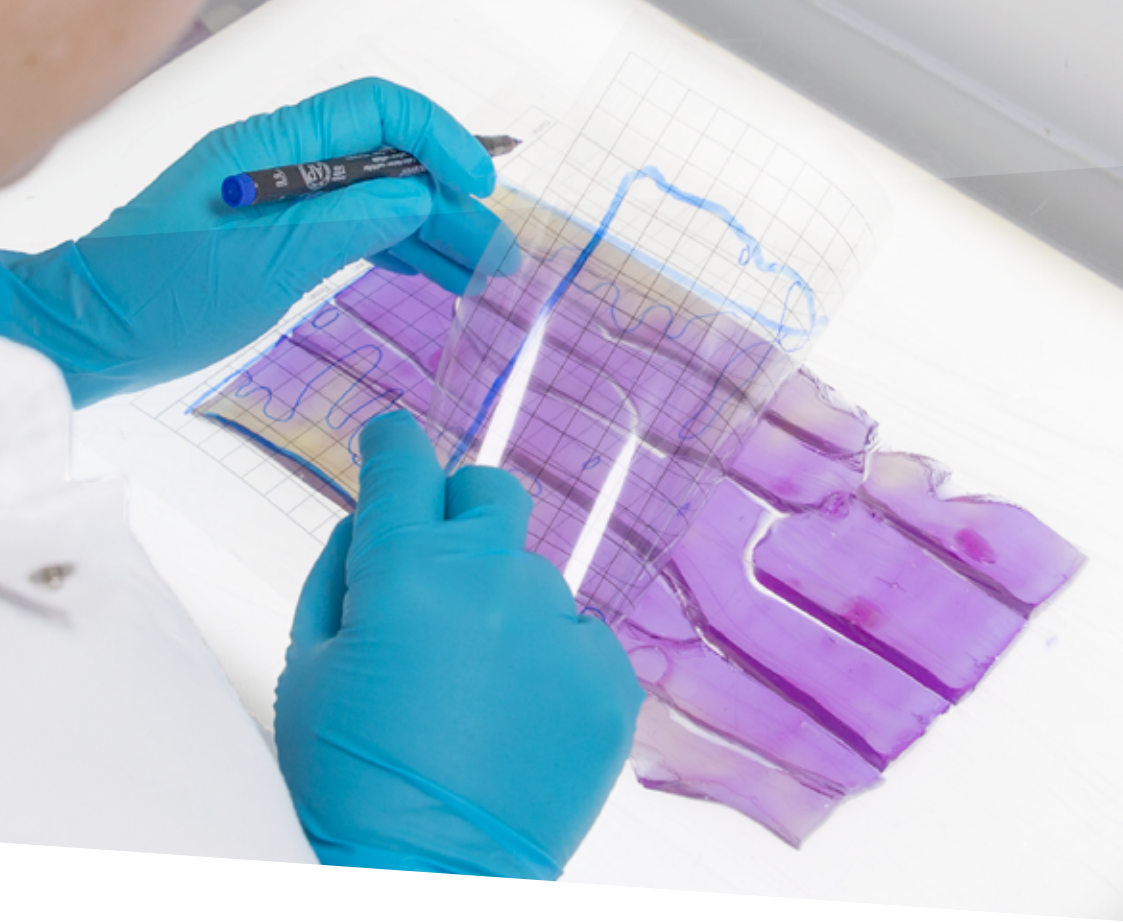

Practical Hygienic Design

Get off to a great start – and see real results from your efforts

by Alan Friis

FORCE TECHNOLOGY

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Cover image: Assessment of agar from reference pipe in EHEDG cleaning test for closed processes

Foreword

It's here: the second and updated edition (first edition only in Danish) of the practical guide on hygienic design and many of the processes related to the topic. I've worked on hygienic design on and off since the late 90s, and I've participated in a variety of domestic, Nordic, and EU-wide research and industrial projects in the field. The result has been a series of research publications and book chapters on hygienic design, as well as broad, in-depth knowledge of the field. Thanks to this background, I've been Authorised Trainer and Authorised Evaluation Officer under the European Hygienic Engineering and Design Group (EHEDG) since 2018.

Over the years, I've been a hygienic design instructor and communicator in many contexts, and I've often thought that the field lacked a cohesive book on the topic. In that regard, publishing a practical book on hygienic design is a dream come true for me.

The goal is that the book is useful to many people in their everyday work ensuring proper process hygiene, practice, and hygienic design in the food production industry and related industries. This book collects and communicates much of the knowledge that is otherwise scattered across PowerPoint presentations and taught only in professional training courses and other educational environments. To a certain extent, this book is a work in progress, as it will be regularly updated with new information and industrial cases.

A peek into history

Hygienic design began receiving recognition as a serious subject in the 1980s. In 1989, the first version of the EU's Machinery Directive–a cornerstone of the field–was adopted. This was the first piece of EU legislation concerning the nature of food contact materials and equipment design in order to achieve hygienically functional processes, if only in very general terms.

At the same time, the industry realised that there was a need for manufacturers of products and equipment to take a common approach to the subject. As a result, the European Hygienic Engineering and Design Group (EHEDG) was founded in 1989 by manufacturers of equipment and food products. The goal was to create a better understanding of how food product hygiene could be translated into appropriate equipment design through dialogue and guidelines that describe common needs. EHEDG has issued guidelines on the hygienic design of components, testing methods for cleanliness validation, and facility design, as well as specific food production processes, CIP cleaning validation, and optimised

processes for achieving hygienic design in existing installations. In 2009, a Danish division of the EHEDG was established.

Early in its work, the EHEDG launched a certification programme for hygienic equipment components, and a Danish testing laboratory was founded to certify equipment according to the EHEDG's guidelines and testing methods. In Denmark this testing laboratory was first housed in the Kolding Technological Institute before moving to the National Food Institute at DTU, the Technical University of Denmark. Today, the EHEDG Accredited Testing Laboratory is part of the Centre for Hygienic Design at FORCE Technology.

Training programmes and education in hygienic design

A Danish-language continuing education course for employees in the industry has existed since 1999. Today, FORCE Technology offers courses for designers, engineers, quality assurance and maintenance personnel, and others. The EHEDG also offers an Advanced Hygienic Design Course. The course is regularly offered in Scandinavia, and FORCE Technology assists in organising the course. FORCE Technology also offers businesses tailor-made courses for tradesmen, fitters, and others who wish to work hygienically in food processing businesses. In 2003, hygienic design was added to the schedule of classes at the Technical University of Denmark.

Acknowledgements

First and foremost, this book exists thanks to one of my colleagues, Lissi Holm. When we were at DTU, she suggested that our course participants ought to have something tangible to take home. It was at FORCE Technology that the process of creating it took shape, and I would like to thank my colleagues for their interest in this project. I would especially like to thank Maria Anja Hansen and Lissi Holm for their constructive criticism and input on the book's structure; as well as Saadia Iqbal, Mehdi Banisi, Maria Lenshøj Lundby, and Henrik Løvbjerg Lindeløv for their regular feedback and active efforts to situate this book in the right context, as well as to develop hygienic design as one of FORCE Technology's business areas.

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1. Hygienic Design in Context

The goal of hygienic design is to create the best conditions possible for the production of safe food products, ingredients, cosmetics, and pharmaceuticals. In all four areas, it is important that finished consumer products not be contaminated with substances that detectably alter the products' characteristics or endanger consumers. In essence, this pertains to ensure the absence of substances in products that pose a threat to consumers' health and safety. In practice, it means minimising the occurrence of conditions that permit substances to migrate between products and parts of equipment and preventing the build-up of residues and other substances that cannot be readily removed during cleaning.

Hygienic design is concerned with minimising and mitigating risks that can arise from equipment in production. In this book the term hygienic design is applied in a broad technical definition, but it is not concerned with the contamination of raw materials before they reach a production process, nor with risks that occur after finished products have left their producer's facilities. Naturally, these issues are critical to consumer safety, but they are addressed in other aspects of risk management. For a thorough overview of product safety and sources of contaminants, the reader is referred to other sources such as books on food product hygiene and food safety management.

The central tasks in hygienic design are about designing and facilitating operation of production equipment in ways that conforms to applicable hygienic standards and requirements to achieve the desired levels of quality and safety in finished products. Of course, hygienic design is critical to promoting a high degree of product safety in a process, but there is an economic side to it, too. Considering a variety of options for ensuring good hygienic performance through the lens of a risk assessment, which considers the process's intended usage and associated expenses, helps to make decisions on the process cost-effective.

1.1 The importance of hygienic design

As described above, hygienic design is one link in the chain of achieving the required level of product safety. Unambiguously identifying the cause of product contamination is often difficult; nonetheless, many problems can be traced back to inadequate cleaning. This, in turn, is often the result of inappropriately designed equipment, installation errors or application of equipment outside the range of intended use. These issues are inseparable as longer cleaning time may solve an issue with poor design or application, but the root cause will always involve taking a step back address basics of the design, installation and/or

application to find a suitable match that allows for hygienic operation. Issues with shelf stability and contaminants in products, especially those involving contamination with microorganisms, are typically rooted in inadequate in some aspect of hygienic design and inappropriate process choices.

Possible failures related to the interaction with the users and use of a process may be:

- The intended use and users' needs have not been identified and described in sufficient detail.
- The risk assessment performed on production equipment during the design phase is not sufficiently specific towards probable failure modes or not thorough enough.
- The process design and installed process equipment were not sufficiently qualified, validated, and verified.
- The specified cleaning procedure is not sufficient.

These topics are related to hygienic design, and as we can now conclude, hygienic design must involve the use of a variety of tools to produce a sufficient level of process hygiene in practice. The risk of reduced sales, loss of consumer trust,

→ The importance of hygienic design

Food products are publicly recalled nearly every day. The recalls, of course, are only the tip of the iceberg. Even more products are caught by companies' internal quality control processes before they can make it onto the market, and some are never discovered at all. While not all recalls are related to hygiene, the number of recorded food poisoning incidents over the years (internationally) shows that not all production facilities have these issues under control.

Naturally, recalls have an impact on all of the actors involved, who may suffer financial losses and damage to their brands. There may also be an undesirable burden imposed on the environment. However, the consequences can go far beyond these, such as if consumers lose trust in a particular brand or kind of product or an entire industry. Exports to more sensitive markets, such as Japan, may also be halted, even if there is no particular reason to do so. The consequences of losing consumers' trust don't end here, either. In a case from the United States involving processed meats, equipment vendors for the food processing industry were also impacted, as their sales fell for several years.

or both ought to be enough to convince most people of the necessity of hygienic design and of a particular focus on operational hygiene. However, this is not always the case. The need for hygienic design and operation is not always clearly acknowledge and integrated into project models and decision-making processes when making greenfield projects or refurbishment of existing plants. One main reason is the lack of quantifiable models to demonstrate effects of hygiene improvements in the total cost of ownership (TCO) showing that increased investments in equipment may lead to substantial savings on running costs. Also, lack of time in the requirement specification phase of projects may lead to deficiencies in understanding proper hygienic design requirements and means of integration of elements into a hygienic production facility.

1.2 What does hygienic design encompass?

Traditionally, hygienic design is a concept aimed at equipment and processes in the food product industry. In the pharmaceutical and biotech industries, practice-based engineering standards for cleanable and sterilisable process equipment are typically used instead. Many of the criteria are either identical or closely related. However, one clear advantage lies in the fact that hygienic design typically targets processes that are only ever cleaned like in the food product industry. In contrast, pharmaceutical and biotech processes–or at least their most critical parts–are also sterilised. Hygienic design is design that promotes ease of cleaning, so it's never a bad idea to include this activity in the design process to minimise the need for cleaning and sterilisation, even in the pharmaceutical, biotech, and cosmetic industries. Obviously, the particular risks, requirements, and needs vary from one industry to the next, but there is a basic need to focus on the same issues, namely:

- Materials in contact with products must not be capable of reacting with products. Contact surfaces must be free of defects and be smooth enough to be cleaned and maintained in a hygienic state throughout their lifetimes, ensuring that they do not lead to the risk of product contamination.

→ Total Cost of Ownership

The total cost of ownership (TCO) is becoming more and more common in arguments for investing in better hygienic design. The TCO is based on a calculation of what a process will cost over its lifetime, including both investments and operation. Using the TCO as a basis for decision-making is enticing. However, it is also complicated by a lack of tools that can effectively assess how much a process will cost in terms of cleaning, and which can demonstrate whether (for example) a 5% increase in the amount invested will result in better hygiene and greater savings over the lifetime of the process.

- Process equipment must be designed and constructed in such a way as to eliminate details that impede cleaning or create small recesses in which microorganisms may collect and form biofilms. Equipment manufacturers must also be able to prove that their equipment meets regulatory requirements and the requirements of their customers.

- When installing production lines and facilities, hygienic components and tubing must be installed in a manner that permits them to be drained for thorough cleaning. It must also be possible to access equipment in order to take samples as needed for cleaning validation.

- The production premises should be designed and used in a way that permits them to be cleaned and minimises risks to the quality and safety of the products being produced. Additionally, the premises should be divided appropriately into zones. Traffic routes (for products and personnel alike) and ventilation systems should also be designed appropriately to minimise transport of contamination. The locations and environments of production lines should be chosen to facilitate the needed cleaning and maintenance.

- Equipment and facilities must be maintained in such a way as to avoid compromising the hygienic status of processes and pieces of equipment over their lifespans.

There is no single, fixed definition of hygienic design. In the most general sense, it may include any specification, instruction, or activity related to material selection, assembly, construction, installation, operation, cleaning, maintenance, personnel training, and so on, provided that it can affect the ability of production processes, equipment, and facilities to maintain the desired level of safety for a given product. Of course, product specifications, operating conditions, and other factors related to creating the desired level of product safety are also included in a broad definition of hygienic design.

→ Requirements specification for hygienic design

Ideally, all hygienic design requirements that apply to a particular project should be listed in the User Requirements Specification (URS) and be actively employed, together with the risks identified in a risk assessment of the chosen solutions. However, if there is a large number of requirements that have not been prioritised and ranked in order of importance, problems can arise.

The tools used to facilitate hygienic design helps in identifying one or more potential process solutions that are relevant to the production of safe products in a particular situation. This means that hygienic design can be viewed as a set of activities whose result is equipment of the required hygienic quality. In this regard, it is a counterpart to risk-based self-assessment during production, and this promotes safe production when the facility is in operation.

1.3 Why is hygienic design sometimes difficult in practice?

Hygienic design is an interesting and challenging field to work with, since it involves a variety of scientific disciplines. For example, there is a great distance between the expertise of a machine designer, who typically holds a technical degree, and a microbiologist or veterinarian who practices food safety monitoring. In between these–or, perhaps more accurately, stretching the field in different directions entirely–are materials scientists, cleaning experts, quality assurance personnel, and others.

More than 30 years of experience in research and development projects show that a multidisciplinary approach produces the best results, bringing people with numerous skills to the table and co-ordinating their efforts. However, the challenge lies in the many traditions and approaches that differ from one area to the next, as well as in the fact that different parts of the value chain have access to different information. Furthermore, they may also be focused on different criteria for success. For these reasons, design and project management models are beneficiary to give direction to the process of hygienic design. They bring structure to specifications, documentation, construction, and installation, as well as to qualification, validation, and verification, allowing them to function optimally together.

1.4 Structure and approaches

This book is a practical introduction to hygienic design and related activities. It is for anyone interested in implementing, or who has a need to implement, best practices related to hygienic production facilities in the course of their daily work, whether as an element of production, equipment design, process installation, maintenance, quality assurance, consulting, or some other supporting process. This book has been written to be just as relevant to those working in or with large-scale kitchens and restaurants as it is anyone working with large industrial facilities.

The ambition is to bridge the gap between the day-to-day work of equipment manufacturers and product manufacturers, enabling each side to understand what it is the other does and focus more intently on collaborating to create the right hygienic design for a given task.

The proper solution ought always to be based on an assessment of the risks particular to a given production process, so there is rarely a single correct solution in general. Most often, there will be numerous workable solutions to a given situation. Productive discussion between users and vendors makes it possible to choose the optimal solution for the situation based on the application in question, regulations, standards, and guidelines.

This book has been structured in such a way to offer readers practical knowledge relevant to their own viewpoints as immediately as possible. From there, readers can find more detailed information on specific topics using the references provided in the text. Beyond the short introduction, the book's structure is as follows:

- Three unique perspectives are described. Each represents what we might call a different class of use cases or approaches. The three perspectives focus on the product, the equipment, and the materials, respectively. Each use case is described in an objective, down-to-earth fashion, focusing on the opportunities and pitfalls that exist along the path to good hygienic solutions.

- A toolbox is presented, featuring tips and tricks for risk assessment, creating good solutions through active dialogue, making the most of hygienic integration, and the "V" model. This section also includes a variety of checklists for use in practical applications.

- There is a detailed review of regulations, food contact material requirements, and declarations of conformity.

- The book closes with a description of the opportunities that lie in the guidelines from the EHEDG and others to improve hygienic design in specific situations and achieve equipment certification.

To the greatest extent possible, information that others have covered in detail is not simply repeated here; instead, the book offers key takeaways and conclusions that support the practical application of hygienic design. It also contextualises the most significant existing works in the field, giving each reader the ability to dive deeper into specific topics by referring to relevant sources.

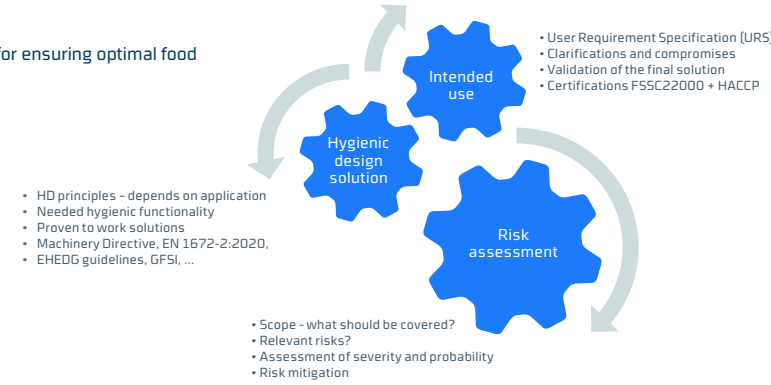
2. Hygienic Design: How It's Done!

Hygienic design of production equipment, the use of the correct food contact materials, and the assurance of food hygiene during production are all encompassed by EU regulations, which impose particular requirements on these. On a basic level, across the regulations for these three areas, the laws specify that production equipment and facilities must be easy to clean and that it must be possible to maintain good hygienic conditions throughout their lifetimes, as well as to regularly verify that these conditions are maintained.

These regulations include significant documentation requirements for equipment and food contact materials. To facilitate HACCP[1] -based oversight programmes, food manufacturers' documentation requirements are often even more stringent. The information and documentation required are typically determined by a food manufacturer's customers. They may be related to third-party auditing requirements, such as those set out in FSSC 22000 and other certification programmes[2].

The fundamental processes for ensuring food safety in practice are shown in Figure 1. A risk assessment is needed to stress-test possible hygienic design solutions in the intended application. Figure 1 describes the context for the processes that will be described in detail later in this book.

Figure 1.
Process for ensuring optimal food safety



[1] *HACCP is an initialism for Hazard Analysis Critical Control Point, an internationally recognised principle for assessing, mitigating and managing risks in food production.*
[2] *Food Safety Systems Certification, FSSC 22000 (based on ISO 22000) is a complete food safety management certification program. This certification is internationally recognised and based on benchmark standards from the Global Food Safety Initiative (GFSI). GFSI promotes food safety management and accountability for quality and provides benchmarking requirements for any certificate programme owners (CPO) also International Featured Standards (IFS) and BRCGS.*

In Chapter 4, With a few additions, assessing process solutions for sustainability and/or circular economics involves the same basic activities. The following considerations apply to the design of processes for food products and pharmaceuticals (for more, see Chapter 4):

1. In the design process, do things right the first time and fully specify users' needs

2. Conduct a thorough risk assessment of hygiene risks in the final process

3. Focus on optimised lifetime and appropriate (hygienic) process solutions

This chapter provides an introductory description of how to specify hygienic design and food safety requirements and which activities are necessary. It also introduces supporting knowledge, which can be broken down into the categories: EU legislation and harmonized standards, guidelines, and internal business documentation.

2.1 Create the best foundation: focus on intended usage

Intended use specification is a key concept in hygienic design. Without a good understanding of the intended use–whether general or specific product wise–it's impossible to assess the risks in a production operation or piece of equipment.

- There are two basic approaches that equipment manufacturers can take when developing equipment: They can make general-use components with no particular use in mind (unassigned), or they can make process equipment designed for a particular application (assigned)[3].

→ The customer-vendor dialogue

It is important to consider a variety of expert perspectives when establishing the requirements for a hygienic process. In particular, this applies to a product manufacturer communicating its requirements to a vendor. Listening to key stakeholders, carefully identifying elements that impact ease of cleaning, and conducting risk assessments relevant to a given product are all crucial. Discussion with an equipment manufacturer enables both parties to arrive at a common understanding of the delivery.

[3] *The terms "unassigned" and "assigned" are used in the context of hygienic integration. These are explained in greater detail in Chapter 3.2.2 and 4.3.*

- Users need to know the capabilities and limitations of the equipment they acquire and what other options they may have. Equipment manufacturers can benefit from greater user involvement in the design process to achieve more appropriate solutions.

This means that equipment manufacturers and users must work together to determine the precise purpose of the equipment. This is a prerequisite to reaching a consensus on a user requirements specification (URS), which ought to be a formalised document. A requirements specification is necessary because it ensures ongoing communication about the significance of any compromises that might be made during the design process. Together with the description of the equipment's intended use, the requirements specification serves as a foundation for a risk assessment with respect to the hygienic performance. This, in turn, is the first step in validating the appropriateness of the chosen solution for the customer's needs. How an installation is to be validated, how its hygienic state is to be verified, and at what point in the process verification is to take place should also be clearly specified and documented.

In practical terms, this means determining whether an intended use is viable, as well as planning for operational activities like process control and automation, internal supervision, quality assurance, cleanness monitoring, and so on. However, whether these activities can be performed effectively and reliably during day-to-day operations depends on whether process equipment and facilities are designed, constructed, and installed according to appropriate hygienic design principles.

Therefore, developing a requirements specification is so essential. Communicating it appropriately, such that the equipment vendor receives and understands it, that is key to obtaining satisfactory deliverables. Also, critically important is the ability to prioritise the most important elements; this includes the ability to distinguish between non-negotiable requirements and that which is merely desirable (described in Chapters 4.1 and 7).

2.2 General requirements for ensuring good hygiene

Naturally, adherence to regulatory requirements is at the core of hygienic design for product and equipment manufacturers alike. This can be summarised in four points:

- Materials which will come into direct contact (or indirect contact, in some cases) with products must be free of defects (e.g., scratches and scuffs). They must be durable, and they must not react with products, cleaners, or disinfectants when used as intended. In other words, there should be

no contamination anywhere along the road. All relevant surfaces must be smooth and easily cleaned.

- Installations and surfaces should either be drainable or easy to disassemble during cleaning. It must not be possible for materials to accumulate on them during production that cannot later be removed during cleaning.

- It must be possible to clean and disinfect equipment and fixtures sufficiently before use. Equipment should also resist the ingress of undesirable substances that could contaminate or alter products. Practically, this also applies to the facilities and spaces surrounding production processes, even if products do not come into direct contact with them. A focus on the surrounding environment is particularly important if insufficient cleaning would lead to a risk of process and/or product contamination.

- Equipment and fixtures should be placed so as to make them easily accessible for cleaning. It must also be possible to verify their hygienic status after cleaning and disinfection (where applicable). Equipment and fixtures must be placed so as to allow their surroundings to be cleaned sufficiently.

Furthermore, when relevant for hygienic purposes, it must be possible to pasteurise or sterilise equipment before use.

Food manufacturers and businesses that handle food contact materials must implement an internal supervision system[4]. This system must ensure that risks are systematically handled, minimised, and/or managed, so as to minimise the risk to consumers.

→ Broad regulatory requirements

Legislation in this area is written with the aim of addressing every condition imaginable, so it is always a good idea to discuss its interpretation. At a minimum, the customer and vendor should agree on the following:

- What is meant by (e.g.) "smooth, easily cleaned surfaces"?
- What methods will be used to verify hygienic status?
- Are there particular standards or guidelines the solution should adhere to?
- How will cleaning actually be performed?

[4] *Internal supervision according to HACCP principles is required in food manufacturing businesses. Less comprehensive approaches are often sufficient for equipment manufacturers and others that handle food contact materials.*

Naturally, alongside hygienic requirements, there are also operational safety requirements and requirements for the process to produce products of the desired quality in the desired volumes. Some other requirements are also typical, such as minimal resource consumption, optimal cost of operation, etc.

