21ST INTERNATIONAL CONFERENCE ON ENGINEERING DESIGN, ICED17
21-25 AUGUST 2017, THE UNIVERSITY OF BRITISH COLUMBIA, VANCOUVER, CANADA

NEW WAYS OF HYGIENIC DESIGN – A METHODICAL APPROACH

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Abstract

Hygienic design is a necessary topic in developing food processing machinery. Designers have access to plenty of guidelines that support embodiment design and detailing of certain equipment. Earlier phases receive little attention in terms of Hygienic Design. Furthermore, developing products that are not covered by any guideline is a laborious challenge. This paper presents an extended approach of Hygienic Design in order to consider earlier product developing phases. Analysing use phase processes and the investigation with regard to their categorization lead to formalised Hygienic Design requirements. Allocating over 70 existing guidelines to fundamental damage processes "adhesion", "accumulation", "intrusion" and "abrasion" offers a new systematic scheme of a guidelines categorisation, which provides an extended understanding of Hygienic Design. In order to illustrate benefits of using Hygienic requirements in early phases, influencing possibilities are illustrated by an example.

Keywords: Design for X (DfX), Process modelling, Early design phases

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Please cite this paper as:
Surnames, Initials: *Title of paper*. In: Proceedings of the 21st International Conference on Engineering Design (ICED17), Vol. 5: Design for X, Design to X, Vancouver, Canada, 21.-25.08.2017.

1 INTRODUCTION

Customers' expectations on food quality are very high, but many current food processing machines cannot meet hygiene requirements. Cutting spoiled parts of food was common practice in the past - today food is often disposed if there is a suspicion of contamination (BMEL, 2014). This example shows the importance of impeccable product quality in terms of food production. In addition to the health of consumers, hygienic production also reduces the amount of rework and rejects of food products (Hauser, 2008b).

Product designers of food processing machinery face the challenge to fulfil product functions under condition to satisfy hygienic requirements. Guidelines of Hygienic Design support designers during the phase of embodiment design or detailing by giving information about possibilities to minimise the risk of contamination (Hauser, 2008b), which does not fully exploit the potentials of Hygienic Design since these guidelines are not considered for early phases. They mainly contain figurative illustrations as examples that show design suggestions for specific components. Applying these guidelines to other components is not sufficiently possible since they mainly describe the individual detailing. Developing machines, which cannot be included in any category of the existing Hygienic Design guidelines, is therefore very difficult, Figure 1.

This paper proposes a new framework for the generalization of the Hygienic Design guidelines. On the one hand, this frameworks aims at the transferability of the guidelines to other components; on the other hand, this approach intends at the support of designers in earlier phases of the product development. The goal is to modify the principles of Hygienic Design to support designers methodically at each phase of the product development process. The basis of this approach is a systematic analysis of the processes of the use phase using the process model. Analysing the use-processes leads to the identification of the so-called "*fundamental damage processes"*, which provide an early consideration of Hygienic Design requirements.

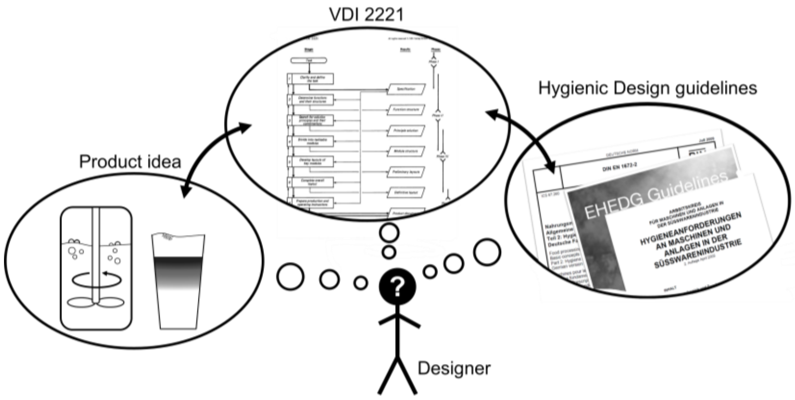

Figure 1. Product designer in the field of tension of developing hygienic products

2 STATE OF THE ART AND REASONING THE NEED FOR ACTION

Machines that process food or are in contact with food must always fulfil the principles of Hygienic Design. The following sections will cover the state of the art and the limits of implementation for Hygienic Design principles in terms of methodical product development.

