41 Ogawa, H., Fukuhisa, K. and Fukumoto, H. (1992) in *High Pressure and Biotechnology* (Balny, C., Hayashi, R., Heremans, K. and Masson, P., eds), pp. 269–278, Editions John Libbey Eurotext, Montrouge, France
42 Dring, G.J. (1976) in *Inhibition and Inactivation of Vegetative Microbes* (Skinner, S.A. and Hugo, V., eds), p. 257, Academic Press
43 Sonoike, K., Setoyama, T., Kuma, Y., Kimura, Y., Shinno, T., Fukumoto, K. and Ishihara, M. (1993) in *High Pressure Bioscience and Food Science* (Hayashi, R., ed.), pp. 213–219, San-ei Publications, Kyoto, Japan
44 Shimada, K. (1992) in *High Pressure and Biotechnology* (Balny, C., Hayashi, R., Heremans, K. and Masson, P., eds), pp. 49–51, Editions John Libbey Eurotext, Montrouge, France
45 Obuchi, K., Iwahashi, H., Kaul, S.C., Uedaira, H., Ishimura, M. and Komatsu, Y. (1992) in *High Pressure and Biotechnology* (Balny, C., Hayashi, R., Heremans, K. and Masson, P., eds), pp. 77–81, Editions John Libbey Eurotext, Montrouge, France
46 Miyao, S., Shindoh, T., Miyamori, K. and Arita, T. (1993) *Nippon Shokuhin Kogyo Gakkaishi* 40, 478–484
47 Takahashi, K. (1992) in *High Pressure and Biotechnology* (Balny, C., Hayashi, R., Heremans, K. and Masson, P., eds), pp. 303–307, Editions John Libbey Eurotext, Montrouge, France
48 Hoover, D.G., Metrick, C., Papineau, A.M., Farkas, D.F. and Knorr, D. (1989) *Food Technol.* 43, 99–107
49 Knorr, R., Böttcher, A., Dörnenburg, H., Eshitaghi, M., Oxen, P., Richwin, A. and Seyderhelm, I. (1992) in *High Pressure and Biotechnology* (Balny, C., Hayashi, R., Heremans, K. and Masson, P., eds), pp. 211–218, Editions John Libbey Eurotext, Montrouge, France
50 Taguchi, T. (1991) in *Pressure-Processed Food – Research and Development* (Hayashi, R., ed.), pp. 111–121, San-ei Publications, Kyoto, Japan
51 Taguchi, T. (1991) in *High Pressure Science for Food* (Hayashi, R., ed.), pp. 235–246, San-ei Publications, Kyoto, Japan
52 Iso, N., Mizuno, H., Ogawa, H. and Iso, S. (1993) in *High Pressure Bioscience and Food Science* (Hayashi, R., ed.), pp. 300–306, San-ei Publications, Kyoto, Japan
53 Goto, H., Kajiyama, N. and Noguchi, A. (1993) in *High Pressure Bioscience and Food Science* (Hayashi, R., ed.), pp. 315–321, San-ei Publications, Kyoto, Japan
54 Lorenz, R. and Molitoris, H.P. (1992) in *High Pressure and Biotechnology* (Balny, C., Hayashi, R., Heremans, K. and Masson, P., eds), pp. 315–319, Editions John Libbey Eurotext, Montrouge, France
55 Yoshioka, K., Kage, Y. and Omura, H. (1992) in *High Pressure and Biotechnology* (Balny, C., Hayashi, R., Heremans, K. and Masson, P., eds), pp. 325–327, Editions John Libbey Eurotext, Montrouge, France
56 Murakami, T., Kimura, I., Yamagishi, T., Yamashita, M. and Satake, M. (1992) in *High Pressure and Biotechnology* (Balny, C., Hayashi, R., Heremans, K. and Masson, P., eds), pp. 329–331, Editions John Libbey Eurotext, Montrouge, France

EHEDG Update

Hygienic design of closed equipment for the processing of liquid food

The European Hygienic Equipment Design Group (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*. This is the 11th in a series of articles featuring the EHEDG to be published in *Trends in Food Science & Technology*. In a previous paper[1] the general criteria for hygienic equipment design were explained. The Design Principles subgroup of the EHEDG has subsequently produced further guidelines, summarized here, giving examples of how to apply the design criteria to equipment intended for use in closed plants.

This paper describes methods of construction and fabrication illustrating how hygienic design criteria can be met in closed process equipment. Examples are given to show how to avoid crevices, shadow zones and areas with stagnating product, and how to connect and position equipment in a process line to ensure unhampered cleaning in-place and draining. Attention is drawn to ways of preventing problems with joints, which might otherwise cause leakage or contamination of product with microorganisms or even with pieces of degraded elastomeric material.