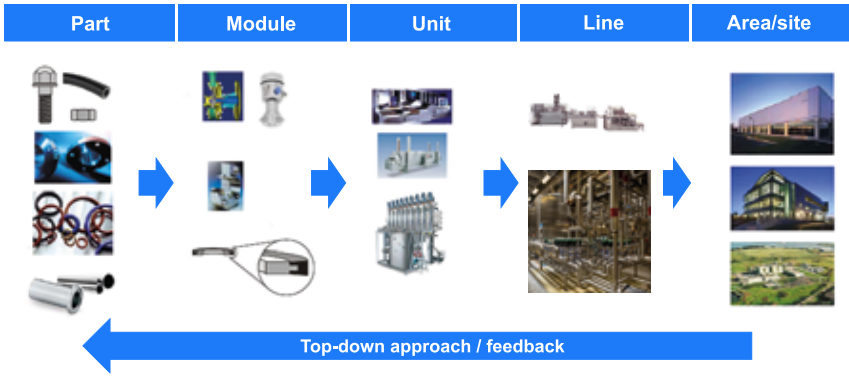
Given the many topics related to each of these requirements, hygienic design is clearly a multidisciplinary field. It includes the following disciplines: microbiology (relevant microorganisms, adhesion and removal of microorganisms); contamination of food contact materials (how contaminants are deposited; how fats, proteins, and microorganisms function in a matrix/biofilm); materials technology (material properties, surface condition, useful life); construction technology (design, layout); flow mechanics (which flow phenomena promote cleaning in closed process systems, how to remove contaminants and spread cleaning agents to all surfaces); cleaning and disinfection (cleaning and disinfecting agents and their uses; cleaning methods); and finally, maintenance, validation, verification, and documentation (whether a process is hygienic throughout its intended lifetime, maintenance plans).

2.3 Hygienic design at different levels

For practical purposes, it makes sense to divide hygienic design needs into levels, each with its own activities and requisite knowledge of hygienic design. These levels are (1) production facilities as a whole and their outer framework, (2) production lines, (3) equipment, (4) modules and components, and (5) parts and materials.

As shown in Figure 2, each activity in a hygienic production process must be built from the right hygienic building blocks. The activities are described in the arrows,

Figure 2. Levels in hygienic design and a description of bottom-up and top-down processes



from left to right. This is the traditional way of working with hygienic design. In a bottom-up process with requirements specified for each building block. However, it is important also to recognise that optimising hygienic design requires the parallel use of knowledge of the final process and the environment in which it will operate, via a top-down process (more about this in Chapter 4.3).

2.3.1 The overall facility (factory, commercial kitchen, or restaurant)

In general, it is important to situate the production process in the intended environments to minimise contamination and other undesirable impacts from the surrounding environment as much as possible. An outer "shell" should prevent or minimise the ingress of undesirable and uncontrollable entities (ranging from pests to airborne particles) into the production facility, where they could contaminate products.

Within the shell, an appropriate layout creates additional safety by routing people and products through the premises in a manner that avoids unintentional contamination (cross-contamination). The safety of the facility can be further strengthened using zoning. Each zone is assigned a well-defined risk level with clear rules for access to and conduct within the zone.

Areal spaces must be outfitted such that they can be cleaned. This applies even to areas where there is no direct food contact. In particular this applies to sewage installations, water pipes, electrical wiring, compressed air, light fixtures, and so on.

→ Three types of production process

Typical industrial production processes are well organised and divided into risk zones and an outer "shell", which minimises contamination from the exterior. These processes typically result in a greater degree of refinement. A fairly large amount of knowledge is available on the hygienic design of a facility's "shell", equipment installation, and the cleaning of equipment and its surroundings.

In many places today, commercial kitchens can be considered small industrial production facilities for organisational purposes. Newer production facilities are often designed to high standards, but challenges still exist in terms of equipment placement and the feasibility of adequately cleaning its surroundings.

Restaurant kitchens are generally the least industrialised. Typically, they are also the most difficult to wall off from the outside environment and any contaminants in it. Their smaller size makes them easier to manage, but they face the same challenges as do large commercial kitchens when it comes to cleaning around large pieces of equipment.

Ventilation systems require special attention: If designed inadequately, they can contribute to the accumulation and spread of airborne contaminants throughout a facility. Typically, allergens and spores from microorganisms pose the greatest risks. It is also important to situate and install equipment and connections in a manner that permits cleaning, monitoring, and maintenance and makes performing daily routines as intuitive as possible.

2.3.2 Production lines

Production lines are traditionally made up of modules that are connected in various ways. At this level, it is crucial that equipment be assembled correctly so as to produce a drainable installation and to facilitate cleaning (potentially after disassembling a part of the process during maintenance and repair).

It is important to control the flow of products and cleaning agents so that elements of the process that come into contact with products during production can be cleaned later. This makes it important to focus not only on oversight using monitoring equipment, but also on how this equipment is connected to automation systems and other systems in the business (quality control, ISO, GMP, etc.).

2.3.3 Equipment/devices

When designing a piece of equipment–that is, a device with a well-defined function–it is essential to focus on how modules and components are integrated. Doing so ensures that the finished assembly is hygienically designed and easy to clean, even when used on a production line that involves other components.

It is critical to account for the risks that can arise when combining different types of materials. Additional risks may come into play at joints between different materials (e.g., plastic and rubber expand more than stainless steel when heated).

- In closed processes, paying attention to the flow of fluids within components to ensure optimal cleaning conditions.

- In open processes, ensure that all areas where products, dirt, and moisture may be present (e.g., from condensation) are sufficiently accessible during cleaning.

2.3.4 Modules/components

FFor modules and components, attention is needed to the manner in which materials and parts are integrated, so that the result after assembly is a hygienic component. This involves choosing appropriate materials, surface properties, shapes, and designs based on some fundamental rules.

Objects should be assembled in a hygienic manner, preferably using full welding, alternatively hygienic bolts and nuts, hygienic pipe couplings, or other means which have been validated to perform in a hygienic manner. A good continuous weld is the most hygienic option, but welding is not always possible or appropriate. The challenge in using nuts and bolts is that cracks and crevices may exist between metal parts and it may be difficult to remove product residues and microorganisms in these areas. Typically, this solved by applying a suitable rubber gasket wherever metal meets metal and assuring that the gasket compression is controlled by a metallic stop in the assembly.

2.3.5 Construction materials

Construction materials must always be appropriately durable and resistant to the environments in which they will be used. It must also be possible to clean them sufficiently before use, so as to avoid contaminating food products. Naturally, there are different requirements for materials which will and will not come into contact with foods. All materials (stainless steel, other metals, plastic and rubber) are subjected to greater or lesser stress from the environment (products and cleaning agents). It is especially important to consider corrosive substances and conditions that may degrade materials. Typically, higher temperatures worsen degradation, particularly in the presence of chloride ions.

Materials in direct or indirect contact with food must also meet regulatory requirements regarding traceability and documentation of suitability (more on this in Chapter 5.5).

2.3.6 Fundamental hygienic design requirements

Administration (FDA)[5] and US Department of Agriculture (USDA)[6]. Furthermore, guidelines produced by the European Hygienic Engineering and Design Group and 3-A Sanitary Standards, Inc.[7] supports these requirements.

→ Food contact materials

As mentioned previously, food contact surfaces must be smooth and free from damage that negatively impacts cleaning. By law, materials may not release substances that measurably alter the composition, taste, smell, or appearance of food products.

[5] *The FDA is responsible for protecting public health in the United States by monitoring the safety of foods, cosmetics, pharmaceuticals, and medical devices. https://www.fda.gov/food/*
[6] *Among the divisions of the USDA is the Agricultural Marketing Service (AMS), which offers two voluntary equipment review and certification programs.*
[7] *3-A Sanitary Standards is a US-based, independent, non-profit company dedicated to promoting hygienic equipment design for the food, beverage and pharmaceutical industries. http://www.3-a.org/*

These requirements can be grouped under the following main ideas:

- Surfaces must be drainable, typically with a slope of at least 3°. This applies to piping and equipment installed in a closed process. For example, in a closed process, it is important for piping to be adequately supported so that it does not sag or warp. This creates depressions in which liquids can collect.

- Accessibility of all food contact surfaces during cleaning. For this reason, there must not be any hidden or shielded areas where cleaning is impossible or cumbersome.

    - In open process facilities this can be overcome by making it possible to open machinery for cleaning. Removing an assembly to clean it separately may be needed and might be combined with replacing it with a fresh one–a kind of plug-and-play solution. Accessibility often comes down to basic practical questions, like whether a person can reach every part of a process when cleaning it. This problem is especially common in very wide processes that can only be accessed from one side during cleaning.

    - In closed processes, this is a matter of where and how efficient fluid flow is. When fluid exchange (replacement rate) is low and/or the energetic impact is low this can reduce the effect of cleaning. This means that

→ About dead ends

Sometimes, dead ends are necessary, such as when installing sensors. There are many other situations which make it difficult to eliminate dead ends completely. Where they cannot be avoided, they should be made as short as possible.

EHEDG permits dead ends where no sensor is installed, provided that the depth L of the dead end is less than or equal to the diameter of the pipe D; that is, $L \leq D$. If a sensor of diameter d is placed inside, then the criterion becomes $L \leq (D - d)$. For practical purposes, this means that dead ends with a depth up to the diameter of the pipe are acceptable.

Without going deeper into fluid mechanics, you can safely assume that this requirement is reasonable for a dead end in any pipe where liquid flows towards the dead end. However, if liquid flows in the opposite direction, allowing dead ends is not advisable.

Air can also become trapped in dead ends, posing an additional challenge. This negatively affects cleanability and sensor functionality alike. Proper placing of a Tee will always involve assuring that the air can be easily extracted here from.

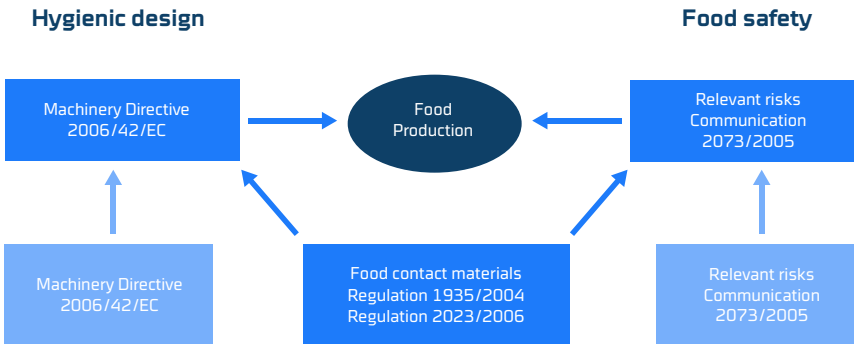
areas with such conditions which also may involve recirculating flow require a special focus. Such areas include dead ends in a T-piece, as well as areas with significant surface irregularities: a bad weld, a sudden expansion, or an edge where two flanges meet, for instance. Proper hygienic design will minimise dead ends, sudden expansions, and surface irregularities but sometimes they cannot be avoided.

Surfaces must be smooth, free of defects, and otherwise easy to clean. EHEDG, 3-A Inc. and the dairy industry, among others, require the roughness parameter Ra to be less than 0.8 µm for stainless steel surfaces. Within the pharmaceutical industry, some impose more stringent requirements, and roughness specifications of Ra ≤ 0.3 µm are not uncommon. The surface smoothness requirement applies to plastic and rubber, too, but measuring their roughness is not always easy. For this reason, microscopy can be applied for surface evaluation and surface roughness can be assessed by use of 3D microscopy.

- Sharp corners, acute angles, and narrow areas are difficult to clean, if not impossible. For this reason, there should be no sharp 90° angles. Corners should be rounded with a radius of at least 3 mm, preferably more in some applications. For open systems, EHEDG requires angles greater than 135° for equipment certification. Similarly, details with small gaps between surfaces are difficult to clean, so there should be a suitable distance between them– minimum 6 mm but preferably more.

- Crevices, cracks, and very small gaps between objects have no place in hygienically designed areas with product contact, and they are best avoided anywhere where product residues and water could penetrate them.

Figure 3. Overview of legislation



- There is always at least a theoretical possibility of microorganisms hiding in them. Because they also impede accessibility, sufficient cleaning will be impossible in practice. Furthermore, there is a risk of crevice corrosion in narrow areas where water is present, this may hamper lifetime of equipment.

- Joints in product contact areas must be properly sealed, so metal-to-metal surfaces are not permitted, except in designs intended for dismantling during cleaning. For this reason, joints between metal surfaces in equipment cleaned in its place must always include a gasket of sufficient flexibility to seal the gap between them. To be hygienic, a gasket should be installed in such a manner as to make contact with the product and be flush with the metal surfaces. This means that recessed O-rings and gaskets are not acceptable, since they create a recessed area around the gasket that cannot be cleaned.

- In welding, objects must be fully welded to eliminate cracks. Welds must also be performed hygienically; the steel must not be allowed to oxidise during welding. Occasionally, hollow spaces can occur in fully welded pipes and conduits. Some experts are sceptical of these, particularly in the United States. This is because if the weld is compromised in even a single spot, microorganisms may be able to enter and live inside the hollow space.

2.4 Legislation and harmonized standards

Legislation and regulatory requirements play a key role in food production, food safety, and internal oversight in production. This also applies to the manufacture of production equipment and food contact materials.

The legislation that applies throughout the EU comes in the form of directives, regulations, and executive orders. In the case of food processing machines, the general requirements are established by the Machinery Directive, 206/42/EC (more on this in Chapter 5.1). Figure 3 presents an overview of the EU legislation and the connections between its various parts.

→ About food contact materials in the EU and USA

It is important to be aware that the EU relies on its own legislation in this area, and that the laws specify required testing methods for plastic and rubber surfaces. This means that EU authorities will not automatically accept the use of plastic or rubber materials approved by the FDA. Documentation that the materials have been tested in accordance with applicable EU regulations is required before they can be used within the EU.

In several areas, harmonized standards support the Machinery Directive (more on this in Chapter 5.4). Use of the harmonized standards is voluntary but applying them makes it easier to achieve the CE mark required for process equipment (see Chapter 5.6). Equipment manufacturers are expected to possess knowledge on par with the harmonized standards.

The requirements for food contact materials are specified in Regulation 1935/2004 on the traceability and absence of contamination, as well as Regulation 2023/2006 on appropriate manufacturing practices for handling materials (more on this in Chapter 5.5). This legislation is primarily focused on consumer protection, traceability in the value chain, and ensuring equal terms of competition in the common EU market.

EU member states may also issue domestic regulations and executive orders extending those of the EU commission; these apply only within the issuing member states. Denmark has more stringent rules regarding the registration of all businesses that handle food contact materials, and it requires all food contact materials to be accompanied by a declaration of conformity. In the remainder of the EU, a description of each material's composition and suitability for use is sufficient.

Regulation 852/2004 is the core piece of food hygiene legislation (more on this in Chapter 5.2). Both the EU and the Danish Veterinary and Food Administration have prepared guidelines on how to best adhere to these laws. In some cases, they also describe the intentions behind the legislation.

In the United States, the Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) handle matters of food contact materials, production procedures at food manufacturing businesses, and rules for hygienic design (more on this in Chapter 7).

2.5 Guidelines

As their name suggests, the use of guidelines is voluntary. Guidelines may describe how to achieve a higher level of hygienic design, with improved food safety as a likely outcome. Guidelines on hygienic design are published by recognised organisations based on collaborations between the food industry, equipment producers, and knowledge organizations. The European Hygienic Engineering and Design Group (EHEDG) has a world-wide focus on hygienic design and practices. Its American counterpart is 3-A Sanitary Standards, Inc. (3-A SSI) which is dominant in North America and certain other parts of the world. EHEDG and 3-A SSI are the primary actors in this space, but there are also other organisations offering recommendations on hygienic design, food safety,

and internal procedures at food manufacturing businesses (more on this in chapter 7).

2.6 Businesses' own specifications (manuals)

An individual business may develop manuals to describe in detail its approach to maintaining the required level of hygiene and any particular requirements it has related to hygienic design and operation.

2.7 Third-party certification of food safety management systems

Ensuring good food safety among food manufacturers depends not only on equipment design, process line design, and operating procedures, but also on the implementation of an appropriate management system and corporate culture. At the global level, the Global Food Safety Initiative (GFSI)[8] issues recommendations on food safety management systems. These recommendations are the basis of specific certification programmes, such as FSSC 22000. In addition, organisations like the British Retail Consortium (BRCGS)[9] and International Featured Standards (IFS)[10] offer food safety certification programmes

2.8 The government's legal framework, and who takes the blame

DIt's important to note that food manufacturers are the ones ultimately responsible to the Food Authorities for the production equipment they use and the products they produce. The Veterinary and Food Administration in Denmark

→ The future of certification programmes

Traditionally the GFSI benchmarking requirements has not included specific requirements on hygienic design but merely focused on the resulting food safety and the management hereof. In August 2020 GFSI issued two voluntary requirements on hygienic design on for equipment manufacturers and building constructors and one for the users (read more in chapter 4.2.2).

Although these are voluntary BRCGS has included parts here of in their recent draft for a new issue (no. 9) of their certification program. This means that certification of food manufacturers soon may inflict on their equipment providers.

[8] *3-A Sanitary Standards is a US-based, independent, non-profit company dedicated to promoting hygienic equipment design for the food, beverage and pharmaceutical industries. http://www.3-a.org/*
[9] *BRC Global Standards https://brc.org.uk was founded in the UK. It specifies requirements for organisations and helps to assure customers that products are safe, legal, and of high quality. Programmes for ensuring high levels of food safety are among the focuses of the BRC.*
[10] *IFS maintains eight food and non-food standards that cover processes throughout the supply chain.*

typically conducts random sampling to ensure that the required documentation for food contact material compliance exists, and that the documentation has either been filed or is available upon request. Formally, of course, it is the machine manufacturer's responsibility to provide this information and document compliance in accordance with the relevant regulations.

This means that food manufacturers cannot claim ignorance of the documentation requirements for food contact materials. Missing or deficient documentation is the food manufacturer's responsibility. Similarly, machine manufacturers, material suppliers, and others that handle food contact materials are responsible for providing the proper documentation in their own businesses upon request from the authorities.

A claim can be filed against a vendor that has made a mistake in this regard. The damage has occurred after any actor receiving a remark in an inspection report. In reality there are no winners in disputes over who is legally liable in these situations–especially financially, but also in terms of prestige. Focus between users and vendors should therefore be on choosing adequate materials and paying particular attention to the conditions that food contact materials must withstand throughout their lifetime (more on this in Chapter 4.1).

The consequences of receiving remarks in inspection reports, and of any subsequent product recalls, are greatest for food manufacturers. As a result, they ought to take a considerable interest in knowing that specifications and requirements are met.

Governmental responsibilities for the safety of machinery, as provided by the Machinery Directive, are quite clear: Working Environment Authorities are responsible for the safe operation of machinery. In fact, it is the only authority that can prohibit the use of a particular machine. The Machinery Directive is not part of

→ About on-site inspections for food manufacturers

Food manufacturers risk being fined in the event that food contact material documentation is insufficient, missing, or incorrect. This also applies if the materials used do not meet the requirements that apply to contact with the foods being produced under the production conditions. Examples of errors and omissions include: absence of relevant migration tests (not applicable to the particular products and temperatures in use), EU declarations of conformity for materials are missing and/or deficient in risk assessments, or spare parts being purchased without regard for documentation requirements.

the legal domain of the Food Authorities, even when they conduct inspections at businesses that manufacture equipment.

Which laws each regulatory body applies when conducting inspections might seem like a technicality, but it has real significance: the hygiene provisions of the Machinery Directive are effectively unenforced. Fortunately, the requirements laid out in food and hygiene directives closely resemble the provisions in the Machinery Directive. Naturally, the overlap between them is no mere coincidence. In practice, the requirements from the "equipment side" and the "food side" are the same, but each one applies them from its own legislation, as shown in Figure 3.

This means that the Food Authorities focuses on overall food safety within a production process, as well as the capacity to maintain the process in a sufficiently hygienic condition, so as to avoid contamination of the manufactured food products. Of course, this is a function of, and directly linked to, the hygienic quality of the production equipment. However, assessments of the hygienic design of a particular piece of equipment rarely occur (if ever) when the cleanliness and food safety at a given food manufacturer are challenged. The Food Authorities does comment on specific issues, but they have yet to forbid the use of a poorly designed machine. Typically, the Food Authorities bans all production on a production line that requires hygienic improvements before it can return to operation.

2.9 Hygienic design through a practical lens

This paragraph presents more subjective considerations about how to ensure good hygienic design in practice. The laws, of course, must be afforded the greatest respect–but we recognise that sometimes, a more pragmatic approach may be necessary. Pragmatism works best when it is based on a thorough, appropriate, and properly validated risk assessment of the case in question. In general, it's important to actively apply a risk-based approach in considering

→ About inspections by the Danish Veterinary and Food Administration

At businesses that simply handle food contact materials, such as equipment manufacturers and importers, the Veterinary and Food Administration's inspections are based solely on the regulations that apply to food contact materials. It does not address the hygienic design of machinery and production lines. It has no legal grounds on which to make comments about hygiene. Food- and hygiene-related legislation applies only to food manufacturers. At a business that handles both foods and food contact materials, inspectors may apply both sets of laws.

specific equipment designs, food contact material choices, installations, cleaning and maintenance, etc.

As a tool for ensuring food hygiene, the hygiene laws provide a legal basis for risk assessments (more on this in Chapter 5.2 and 5.3). Risk assessment is also a part of the CE marking process and the contribution of safety equipment to achieving the necessary level of food safety as specified in the Machinery Directive and the European standard DS/EN 1672-2:2020 (more on this in Chapters 4.2 and 5.4). Selection of appropriate food contact materials for a given application should also be based on a risk assessment.

Assessment of relevant risks, and analyses of how to eliminate or minimise them, are central to ensuring good process hygiene and the production of safe food products alike. An effective risk assessment requires knowledge–often, knowledge from a variety of actors within a value chain, and at minimum, a dialogue between a food manufacturer and an equipment vendor. To highlight

the importance and complexity of this issue, two sections of the "toolbox" in this book deal with this topic: Chapter 4.1 is about the customer-vendor dialogue, and Chapter 7 is about practical risk assessments for equipment.

The day-to-day work of a food manufacturer goes beyond adhering to regulatory requirements; often, it is also about adhering to customers' requirements, which may be more stringent than those applied by the Food Authorities.

In an ideal world, we would have enough resources to make everything perfect and ensure the very best hygienic design possible in a given situation, but this takes more time and (of course) more resources than is typically in the budget for most procurement projects. Because of that, we have to set priorities and make some compromises on what we initially wanted to achieve. In doing so, we have

→ Food contact materials–a hot topic

There is no doubt that more stringent demands from the food manufacturers customers have contributed to a greater focus on food contact materials in recent years, thereby also drawing attention to the need to ensure that the relevant documentation for the use of these materials is available. This means that equipment providers have greater focus on requirements from their customers in a way that reassures food manufacturers that these materials are safe to use and properly documented. In practical terms this means that vendors aim to supply materials which are sufficient, but without incurring unnecessary costs.

to be careful not to compromise food safety. The consequence of saving time and money in the "wrong" ways may amount to daily inconveniences and expensive cleaning procedures for a production process. That makes this topic especially important during risk assessments and the customer-vendor dialogue.

Doing things right the first time is a key element of good hygienic design. This is only possible with an active dialogue between customer and vendor throughout the process. At the same time, when specifying requirements for a new process, users should involve any and all actors with relevant knowledge–including the ones who will be cleaning the equipment later on. On this point, it's important to challenge some of the dogmas that can contribute to limitations in hygienic design, such as:

- Better hygienic design is always more expensive. This may be correct when focus is only on procurement. It can be more expensive not to use standard components, but the gain should be that cleaning and maintenance costs are reduced. However, making an inadequate solution that needs correction in the future will be costlier still.

- Food manufacturers assume that equipment manufacturers know what they need. While they do have extensive knowledge, keep in mind that they also need to know about the specific requirements of your project.

- Equipment manufacturers don't ask in-depth questions, such as to find out whether a cheaper solution would be sufficient. They may rely on that they have a suitable solution at hand which will 'pass' a risk assessment. There is nothing wrong with this, but users may miss out the chance to obtain cheaper solutions for less critical parts of a process and the possibility to direct resources to particularly hygiene critical parts.

Each of the three bullets above are generalized to prove a point which is that the customer-vendor dialogue (sew chapter 4.1) is critical for achieving the best hygienic design for the money and that in essence the best solution is made when both parties join forces in an openminded collaboration.

2.10 Risks and contamination sources

The purpose of focusing on food safety is to minimise the risk of product contamination by foreign substances, particularly those that may be hazardous to consumers. In this regard, contamination sources can be divided into three groups: biological agents, chemical substances, and physical objects or particles. An overview of these is presented in Figure 4.

Figure 4. Typical consumer health hazards that may come from foods

Biological agents	• Diseases of animals (rats, mice, birds, ..) • Insects, mites ol. • Microorganisms
Chemical substances	• Particles from the surroundings (dust etc.) • Personnel (particles from skin and clothing, jewelry, watches, etc.) • Foreign objects (metal, glass, plastic, etc.) • Toxic substances and allergens formed
Physical / particles	• Particles from the surroundings (dust etc.) • Personnel (particles from skin and clothing, jewelry, watches, etc.) • Foreign objects (metal, glass, plastic, etc.)

Naturally, microorganisms are a major focus in the field of hygiene, since they can relatively easily lead to reduced product quality and various types of food poisoning among consumers. Fortunately, pathogenic bacteria that can cause serious, life-threatening illnesses are still rare. The microorganisms in this last category are the ones that we do everything in our power to clean away or inactivate, and they receive the greatest attention in risk assessments–the consequences of not doing so could be fatal.

Nonetheless, reducing the number of microorganisms, the presence of allergens, and any foreign substances in general is paramount. Their presence can necessitate product disposal and recalls, and before becoming a threat to consumers these have major financial consequences for manufacturers.

The proper cleaning strategy can remove microorganisms from processes. Furthermore, disinfectants and/or heat treatments can also inactivate them. Bear in mind, however, that a little water, nutrition, and the right temperature are all microorganisms need to grow. Room temperature in a production facility may well be the "right temperature". This means that cleaning and validation of the cleaning process are highly important when manufacturing foods and simular consumer products.

