterilizing grade hydrophobic membrane filters, a bacterial aerosol challenge test methodology (TBAC) was developed. The method was used to qualify filter systems for air filtration and exhaust gas filtration on fermenters. In these applications, filters are intended to prevent micro-organisms from contaminating the environment.

> Languages available: Second Edition, June 2012: Croatian, Dutch, English, German, Japanese, Lithuanian, Macedonian, Russian, Serbian

First Edition, June 2000: Armenian, French, Spanish

Doc. 20. Hygienic design and safe use of double-seat mixproof valves

First edition, July 2000 (20 pages)

This document describes the basic hygienic design and safe use of single-body double-seat mixproof valves. Today, food process plants incorporate various multifunctional flow paths. Often one piping system is cleaned while another still contains product. This simultaneous cleaning can potentially result in the dangerous situation where product and cleaning liquid are separated by just one single valve seat. Any cleaning liquid that leaks across such a seat will contaminate the product. Therefore, often two or three single seat valves in a "block-and-bleed" arrangement are applied.

> Languages available: Armenian, Dutch, English, French, Italian, Japanese, Macedonian, Russian, Thai

Doc. 21. Challenge tests for the evaluation of the hygienic characteristics of packing machines for liquid and semi-liquid products

First edition, July 2000 (32 pages)

After documents 3 and 11, this is the third test method in the series. It discusses how packing machines should be designed to comply with hygiene design criteria and thereby with the requirements specified in Annex 1 of the Machinery Directive1. To determine whether those criteria are met requires validation of the design and measurement of essential parameters. Proven methods for testing the performance of the various functions of packing machines are described.

These methods may also be used by the manufacturer to optimise or redesign a packing machine and by the food processor who may want to compare different packing machines.

Upon delivery, a packing machine needs to be checked by a commissioning procedure to be agreed in advance between the food processor and the supplier. Commissioning may include physical as well as microbiological tests. Additional tests are specified for commissioning of machines for aseptic packing.

1 Machinery Directive 98/37/EC – Annex 1, point 2.1, Agrifoodstuffs machinery

Languages available: Armenian, Dutch, English, French, German, Macedonian, Russian, Spanish

Doc. 22. General hygienic design criteria for the safe processing of dry particulate materials

Second Edition, March 2014 (28 pages)

In the food industry many different types of dry particulate food related materials are produced and handled. This requires different design criteria for specific process equipment and process lines in relation with the various food safety requirements of each material.

The first edition of this document was the first EHEDG guideline in which the requirements for powder handling processes were highlighted. Previous EHEDG guidelines were mainly focused on the hygienic design criteria in liquid processing of foods. This general and updated document relates to processing of powders, agglomerates and granular materials. Fluid and moist solid materials like slurries and wet cakes are not taken into account. Typical aspects of hygienic equipment design involve cleaning of equipment, prevention of any physical, chemical or biological contamination and microbial survival and growth, all in relation to dry particulate materials. If wet cleaning is applied, the design criteria are similar to those as described in other EHEDG documents (ref. 1, 2, 3 and 5). Sometimes other procedures (such as dry cleaning) need to be used and these are described in this document.

> Languages available Second Edition, March 2014: Armenian, Croatian, English, German, Japanese, Lithuanian, Macedonian, Portuguese (Brazil)

> First Edition, March 2001: Dutch, French, Macedonian, Russian, Spanish

Doc. 23. Production and use of food-grade lubricants, Part 1 and 2

Second edition, May 2009

(Part 1: Use of H1 Registered Lubricants – 23 Pages / Part 2: Production of H1 Registered Lubricants – 10 Pages)

Lubricants, grease and oil are necessary components for the lubrication, heat transfer, power transmission and corrosion protection of machinery, machine parts, instruments and equipment. Incidental contact between lubricants and food cannot always be fully excluded and may result in contamination of the food product. This risk applies to all lubricants equally. PART 1 of this guideline covers the hazards that may occur when using food grade lubricants and describes the actions and activities required to eliminate them or to reduce their impact or occurrence to an acceptable level. PART 2 of this guideline lays down the general requirements and recommendations for the hygienic manufacturing and supply of food-safe lubricants.

Languages available: Armenian, Croatian, Dutch, English, French, German, Japanese, Lithuanian, Macedonian, Portuguese (Brazil), Russian, Serbian, Spanish

Doc. 24. The prevention and control of legionella spp (incl. legionnaires' disease) in food factories

First edition, August 2002 (21 pages)

There are many locations in food industry sites where the potential for the proliferation of Legionella spp in water systems exists. These bacteria can give rise to a potentially fatal disease in humans, which is identified as legionellosis or legionnaires' disease.

This document applies to the control of Legionella spp. in any undertaking involving a work activity and to premises controlled in connection with a trade, business or other undertaking where water is used or stored and where there is a means of transmitting water droplets which may be inhaled, thereby causing a reasonably foreseeable risk of exposure to Legionella spp.

The guidelines summarises the best practice for controlling Legionella in water systems. It consists of two parts; namely, Management Practices and Guidance on the Control of Legionella spp. in Water Systems.

The first section describes a management programme: risk identification and assessment; risk management (incl personnel responsibilities); preventing or controlling risk of exposure to the bacteria; and record keeping.

The second part provides guidance on the design and construction of hot and cold water systems as well as the management and monitoring of these systems. Water treatment programmes, with attention to cleaning and disinfection, are also discussed.

> Languages available: Dutch, English, French, German, Lithuanian, Macedonian, Portuguese (Brazil), Russian, Serbian

Doc. 25. Design of mechanical seals for hygienic and aseptic applications

First edition, August 2002 (15 pages)

This guideline compares the design aspects of different mechanical seals with respect to ease of cleaning, microbial impermeability, sterilisability or pasteurisability. It can serve as a guide for suppliers and users of this important component. Using EHEDG definitions, mechanical seals are classified according to use in the food industry into three categories: Aseptic, Hygienic equipment Class I, and Hygienic Equipment Class II. Both single and dual mechanical seals fall under the first two categories, which by definition, are subject to more stringent hygienic demands. General design criteria and basic material requirements for food applications are explained. Materials covered include carbon-graphite, ceramics, elastomers and metals. Hygienic implications of seal elements and components are also discussed. Finally, installation requirements are described and illustrated, taking into account the product environment side, the flushing side and the cartridge design.

> Languages available: Armenian, Dutch, English, German, Japanese, Macedonian, Russian, Thai

Doc. 26. Hygienic engineering of plants for the processing of dry particulate materials

First edition, November 2003 (28 pages) NOTE: Document was withdrawn in March 2016. Doc. 26 has been integrated into Doc. 44

Doc. 27. Safe storage and distribution of water in food factories

First edition, April 2004 (16 pages)

Water is a vital medium used for many different purposes in the food industry. Systems for storing and distributing water can involve hazards, which could cause water quality to fall below acceptable standards. It is therefore critical to ensure that water storage and distribution in a food manufacturing operation takes place in a controlled, safe way. This Guideline summarizes the best practice for three water categories used in the food industry: product water, domestic water and utility water. See also Doc. 24.

> Languages available: Armenian, Dutch, English, French, Japanese, Lithuanian, Macedonian, Portuguese (Brazil), Russian, Serbian, Spanish

Doc. 28. Safe and Hygienic Water Treatment in Food Factories

First Edition, December 2004 (21 pages)

This guideline summarizes the best practice for the management and operation of water storage and distribution systems in a food manufacturing plant. System requirements are described for three categories of water used: domestic, product and utility water. The product water distribution system within the plant must be hygienically designed. Water storage tanks should be enclosed, fitted with an air vent and a backflow prevention device and be completely drainable. A suitable-sized tank based on water consumption is essential to minimize stagnation. Chemical or thermal disinfection is recommended. Hazards and risks associated with utility water can have significant implications on process reliability. The document provides some recommendations with regard to specific utility water applications in the food industry, both for hot water and cold water. Attention is given to once through cooling systems, those using cooling towers and some examples of closed circuit systems.

> Languages available: Armenian, English, French, Japanese, Macedonian, Russian, Spanish

Doc. 29. Hygienic design of packing systems for solid foodstuffs

First edition, December 2004 (24 pages)

This document addresses packing systems of solid food products and supplements earlier guidelines. Solid food is characterised as having a water activity of >0.97, low acid, not pasteurised or sterilised after packaging, and distributed through the cool chain. Examples include fresh meat and some meat products, cheeses, ready meals, cut vegetables, etc. Hygiene requirements of the packaging operations, machinery as well as personnel, are described and reference is made to the American Meat Institute's principles of sanitary design. See also Docs. 3 and 11.

> Languages available: Armenian, Dutch, English, French, Macedonian, Russian

Doc 30. Guidelines on air handling in the food industry

First edition, March 2005 (43 pages) NOTE: Document was withdrawn in September 2016.

Doc. 31. Hygienic engineering of fluid bed and spray dryer plants

First edition, May 2005 (19 pages)

Because these plants handle moist products in an airborne state, they are susceptible to hygiene risks, including a possible transfer of allergens between products. It is therefore critical to apply hygienic design considerations to both the process and machinery to prevent occurrence of such risks.

Starting from the basics with regard to design, construction materials, layout, and zone classification of the drying systems to meet hygienic requirements, this paper outlines component design aspects of the processing chamber, with particular attention to the atomization assembly and the distribution grids for fluidization. Systems for both supply and exhaust air should operate in a hygienic manner and recommendations for the use and installation of various types of filters are listed. Finally, operational aspects, including sampling, control and general housekeeping are briefly discussed.

> Languages available: Dutch, English, French, Russian, Macedonian, Spanish

Doc. 32. Materials of construction for equipment in contact with food

First edition, August 2005 (48 pages)

This guideline aims to offer a practical 'handbook' for those responsible for the specification, design and manufacture of food processing equipment. It offers guidance on the ways in which materials may behave such that they can be selected and used as effectively as possible. The properties and selection procedures with regard to metals, elastomers and plastics are covered in detail. Potential failure mechanisms and influenced of manufacturing processes are also discussed. A more general overview of composites, ceramics and glass and materials is provided.

