

EHEDG Update

Design of mechanical seals for hygienic and aseptic applications

This article is an extended summary of the report prepared by the Mechanical Seals Subgroup of the European Hygienic Equipment Design Group (EHEDG). Originally published in August 2002, it is the 25th in the series of EHEDG summaries published in TIFS. The full report was prepared by G. Anderberg (Chairman), R. Cocker, R. Curiel, R. Feenstra, W. Mathes, H van Eijk and R. Wallis and is available from CCFRA at pubs@campden.co.uk. Information about EHEDG can be found on the website at www.ehedg.org. The production of EHEDG guidelines is supported by the European Commission under the Quality of Life Programme, project HYFOMA (QLK1-CT-2000-01359). For application in the field, it is strongly recommended that the guideline be read in its entirety.

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Introduction

Inappropriate design of mechanical seals can cause contamination of a food product by micro-organisms, and/or residues, which may be toxic or allergenic. The main contamination risks are:

- Micro-organisms enter the product from the atmospheric side through the seal gap.
- Product passes the seal gap to the non-product side and micro-organisms start growing in the residues. These micro-organisms then re-enter the product.
- Product sticks to the seal or the seal chamber and micro-organisms start growing.

In addition, cleaning of equipment should not cause environmental problems and stagnant zones or small

gaps between equipment parts must be avoided. These risks warrant the setting of more stringent requirements. This guideline compares the design aspects of different mechanical seals with respect to ease of cleaning, microbial impermeability, sterilizability or pasteurizability. This document is intended to serve as a guide for suppliers and users of mechanical seals in the food industry.

Classification

Using EHEDG definitions, mechanical seals are classified into three categories, according to their use in the food industry: Aseptic, Hygienic Equipment Class I, and Hygienic Equipment Class II (see [Table 1](#)). This guideline covers both single and dual mechanical seals under the first two categories, which by definition, are subject to more stringent hygienic demands. For Class II seals less stringent hygienic demands are needed and are therefore not included in this guideline.

Basic principles

In closed food processing equipment, the mechanical seal is capable of reducing the risk of microbial contamination in a wide variety of products under very demanding operating conditions. For this reason, mechanical seals are commonly in use for pumps, agitators, mixers, and other types of rotary equipment. Dynamic sealing takes place at the interface between a stationary seal ring and a rotating ring. It is accomplished by using perfectly flat face surfaces, and using the product pressure along with spring force to press the components together. Typically, a microscopic film of product fluid between the faces of the rings acts as the sealant. This fine liquid film separates the two faces, and conflicts with the general requirement of a crevice-free design for the food industry. In principle, it cannot be cleaned in place (CIP) properly when the shaft stands still. Under normal operating conditions, the seal has a certain transfer of liquid from the high-pressure side to the low pressure side of the seal gap.

- In a single seal this will stay as a residue on the non-product side of the seal face.
- In a flushed single seal, this residue will be flushed away with the flushing fluid.
- In a dual-seal with higher pressure in the barrier fluid it will be this fluid transferred over the seal

gap into the product. Also, the temperature of the flushing liquid will secure a safe barrier between product and atmosphere.

General design criteria (Fig. 1)

- The parts of the seal in contact with product must be suitable for CIP and SIP according to EHEDG guidelines.
- The non-product side of the seal shall be cleanable and capable of being disinfected and shall not contaminate or have any adverse influence on the food.
- Product-contact surfaces have to be smooth and crevice free.
- The non-product side must be as smooth and as crevice free as possible.
- Dead ends are not permitted on the product side.
- Springs are not permitted on the product side.
- Designed corners must have a minimum radius of 3 mm.

Single mechanical seals

The single seal is most common. It provides some risks of contamination from the atmosphere. This can be handled by regularly inspecting the non-product side of the seal and cleaning manually according to the HACCP programme. Alternatively the non-product side of the seal can be provided with a flushing device to minimize the risk for microbial growth in a humid environment.

Dual mechanical seals

When processing sterile products, no ingress of micro-organisms is allowed and the equipment has to be in accordance with the EHEDG class: 'aseptic'. The single seal does not meet the requirements of aseptic processing. A solution to this problem is to provide a flush at the non-product side of the seal, using a fluid with bactericidal properties, or another sterile barrier system. For these applications, dual mechanical seals are used. Such seals prevent product contamination and avoid product leakage to the atmospheric side. In some applications (e.g. top-driven agitators or hazardous product) the liquid between the seals is applied at a higher pressure than the product.

Component materials

Materials used for components in mechanical seals must:

- Be non toxic
- Be anti-corrosive
- Be crevice free
- Be non-absorbent
- Not transfer undesirable odours, colours or taints to the product
- Not contribute to the contamination of food nor have any adverse effects on the food.
- Have surfaces and coatings which are durable, cleanable and capable of being disinfected, without breaks, resistant to cracking, chipping, flaking and abrasion and prevent penetration of unwanted matter.