→ Specific reasons for food recalls

A quick glance at the Danish Veterinary and Food Administration's list of reasons for product recalls reveals such reasons as: undeclared allergens, risk of mould, overpressure in packaging, risk of metal fragments, occurrence of listeria, several instances of products with risks of fungal growth, and a plastic spoon that posed a PAA (polyacrylic acid) release risk.

The potential presence of allergens can be just as catastrophic for people with allergies as pathogenic microorganisms can be in general. For that reason, food legislation requires that any potentially allergenic ingredients be listed in boldface on product labels. Typical issues involving allergens involve products that are unintentionally contaminated by allergens. Usually, allergens can be removed completely from a process through thorough cleaning. Unlike microorganisms, though, they cannot be inactivated. In many cases, it may be possible for traces of allergens to be transferred between products over the course of a day. Because of this, many manufacturers choose to produce products containing ingredients like nuts and shellfish during the day's final production runs.

It's reasonable to assume that hygiene issues can primarily be attributed to poor hygienic design of production equipment, inadequate cleaning and disinfection, or both. However, they can just as easily be caused by cross-contamination resulting from inappropriate production procedures. Regardless of the reason, it's crucial to locate the core of the problem instead of merely treating the symptoms.

2.11 Contamination risks during production

The purpose of focusing on possible reasons for product contamination, of course, is to prevent them from actually occurring. This means that it's important to gain as much knowledge as possible about any given production process and the products it manufactures. In this context, there are two relevant activities described in the legislation: delimitation of intended uses and a subsequent risk assessment based on that (more on this in Chapter 7).

Conducting a risk assessment requires knowledge of the most significant ways in which contamination can be transmitted or allowed to remain in production equipment. These are, in no particular order:

- From people to products or processes:

→ Focus on allergens

One reason for the focus on allergens is that they can be carried through the air in the form of dust or particles from dry ingredients, for example. This means that inappropriately designed ventilation systems can play a nefarious role in distributing allergens, which may suddenly turn up in products or production facilities. This problem is further complicated by the fact that allergens may stem from additives and aids used in processing, and these can be overlooked. While specific examples of this exist, it often turns out that the concentration of an allergen in a food product falls below the established limit value.

- As humans, there is a fundamental risk in that we shed particles from our bodies. When we cough and sneeze, we expel aerosols into the air. This is why it's important to stay away from a food production process if you're sick.

- In practice, however, the greatest risk comes from contaminants that become attached to clothing and footwear. These can be transferred to other sites by the hands, clothing or footwear. This is why everyone moving throughout a production facility needs to be mindful of hand hygiene and sometimes also changing clothes and footwear when entering areas with higher risk levels.

- Insufficient cleaning:

  - Equipment and processes should be designed so that all relevant elements can be cleaned. These elements may include more than just food contact surfaces. If this is not possible, nutrient-rich residues may be left behind, allowing microorganisms to survive within the process.

  - Issues may also arise if a cleaning procedure is changed from one that was sufficient to one that is less effective. This may be cause by efforts to save time and money, such as by switching to a different detergent.

- Unknown connections in the ventilation system or imbalances that affect positive and negative pressures. Both of these can compromise productsafety. Airborne contaminants include bacterial spores, allergens, dust, sand, etc.

- Moisture on process surfaces and in the environment. Moisture in general is a potential risk, since water allows microorganisms to grow. Because of this, some businesses require equipment left unused for an extended period after its last cleaning and disinfection to be cleaned and disinfected again before it is used again. In some processes, surfaces are dried with air to prevent microbial growth issues. However, this approach cannot always solve a problem with microorganisms. Research has shown that listeria can survive drying on steel surfaces for up to 72 hours, then continue growing again in the presence of water and nutrients.

Depending on the type of contamination and where it occurs, one or more of the situations above may be involved.

In practice, risk assessments vary depending on the type of process in question. Naturally, the legislation is not flexible in this regard, and food products must

always be protected from contamination from the surroundings and materials they come into contact with. Nonetheless, the examples below illustrate differences in risk levels and how critical cleaning and protection against external contaminants are:

- Handling of raw ingredients and processes that occur before pasteurisation, sterilisation, or any other product stabilisation procedures. This section of a production process typically requires less strict focus on hygienic design. Protecting products from foreign objects and substances is still important, but microorganisms will ordinarily be inactivated during pasteurisation. What matters in this part of a process is to avoid storing ingredients and partially partly processed products at elevated temperatures, where microorganisms can grow and exceed the levels that the stabilisation stage is not intended to treat.

- Managing and cleaning the pasteurisation stage or a similar stabilisation stage is critical to product safety. These steps are also crucial from an internal oversight perspective. Automation failures here can be fatal. Insufficient cleaning can also impact heat transfer during pasteurisation and sterilisation, potentially leaving the procedure incapable of inactivating microorganisms to the desired degree.

- Handling unpackaged products that will not be further processed before reaching consumers involves a high level of risk because there will be no further stage of the process to remove or inhibit subsequent contamination.

- Handling products in closed systems that have an extended shelf life after packaging, whether at room temperature or under refrigeration (such as milk and juice), require a high degree of cleanliness of the process equipment. In these cases, products are adequately protected from external contaminants by the enclosure, but the process itself must be very clean and sometimes sterile before operation begins in order to avoid even small numbers of microorganisms from entering the product. The product may be pasteurised or sterilised. This, along with the packaging and storage conditions, are key to its shelf life.

2.12 Cleaning and its effects on processing equipment and surfaces

The Machinery Directive and the EU regulations on food hygiene as well as other legal requirements world-wide prescribe that cleaning must be possible and that food contact surfaces must be in good hygienic condition before production begins. This means that cleaning efforts go hand in hand with hygienic design to

ensure the necessary level of food safety. On a general level, the argument is that a good hygienic design that is appropriate for its intended use will be easy to clean and maintain in good hygienic condition.

When processing biological products, like foods, it's important to realise that product contact surfaces will never be returned to a virgin, unused state after use. Minerals and other substances are gradually deposited on these surfaces in microscopic quantities over the course of the first 20-30 uses before reaching a stable state. This deposition process may be invisible to the naked eye, and it does not mean that the surface cannot be assumed to be the original material. However, the deposits affect the adhesion and removal of microorganisms from the surface. In practical terms, this means that it's best to allow some time to pass before verifying the hygienic status of a process until it's been "broken in", so to speak.

The purpose of cleaning and subsequent disinfection is to maintain the process in a sufficiently hygienic state so that the manufactured product is not contaminated to a detectable degree, and so that the quality and shelf life of the product meet specifications. This means that production equipment is rarely sterile after cleaning, and that there is always a greater or lesser amount of biological residue left behind.

In practise cleaning is performed at appropriate intervals to keep contaminants, especially microorganisms, at a level where they cannot multiply enough to cause diseases, degrade product quality, or shorten a product's shelf life. Consequently, cleaning can be performed at various intervals. For instance, a mild cleaning procedure can be performed at shorter intervals, or a more thorough procedure can be performed at longer intervals.

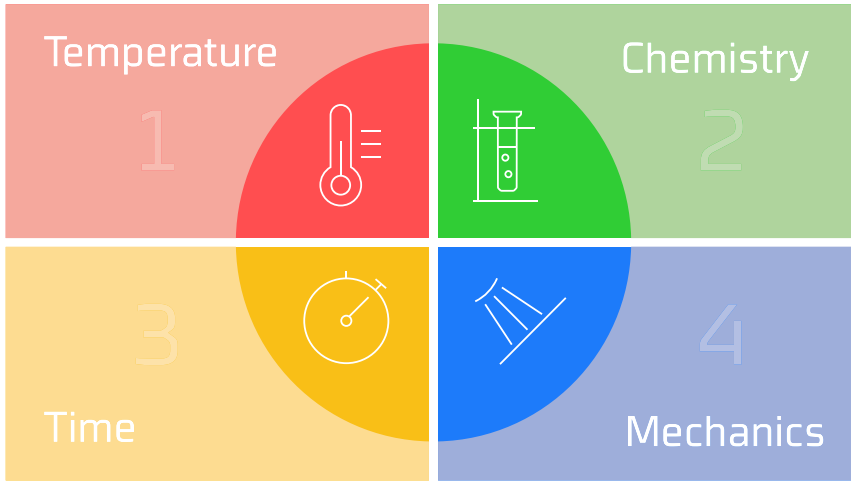
Sinner's Circle can be used to describe the effect of a cleaning procedure. It lists the four decisive factors for cleaning: temperature, chemistry (detergents), time, and mechanical power. Sinner's Circle shows that these four parameters are linked, such that a reduction in one requires one or more of the remaining three to be increased. There are no formulas for the relationship between them, so establishing the right combination of these parameters for a specific case requires a validation process.

Most often, we represent cleaning as a situation in which all four parameters are equal. This is fine, since the relationship between them is relative. Sinner's Circle can also be used to describe and compare cleaning processes that deviate from the norm, such as:

- A closed process in which poor hygienic design results in weakened mechanical power. Because the effects of chemistry and temperature in this situation cannot be altered significantly, this situation typically requires an increase in cleaning time.

- An open process that requires extra water pressure to clean a surface. This corresponds to increasing mechanical power. However, time may also be increased simultaneously, meaning that temperature and chemistry will play a comparatively lesser role in this cleaning procedure.

Figure 5. Sinner's Circle.



In general, the components and parts of a process that are more difficult to clean require a greater focus. These may need to be cleaned separately, the process may need to be partially disassembled, or special equipment may be needed for cleaning.

Verification of cleanability and actual cleaning must follow agreed-upon procedures which always comprise two steps. The first step is a visual inspection of cleanliness, and the second is a measurement of bacteria-level cleanliness.

3. Three user approaches to hygienic design

Different viewpoints to hygienic design are presented. The goal may seem in essence to be the same no matter the approach you choose. However, the path taken to reach them, the questions asked, and the actions taken are different for each of them. Often, there is some overlap between the knowledge that each actor has, but they approach issues from different perspectives. For these reasons achieving, hygienic design is presented from three different perspectives:

- The product perspective covers the approach that manufacturers (in food, cosmetics, biotech, or pharmaceuticals) and typically also consultant take to hygienic design. There is some variation in this approach between established businesses and start-ups; the latter typically do not have a broad spectrum of in-house knowledge to draw upon.

- The equipment perspective covers the approach that equipment manufacturers and solution vendors take. This includes companies that provide complete solutions with the help of various subcontractors.

- The material perspective is the perspective of businesses that solely supply materials, whether these are basic materials or processed products consisting of a single material (e.g., steel plates, steel pipes, plastic granules, plastic hoses, and rubber gaskets).

Theoretically, we could also consider a fourth approach; namely, one that includes the viewpoint of inspectors, whether from the Food Authorities or from third-party certification program owners. The attempt is to incorporate this perspective into the three described here.

→ Improvement comes from rocking the boat

The idea is to open people's eyes and create improvements by getting right to the heart of the matter and shaking things up a bit. The intension is not to point fingers at anyone or criticise existing practices, and definitely not to imply that some people are stuck with inadequate approaches to hygienic design. Still the approach may seem a bit generalised and perhaps slightly provocative for some, and this in fully intended to – **rock the boat**

These sub-chapters deal with the basics of each approach in terms of current best practice, required activities, needed knowledge, improved working processes, and–where relevant–information about regulatory requirements that apply to food contact materials and process hygiene. The starting point for this section is the traditional project model for designing production facilities, which can be a bit conservative.

3.1 The product perspective

A product manufacturer is fundamentally interested in process solutions that provide maximal product quality, capacity, and production hygiene within the available budget for a given situation. This typically results in a process where various solutions are compared in terms of price and performance. In spite of every intention to have processes meet high standards of hygienic design, the goal of securing a suitably low price and ensuring ample production capacity tends to take precedence in a typical contracting process.

Product manufacturers often hear from equipment suppliers that high-quality hygienic design will lead to higher investment costs. As a result, it's not uncommon to be presented with two options that vary significantly in price, based on each option's level of hygienic design. This means that before discussing possible solutions, there's already a mental block in the way of giving any extra attention to hygienic design. Of course, not every negotiation goes exactly like this, but making room for hygienic design means that price cannot be the only criterion for comparison. For instance, focus might be first on operating and total lifetime costs, then on resource needs for cleaning and maintenance. Also risk assessment specific to a variety of process solutions could be included in the discussion.

While this may be a dangerously broad generalisation, it's not wholly unreasonable to claim that product manufacturers are more interested in how the end result

→ Investing in cleanability alone is a tough sell

Even in large companies, there are countless examples of situations where essential hygienic design requirements aren't given the priority they deserve. Here are two examples of how this happens:

- •Hygienic design requirements are not communicated clearly enough in the tender documents after they have been reviewed by the purchasing department, as they may consider such specifications being too detailed.
- Management does not prioritise investments and improvements on the sole basis of improved hygienic design.

compares to their specifications than the exact process of getting there. However, there is a pitfall in this approach because the functionality of a production process largely depends on the preparations made to bring it about. This includes the work of specifying design and installation requirements, making careful, well-thought-out compromises during the process, and establishing appropriate requirements for verifying the cleanability of the equipment purchased.

The product manufacturer's active participation is required in every phase of the project. To get there, the product manufacturer must recognise that the equipment manufacturer cannot specify the solution alone, in spite of the belief that the equipment manufacturer fully understands their needs and will be able to find the best solution. Equipment manufacturers have plenty of knowledge and experience, but they cannot read minds; in particular, they cannot guess whether a customer would be interested in less traditional solutions. If a vendor is given a set of rules to play by, the answer they produce will naturally follow that set of rules. This is what makes the requirements specification process and the interaction so important.

3.1.1 Requirement's specification

EOne of the first steps in designing a new process or part of process is to develop a requirements specification as a basis for vendors to submit bids. The foundation of a requirements specification is input from, and internal clarification of what, all stakeholders need in order to ensure good process hygiene in practice (more on this in Chapter 4.3).

It's important for the requirements specification to clearly express the most significant hygienic design requirements. It's equally important to avoid watering them down during the procurement process or eliminating them from the specification entirely. Clearly indicate how fixed or open-ended the job is–that is, how much freedom the vendor has in coming up with a solution. A lack of clarity can result in missing a golden opportunity or receiving an unsatisfactory solution. The former is certainly regrettable, and the latter could very well be catastrophic.

→ A constructive customer-vendor dialogue

Good examples really do exist: Sometimes, a customer chooses a more expensive solution with better hygienic design despite initially wanting something cheaper. The discussion leading up to this typically revolves around risk assessments and illustrating the costs of cleaning and maintenance during operation. This is a process that more customers ought to engage in to be able to make more informed decisions about processes.

It's not entirely unreasonable to say that without detailed clarifications, whether the customer receive what they need can be something of a coin toss. One thing, though, is certain: Without broader dialogue, there is no shortcut to a better, perhaps cheaper, solution (more on this in Chapter 4.1).

3.1.2 Choosing the supplier: What can be asked of equipment vendors?

Ideally, after narrowing the field down to a shortlist of vendors who will submit final bids, customers should have a detailed discussion with each vendor about its interpretation of the hygienic design requirements and how it intends to meet them. A natural part of this process is explaining why the requirements are what they are. The vendor may also have alternative solutions that are worth considering. Theoretically, there is no limit to what you can ask for, provided it's relevant to the job. As far as hygienic design is concerned, addressing at least these topics is an excellent idea:

1. The intended use of the process, including whether there are any new products it might be desired to manufacture with the equipment in the future. The idea here is to avoid introducing unnecessary limitations, such as in the choice of materials or documentation, which may be difficult and time-consuming to work around later.

2. The equipment's intended use plays a major role in the risk assessment, as the vendor really has no need to carry out a risk assessment that covers anything beyond that intended use. Significantly, though, the vendor may need some inspiration or information about elements that are critical to perform an appropriate and comprehensive risk assessment.

3. It may need clarification as to the relevant underlying information and the knowledge on which the solution must be based. Merely asking for regulatory compliance in general terms is not enough. For instance, there are benefit from discussing harmonized standards and guidelines whose use is desirable or required to achieve a satisfactory solution. This is particularly important if large amount of information is provided for vendors to consider. By drawing attention to the parts that are most significant in the particular context, prioritisation is not left to the vendors.

To promote a common understanding of a process, many vendors today can also supply 3D drawings and/or simulations of large, complex facilities, giving the opportunity to have a "peek inside".

3.1.3 Particulars for development consultants

The focus here is solely on hygienic design, with no regard for the many other activities that development consultants are involved in. Precisely because consultants in this role must possess a broad spectrum of knowledge, it's important to be able to navigate the field of hygienic design with confidence. Product manufacturers need to determine whether consultants really understand the field, as opposed to merely having the vocabulary necessary to hold a "surface-level" discussion. Consultants must know what is required by law and what is "voluntary" requirements. There have been instances of consultants insisting on imposing strict documentation requirements on suppliers in the middle of a project without any contractual or legislative basis for doing so. This can result in unnecessary frustration for the supplier. In the worst-case scenario, it may also lead to increased costs or a possible dispute. To put it simply, efforts should be made to communicate just as clearly with a consultant as you would with a vendor if you were handling the task yourself.

3.1.4 What does the Danish Veterinary and Food Administration require?

As might be expected, the Danish Veterinary and Food Administration is interested in whether a production facility as a whole is capable of producing safe food products. Their assessment is based on a review of internal oversight procedures in the context of the flows in the production facility. They focus on overall food hygiene, adequate cleaning procedures, and effective internal oversight. Hygienic design is a rare topic of discussion in this regard. More likely topics included are risk assessments and internal oversight. This makes it a good idea to have a solid grasp of the intended use of a process and the risk assessments that have been performed as this is of the authority's interest.

The Danish Veterinary and Food Administration pays particular attention to food contact materials and their suitability to a given process. This is because

→ Practical handling of food contact materials in food manufacturing businesses

In praxis, for a material e.g. a rubber gasket, there must be corresponding documentation that includes a declaration of conformity or a link to one. This makes it possible to document the suitability of the material in given relation. The work becomes much simpler if it is possible to stick to a small assortment of materials and order from suppliers that have their declarations of conformity in order. Additionally, there is a need to know where each material is used throughout a given process plant.

they constitute a potential source of risks for consumers. For that reason, the Administration requests declarations of conformity for a sample of food contact materials during its inspections. Most samples are selected from the areas in the production facility that the Administration believes to be the most critical. Requirements for handling food contact materials are described under the Material Perspective (more on this in Chapter 3.3.3).

3.1.5 Maintenance

Maintenance is crucial to ensuring that a production line can remain in the required hygienic state over time. During the lifetime of a process, hygienic functionality is ensured through continuous monitoring of critical components, as well as the performance of planned maintenance at appropriate intervals. Hygienic maintenance means replacing consumable parts even if they still function as intended and replacing these parts with either original or components validated for the application. This way, it can be guaranteed that the hygienic functionality is not compromised.

As might be expected, convincing a company's decision makers of the value of hygienic maintenance requires some financial figures. Even then, they may have trouble coming to terms with the idea of replacing components that are still functioning. Therefore, there are still many businesses that continue production until components fail, in spite of the fact that this often results in prolonged downtime for maintenance. Producing until a component fails is a severe issue in the case of hygiene-critical components. In this case, it is not certain how long the hygienic function of a part has been compromised–and by extension, whether contaminated products have made it into the hands of consumers. This alone ought to be enough of a reason to perform hygienic maintenance.

3.1.6 Cleaning

Ideally, the cleaning process is designed based on a risk assessment that takes into account the specific process and its intended use. The Machinery Directive

→ The consequences of lacking maintenance

While it isn't possible to name specific cases here, there are some general conclusions to present. Unfortunately, there have been numerous instances of product manufacturers choosing not to carry out scheduled maintenance. Several of these cases, this has led to product quality issues; for example, foreign objects have made their way into products, prompting those products to be recalled. There have also been instances of equipment breakdowns with financial consequences much greater than those of simply performing scheduled maintenance.

requires a description of an appropriate cleaning procedure for a machine or process, and this is a perquisite for CE marking.

There are many situations in which these cleaning descriptions are of limited utility. For example, when:

- The description may be of a very general character and not practically sufficient for a given product.

- The description may prescribe the use of cleaning agents or processes that are not actually in use.

- The description may not account for the means of actually ensuring that all product contact surfaces are cleaned using ordinary cleaning equipment and methods.

Placing the blame for this on the equipment manufacturer is easy, but the responsibility here is shared. In the absence of specific requirements, there is room to interpret the requirements, which is not ideal. Fundamentally, reputable equipment manufacturers and/or those with extensive industry experience will be aware of the cleaning requirements. Even then, it can be risky not to discuss the cleaning needs of the specific project at hand, as there may be project-specific needs to address.

Cleaning is crucial for hygienic performance because the cleaning process and the options available may ultimately dictate hygienic design needs and material selections. For instance:

- The cleaning procedure is founded on having access to all relevant surfaces with an appropriate combination of the parameters in Sinner's Circle (Chapter 2.12). In practical terms, this means that it must be possible to spray/reach/access all relevant surfaces in an open process. There are processes out there in which doing so would essentially require you to break an arm or spray the equipment from an impossibly low position. Such solutions are not optimal hygienic design and may hamper proper cleaning.

- Typical cleaning agents for closed systems are selected based on the stainless steel grade EN 1.4401/1.4404 (AIST 316/316L), though in many cases, EN 1.4301/1.4307 (AIST 304/304L) is used instead (read more about the types of stainless steel in Chapter 6.1). There may be a problem in that the latter type of steel is significantly less resistant to corrosion, which may make it incompatible with the cleaning agents used.

Both cases show why it's such a good idea to discuss in advance the opportunities and limitations that apply to a particular cleaning scenario relative to the hygienic functionality of the facility when in operation.

3.1.7 Established companies and start-ups: big or small

It might not be obvious why the type and size of a business matter in the context of hygienic design as a technical discipline. The main difference lies in the fact that larger businesses have more in-house knowledge, and perhaps also dedicated positions focused on engineering.

This means that large companies may impose more formal requirements on their equipment vendors, and for very large companies these requirements tend to be quite detailed and they may have their own design manuals with internal regulations to adhere to.

Although medium-sized businesses typically do not have this same design-orientated focus, they do often have considerable practical experience in this area. At the same time, they may have yet to formalise that experience, and the result can be a failure to apply essential knowledge when investing in new equipment.

Lastly, small businesses and start-ups that have yet to find their place in the market often choose to lease production facilities or share them with other businesses. Doing so poses challenges in ensuring that the materials used are compatible with all of the products being produced, and in performing risk assessments that are appropriate to the intended use of the equipment. There is also a significant risk that a small business has access to only a limited amount of knowledge, so the business may be wholly unaware of these requirements.

3.2 The equipment perspective

Equipment vendors are naturally interested in being able to deliver solutions that match their customers' wishes in terms of quality and price, but they also need to focus on turning a profit themselves. There's nothing wrong with that–but it's worth mentioning here simply because pressure from a very price-sensitive customer can easily impact the hygienic quality of the solutions presented.

This doesn't mean that equipment manufacturers are slacking on hygienic design. There are many skilled, ambitious manufacturers and vendors that are constantly improving their products. They do this not only to raise the lower level of hygienic design – what constitutes the bare minimum – but also to improve their solutions. This does mean that hygienic design can incur extra investment costs, but it also means that product manufacturers get extra hygienic value for their money in

the long run. During negotiations, what matters most is to focus on the desired outcome and the functionality of the process in pratice.

As a product of its experience from previous projects, an equipment vendor may have solutions that it prefers. It may also have standard modules and components to offer. Pricing is important here, since vendors typically must submit bids or proposals for a project. Then, the customer compares the various solutions in terms of price and performance. Ideally, this is something that can be done jointly, at least after a pre-qualification phase.

Compared to product manufacturers, equipment manufacturers are typically more accustomed to carrying out design projects. This means they are more accustomed to comparing solutions to find the right process for a particular customer. This is especially true of design firms with experience in the food industry.

It can be a good idea for a vendor to have a detailed discussion with a customer to challenge the customer's notion of the best solution, even if the project requirements are fixed. This discussion may reveal information that the customer did not explicitly specify for whatever reason–perhaps because the client assumed it was common knowledge. In other words, a good vendor is also a source of feedback for the customer. In this way, the vendor can challenge the customer to consider alternative solutions. This process can also be a good opportunity to invite the customer to participate more actively in conducting risk assessments of the hygienic design and developing cleaning procedures.

3.2.1 Installation, service, and maintenance

Once the design process has concluded and the right process equipment has been selected, it's important to continue focusing on hygienic design during installation but also in the processes that follow later like service, maintenance, and repair. In the installation phase, be sure to keep tabs on the hygienic design requirements like drainability, accessibility, and so on. This ensure that the entire process is hygienically designed (more on this in Chapters 2.3.6 and 4.3). It might

→ A constructive customer-vendor dialogue: part 2

In communicating the hygienic advantages of a more expensive solution, an equipment vendor will present this in terms of improved performance. Even though improved hygienic design is the goal, these arguments are typically combined with other advantages, such as reduced operating costs, or perhaps even increased capacity.

be a good idea to include conditions concerning service and maintenance in the customer-vendor contract. This to facilitate that service is performed at the correct intervals, and that hygienic maintenance is performed as described in Chapter 3.1.4.

3.2.2 Assigned and unassigned equipment

The difference between assigned and unassigned equipment is introduced briefly in Chapter 2.1 and discussed in greater detail in Chapter 4.3. The main difference between these two categories is how detailed the associated risk assessments can be and what declarations of conformity must be on file.

For assigned machines and bespoke manufactured machines and lines, this is a straightforward matter. Materials are used that complies with the products, the intended use and so on. Risk assessments and declarations of conformity addresses the particular application.

