

PRINCIPLES OF HYGIENIC DESIGN

Dirk Nikoleiski^{1*}

¹Kraft Foods R&D Inc., Bayerwaldstrasse 8, 81737 Munich, Germany

*e-mail: Dnikoleiski@kraftfoods.com

Abstract

Hygienic Design is much more than bright and shiny stainless steel installations in a facility, but it isn't a science on its own either. Basically it's the application of design techniques that allow for all assets to be cleaned effectively and efficiently in order to minimize the risk of any kind of hazards. Thus it can be considered a prerequisite program within a robust HACCP program and its importance should be recognized by all stakeholders as such. The application of appropriate standards and best practices specific to the sensitivity of products and processes should not be negotiable.

EHEDG provides with document 8 "Hygienic Equipment Design Criteria" [1] a basic guideline allowing food manufacturers and equipment suppliers to calibrate on the expectations of hygienic equipment design. This lecture will provide an overview of the principles of hygienic design based on EHEDG document 8 with some practical examples.

Key words: *Hygienic Design Principles, Prerequisite Program, HACCP.*

1. Introduction

Hygienic design is actually the application of design techniques that allow for all assets to be cleaned effectively and efficiently in order to minimize the risk of any kind of hazards. Thus it can be considered to be a prerequisite program within a robust HACCP system and its importance should be recognized as such.

Stakeholders who design equipment should be familiar with applicable regulations, laws, standards and guidelines and understand their scope, but also their limitations. In Europe fundamental requirements are laid down in view of health and safety risks in relation to design and manufacture with the Machinery Directive 2006/42/EC [2]. The Machinery Directive makes it a legal obligation that all machinery sold within the European Union must comply with safety and basic hygiene aspects. Compliance is shown accordingly with the 'CE' mark. Examples for directly

applicable Regulations relative to hygienic design are the EC regulation 852/2004 (General Food Hygiene) [3] or the EC regulation 1935/2004 (Food Contact Materials) [4].

2. The Machinery Directive in the EU

In reality safety aspects of the Machinery Directive, like for example emergency stops, ergonomics, mechanical strength, noise emission, etc., are probably better known than its hygienic design principles, though they are expected to be covered when risk assessments in view of health aspects are done. Therefore Food Manufacturers should never rely on a CE mark to confirm compliance with hygiene, as equipment manufacturers actually are not aware of that by affixing the mark they basically confirm compliance to both safety requirements and Hygienic Design.

In fact, the section covering hygienic design is relatively short. The requirements laid down for foodstuffs machinery and - interestingly without differentiation - cosmetics or pharmaceutical products cover the following key principles:

- Design and construction must ensure any risk of infection, sickness or contagion is avoided.
- Food contact materials shall satisfy the requirements laid down in other Directives (e.g. Directive 2007/19/EC [5] for plastics in food contact). In other words: food contact materials must be compatible to the foodstuffs and cleaning chemicals. They shall be non-toxic, non-tainting, non-absorbent and resistant to abrasion, cracking, chipping, flaking and corrosion.
- Food contact materials and surfaces must be cleanable before each use, if materials are not disposable.
- All food contact surfaces and their joining must be smooth without ridges or crevices.
- For all food contact surfaces projections, edges and recesses must be minimized.

- All food contact surfaces must be easily cleaned and disinfected, where required after removing easily dismantled parts.
- Inner surfaces in the food contact areas must have sufficient radii to allow thorough cleaning.
- Design and construction must ensure liquids, gases and aerosols deriving from foodstuffs or cleaning can be discharged, if possible in a cleaning or draining position (self draining).
- Design and construction must prevent any substances or living creatures can accumulate or enter the machinery (no harbourage areas).
- Per design the machinery shall prevent any hazardous substances (e.g. lubricants) can come into contact with foodstuffs. Where necessary design and construction must allow the compliance can be verified.
- Recommendations on applicable cleaning and disinfection chemicals and procedures must be provided with the instructions for the machinery.