Table 1. Classification criteria for mechanical seals

Class/demand	Description
Aseptic equipment High demand	Equipment can be cleaned in-place (CIP) and freed from micro-organisms and spores (sterilisation in-place, (SIP)) without any dismantling. A sterile barrier is needed between the product and the atmospheric side. Normally this is achieved by using two seals between which a sterile medium is present. This medium can be a liquid e.g. steam condense, or a gas. The barrier chamber has to be clean during production and cleaned during CIP by a flow. The barrier can have a lower or higher pressure than the product. The sterile barrier medium must be food-compatible.
Hygienic equipment Class 1 Average demand	Equipment that can be cleaned in-place (CIP) and freed from micro-organisms and spores without any dismantling (SIP). Rotating and stationary mechanical seal parts with smooth and crevice-free product contact surfaces. All components with, or forming unavoidable crevices or gaps, e.g. springs, torque transmitters, and shall be located at the non-product side. In addition to the main seal on the product side a secondary sealing device is needed on the atmospheric side, e.g. a lip seal or another mechanical seal. To keep the non-product side of the seal clean, this sealing chamber can be flushed with a fluid acceptable for the application.
Hygienic equipment Class II Low demand	Equipment that is cleanable after dismantling and can be freed from relevant micro-organisms (SIP) after re-assembly. The seal has to be dismantled for cleaning regularly. The need for hygienic design is not as stringent as for Class I equipment. The materials used in the seal must be acceptable for food contact application, as for Class I equipment.

All materials for food application must be compliant with FDA CFR 21 or equivalent European legislation. This can take the form of an affirmation statement from the FDA, that the material is generally recognized as safe (GRAS statement). It is the supplier's responsibility to hand over such a statement for food production equipment on request. Stainless steel, aluminium-oxide and silicon carbide have such a general GRAS statement.

Seal face materials

The current regulations for materials for use in food applications tend to use the broad statement that they should be 'pore free'. In the materials used for mechanical seal faces (e.g., carbon, ceramics) this is not strictly true. These materials are inherently porous as a result of the material manufacturing process. This porosity is, to a certain extent, positive for seal face lubrication. A method for the determination of surface porosity is standardized in EN 993-1. The surface finish of the component will affect this.

Current machining procedures ensure good surface properties (e.g., turning/finishing, grinding, lapping and polishing). It is important that the materials are compatible with the product and cleaning liquids in use. Otherwise the surface properties are affected negatively.

Elastomer materials

The secondary sealing elements consist of elastomeric or plastic materials (e.g., O-rings, gaskets). The materi-

als shall be smooth and free of flash lines, of low porosity, without blisters and tears at any surface in contact with the product-wetted area. The material should be selected according to the requirements of the responsible certified bodies such as FDA and BGVV or evolving European Legislation. Only plastic materials produced from monomers according to EU Directive (The Plastic Directive) and subsequent amendments shall be used.

Metal materials

The metal components shall be made of austenitic stainless steel to a specification corresponding to AISI type 316 or EN 10088 Part 1. The cast equivalents of this grade will be permitted provided that the composition is such as to ensure that the structure is fully austenitic. Sintered metal components, because of their inherent high levels of porosity, will not be permitted.

Other metals generally accepted as showing superior chemical resistance to type 316 stainless steel, for example, Duplex stainless steels, super austenitic stainless steels, corrosion-resistant nickel alloys and titanium, will also be acceptable. As the springs may be exposed to aggressive fluids, e.g., cleaning agents, they must be made of corrosion resistant materials. In this case stainless steel or even better Hastalloy springs are to be preferred.