In the case of off-the-shelf products, which are produced without a particular use in mind, things can be a bit more difficult. In theory, when a component is marketed for use, a declaration of conformity for it should exist. It is possible to prepare a general declaration of conformity and risk assessment taking into account the fact that (for example) various gaskets may be used in conjunction with different products and temperature ranges. The use of a component might be limited in terms of product groups based on viscosity and/or other significant properties that impact the effectiveness of cleaning and the preservation of hygienic function in practice (more on this in Chapters 4.2.4 and 5.6.4).

3.2.3 Cleaning and operating conditions

Equipment manufacturers naturally have some idea of what cleaning procedures should look like. However, unless this area is one of the company's specialities, discussing this with the customer is a good idea. This is also likely to make it easier to determine when the delivery will be finalised–that is, when the customer will feel satisfied with their ability to validate the system's hygienic performance, so the equipment vendor can receive its final payment.

Lastly, it might be a good idea to consider the experiences of actors in the cleaning space concerning equipment cleanability, as well as to remember to formalise feedback from previous projects. That way, it can serve as a foundation for even better solutions in the future.

3.2.4 Procedures and food contact materials

Adherence to formal procedures for food contact materials is described in detail in Chapter 5.6.3 for Regulation 1935/2004, and in Chapter 5.6.5 for Regulation

2023/2006. Equipment manufacturers are expected to ensure that their employees have been trained in internal quality control systems, thereby helping to ensure that the only materials coming into contact with products are the ones chosen for a given piece of equipment. In particular, they must know better than to simply choose a random material off the shelf.

3.2.5 Subcontractors

It's crucial to recognise the need for any subcontractors to live up to the same requirements as whoever is hiring them. For this reason, helping subcontractors to achieve the requisite level of knowledge is a good idea. Subcontractors may not deal exclusively with process solutions for the food and pharmaceutical industries. Consequently, it's good to ensure that the employees subcontractors use have the right qualifications for the job and that their quality assurance procedures are in order.

To choose the right subcontractor for a job it may be a good idea maintain a list of subcontractors with notes on the types of tasks they have "approved" to perform.

3.2.6 The technical file and interfacing with customers

A technical file is a collection of documentation that must be compiled to perform CE marking, and this same documentation is needed for compliance with EU regulations (more on this in Chapter 5.7.7). Every machine or sub-machine must have a declaration of conformity (for full machines; see Chapter 5.7.3)

→ Discussing customers' needs: What could go wrong?

Unfulfilled expectations regarding cleanability and hygienic performance can often become sources of disputes between vendors and customers. There can be several reasons for this.

The customer-vendor dialogue may not have been detailed enough, resulting in a cleaning procedure that is excessively general and inadequate.

The vendor may have "oversold" the equipment's performance, believing that the issue could be solved later.

Proper risk assessments may not have been performed for the processes chosen. The equipment needed for cleaning may not have been included by default in the sale.

There are vendors out there that are still "putting out fires", so to speak, years after delivering process lines to their customers in order to maintain good relationships with them. This kind of work typically is performed at a loss, however. These situations could have been avoided through detailed dialogue and thorough preparations.

or declaration of incorporation (for sub-machines; see Chapter 5.7.4). These declarations must be available as of the date the machine arrives on the EU market.

In theory, only declarations of incorporation and conformity should be shared with customers. However, many equipment manufacturers have found that customers want more knowledge in this area and a deeper look into the field of machinery. There is no legal basis for this and the technical file is the property of the equipment manufacturer.

The customer's real interest here may be in risk assessments; as mentioned previously, it can be appropriate to involve the customer in this process. It's also a good idea to agree on the kinds of additional information that the customer would like insight into when concluding a contract. In the case of a risk assessment, it's possible to prepare a version of this document suitable for customer use that doesn't compromise any details the equipment manufacturer would prefer to keep confidential.

3.2.7 What does the Danish Veterinary and Food Administration require?

The Danish Veterinary and Food Administration focuses heavily on the format and level of detail of declarations of conformity, as well as on each material's suitability for a given task. It checks to see whether materials are marked and stored clearly and unambiguously, minimising the risk of material misuse. Apart from that, there is no difference between equipment vendors and material vendors in this regard (more on this in Chapter 3.3.4).

→ Customers are seeking to know more and more

There's no doubt about it: Customers' demands to look deeper into the documentation will only continue to increase. This stems partially from customers' desires to guard themselves against the risk of a public scandal.

However, vendors can also expect more questions about hygienic design in connection with third-party audits performed according to the GFSI's benchmarking requirements. In the summer of 2020, the GFSI launched two new sets of hygienic design-focused requirements known as JI and JII. While compliance with them at present is voluntary, they will gradually make their way into auditing programmes like FSSC22000, BRCGS, and IFS

3.3 The material perspective

Manufacturers and vendors of materials are typically responsible for starting the chain of documentation on compliance for food contact and ensuring that each material is linked to the right documentation. Therefore, it is important to understand the relevant legislation and be able to interpret test reports and other documentation distributed with these materials. If a mistake occurs early in the chain and isn't caught, it could result in the improper use of a material, which could be catastrophic.

In EU at large, documentation of a material's composition and suitability, including any tests that may have been conducted, is sufficient. Uniquely among EU countries, Denmark also requires food contact materials to be accompanied by a declaration of conformity. This is described in Executive Order 681/2020 (more on this in Chapter 5.6.4). This is intended to provide an extra level of safety by documenting the suitability of a material for a particular purpose. However, it does make life a bit harder for some suppliers of materials: In some contexts, they may feel as if they're forced to either issue a "blank cheque" covering a great many uses, or to describe an excessively limited scope of usage (more on this in Chapter 6).

3.3.1 Procedures and food contact materials

Adherence to formal procedures for food contact materials is described in detail in Chapter 5.6.3 for Regulation 1935/2004, and in Chapter 5.6.5 for Regulation 2023/2006. It is crucial that the link between a given material and its accompanying documentation is unambiguous, as well as for materials to be marked in a way that makes errors unlikely.

A key question to ask here is when a material becomes a food contact material. The answer is rather clear for plastic and rubber materials. There are specific considerations to apply regarding the potential transfer of constituent substances, and these are based on the EU's rules. For plastics, these rules are listed in Regulation EU 10/2011 and in more detailed regulations and executive orders. Apart from the general rules that apply to all materials, there are no EU-wide rules on the product-inertness of rubber materials. For application if plastics I EU, follow the EU legislation. For rubber, the FDA's rules collected in CFR 177.xxx can be applied, provided the appropriate tests have been performed to assure compliance with the general EU regulations (read more about plastic in Chapter 6.3 and about rubber in Chapter 6.4).

The conditions for stainless steel are a bit different. There is a wide range of chromium and nickel-chromium stainless steels that are generally suitable for food contact. The limitations have to do with whether environmental conditions

will remain below the limits at which a given stainless steel can corrode. Consequently, we can say that stainless steel is fundamentally a food contact material; all the Danish Veterinary and Food Administration requires is that the steel's composition is known and that the steel is not contaminated with unsuited substances that are not on the EU's list of approved substances (more on this in Chapter 6.1).

3.3.2 Materials with no specific use

The recommended strategy here is to issue declarations that are as general as possible, perhaps with some examples of uses that cover a wide range of possibilities. What the material cannot be used for might also be appropriate to mention. Note that this applies to both declarations of conformity and risk assessments.

3.3.3 What does the Danish Veterinary and Food Administration require?

The Danish Veterinary and Food Administration will want to see declarations of conformity that clearly define the possible or intended uses of a material, including product and temperature range specifications. This typically involves taking samples of materials and discussing the quality of the documentation. When inspecting suppliers and producers of materials, the Administration cannot address issues of hygiene in storage; it cares only about documentation requirements.

It may be beneficial to categorise suppliers, as well as to document quality assurance and sampling procedures

4. The Toolbox

A look back at Figure 1 will help us to identify some of the tools to put in the hygienic design toolbox. This figure describes the basic activities of selecting or creating a process solution with the right level of product safety for a given application. These three activities shown in Figure 1 are:

- Describing the intended use, which leads to a requirements specification and clarification between the customer and supplier (Chapter 4.1).

- Risk assessment of the hygienic design, which includes these activities: risk identification, risk analysis, and risk evaluation (Chapter 4.2).

- Methods for choosing hygienic design, including hygienic integration and documentation, basic hygienic principles, and the use of harmonized standards and guidelines (Chapter 4.3).

These three topics are covered below in detail, and all this information is consolidated in a series of checklists that you may find useful when working with hygienic design. Chapter 4.4 describes some practical checklists that can support everyday hygienic design work.

As already mentioned in Chapter 2, these three activities are key to evaluating process solutions in terms of hygienic performance as well as sustainability, circular economics and other relevant aspects, as described below:

1. In the design process, doing things right the first time according to the central user needs is the goal. Above all else, this means making a management-level decision (both vendor and customer) to use the needed resources in the pre-project phase to create room for opportunities to create the best solution overall. It takes patience to dig deep into a requirements specification and clarify for both parties–customer and vendor alike–what is optimal, necessary, or desirable. However, this creates the best foundation for making the right decisions when designing the process solution.

2. A thorough assessment of hygiene risks in the final process is required. This needs to be an appropriate, detailed risk assessment of the hygienic conditions in the suggested process taking all realistic failures and failure modes in account. This can very well be based on the HACCP plan that the product manufacturer has in mind for the production. This makes it possible

to stress test and adjust the requirements specification, as well as to assess where, specifically, a high degree of hygiene is needed (and where it is less necessary). The result of this is the identification of specific needs for additional hygienic considerations, and by extension, the degree of hygienic design that is necessary or sufficient in the given situation.

3. A focus on lifetime of appropriate process solutions involves choosing materials for optimum hygiene, preventing corrosion or other kinds of degradation, and reducing the degree of wear. This is the time and place to evaluate a specific hygienic design in terms of its ability to be sufficiently cleaned and achieve the required level of process economy. It's also an opportunity to compare solutions in order to achieve optimal operations and good process economy. These are, in turn, a function of factors like the capacity to reuse materials and process equipment, and opportunities for circular life cycles.

4.1 Requirement specifications and the customer-vendor dialogue

The requirements specification and other tender materials serve as a single point of truth: It is always possible to refer to it to identify what was specified and–sometimes more importantly–what was not. This makes it important to be thorough and ensure that both parties have the same understanding of these documents. There is really no reason to leave anything unsaid, particularly things that a customer, expect to be delivered or the vendor has of standard conditions concerning construction materials and/or limitations of use.

It's important to identify which requirements are truly mandatory and where there is room for compromise or interpretation. Doing that means preparing properly and minimising the risk of making mistakes. When a customer, don't have detailed

→ Is legal compliance enough?

This question gets asked quite often. Why is it necessary to repeat all the regulatory requirements and be specific about their meanings in a particular context? Perhaps it shouldn't be necessary. It is best to acknowledge that the text of the legislation is not cut and dried.

There have been cases where food manufacturers specify nothing beyond the need to comply with the Machinery Directive and other relevant regulations. Doing this leaves a whole mountain of unanswered questions. In cases where there are only a few vague requirements, disputes often arise.

Therefore, a customer-vendor dialogue is needed to fill in the blanks, so to speak

ideas of which requirements are most important, the vendor will be hard pressed to figure it out.

Long lists of specifications and requirements with no priorities are a common sight. If you stop and think about this for a moment, it's virtually impossible to meet 100% of the requirements on a long list, so potential vendors will have no choice but to compromise on some of them. Without any guidance, human nature will lead vendors to compromise wherever doing so is easiest. It's just natural.

4.1.1 Focus on key requirements

To evaluate the importance of the specifications and hygienic performance requirements against which possible solutions are best (provided they can deliver the desired quality and capacity), it can be helpful to divide requirements into groups:

a) The basic level everyone has to be at in order to participate. This includes adherence to EU legislation (the Machinery Directive, Regulation 1935/2004, and Regulation 2023/2006), any applicable standards (such as DS/EN 1672-2:2020) and a basic level of material durability.

b) Specification of any guidelines (like EHEDG or 3-A SSI), any third-party certification programme requirements, and any other documents considered important to reach a suitable solution.

c) Identify three to five need-to-have requirements. The number is up to you, of course, but push yourself to stick with a small number. This will help you get to the core of what is really essential to achieve the right level of food safety in your process. These should be specific, measurable, requirements with high-level relevance, and they should be directly linked to opportunities for operating a proper hygienic process. For instance, these might be related to cleaning duration and frequency, uptime, maintenance costs, accessibility for cleaning, validating the effectiveness of cleaning procedures, etc.

d) The remaining specifications of lesser importance and requirements (nice-to-have). This is the set of requirements where you can accept less than 100% fulfilment.

To get a sense of what to expect, it's a good idea to ask vendors about how they intend to approach your requirements.

When preparing a requirements specification, it can be beneficial to seek input from a wide range of in-house (and external) experts. In particular, consider process details and conditions that have previously led to inconveniences, as

well as other things that could have been better during this project compared to previous projects.

The HACCP plan, which the food manufacture already may have outlined or have at hand, is a great place to start (read more about HACCP in Chapter 4.2.4). Here are some key questions that can feed into the risk assessment and help clarifying hygiene risks:

- What areas might require special attention (e.g., because errors could be frequent and/or catastrophic)? Think about the operating situation and about areas where manual interaction with an otherwise automated process will occur often.

- What worst-case scenarios would be appropriate to consider? Be sure that these are realistic and imbedded in the risk assessment.

- Are there any known issues that should be avoided?

4.1.2 The dialogue between vendor and customer

IThe process of choosing a vendor typically begins with a pre-screening of potential equipment vendors, possibly with the help of a consultant or a dedicated consultancy firm contracted to handle the design specifics, planning, and installation oversight. The initial requirements specification is typically put in writing and, on occasion, accompanied by a verbal discussion. This is generally enough for a pre-screening.

If subsequent discussions are held exclusively in writing, however, this could ultimately serve as a "filter" that runs the risk of distorting the process of choosing a vendor. If both parties aren't speaking the same language, there may be concepts and terms whose meanings are misunderstood. It's also possible to present requirements that are too weak or lax out of ignorance. There may be little overlap between each party's knowledge, and each side may completely misunderstand the other's intentions.

For these reasons, it's good to have a discussion and ensure that everyone is in agreement about the most significant points. On top of that, a chat in person or over the phone can be an opportunity to bring up alternatives that might not have been convenient to present in written negotiations.

Have a good talk together. Do this often, and feel free to take some extra time in the early phases of the project to search for the best solutions from a total cost of ownership perspective.

For larger jobs, it's beneficial for the customer to visit the vendor during the vendor's construction and assembly process. For instance, the customer can participate in a process equipment verification procedure known as a factory acceptance test[11] (FAT). The customer will be in a better position to request any necessary changes while the equipment is still on the vendor's premises. In contrast, this is more difficult to do following a site acceptance test[12] (SAT), when the equipment has arrived on the customer's premises. FATs and SATs aren't a part of every project, but they can help significantly to ensure good performance also concerning the hygienic performance. (read more about FATs, SATs, and their place within the activities described by the "V" model in Chapter 4.3)

4.1.3 What can go wrong?

Naturally, there are many possible reasons for which a process can ultimately fail to function as intended. Plain and simple accidents are one possible reason, but the odds are greater that a hygiene related problem is linked to one of the points listed below:

1. Input from key stakeholders (such as operators, assembly personnel, and cleaning personnel) was ignored

2. Insufficient validation: Not enough was done to ensure that the process would be capable of performing the intended operation before actually using it to produce products

3. Skipped verification: Not enough has been done to ensure that the process continually meets specifications

4. Inadequate risk assessment: Either some possible issues were not identified, or the likelihood or severity of a risk was underestimated.

5. Inadequate or lacking training of staff: If a food manufacturer's staff lack necessary information about new processes, they may operate equipment incorrectly or remain oblivious to error indicators.

6. Sequencing errors: For instance, designing a building before designing the equipment it will house can lead to the equipment not fitting inside the building.

[11] *An FAT is performed to document the fact that a piece of equipment or a system has been tested using a validated method at the manufacturer's facility and built according to the construction specifications before it is delivered to the end user. It really only makes sense to perform an FAT on a prefabricated device integrated at the module level or above.*
[12] *An SAT is performed to document that a piece of equipment or a system has not been altered in any way while in transit, and that it has been validly tested at the end user's facility in accordance with its functional specifications.*

7. Lack of plans for foreseeable expansions: This includes changes to, and expansions of, products and processes.

8. Insufficient information available; e.g., in terms of laws, standards, and guidelines

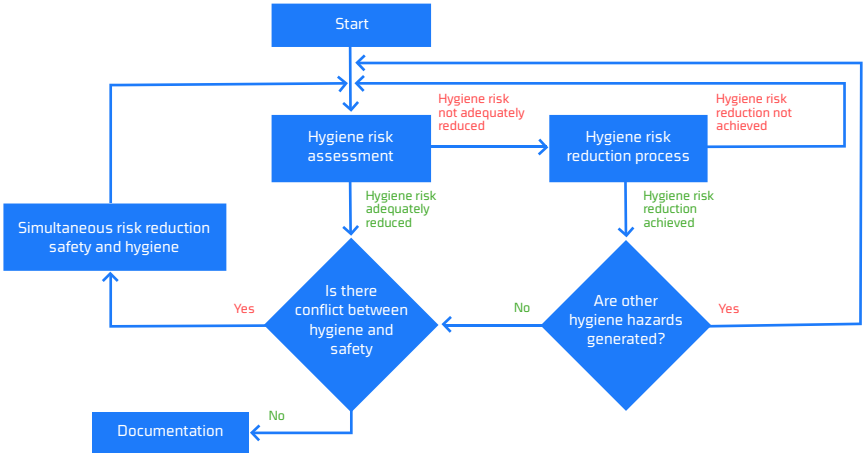
Even minor mistakes in any of these areas can lead to hygiene issues. All it takes is one weak link in the chain. In instances where multiple mistakes are compounded, the resulting problems can be further exacerbated. I can't say it enough: There is no substitute for thorough preparations.

4.2 Reducing hygiene risks in practice

The purpose of hygiene risk reduction is to eliminate significant hazards. Reducing their associated risks involves ensuring that machines and processes are properly designed, constructed, and installed so that they can be properly operated, cleaned, and maintained.

The European standard DS/EN 1672-2:2020 extends the risk-based approach with a more detailed description of an iterative reduction process for hygiene risks. The standard describes this process with a flow chart, presented in a condensed form in Figure 6. As shown in the chart, reducing hygiene risks appropriately involves an initial hygiene risk assessment, followed by a hygiene risk reduction process to address any identified risks. The latter is employed only in situations with an unacceptably significant hygiene risk in the initial state. Some situations require an iterative process in which a new risk assessment is

Figure 6. Simplified iterative risk reduction process per EN1672-2:2020

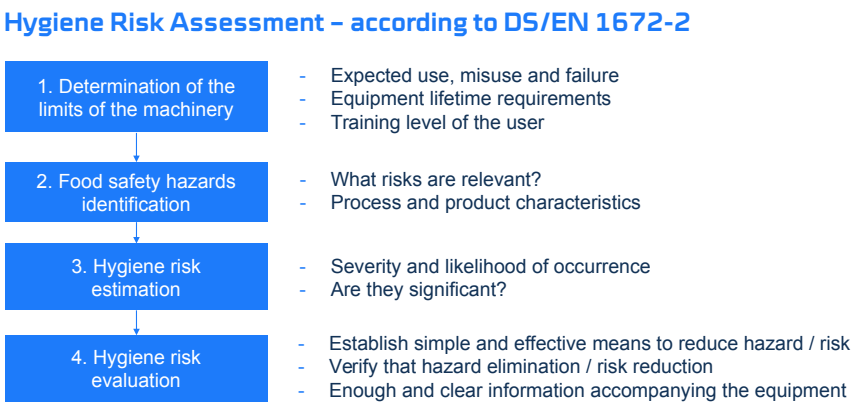


conducted after redesigning the process, modifying procedure descriptions, or both. In cases where conflicts arise between addressing hygiene issues and other risks, the method described in EN ISO 12100:2010 is applied to minimise these risks.

As shown here, there are two core tools: (a) the risk assessment, for identifying and evaluating the severity of risks; and (b) the mitigation process of reducing or eliminating risk elements. The complete flow chart from EN1672-2:2020 is reproduced in Appendix 1.

The phases of the risk assessment according to DS/EN 1672-2:2020 are described in Figure 7. The focus is on establishing the intended use and usage restrictions, identifying hygiene risks, assessing their severity, and selecting risk elements that must be minimised or eliminated based on the risk analysis. This is a classic risk assessment process.

Figure 7. Risk assessment per EN1672-2:2020. Points 1-3 constitute risk analysis.



The four main activities in the risk assessment are described below:

1. Determine the intended process for the products in question and describe the limitations of the machine/process:

    a. All imaginable uses must be either included or excluded by clear limitations across the lifetime phases of a machine or process. This also applies to failure modes and any possible means of incorrectly operating the equipment.

b. There are specific risks associated with each phase: assembly and installation, start-up, operation, cleaning and disinfection, maintenance, and temporary disassembly.

c. It is also appropriate to include the expected lifetime and training needs for the customer's staff, if applicable.

2. Hdentify the relevant food safety risks associated with the specific product(s) being manufactured (see Chapters 2.10 and 4.3.2 for details on potential risk elements):

   a. A risk is typically associated with an action in the manufacturing process and/or a state which all or part of the process is in (installation, start-up, operation, cleaning, maintenance).

   b. Risks may be related to the type of food product in question and what processing stage a product is in.

   c. Acknowledge that there is a significant difference between moist and dry food products, as well as between methods of stabilising products (e.g., pasteurisation, packing in a controlled atmosphere, chilling, or freezing)

   d. The nature and characteristics of the process; for instance, whether the process is open or closed, its intended use, locations within the process (early or late; before or after pasteurisation, baking, etc.), and the function of the machine.

   e. It may also make sense to consider errors that might occur during the process, which is what the customer will do in a HACCP analysis. FMEA is briefly described in Chapter 4.2.3, and HACCP is described in Chapter 4.2.4.

3. Hygiene risks are assessed relative to any significant hazards they may lead to. These are often limited to hazards that occur when the machine is used as intended (or misused in a foreseeable manner). Each hygiene risk is evaluated to determine whether it must be reduced (using the hygiene risk reduction process described below) or the level of food safety is already acceptable with the current design:

   a. The evaluation involves categorising hazards according to their severity and likelihood of occurring. If a hazard is highly likely to occur and highly

severe, that hazard needs to be addressed. Meanwhile, hazards that are less severe, less likely to occur, or both might be judged acceptable in a particular context.

b. This process is specifically supported by DS/EN 1672-2:2020, in which each hazard is rated low, medium, or high based on its overall effect. The size of the consumer group that would be impacted is also considered. Alternatively, a three-by-three matrix can be used for evaluation, with each parameter rated low, medium, or high. A specific tool should be used for risk assessments (see ISO/TR 14121-2:2012, 6).

4. After risk assessment, hygiene risks are evaluated to determine if they must be reduced or if the level of food safety is acceptable:

- The purpose of the risk assessment is to determine what dangers to food safety exist, and whether additional risk reduction is required.

- Note that simple, yet effective risk reduction measures that address low-priority risks should not be overlooked in favour of focusing only on the greatest risks.

- What matters is that the result clearly identifies risks that must or should be addressed, whether these risks are associated with food safety, product shelf life, or the hygienic quality of the process over its lifetime.

The iterative hygiene risk reduction process is designed to further reduce hygiene risks where needed to achieve the desired level of food safety. Doing so involves a reduction process that can last for up to three phases. After each phase, the process can be interrupted if the result is satisfactory. The three phases are hygienic design improvement, implementation of technical measures, and cleaning and disinfection:

1. Is it possible to identify a different, improved hygienic design that would solve this problem by eliminating the risk? If so, implement the design and end the risk reduction process. If not, proceed to step 2.

2. Is it possible to take technical actions that would solve this problem? This might include adjusting environmental parameters (e.g., temperature and/or humidity), diverting contaminated products out of the process, improving process control, or addressing other factors that affect the process in order to create the necessary level of food safety. If this is possible, you can end the risk reduction process here. If not, proceed to step 3.

3. Cleaning and disinfection measures are the last step. These should be considered if hygiene risks cannot be eliminated or reduced to acceptable levels using the two previous steps. Investigate whether appropriate cleaning and (if necessary) disinfection could resolve the issue in practice. This might involve light cleaning or disinfection during the process itself, such as automatic or manual cleaning of knives and blades.

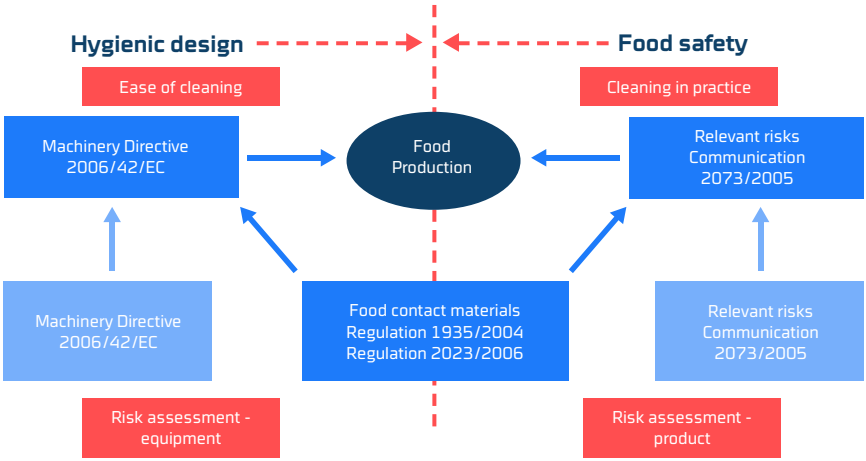
In doing so, it's important to consider whether implementing the new food safety measures will create additional or new hazards. If it will, the iterative process described in DS/EN 1672-2:2020 prescribes a return to the initial risk assessment step.