2.1 Literature overview

Machines and equipment used for the processing of food are subject to Hygienic Design requirements. The requirements aim at the minimization of the risk of contamination to ensure the protection of the food consumers (Hauser, 2008b). Based on legal regulation, experts in the field of Hygienic Design have created several guidelines - provided by organisations like European Hygienic Engineering & Design Group (EHEDG) - to support the development of hygienic products and equipment. These guidelines mostly provide information about *positive and negative examples* of selected equipment, sub-systems or system elements (DIN EN 1672-2:2009, 2009, Hauser, 2008a).

Food processing machinery is structured into different areas depending on the distance between machine components and the processed food. EHEDG (2004) proposes to differentiate between three major

Hygienic Design areas: food area, splash area and non-food area. Depending on the classification of the component, they are subject to more or less strict requirements due to hygienic aspects. For example, drives or control cabinets, which do not come into contact with the food on purpose, have less strict Hygienic Design requirements than a stirrer that is in direct contact with the food on purpose (VDMA, 2002). A typical example for a Hygienic Design guideline is to round off inner edges instead of keeping a sharp 90-degree angle, Figure 3. This instruction refers to the detailing of the embodiment and aims at the prevention of food adherence. Furthermore, another recommendation is to avoid gaps between components or so-called dead spaces or dead water cavities in the food area (DIN EN 1672-2:2009, 2009, EHEDG, 2004).

A further criterion for a machine or equipment according to Hygienic Design requirements is the ability of a simple cleaning process. This includes two different processes: the cleaning of the machine as the basis for a food changeover within the machine as well as the thorough cleaning at the end of the production. There is a basic distinction between to two cleaning procedures: "Cleaning in Place" (CiP) and "Cleaning out-of Place" (CoP). Machines with the ability of CiP do not need a disassembly whereas machines with CoP-ability are cleanable only after dismantling (EHEDG, 2013). In addition, there are machines, which, although they are capable of cleaning in an assembled state, require manual cleaning. The determining factors for the required type of cleaning are in particular the embodiment design of the machine and the properties of the processed food (Hauser, 2008a).

However, Hygienic Design is not only a legal obligation: through a systematic consideration of the requirements, there are chances of competitive advantages and scope for innovation (Juriaanse, 2006). Machines and equipment that meet Hygienic Design requirements are easier to clean, which results in a reduction of cleaning time and increased productivity. (Hofmann, 2007). By simplifying the cleaning processes, it is also possible to reduce the amount of detergent and water or wastewater (Tamime, 2008).

2.2 Analysis of the current Hygienic Design approach

Figure 2 illustrates the current approach of the development of food processing machinery with the help of the Hygienic Design guidelines. For the selection of material criteria and lists exist that recommend certain materials for use in food processing machinery, Figure 2 - (a) (for example "temperature-resistant", "abrasion-resistant"). There are also requirements for acceptable joining technologies in terms of adhesives, welding specifications, detachable connections etc. and manufacturing technologies. All these requirements are part of the requirements list during the clarification of the task and designers need to consider them during the entire development process (Pahl *et al.*, 2007).

Besides the mentioned lists, which refer to material selection and production, there are so-called Hygienic Design suggestions or *Hygienic Design guidelines*, Figure 2 - (b). For this purpose, several organisations (EHEDG, 3-A, VDMA) have developed guidelines with the help of experts from various specialist disciplines (Hauser, 2008b). In order to support developers of food processing machinery they have developed practical examples for an easy-to-clean design. These guidelines are also available to designers at the beginning of development, but they are particularly suitable for use in the phase of embodiment design or detail design (Hauser, 2008a), Figure 2 - (c).

