Hygienic design of valves for food processing

Valves are essential components of all food-processing plants, and the quality of the valves used strongly influences the microbiological safety of the food production process. Valves for food-contact use must therefore comply with strict hygienic requirements. This paper summarizes guidelines prepared by the Valves subgroup of the European Hygienic Equipment Design Group (EHEDG) for the hygienic design of valves for food-processing applications. This is the 14th in an ongoing series featuring newly released EHEDG guidelines to be published in *Trends in Food Science & Technology*. The EHEDG is an independent consortium formed to develop guidelines and test methods for the safe and hygienic processing of food, and includes representatives from research institutes, the food industry, equipment manufacturers and government organizations in Europe.*

Every process plant is equipped with valves. Depending on system size, hundreds, even thousands of valves can be found in piping matrices in liquid-processing plants. Valves fulfil numerous functions in process plants: shut-off and opening of product routes, changeover, flow and pressure control, protection against excessive or insufficient pressure, and protection against the intermixing of incompatible media at intersection points in pipes.

The quality of the valve may have a considerable influence on the quality of the production process and, hence, the product itself. Hygienic deficiencies resulting from valve design may result in microbiological hazards in the production of food products. The risk for the product increases with each valve installed in the process plant. Therefore, it must be ensured that valves for food-processing use comply strictly with hygienic requirements, as discussed in Refs 1–3.

This paper discusses the basic requirements for hygienic and aseptic valves. The guidelines apply to all valves used in contact with food or food constituents that are to be processed hygienically or aseptically. A list of definitions specific to hygienic aspects of equipment design has been prepared by the EHEDG (see box).

General requirements

Materials, surface roughness and cleanability

All surfaces in contact with food must be cleanable. Outside surfaces of valves should also be easy to clean.

Surface roughness has a significant influence on cleanability. The greater the surface roughness, the longer the required cleaning time. In principle, any treatment of product-contact surfaces should result in a surface roughness value of $R_a \leq 0.8$ μm (Ref. 1). A rougher surface may be acceptable, but the deviating surface roughness must be clearly specified. (In the beverage industry, a roughness of $R_a = 1.6$ μm is usually acceptable.)

The materials used, including those for static and dynamic seals, self-evidently must be suitable for the intended application and comply with regulations for food contact application. For details see Ref. 1.

Geometry, drainability and leak detection

Valve design must ensure liquid exchange in all areas in contact with food. In addition to ensuring the exchange of liquids in all areas during production and

Definitions

Aseptic equipment: Hygienic equipment that is, in addition, impermeable to microorganisms.

Cleanability: The suitability to be freed from soil.

Destruction of microorganisms: Irreversible physical or chemical damage to microorganisms to prevent them from surviving and multiplying. Thermal destruction employs heat, possibly in combination with water or steam; chemical destruction employs biocidal chemical(s).

Hygienic equipment Class I: Equipment that can be cleaned in-place and freed from relevant microorganisms without dismantling.

Hygienic equipment Class II: Equipment that is cleanable after dismantling and that can be freed from relevant microorganisms by sterilization, pasteurization or chemical treatment after reassembly.

In-place cleanability: Suitability to be cleaned without dismantling.

Microbial impermeability: The ability of equipment to prevent the ingress of bacteria, yeasts and moulds from the environment to the product area.

Pasteurization: Thermal destruction of vegetative microorganisms (i.e. excluding thermoresistant bacterial spores).

Product-contact surfaces: All surfaces of the machine that intentionally or unintentionally come in contact with the product, or from which product or condensate may drain, drop or be drawn into the product or container, including surfaces (e.g. unsterilized packs) that may indirectly cross-contaminate product-contact surfaces or containers.

Relevant microorganisms: Microorganisms (bacteria, yeasts and moulds) able to contaminate, multiply or survive in the product and harmful to the consumer or to product quality.