The guideline can serve as an aide-memoir during the design process, so that equipment manufacturers and end-users can together ensure that all aspects of materials behaviour are taken into account in designing safe, hygienic, reliable and efficient equipment which can be operated, maintained and managed economically.

> Languages available: Armenian, Dutch, English, French, Italian, Japanese, Lithuanian, Macedonian, Russian

Doc. 33. Hygienic engineering of discharging systems for dry particulate materials

First edition, September 2005 (16 pages)

The introduction of the product into the processing system is a key step in maintaining the sanitation and integrity of the entire process. Discharging systems are designed to transfer, in this case dry solids, from one system into another without powder spillage, contamination or environmental pollution. Many dry systems do not have any additional protective heating steps, as they are merely specialty blending processes. Therefore, any contamination that enters the system will appear in the finished product.

Guidelines for the design of bag, big bag, container and truck discharging systems are presented. They are intended for use by persons involved in the design, sizing, and installation of bag, big bag and truck discharging systems operating under hygienic conditions.

> Languages available: Armenian, Dutch, English, French, Macedonian, Russian, Serbian, Spanish, Thai

Doc. 34. Integration of hygienic and aseptic systems

First edition, March 2006 (45 pages)

Hygienic and/or aseptic systems comprise inter alia individual components, machinery, measurement systems, management systems and automation that are used to produce for example food products, medicines, cosmetics, home & personal products and even water products. This horizontal guideline is about the hygienically safe integration of hygienic (including aseptic) systems in a food production/ processing facility.

Systems and components are frequently put together in a way that creates new hazards, especially microbiological ones. Deficiencies during the sequence of design, contract, design-change, fabrication, installation and commissioning are often the cause of these failures, even when specific design guidelines are available and are thought to be well understood. Errors in sequencing and content can also result in major penalties in terms of delays and in costs of components and construction. This document examines integration aspects that can affect hygienic design, installation, operation, automation, cleaning and maintenance and uses system flow charts and case studies describing the integration processes and decision steps. It does not provide detailed guidance on specific manufacturing processes, products, buildings or equipment.

> Languages available: Armenian, English, French, German, Italian, Lithuanian, Macedonian, Russian

Doc. 35 Welding of stainless steel tubing in the food industry

First edition, July 2006 (29 pages)

Abundantly illustrated, this paper provides guidelines for the correct execution of on-axis hygienic (sanitary) welding between pipe segments, or between a tube and a control component (e.g. valve, flow meter, instrument tee, etc.) It deals with tube and pipe systems with less than 3.5 mm wall thickness, built in AISI 304(L) (1.4301, 1.4306 or 1.4307), 316(L) (1.4401, 1.4404 or 1.4435), 316Ti (1.4571) or 904L (1.4539) and their equivalents. The requirements for a weld destined for hygienic uses are first described, then the possible defects which can affect the weld are listed, and at the end the procedure for a state-of-the-art welding execution is illustrated, including preparation of pipe ends, final inspection and a trouble shooting guide.

It mainly refers to the part of the weld in contact with the finished or intermediate product and the only welding method considered is the GTAW (Gas Tungsten Arc Welding, commonly known as TIG) without filler material (autogenous weld), since this technique is capable of assuring the best performance in the execution of welds for the fabrication of thin wall stainless steel tubing. Inspection of welds will be covered in more detail in the next project.

> Languages available: Armenian, Dutch, English, French, German, Japanese, Macedonian, Russian, Spanish

Doc. 36. Hygienic engineering of transfer systems for dry particulate materials

First edition, June 2007 (21 pages)

Transfer (also known as transport or conveying) of dry particulate materials (products) between or within plant components in a process line is well practiced in the food industry. The transfer operation must be carried out in a hygienic and safe manner and the physical powder properties must not be affected during this operation. In this document, hygienic transfer systems for transport of bulk materials within a food processing plant are described. This document also covers situations where transfer systems are used as a dosing procedure.

In principle, the less the need for product transfer within a food processing plant, the easier it is to make a factory hygienically safe. Furthermore, with a minimum of product transfer between equipment, there are the added advantages of a more compact plant, lower energy consumption and reduced cleaning time. Less product handling results in less adverse effects on product properties.

This guideline is intended for use by persons involved in the design, technical specification, installation and use of transfer systems for dry bulk particulate materials operating under hygienic conditions.

> Languages available: Armenian, Dutch, English, French, Macedonian, Russian, Serbian

Doc. 37. Hygienic design and application of sensors

First edition, November 2007 (35 pages)

According to their working principles, all sensors rely on an interaction with the material to be processed. Therefore, the use of sensors is commonly associated with hygiene risks. In many cases, the basic measuring aspect of a sensor and the optimum hygienic design may conflict.

This guideline is intended to advise both, sensor designers and manufacturers as well as those in charge of production machinery, plants and processes about the appropriate choice of sensors and the most suitable way for application in dry and wet processes.

Sensors are crucial in the monitoring of the critical process steps as well as the CCP's as established by the HACCP study of the process. Therefore validation and calibration of sensors in time sequences are essential.

This guideline applies to all sensors coming into contact with liquids and other products to be processed hygienically. However, it focuses upon sensors for the most common process parameters, particularly temperature, pressure, conductivity, flow, level, pH value, dissolved oxygen concentration and optical systems like turbidity or colour measurements.

> Languages available: Armenian, English, French, German, Japanese, Macedonian, Russian, Thai

Doc. 38. Hygienic engineering of rotary valves in process lines for dry particulate materials

First edition, September 2007 (13 pages)

Rotary valve selection and operation has a considerable influence on the hygiene standard of a process line and thus, the end-product quality of the dry material handled. Incorrect selection of valve type and size must be regarded as a serious hygienic risk in the food industry. Hence, only valves strictly conforming to hygienic design standards and suited for hygienic operations must be used.

This guideline applies to rotary valves that are in contact with dry particulate food and/or food related materials being processed hygienically in designated dry particulate material processing areas. The objective of this guideline is to provide guidance on the essential requirements for hygienic rotary valve design and operation. The guideline is intended for persons involved in the design, selection, sizing, installation and maintenance of rotary valves required to operate under hygienic conditions.

> Languages available: Armenian, Dutch, English, French, Macedonian, Russian, Serbian, Spanish

Doc. 39. Design principles for equipment and process areas for aseptic food manufacturing

First edition, June 2009 (14 pages)

In many areas there is an increasing demand for self stable products. However, microbial product contamination limits the shelf life of sensitive products which are not protected by any preservatives or stabilised by their formulation. Products which fail this inherent protection have to be sterilised and in consequence, the equipment must be cleanable and sterilisable. Micro-organisms which are protected by product residues or biofilms are very difficult or impossible to inactivate and the same applies to process areas if resulting in a recontamination risk. This guideline is intended to describe the basic demands for equipment and process areas for aseptic food manufacturing.

> Languages available: Armenian, Chinese (Taiwan), Croatian, English, French, German, Japanese, Lithuanian, Macedonian, Portuguese (Brazil), Russian, Serbian, Spanish

Doc. 40. Hygienic engineering of valves in process lines for dry particulate materials

First edition, October 2010 (26 pages)

Every process plant is equipped with valves. In dry particulate materials processing, valves fulfil numerous functions: shut-off and opening of flow lines, direction and flow control, protection against excessive or insufficient pressure and against intermixing of incompatible media at intersection points in the process. The quality of the valve has a considerable influence on the quality of the production process and hence, the product itself. Hygienic deficiencies resulting from poor valve design must be regarded as a production risk in the food industry which must ensure that only valves strictly conforming to hygienic requirements are used. This Guideline describes in detail the hygienic requirements of butterfly valves, slide gate valves and ball segment valves. It also briefly mentions pinch-off valves, ball and plug valves as well as cone valves. The hygienic design requirements of rotary and diverter valves are subject of separate EHEDG Documents (Doc. 38 and 41).

> Languages available: Armenian, English, French, Russian, Serbian, Spanish

Doc. 41. Hygienic engineering of diverter valves in process lines for dry particulate materials

First edition, August 2011 (22 pages)

Every process plant is equipped with valves, which fulfil numerous functions. These include line shut-off, opening, change-over and control of product flow, while also giving protection against both excessive or insufficient pressure and intermixing of incompatible media at intersection points in the process line.

When dry particulate material (product) flow has to be diverted into several directions during processing or product coming from different lines converges into one line, diverter valves are applied. In the area of dry product handling, these valves need a dedicated design.

This Guideline deals with the hygienic aspects of diverter valve design.

Valve construction, however, has a considerable influence on the quality of the production process and hence, the product itself. Hygienic deficiencies resulting from poor valve design must be regarded as a production risk in the food industry which must ensure that only valves strictly conforming to hygienic requirements are used.

> Languages available: Armenian, English, French, Macedonian, Russian, Spanish

Doc. 42. Disc stack centrifuges

First edition, April 2013 (24 pages)

Special demands are made with regard to CIP-capability of disc stack centrifuges used in the food processing and pharmaceutical industry. These requirements, their implementation and related design principles are handled in detail in this guideline.

This guideline covers the hygienic aspects of disc stack centrifuges used to separate fractions of liquid food products or to remove dense solid matter from products. The hygienic operation of a disc stack centrifuge, which is a complex machine with the purpose of collecting non-milk-solids (NMS) or other solid matter from liquid products, relies on proper cleaning by CIP/COP. Therefore, this guideline deals with cleaning as well as design.

The guideline does not cover cyclonic types of separators, decanters, basket centrifuges or other types of devices.