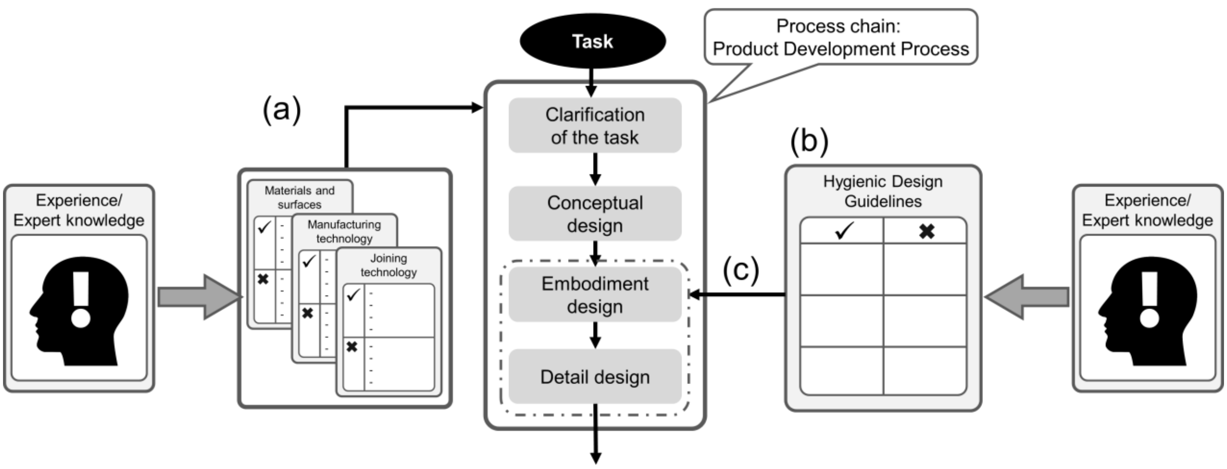

Figure 2. Current Hygienic Design approach

2.3 Limited possibilities of Hygienic Design by using existing guidelines

In early stages of product development (clarification of the task, conceptual design), possibilities of influencing the functionality of products and considering specific requirements are still very high and involve comparatively little effort or cost (Ehrlenspiel *et al.*, 2007).

Different organisations have developed various guidelines (e.g. in the form of "more"- and "less"-recommended examples) to support the process of Hygienic Design. Almost all Hygienic Design requirements refer to the food area. Less strict requirements refer to the splash area or non-food area. However, there is no general classification within the guidelines.

The< authors and organizations structure the developed guidelines individually, but the ideas of the guidelines overlap within their basic requirements, Figure 3. DIN EN 1672-2:2009 (2009), for example, structures the content according to the relevant area. EHEDG (2004) differentiates between the segments: materials of construction, functional requirements and construction. Hauser (2008a) outlines very specific examples giving representations of components, machines and systems, which have proven in practice to fulfil the requirements Hygienic Design.

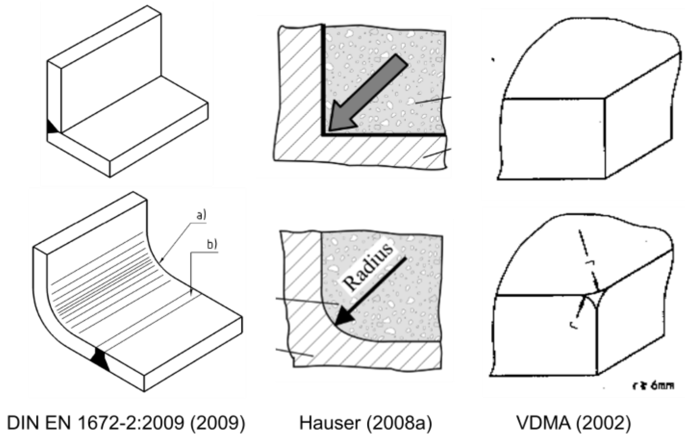

Figure 3. Different forms of presenting the same Hygienic Design guideline

Figure 4 illustrates a brief compilation of some exemplary guidelines and the associated requirement or explanation from different sources. It is noticeable that these design examples refer to very different issues. The formulation of the guidelines differ in terms of concretisation. For example, the requirement "rounding corners" is quite general, Figure 4 - (c), while the prohibition of screws in the food area, Figure 4 - (f), is very component-specific.

During the development process, designers have to ensure that the product design meets the Hygienic Design requirements in multiple decisions (Pahl *et al.*, 2007). In order to assist the decision making or the concretisation of properties, designers need to select appropriate guidelines.