Soil: Any undesired matter, including product residues, whether or not containing microorganisms.

Sterilization: Removal or destruction of microorganisms, including all relevant bacterial spores.

*Readers requiring further information on the EHEDG are referred to *Trends in Food Science & Technology* (1992) Vol. 3(11), p. 277.

cleaning, it is also desirable that no gas pockets remain in the valve when the liquid flows through. Therefore, in the food area:

- pits and crevices must always be avoided;
- sharp edges should be avoided;
- screw threads should not be used;
- dead ends, which may trap product or prevent adequate cleaning, should be avoided. Should a dead end be unavoidable, it must be as short as possible, and must be installed in a drainable and cleanable position. If cleanability depends on a specific procedure [i.e. flow direction during cleaning in-place (CIP)], this must be clearly indicated in the cleaning instructions.

It must be possible to drain valves completely without dismantling in at least one installation position.

The design of valves must allow rapid detection from the outside of any leakage.

Seals and springs

There should be as few seals in a valve as possible. Care must be taken to ensure that the maximum compressibility of the sealing material (usually an elastomer) is not exceeded during processing, cleaning, pasteurization or sterilization. The sealing material should project as little as possible into the product area and should not inhibit drainage. Crevices or gaps between seals must be avoided. Seals must also be resilient enough that heating and cooling do not result in the formation of gaps.

As the properties of bearing materials are vastly different from the properties of materials intended for sealing, in no case should seals substitute bearings; shafts of valves should always be provided with adequate bearings.

Springs in contact with product should be avoided. Where springs are in contact with product they should have minimum surface-to-surface contact. It must be specified how to ensure that all product-contact surfaces can be cleaned.

Microbial impermeability

For aseptic applications, moving shafts in valves must preferably be separated from the product side by either a diaphragm or bellows. Dynamic seals of moving shafts in contact with product must incorporate a barrier between the environment and the product. Double seal arrangements should preferably be designed such that the distance between the two seals is greater than the stroke of the shaft. If this is not the case, the ability to prevent the ingress of microorganisms must be demonstrated. It must be possible to free all product-contact surfaces and all surfaces between the two seals from relevant microorganisms.

Additional requirements for specific valve types

There are additional requirements for certain valve types, as described below.

Diaphragm and bellows valves

Leakage must be detectable by free outlet to the atmosphere or by a specific leakage detection system.

Plug valves

Plug valves are not suitable for CIP and therefore the instructions for use must state clearly that dismantling is necessary for cleaning. Therefore, provided that they can be freed from relevant microorganisms after reassembly, plug valves can only be considered Hygienic Equipment Class II.

Pressure-relief valves

Pressure-relief valves must be self draining to the outlet side in order to avoid the accumulation of product residues. Pressure-relief valves must be provided with a device that makes it possible to clean the seal and the outlet side.

Non-return valves

A non-return valve must close when the pressures on both sides are equal.

Ball valves

The area between the ball, housing and seat faces must be cleanable and it must be possible to free the valve from relevant microorganisms. Traditional ball valves are not designed for CIP.

Mix-proof valves

Mix-proof valves are defined as valves that safely exclude the intermixing of incompatible fluids between separate product lines by forming a neutral area between the product lines. The neutral area must be drainable to the atmosphere, cleanable, and designed in such a way that a leak cannot result in a build-up of pressure. The specific design must be selected with respect to the hygienic and safety requirements for the application. For aseptic applications, the neutral area must be flushed with a microbicidal barrier medium (e.g. steam), similar to the case of shaft seals (see 'Microbial impermeability', above).

Documentation

Comprehensive information and recommendations on valve installation, operation, draining, cleaning, decontamination and maintenance are the responsibility of the valve manufacturer.

Conclusions

Like all other equipment for the hygienic manufacture of food, valves should be designed following the hygienic equipment design criteria (Ref. 1) and meet the specifications given in 'Hygienic design of closed equipment for the processing of liquid food' (Ref. 2).