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

Joints and seals

It is strongly recommended that joints are avoided where possible. For piping, bending of the pipe is highly preferable over the use of prefabricated bends with couplings. If pipe bending is not possible, welding is the preferred method, provided that the welding is done correctly, to ensure a smooth and continuous weld[2]. Where detachable joints are necessary, they should be sealed by elastomers.

Compression of elastomers

Overcompression of elastomers may affect the hygienic characteristics of equipment in two ways.

Firstly, overcompression may lead to destruction of the elastomer, particularly if the overcompressed elastomer is heated (such as during pasteurization or sterilization). The elastomer may become brittle and fail to

provide the required seal, while parts of the elastomer may contaminate the product. Secondly, overcompression may lead to protrusion of the elastomer into the equipment, thereby hampering cleaning and draining.

Undercompression too is highly undesirable as it may lead to crevices and fail to provide a reliable seal. Even when it is not visibly leaking, the seal may permit the ingress of microorganisms.

Self-evidently, not only the dimensions of the metal components, but also those of the gasket must be correct, ensuring adequate compression at the product side, taking into account differences in thermal expansion under all operation conditions (cleaning, pasteurization or sterilization, and processing).

Misalignment

Improper alignment may also result in inadequate cleaning and reduced drainability. Many designs of joints (e.g. traditional flange connections or the coupling according to DIN 11851) do not control compression of the gasket and automatically result in misalignment. In such cases the design incorporates relatively large clearances, intended to facilitate assembly. Both alignment and compression of the gasket can be controlled by the use of an 'I-line' coupling. The features that make the design hygienic can also be applied to flange connections.

O-rings

Installations containing conventionally designed O-ring seals invariably create crevices that are impossible to clean in-place. Further, it is difficult to inactivate microorganisms present in conventional O-ring seals, as elastomers have significantly higher thermal expansion coefficients than steel (e.g. that of rubber is $\sim 200 \times 10^{-6}$/K while that of steel is $\sim 16 \times 10^{-6}$/K); therefore, when heating equipment with O-ring seals, the expanding O-ring will cover an increasingly large surface of steel, protecting microorganisms trapped between the O-ring and the steel surface against contact with the hot water, chemical solution or steam used for cleaning (Fig. 1a). After cooling down and shrinkage of the O-ring, the survivors will be freed and will infect the product that will fill the gap at the start of production[3].

Note that although the seal contact surface will usually reach the correct temperature during treatment with hot water or steam, the water activity (a_w) will be too low for the destruction of many microorganisms at the temperature and time applied, which will have been chosen on the basis of $a_w = 1$ (see Pfeifer, J., PhD thesis, Technischen Universität München, Germany, 1992).

O-rings can be acceptable from a hygienic point of view if mounted in a way that ensures that the area of steel covered by the rubber at the product side is not influenced by thermal expansion. Examples of acceptable applications are shown in Fig. 1b. Because of the volume of the elastomer, its virtually complete enclosement and the differences in expansion between elastomer and steel, forces inside the elastomer may be high and may result in accelerated ageing, so that periodic replacement may be required. Metallic stops should

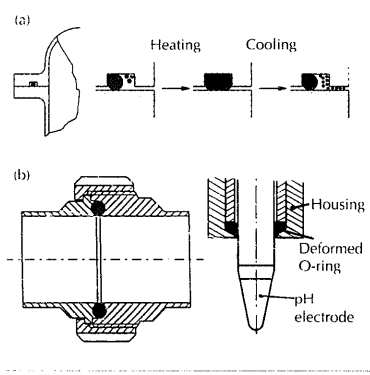

Fig. 1

(a) O-rings made from elastomers may protect microorganisms against contact with hot water or steam as a result of differences in thermal expansion (scale exaggerated). (b) Acceptable uses of O-rings in a pipe coupling (left) and a pH electrode fitting (right).

ensure bacteria tightness but avoid destruction of the elastomer during heating.

Metal-to-metal joints

Metal-to-metal joints (other than welds) seal as a result of the deformation of the contacting metal surfaces. The result is permanent damage to these surfaces, which makes it more difficult to obtain a tight seal after every disconnection. Even when these joints are not visibly leaking, the ingress of microorganisms is possible. Further, the seal obtained is very unlikely to be at the product side; more likely, the actual seal follows an irregular line between the inside and outside. The resulting annular crevice will trap product. Therefore, metal-to-metal joints must not be used in a hygienic plant.