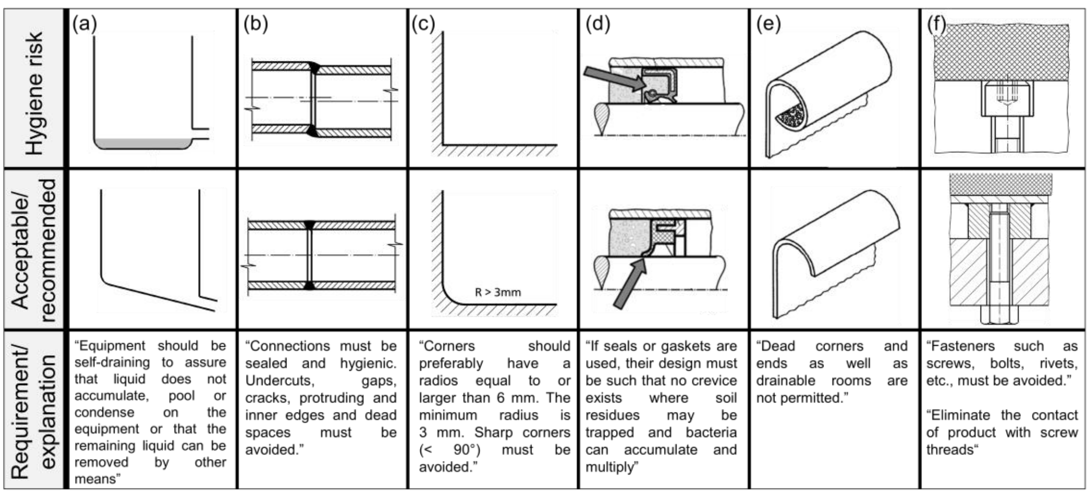

Figure 4. Compilation of existing guidelines (DIN EN 1672-2:2009, 2009, Hauser, 2008b; VDMA, 2002)

The following sections present an approach for the methodical support of designers in the field of Hygienic Design. Based on established guidelines, the new approach is characterised by the systematic analysis of use-processes and extension of content of current guidelines.

3 EXTENDED APPROACH FOR HYGIENIC DESIGN

The key steps of the extended approach are the systematic analysis of the processes of the product use phase (of the machine or the equipment), determination of requirements as well as the extension and generalisation of existing requirements. Finally, this section shows that the guidelines as well as the methodically determined requirements aim for the prevention of so-called "*fundamental damage processes*" (discussed in section 3.2). Designers can use the findings about damage processes to reduce risks of contamination considering earlier decisions within the development process.

3.1 Structure of the extended Hygienic Design approach

Figure 5 illustrates the structure of the extended Hygienic Design approach based on the current approach of Figure 2. The model represents an extension of the model of holistic product and process development of Birkhofer et al. (2012): it merges the product development processes (based on the methodology of VDI 2221 (1993)) with the product life process cycle chain.

Late consideration of Hygienic Design requirements may lead to iteration loops during the development if the concretisation of the chosen concept cannot be achieved in a hygienic manner. Thus, it is desirable to extend the scope of Hygienic Design as described in the following.

If hygiene requirements are not met, there is a risk of contamination of the food within the use-phase of food processing machinery or products. Therefore, it is useful to analyse the main processes of the product use-phase (operation, cleaning-in place, cleaning out-of-place, changeover, maintenance) systematically using the process model, Figure 5 - (b). This analysis results in hygiene requirements for the machine. The following section shows that the requirements from the process model aim at preventing the undesired interactions and disturbances, which are the reason for contamination. Existing design guidelines must also pursue the same goal in order to fulfil requirements of preventing contaminations. Thus, Hygienic Design guidelines provide component-specific design solution to fulfil these requirements (see Figure 5 - (a)).

The approach therefore assumes that the identified Hygienic Design requirements support the developer in each phase of the development process. They are comparable to "classical" requirements and allow early influencing of the product.