It is recommended that equipment and food manufacturers alike acquire a copy of the latest version of DS/EN 1672-2:2020.

2.1 The equipment's hygienic quality

Take deeper look at Figure 3, and notice that the left half is about hygienic design and ease of cleaning, while the right half is about food safety and actual cleaning practices. In light of this, as shown in Figure 8, we can also say that the left half is associated with risk assessments for equipment, while the right half is associated with risk assessments for products and actual production processes. These two activities really go hand in hand: A thorough equipment risk assessment leads to better hygienic performance; this, in turn, creates a better foundation for a risk assessment of an actual production process..

Figure 8. The relationship between the hygienic quality of equipment and food safety



As mentioned previously, the level of hygienic design and risk minimisation required in a given situation depends on the product and the portion of the process in focus.

4.2.2 Global Food Safety Initiative (GFSI) benchmarking requirements

GThe GFSI's goal is to promote the development of food safety management systems to ensure that food manufacturers can produce safe food products for the consumers. The GFSI evaluates and approves various auditing programmes that meet their criteria, such as FSSC 22000, BRCGS and IFS.

Food manufacturers can submit to audits as part of a GFSI-approved food safety management system in order to assure their customers that they adhere to a high standard of food safety, and to reduce the likelihood of food safety issues occurring with their products. This kind of certification can be a strong selling point and sometimes a requirement to do business with large retailers. Food safety is the top priority in the steps that a food manufacturer takes to achieve a sound, safe process.

The GFSI itself does not develop audit programmes; rather, it creates general platforms for achieving high levels of food safety. As part of these efforts, the GFSI has created a benchmarking process in which it compares the procedures of food safety programmes and platforms with GFSI guideline documents. The guideline documents are developed using input from food safety experts. They help to define a process in which food safety programmes can be evaluated against the GFSI's benchmark requirements and achieve global recognition.

Each GFSI standard essentially addresses three factors, each of which helps to ensure that a vendor produces safe food products:

- Does the vendor say what it does? (Review of policies and procedures)
- Does the vendor do what it says? (Observation of processes in operation, interviews with employees, facility inspections)
- Can the vendor prove that it does what it says? (Review of records)

There are several parts to the GFSI's benchmarking requirements. Part III of the requirements defines the key elements required in a certification programme, in terms of:

- Hazard analysis and critical control points (HACCP)

- Hygienic design management systems
- Good manufacturing practices (GMP) and good industrial practices

Only the two sets of requirements concerning hygienic design are presented here and it is important to notice that they at present voluntary. These two sets of benchmarking requirements are:

- J1 Hygienic Design of Food Buildings and Processing Equipment (for building constructors and equipment manufacturers)
- J2 Hygienic Design of Food Buildings and Processing Equipment (for building and equipment users)

While the approaches taken in J1 and J2 are slightly different, it's clear that equipment and facilities produced according to J1 are intended for use in environments where J2 is applied.

J1 focuses on requirements for providers of services, equipment, and activities for the food industry such as:

- Manufacturers of equipment for use with food products, including all components required for their assembly, as well as auxiliary functions and tools necessary for the operation of food production facilities, food retail and wholesale activities, and packaging.
- Architects, engineers, and designers of food facilities, including agricultural, food manufacturing, warehouse, and retail buildings.
- Building developers for the above facilities.

J1 contains three sections:

- Requirements for hazard and risk management systems, which address the soundness of the design process, the description of the intended use, risk assessments, and hygienic design measures as presented in Figure 2; as well the understanding and application of HACCP principles (see Chapter 4.2.4), risk elements, and fault conditions (see Chapter 4.2.3).
- Requirements for hygienic design management systems, which address management's responsibilities and dedication in defining hygienic design policies, the presence of management systems, documentation

requirements, handling of vendors and subcontractors, traceability, internal audits, handling of serious errors, and processes for handling delivery.

- Requirements for good industrial practices, which address internal procedures for preventing the accidental contamination of produced items (including pest control), training of staff, and transport procedures.

J2 focuses on requirements for those who use buildings and equipment. It also presents requirements in these areas:

- Specification, procurement, design, and construction of buildings and renovations carried out by food manufacturers, wholesalers, retailers, and packaging manufacturers for their own use.

- Specification, procurement, design, and construction of equipment, including components required to assemble equipment, connections to utilities, and tools needed to operate them; as well as facilities needed for food manufacturers, wholesalers, and retailers to make use of these items.

J2 contains the same three sections as J1, but with a slightly different focus:

- Requirements for hazard and risk management systems, which address the soundness of requirements for the design process, the description of the intended use, risk assessments, and descriptions of requirements for hygienic design measures as presented in Figure 2; as well the understanding and application of HACCP principles (see Chapter 4.2.4) and risk minimisation.

- Requirements for procurement procedures with regard to hygienic design, as well as management and documentation of modifications to processing facilities.

- Requirements for good industrial practices, including internal procedures for preventing the unintended contamination of produced items, appropriately separating products with different risk levels, and training staff.

- Naturally, there are various other food safety requirements related to hygienic design that apply to food manufacturers.

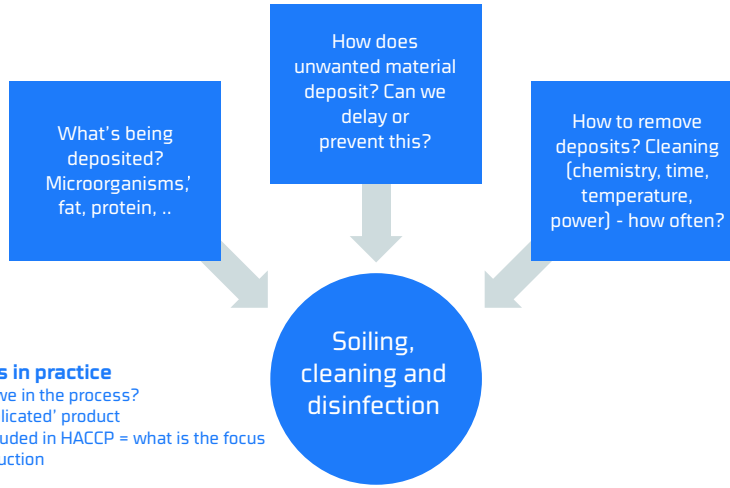
The activities described under J1 and J2 are largely the same as those described in this book. What will be new to many are the heightened requirements for process documentation and for equipment manufacturers to ensure that the

appropriate management figures are involved in establishing and nurturing a proper hygienic design policy.

4.2.3 Risk elements and identification of fault conditions

Every relevant risk must be considered individually, and in some cases, combinations of risks must also be considered. For instance, a microorganism growth issue could be exacerbated by a combination of poor hygienic design, the presence of nutrients, and conditions that facilitate microbial growth. Figure 9 shows the effect of various risk elements on contamination, thereby also impacting the need for cleaning and disinfection.

Figure 9. Evaluation of risk elements



Questions in practice
Where are we in the process?
Is it a 'complicated' product
What is included in HACCP = what is the focus during production

The following topics may be important to consider in a hygiene-related risk assessment:

- Are there areas in a machine, process or environment that are difficult to clean, and in which conditions that facilitate microbial growth could arise? In practical terms, the presence of water and cracks or similar imperfections in an area that contains products or product residues is enough to create an elevated risk of hygiene issues.

- Which microorganisms could be present in the products produced? What are the appropriate criteria to apply? One source of information about this is Regulation 2073/2005. As an alternative, if there is no prior experience with a given product, Google is a great place to start looking.

- Is the required cleaning procedure aligned with the standards that the product manufacturer already applies, or are there challenges in this area?

Failure mode and effects analysis (FMEA) is a process for reviewing components, assemblies, and subsystems to identify potential fault conditions, their causes, and their effects. The failure conditions for each component should be listed along with their effects on the rest of the system. This can be a useful tool when identifying risks related to the hygienic functionality of a processing facility.

FMEA is typically a qualitative process, but it can be made qualitative, too. Doing so requires the use of mathematical fault rate models combined with a statistical fault condition database. Various types of FMEA analyses exist to target functionality, design, or a whole process, for example.

A successful FMEA analysis helps identify potential fault conditions based on experience with similar products and processes–or based on ordinary fault logic. It is widely used in the development and manufacturing industries at various stages of a product's life cycle. The Effect analysis refers to an investigation of the consequences of these faults at different levels of a system.

To determine the correct fault conditions at all levels, functionality analyses are also needed as input. An FMEA is used to structure the risk reduction process, based on a reduction of the severity of a fault effect, the likelihood of a fault, or both.

The food industry already uses HACCP, which is a "descendant" of FMEA, as a tool for analysing and managing food safety risks in production processes. Thus, it would be quite natural to also use FMEA in construction and design change contexts. HACCP itself does not address hygiene-related hazards that could occur as a result of faults in equipment and procedures. For that reason, using FMEA to bring in a broader perspective can be a good idea.

4.2.4 HACCP and internal oversight

As mentioned previously, HACCP is the foundation of internal oversight in food manufacturing businesses. Consequently, knowledge of the principles of HACCP is useful to know. HACCP is effective for identifying and managing risks in food manufacturing facilities when considering the safety of a processing line or production process.

Manufacturers of equipment and tools for use in food production are supplying technical solutions for incorporation into a production process where HACCP is used. This alone makes it a good idea to learn about how the principles are applied. With a bit of creativity it is actually possible to perform a provisional

HACCP review of a processing line "on paper" before it is even installed. This helps to minimise risks and identify any possible weak points before they can pose real hygiene risks during process operation. It is beneficial to make this a joint activity between customer and vendor, as this maximises the amount of relevant knowledge available.

A detailed description of the principles of HACCP is presented in article 5 of Regulation 852/2004; its main features are presented in the following list with minor modifications for greater readability:

a) identify the risks to be prevented, eliminated, or reduced to an acceptable level

b) identify the critical control points for the production phase(s) in which it is important to control the process in order to prevent, eliminate, or reduce a risk to an acceptable level

c) establish critical limits on critical control points to distinguish acceptable and unacceptable conditions for the purpose of preventing, eliminating, or reducing the identified risks

d) establish and implement effective monitoring procedures at the critical control points

e) establish corrective actions to take if monitoring indicates that a critical control point is not under control

f) establish procedures to regularly verify the efficacy of these measures

g) prepare documentation appropriate to the nature and size of the business to demonstrate that the measures are applied effectively.

4.2.5 Food contact: direct, indirect, and no contact

Although this was already covered in a previous section, it's worth repeating here that a risk assessment must include all surfaces and areas where product residues may be present after production has stopped. No stone should be left unturned in this process. In the future, problems could arise from a "forgotten" part of a machine where it was thought that no food remains could collect, but they did so anyway. This might happen because not enough consideration was given to cleaning procedure when evaluating possible risks in the process, for example. Generally, it's a good idea to have a layperson review the assessments made to see if they seem reasonable, or if there might be risks that have not been sufficiently addressed.

4.2.6 Known and unknown uses

Risk assessments can be performed on both assigned and unassigned equipment and components (i.e., with known and unknown uses). In cases involving unknown uses, the assessment made should be a general one that addresses fundamental hygienic design conditions, such as accessibility and ease of cleaning. To the extent that the use of the process is known, it may be beneficial to think along the same lines as the food manufacturer will in establishing a HACCP plan (see Chapter 4.2.4).

4.3 Methods for managing hygienic design activities

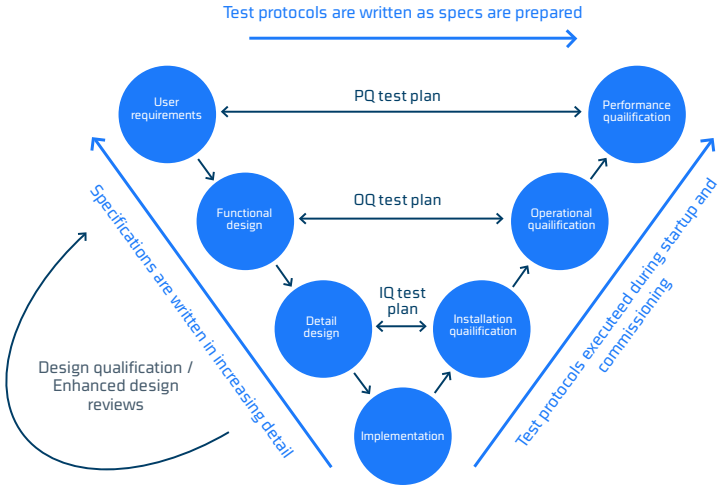
To achieve good results from a design and installation process, it's a good idea to use a process tool to systematise the work–and hygienic design and construction is no exception here. A project model-based system can be useful in documenting solutions and considerations made during the process; in specifying qualification, validation, and verification activities; and in performing hygienic integration. Hygienic integration is defined as a process in which two hygienic components, modules, pieces of equipment, etc. are joined without introducing any significant new risks into the resulting assembly.

The V-model (also known as the product life cycle model) is a well-known project model used in some places within the pharmaceutical industry, as well as in the food manufacturing industry–primarily in connection with larger projects.

The V-model is shown in Figure 10. The left-hand side deals with the specification of concepts and requirements, as well as the gradual development of a more and more detailed design. The figure shows how each design phase depends on the previous one, and how design solutions are often developed in an iterative process. The right-hand side represents the installation, verification, qualification, and validation of the system. The double-headed arrow connecting the two sides shows how specifications for testing expectations (updated when the iterative process on the left produces changes in the solution) are held up against the current solution. The phase at the bottom of the V is where the solution becomes "crystallised" and the specific design begins to take shape. At this point there should be a freeze of the design as changes beyond this point in time are costly and will have reduced effect.

After the last activity in the upper-right corner, there are actually two more activities; namely, process validation, including validation of cleaning and disinfection procedures; and the operation phase, including hygienic maintenance and updating of processing facilities when appropriate.

Figure 10. The V-model



Using the V-model creates a structure in which decisions are documented, test plans are updated, and the final solution is assessed in the propper context. This ensures that ongoing decisions and trade-offs regarding hygienic performance are visible and assessed in relation to the requirements specification.

Naturally, modifying the hygienic design at the beginning of the project has the greatest effect and is the least expensive. This is equally true when creating new processes and updating old ones. As the project progresses and the specifications become more detailed, there is a tendency for changes to have a reduced impact and be more expensive to implement, especially if the project is already in the implementation phase. As a result, it might be appropriate to operate on the principle that the design is locked in once the implementation phase begins, and especially when the construction and/or manufacturing of the process has begun.

→ Avoid compromising on hygiene requirements

Particularly when designing a new process, significantly compromising on the project's original hygiene requirements is rarely a good idea. Those compromises will essentially become permanent parts of the process, and compensating for them with more intensive cleaning and disinfection can be both irritating and costly. This results in greater operating expenses and a greater total cost of ownership.

The essential activities associated with creating and testing a hygienic design are briefly described below, based on the phases of the V model[13]:

- User requirements are addressed in Chapter 4.1. It is essential to consider the project from all angles, include all stakeholders, and ensure that specific, quantitative criteria for validation and qualification of activities are specified, even at this early stage. This phase is extremely important because possible design solutions must be compared to the requirements specification. An incomplete requirements specification could jeopardise the hygienic quality of the final solution.

- Preparing a functional specification, which deals mainly with the process's primary function, as well as interface with other activities, such as process control. It is essential to begin comparing potential solutions to the requirements specification even at this point. This reduces the risk of beginning to take steps in the wrong direction.

- The detailed design culminates in a construction specification, which must be verified in relation to the functional specification and must be verified in relation to it. This is also the phase in which a risk assessment takes place. This should be the last activity before installation and implementation. The construction specification contains instructions for manufacture and operation, cleaning, maintenance, and qualification/validation of the process and its parts. At this stage, it is advisable to prepare written instructions for calibration, maintenance, and cleaning. People other than the designers themselves should verify these instructions.

- As mentioned previously, a FAT should be performed as part of the process of qualifying the installation while the equipment is still on the vendor's premises. Units should be evaluated to confirm their adherence to hygienic design specifications. If possible, functional tests can also be performed at this time, such as a preliminary ease-of-cleaning assessment for example by using fluorescent substances, provided that subsequent transportation and installation will not invalidate these tests. What matters is that the customer and vendor do as much testing as possible during this phase to demonstrate the performance of the process solution in operation.

- Operational or functional qualification involves verifying that all functional parameters, limit values, and tolerances can be met. This is also the time to consider whether the hygienic operation goals listed in the requirements

[13] *A deeper, more detailed description of integration in hygienic design and use of the V model is described in the EHEDG's Guideline 34: Integrating Hygienic Entities.*

specification are achievable. If an FAT has already been performed, an SAT will cover functional testing once the equipment or building components have been installed at the customer's facility. Notably, this is also the latest time at which employee training should begin; truthfully, it should begin earlier so that the FAT and SAT can be performed by the customers trained operators.

- The purpose of performance qualification is to document that the overall (integrated) process unit consistently meets the specifications presented in the requirements specification. Part of this includes ensuring that hygienic elements and procedures work reliably and consistently. This phase should include validation of cleaning and validation of corrective actions related to Critical Control Points (HACCP), such as removing foreign objects and ensuring proper pasteurisation and sterilisation, but initial activities will begin in this phase. The initial cleaning validation can be conducted after short production runs.

- Process validation is the final step in the validation phase. Thereafter, the process solution is formally transferred to the customer. Test runs are conducted in this phase; these must be monitored to ensure that hygiene measures function as intended, and that any required corrections are made. Cleaning validation is completed in this phase, and processes can gradually be extended up to their expected durations.

4.4 Checklists and flow charts

Checklists and flow charts are highly useful–and sometimes necessary–to perform the activities described in this chapter. These are available from a variety of sources:

- DS/EN 1672-2:2020, for risk assessments and risk reduction. Condensed portions of the flow chart in this standard are presented in the text of this book, and the complete flow chart is presented in Appendix 1. However, it is strongly recommend acquiring a copy of DS/EN 1672-2:2020 in order to experience the full benefits of the working processes and specific hygienic design recommendations it contains.

- EHEDG Guideline 34, titled "Integrating Hygienic Entities", describes how to apply FMEA and HACCP to hygienic design. It contains flow charts for structuring and documenting processes in which hygienic components are combined to produce a hygienic process.

- Tools and checklists are regularly published on FORCE Technology's website. These address topics like requirements specifications, the customer-vendor dialogue, process validation, and cleaning.

- The Danish Veterinary and Food Administration provides a range of specific checklists to address topics like adherence to food and hygiene legislation, food contact materials in general, details for specific groups of materials, necessary documentation and declarations, and the purchase and use of previously used process equipment. These are covered along with other guidelines in Chapter 7.2.

To get the most out of these tools, it's important to

1. clarify the particular topic or area being addressed,

2. verify that the tool or checklist is relevant to that topic or area, and

3. ensure that its users have been instructed and trained in its use.

Also, exercise caution when combining multiple approaches or requirements from different guidelines and checklists. In the worst case, one source may directly contradict another. Often, however, they are simply not aligned with each other.

5. Application of legislation and standards

Legislation on hygienic design and food safety is based on EU directives and regulations. The domestic legislation in each EU country implements these in slightly different ways. Legislation on food safety and quality is based on standards developed by the Codex Alimentarius Commission, an independent body under the FAO and WHO[14]. The standards in the Codex Alimentarius ("the book about foods") are a major influence on EU legislation, and some countries elevate the standards in the Codex to the level of laws more or less unchanged.

There may be small differences in how a piece of EU legislation is implemented among member states, and some countries pass additional laws of their own that apply to food processing equipment and its constituent materials.

There are three types of legislation in the EU–and the member countries, for that matter. Directives establish goals that all EU countries must eventually achieve and implement in their domestic legislation. Exactly how this is done is up to each member state. Regulations and executive orders, which are the other two types, must be implemented in all member states exactly as issued by the EU.

The entire body of legislation relevant to maintaining the desired level of food safety addresses, on one hand, hygienic design requirements for equipment (Chapter 5.4) and the provision of acceptable food contact materials (Chapter 5.5); on the other, it addresses the manufacture and distribution of food products that are healthy and safe for consumers (Chapter 5.2). The remainder of this chapter should be taken as a presentation of the key elements of the entire body of legislation that is relevant to hygienic design and hygienic operation of food manufacturing processes. By no means does it exhaustively cover every requirement that a food manufacturer must adhere to in its everyday business.

In some instances, portions of legal texts are reproduced in an abbreviated form. Reading this chapter provides a good overview of the legislation on hygienic design and food hygiene. However, the reader is strongly discouraged to use the excerpts presented in this book as a basis for interpreting specific details in a given legal text. Firstly, the law in question may have been revised or updated since this book was written; secondly, the legally valid text of a law should always be consulted if there is any need for interpretation.

[14] *The Codex Alimentarius Commission produces international standards, guidelines, and codes of conduct concerning the safety, quality, and fair trade of food products. You can read more about the Codex Alimentarius on the FAO's website.*

5.1 The Machinery Directive

The Machinery Directive, 2006/42/EF, establishes the basic harmonisation of occupational health and safety requirements in the EU, as well as the free movement of machinery on the internal market. The current version entered into force on 21 December 2020. In brief, the Machinery Directive applies to all assemblies intended to be connected to an external drive system (article 2)[15]. The new version is a radical revision in the areas that apply to mitigation of hygiene related risks in food processing machinery. The Directive is at the core of EU member states' obligation to protect the health and safety of their peoples from risks associated with machinery.

The Machinery Directive states that national authorities are responsible for the implementation of the Directive's provisions, and for establishing appropriate sanctions in domestic laws and regulations. Typically, EU countries do not implement the Machinery Directive in a single piece of legislation, and this can create some ambiguity as to the responsible authorities. However, it is safe to assume that the Machinery Directive is fully implemented in the EU countries– and by extension, that its provisions MUST be adhered to. By January 2022 the implementation of the directive has been strengthened by the Executive order 1094/2021 which clarifies responsibility and legal re-precautions following misuse of the CE mark.

The primary portion of the Machinery Directive applies to all types of machinery. Its most essential elements are: article 12, on procedures for assessing the conformity of machinery; article 13, on partly completed machinery; and article 16, on CE marking (Chapter 5.6), including the role that harmonized standards (Chapter 5.4) play in supporting compliance with the conformity requirements–see article 7 of the Directive. Official EU guidance has also been developed. This guidance forms the basis of this point and several of those that follow in this chapter[16] .

In principle, the Machinery Directive does not apply to a machine until it is marketed (made available or potentially be available at the market)[17]. A machine transferred from its manufacturer to its representative in the EU for the purpose of meeting applicable requirements is not considered to have been marketed until it is declared ready for distribution or use. The same applies to machinery that is not yet fully manufactured and is transferred by its manufacturer to a manufacturing facility outside the EU for later completion within the EU.

[15] *The definition of a machine is an assembly with at least one moving part designed to be connected to a drive system (e.g., an electric or pneumatic motor) in order to produce movement.*
[16] *Guidance on applying the Machinery Directive, 2006/42/EF, is available from the website of the Danish Safety Technology Authority's website.*
[17] *A machine is considered to be marketed in the EU as soon as it can be acquired within the EU. Consequently, "marketing" also includes the presentation of a design in a brochure or on a website*

5.1.1 Specific requirements for food processing machinery

Application-specific guidelines for machines are presented in Annex I, section 2, titled "Supplementary essential health and safety requirements for certain categories of machinery". Paragraph 2.1 presents requirements for food processing machinery and machinery for manufacturing cosmetic or pharmaceutical products (all three categories will be mentioned by 'products'). This is addressed in the Guide to the Machinery Directive in § 276 and § 277, pages 272-275. Its purpose is to ensure that all products manufactured are free from contamination and the machines otherwise safe to come in contact with products, so as to not pose a danger to consumers.

The basic requirements set out in paragraph 2.1.1 of Annex I of the Machinery Directive are:

- Materials in contact with products must neither contaminate them nor absorb substances from them, and it must be possible to clean them before each use. Food contact materials are essentially covered by Regulation 1935/2004 and by regulations applying to specific materials and applications (see Chapter 5.5).

- All surfaces in contact with products must be smooth and free of irregularities such as scratches etc. which could harbour organic materials. The same applies to joints between materials, which must also be easy to clean and disinfect.

- Constructions must be designed so as to minimise the occurrence of edges and projections. Internal corners must be sufficiently rounded to facilitate their cleaning–after dismantling easily removed parts, if necessary.

- It must be possible to drain machinery of all liquids, gases, and aerosols from products, potentially after placing a machine in a special cleaning position.

- Machines must be designed so as to prevent the ingress and accumulation of organic materials in places that cannot be adequately cleaned.

- Finally, machines must be assembled so as to prevent products from coming into contact with harmful auxiliary substances such as lubricants.

It also requires the development of a user manual that includes recommended methods of rinsing, cleaning, and disinfecting all parts of a machine, including in soiled areas where access is impossible or discouraged for safety reasons.

5.1.2 Complying with the requirements of the Directive

The Guide to the Machinery Directive states that machine builders are expected to possess knowledge on par with that presented in the harmonized standards (Chapter 5.4). While the use of the harmonized standards is voluntary, their contents are considered to represent the state of the art in the field they cover. Consequently, having no knowledge of the harmonized standards and their contents may seem difficult.