Dynamic seals

Care must be taken that dynamic seals do not only seal, but that their construction can be cleaned as well. The narrow annular space which is usually found at the product side in the proximity of the seal must be avoided. The space around the seal should be as wide as possible. Single dynamic seals will not prevent the passage of microorganisms. Equipment with single dynamic seals, if properly designed, will be hygienic, but not aseptic.

Bacteria tightness

For aseptic equipment bacteria tightness is an additional requirement. For static seals, elastomers should be used, as discussed above. The materials should be resilient enough to guarantee an adequate seal under all process conditions. Consequently, attention must be

given to the thermal expansion in relation to both the maximum temperature (e.g. during pasteurization or sterilization) and minimum temperature (e.g. during the manufacture of ice cream).

Materials that have insufficient resilience and which expand to a different extent than stainless steel, such as polytetrafluoroethylene (expansion coefficient of $\sim 100 \times 10^{-6}$/K), may change shape as a result of heating, resulting in the material not providing a tight seal anymore after cooling down.

Dynamic seals should be avoided in aseptic equipment. This may be achieved by using bellows or diaphragms that separate the seal from the product side. Where that is not possible (e.g. in the case of rotary seals), double seals must be used. The space between the seals must be flushed with either an antimicrobial fluid (such as hot water, steam or a solution of an antimicrobial chemical) or with sterile water, to simply flush away microorganisms that enter the space between the seals. Which flushing fluid should be used will depend on product requirements.

To avoid the transfer of microorganisms from the outside of the equipment to the inside, the distance between the two seals must always be greater than the stroke of the reciprocating shaft, to ensure a sufficiently long exposure to the amtimicrobial fluid. It should be realized that rotating shafts too often exhibit some axial mobility and hence assist the penetration of microorganisms.

Drainability

Care must be taken that any closed process line can be fully drained. Piping should slope 3° towards draining points. Even smooth constructions may hamper draining. This is illustrated in Fig. 2a, which shows connections between pipes of different diameters. Although for vertical piping a concentric reducer is fully acceptable, this is not so for horizontal piping, where a concentric reducer would affect drainability. For horizontal piping an eccentric reducer must be used. Self-evidently, reducers should be long enough to avoid shadow zones.

To avoid dead areas in equipment, it is recommended to avoid the use of 'tees'. If that is not possible, short, right-angled tees or 'swept tees' (Fig. 2b) may be used. Swept tees must be used with caution, however, as in horizontal pipelines a swept tee could hamper draining.

Some types of pumps are traditionally positioned in such a way that draining is impossible without dismantling. The same type of pumps can also be designed for positioning in a drainable position (Fig. 2c).

Avoidance of dead areas

The traditional way of mounting pressure transmitters and temperature probes in process lines, on 'tees', results in large dead areas, which are unacceptable (Fig. 3a; left).

It is easy to avoid such dead areas, for example by mounting the pressure transmitter on a swept tee or by using transmitters with tubular membranes with the same inner diameter as the adjacent pipelines.

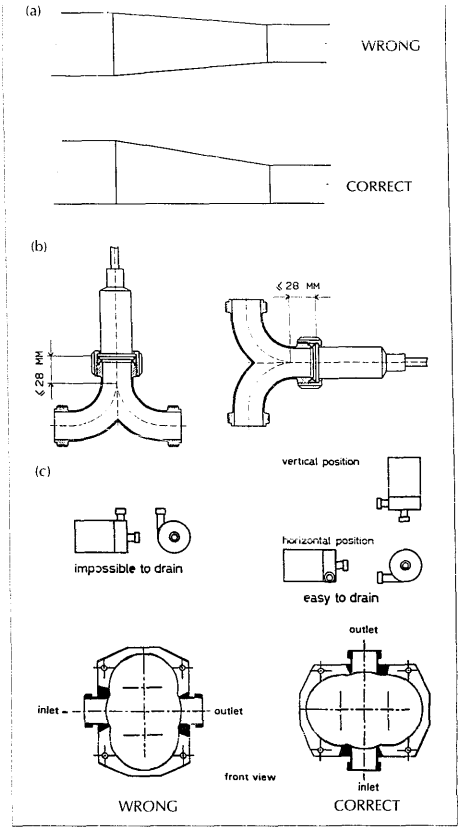

Fig. 2

Ensuring drainability. (a) Even smooth transitions between pipe diameters may hamper draining if the upper, concentric method is used for horizontal piping; the lower, eccentric method will not affect draining in either direction. (b) The use of swept tees avoids dead areas, but if mounted in a horizontal pipeline (left) may hamper draining; swept tees must preferably be mounted in a vertical pipeline (right). (c) It is important to position centrifugal (top) and lobe (bottom) pumps in such a way that they are drainable (right).