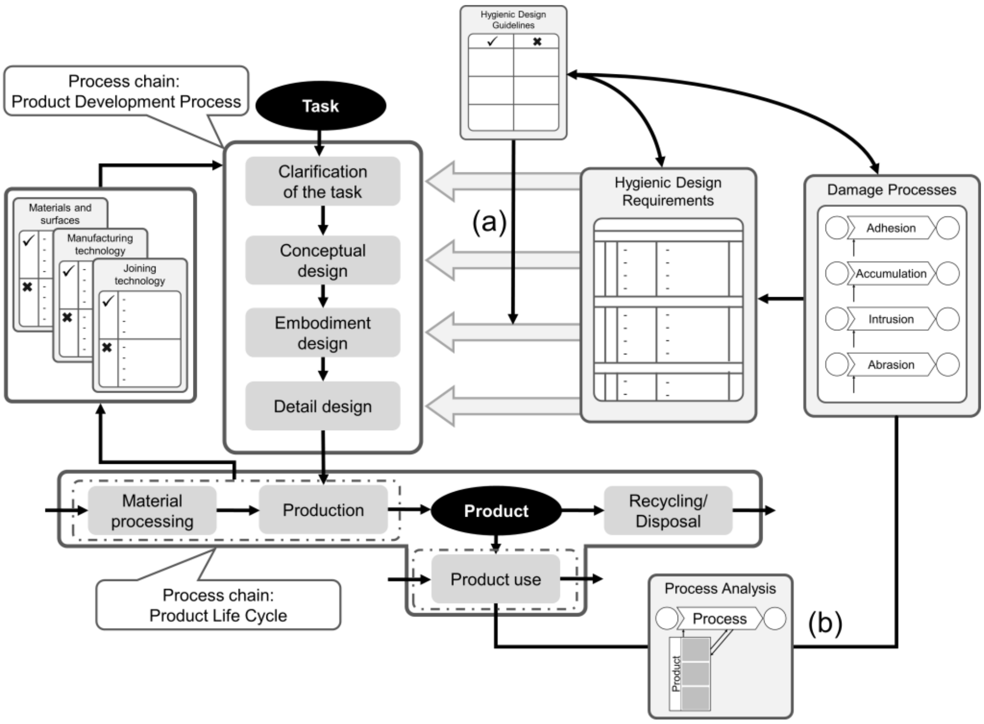

Figure 5. Overview of the extended approach referring to Birkhofer et al. (2012)

3.2 Detection of fundamental damage processes

The extended process model, Figure 6 (Beetz and Kloberdanz, 2016), represents a Hygienic Design adjusted extension of the process model according to Kloberdanz *et al.* (2009). Due to the structure of the model, a detailed analysis of the processes of the product use phase is possible. The focus of the model is the determination of disturbances, interactions and incidental quantities (sloping arrows). The goal of a Hygienic Design is minimizing unwanted influences.

An automatic milk frother serves as an example to explain the process model. The "process" represents the purpose of the product, Figure 6 - (a). In this case, the process is the *heating and foaming* of milk (representing the operand) using the milk frother (product). All sloping arrows are unwanted influences whose occurrence designers have to prevent. The following step is to determine successively these influences. The division of the machine and the environment into the different Hygienic Design areas facilitates the analysis. It is therefore necessary to distinguish between "disturbances", Figure 6 - (c) which are *eliminable* and "interactions" which are *ineliminable* because of the nature of the process

Starting with the process, there are, for example, interactions between the process and the product in particular with its three areas, Figure 6 - (b). In the case of the milk frother, for example, particles from the food area dissolve from the storage container and contaminate food. As mentioned before, this interaction is not completely eliminable caused by choosing the specific characteristic of this process.

Likewise, milk can leak out of the storage and ingress into area of the drive (non-food area). Furthermore, it is also possible that milk pour into gaps or crevices of the storage.

The analysis of the disturbances from outside the systems boundary shows that either the product itself or the food is affected, Figure 6 - (c). An example for a disturbance is a user who touches food or components of the food area by hands. In addition, the entry of dust or comparable particles into the food area is not wanted. Likewise, the spillage of milk into the environment is undesired.

The process analysis allows the systematic detection of unwanted interactions. Sloping arrows always point in both directions in the process model. Thus, there are cases where elements of the process model are source for interactions on the one hand and target on the other hand.

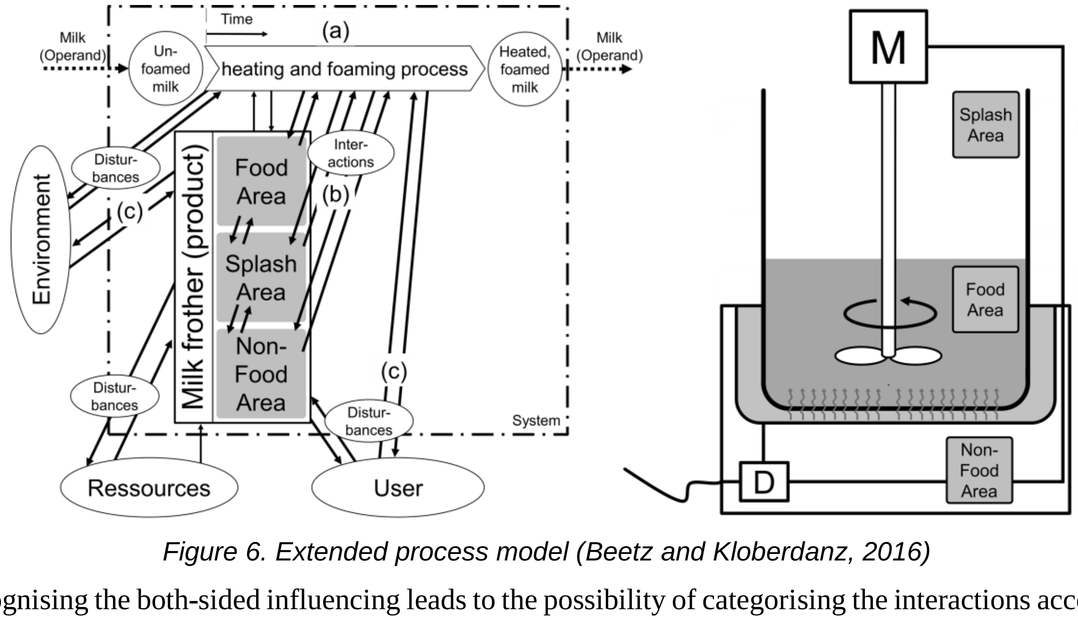

Figure 6. Extended process model (Beetz and Kloberdanz, 2016)