The Guide to the Machinery Directive describes this as the "New Method" in the context of technical harmonisation and standardisation[18]. The principle is that the legislation contains the mandatory and essential health and safety requirements that products and machines marketed in the EU must adhere to, and that it describes the procedures for assessing their compliance. The European harmonized standards also include detailed technical solutions for adherence to essential health and safety requirements. As mentioned above, the use of the harmonized standards is voluntary, but using them comes with a presumption of adherence to the most essential relevant health and safety requirements and thus providing a fast track to compliance. Otherwise, this must be documented by other means in the declaration of conformity for the machine in question.

5.2 Legislation on food safety, hygiene and authorisation

The requirements for food hygiene in the EU are specified in Regulation 178/2002 "laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety". This regulation specifies a basis for general food legislation, including such general principles as risk assessment (Chapter 5.3), the requirement that food products not be dangerous to consumers, and the requirement of traceability throughout the supply chain.

Regulation 852/2004 "on the hygiene of foodstuffs" focuses on general hygiene provisions for food products, traceability throughout the supply chain, and assignment of this responsibility to business management. The Regulation applies to all stages of the manufacturing, processing, and distribution of food products unless otherwise stated in more specific provisions. It also requires food businesses to establish an internal oversight system based on HACCP principles (Chapter 5.3). The Regulation describes requirements for public oversight, registration, and authorisation. In Annex II, it also presents provisions on hygiene, premises, and equipment with wording that matches that of the Machinery Directive.

[18] *The presumption of conformity by virtue of the use of harmonised standards is described in § 110, pages 103-105 of the guide.*

Typically, the regulations above will give businesses that supply food handling materials and machinery sufficient knowledge of food safety and hygiene. In some cases, it may be appropriate to learn more about the relevant microbiology criteria. This is covered separately in Regulation 2073/2005. Additionally, there are several more specific regulations and executive orders that deal with food hygiene. The Danish Veterinary and Food Administration offers a comprehensive approach to these[19].

There is a requirement in Denmark to register with the Danish Veterinary and Food Administration both for businesses that handle food products and those that handle food contact materials, including manufacturers that produce equipment or other items intended for contact with foods. The registration process is essentially the same for both of these categories. It is described in the authorisation order[20].

For businesses that exclusively produce equipment or handle food contact materials, packaging, etc., the Danish Veterinary and Food Administration offers some advice and guidance[21].

In principle, all businesses that handle food contact materials must be registered, but there is a de minimis limit. Businesses are not required to register if they handle no more than 1000 units and/or have a turnover not exceeding 50,000 DKK. This means that some smaller businesses are exempt from registration. Although the Danish Veterinary and Food Administration does not conduct on-site audits of these businesses, they must still comply with the rules.

5.3 Risk assessment: a fundamental principle

Risk assessment and the use of a risk-based approach in general to achieve the best possible food safety at every stage of every process is fundamental to ensuring good process hygiene. If risks and potential means of eliminating them are unknown, choosing the right hygienic design solutions will be difficult, if not impossible. This means that a risk-based approach to product hygiene is necessary to put forth the best possible overall effort in terms of consumer protection. This is the primary goal of the EU legislation.

The laws contain several essential definitions that create a common basic understanding of food safety work:

- A risk is defined as the likelihood of a specific hazard having a negative

[19] *This is available in the self-service section of the website of the Veterinary and Food Administration.*
[20] *Danish executive orders can be found at www.retsinfo.dk*
[21] *Information is available on the website of the Danish Veterinary and Food Administration, under "food contact materials"*

impact on health. The severity of the hazard's potential effects must also be considered.

- Risk assessment is a scientific process with four stages: hazard identification, hazard characterisation, exposure evaluation, and risk characterisation (consisting of risk identification, analysis, and evaluation).

- Risk management is the process of evaluating possible mitigation measures together with the relevant parties. In this process, the risks are evaluated along with other relevant factors. If necessary, appropriate prevention and management measures are also evaluated.

- Risk communication is an interactive exchange of information and views that occurs throughout the risk assessment. Risk communication is based on risk-related factors, the perceptions of the experts evaluating a risk, and the perceptions of decision makers and other stakeholders involved in the risk management process. This includes an explanation of the results of the risk assessment and the basis for the decisions made during risk management.

Risk assessment is a key tool in meeting consumer safety requirements when designing equipment and processes to which the Machinery Directive applies. The Directive requires a relevant risk assessment to be performed for health and safety purposes. This is described in detail in the European standard DS/EN 1672-2:2020 "Food processing machinery – Basic concepts, Part 2: Hygiene requirements" (see Chapter 4.2 for a practical approach to risk assessment, and Chapter 5.4 for information on harmonized standards). In particular, a risk assessment must be performed to evaluate the suitability of materials for food contact (see Chapter 5.5.4).

This book promotes and exemplifies the use of risk-based approaches as a basic tool for achieving good hygienic design in processes and their operation. One element of this approach is HACCP, which serves as the foundation of internal oversight in food manufacturing businesses (see Chapter 4.2.4).

5.4 Harmonised standards and basic requirements for food processing machinery

Harmonized standards are EN standards developed under the European Committee for Standardisation (CEN)[22] and adopted throughout the EU. The wording of these standards is unified, both in their capacity as common European standards and in translation, in the national languages of EU member states.

[22] *Comité Européen de Normalisation (CEN) www.cen.eu*

Within the CEN, harmonised standards for food processing machinery are developed by Technical Committee 153, "Machinery intended for use with foodstuffs and feed". Within Denmark, Danish Standards (DS) Committee S-246 performs this function. Anyone can participate in standardisation work, and doing so allows you to influence how standards are designed while gaining first-hand knowledge of topics that new standards will address.

The Machinery Directive is supported by harmonized standards divided into three categories: A, B, and C. The A standards define basic safety- and risk-related requirements for all types of machines. Currently, DS/EN 12100 is the only A standard, and it cannot be used as the sole basis of CE marking for a machine. The B standards deal with specific safety aspects, and when referenced by a C standard, they can be used as a basis for CE marking. The C standards are concerned with specific machines or types of machines. The C standards present specific requirements for machines in terms of adherence to the most significant requirements in the Machinery Directive. If a requirement in a C standard deviates from one specified in an A or B standard, the C standard takes precedence over the others[23].

The basic standard supporting the Machinery Directive is DS/EN 1672-2:2020 "Food processing machinery – Basic concepts, Part 2: Hygiene requirements", the latest revision of which is a C standard. Although this standard is not harmonized at present it is still valid as support for compliance to the Machinery Directive.

The standard contains common hygiene requirements for all machines used to prepare and process food products. The purpose is to eliminate or reduce the risk of infection, disease, or injury from the food products in question. The standard identifies the relevant hazard sources when using such food processing machinery. It also describes design methods and guidance for users that can eliminate or minimise these risks. The risk[24] assessment process described in Chapter 4.2 is based on DS/EN 1672-2:2020.

Another standard is DS/EN ISO 14159:2008 "Safety of machinery – Hygiene requirements for the design of machinery", which has a broader focus than DS/EN 1672-2:2020. This standard specifies hygiene requirements that apply to all machines which could pose a hygiene risk to consumers. The standard also provides information about the manufacturer-specified intended use.

In general, the use of either standard is acceptable for compliance with the basic requirements of the Machinery Directive. Consequently, equipment

[23] *Read more about harmonised standards on the Danish Standards website*
[24] *Where relevant, the standard also covers feed for animals.*

manufacturers ought to know and adhere to one of these standards.

5.4.1 The standardisation process in a nutshell

The creation of a new standard is a relatively long process that begins with a proposal from either a technical committee (like TC 153) or a member organisation. After that, a working group is set up to prepare a working document for the relevant TCs to review. Then, member countries decide whether to move forward with the proposal. If there is a majority in favour of this, a proposed standard known as a prEN is developed for review by CEN members and others. If the review process generates positive feedback and does not result in significant changes to the prEN, it is sent to the TC for a final vote. In principle, a simple majority of members is required for the adoption of a standard[25]. The CEN publishes adopted standards in its three main languages: English, French, and German.

The process of revising already published standards is similar. A TC typically evaluates the validity of a standard every five years. Then, it decides whether the standard needs revision. Occasionally, it may decide to abolish the standard entirely.

Within TC 153, there are several working groups involved in standardisation work. These are: baking machinery (WG 1), meat processing equipment (WG 2), process equipment for cutting meat (WG 3), commercial kitchen equipment (WG 4), equipment for handling oils and fats (WG 5), pasta processing equipment (WG 7), raw milk storage (WG 8), animal feed (WG 9), the dairy industry (WG 10), and the fish industry (WG 11). As you can see, some of these working groups have very limited, specific working areas. This, naturally, is reflected in the harmonized standards that are developed.

5.4.2 Where can I find relevant standards?

De relevante harmoniserede standarder findes på Dansk Standards webshop i delvist dansksprogede versioner under sektion 67 Levnedsmiddelteknologi og undergruppe 67.260 - Anlæg og udstyr til levnedsmiddelindustrien og tillige på CEN's webshop på de tre hovedsprog under TC 153. Oversigten er mere overskuelig hos CEN og kan derfor med fordel bruges til at skabe overblik. En harmoniseret standard koster mellem 600 og 800 kr (2020 priser).

5.5 Food contact materials: relevant legislation

Fundamentally, the EU legislation on materials intended for contact with foods ("food contact materials", often abbreviated to "FCM") consists of two parts:

25. *Read more about standardisation work and the process of creating a standard in "Introduction to Standardisation", a DS publication.*

- Framework Regulation 1935/2004 "on materials and articles intended to come into contact with food", which focuses on internal market regulation (i.e., uniform rules throughout the EU), material traceability, and a high level of consumer safety; and

- "GMP Regulation", 2023/2006 "on good manufacturing practice for materials and articles intended to come into contact with food", which focuses on appropriate handling of materials during the manufacture of machinery (see Chapter5.5.5).

Denmark also has special legislation in this area; namely, Executive Order 681/2020 "on food contact materials", which further clarifies what constitutes a suitable food contact material. In general, Executive Order 681/2020 clarifies the requirements of Regulation 1935/2004 in detail and addresses high-risk materials and ingredients. It also integrates the requirements of Regulation 10/2011 "on plastic materials for contact with food".

5.5.1 What makes a material a food contact material?

Regulation 1935/2004 applies to materials and objects, including active and intelligent materials, and objects which, in their finished form, are intended to come into contact with, or which do come into direct contact with, foods. The Regulation also applies to materials and objects which can reasonably be expected to come into contact with foods or release their constituents into foods under ordinary or foreseeable usage conditions.

The suitability of a material for food contact is theoretically determined at the time it is manufactured, based on knowledge of its composition and the absence of significant migration to food products. Details for specific materials are presented in Chapter 6.

By law, the materials in a given process which are intended to come into contact with food and which may inadvertently come into contact with food must be identified. This identification is crucial for the correct selection of materials, as well as for the procurement, processing, and documentation of objects, components, machines, and entire process line for food processing.

5.5.2 Suitability for food contact: consumer safety and labelling

Regulation 1935/2004, article 3, stipulates that food contact materials must not be capable of releasing substances into foods that would cause them to become harmful to health. Consequently, all food contact materials and objects must be manufactured in accordance with good manufacturing practices. In practical

terms, this means that under ordinary or foreseeable usage conditions, these items must not release their constituents into food products in quantities that could:

- Present a danger to human health
- Cause an unacceptable change the composition of the food
- Cause the deterioration of the sensory (taste, smell, etc.) properties of the food

Article 5 and Annex I of Regulation 1935/2004 also list a variety of materials that may be subject to specific measures.

Executive Order 681/2020 addresses specific migration risks for high-risk materials, including: plastics and recycled plastics (see chapter 6.3), vinyl chloride, regenerated cellulose films, ceramic and enamelled objects, glass, active and intelligent food contact materials, and epoxy derivatives. The appendix discusses each of the materials named in detail. There are limits imposed on the permitted quantities of some ingredients in order to ensure that materials can be used in contact with food and without harming humans.

Note that Executive Order 681/2020 does not impose any requirements on metals. The Danish Veterinary and Food Administration maintains a website on metals and alloys. It lists a variety of materials, alloy components, and ingredients, with guidelines for their use in contact with food. Where relevant, it lists the permitted migration limits set for specific constituents. The site also offers guidelines for the use of aluminium (see Chapter 6.2) and stainless steel (see Chapter 6.1). Generally, both of these materials are suitable for food contact use provided that they are not unintentionally contaminated, corroded, or otherwise degraded by environmental conditions.

Article 15 of Regulation 1935/2004 describes the requirement for unambiguous labelling of food contact materials in order to show that these materials are intended to come into contact with foods. A symbol for a specific purpose may be used, such as a coffee maker, wine bottle, or soup spoon; alternatively, the generic symbol (a glass and fork) may be used. Information should also be provided about special conditions that must be met for the safe and correct use of the materials and objects in question. Additionally, the manufacturer or vendor must be clearly identified.

5.5.3 Traceability, marketing, and recalls

An important element of Regulation 1935/2004 is the requirement for traceability of food contact materials (similar to the requirements for food products), this is described in article 17. The requirement stipulates that at any given point in the chain of use, it must be possible to trace the material one step back and one step forward (if relevant). This is to ensure that it is possible to recall materials that do not meet the safety requirements described above.

That means that food contact materials should be bought and sold in clearly identified lots or batches. Equipment manufacturers must know which materials are part of an outgoing order–and by extension, which orders a given batch of materials was used to fulfil. Similarly, those using the equipment must know where any purchased spare parts are in use, and otherwise establish a system to ensure that only materials suitable for food contact are used for product contact. This traceability also ensures unambiguous correspondence between the materials used and their declarations of conformity (see Chapter 5.5.4).

Regulation 1935/2004 also establishes rules for the labelling and presentation of materials and objects. These must not mislead consumers or others who will use them. It also requires that anyone marketing food contact materials be aware of the rules and actively work to produce the relevant documentation.

5.5.4 Declarations of conformity for materials

Article 16 of Regulation 1935/2004 states that food contact materials to which special rules apply must be accompanied by a declaration of conformity. In the greater EU, this applies only to materials covered by a specific regulation or executive order, such as plastics. In Denmark, however, the provisions of Executive Order 681/2020 state that all food contact materials must be accompanied by a specific declaration of conformity. The declaration must explain that the material is suitable for contact with a given food product or groups of such products, and it must mention any restrictions on the use of the material as to temperature ranges and other environmental parameters. The formal requirement is considered met if the declarations of conformity are available on the manufacturer's or importer's website and the next link in the chain has been informed of their location.

Preparing a declaration of conformity requires knowledge of the material's intended use and the risks that may be present during food manufacturing, cleaning, and other relevant processes to which the material may be subjected. For this reason, a specific risk assessment must be conducted for a food contact material under the applicable process conditions (temperature, product, and cleaning procedures). In the case of plastics and rubber materials, this means

that a migration test must also be performed unless they contain only accepted substances (see the specific requirements in Chapters 6.3 and 6.4). In the case of stainless steel, a "theoretical" risk assessment is sufficient (see Chapter 6.1). Thus, the legislation only requires documentation of the fact that migration to the food products in question does not occur when the material is used for the specific purpose determined in advance. This makes it possible to document that the intended use of the material does not pose a risk to consumers.

5.5.5 Good manufacturing practices (for machine manufacturers)

Regulation 2023/2006 concerns the implementation of good manufacturing practices in the handling and manufacturing of materials and articles intended to come into contact with products. This Regulation operates in concert with Regulation 1935/2004. Fundamentally, it requires a clear understanding of which materials will come into contact with products and which will not. This applies to all employees of a business involved in the manufacturing of machinery in which food contact occurs.

It specifically requires businesses to establish, operate, and maintain a quality assurance system. Manufacturing procedures must be consistent, and there must be a quality assurance system for organising and documenting process conditions. There must also be systematic quality assurance follow-up and suitable paper or electronic documentation showing that the manufactured products meet the specifications.

It is important to recognise that this applies not only to one's own business, but also to subcontractors and vendors. For this reason, it can be a good idea to maintain a list of preferred vendors that are aware of the rules that apply to them, as well as to assist subcontractors with implementing the necessary routines.

5.6 CE marking

The CE mark[26] allows manufacturers of machinery and process lines to declare that they adhere to the requirements of the Machinery Directive. For this reason, CE marking is mandatory for all machinery and process lines intended for food manufacturing that are marketed within the EU. CE marking is performed by an equipment manufacturer or its representative. It is a self-declaration that the manufacturer has adhered to the Machinery Directive and the relevant executive orders that apply to food contact materials, as well as that the knowledge used is on par with the relevant harmonized standards. Consequently, a CE mark is not a quality guarantee. It represents neither the approval of a public authority

[26] *The CE mark itself has a standardised appearance. It is an abbreviation of Conformité Européenne ("European Conformity"). CE marking has been required since 1993.*

nor a comprehensive assessment of whether the assembly meets the applicable requirements (see Chapter 2.8).

This chapter discusses how to conduct the various processes associated with CE marking. The CE marking procedure is essentially as follows:

1. Find the relevant EU directives (there are also high- and low-voltage directives)

2. Conduct a risk assessment for each machine, product, and/or process (see Chapter 5.6.2)

3. Find the relevant harmonized standards (see Chapter 5.4).

4. Evaluate and test the assembly against the requirements in the standards

5. Establish a quality assurance system to ensure consistent manufacturing of the machine, product, and/or process

6. Prepare a technical file for the product (see Chapter 5.6.7).

7. Issue a declaration of conformity

8. Affix and use the CE mark

5.6.1 Manufacturers and responsibility

Fundamentally, the manufacturer[27] of a machine is responsible for ensuring compliance with the Machinery Directive, and by extension, that CE marking is conducted correctly and on the appropriate basis. For producers situated and producing within the territory of the EU, the responsibility lies indisputably with the person or the company manufacturing the machinery. The same applies to machinery manufacturers outside the EU which import and/or market their products within the EU. Should a third party assume the legal responsibility for a machine or sub-machine, this party must adequately verify that the vendor has the knowledge necessary to adhere to the laws. The Machinery Directive does not impose specific requirements on independent distributors of machinery. They are responsible only for ensuring that machines are CE marked and accompanied by declarations of conformity and instructions for use. However, distributors are expected not to supply machinery that clearly does not meet the requirements of the Machinery Directive.

[27] The terms "manufacturer" (fabrikant in Danish) and "representative" (representant) are described in greater detail on pages 59-63 of the Guide to the Machinery Directive.

Picture kindly lent by Hydract Aps

Ultimately, the entity that assembles and installs a complete process line or modifies a machine (e.g., during repairs or maintenance) is responsible for its conformity, and by extension, for the continued validity of its CE mark and adherence to the requirements of the Machinery Directive. An entity which manufacturers, modifies or assembles machinery is considered a manufacturer even if it does not market the machinery itself, and it must comply with the Machinery Directive. This means that the product manufacturer can become the responsible equipment manufacturer.

The CE marking process may be delegated to an external consultant if the knowledge and skills necessary are not available in-house.

5.6.2 Risk assessments in relation to hygienic design

According to the Machinery Directive, a risk assessment encompasses not only materials, but also the evaluation of relevant risks in terms of health and safety. In a hygienic design context, the design of the machine and the manner in which it will be used must be evaluated to determine whether they introduce risks that could endanger consumers. In practice, this is aligned with the requirement that machines be designed so that they can be adequately cleaned before use. Therefore, at minimum, a risk assessment should address the design's ease of cleaning, the risk of unwanted substances entering the machine, and the potential for organic materials to collect in parts of the machine (these risks are described in greater detail in Chapter 2.10). The general design requirements in the Machinery Directive, described in Chapter 5.1.1, naturally indicate the areas relevant in a risk assessment, but to achieve the required level of specificity relative to a particular machine, the use of harmonized standards and other validated sources that address the field in question is advisable (see also Chapter 4.1). A risk assessment methodology[28] is described in DS/EN 1672-2:2020 (see Chapter 4.2).

5.6.3 The declaration of conformity for a machine

The declaration of conformity for a machine demonstrates that it was manufactured in accordance with all relevant requirements in the Machinery Directive. The declaration of conformity applies to the machine within the context in which it is marketed and when used according to the intended use as described[29].

There are several formal requirements for a declaration of conformity, including an indication of the manufacturer's company name and full address, the legal

[28] *A hygiene risk assessment should follow the methodology described in DS/EN 12100:2011, "Safety of machinery – General principles for design – Risk assessment and risk reduction".*
[29] *The full requirements for declarations of conformity for machinery can be found in § 382 and § 383 on pages 364-369 in the Guide to the Machinery Directive.*

entity able to provide portions of the technical file to public authorities upon request, and unique identifiers (e.g., serial numbers) for one or more identical machines.

Most importantly, a declaration of conformity must state that the machine adheres to all of the applicable requirements in the Machinery Directive. In fact, this can be done in a single sentence. In doing so, the manufacturer declares that the machine adheres to all relevant health and safety requirements as presented in Annex I of the Machinery Directive, and that a conformity assessment, including an appropriate risk assessment, has been performed to address the intended use of the particular machine in question. Remember that this process can be simplified by listing very specific usage limitations.

If the manufacturer wishes to avail itself of the presumption of conformity implied by the use of the relevant harmonized standards, the declaration must list the specific standards applied. Of course, the use of these standards is voluntary; alternatively, the manufacturer can reference other sources, such as guidelines, used in the design and manufacture of the machine. However, if it chooses to do so, there is no presumption of conformity. This means that the declaration must also explain the relevance of the sources used and demonstrate that the requirements specified therein are at least on par with those in the harmonized standards. Specific examples of information that is good to include in declarations of conformity is presented in Appendix 2..

5.6.4 Declarations of incorporation

Declarations of incorporation are prepared for sub-machines[30] with no independent function, intended solely for incorporation into another assembly that will ultimately form a complete machine. The declaration of incorporation accompanies the sub-machine when it is delivered to the manufacturer of the final machine. It informs the manufacturer of the health and safety requirements that the sub-machine meets with reference to Annex I of the Machinery Directive. This makes it possible for the manufacturer to include relevant information in the conformity assessment of the complete machine. Importantly, a declaration of incorporation should contain a clear description of the field of application and any limitations there may be on the use of the sub-machine, such as in regard to specific groups of food products. Additionally, as with a declaration of conformity, it must state that appropriate documentation has been prepared in order to ensure adherence to the requirements in the Machinery Directive.

[30] *The full requirements for declarations of incorporation for sub-machines can be found in § 384 and § 385 on pages 368-371 in the Guide to the Machinery Directive.*

It is essential that the declaration of incorporation is accompanied by assembly instructions explaining the correct use of the sub-machine so that it can be used safely. It must also describe any special health and safety requirements that the manufacturer must consider when incorporating the sub-machine into a complete machine.

5.6.5 Conformity for machine assemblies

Assembled process lines consisting of several machines are also subject to the Machinery Directive because their overall safety depends not only on their constituent parts, but also on the suitability of those parts to be used together and on the interfaces between them. The risk assessment performed by the manufacturer of a complete process line must therefore include an evaluation of whether the individual parts are suitable for incorporation into the complete construction, as well as whether the complete assembly can be guaranteed safe given the use of various connectors (pipes, welds, pipe couplings, valves, pumps, etc.).

The risk assessment performed must additionally encompass any hazard not covered by the relevant declarations of conformity for machinery and declarations of incorporation for sub-machines. In a hygiene context, for instance, safety means not introducing any parts or details that are more difficult to clean than the machines being assembled. Specifically, this means that details such as uneven surfaces, protrusions, etc. where organic material could accumulate must not be introduced, and the entire assembly must remain drainable.

5.6.6 Combinations of new and existing machinery

The Machinery Directive actually applies only to new machines; that is, machines being marketed or put into service for the first time within the EU. It is assumed that the business responsible for putting a machine or assembly of machines into service will also be responsible for its conformity and safety during its entire lifetime[31]. For this reason, the above applies only to assemblies of new machines.

In specific cases where portions of an existing process line are being replaced with new machinery or supplemented with additional machinery, it isn't possible to conclusively say whether or not the Machinery Directive applies. However, the provisions of the Directive do apply to the following cases:

1. Parts that are not significant to the operation of safety of the complete process line may be freely replaced; continued compliance with the Machinery Directive is presumed.

31. *More information on this is presented in § 39 on pages 39 and 40 of the Guide to the Machinery Directive*

2. A new conformity assessment is not required when adding a machine that bears a CE mark, as its incorporation is considered to constitute simple assembly.

3. When adding a sub-machine accompanied by a declaration of incorporation and installation instructions, the manufacturer must conduct an appropriate risk assessment for the interfaces between the sub-machine and the complete system of which it is a part. Then, it must develop a new declaration of conformity and repeat the CE marking process for the new unit.

4. If existing machines are replaced with new machines, or if new parts are added that significantly impact the operation and/or safety of an assembly, this is considered a new assembly of machinery. In this case, a new overall conformity assessment must be performed as described in Chapter 5.6.5.

5.6.7 The technical file

Manufacturers or their representatives within the EU must prepare a technical file containing all relevant information before issuing a declaration of conformity. Specifically, the technical file must contain all declarations of conformity and incorporation for the machines and sub-machines in an assembly, as well as documentation of any changes made to them when manufacturing the complete machine or process line.

Upon request, the documentation in a technical file must be made available for inspection by public authorities. The technical file is the manufacturer's means of documenting that a machine conforms to the Machinery Directive; consequently, public authorities may access its contents if needed to verify conformity once the machine is on the market. The technical file is the property of the manufacturer, and the authorities are not permitted to disclose any information they receive in this context. When providing a technical file to the authorities, the manufacturer may omit detailed plans unless they are absolutely necessary to verify compliance with essential health and safety requirements.