Languages available: Armenian, English, Japanese, Macedonian, Spanish

Doc. 43 Hygienic Design of Belt Conveyors for the Food Industry

First Edition, April 2016 (76 pages)

This document provides guidance to the hygienic design of belt conveyors specifically for use in an environment where wet cleaning is mandatory, and is supplementary to the general requirements and standards for hygienic equipment. The guidance is relevant where the foodstuff is in direct contact with the conveyor and also in areas where there is a hygienic risk from indirect contamination. Although applicable for use in all food production environments, care must be taken when using these guidelines in considering the actual conditions, product types and the hygienic risks of contamination. Similarly, where a dry application precludes the use of water and liquids in cleaning, different systems may be suited, as described in EHEDG guideline, document 22.

> Language available: Armenian, English, Lithuanian, Thai

Doc. 44 Hygienic Design Principles for Food Factories

First Edition, September 2014 (133 pages)

This document provides those responsible for the design and construction of food factories with best hygienic practice guidelines. Following the advice in this document should, therefore, ensure that the building will be designed to the minimum hygienic building design standards that are applicable worldwide. Whilst primarily aimed at food manufacturing sites, this guidance is also applicable to food service buildings. This document does not consider any international or national building standards or safety standards (e.g. fire). It also does not cover hygiene within the construction process which is intended to be provided via EHEDG guidance on maintenance procedures.

This document does, however, assume that buildings will be constructed following general civil engineering best practice as failures in the construction process will lead to potential unhygienic features related to hazard harbourage and the reduction of cleaning efficacy.

It is also recognised that during the project development, the scope of some hygienic design features may have changed in an effort to reduce costs. In such cases it may be possible to argue for the hygienic approach based upon the long term costs of any additional measures necessary to ensure the hygienic functioning of the alternative approach, e.g. the extra cost per day of any additional hygienic practices required.

> Language available: Armenian, Croatian, Dutch, English, Lithuanina, Macedonian, Portuguese (Brazil), Spanish

Doc. 45 Cleaning Validation in the Food Industry – General Principles, Part 1

First Edition, April 2016 (14 pages)

The objective of cleaning validation is to prove that the equipment is consistently cleaned of product, microbial residues, chemicals and soiling, including allergens to an acceptable level, to prevent possible cross-contamination of hazards between products. This document focuses on the overall concept of cleaning validation and is intended as a general guideline for use by food manufacturers and inspectors. It is not the intention to be prescriptive in specific validation requirements. This document serves as general guidance only, and the principles may be considered useful in their application in the production of safe food, and in the development of guidelines for the validation of specialized cleaning or inactivation processes.

Language available: Armenian, English, German, Portuguese (Brazil), Serbian

Doc. 47 Guidelines on Air Handling Systems in the Food Industry – Air Quality Control for Building Ventilation

First Edition, September 2016 (55 pages)

The "Guidelines on air handling systems in the food industry - air quality control for building ventilation" have a focus on air handling systems installed for food factory building ventilation and its air quality control. Supply systems for process air, compressed air and exhaust air systems such as grease filter systems or dust removal units are excluded from the scope of this document. These guidelines are intended to assist food producers in the design, selection, installation, and operation of air handling systems to meet the air quality and hygienic requirements of the food manufacturing process. Information is provided on the role of air systems in achieving and maintaining microbiological standards in food products. The guidelines cover the choice of systems, air filtration types, system concepts, construction, maintenance, sanitation, testing, commissioning, validation and system monitoring.

> Language available: English



EHEDG World Congress on Hygienic Engineering & Design 2016 – Denmark, Herning, 2–3 November 2016



With an attendance of about 320 high-level professionals from food and food equipment manufacturers, food safety and quality experts, engineers and designers as well as managers of food-related industries and academia, the EHEDG World Congress on Hygienic Engineering & Design held from 2-3 November 2016 in Herning/ Denmark offered an excellent platform for sharing the EHEDG expert know-how.



Congress audience

The range of topics was of high relevance to the target industries, starting with the keynote lectures on the importance of hygienic engineering & design in food safety and auditing programs, as well as on the requirements to hygienic design from a food producer's viewpoint. Other expert lectures highlighted product contact surface materials, latest findings in surface aspects and easyto-clean equipment design, as well as typical hygienic hazards in critical equipment areas such as elastomeric seals. The speakers of the open processing equipment session introduced the needs of hygienic manufacturing in particular industries such as fish, meat and fresh produce. On congress day two, the lecturers gave an insight into new trends in cleaning validation, EHEDG test method development and dry cleaning aspects, while the final session was dedicated to the economic and environmental benefits of hygienic design as a tool for cost reduction and improvement of factory design. By the lecture program, the congress delegates gained a comprehensive overview of the most recent EHEDG guideline know-how, future trends and best practices recommended by the EHEDG experts.

The event was enriched by plenty of networking opportunities, expert talks and discussions in the dedicated sponsor's and poster exhibition area. Taking place in the framework of Northern Europe's leading trade fair in food technology, the delegates were also invited to visit FoodTech, where they had an opportunity to make their individual one-to-one business meeting appointments in the "EHEDG lounge" on the fairground.



The delegates used the opportunity to have their questions answered by the lecturers



Sponsor's exhibition area

The delegates enjoyed a perfectly organized event hosted under the umbrella of EHEDG International and EHEDG Denmark in cooperation with MCH Messecenter Herning. "The Danish EHEDG Committee ambitiously applied for the EHEDG World Congress 2016 and is proud of having been rewarded with hosting this major event", said Congress Chairman Jon Kold.

On the pre-congress day of 1 November 2016, 80 EHEDG chairpersons from 31 countries together with the Executive Committee and the Advisory Board members gathered for their annual Plenary Meeting. The participants discussed the future alignment of the EHEDG strategy and operational work with a focus on further geographical expansion, technical portfolio and activity clusters, as well as on added value proposals for food producers.



EHEDG Plenary Meeting 2016

The Congress gala dinner offered the platform for the "Hygienic Study Award" in honor of three outstanding PhD theses. In addition, EHEDG gladly honored three of its experts for their outstanding and long-term commitment as well as for their distinguished services to the organization, namely Patrick Wouters (Netherlands), Dirk Nikoleiski (Germany) and Vladimir Kakurinov (Macedonia).

90 percent of the participants considered the event as highly relevant for their day-to-day business and said that they would like to attend again. Like this, the EHEDG World congress days in Herning fulfilled all expectations of the delegates and the organizers and there is demand and commitment to repeat the event in the future.

The next opportunity for participating in this biennial major event of EHEDG will be the EHEDG World Congress on Hygienic Engineering & Design – UK from 21 to 22 November 2018 on occasion of Food Matters Live at the ExCel Exhibition Centre in London.



The next EHEDG Plenary Meeting will take place from 19–20 October 2017 in Amsterdam/Netherlands.



EHEDG Working Groups

To date, about 400 experts are active in the EHEDG Working Groups. They have developed and published a variety of guidelines which are subject to regularly update. Various other topics are under progress and will complement this document series. Each Working Group is responsible for an area of expertise, and within each area certain specific scopes are defined.

The international EHEDG working group experts meet regularly to update existing and draw up new Guidelines. The EHEDG documents offer their readers guidance and practical advice in implementing national and international legislation into their good design practices and manufacturing processes. Specialists with the relevant expertise are always welcome to join these Working Groups and to contribute by their expertise.

EHEDG is grateful for the participation of these volunteers who share their expertise and invest their time for the advancement of EHEDG – for the good of all. Without these excellent specialists the good work of EHEDG would not be possible as it is.

The EHEDG working groups are clustered into the following subject areas:

- General Principles including Materials and Surfaces
- Test Methods
- Factory Design including Design of Utility Systems
- Closed Equipment for Liquid Food
- Closed Equipment for Dry Particulate Materials
- Open Equipment
- Packaging Machinery including Filling Machinery
- Heat Treatment
- Cleaning & Validation
- Training & Education

New guidelines still in the process of being drawn up are:

- Aseptic and hygienic filling machines
- Bakery Equipment
- Cleaning and Disinfection
 (additional modules to Doc. 45)
- Cleaning in Place
- Elastomeric Seals
- Fish Processing
- Food refrigeration equipment
- Foreign Bodies

- Meat Processing
- Pack-off systems in process lines for dry particulate materials
- Tank cleaning systems
- Welding Inspection

Currently under revision and in progress of being updated:

- Microbiologically Safe Continuous Pasteurisation of Liquid Food (Doc. 1)
- Microbiologically safe aseptic packing of food product (Doc. 3)
- The Microbiologically Safe Continuous Flow Thermal Sterilisation of Liquid Foods (Doc. 6)
- Hygienic equipment design criteria (Doc. 8)
- Hygienic welding of stainless steel tubing in the food processing industry (Doc. 9)
- Hygienic packing of food products (Doc. 11)
- Hygienic design of equipment for open processing (Doc. 13)
- Hygienic design of valves for food processing (Doc.14)
- Hygienic design and safe use of double-seat mixproof valves (Doc. 20)
- Challenge tests for the evaluation of the hygienic characteristics of packing machines for liquid and semi-liquid products (Doc. 21)
- Design of mechanical seals for hygienic and aseptic applications (Doc. 25)
- Safe storage and distribution of water in food factories (Doc. 27)
- Safe and hygienic water treatment in food factories (Doc.28)
- Materials of construction for equipment in contact with food (Doc. 32)
- Hygienic System Integration (Doc. 34)
- Hygienic welding of stainless steel tubing in the food processing industry (Doc. 35)

- Tanks with and without additional tools
- Dosing and portioning machines
- Processing machines
- Ovens
- Cooling systems
- Accessories like sheets, tables, vehicles, etc. (open only)

The draft of the guideline contains a general part that provides definitions, general statements on hygienic design, recommended materials, types and application of cleaning, and requirements of design for commonly used components of equipment in the bakery industry. The bakery process mainly uses open equipment. In addition, three tables are included that comprise recommendations on hygienic design of specific equipment used in the bakery process, from raw materials to finished products. The tables identify problems with poor design and recommend improvements. A final draft of the guideline was prepared in August 2016 in German. An editorial group is now revising the content to harmonise the general part and the tables. Simultaneously, the draft guideline is being translated into English, and this draft is expected to be circulated in December 2016.