Recognising the both-sided influencing leads to the possibility of categorising the interactions according to their direction. By gathering the disturbances and interactions, it is possible to classify them into four different "*fundamental damage processes*". This constitutes an extension of Hygienic Design, which goes beyond previous definitions and the state of the art by abstracting the basic goals of Hygienic Design principles, Figure 3 - (b).

As mentioned, there is a difference of contaminating processes between the contaminating of the food by *ingress of foreign matter* and the food contamination by *permanent adhesion or intrusion* into the machine. Nevertheless, both types of processes lead to contamination. It is important to consider this double-sided source. It is also important to consider the fundamental damage processes as *processes* since they cause a state change of an operand (even if that is not the intension). Another important characteristic of a process is the existence of a working factor that initiates the process (Heidemann, 2001). It allows the analysis of the damage processes with regard to their working factor. Therefore, the

goal of Hygienic Design must be either to minimise or contain the working factor or to alleviate the effects.
The following section briefly describes the characteristics of the newly defined damage processes and presents possibilities of influencing by designers.

3.2.1 Adhesion of matter

Adhesion in the case of food processing means sticking food on surfaces. There are several theories about the cause of adhesion. A common reason for this effect are surface forces. These forces include molecular interactions in the form of tangential forces and normal forces. The adhesion force is the required quantity for overcoming the adhesion (Dutschk 2000). The measured value of the surface tension is the contact angle. The contact angle indicates the angle between the surface of the liquid droplet (e.g. food-droplet) and the surface of the solid (Young, 1805).
Designers are able to influence the shape and material of the surface, which relates directly to the adhesion of food. The risk of contamination by adherent food is, for example, the growth of bacteria or moulds within the food.
In the case of the milk frother the risk involves, for example, remaining residues of the foamed milk on the surface of the stirrer after emptying. Designers have therefore to ensure that no milk remains stuck or that remains are easy to clean.

3.2.2 Accumulation of matter

"Accumulation of matter" also relates to remaining food but macroscopically in terms of accumulations. For example, accumulation of food in sinks in which food flows by gravitational force. Accumulation also leads to the growth of bacteria or mould in the case of insufficient cleaning.
The working factor of this process is usually the gravitational force or pressure differences. One way to prevent this damage is to avoid sinks and horizontal surfaces in the food area (EHEDG, 2004).
In the event of overflowing milk by foaming, designers have to make sure that no uncleanable puddles form.

3.2.3 Material abrasion

In addition to the adhesion or accumulation of food, foreign material enhances contamination. Material abrasion represents a further fundamental damage process. The prevention of abrasion of material within the food area or spray area is of great importance. Each detached particle passes directly into the food and leads to contamination (DIN EN 1672-2:2009, 2009).
Various working factors activate the process of material abrasion: chemical energy or friction by relative movement between surfaces represent only examples. Designers are able to influence material abrasion by different properties. Czichos and Habig (2015) provide a comprehensive overview about these properties. They distinguish between the properties of the load and the properties of the structure of the tribological system (elements and their properties and interactions).
The example of the milk frother shows that designer have to take into account that contact with milk does not lead to chemical interactions with the stirrer and the container material.

3.2.4 Intrusion of foreign matter

In addition to the abrasion of material by tribological or chemical reasons in the terms of wear, another damage process is of particular relevance. Besides the abrasion of material, there is a risk of intrusion of foreign matter. The physical state of the foreign matter is solid, liquid or gaseous. Exemplary foreign matters are lubricants, dust or similar contaminants, or even components (e.g. screws).
Designers must ensure that foreign matters do not get into the food. Responsible working factors are, for example, the gravitational force and other external forces. Physical barriers such as advantageous layout arrangements or seals may prevent intrusion.
The concept of the milk frother in Figure 6 shows that the motor placement is above the food area. Leaking lubricant from the engine leads to contamination of food. Therefore, designers must prevent either the cause (position of the motor) or the effects (e.g. by seals).
Extraction and definition of four fundamental damage processes represents an important advance for developing hygienic products - they have not been associated with Hygienic Design so far. Furthermore, damage processes outline the basis of the extended Hygienic Design approach by allowing a definition of unique and extended hygiene relevant requirements.