The European norms EN 14159 [6] and EN 1672-2 [7], have been issued to detail the Machinery Directive. Though providing more details, the norms are also very generic and based on the common design principles as laid down with the Machinery Directive. Additionally a number of sector specific standards on bakery, meat, dairy equipment and other business have been issued. It must be noted that only standards identified by the abbreviation "EN" are mandatory in the EU, other standards are voluntary and must be included in the contract between equipment supplier and food manufacturer, if considered to be necessary and applicable.

2.1. EHEDG Guideline No. 8 on Hygienic Equipment Design Criteria

Besides legally binding Directives, Regulations and Norms and also specific local standards, a great number of guidelines and accepted practices are published in Europe and internationally. In response to the Machinery Directive, which may leave some grey areas, the European Hygienic Engineering and Design Group (EHEDG) has issued several guidelines to close the gap and allowing food manufacturers and equipment suppliers to calibrate on the expectations of hygienic equipment design. The guideline No. 8, Hygienic Equipment Design Criteria [1], is available as a free download from the EHEDG web site and can be considered as the core document for all other guidelines. This document has been issued firstly in 1993 for providing guidance on preventing food safety concerns through hygienic design. The second edition has been published in 2004. The approach is to

effectively incorporate hygienic design upfront in the design stage already instead of reacting to hygienic issues and upgrading existing design resulting in high costs. Actually some content of the EHEDG document 8 [1], can be found in the norms EN 14159 [6] and EN 1672-2 [7]. This article details the basic hygienic design principles based on the EHEDG guideline.

2.2 Compatible Materials

All construction materials must be entirely compatible with the product, environment, and cleaning practices (chemicals, method). Thus product contact materials of construction must be inert, corrosion resistant, non-toxic, non-absorbent mechanically stable and their surface finish must not be adversely affected under the conditions they are used. Non-product contact materials must be easy to clean, mechanically stable and smooth. Incompatible materials in the construction may increase the likelihood of food safety risks, for example through corrosion or pitting.

Related to plastic materials the European Commission implemented (EC) Directive 2007/19/EC [5] that must be converted into national regulations by the individual EU member states. For all other materials intended to come into contact with food Regulation 1935/2004 [4], EC becomes mandatory, which is actually requiring that these materials must not harm consumers.

Material of choice in food contact is usually stainless steel. However, polymeric materials and elastomers are often used for good reasons. For all these it is absolutely vital that they are compatible and non-toxic.

A wide range of stainless steels is available offering different resistances to corrosion, strength, formability or welding properties. Typically AISI 304 or if higher corrosion resistance is needed AISI 316 / 316L is used for most applications.

Synthetic polymeric materials ("plastics") shall be generally recognized as safe under the FDA regulation. In the EU Directive 2002/72 [8] sets out rules for plastic materials that come into contact with food. As each plastic material has advantages and disadvantages the selection is very much depended on the application. Compatibility with food stuffs and ingredients, as well as the cleaning and process conditions must be taken into account. The specific product data sheets of the polymer should be consulted in any case to understand the capability of the material before it's selected.

Elastomers ("rubbers") that are used for example for gaskets, sealing or hoses is composed of a couple of ingredients, like polymers, fillers, plasticisers, activators, antioxidants, accelerants and vulcanising agents. The composition determines the physical and chemical properties.

For materials that come into contact with food other than ceramic, plastic (see above) and regenerated cellulose the Regulation 1935/2004 [4] is applicable in the EU for all other materials, for which a specific national or European legislation does not exist. In the absence of a positive list for elastomers or their ingredients the FDA regulation should be applied here as well.

The same as for elastomers applies to adhesives. Adhesives shall not lead to corrosion, if they come into contact with stainless steel and they shall not release any toxic material.

Lubricants that are used in food manufacturing equipment and that can come into contact with food or food stuff incidentally shall be food grade. The same applies for liquids used for signal transfers.

Insulation shall be constructed and installed in such way that the material does not hold moisture or water through cleaning practices or condensation. If the insulation material contains chloride ingress of water may even lead to corrosion issues with stainless steel installations.

2.3 Cleanability

All equipment should be constructed that it can be effectively cleaned and disinfected to a standard that minimizes the risk of product hazard (microbiological, chemical, physical) and to quality levels that comply with good manufacturing practices. Poor cleanability of equipment may not only lead to food safety risks in view of pathogens, allergens or physical contaminants, but can also result in high costs for cleaning and a reduced lifetime of the installation.