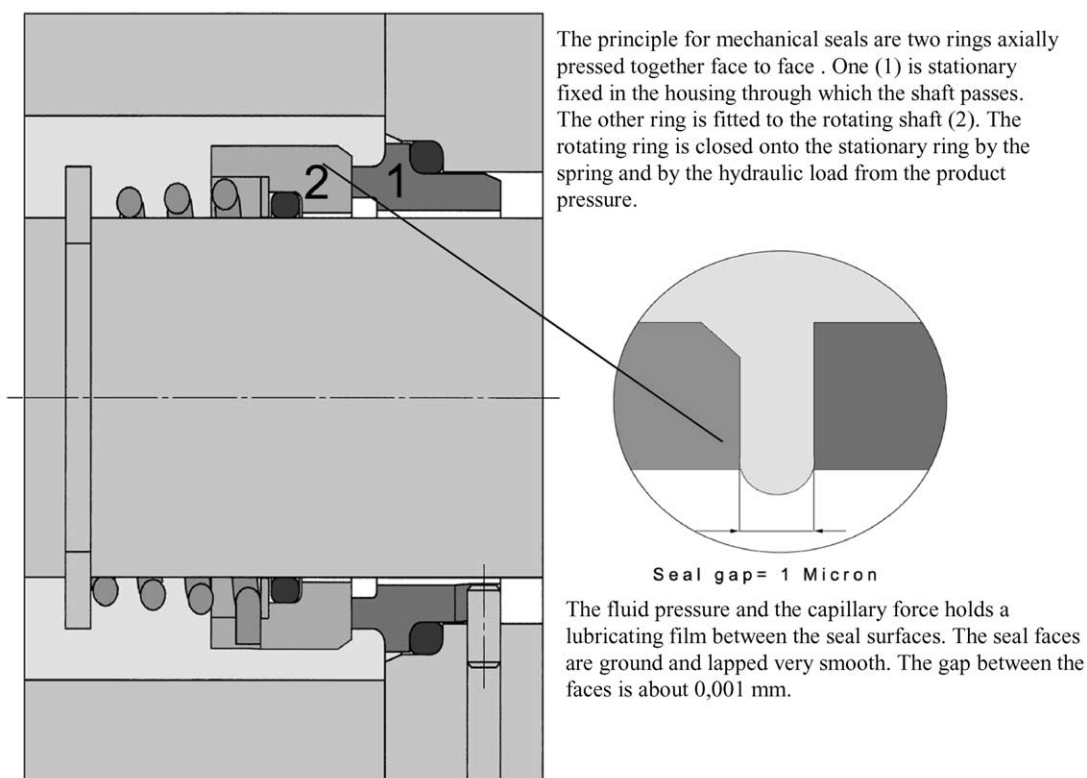


Fig. 1. Design principle for mechanical seals.

Parts/components and their hygiene implications

Elastomeric seal elements

Both the dynamic seal ring (taking up some axial movements) and the static seal ring need to be adequately sealed to either the rotor shaft or the housing.

With specially shaped elastomeric sealing elements the demand of a gapless design can be realized, although the above remains valid and must be considered to ensure proper functioning.

Metal and elastomeric bellows seals

Bellows in general have the advantage that they need not overcome any friction forces and that they are less sensitive to leakage deposits on the atmospheric side of the seal; this means that their axial motion is better than that of O-rings. The bellows are usually in direct contact with the product.

Because of the large surface area in contact with the product when using elastomeric bellows, a smooth and pore-free surface needs to be assured. Additionally, deformations under influence of temperature and pressure may be a problem. An elastomeric bellows seal is normally energized by a spring which fits between the shaft and elastomer bellows.

Welded metal bellows should not be used due to their narrow and deep gaps between the metal disks. Metal rolled bellows can be used with low viscosity products to overcome stagnant product areas.

Location and housing of springs

For adequate cleanability, springs should not be exposed to product and must therefore be at the non-product side.

Installation requirements

Mechanical seal design

The seal should be positioned in the product flow to prevent adhesion of product particles and avoid dead or stagnant zones. This will improve the cleanability by CIP and help to take frictional heat away from the seal, thus minimizing coagulation of proteins. Outboard seal designs are not acceptable if they have an annular dead end on the product side of the seal. The springs have to be on the non-product side to prevent product from sticking and to improve CIP.

Flushing system on non-product side

It is important that there is a controlled flow around all surfaces in the flushed chamber, particularly at the non-product side of the seal faces. The flushed area shall be as smooth and free of crevices as possible to prevent adhesion of residues.

The flushed area must be fully drained when the flushing is off (a small amount of water will vaporize during SIP).

Continuous flushing

A flushed seal is of benefit in keeping the seal clean (instant removal of product), and avoiding dry start-ups. This will prolong the life of the seal. Inadequate control of the seal flush system could therefore cause seal failures. The flush provides a means to dilute the leaking product into the flush liquid (sometimes called barrier fluid, or quench) instead of into the atmosphere. It requires uninterrupted replenishment of the sterile flush liquid together with monitoring and maintenance to ensure faultless operation of the flushing system. This flow has to be good enough to remove particles from the flushing chamber.

Aseptic operation

Aseptic operation requires a sterile barrier between product and atmospheric side of the equipment. In aseptic applications, the flushing medium itself forms the sterile barrier. Often condensate made from food-grade steam is passed between the seals for this purpose. The temperature of the steam condensate during production is typically 70–135°C and during sterilization, 125–145°C. Flow rates of condensate are typically 0.1 l/min.

Cartridge design

In general all mechanical seals can be integrated in pre-mounted units, ready to be installed, including sleeves, sealing housings, glands, etc., known as *cartridges*. The cartridge seal prevents damage to the seal faces during the assembly/disassembly operation of the food equipment. It has a built-in sleeve to fit an existing shaft. It allows for easy seal installation because the seal can be assembled and pre-tested prior to installation. The ways of mounting the seal requires attention to assure hygienic installation. It is important to ensure correct fitting of the seal and its cleanability. Edge-moulded rubber gaskets (or metal–rubber bonded seals) maintain a sufficiently tight seal, because the rubber will not compress past the metal carrier thickness. Cartridge designs are to be preferred whenever possible.

The mounting and static sealing of the cartridge in its adjacent machinery environment should be designed considering hygienic/aseptic aspects. This means for example no screws or threads in contact with the product and the static sealing with a special encapsulated O-ring or elastomeric edge-moulded gasket.

Definitions

For the purposes of this guideline, the definitions given in ENV 1070 apply. A full list of definitions is given in the full document.

References

Please refer to the original document for references on legislation/guidelines mentioned in this summary.