3.3 Matching of Hygienic Design guidelines with damage processes

The preceding sections contain the gathering of unintended disturbances and interactions by means of process analysis and the process model. These collected factors establish four fundamental damage processes. For a consistent reasoning, it is necessary to ensure that the existing guidelines aim at preventing the occurrence of contamination, in particular at preventing fundamental damage processes. Each of the mentioned fundamental damage processes on its own is responsible for the occurrence of contamination. Hence, there is no need for a combination to contaminate food and make it unusable (Hauser, 2008a). Figure 7 shows the approach for matching existing Hygienic Design guidelines with fundamental damage processes.

In this way, the correlation of Hygienic Design guidelines with fundamental damage processes is possible. Figure 7 shows only a small selection of over 70 evaluated guidelines. The investigation points out which guideline prevents what kind of damage process. The result of this analysis is that each Hygienic Design guideline aims at one or more damage processes.

Matching of the guidelines with the damage processes leads to two advantages: Firstly, design notes refer to individual damage process categories so that they are available to designers in an orderly manner. Secondly, it is possible to develop new, extended guidelines based on fundamental damage processes due to their formalisation. These extended guidelines need to be less specific to the component and allow use at all phases during the product development process. Thus, fundamental damage processes represent the basis of developing extended Hygienic Design guidelines. Their description is solution-neutral by properties of the operand and by means of working factors.

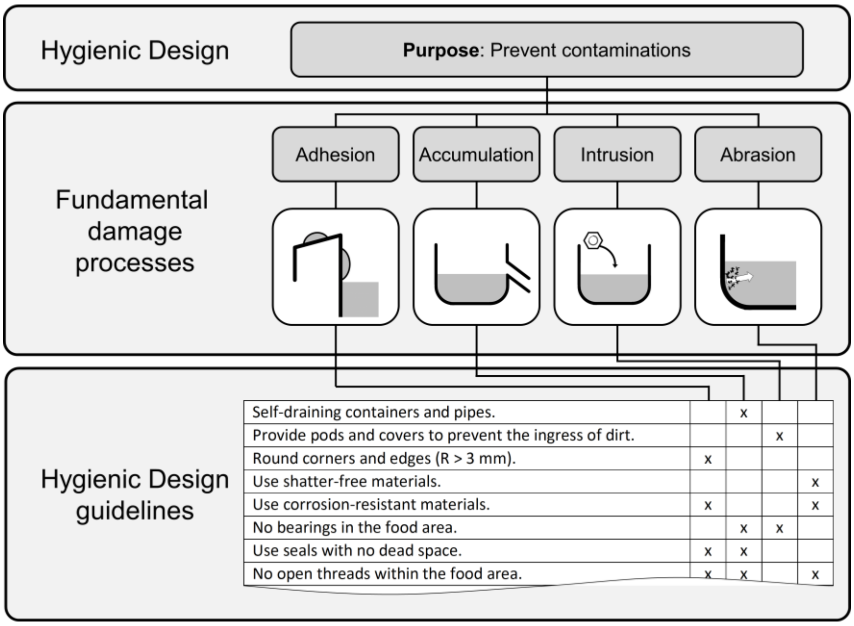

Figure 7. Matching fundamental damage processes with Hygienic Design guidelines

3.4 Benefits for earlier phases of Hygienic Design

An important issue for product development is to archive fulfilment of the product-purpose. For example, developing of a milk frother, the main task of the product is to ensure foaming and, if appropriate, heating of milk. Designers may follow the development methodology of VDI 2221 (1993). The requirements of Hygienic Design therefore do not represent an obvious goal. Customers notice the consideration only indirectly through secondary processes of the product use phase - for example by simplifying the cleaning of the product. Considering Hygienic Design, prevention of the mentioned damage processes is a main objective.