6. Food Contact Materials and Their Conformity in Practice

This chapter focuses on the properties and suitability of materials that may be intended to come into contact with food products in various contexts. Here, "suitability" means a material's overall compatibility with general or specific groups of foods and relevant types of cleaning agent, as well as the absence of significant migration to and from the material. Materials also must not be degraded by any environmental factors during use.

This chapter is divided into four sub-chapters that cover the most important product contact materials in use: stainless steel, aluminium, plastic, and rubber. It is important to note that plastic and rubber are wholly different families of materials, so they are governed by different sets of rules in the context of ensuring suitability for food contact, compared to the metals.

The general legislation on food contact materials and risk assessments for surfaces that come into contact with foods are reviewed in Chapters 4.2.4 and 5.5. This chapter focuses instead on regulatory requirements that target specific materials or groups of materials, and on more specific requirements for declarations of conformity. These come in a variety of forms depending on one's position in the chain, from manufacturing materials to using them in specific food contact situations.

At first, meeting food contact material requirements and issuing a declaration of conformity (examples in Appendix 2) for a material might seem quite straightforward. However, finding the right level of detail and minimum documentation requirements is not always easy in practice. However, the following points are a good place to start:

- The declaration should include information about potential or intended uses, the products with which the material can be used, and any temperature limits that may apply.

- At minimum, consult Regulation 1935/2004 and Regulation 2023/2006. For plastics, also consult Regulation 10/2011. There may be additional, more specific executive orders that apply.

Typical forms of corrosion in stainless steel and certain aluminium alloys are pitting, coating corrosion, and crack corrosion. All three of these attacks a

localised portion of the material's surface and can occur in places where the material's corrosion resistance is weakened for one reason or another. Stress corrosion is another phenomenon that can occur in austenitic stainless steel and aluminium. Plastic and rubber degrade differently, but acids and bases alike can still damage these materials given concentrations and exposure times beyond established limits.

6.1 Stainless steel

The name "stainless steel" can be somewhat misleading, as stainless steel can, in fact, corrode in unfavourable environmental conditions. Stainless steel contains enough chromium to form a passive chromium oxide film that prevents surface corrosion by blocking the diffusion of oxygen to the steel surface. The chromium oxide layer also prevents corrosion from spreading to the internal structure of the metal. The process by which the chromium oxide layer forms is known as passivation. It can only occur given a sufficient concentration of chromium (at least 16%) and in the presence of oxygen.

In theory, corrosion is possible at temperatures above 50-60°C in the presence of a chloride ion concentration above 30 PPM and given a sufficiently long contact time for the surface to be attacked by corrosive elements. However, it is difficult to unambiguously determine a single limit for the temperature, chloride ion concentration, and contact time. Consequently, if there are any doubts in this regard, a risk assessment under real-world conditions is required.

In general, though, increasing the temperature, the chloride ion concentration, or both above the critical level will escalate the problem. Corrosion resistance depends on certain components of the steel alloy. For this reason, the actual composition of the steel must always be known. This can be based on a certificate of type 2.2 or 3.1, or a positive material identification (PMI)

→ All materials can be degraded or corroded through improper handling

It is important to recognise that all materials may be impacted and altered to some extent during use. In the context of food contact materials, what matters is choosing materials for a given application such that these changes will not render the material unsuitable for product contact. For instance, corrosion and degradation can impact all of the most common materials in machinery (stainless steel, aluminium, plastic, and rubber) if used in conditions other than those intended. This can occur in the presence of very high concentrations of corrosive elements, or when materials are used beyond their indicated service lives.

measurement. The Danish Veterinary and Food Administration has published a guideline on the use of stainless steel (see Chapter 7.2); the information below is quite close to the information presented there. This guideline offers additional information on the use of stainless steel for food contact applications.

The most commonly used stainless steels in machinery are austenitic steels, as they have the best overall properties for processing. As a result, it's quite natural to compare other kinds of stainless steel to austenitic steels. A number known as a PREN (pitting resistance equivalence number) allows us to compare different types of steel in general terms. PREN describes the resistance of a particular steel to pitting. Figure 11 presents a variety of stainless steels with their PRENs. The most practically adjustable alloy component is molybdenum (Mo). As shown here,

it contributes significantly to corrosion resistance, but it also has a significant impact on the price of a given steel.

There are four kinds of stainless steel that are relevant for food contact applications. They are described in general terms below:

- Ferritic stainless steels contain chromium, but no nickel. They may be alloyed with molybdenum. They are magnetic and generally exhibit low corrosion resistance. However, there are alloys with the same pitting resistance as common austenitic stainless steels, as shown in Figure 11. Ferritic stainless steels are commonly used for the exterior surfaces of household appliances and steel tables. To a lesser extent, they are used in machine assemblies.

- Martensitic stainless steels are magnetic, and they have the poorest corrosion resistance of these four types. They are used primarily for knife blades because they can be hardened. This makes it possible to sharpen them and have them remain sharp for longer. However, the alloy composition still significantly affects their hardness, and there is much work being done to improve these alloys for high-end culinary and utility knives.

- Austenitic stainless steels are not magnetic. They contain both chromium and nickel, and they may also be alloyed with molybdenum. The two most common varieties are EN 1.4301 (AIST 304) and EN 1.4401 (AIST 316); naturally, these are also available in low-carbon varieties to facilitate welding. In the AIST notation, an L is added after the type number to indicate low carbon content. EN 1.4301 (and its low-carbon variants, EN 1.4306 and EN 1.4307) do not contain molybdenum. EN 1.4401 (and its low-carbon variant, EN 1.4404) contains between 2.0 and 2.5% molybdenum, as well as a bit more nickel. This results in improved corrosion resistance. However, there

are some applications in the food manufacturing industry where this is not sufficient. In those instances, these steels can be alloyed with a greater concentration of molybdenum. One disadvantage of austenitic stainless steels is that stress corrosion can occur in them; for instance, they may corrode when subjected to thermal stress.

- Duplex stainless steels contain ferritic and austenitic structures in equal proportion. As shown in Figure 11, duplex stainless steels generally exhibit high corrosion resistance due to both their unique structure and their molybdenum content. Another advantage of these steels (and another reason to choose them) is that they do not present a stress corrosion risk.

Figure 11. Pitting resistance equivalence number (PREN = Cr + 3.3·Mo + 16·N)

Grade	Type	Cr %	Mo %	N %	PREN
Ferritisk Ferritisk					
1.4016	430	16.0-18.0	-	-	16.0-18.0
1.4509	441	17.5-18.5	-	-	17.5-18.5
1.4521	444	17.0-20.0	1.8-2.5	0.030 max	23.0-28.7
Austenitisk					
1.4301	304	17.5-19.5	-	0.11 max	17.5-20.8
1.4404	316L	16.5-18.5	2.0-2.5	0.11 max	23.1-28.5
1.4547	254SMO	19.5-20.5	6.0-7.0	0.18-0.25	42.2-47.6
Duplex					
1.4062	2202	22.0	0.4	0.2	26.5
1.4410	SAF2507	24.0-26.0	3.0-4.0	0.24-0.35	> 40
1.4501	Zeron 100	24.0-26.0	3.0-4.0	0.20-0.30	> 40
1.4507	Ferrinox255	24.0-26.0	3.0-4.0	0.20-0.30	> 40

Aside from pitting, crevice and coating corrosion are also possible. Like pitting, these attack a localised portion of the steel, typically in an area subjected to a high concentration of chloride ions. This could occur after water has evaporated or been transported away by diffusion.

All three forms of corrosion can be countered in austenitic stainless steels by the use of better alloys. In practice, this means using an alloy with a greater proportion of molybdenum. However, there is no formula to describe resistance to stress corrosion as there is for resistance to pitting. That said, the basic method of solving this problem is the same. Stress corrosion issues can be solved by replacing an austenitic stainless steel with a duplex steel.

In the United States, the FDA (Chapter 7.6.1), American National Standards Institute (ANSI), and NSF International (Chapter 7.7) all prescribe the use of stainless steels with chromium content above 16% for food contact uses. This

applies to all stainless steels listed in Figure 11. To be approved by the FDA, ANSI, and NSF, stainless steel for use in food processing equipment must be of a type in the SAE 200 series (chromium-nickel-manganese alloys), the SAE 300 series (chromium-nickel alloys), or the SAE 400 series (chromium alloys). The SAE steel grade standard classifies steels in the same way as EN numbers. The SAE 200 series contains cheaper austenitic steels, in which manganese replaces nickel; this explains their reduced corrosion resistance. The SAE 300 series comprise other austenitic steels, including the EN 1.43xx and EN 1.44xx steels. Lastly, the SAE 400 series comprise ferritic steels.

Appendix 3 contains tables of the various steel types according to the European and American notations.

6.2 Aluminium[32]

AAluminium is often wrongly considered a material incapable of withstanding ordinary environmental conditions in areas with direct product contact. However, like stainless steels, aluminium encompasses a variety of alloys these being with or without surface treatments. These materials vary significantly in terms of their resistance to corrosion. Even more so than for stainless steel, it is important to assess the influence of cleaning chemicals, temperatures, and contact times when using aluminium.

The increased interest in expanding the use of aluminium is due to its obvious advantages, such as its low weight, ease of processing, and fundamental compatibility with foods. The disadvantages lie in its resistance to cleaning agents–and it isn't trivial to simply switch these out to accommodate some new aluminium parts that need to be protected.

As mentioned, aluminium is available in a variety of alloys. The purest and most typical alloys are the 1000, 3000, and 5000 series. Naturally, these offer better corrosion resistance. However, these are also rather soft materials with limited structural applications. They are also highly susceptible to scrapes and scratches, which can degrade the hygienic quality of a surface. For a stronger option, the 6000 series is the best candidate. If the surface is anodised, it becomes more resistant to abrasion and scratching. After being anodised, the surface must be sealed to achieve good surface functionality, but its lifetime and corrosion resistance will be significantly better than those of non-anodised surfaces.

While aluminium cannot replace stainless steel in all situations, there are some applications where it can be beneficial to consider it as a substitute for stainless steel.

[32] *Tak til Anne Deacon Juul, AluConsult for vejledning om aluminium til fødevarekontakt*

6.3 Plastic and recycled plastic

Plastics are the most highly regulated of all food contact materials in the EU. Regulation 10/2011 contains lists of approved constituent substances and migration limits for substances that could migrate from a plastic into a product. The Regulation does not apply to rubber or silicone. The positive list of substances accepted as constituents of plastics is given in Annex II. If a plastic consists exclusively of substances on the positive list, it is presumed suitable for food contact applications; if it contains other substances, it must first be tested.

Specific migration limits are set for several substances that are not desirable in food contact plastics (article 11 and Annex I), along with overall limits on total migration (article 12). Articles 13 and 14 describe requirements for multilayer materials. Annex III describes the simulants to be used for testing plastic materials for contact with food products contain fats/oils, acids, and alcohol. Additional guidelines exist for recycled plastics; these can be found in Regulation 282/2008. The Regulation establishes rules for constituent substances and manufacturing procedures for materials consisting of recycled plastic products.

6.3.1 Examples of plastics

Plastic vendors offer a variety of materials with greater or lesser food product compatibility in the EU and the US (FDA). These include:

- HDPE (high-density polyethylene), which exhibits low resistance to strongly oxidising chemicals, such as nitric acid; however, it can withstand many organic solvents. HDPE is a very tough material with good wear resistance, and it can typically be used at temperatures ranging from -60 to 80°C.

- PA (polyamide) resists many weak acids and bases, many types of oils and fats, and many solvents. PA has good wear resistance, but it can be altered if it takes on water. It can typically be used at temperatures ranging from -40 to 100°C.

- POM (polyoxymethylene) resists most bases, but not acids. POM is highly stiff and tough. It has good wear resistance, retains its shape well, does not take on much water, and can typically be used at temperatures from -50 to 100°C.

- PEEK (polyether ether ketone) generally resists chemicals well, but it exhibits poor resistance to sulphuric and nitric acid. PEEK retains its shape well and has good wear resistance. It can typically be used at temperatures from -65 to 260°C.

- PTFE (polytetrafluoroethylene), also known as Teflon, resists acids, bases, salts, and oils. PTFE has high impact strength, retains its shape, and has

uniform stiffness across a range of temperatures. It can typically be used at temperatures from -200 to 260°C.

- PP (polypropylene) resists many chemicals. PP has high impact strength and is known to work especially well in hinges. It can typically be used at temperatures from 5 to 85°C.

- PVC (polyvinyl chloride) resists many acids, bases, oils, and fats. PVC is very stiff and has good impact strength. It can typically be used at temperatures from -10 to 60°C.

- PMMA (poly(methyl methacrylate)) exhibits moderate resistance to weak acids, bases, oils, and fats. PMMA has good stiffness and takes on little water. It can typically be used at temperatures from -20 to 80°C.

- Plastics break down to a greater or lesser degree during use. It is not uncommon for them to shrink, change colour, and take on different physical properties after contact with food products and cleaning agents. All plastics age and have finite service lives, after which they must be replaced with new materials.

6. 4 Rubber and silicone[33]

There are currently no EU-wide rules (Some countries do have their own regulations) that apply specifically to rubber, meaning that only the general rules apply i.e., that no significant product contamination is permitted. This can be a bit of a hassle for manufacturers, as they cannot always sell the same products in every country. In the absence of any specific rules, some organisations, such as the EHEDG, apply the FDA's rules on rubber. These can be found in CFR 21, section 177.2600, which includes a positive list. However, it is important to recognise that European authorities do not accept the application of American regulations. Because every rubber manufacturer has recipes that it would rather not share, each one must conduct its own tests.

6.4.1 Examples of common gasket materials

DThe main elastomers used for gaskets and other sealing applications in the food and pharmaceutical industries are:

- NBR (nitrile butadiene rubber), which resists oils and fats well. NBR has excellent dynamic properties and can typically be used at temperatures from -30 to 100°C. Given the low maximum temperature, it should only be used in open systems and other situations with moderate operating temperatures.

[33] *Tak til Anders Guldbæk Christensen, AVK Gummi A/S for vejledning omkring gummi til fødevarekontakt*

- HNBR (hydrated nitrile butadiene rubber) offers good resistance to chemicals, oils, and fats on par with that of NBR. HNBR has excellent dynamic properties and can typically be used at temperatures from -30 to 150°C. The broad range of temperatures and generally good durability make HNBR a good choice for gaskets in closed process systems.

- EPDM (ethylene propylene diene monomer rubber) exhibits excellent resistance to chemicals, but poor resistance to oils, fats, and solvents. EPDM resists heat and cold well. It has good dynamic properties, and it can typically be used at temperatures between -50 and 150°C. EPDM is by far the most common gasket material in dairies, where fat concentrations are low. EPDM has limited used in dairies because of the link between temperature and fat concentration; for products containing 5% fat, EPDM can be used at temperatures of up to 85°C. Higher temperatures is allowed at lower fat concentrations, in general higher fat concentrations require lower temperatures.

- VMQ (vinyl methyl silicone rubber) exhibits good heat resistance and flexibility at low temperatures. It also resists many acids, but it is not compatible with superheated steam. VMQ has good elasticity, but its mechanical properties are not so good. It can typically be used at temperatures from -60 to 200°C.

- FKM (fluorine rubber) exhibits broad chemical compatibility and ages exceptionally well. It can withstand harsh chemicals. FKM has good mechanical properties and can typically be used at temperatures between -20 and 200°C. FKM is considered one of the most important elastomers developed in recent times. Its use in industrial applications is growing.

Based on gasket prices, the order of these materials from cheapest to most expensive is: EPDM, NBR, VMQ, HNBR, FKM. FKM is significantly more expensive than the other materials.

As a rule of thumb, the service life for a rubber product at a temperature above 60°C is doubled by a 10°C reduction in operating temperature and halved by a 10°C increase in operating temperature.

Rubber materials break down to a greater or lesser extent during use. Typically, their mechanical properties are impacted. However, their weight and colour can also change as a result of contact with food products and cleaning agents. All types of rubber age and have finite lives, after which they must be replaced with new materials.

6.5 Compliance with regulations outside the EU and US

While the rules described here cover a large portion of the global market, there are other important markets, such as the Chinese market, where different rules apply. In many ways, the rules in China resemble those in Europe. There are some differences and stricter requirements in certain areas; for instance, materials must be tested in Chinese test laboratories.

7. Guides, guidelines, and other references

To make good choices when it comes to materials and hygienic solutions, access to as much knowledge as possible is valuable, whether in terms of legislation, harmonized standards, or guidelines. This chapter offers an overview of additional references to support the topics covered in this book.

Some of the references in this chapter are links to websites. The text to search for in order to find the information mentioned here is presented in boldface

7.1 The EU and the European Council

At the EU level, there is a strong focus on consumer protection and, by extension, on contamination with metals and other substances. Essentially all metals and alloys apart from stainless steel are included:

- The European Council's guidance on metals and alloys

7.2 The Danish Veterinary and Food Administration and Environmental Protection Agency

In Denmark Veterinary and Food Administration and Environmental Protection Agency have several good web pages with self-service features, guidance on interpreting laws, and information on how to best adhere to the spirit of the laws.

Selected web pages and guides on food contact materials (FCM) in general:

- Food contact materials folder
- Declarations of conformity for food contact materials
- Requirements for FCM businesses
- Requirements for FCM in food processing businesses
- Internal oversight and food contact materials
- Registration for FCM businesses
- Boundaries between food contact materials and fixed water installations

- Hygiene and food contact materials
- Lubricants and food contact materials
- Legal texts and rules on food contact materials

Selected web pages and guides specifically about food contact materials made from metals and alloys. Here are links to a number of relevant pages:

- Nordic guidance on metals and alloys
- Aluminium
- Beryllium, lead, cadmium, iron, copper, cobalt, chromium, mercury, manganese, nickel, titanium, and zinc content in food contact materials
- Stainless steel and other alloys for use with food products, including guidelines for stainless steel food contact materials
- Silver for use with food products
- Tin and canned foods

Selected web pages and guides on plastic food contact materials:

- Definition of plastic in rules for food contact materials
- Bamboo in plastic food contact materials
- Phthalates in plastic food contact materials
- Food contact materials made of recycled plastic
- Materials not considered plastics in rules for food contact materials
- Biocides in plastic food contact materials
- Legal texts and rules on food contact materials

Marking of food contact materials

- The "glass and fork symbol"

- Requirements for labelling and label information
- Fact sheet on FKM in retail

Selected web pages and guides on rubber in relation to food contact materials can be found in the Survey and study of migration of monomers in toy materials

Selected web pages and guides on other topics related to food contact materials:

- Wooden food contact materials
- Porcelain and earthenware food contact materials
- Ion exchangers for use with food products

7.3 Guidelines in other EU countries

When one EU country lacks knowledge on a particular subject, it is common for that country to turn to relevant guidelines produced by another country. Before the Danish guidelines on stainless steel were published, the government referenced the guidelines developed in France and Italy instead. With the exception of very few differences of no practical relevance, the provisions regarding the use of stainless steel in the Danish guidelines are the same as those in the French and Italian guidelines, though the latter are more detailed in some aspects.

7.4 Other credible sources

Other English-language books on hygienic design and ensuring good hygiene in food processing businesses are available. The most recent and up-to-date of these is the Handbook of Hygiene Control in the Food Industry, second edition; edited by H. L. M. Lelieveld, J. Holah, and Domagoj Gabrić, Woodhead Publishing, ISBN 9780081001554/9780081001974 and Hygienic Design of Food Factories, first edition; edited by J. Holah and H. L. M. Lelieveld, Woodhead Publishing, ISBN 9781845695644/9780081016350/9780857094933.

A report titled "Metal in Food", developed jointly by the Technical University of Denmark and the Rigshospitalet Allergy Clinic. This report covers a wide range of questions on migration from metals and the significance of metallic contaminants in food products. It is available from Nichro's website (search for Metal in Food Nichro).

7. 5 The European track and the EHEDG

The European Hygienic Engineering and Design Group (EHEDG) was founded in 1989 as a non-profit consortium of equipment manufacturers, food

manufacturers, suppliers to the food industry, research institutes and universities, public health authorities, and governmental organisations. EHEDG's primary purpose is to promote safe food products by improving hygienic technology and design in all aspects of food production.

EHEDG promotes European legislation on hygienic design and hygiene (see Chapter 5) actively, and it supports the implementation of the best standards among equipment manufacturers and users. EHEDG's mission is to raise awareness of hygienic technology, develop guidance and solutions, and make knowledge available in ways that facilitate networking between hygienic experts from around the world.

EHEDG's principal activities are the production and maintenance of guidelines, equipment testing and certification (more on this in Chapter 8.1), and training and knowledge dissemination within hygienic design.

As of late 2021, EHEDG had 45 active guidelines, which can be divided into the following groups:

- General principles, materials, surfaces
    - General criteria and hygienic integration
    - Welding, food contact materials, and lubricants
- Testing methods
    - CIP cleanability

→ Minimal risk of migration of alloy components from stainless steel to food products

"Metal in Food" concludes that, for food products manufactured in large-scale production processes, contamination with nickel is not an issue. The authors also found no examples of instances in which migration from stainless steel has resulted in health problems among consumers. The report additionally concluded that degraded surfaces result in shorter equipment lifetimes, reduced ease of cleaning, and increased risk of particle transfer.

In practice, this means that alloyed stainless steels are safe to use in food contact applications as long as they are not corroded or otherwise compromised during use.

    - Aseptic technology and bacterial exclusion
- Factory design, incl. supply system design
    - Factory planning
    - Water and air handling
- Open equipment
    - General principles
    - Transporters, fresh fish and bakery equipment production
- Closed equipment for liquid food products
    - General principles
    - Pipe couplings
    - Pumps, homogenisers, centrifuges, valves, and sensors
    - Pipe couplings and a 'Position Paper' on pipe and process couplings
- Closed equipment for dry particulate products
    - General principles
    - Spray dryers, fluid beds, transfer systems and valves
- Packing and filling machines
    - General principles
    - Aseptic conditions
- Heat treatment
    - General pasteurisation and sterilisation principles
    - Particulate material handling

- Cleaning and validation
    - Validation of cleaning
    - Hygienic design of CIP installations

The specific guidelines are available on the EHEDG's website. Guideline 8 can be downloaded for free, as well as the Position Paper and a glossary relating the terms used by the EHEDG to those used by 3-A SSI.

Furthermore, EHEDG certifies easy to clean equipment through a certification scheme (read more in chapter 8.1)

7.6 US-based organisations

In the US several official and private actors define different aspects of requirements and recommendations for food contact materials, hygienic design, and equipment certification. Within the federal government, the major players are the Food and Drug Administration (FDA) and the US Department of Agriculture (USDA). In the private sector, these are 3-A Sanitary Standards, Inc and NFS International. All four are described in this sub-chapter.

7.6.1 Food and Drug Administration (FDA)

The Code of Federal Regulations (CFR) codifies the general and permanent rules that are published in the American Federal Register (FR) for all executive departments. Section 21 of the FR is reserved for Food and Drug Administration regulations. A new revision of section 21 is published around April 1st each year, and it is usually publicly available a few months later. For information on food contact materials, consult CFR 21, subsections 174 to 178, on coatings, paper, cardboard, polymers (plastics and rubber) and auxiliary substances:

- § 174: Indirect food additives: General
- § 175: Indirect food additives: Adhesives and components of coatings
- § 176: Indirect food additives: Paper and paperboard components
- § 177: Indirect food additives: Polymers
- § 178: Indirect food additives: Adjuvants, production aids and sanitizers

7.6.2 3-A Sanitary Standards, Inc (3-A SSI)

3-A SSI maintains a broad inventory of design criteria for equipment and

processing systems for use in the food and pharmaceutical industries. These criteria are developed using a consensus process to promote their acceptance by the USDA (see Chapter 7.8), the FDA, and other government agencies.

3-A SSI also oversees its own authorisation programme and issues a number of voluntary certificates that help to verify the integrity of hygienic equipment and systems (read more in Chapter 8.2). It also supplies comprehensive knowledge resources to support education and training needs in the food and pharmaceutical industries.

The 3-A symbol, established in 1956, is a registered mark used to identify equipment that meets 3-A's sanitary standards for the design and manufacture of equipment. Equipment with the 3-A symbol provides assurance that equipment for dairy and food production meets sanitary standards developed for the US market. Standards give equipment manufacturers generally accepted criteria for sanitary design, and they establish guidelines for maintaining and evaluating sanitation.

The 3-A symbol can be used after approval via a certification process described in greater detail in Chapter 8.2.

3-A SSI produces standards and guidelines that address the same basic areas as the EHEDG. However, it covers several topics in detail:

- Standards for the sanitary design of closed processes:
    - Valves, pumps,
    - homogenisers, heat exchangers, freezers, mixing equipment, spray dryers, and separators
    - Sanitary fittings and pipes
    - Tanks used in process facilities and for transportation
- Standards for the sanitary design of closed processes:
    - Pasta equipment and open cheese pots
    - Feet for machinery
- Standards for the sanitary design of processes for dry products:

    - Removable containers, conveyors, packaging machines and level sensors

- Materials
    - Rubber
    - Recyclable plastic

3-A SSI also has a number of "accepted practices" in such areas as these:

- Sanitary construction, installation, testing, and operation of high-temperature-short-time and higher-heat-shorter-time pasteurisation systems
- Pressurised air in contact with products and product contact surfaces
- Permanently installed pipelines and cleaning systems
- Spray drying systems
- Sanitary construction, installation, and cleaning of membrane treatment systems
- Air quality in production facilities

Further information on documents from 3-A SSI can be found on its website.