In 2015/2016, seven working group meetings were held. Approximately 25 experts from various sectors of the bakery industry, including bakery product producers and equipment manufacturers from Austria, Belgium, Germany, The Netherlands and Switzerland, have joined the EHEDG Working Group "Bakery Equipment."

Chairman:

Dr. Gerhard Hauser Goethestr. 43 85386 Eching GERMANY E-mail: gerhardwrhauser@yahoo.de

EHEDG Working Group "Basic Principles of Cleaning and Disinfection of Food Manufacturing Equipment"

Dirk Nikoleiski, Mondeléz International, e-mail: dnikoleiski@mdlz.com

The EHEDG Working Group "Basic Principles of Cleaning and Disinfection of Food Manufacturing Equipment" was established in 2016 to develop a new guideline to serve as the basis for the new guideline cluster "Cleaning and Disinfection." The cluster will include guidelines focused on several topics such as cleaning validation, cleaning in place, tank cleaning, and foreign body prevention.

Background

Hygienic design is the foundation for cleaning and disinfection and in turn, anticipated cleaning regimes will affect hygienic design solutions. Thus, in the absence of an EHEDG document that covers basic principles of cleaning and disinfection, many working groups are including some of those aspects when developing or updating their guidelines, even though the objective of these EHEDG documents is to provide guidance on the design and fabrication of hygienic entities. This guideline will close the gap and cover the basics of cleaning and disinfection that are relevant for dry- and wet-cleaned food manufacturing equipment.

Proposed content

Summary Introduction

- Introduction
- 1 Objective and Scope
- 2 Normative References3 Definition of Terms
- 4 General Considerations
- 5 Soil Characteristics
- 6 Wet/Dry Cleaning
- 7 Disinfection
- 8 Cleaning Programs
- 9 References
- 10 Key Learning Points

Progress to-date and timing

After the kick-off in May 2016, the working group held two online meetings for populating the guideline with content. It is expected that the first draft will be ready by mid-2017.

Chairman:

Dirk Nikoleiski Mondeléz International Unterbiberger Str. 15 81737 München GERMANY E-mail: dnikoleiski@mdlz.com

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Chairman:

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EHEDG Working Group "Basic Principles of Cleaning and Disinfection of Food Manufacturing Equipment"

Dirk Nikoleiski, Mondeléz International, e-mail: dnikoleiski@mdlz.com

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Chairman:

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EHEDG Working Group "Cleaning in Place"

Hein Timmerman, e-mail: hein.timmerman@sealedair.com

The EHEDG Working Group "Cleaning in Place" (CIP) was established in 2013 to develop a new guideline to provide a guideline to assist in the selection and the design of new CIP installations or upgrading existing ones, as well as providing key considerations about their operation. It will support the design of CIP installations that better enable producers to meet the requirements outlined in the food safety standards to ensure safe food manufacturing.

Although CIP is a well known and well-described technology, there is a lack of standardisation and common approaches within this key operation in hygienic processing. Often, the CIP installation is a combination of older and assembled tanks, pumps and valves, and is placed in a secured or hidden area of a factory, without the proper and required attention. Every individual supplier or integrator has his or her own opinion about CIP, and installations vary widely. Installations often are modeled on past experiences or copied from other production facilities, such as traditional dairy technology and systems. Older systems are not validated and newer installations are hardly optimised for cleaning, resulting in additional operational costs. It is the aim of the EHEDG Working Group "CIP" to create a guideline that provides the latest knowledge on hygienic design to food producers planning to buy a new cleaning station or to upgrade an existing CIP installation.

The new guideline intersects with several other EHEDG documents and working group topics, and thus must integrate the existing know-how of these resources. Due to the fact that a CIP installation is an assembly of multiple process elements, such as tanks, pumps, valves and instruments, the principles of hygienic design mentioned

in other EHEDG published guidelines also are valid for this CIP guideline. As the new Working Group "Cleaning & Validation" has been created to avoid overlap, the draft guideline in progress is undergoing a rewrite to avoid overlapping chapters with other EHEDG documents, including:

- Cleaning and Disinfection
- Cleaning-in-Place
- Cleaning Validation
- Foreign Bodies
- Tank Cleaning

It is anticipated that the new guideline will be ready for publication in 2017.

Chairman:

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EHEDG Working Group "Design Principles"

Dr. Jürgen Hofmann, e-mail: juergen.hofmann@ehedg.org

The current version of the fundamental EHEDG Guideline Doc. 8, Hygienic Equipment Design Criteria, 2nd edition, was published in April 2004. In the 12 years since its publication, many things have changed in the field of hygienic design, making an update long overdue.

First, the understanding of the term 'hygienic design' has evolved over the years and the industry uses this expression in a different way than EHEDG originally defined the term. Second, many new EHEDG guidelines have been published on specific hygienic design topics. In other words, the information about hygienic materials and surface finishes covered in the 2004 version of Doc. 8 is no

longer necessary due to the publication of this information in Guideline Doc. 32, Materials of Construction for Equipment in Contact with Food.

Another important aspect of the update is that this guideline needs to provide a comprehensive overview of all principles of hygienic design without going into too much detail. Therefore, the working group will change the word 'criteria' in the document title to 'principles.' The reasoning is that specific hygienic design criteria belong in all of the other EHEDG guidelines on dedicated equipment.

Meeting activities in 2015 and 2016

The EHEDG Working Group "Design Principles" began its work as a small group to be effective. The first draft will be discussed in a larger group. The members of the small working group are:

- Jürgen Hofmann, Hygienic Design Weihenstephan, Germany (chair)
- Patrick Wouters, Cargill, The Netherlands
- Andy Timperley, Timperley Consulting, United Kingdom
- Stefan Akesson, Tetra Pak, Sweden
- Roy Curiel, formerly Unilever, The Netherlands

Five meetings of this group were held in 2015 and 2016 to develop the first draft of the revised version of Doc. 8, which will now be titled 'Hygienic Equipment Design Principles.'

Drafted guideline contents

The content of the new edition reflects necessary changes to the previous version of the guideline. For example, the order of the several paragraphs have been changed and chapters about hygienic design assessments have been added. The draft contents of the new edition is as follows:

Introduction

- 1 Objectives and scope
- 2 Normative references
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- **Functional requirements** 4
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- 4.2 Prevention of ingress of microorganisms
- Prevention of growth of microorganisms 4.3
- Prevention of foreign matter 4.4
- 4.5 Prevention of chemical contamination
- 4.6 Compatibility with other requirements
- Materials of construction 5

- 5.1 General
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- 5.3 Polymeric materials
- 5.3.1 Plastics
- 5.3.2 Elastomers
- 5.4 Other materials
- 5.5 Adhesives and sealants
- 5.6 Lubricants
- 5.7 Signal transfer liquids
- 5.8 Thermal insulation materials 6
 - Hygienic design and construction
- 6.1 General
- Surfaces and geometry 6.2
- 6.3 Welding
- Drainability 64
- 6.5 Insulation
- 6.6 Installation, supports and layout
- 6.7 Integration of equipment
- Hygienic design assessments 7
- 7.1 EHEDG testing and certification scheme
- 7.2 Qualification stages for equipment
- 8 References

Publication timeline

The publication of the updated version is expected in 2017 after final discussion.

Chairman:

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EHEDG Working Group "Elastomeric Seals"

Angelika Ruhm, e-mail: angelika.ruhm@fst.com

In 2016, the EHEDG Working Group "Elastomeric Seals" worked on the final draft of a guideline with the aim to publish.

The guideline "Elastomeric Seals" will cover the hygienic aspects of elastomeric seals used in equipment for food processing and food packaging. It focuses on the basic design principles at the interfaces between seals and product contact surfaces, such as the choice of the correct material in accordance with the planned operating conditions.

The draft document offers a look at the behaviour of seal materials under the influence of temperature and pressure, as well as on the effects of media on a seal. It highlights the general design principles that must be taken into consideration when designing a sealing point. The guideline also shows a selection of the various causes of seal damage. In those cases a detailed failure documentation helps to find the reason of failure.

In conjunction with the EHEDG Working Group "Materials of Construction," it was decided that Doc. 32, Materials of Construction describes the properties of elastomers, whereas the draft guideline "Elastomeric Seals" focuses on the basic seal design and hardware design principles and discusses the parameters taken into consideration according to operating conditions.

The latter finally provides information for the packaging and storage of seals, as well as the specific part of legislation that must be observed. Figures used in the document represent the problems graphically and explain possible solutions. The draft guideline "Elastomeric Seals" refers to both European and international regulations.

Chairman:

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EHEDG Working Group "Food Refrigeration Equipment"

As. Prof. Kostadin Fikiin, e-mail: agf@tu-sofia.bg

The EHEDG Working Group "Food Refrigeration Equipment" was set up in 2013 and actively liaises with other international organisations involved with food refrigeration, including IIR, IAR, ECSLA, and the Global Cold Chain Alliance, in order to integrate state-of-the-art hygienic design solutions in modern refrigeration technologies.

Membership

The EHEDG Working Group "Food Refrigeration Equipment" has as members more than 20 top experts and key companies in refrigerated food processing across Europe.

Meetings and attendance

The kick-off meeting for the working group was held on 6 December 2013. Regular meetings took place in Amsterdam on 21 March 2014, 21 November 2014, and 27 March 2015, and in Brussels on 20 January 2016.