The approach of this paper provides first possibilities for implementation, which do not only affect the phase of embodiment design or detailing. In each development step, designers define product properties. Designers select properties as best as possible according to the requirements. Choosing and defining of properties occurs from the clarification of the task until the last step of the product development process. Every choice of a product property (especially in the food area) must aim at preventing (or not influencing negatively) impacts or incidence of fundamental damage processes. Preventions are possible

at different phases of concretisation. For example, choosing of physical effects, working principles, layout design and rough and detailed design also influence the hygiene of the product.
The following example of the concretisation of a product idea shows the possibilities of the extended approach: The task is developing a hygiene-improved milk frother. The original product version has some weaknesses in the prevention of damage processes, Figure 8 - (a). Starting with the search for an appropriate working principles for fulfilling subfunctions (Pahl *et al.*, 2007), conversion of electrical energy into mechanical energy has an important role in this example, Figure 8, due to the amount of damage processes caused by the drive, Figure 8 - (a). Mechanical effects takes place in the food area. Electrical energy is generally not permitted inside the food area. It is therefore appropriate to critically examine the conversion of electrical energy as well as transferring mechanical energy into the milk. Selecting a working principle, which is based on mechanical transmission of a torque from a drive to a shaft, it is obvious that a seal of the passage is always necessary in a later phase of concretisation. In order to minimise the fundamental damage processes "adhesion", "accumulation", "intrusion" and "abrasion", a mechanical working principle for linking electrical and mechanical energy seems not appropriate. For this reason, it is useful to select a contactless alternative, for example magnetic forces (Koller and Kastrup, 1998), which prevents a mechanical passage (e.g. a hole) through the container, Figure 8 -(b).
After the conceptual design, the embodiment design phase follows. For this purpose, spatial constraints must be identified (Pahl *et al.*, 2007). In terms of Hygienic Design, clarifying the layout design by allocation of food area and non-food area. After the use of the product, cleaning is an important process for the removal of food residues. This includes the requirement that the food area and splash area are separable from the non-food area to archive a simple cleaning. In this example, it is therefore worthwhile to improve the layout by ensuring the separation of the container and the stirrer from the mount and drives. This allows cleaning of all food contacting components, Figure 8 - (b). In addition to decomposability, it is important to ensure that the layout minimises the generation of fundamental damage processes. In this example, drives may not be arranged above the food area, Figure 8 - (a). Even by using seals and other preventions, force of gravity increases the risk of contamination by intrusion of foreign matter. The improvement provides the arrangement of the engine below the food area, Figure 8 - (b).
Finally, Hygienic Design guidelines are still valid for the phase of embodiment design and detailing. This concerns, for example, rounding off corners and edges in the container or the prohibition of open threads in the food area. As mentioned before, the guidelines do not cover all areas of design and not all components. For those, it is also useful to consider the prevention of the fundamental damage processes.

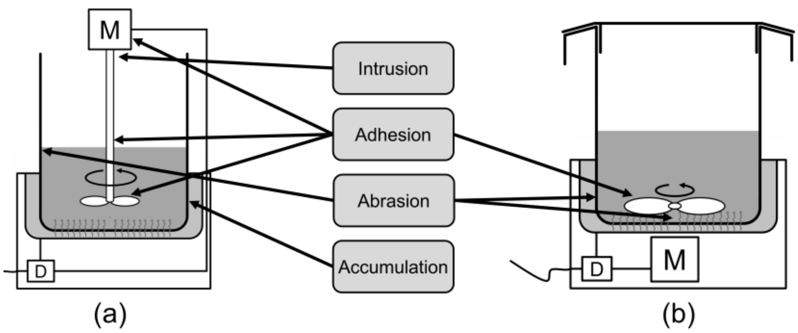

Figure 8. Development task: Example of a hygienic milk frother

4 CONCLUSION AND OUTLOOK

Hygienic design is a fundamental issue in the development of food processing machinery. This paper introduces a methodical approach of Hygienic Design. Analysing processes of the use phase with the process model and examining with regard to their categorisation leads to formalised Hygienic Design requirements. Comparing existing guidelines with fundamental damage processes "*adhesion*", "*accumulation*", "*intrusion*" and "*abrasion*" provides a new systematic scheme of a guideline categorisation, which provides an extended understanding of Hygienic Design.
Designers can use the knowledge about damage processes: based on fundamental damage processes, one possibility is developing guidelines that are more general. The other possibility is using the

knowledge about damage processes in each decision to support the choices of designers. These two types of support allow a new methodological approach to Hygienic Design so that the implementation of the requirements takes not only place in the design phase, but also in earlier phases.
The next step is the detailed analysis of the damage processes. Working factors require an exact description in order to develop useful tools. Furthermore, the goal is to analyse how designers transform hygiene requirements into design properties with the help of working surfaces, working bodies and working space during the rough design.
Finally, the results should be used for developing a methodology that supports designers of food processing machinery in every phase of the product development process.

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