Cleaning effectiveness rely typically on 4 factors: time, mechanical action, temperature and chemicals. If the design does not allow for good cleanability some or all factors must be increased, for example time and chemical concentration. This very important design principle should be applied to product contact and non-product contact surfaces.

2.4 Smooth Surfaces Free of Imperfections and Dead Areas

Ingress and growth of microorganisms must be avoided. Thus harbourage areas, dead ends, gaps, recesses and crevices shall be avoided.

All permanent joints such as welds should be smooth and continuous without misalignment. Welding must be carried out properly and may require post weld treatments, such as grinding, polishing, pickling and passivation.

Pipe couplings must be free of crevices and be sealed with a gasket. Any seal or gasket used must not allow for soil or bacteria to be trapped. Metal to metal joints should be avoided entirely. Items like bolts or name plates should be welded to the surface and not attached via drilled holes. Exposed threads, screws, rivets and bolts should not be present in product contact zones. Sharp corners should be avoided. All corners should have a radius not less than 3 mm.

Product contact surfaces should be finished to an appropriate roughness that is smooth enough to enable them to be easily cleaned and disinfected. The surface finish should be $0.8\mu\text{m} R_a$ or better. Higher R_a values may be acceptable, if the cleanability is being verified.

2.5 Drainability

All equipment and installation must be self-draining or drainable. Thus horizontal surfaces shall be avoided, but sloped to one side. This principle is valid for both, product contact and non-product contact surfaces. Liquid on external surfaces shall flow away from the product zone.

2.6 Validation of Hygienic Design

Food manufactures are accustomed to manage risks based on HACCP principles including assessment, verification and validation of systems. Additionally equipment manufacturers must ensure that their machinery does not pose any health or safety risk. That means both, equipment manufacturers and the food producers have an obligation to minimize risks and a joint approach is the most effective way to get good results. Therefore the concept is to connect these requirements.

Equipment manufacturer should estimate, evaluate and minimize the risk associated with the equipment in order to make sure the machinery is appropriate for its intended use. However, there are many factors which may have an impact on product attributes such as: recipe, processing steps or consumption behaviours. All these are usually not known by the equipment manufacturer and they may not be able to conduct a reasonable assessment and give appropriate ratings without linking with their customers, as there is knowledge and experience on the customer's end, i.e. the food manufacturing companies. To enable these resources, a communication process that allows for a cross functional team, consisting of designers, engineers, quality staff and operators can work out the ideal design without compromising food safety and product quality. Experts from both, the food industry and equipment manufacturers, should define early on during a project life cycle the requirements and

develop specifications based on that. Once agreed on the specifications the hygienic design aspects should be reviewed constantly at all project stages from design to commissioning later on until the factory acceptance test and equipment validations.

Hygienic design reviews at all relevant project stages using a checklist based on design principles is powerful and easy to use tool. Potential hygienic design solutions to minimize risks as well as the most cost effective design to maintain the defined hygiene level can be identified early on. The American Meat Institute (AMI) has published, for example, on their web site checklists for equipment and facility design. Questions shall be answered with yes, no or not applicable. A question answered with a no would mean the design as planned does not fulfil hygiene aspects and require workarounds or alternative solutions. The key aspects based on 10 design principles covered by the AMI checklist is very similar to those laid down in the Machinery Directive or the norm 1672-2 [7] and may serve as the basis for a tailor-made, sector specific checklist. An action register and a sign off after each review are recommended to be part of the documentation. A similar check list based on the AMI check list is available for dry products from the American Grocery Manufacturers Association (GMA).

Test methods for validating the cleanability of equipment has been published by EHEDG Cleaning certificates for components or devices like valves can be provided subject to passing the standardised test performed by an approved institute.

3. Conclusions

The application of hygienic design principles is the foundation for GMP in a food manufacturing environment. As regulatory bodies usually do not lay down detailed requirements, the EHEDG document 8 "Hygienic Equipment Design Criteria" [1] may be used along with other EHEDG guidelines by equipment and food manufacturers when designing equipment and to facilitate validation of equipment.

4. References

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