The WG meetings held so far were attended by Kostadin Fikiin (Technical University of Sofia, Bulgaria); Christian James (FRPERC, University Centre Grimsby, UK); Trygve Eikevik and Ignat Tolstorebrov (Norwegian University of Science and Technology, Norway); Frank Moerman (KU Leuven, Belgium); Christopher Fogelqvist (JBT FoodTech -Frigoscandia, Sweden); Marc Schreurs (University College Limburg, Belgium); Didier Pathier (Air Liquide, France); Eric Delforge (Mayekawa Europe, Belgium); Mads Sigsgaard (Dybvad Stål Industri, Denmark); Robert Long (StarFrost, UK); Peter Wilyman (Wilyman Technical Services, representing Air Products, UK); Wim Heinkens and Danny T'Kindt (Packo Inox, Belgium); Fernando dos Santos Moreira (Viessmann Kältetechnik, Germany); Patricia Makiyama (TÜV SÜD Industrie Service, Germany); Germ Buter (Ammeraal Beltech, The Netherlands); Godart Gouda (Ashworth Belts, The Netherlands); Georgio De Ponti and Francesco Scuderi (Epta Group, Italy); Ruben Larsson (OctoFrost AB, Sweden); Patrick Wouters (Cargill, The Netherlands); and Piet Steenaard (EHEDG Treasurer).

Primary focus

The working group's primary focus is on the development of the EHEDG Guideline 'Hygienic Design of Processing Equipment for Chilling and Freezing of Food' addressing adequate hygienic design solutions to advanced food refrigeration technologies.' Although the hygienic risks in chilled and frozen food production are different, industrial chilling and freezing systems possess numerous design similarities that require a uniform approach. Thus, the document will include common (immersion, multiplate, air blast, fluidised-bed, air impingement and cryogenic) industrial systems for chilling and freezing of solid, semi-solid or liquid products of plant or animal origin (fruits, vegetables, meat, fish and dairy products).

The detailed table of contents of this guideline can be accessed from the EHEDG Yearbook 2015/2016, pp. 168-172, available online at www.ehedg.org/about-ehedg/ publications.



Key events and publications

Two EHEDG Working Group "Food Refrigeration Equipment" members (Kostadin Fikiin and Frank Moerman) delivered oral presentations at the 7th Central European Congress on Food (CEFood 2014), 21-24 May 2014 in Ohrid (FYR of Macedonia), which was co-supported by EHEDG, IIR, EFFoST, GHI and EuCheMS. A number of members also took part in the EHEDG World Congress on Hygienic Engineering and Design, held on 30-31 October 2014 in Parma, Italy and on 2-3 November 2016 in Herning, Denmark. Frank Moerman visited many companies at their stands during Anuga FoodTech in March 2015 and collected illustrative material regarding recent systems for refrigerated food processing. A number of these industrialists expressed an interest to join or re-join EHEDG and the working group.

Kostadin Fikiin attended the 24th IIR International Congress of Refrigeration (ICR 2015), held 16-22 August 2015 in Yokohama, Japan, as an IIR Executive Committee and General Conference member, author and session chair. He met there key representatives of relevant Japanese companies (e.g., Mayekawa), along with European companies that are active in publishing industrial guidelines and certification. In that context, Mr. Gérald Cavalier, chairman of Cemafroid in France and president of the French Refrigeration Association, was persuaded to join this working group as an active member.

Writing of relevant book chapters is another action item for the EHEDG Working Group "Food Refrigeration Equipment." Such publications include:

Moerman, F. and K. Fikiin. (2016). Chapter 20: Hygienic design of air-blast freezing systems.

In: *Handbook of Hygiene Control in the Food Industry,* 2nd edition. Eds: HLM Lelieveld, J. Holah and D. Gabrić. Woodhead Publishing. Cambridge, UK, pp. 271-316. http://bit.do/blast_freezers.

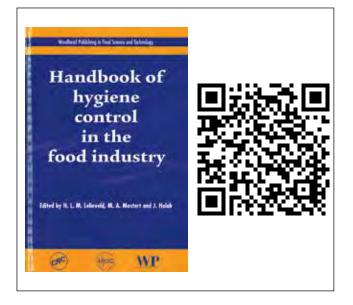
Moerman, F. and K. Fikiin. (2015). Chapter 14: Guiding principles for hygienic design of evaporators to mitigate contamination-related risks in air-blast freezing systems.

In: Handbook of Research on Advances and Applications in Refrigeration Systems and Technologies, 1st Ed. Eds: P.D. Gaspar and P.D. da Silva. IGI Global. Hershey, Pennsylvania, USA, pp. 490-542. http://bit.do/ evaporators



Moerman, F. and K. Fikiin. (2015). Chapter 18: Effect of hygienic design and operational parameters on frosting and defrosting of evaporators in refrigerated food processing and storage facilities.

In: Handbook of Research on Advances and Applications in Refrigeration Systems and Technologies. Eds: P.D. Gaspar and P.D. da Silva. IGI Global. Hershey, Pennsylvania, USA, pp. 660-719. http://bit.do/defrost





Actual and future plans

Publishers are contacted to see if a guideline-related book might be produced in order to enhance the interest of the authors involved and to reach a wider audience around the world. In the future, the working group will address refrigeration facilities and equipment throughout the entire cold chain for refrigerated processing, warehousing (cold storage), distribution and retail of chilled and frozen food commodities. The organisation of an international refrigeration-related conference also might be a future target.

New members welcome

The EHEDG Working Group "Food Refrigeration Equipment" welcomes additional participants who are willing to volunteer. Whether you represent a large multinational company, a dynamic SME (producing or operating industrial food chilling

and freezing systems), or a well-known academic and research centre, do not miss the unique chance to become part of this exciting international initiative that is going to shape the future of food refrigeration businesses on a European and worldwide scale.

Chairman:

As. Prof. Kostadin Fikiin Refrigeration Science and Technology Technical University of Sofia 8 Kliment Ohridski Blvd. BG-1756 Sofia BULGARIA Phone/Fax: (+359 2) 965 33 22 E-Mail: agf@tu-sofia.bg

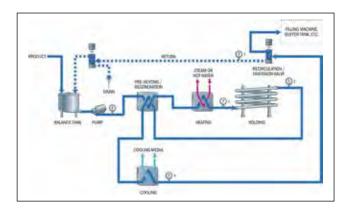
EHEDG Working Group "Heat Treatment"

Bengt Eliasson, Tetra Pak, e-mail: bengt.eliassoan@tetrapak.com

EHEDG guidelines Doc. 1, Microbiologically Safe Continuous Pasteurisation of Liquid Food and Doc. 6, The Microbiologically Safe Continuous Flow Thermal Sterilisation of Liquid Foods, were among the first guidelines to be published by the consortium. The guidelines had not been updated since their release in 1992 and 1993, respectively, and were in need of major revision. In the last few years, the EHEDG Working Group "Heat Treatment" has made a complete update of the two guidelines. The updates of Doc. 1 and Doc. 6 will be published early 2017 following final approval by the EHEDG peer review team. The overall aim of these guidelines is to minimise the risk that pasteurised or sterilised products are not safe to consume. The guidelines cover the design, operation, process control and monitoring, and inspection and maintenance of continuous pasteurisers and sterilisers.

During 2017, the working group will start the update of EHEDG Doc. 12, The Continuous or Semi-Continuous Flow Thermal Treatment of Particulate Foods, originally published in 1994.

The working group has 11 active members with a good mix of representatives from equipment and food manufacturing companies. Specialists in the area of continuous thermal treatment of food containing particulates are welcome to join.



Example of illustration from EHEDG guidelines Doc. 1 and Doc. 6.

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EHEDG Working Group "Integration of Hygienic Systems"

Dr. Roland Cocker, e-mail: r.cocker@gmail.com

EHEDG Document 34, The Integration of Hygienic Systems, currently is being updated from the first version, published in 2006. The original reason for producing this guideline was that, in many cases, hygiene hazards were created in equipment and systems for producing food through the inadequate way in which equipment and processes were combined. Most notably, hazards arose due to the lack of systematic challenges at each stage of design and specification. In other words, systems that prove - rather than rely on opinion, untried assumptions, tradition or chance - that the resulting designs of equipment and processes were capable of producing safe food, as cost-effectively as possible and to customer requirements. Another common problem was that hygienic design aspects were not considered in a timely way; that is, concurrently with all of the other design and engineering activities.

Reference was, and still is, being made to established procedures for integration used across the spectrum of sectors that require safety- and quality-critical engineering and design, particularly pharmaceuticals, medical devices, and automation. However, since the original version of Doc. 34, newer EHEDG guidelines, with related procedural content, have been initiated, including cleaning validation and cleaning-in-place of filling machines. Therefore, as this guideline is updated, the EHEDG Working Group "Integration of Hygienic Systems" is taking care to ensure that the guidance on procedural aspects is complementary to those in other EHEDG documents and avoids replication in accordance with good documentation management. Consistent with the latter, supporting information from other EHEDG guidelines will be introduced by reference only.

When reading Doc. 34 it is necessary for users to jump between the master flowchart and other detailed flowcharts that explain each step. Therefore, it is intended to utilise hyperlinks to ease this process and for cross-referencing within this document. It is hoped that eventually this will include references to other EHEDG documents, such that the user has a full electronic set of EHEDG documents.

Latest news

Target for completion

It is intended to submit the updated document for review by mid-2017.

Terminology

It was recognised that the use of the terms validation and qualification in the original version was not consistent with those used in other industries, and therefore these definitions have been updated. Simply, 'qualification' is proof that physical items perform as specified and 'validation' is proof that abstract items, including procedures, processes and methods, perform as specified. In the context of integration processes, different organisations use either functional or operational and either stakeholder or user, which translate into abbreviations and acronyms such as stakeholder requirement specification (SRS) and so on, which may be confusing. The working group has decided to select one of each, while carefully explaining this issue.

User-friendly

Feedback on the original document was that it could seem academic and abstract for some groups of users. Attempts have been made to simplify the visual appearance of flowcharts and to simplify the flowcharts themselves. The master flowchart currently is titled "The 8-Step Path," but in the working group's efforts at simplification, it has had several incarnations—from 7-step, to 8-step, to 9-step, to 7-step and now 8-step—as the working group wrestled to simplify it. It is salutary that it was not felt possible to omit steps without showing how each stage of design is proven against its matching specification. Because of its fundamental importance, it has not yet been practicable to update the detailed flowcharts and much of the text until the 'V'-diagram and master flowchart are finalised.