Valves designed and manufactured accordingly, complying with the requirements specified above, are suitable for the hygienic or aseptic processing of food.

Acknowledgement

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References

1 *Hygienic Equipment Design Criteria* (1993) in *Trends Food Sci. Technol.* 4, 225–229

2 *Hygienic Design of Closed Equipment for the Processing of Liquid Food* (1993) in *Trends Food Sci. Technol.* 4, 375–379

3 *Welding Stainless Steel to Meet Hygienic Requirements* (1993) in *Trends Food Sci. Technol.* 4, 306–311

This paper summarizes guidelines recommended by the European Hygienic Equipment Design Group (EHEDG) subgroup on Valves, and has been approved by the EHEDG. The full report, by I. Abram, F. Baumbach, G.J. Curiel, D.C. Harrison, T. Pederson, P. Peschel, S. Querte, B. Sondergaard and T. Tuuslev, is available from: D.A. Timperley, Campden Food and Drink Research Association (CFDRA), Chipping Campden, UK GL55 6LD (tel. +44-386-840319; fax: +44-386-841306).

Conference Report

Glycotechnology*

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This three-day conference was organized by IBC USA Conferences (Southborough, MA, USA) and was attended by ~100 participants, half of them from industrial laboratories, and predominantly from the USA and Europe. In 30 lectures the current state of knowledge of the whole field of glycotechnology was discussed, with a special focus on therapeutical carbohydrates. With the increasing knowledge about the key role of carbohydrates in recognition and adherence processes, carbohydrate-based drugs are now beginning to emerge from the laboratories.

During the past decade, the increased interest in the biological functions of carbohydrates has resulted in significant improvements in methodology for the separation and analysis of carbohydrates. High-performance anion-exchange chromatography (HPAEC) with pulsed-amperometric detection is nowadays a common and indispensable tool for the separation and detection of mono- and oligosaccharides, and in many laboratories it is gradually replacing some gas–liquid chromatography (GLC) methods. Two interesting new methods for separation were presented by R.A. O'Neill (Applied Biosystems Inc., Foster City, CA, USA), who illustrated the use of capillary electrophoresis (CE) as a powerful method for oligosaccharide mapping, and by C. Starr of Glyko Inc. (Novato, CA, USA), who presented their FACE® (fluorophore assisted carbohydrate electrophoresis) technology, which is based on the use of fluorescent tags and polyacrylamide gel electrophoresis for oligosaccharide profiling. CE looks especially promising and it can be anticipated that CE and HPAEC will develop into the separation techniques of the future.

Classical methylation analysis is still useful for the structural characterization of carbohydrate polymers, but nuclear magnetic resonance (NMR) spectroscopy, molecular modeling and mass spectrometry techniques are becoming increasingly important. Due to significant improvements both in the magnets used and in computer technology, NMR now provides a powerful non-destructive way to characterize glycoprotein carbohydrates structurally, and is an indispensable part of the current methodology of glycosylation site mapping, as presented by H. van Halbeek (Complex Carbohydrate Research Center, Athens, GA, USA). A new development in the characterization of the glycosidic linkage of carbohydrate residues is the reagent array analysis method (RAAM), developed by Oxford Glycosystems (Abington, UK) and described by D.L. Fernandes. This method, based on the use of different specific exogl,cosidases in multiple defined mixtures, looks promising, and over the past two years much has been done to validate the system. However, due to several reasons, this method is currently only useful for the routine analysis of well-known sources of animal glycoproteins. For unknown samples, NMR spectroscopy will remain indispensable.

A lot of work currently going on in laboratories is revealing important new roles of carbohydrate residues in biological processes. R.A. Dwek (Oxford Glycobiology Institute, UK) described the functional significance of glycoproteins as diverse sets of glycoforms in biological processes. The particular glycosylation pattern of a protein reflects the required balance of all

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