For temperature measurement a surface probe (again, with the inner diameter of pipe the same as that of the adjacent piping) is – from a hygienic point of view – the best choice. Alternatively, a welded pocket may be used. Sufficient attention should be given to the quality of the weld, which must be smooth and continuous. Further, to avoid shadowing, the direction of the flow must be as shown in the right-hand side of Fig. 3a.

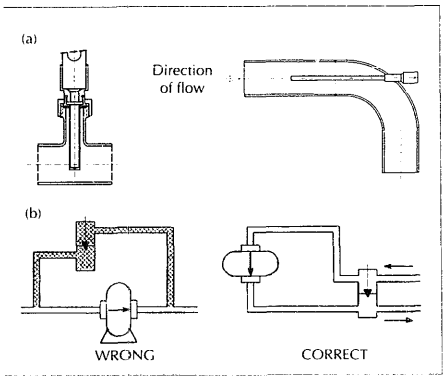

Fig. 3

Avoiding dead areas. (a) The temperature probe at left is mounted such that an unacceptably large dead area is created; that at right is mounted in a welded pocket, avoiding dead areas. (b) The pressure relief/bypass valve for the positive displacement pump shown at left has a dead leg with a large amount of product (shaded area) when the valve is closed, as shown (note also that the pump is not in a position that allows draining). The same valve, in the arrangement shown at right, can be mounted in such a way as to avoid dead legs in the bypass and to allow draining of the pump.

Flow diversion should not be done in a way that would cause some of the product to stand still[3]. Dead legs towards a closed valve mounted on a tee must be avoided (Fig. 4).

Dead areas are also created where product pumps are equipped with a pressure relief valve or with a bypass in case the pumps have insufficient capacity for circulating the cleaning liquid at the required velocity. If arranged as shown in the left-hand side of Fig. 3b, during production product is entrapped in two large-volume dead legs. Such product may spoil and infect the passing product. With the same valve it is also possible to construct a bypass that is free of dead legs (Fig. 3b; right).

If a dead leg is unavoidable, it must be as short as possible. For pipe diameters of ≥25 mm, the dead leg should preferably be <28 mm; for smaller pipe diameters the length should be smaller than the diameter. The position of the dead legs is also important. For most liquids, a dead leg should be positioned as shown in Fig. 5c; this configuration may not be suitable, however, if products contain any particulate matter, which may accumulate in the dead leg. The configuration in Fig. 5a can be acceptable if the dead leg is very short. The direction of the flow of product has a significant influence on the residence time in the dead leg and should therefore be as indicated by the arrows. Upwards-pointing dead legs (Figs 5a, 5b) may prevent cleaning fluids (hot water or chemical solutions) from reaching all surfaces to be treated. A downwards-pointing dead leg will collect condensate during steam sterilization. In such a case, as well as if hot water is used, the temperature of the surfaces in the dead leg may be too low for pasteurization or sterilization, due to heat dissipation from the trapped water.

Surface roughness

For hygienic equipment the product contact surfaces should have a roughness of $R_a \leq 0.8$ µm, unless there is – in individual cases – evidence that a rougher surface is acceptable[1]. Table 1 lists the relation between different treatments of stainless steel and the surface roughness that can be obtained by each treatment. This table is intended as a guide only; whether the intended surface roughness has been obtained should be measured. Measuring instruments are readily available, and for surfaces that cannot be reached by such instruments, surface replicas can be made for indirect measurement[5–7].

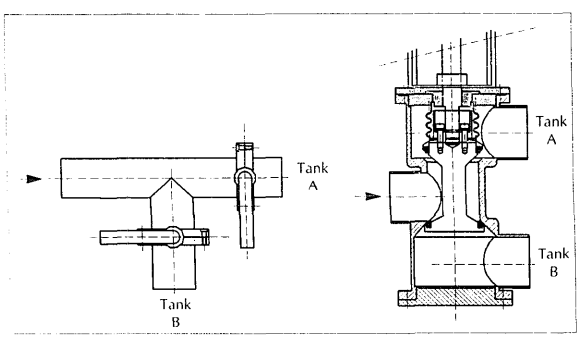

Fig. 4

Flow diversion should be done such that dead legs are avoided. The two-valve system for flow diversion (left) creates a dead leg towards the closed valve. The correct type of valve is shown on the right.