The 'V'-diagram

In order to emphasise not only the step-wise nature of the integration process, together with its routine of specifythen-validate or specify-then-qualify, a variety of industry sectors have adopted the 'V'-diagram model. In the original Doc. 34, this appeared in an appendix under the automation example, but because of its fundamental value, it will now appear before/alongside the master flowchart for emphasis. An example (that is still being adapted) is shown in Figure 1:

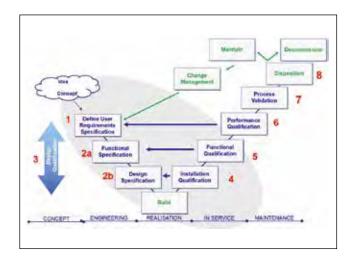


Figure 1. Example of a 'V'-diagram.

Guidance on practical application

In addition to the examples provided in the appendices, work is underway to show how integration sequences may be married with project planning and to explain the relationship with common terms and activities such as EHEDG certifications, factory acceptance tests (FATs), commissioning trials, water-testing, etc.

In addition, to emphasise the need to follow systematic integration procedures, examples of typical integration failures and their consequences will be expanded. The solutions to each of these also will be presented, and where possible, with reference to existing examples in other relevant EHEDG guidance documents.

Chairman:

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EHEDG Working Group "Materials of Construction for Equipment in Contact with Food"

Eric Partington, Nickel Institute, eric@ffex.co.uk

The EHEDG Working Group "Materials of Construction for Equipment in Contact with Food" is currently updating Issue 1 of EHEDG Doc. 32, which was originally published in August 2005. In doing so, the group is expanding the scope of the guideline considerably. Issue 1 covers metals, elastomers and plastics, and very briefly mentions composites, ceramics and glasses. The revision will cover metals (including solders and brazes); coatings (where they are applied for engineering, rather than just for cosmetic, reasons); elastomers, plastics, composites, ceramics, glasses, nano-materials, antimicrobial surfaces, adhesives, lubricants (for food, rather than for equipment), and legislation.

The scope of this working group is sufficiently extensive as to warrant the sharing of the chair. Until early 2016, Rehana Mukhtar of Tetra Pak concentrated on two sub-groups (SGs) focused on elastomers and plastics and Eric Partington of the Nickel Institute specialised in legislation and certification, metals and alloys, and ceramics and glasses. When, at the end of May 2016, Rehana changed her job, Stephan Engler of the Bühler Group took over as co-chair, adopting Rehana's sub-groups.

Each of the sub-groups has its own coordinator to lead meetings/webinars and guide progress on a day-to-day basis.

As a whole, the Working Group has 25 active members and many participate on more than one SG. SG Elastomers has nine members, SG Plastics has four, SG Legislation and Certification has nine, SG Metals and Alloys has 24 and SG Ceramics and Glasses has eight. Most of the Doc. 32 revision and development is progressed via webinar. We hope soon to be able to edit draft texts online (with appropriate document control so that one member's suggested change does not overwrite a previous suggestion and we know who proposed each amendment).

Once a year (in May/June) the Working Group meets to compare progress and to share solutions to common practical problems. In 2016, the group met for two days in Amsterdam and welcomed a number of new participants.

Some of the SGs have broken down their topic into smaller 'bite-sized' pieces and asked a specialist to develop that particular section. For instance, under Bryan Downer's SG Metals and Alloys section, his C.S.I Designs (USA) colleague Yogini Dhopade is writing the section on 'Possible Failure Mechanisms.' For the same SG, Frank Moerman (Catholic University of Belgium) has written sections specifically addressing the resistance of materials of construction to cleaning solutions and the selection of materials for process support and utility systems. In the SG Elastomers, Marc Collet (SealTec b.v.) has edited all the agreed texts. The SG has now held four webinars and signed off on the 'General' and 'Design and Selection Procedures' sections.

Chairman:

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EHEDG Working Group "Mechanical Seals"

Susanne Berezin, susanne.berezin@huhnseal.com

The published guideline on mechanical seals was released in 2002 as Doc. 25, Design of Mechanical Seals for Hygienic and Aseptic Applications. At the time, the working group was chaired by Göran Anderberg (formerly of Huhnseal), who also initiated a new working group in 2011 to revise the existing document. Since then, comments and discussions by the EHEDG Working Group "Mechanical Seals" have resulted in an updated draft of Doc. 25.

After the retirement of Göran Anderberg, Per Hellman of Huhnseal stepped in as working group chair and organised a February 2016 meeting in Amsterdam. Most of the existing group members participated and some new members joined. In total, 18 people attended. This also marked the starting point of a new setup for work procedures within the working group. During the year, there were additional changes in the chairmanship when Per Hellman left Huhnseal, but the continuity of the work within the group has remained.

In addition to the meeting in Amsterdam, the group held five WebEx meetings in 2016. During the meetings, comments on the existing draft of Doc. 25 are discussed and proposed editing changes and added paragraphs, chapters and other content are considered by the group

The working group will continue to focus on the following main topics:

- Enhancement and harmonisation of terminology
- Clarification of testing and certification requirements for mechanical seals
- Classification of mechanical seal types and designs
- Installation requirements
- Seal auxiliary systems

In 2017, the working group aims to have two in-person meetings and to continue with regular WebEx meetings. The goal is to release the revised version of Doc. 25 in 2018.

The majority of the 10 active members of the working group are equipment manufacturers. EHEDG members from the food manufacturing sector are encouraged to join, as their input will be valuable to the Doc. 25 update and highly appreciated.

Chairpersons:

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EHEDG Working Group "Pumps, Homogenisers and Dampening Devices"

Ralf Stahlkopf, e-mail: ralf.stahlkopf@gea.com

The EHEDG Working Group "Pumps, Homogenisers and Dampening Devices" is focused on revising and updating EHEDG Doc. 17, Hygienic Design of Pumps, Homogenisers and Dampening Devices. This document sets the requirements for pumps, homogenisers and dampening devices for hygienic applications. The scope includes all pumps intended for use in food processing, including centrifugal, piston, lobe, rotor, diaphragm, screw and gear pumps (Figure 1). The requirements also apply to valves integral to the pump head and the complete homogeniser head. Design aspects and the characteristics of materials, surfaces and seals are discussed. The revised and third edition of Doc. 17 was published in April 2013.

The constituent session for a fourth edition took place on 15 April 2016. The following topics are under consideration:

- Approximation and differences between EHEDG and 3-A Sanitary Standards
- Materials (hygienic/unhygienic examples)
- Demarcation between aseptic and hygienic pumps

- Lantern (inspectability)
- Exposed threads
- Enclosed threads

The working group expects that it will take approximately eight meetings and up to four years to produce a revised guideline.

The 3rd edition is available in Armenian, Croatian, Dutch, English, German, Japanese, Macedonian, Russian. As of September 2004, the second edition is available in French, Italian and Thai.

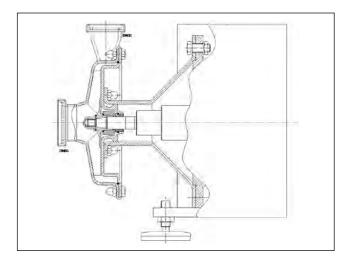


Figure 1. A hygienic centrifugal pump is one example of the types of pumps covered in Doc. 17.

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EHEDG Working Group "Safe and Hygienic Treatment, Storage and Distribution of Water in Food Factories"

Dr. Anett Winkler, Mondeléz International, Germany, e-mail: anett.winkler@mdlz.com

Published in 2004, EHEDG Guidelines 27 and 28 are related to adequate water treatment, distribution and storage. In addition, EHEDG Doc. 24, published in 2002, discusses aspects of control of Legionella. Since more than 10 years have passed, it was felt necessary to update these guidelines, which are related to water at several stages in the food industry. Therefore, the EHEDG Working Group "Safe and Hygienic Treatment, Storage and Distribution of Water in Food Factories" was formed at the beginning of 2016 to update all guidelines related to water sourcing, treatment, distribution and storage in the food industry. Finalisation of the new guideline is expected by the end of 2016 or the beginning of 2017.

Background

In the food manufacturing industry water is used for many different purposes. The quality of the water used can be critical with respect to product safety in the market, the reliability of production processes and the safety of personnel in the workplace. Therefore, existing guidelines refer to application of Hazard Analysis and Critical Control Points (HACCP) principles in water sourcing, treatment and distribution. Although this is outlined in EHEDG Doc. Nos. 27 and 28, the guidelines need updates based on current developments in water treatments (e.g., electrodialysis reversal [EDG]) and increased understanding of the criticality of water supplies. Furthermore, the separate guideline No. 24 discusses effective control strategies of Legionella spp. in water systems. Inclusion of that guideline would expand the scope beyond food/product protection to occupational health and public health in general. However, control of Legionella spp. includes measures to be taken at water distribution systems, and would therefore warrant its inclusion in the new water guideline.

The new guideline is intended to provide guidance on hygienic and safety related issues concerning water treatment and will provide recommended practices for two water categories used in the food industry: product and utility water.

Proposed Content

Summary

Introduction

- 1. Objective and scope
- 2. Normative references
- 3. Definition of terms
- 4. Sources of water and water types applied in the food industry
- 5. Overview of common treatment techniques and main hazards
- 6. System requirements: Product water Product water referring to:
 - Water for all personal (employees) uses such as washing, food and drink preparation
 - Water used as a product ingredient
 - Water used as a transport vehicle in direct contact with the (intermediate) product
 - Water used for rinsing the surfaces in contact with food, and water for cleaning and disinfection solutions
 - Water shall be of potable quality (mineral content can be lower than for potable water for defined applications).