7.7 NSF

NSF International offers the global food industry a wide range of certification and audit programmes, training programmes, and publications. Specifically, NSF and 3-A SSI have jointly developed NSF/ANSI/3A 14159-1-2019, which concerns hygiene requirements for the design of machines that process meat and poultry. A number of NSF/ANSI standards on hygienic design in a broader sense are also available.

The NSF mark commonly appears on equipment and aids used in commercial kitchens, but it can also be found in the food industry. It is a recognised indicator that the equipment meets NSF/ANSI standards, as well as FDA requirements. NSF markets itself as having a science-based certification process for evaluating and testing:

- Hygienic design and construction: Equipment must be cleanable, and it must be demonstrated that bacteria and other microorganisms are unlikely to collect on it.

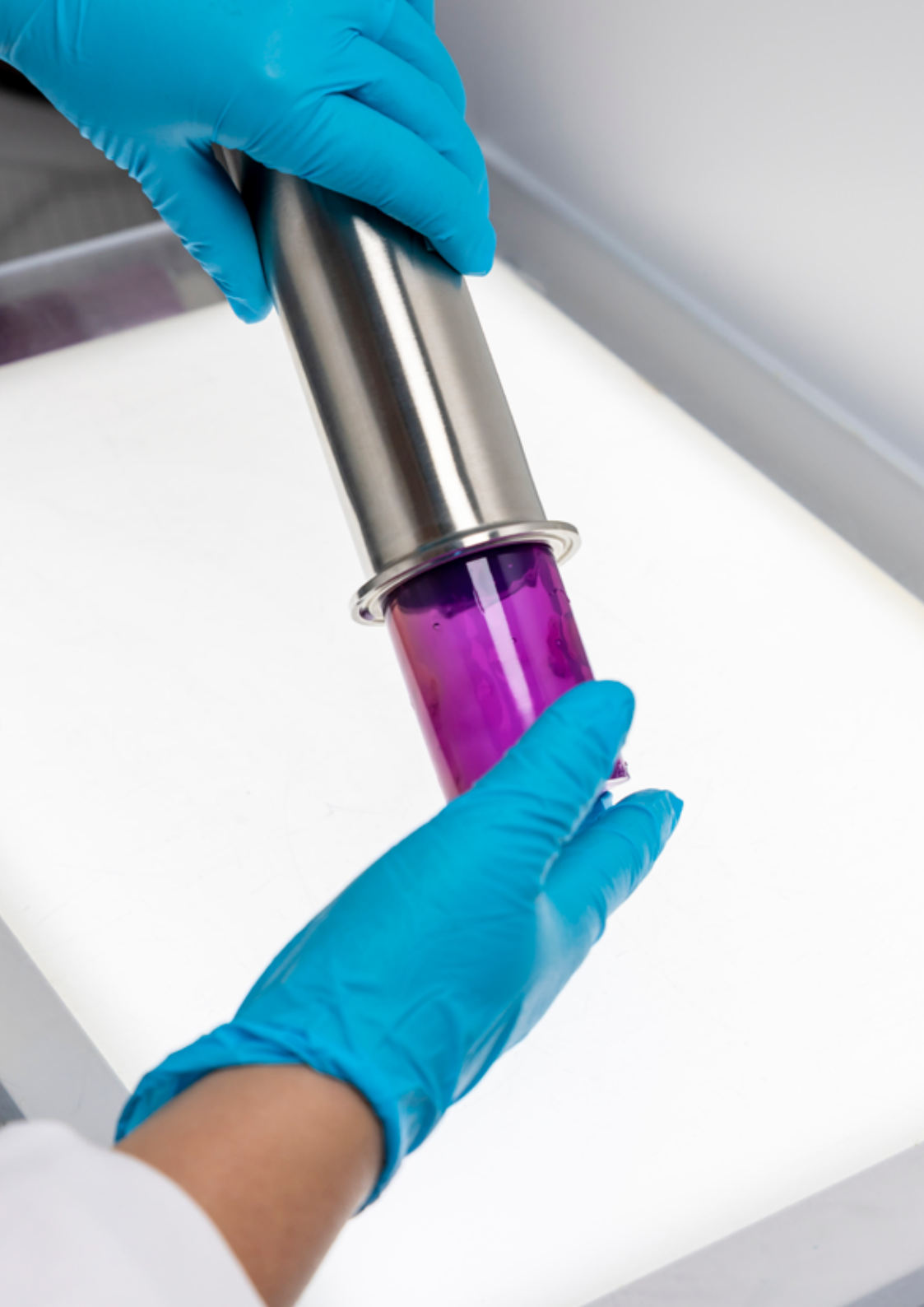
- Material safety: Materials that come into contact with food during normal use must not release harmful chemicals into food products.

- Performance: Where relevant, a product must meet minimum requirements for food storage at safe temperatures and cleaning procedures.

Certified equipment can be found on the NFS website. The NSF mark is not especially common on food processing equipment in EU, but some products have obtained this certification, such as hand dryers.

7.8 USDA

The US Department of Agriculture (USDA) and the Agriculture Marketing Service (AMS) offer two voluntary programmes for food processing equipment review and certification: one for dairy production and one for meat and poultry production. The AMS has its own specialists who assess equipment using both technical drawings and instances of the actual equipment. The review often takes place with the participation of design engineers. Equipment manufacturers themselves decide whether to have their equipment certified; certification permits the use of the official AMS mark on their equipment (for meat and poultry equipment only).



8. Certification of easy to clean equipment

Certification of hygienic process equipment according to internationally recognised standards assures end users of the equipment's cleanability. Certification provides a good foundation. It shows that the manufacturer has put thought into the design and followed guidelines from one or more internationally recognised organizations in the design process. The two main certification programmes for hygienic and sanitary equipment for the food and pharmaceutical industries are from EHEDG and 3-A SSI. They are not mutually exclusive; some equipment is certified by both organisations.

8.1 EHEDG certification

EHEDG offers several types of certification programmes that benefit equipment vendors and food manufacturers. Equipment vendors can have their equipment certified if it meets the EHEDG's criteria. In some cases, certification is only granted after testing at an accredited laboratory using the EHEDG's testing methods. Food manufacturers are then able to choose equipment that has been objectively recognised as hygienically designed. Of course, they must still validate the suitability of the equipment for their intended use.

8.1.1 The EHEDG's Certification Programme

The certification programme has two main categories: one for wet processes (designated EL) and one for dry processes (designated ED). There are several subgroups; typically, two classes of certification are offered:

- Class I, in which equipment must be cleanable without disassembly.

- Class II, in which disassembling equipment during cleaning is allowed (and, in fact, required). Class II certifications are issued only if disassembling the equipment for cleaning is both possible and realistic.

The design requirements for Class I are stricter than those for Class II, but in both cases, the equipment must be hygienically designed and adhere to the EHEDG's guidelines. Functional deviations in gaskets, shaft seals, and distances within the equipment can be accepted, though.

The certification categories are:

- EL (Class I & II) is for closed process equipment with wet or dry products and with a wet cleaning process. Class I is for components intended for processing facilities that use CIP cleaning. Class II components are typically

removed from the CIP area and cleaned individually, with some degree of disassembly required. EL Class I is the only category that can currently be supported by testing. This means that minor deviations from the criteria can be permitted, and certification is possible if the component passes the test described in EHEDG Guideline no.2.

- EL Aseptic (Class I & II) is largely the same as above. The equipment must meet the ordinary EL requirements. It must also be sterilisable and impenetrable by bacteria.

- EL Class I AUX is for open equipment and auxiliary equipment. Unlike the other categories, there is no option for disassembly during cleaning in this category. This means that only equipment that can be cleaned through normal cleaning procedures can be certified.

- ED (Class I & II) addresses processes where production and cleaning alike are dry processes. This category includes a strict requirement that no water be present. The absence of water allows for more lenient design criteria in both classes. Class I equipment includes pneumatic conveyance systems, valves, and sensors; Class II equipment includes rotary valves, mixers, metal detectors, and hoppers.

EHEDG certification is performed by an Authorised Evaluation Officer (AEO) associated with an EHEDG Authorised Testing Laboratory (ATL). The laboratory must also be nationally accredited according to ISO 17025. There are eight ATLs, some of which have more than one AEO. AEOs are actually members of the EHEDG's Testing & Certification Subgroup, which holds frequent meetings to ensure consistency across decisions, as well as to conduct quality assurance on the certification process and the testing methods used.

→ FORCE Technology is an EHEDG ATL

FORCE Technology is the only institute in Northern Europe accredited to perform EHEDG testing for certification of EL Class I equipment. This is an integrated part of the Centre for Hygienic Design, which also includes other industry services: cleaning validation according to non-EHEDG protocols; functionality, durability, and composition testing for steel and plastic; service life calculation for rubber gaskets; etc. Additionally, FORCE Technology offers various hygienic design training programmes.

8.1.2 The EHEDG certification process

Obtaining an EHEDG certification involves the following steps:

1. The business must register with the EHEDG certification database and choose an AEO, who will contact the business to arrange the rest of the process. The AEO will ensure that the correct classification class and category have been selected.

2. Then, the first step is a theoretical design evaluation using 2D drawings of the component to determine whether the component meets the EHEDG's design criteria as specified in Guideline 8, other relevant guidelines, the EHEDG's Position Paper with the use of approved process and pipe couplings, and the Supplementary Certification Requirements (SCR) when applicable. If there are circumstances that require clarification, the AEO can address them at meetings with the rest of the group. From here, there are three possibilities:

    a. If the component is found not to meet the design requirements, the applicant is informed of the deficiencies so that they can correct them and reapply for certification.

    b. If the component is found to be 100% compliant with the design requirements, the design evaluation continues. The applicant submits a physical copy of the component for design review, surface roughness measurements, and gasket material inspections.

    c. If the component was submitted for an EL Class I certification, it may be found to meet the design requirements with a few minor deviations that can be verified through cleaning testing. The remainder of the process is as described in point b. Thereafter, the component proceeds to testing as described below in point 4.

1. The product of the theoretical design evaluation (point 2) is a report called a design review. If the component meets the certification requirements, this review will serve as the basis for the final certification report. If the component cannot be certified, the company will not receive a design evaluation report.

2. If testing is to be performed as part of an EL Class I certification, a worst-case scenario is typically selected for testing. There may be exceptions to this, such as if the applicant wishes to certify only one size of a component, or if there is only one relevant process coupling. The worst-case scenario is

selected collectively by the AEO group based on a number of standard criteria (documented in the EHEDG guidelines or the SCR) used to identify the size, model, process coupling, or configuration that will be most difficult to clean. In some cases, the selection process is assisted by CFD simulation of the flow through the component. The selection depends on the component in question, and this process is always performed in close dialogue with the business.

3. The test is performed according to the "in-place cleanability of small and moderately sized closed equipment" method. This test is described in EHEDG Guideline 2 (testing methods are described in Chapter 8.1.3). To achieve certification, the component must pass three tests showing that the component is more cleanable than a straight pipe, represented by a reference pipe. A maximum of five tests may be performed. Each type of gasket material to be certified must pass the test. If the component passes, a testing report is prepared and included in the certification.

4. To conclude the process, the AEO prepares a certification report containing the design review report and a conclusion on the overall evaluation. Any testing reports, drawings used in the design review, and relevant documentation of hygienic installation, cleaning, and maintenance from the business may also be included.

5. In collaboration with the applicant, the right title for the certificate must be chosen. The title must include all variants of a component covered by the certificate, and it must exclude all those that the certificate does not cover. Additionally, the gasket materials that have passed the test must be named specifically. As a result, the titles can be rather long.

6. The certification report is subjected to peer review in the AEO group for quality assurance. In the case of a certificate based solely on a design review,

→ Examples of worst-case scenarios selected for testing

A sensor that may be mounted in various EHEDG-approved process couplings can be certified for all of them if it passes testing in one of these.

For a pump, a typical worst-case scenario will involve the pump with the lowest rotational speed and the greatest internal volume relative to the inlet diameter. For a centrifugal pump, the diameter of the impeller (e.g.) must also be considered, and the worst-case scenario will involve a small impeller in a large housing.

the report is sent to all AEOs for approval. Certifications based on a testing report are approved by one other AEO.

7. After approval, the complete set of documentation is uploaded to a restricted area of the EHEDG website that only the business can access. A summary document called Appendix 3 is prepared, containing unique references to all reports, drawing numbers, and other documentation on which the certificate is based. Appendix 3 also contains signatures from AEOs, and a certificate is prepared based on its contents. The certificate contains class and category information, as well as the month and year in which it was issued. The certificate and the corresponding Appendix 3 are both publicly available. The certificate is issued by the EHEDG.

EHEDG permits the applicant to use the EHEDG certification logo on the certified equipment and in marketing materials for it. Certifications must be renewed every five years, which requires the theoretical evaluation to be repeated. Typically, testing reports may be reused if there are no changes to the design that affect its hygienic functionality. A renewal fee is charged each year. All certificates are available from the EHEDG website.

tests. Resultatet af hver test bliver altid formidlet til virksomheden. Hver type af pakningsmateriale, som ønskes certificeret skal bestå testen. I de tilfælde, hvor komponenten består, udarbejdes en testrapport, som indgår i certificeringen.

8.1.3 EHEDG testing methods

The EHEDG's guidelines for various testing methods are publicly available, and they are reviewed regularly. This work is also conducted by the Test & Certification Subgroup.

The most commonly performed test is called "in-place cleanability of small and moderately sized closed equipment". It demonstrates that EL Class I equipment can be cleaned at least as well as a straight piece of pipe using CIP; the method is described in EHEDG Guideline 2.

The method is based on comparing the cleanability of a component with the cleanability of a reference pipe. The steps in the testing methods are:

1. The object to be tested is cleaned and sterilised along with the reference pipe

2. The object and reference pipe are soiled with a mixture of buttermilk and a concentrated Geobacillus stearothermophilus spore suspension. This is a thermally resistant spore. To ensure that the spores are able to reach all

corners and edges, the soiling is conducted at a pressure of 5 bars for 3 cycles of each 2 minutes duration.

3. The objects are dried using dry air for at least 2 hours and until all of the buttermilk has dried on the surface of the component.

4. Then, a mild cleaning process is conducted with a specially designed cleaning agent. The cleaning process is designed so that a small number of spores will remain in the reference pipe. This is necessary for a reliable comparison.

5. The objects are then completely filled with an agar growth medium that has been heated so that it is liquid. The objects are cooled to allow the agar to solidify, and they are then incubated at 58°C for 16 to 24 hours. The exact time depends on the batch of buttermilk and spores.

6. The growth medium is purple, but any spores present during the incubation will trigger a pH change, changing the colour of the agar to yellow. For the test to be valid, 5% to 30% of the growth medium in the reference pipe must turn yellow. To pass the test, the component being tested must have less yellowing than the reference pipe. If yellowing is observed on the object being tested, it must be randomly distributed across the three tests to pass.

When certifying components for their hygienic function in aseptic processes, steam sterilisability and bacteria tightness tests are performed. The methods for these tests are described in EHEDG Guidelines 5 and 6; however, because they are not very widely used, they are not described in detail.

EHEDG is in the process of developing a new testing method that can be used to support the certification of open facilities. It is not clear when the method will be ready for use, but it is likely to be offered at some point in 2022.

8.2 3-A SSI's certification

3-A SSI's certification programme is based on an evaluation of working drawings and an on-site inspection of components and the manufacturing process.
This is performed by an independent third-party auditor known as a Certified Conformance Evaluator (CCE). The process is called Third-Party-Verification (TPV). The TPV programme is used for all equipment built according to 3-A's sanitary standards and licensed to use the 3-A symbol. A licensee must engage a CCE to conduct the required on-site evaluation of finished equipment and other product attributes, and to confirm that the equipment adheres to the provisions of the applicable 3-A Sanitary Standard. Any defects discovered during an inspection must be remedied before the equipment can display the 3-A symbol. Equipment

manufacturers that do not comply with TPV inspection requirements risk losing the license to use the 3-A symbol.

3-A SSI's website contains all of the information on obtaining a license to use or display the 3-A symbol. The site also offers publicly available certificate information for all 3-A Symbol licensees. This public information gives details about the models and equipment covered by a business's license. The site supports searching for information by authorisation number, equipment type, standard, and company name. A copy of the actual authorisation certificate can also be printed from this database.

8.3 EHEDG and 3-A SSI

The largest formal differences between the two certification programmes are:

- The EHEDG can use test results to support certification; 3-A SSI does not do this.

- 3-A SSI visits businesses to verify that they actually meet the specifications in their drawings; the EHEDG does not do this.

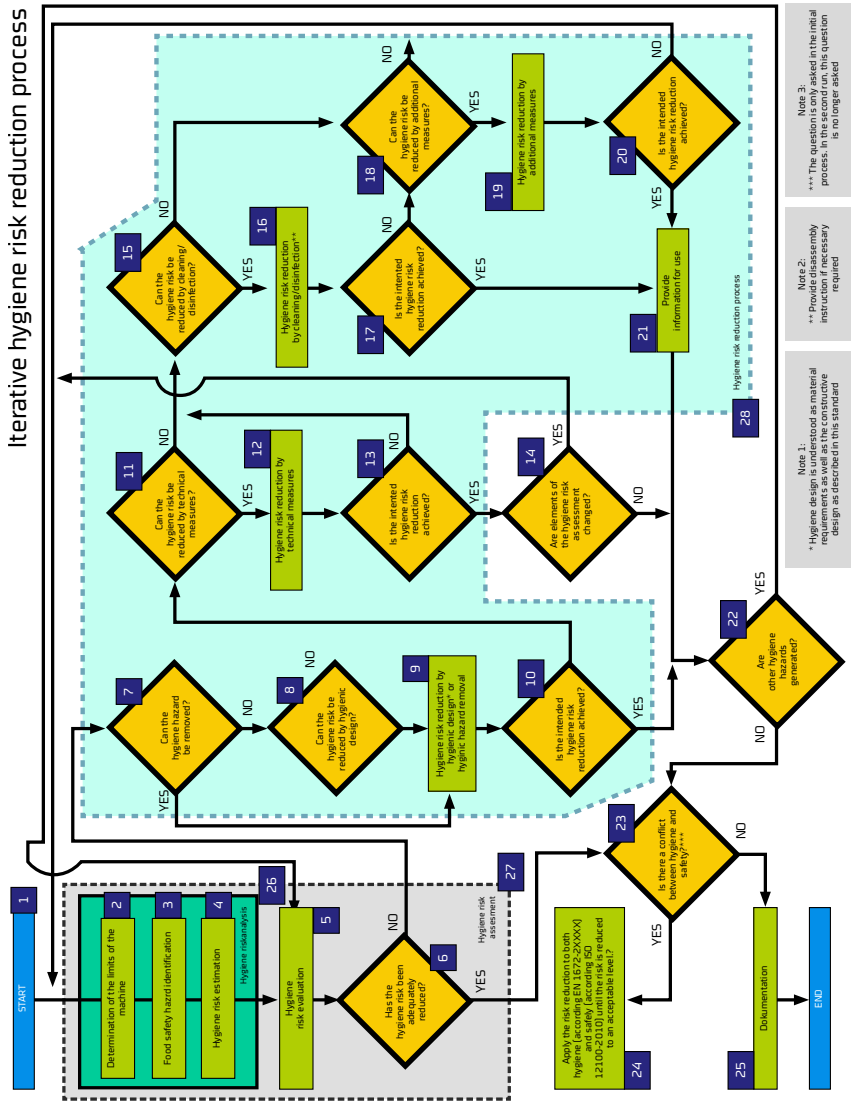
Apart from this, both programmes are based on evaluation against guidelines, though the guidelines vary slightly. Neither certification programme is clearly better than the other. As mentioned previously, some equipment manufacturers have certificates from both the EHEDG and 3-A SSI to cover a wide range of markets.

In conjunction with the launch of the GFSI's new benchmarking requirements, J1 and J2, the EHEDG and 3-A have jointly published a document on how the necessary hygienic design knowledge can be provided.

9. Alphabetical index

10. Appendix

Appendix 1:
The risk handling flow chart from DS/EN 1672-2:2020



Appendix 2:
Information to include in declarations of conformity

The declaration of conformity on a machine or process is intended for the manufacturer to declare the proper application of this in contact with food products. Therefore, it should contain a clear definition of either the scope of application or the specific intended use and also any limitations arising from decisions made based on risk assessment during the design specification. The application can be broad or narrow as the manufacturer sees fit.

It is relevant to state that the basic legislation has been applied in the design process by referencing the Machinery directive and any harmonized standards or other standards which have been applied to obtain conformity with the directive and for justification of application of the CE-mark. The standard EN 1672-2:2020 (or ISO 14159:2008) should be mentioned to show knowledge of how to perform proper risk assessment and risk mitigation.
The material regulations 1935/2004 and 2023/2006 should also be listed as they document knowledge on specification and handling food contact materials and requirements for traceability and application good manufacturing procedures during the build of components and machines.

The applied construction materials should also be documented in a manner that shows that these are appropriate for the intended use. This can be done in greater or lesser detail, but the minimum would be to reference any legal requirements like regulation 10/2011 for plastic.

The selection of the materials applied should be based on a risk assessment of the corrosion risk arising from the product and the cleaning procedure.

Stainless steel

Often this selection is based on experience and tradition which is fine and either 1.4307 for open processes or 1.4404 for closed processes is often sufficient.

A more detailed documentation could contain a selection based on the pitting equivalence resistance number (PREN) and one of the guidelines produced in EU like the one from the Danish Food Authorities or the French equivalent.

Plastic

The plastic materials applied must comply to the specifications of regulation 10/2011 which may require testing of materials in contact with model foods. It is important to be certain that the testing conditions match the conditions in the actual application. Thus, temperature ranges may be relevant to state.

Rubber

There is no EU regulation on rubbers, thus manufacturer declarations documenting absence of migration from the tubber is pivotal. Please notice that compliance to FDA regulations is not enough in EU.

Appendix 3:
European and American notations for types of steel

With European and American notations and corresponding PREN

Type	AISI	EN	%Cr	%Ni	%Mo	%N	PREN	Comment / tradenames
Ferritic	430	1.4016	16.0	-	-	-	16	
	439	1.4510	16.0	-	-	-	16	
	441	1.4509	17.5	-	-	-	17.5	PREN like 1.4301
	444	1.4521	17.5	-	1.8	-	22.9	PREN like 1.4401
Martensitic	410	1.4006	11.5	-	-	-	11.5	
	420	1.4021	12.0	-	-	-	12.0	
	420MoV	1.4116	14	-	0.5	-	15.7	
	440C	1.4125	16	-	0.7	-	18.3	
Austenitic	304	1.4301	17.5	8.0	-	-	17.5	
	304L	1.4307	17.5	8.0	-	-	17.5	Low carbon
	316	1.4401	16.5	10.0	2.0	-	23.1	
	316L	1.4404	16.5	10.0	2.0	-	23.1	Low carbon
	316L	1.4435	17.0	12.5	2.5	-	25.3	Low carbon
	904L	1.4539	19.0	24.0	4.0	-	32.2	
	926	1.4529	20.0	24.0	6.0	0.15	42.2	Super austenitic
	254SMO	1.4547	19.5	17.5	6.0	0.18	42.2	Super austenitic
	654SMO	-	24.0	22.0	7.3	0.50	56.1	Very high N steel
	-	1.4652	22.0	21.0	7.0	0.45	52.3	Super austenitic

Type	ASTM/ ASME/ AISI	EN	%Cr	%Ni	%Mo	%N	PREN	Comment / tradenames
Duplex	S32304	1.4362	22.0	3.5	0.1	0.05	23.1	
	329	1.4460	25.0	4.5	1.3	0.05	30.1	
	S31803	1.4462	22.0	4.5	3.0	0.10	31.9	
	A182F53	1.4410	24.0	6.0	3.0	0.24	37.4	Superduplex
	Alloy 2507[1]	-	25.0	7.0	4.0	0.27	42.5	Superduplex
Other types	Alloy C22 [1,2]		22.0	56.0	13.0	-	64.9	Hastelloy® C22
	Alloy C276[2]	2.4819	16.0	57.0	16.0	-	68.8	Hastelloy® C276
	Alloy 625	2.4856	20.0	58.0	8.0	-	46.4	Inconel[3] 625
	630	1.4542	17.0	4.0	-	-	17.0	Alloy 17-4 PH[4]

Inconel vs basic austenitic stainless steel

Inconel is much more expensive than the basic austenitic stainless steel alloys. Inconel has much better corrosion resistance and strength at high temperatures. However, at lower temperatures, steels like 17-4PH stainless will have a higher strength than Inconel. When deciding between the two different alloys, the main deciding factor is cost, temperature, and strength. If a lower cost, but relatively strong part is required, a basic austenitic stainless steel is probably the way to go. If an oxidation corrosion critical component is required in high temperature environments, then Inconel is the better alloy for that application.

[1] *Cost-effective vs 904L and SMO254*

[2] *Hastelloy C22 and C276 are nickel-molybdenum-chromium superalloys with an addition of tungsten designed to have excellent corrosion resistance in severe environments. The high nickel and molybdenum contents make the nickel steel alloy especially resistant to pitting and crevice corrosion in reducing environments while chromium conveys resistance to oxidizing media. Hastelloy C22 is more readily available than Hastelloy C276*

[3] *Inconel is a registered trademark of Special Metals Corporation for a family of austenitic nickel-chromium-based superalloys with very high nickel content.*

[4] *Alloy 17-4PH is a chromium-nickel-copper precipitation-hardening martensitic stainless steel with an addition of niobium. 17-4PH combines high strength and hardness with good corrosion resistance (comparable to 1.4301). It is used in applications where the combination of moderate corrosion resistance and unusually high strength are required.*

Notes

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