Sharp corners

Sharp corners must be avoided. All internal angles and corners should be well radiused to facilitate cleaning, both in the welding of metal plates perpendicular to each other and in the mounting of tank lids.

Screw threads

Exposed screw threads must not be used at the product side. If the use of screwed connections is unavoidable, a metal-backed elastomer gasket such as that specified by ISO 225:1983 should be used. Where possible, welding must be used at the product contact side, following the guidelines for hygienic welds[2]. An acceptable alternative might be the use of adhesives. If adhesives are used, care must be taken to ensure

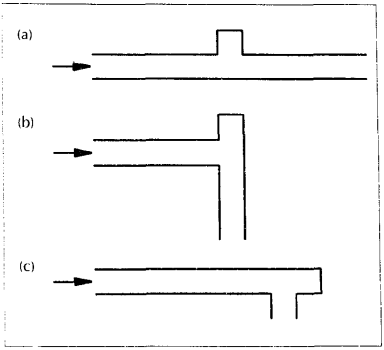

Fig. 5

Upwards-pointing dead legs (a,b) result in greatly reduced exchange of product or cleaning fluids between dead leg and main flow. Unavoidable dead legs should usually be arranged as shown in (c), with the direction of flow as indicated by the arrow. See text for details.

Table 1. Examples of surface treatments of stainless steel and the resulting surface roughness

Treatment	R_a (μm)
Cold rolling	0.2–0.5
Hot rolling	>4
Glass bead blasting	1.0–1.2 (Depends on bead size)
Descaling	0.6–1.3
Bright-annealing	0.4–1.2
Pickling	0.5–1.0
Electropolishing	Depends on original finish[a]
Mechanical polishing with aluminium oxide or silicon carbide of abrasive grit number:	
500	0.1–0.25
320	0.15–0.4
240	0.2–0.5
180	≤0.6
120	≤1.1
60	≤3.5

[a] Electrical polishing does little to improve the R_a value, but does round off peaks, improving cleanability[4].

that the seal obtained is reliable and can withstand process and cleaning conditions. Self-evidently, the adhesive must be acceptable for food-contact applications.

Thermal insulation

Pipework can be insulated by the evacuation of air from the shell of a double-walled pipe. This is a very effective way of meeting hygienic design criteria. If no vacuum is used, non-chloride-releasing insulation material should be used (such as appropriate qualities of rockwool). The insulation material should be covered by a stainless steel outer tube, fully welded to prevent the ingress of air, moisture or insects. Such ingress would promote corrosion between the walls, assisted by possible microbial growth. Ultimately, this would result in leaks, allowing microorganisms to contaminate the product. The same applies to the insulation of process vessels, which should therefore be fully enclosed. Depending on the duty of the vessel, it may be necessary to provide a vent hole to prevent unacceptable pressures between inner and outer wall (e.g. during sterilization).

Conclusions

There are generally various solutions to meeting hygienic design criteria. The examples discussed above illustrate this for a limited number of design principles; further examples are given in the full document, available from the EHEDG (see below). Other solutions may also be equally acceptable. Sometimes a solution is unconventional (such as in the case of the position of pumps) but can nevertheless be achieved without technical difficulties. Care must be taken that the hygienic characteristics (such as cleanability and drainability) of the individual parts of the equipment are not compromised by building a process line such that new shadow zones, crevices and undrainable situations are created.

Acknowledgement

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This paper summarizes guidelines recommended by the European Hygienic Equipment Design Group (EHEDG) subgroup on Design Principles, and has been approved by the EHEDG. The full report, by G.J. Curiel, G. Hauser, P. Peschel and D.A. Timperley, 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).

References

1 *Hygienic Equipment Design Criteria* (1993) in *Trends Food Sci. Technol.* 4, 225–229
2 *Welding Stainless Steel to Meet Hygienic Requirements* (1993) in *Trends Food Sci. Technol.* 4, 306–310
3 Lelieveld, H.L.M. (1990) *Processing Equipment and Hygienic Design* in *Microbiological and Environmental Health Issues Relevant to the Food and Catering Industries, Symposium Proceedings*, Campden Food & Drink Research Association, Chipping Campden, UK
4 Timperley, D.A. (1984) *Inst. Chem. Eng. Symp. Ser.* 84, 31–42
5 *Instruments for the Measurement of Surface Roughness by the Profile Method: Profile Recording Instruments (ISO 1880)* (1979) International Standards Organization
6 *Surface Roughness - Terminology - Part 2: Measurement of Surface Roughness Parameters (ISO 4287-2)* (1984) International Standards Organization
7 Dagnall, H. (1980) *Exploring Surface Texture*, Rank Taylor Hobson