- System requirements: Utility water Utility water refers to water used in a secondary process where no direct contact with the product should be possible at any stage (e.g., hot and cooling water systems, fire fighting water storage).
- 8. Control of Legionella in water systems
- 9. References

Progress to date and timing

The working group was formed at the beginning of 2016 and four conference calls were held during the year. There are nine members in the group representing the food industry (Nestle, Coca Cola, PepsiCo, Mondelez International), as well as equipment manufacturers (Krones AG) and water processing companies (Nalco). The goal is to finalise the update and consolidation of the new water guideline by end of 2016 and to publish it in early 2017.

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EHEDG Working Group "Sensors"

Holger Schmidt, e-mail: xjrholgerschmidt@gmx.de

The main objective of the EHEDG Working Group "Sensors" is to update EHEDG Guideline Doc. 37, which describes the design and application of sensors that come into direct contact with food. The 35-page document, created in 2007, explains the function of sensors, which can play a double role in food processing. First, they can have a possible impact on the cleanability of a system. Second, the signals generated by sensors often are necessary to control and ensure successful cleaning. However, the latter might result in unavoidable compromises to hygienic operation in the food production environment, which makes an update to the guideline imperative.

During the first meeting of the working group on 14 April 2016 in Weil am Rhein, members decided to include more information about process sensor lines and splash area sensors in the Doc. 37 update. The revision also will focus more on the impact of sensor installation, offering details about the design of the different technologies when installed in the process. Basic requirements will be excluded and handled by referring to other relevant EHEDG guideline documents.

Participants of the EHEDG Working Group "Sensors" kick-off meeting included: Hans Turck, GmbH & Co. KG; Michael Bonk, VEGA Grieshaber KG; Natalie Waldecker,

WIKA; Alexander Wiegand, SE & Co. KG; Joachim Zipp, KROHNE Messtechnik GmbH; Bernd Schumacher, Bürkert Werke GmbH; Arne Kleinpeter, Baumer Electrics AG; and Martin Leupold, Martin Pfändler, and Holger Schmidt of Endress+Hauser Messtechnik GmbH & Co. KG. The results of the first meeting were gathered in August 2016, and considered during the group's second meeting on 20 October 2016 in Frankfurt.

At present, all EHEDG Working Group "Sensors" participants and potential supporters are employed by the related supplying industry. To ensure a well-rounded and comprehensive approach to the revision of Doc. 37, the working group will invite scientists and experts from food processing companies and relevant academic institutes to join these efforts.

Chairman:

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EHEDG Working Group "Tank Cleaning"

Bo Boye Busk Jensen, Alfa Laval, bobb.jensen@alfalaval.com

The EHEDG Working Group "Tank Cleaning" began its work in 2012. Cleaning vessels are an important part of any cleaning operation in the food industry. This can be a time and resource demanding task if it is not done with the most appropriate vessel cleaning technology for the task at hand and if the vessel has a poor hygienic design. This working group is developing a new EHEDG guideline that will set recommendations for vessel and appurtenance design and provide a selection guide for appropriate vessel cleaning device. Specifically, the guideline is intended to provide recommendations on cleaning aspects and hygienic design of vessels. It is limited to product contact surfaces of vessels for liquid processing, both vertical, horizontal and of any arbitrary shape. Excluded are the selection of chemistry and temperature for cleaning specific products.

The guideline will cover many different aspects related to hygienic design of vessels, their appurtenances, the installation of such vessels and the technology applied for clean-in-place (CIP) cleaning. The guideline will focus on the different ways that the choice of vessel cleaning technology influences the hygienic design criteria for appurtenances used in and on vessels. During vessel cleaning, the cleaning mechanisms are somewhat different than those found in a closed pipe system. This is because the vessels are seldom cleaned by a pressurised liquid flowing through the vessel, but rather a free falling film or a local high impact cleaning regime (i.e., the wall and appurtenances are not under constant pressure as seen in a pipe system). Also the category of soil may influence the best value for money choice when selecting vessel cleaning technology and cleaning strategy. Finally, validation of vessel cleaning also will be included as this is a prerequisite for the satisfactory and consistent cleaning of a vessel.

During 2015 and 2016, a total of 11 working group meetings have been held, most of them conducted as WebEx meetings. The participants represent end-users, contractors, hygienic design experts and vessel cleaning fabricators. Currently, the guideline content is being refined and discussed in the group and this work will continue in the near future. If any vessel builders are available to join this group, their contribution would be highly appreciated.

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EHEDG Working Group "Test Methods"

Andrew Timperley, e-mail: andy.timperley@tesco.net

The EHEDG Working Group "Test Methods" was one of the first groups established by EHEDG. The group is responsible for publishing test methods, defining validation criteria and providing assessments of equipment according to the hygienic design criteria of EHEDG in conjunction with the operation of the EHEDG Certification Scheme.

The period 2015/2016 has seen many improvements within EHEDG as an organisation, including the launch of a revised certification scheme. Consequently, the working group's efforts have been concentrated on further refinements to the certification scheme in close liaison with the EHEDG Executive Committee and the Sub Committee Products Portfolio.

The significant updates to the certification scheme, launched in January 2015, include the creation of a specific certification class for auxiliary equipment and components, Type EL CLASS I AUX, and the introduction of a formalised recertification process based on a five-year renewal cycle. In addition, during 2016, a decision was taken to centralise the certification.

The generation and publication of flow sheets on the EHEDG website describing the evaluation and certification procedures is also intended to assist the industry in gaining a clearer understanding of the complete certification process for all equipment classes (Figures 1 and 2).¹ The generation of more transparent procedures and clarification of types of equipment suitable for specific classes of certification will enable EHEDG to continue to meet the needs of the industry and further enhance the credibility of the EHEDG Certification Scheme.

In parallel to the aforementioned activities, the day-to-day operation of the Test Methods Working Group has been fervently maintained, and activities include:

- Reviewing and updating of test method documents.
- Doc. 2 has been finalised after incorporation of comments and is now ready for submission as a final draft.
- Doc. 7 has been revised and is ready for circulation and comments.

- Updating of the EHEDG Position Paper: Pipe Couplings and Process Connections.
- Completion of 'ring trial' testing for the period 2015/2016.
- Continuing the development of an 'open' equipment test method coordinated by a focused task force consisting of specific experts from within EHEDG in conjunction with technical resources provided by Fraunhofer Institute.

Additionally, a new EHEDG Authorised Testing Institute has been successfully established at the University of Parma in Italy. The relocation of the Authorised Testing Institute in the United States at the University of Tennessee was finalised. Applications for new testing institutes have been accepted from FIRDI in Taiwan, and more recently from TÜV Rheinland in The Netherlands. These new institutes will provide accessibility to manufacturers for testing and certification of equipment in these regions. The working group will continue to work with these new institutes to satisfy the criteria for authorisation.

In addition to meetings in Amsterdam in April 2015 and 2016, the EHEDG Working Group "Test Methods" held two full meetings at the University of Tennessee in September 2015 and at the University of Parma in September 2016. Regular interim WebEx meetings also were arranged to manage the extra work required during this busy period.

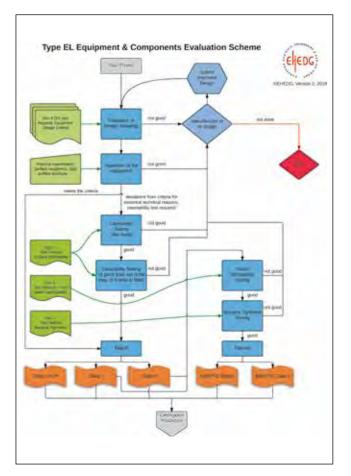


Figure 1. Type EL Equipment and Components Evaluation Scheme.

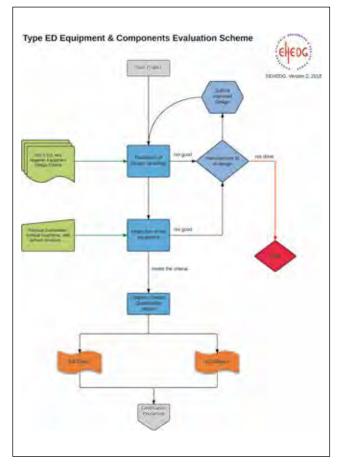


Figure 2. Type ED Equipment and Components Evaluation Scheme.

Reference

1. www.ehedg.org/testing-certification

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EHEDG Working Group "Training and Education"

Knuth Lorenzen, e-mail: knuth.lorenzen@ewetel.net

EHEDG's mission to disseminate hygienic design knowledge by establishing and offering training and education courses began in the early 1990's like a wave in the ocean. Initially, 12 experts joined the EHEDG Working Group "Training and Education" but after a short time, the activities got postponed and several members re-signed.

Spin-off of the HYFOMA project

Fortunately, a second wave of activity for this working group began in 2002 as a spin-off of the European Network for Hygienic Manufacturing of Food (HYFOMA) project on the EHEDG Training Facilitator Guideline. The EHEDG Working Group Training and Education was reestablished with a core group of members, including Bo Boye Busk Jensen, Wouter Burggraaf, Ronald Cocker and Jacques Kastelein. The objective was to develop an EHEDG training course based on the work presented in the training facilitator guideline. The idea was to create both a train-the-trainer course and an advanced hygienic design course that could be conducted throughout the European Union. The goal was to establish a large group of trainers able to teach EHEDG hygienic design in their local languages and at the level required for students.

The first train-the-trainer course was held in Vienna in 2004 and was attended by approximately 25 participants from Austria and several Eastern European countries. After presenting the concept to the EHEDG Executive Committee, the working group began to establish the advanced hygienic design course and the training materials. In parallel, during the HYFOMA project, a programme supported by the European Commission under the 5th Framework Programme, the trainer's toolbox was developed. After collecting and finalising the training material, the first official EHEDG Advanced Hygienic Design Course was held in Copenhagen, Denmark in 2005 with more than 20 participants. Another three courses held at the Danish Technical University were realised. After that, Bo Boye Busk Jensen left the group and was succeeded by Knuth Lorenzen as chair.

New challenge

Ultimately, new members were invited to help realise a broader, global training concept. They were committed to sharing both their know-how and existing training materials with the working group, enabling EHEDG International to develop training modules based on the information and criteria presented in the published EHEDG guidelines.

In 2008, new training materials were developed based on EHEDG guidelines with a much broader participation by EHEDG experts. University and institute members also were invited to give input and to transfer hygienic design information to the students. All materials developed by the new working group have been adapted as ready-to-use training modules and are EHEDG copyrighted documents. The materials can be used globally in EHEDG-organised training courses, as well as at EHEDG member universities and institutes. For this reason, the materials used in all training modules have been translated into participants' local languages.

Today, a number of universities worldwide offer hygienic design courses based on EHEDG materials. One university, Hochschule Mittelhessen, THM located in Wetzlar, Germany is the first to offer bachelor's and master's degrees in hygienic design. Please visit the EHEDG website page at www.ehedg.org/training-education/university-study-courses.

Training modules

The following training modules are available at www.ehedg.org and can be downloaded by all authorised EHEDG trainers:

- Legal Requirements
- Hazards in Hygienic Processing
- Hygienic Design Criteria
- Materials of Construction
- Welding Stainless
- Static Seals and Couplings
- Cleaning and Disinfection
- Valves and Pumps
- Hygienic Design Criteria for Dry Materials
- Verification of Hygienic Design, Test Methods and Certification
- Building and Process Layout
- Integration/Installation and Maintenance, Lubricants
- Packaging Machines
- Case Study

The following training modules are under development:

- Hygienic Conveyor Systems
- Tank Cleaning
- CIP Plant design
- Cleaning Validation
- Sensors
- Continuous Thermal Treatment
- P&ID Drawing Study

New projects

To provide basic elements of hygienic design and engineering to a wider global audience, the EHEDG Working Group Training and Education has launched the first pilot e-learning module, available in multiple languages. More modules may follow as the learning management system (LMS) for administration and hosting is established. Further training projects include:

- Recorded trainings/lectures on specific topics
- Live webinars on various hygienic design topics with opportunities for participants to ask questions
- Online training, consisting of various live training webinars with specific tasks (homework) that will need to presented and explained by course attendees during subsequent webinar sessions
- Hygienic design capability building through EHEDG checklists

The EHEDG Working Group Training and Education envisions that all of these training and education modes will allow students and industry professionals the opportunity to develop expertise in hygienic design principles. By successfully disseminating EHEDG's expert hygienic design knowledge at the university and institute level, more people will have access to EHEDG know-how and will be able to implement it into their businesses.

Chairman:

Knuth Lorenzen EHEDG Chairman WG Training and Education EHEDG Past President Flurstr. 37 21445 Wulfsen GERMANY Phone: +49 4173 8364 Mobile: +49 1520 8898 442 Fax: +49 69 6603 2217 E-mail: knuth.lorenzen@ewetel.net Internet: www.ehedg.org

EHEDG Working Group "Valves"

Ulf Thiessen, e-mail: ulf.thiessen@gea.com

The EHEDG Working Group "Valves" is focused on the hygienic quality of valves used in food, pharmaceutical and other sensitive production facilities. Every process plant is equipped with valves. Hundreds, even thousands of valves can be installed in a matrix-piped, liquidconveying plant, depending on the system's size. Valves fulfil numerous functions in process plants: shut-off and opening of paths, changeover, and control and control protection against excessive or insufficient pressure as well as intermixing of incompatible media at intersection points in pipes.

The quality of the valve has a considerable influence on the quality of the production process, and hence on the product itself (Figure 1). Hygienic deficiencies resulting from poor valve design must be regarded as a production risk in the food industry, pharma and healthcare and other industries, all of which must ensure that valves strictly conform to hygienic requirements.

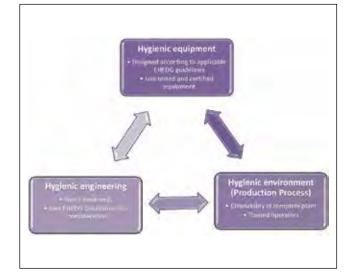


Figure 1. The challenge of hygienic design is "to make it an integral whole."

Working group activities and achievements

The EHEDG Working Group "Valves" currently is working on revisions and updates to two guideline documents. The first, Doc. 14, Hygienic Requirements of Valves for Food Processing, has undergone a comprehenisve revision process. After several withdrawals to sign off the revised document, the working group decided at its last meeting in June 2016 to finally close work on Doc. 14 and prepare it for another sign-off procedure.

The primary area of focus for the working group is to continue the revision of Doc. 20, Hygienic Design and Safe Use of Double-Seat Mixproof Valves. Due to the fact that the guidance document is 16 years old, there are many details that must be reviewed, considered and verified against the state of the art. The working group is finding this a challenging task because the majority of the document's artwork needs to be redone to bring it up to the state of the art and to keep the generic character of the graphics.

The working group is discussing the possibility of holding a two-day meeting or workshop in 2017 to speed up the revision of Doc. 20. The main problem will be to find resources and specialists to prepare the drawings and artwork needed for the updated document.

General issues

On average during the last two or three years, the working group has welcomed 13 to 14 participants per meeting. However, only two of the 20 regular members represent the food manufacturing sector. The group welcomes new members from the food producing industry to contribute to the guideline revisions.

Chairman:

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EHEDG Working Group "Welding"

Peter Merhof, e-mail: peter.merhof@gea.com

The EHEDG Working Group "Welding" started in 2014 to prepare the first draft of a new guideline for the inspection of hygienic welds. This draft currently is ready for translation and is expected to be published in 2017.

EHEDG Doc. 9, Welding Stainless Steel to Meet Hygienic Requirements, and EHEDG Doc. 35, Hygienic Welding of Stainless Steel Tubing in the Food Processing Industry, are increasingly accepted as basic documents for vendors and suppliers as a common base to describe their needs regarding the quality of welds they expect. Also, international standards organisations, such as 3-A Sanitary Standards, are referring to Doc. 9 and Doc. 35. These two documents are moving from European to worldwide acceptance.

The revision of both guidelines is planned to begin in the second half of 2017 to ensure that all referenced standards will be updated. The working group also will consider whether or not the existing two documents (Doc. 9 and Doc. 35) should be combined into one document.

There is also an interest by welding institutes in different countries to offer practical training lessons on hygienic welds to educate welders. These activities should be overseen to ensure that the EHEDG guidelines will be covered.

Chairman:

Peter Merhof GEA Tuchenhagen GmbH Am Industriepark 2-10 21514 Büchen GERMANY Phone: +49 4155 19 22 07 E-Mail: peter.merhof@gea.com The easiest way to apply for EHEDG membership is via the EHEDG website www.ehedg.org. You can apply directly online.



Company Membership Application

An EHEDG company membership is open to equipment manufacturers, food industries, suppliers to the food industries and consultants. The annual contribution is based on the company's turnover in food related business as outlined in the following table. Companies avail of at least one free individual member as well as of the whole series of EHEDG guidelines for free download from the EHEDG website.

Membership class	Food related turnover in EUR p. a.	EHEDG contribution in EUR p. a.	Free staff members
1	over 500 millions	10,000	4
2	50 to 500 millions	5,000	2
3	10 to 50 millions	2,500	1
4	1 to 10 millions	1,000	1
5	less 1 million	500	1

p.a.

We hereby apply for an EHEDG company membership at the contribution of:EURp.a.Our annual company turnover is EUR

(Please attach a company letter or a recent business report stating annual turnover p.a., as a proof)

All corporate and personal data will be treated confidentially. Fields marked by * to be filled in mandatory

Company*
Address*
VAT no. (USt.ID-Nr.) if within EC*
Invoice address (if different from above)
Name and position of company representative* (Please also attach business card)
e-Mail*
Phone*
Fax

For membership class 1 and 2 additional free staff members can be named. If interested please contact: secretariat@ehedg.org

We understand that our membership becomes effective upon receipt of our application by the EHEDG Secretariat who will then issue a membership invoice for the current year. The minimum duration of our EHEDG membership is one year and will be extended from one calendar year to another, if not cancelled in written before 30th September of the current year for the year to come.

I hereby acknowledge to have duly taken note of the above membership conditions:

Date / Signature	
------------------	--

Please return to: EHEDG Secretariat Phone +49 69 66 03 12 17 / - 1430 / - 1882 Lyoner Straße 18 Fax +49 69 66 03 22 17 60528 Frankfurt am Main E-Mail secretariat@ehedg.org Germany Web www.ehedg.org

Institute Membership Application

An EHEDG institute membership is open to institutes, universities, schools, research centres and governmental authorities. Institutes avail of up to four (4) free individual members as well as of the whole series of EHEDG guidelines for free download from the EHEDG website.

Institutes / Universities / Schools / Research Centres /	EHEDG contribution in EUR p. a.	Free staff members
Governmental Authorities	500	up to 4

We hereby apply for an EHEDG institute membership at the contribution of EUR 500 p.a.

All corporate and personal data will be treated confidentially. Fields marked by * to be filled in mandatory

Institution*
Address*
VAT no. (USt.ID-Nr.) if within EC*
Invoice address (if different from above)
Name and position of institute representative* (Please also attach business card)
e-Mail*
Phone*

Fax

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 E-Mail
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 Web
 www.ehedg.org



Individual Membership Application

I hereby apply for an EHEDG individual membership at the contribution of EUR 100 p.a.

Working party Corresponding No particular interest

Topics of interest:		
1.		
2.		
ζ.		
3.		
4.		

All corporate and personal data will be treated confidentially. Fields marked by * to be filled in mandatory

Name / First Name*
Company / Institution*
Address*
e-Mail*
Phone*
Fax
VAT no. (USt.ID-Nr.) if within EC*

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Date / Signature

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