BS EN 13951:2012

BSI Standards Publication

Liquid pumps — Safety requirements — Agrifoodstuffs equipment; Design rules to ensure hygiene in use

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National foreword

This British Standard is the UK implementation of EN 13951:2012. It supersedes BS EN 13951:2003 + A1:2008 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee MCE/6, Pumps and pump testing.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Liquid pumps - Safety requirements - Agrifoodstuffs equipment; Design rules to ensure hygiene in use

Pompes pour liquides - Prescriptions de sécurité - Matériel agro-alimentaire; Règles de conception pour assurer l'hygiène à l'utilisation

Flüssigkeitspumpen - Sicherheitsanforderungen - Nahrungsmittelausrüstungen; Konstruktionsregeln zur Sicherstellung der Hygiene bei der Verwendung

This European Standard was approved by CEN on 22 January 2012.

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Foreword

This document (EN 13951:2012) has been prepared by Technical Committee CEN/TC 197 “Pumps”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13951:2003+A1:2008.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The modifications brought to the previous version of EN 13951:2003 deal with normative reference updates, minor editorial changes, minor details add-on and the clause renumbering has been adapted accordingly.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This document is a type C standard as stated in EN ISO 12100.

The machinery concerned and the extent to which hazards, hazardous situations and events are covered are indicated in the scope of this document.

When provisions of this type C standard are different from those which are stated in type A or B standards, the provisions of this type C standard take precedence over the provisions of the other standards, for machines that have been designed and built according to the provisions of this type C standard.

In drafting this European Standard, it was assumed that pumps within the scope of this European Standard are in accordance with all relevant requirements of EN 809. EN 13951 provides additional hygiene related requirements to prevent the pump causing contamination of the pumped product when used in accordance with the instruction handbook.

It is the responsibility of the manufacturer to ensure that the pump is designed and manufactured such that it can be adequately cleaned. However, due to the influence of the product, the process and the cleaning regime adopted, it is only the end-user that can ultimately ensure hygienic conditions during operation.

1 Scope

This European Standard deals with the special technical safety requirements for liquid pumps and pump units operating with agrifood-stuff. This European Standard is intended to be used with EN 809 to give the additional requirements for hazards arising from the pumping of substances intended for human and domestic animal consumption (see Clause 4).

This European Standard also establishes requirements and/or measures for the reduction of risks during use, including misuse foreseeable by the manufacturer.

This European Standard is not intended to be used for pumps and pump units at any stage in the public water supply, nor for pumps handling pharmaceutical products, nor for any other application for which more appropriate standards exist.

The pumps and pump units covered by this European Standard are the following:

— rotodynamic pumps;

— rotary positive displacement pumps;

— reciprocating positive displacement pumps.

Pumps dealing with agrifood-stuff which are not indicated in this scope are potentially covered by EN 1672-2:2005+A1:2009.

This document is not applicable to liquid pumps for agrifoodstuff applications which are manufactured before the date of its publication as an EN.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 809, *Pumps and pump units for liquids — Common safety requirements*

EN ISO 4287, *Geometrical product specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters (ISO 4287:1997)*

EN ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100:2010)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 12100:2010 and the following apply.

3.1
food/agrifood-stuff products
product, ingredient or material intended to be orally consumed at any stage of its production process

3.2
food hygiene
taking of all measures during the preparation and processing of food to ensure that it is fit for human or animal consumption

[SOURCE: EN 1672-2:2005+A1:2009]

3.3
adverse influence
reduction of the fitness for consumption of a food; a food can be adversely influenced in particular by microbial pathogens or other unwanted micro-organisms, toxins, vermin, domestic animals and other contaminants

3.4
areas of equipment

Note 1 to entry: These areas are not to be confused with any others amongst those defined in other standards (e.g. electro-technical standards).

3.4.1
food area
set of machinery surfaces which are exposed to the food and from which the food or other materials can drain, drip, diffuse or be drawn into (self returned) the food or food container

[SOURCE: EN 1672-2:2005+A1:2009]

3.4.2
non-food area
area other than those specified above

3.5
product/pumped product
products passing through the pumps as a result of process, testing, cleaning, rinsing, or disinfecting products

3.6
cleaning
set of operations which reduce the potential for contamination to an acceptable level

3.6.1
cleanable
design and construction which permits soils to be removed by appropriate cleaning methods

3.6.2
cleanability
ability of the pump to be cleaned by a defined procedure to defined conditions of cleanliness

3.6.2.1
cleaned in place or mechanical cleaning (CIP, NEP)
CIP or NEP means soil removal by impingement, circulation or flowing chemical detergent solutions and water rinses into and on to the surfaces to be cleaned without dismantling

Note 1 to entry: The term CIP corresponds to the abbreviation of the English wording "Cleaned In Place". In French, the term NEP is the abbreviation of the wording "Nettoyage En Place". In German, the term CIP is used.

3.6.2.2
cleaned out of place or manual cleaning (COP, NHP)
COP or NHP means soil removal when the equipment is partially or totally dismantled

Note 1 to entry: The term COP corresponds to the abbreviation of the English wording "Cleaned Out of Place". In French, the term NHP is the abbreviation of the wording "Nettoyage Hors Place". In German, it is the term COP which is used.

3.7
contamination
presence of soils

[SOURCE: EN 1672-2:2005+A1:2009]

3.8
corrosion resistant material
material resistant to normally occurring action of chemical or electrochemical nature at all stages of food processing, cleaning and disinfection according to the instructions for use

3.9
crevice
surface defect e.g. crack, fissure, which has an adverse influence on cleanability

3.10
dead space
space wherein a pumped product, or soils may be retained or not completely removed during the cleaning operation

3.11
disinfection
process applied to a cleaned surface which is capable of reducing the numbers of viable micro-organisms, but not necessarily their spores, to a level considered safe for product production

3.12
sterilization
validated process used to reach a state free from viable micro-organisms including all relevant bacterial spores

Note 1 to entry: In a sterilization process, the nature of microbial death or reduction is described by an exponential function. Therefore, the number of micro-organisms that survive a sterilization process can be expressed in terms of probability. While the probability can be reduced to a very low number, it can never be reduced to zero.

3.13
durable
ability of a surface to withstand the intended conditions of use, for example: to resist damage caused by the action of the process, contact with the pumped product including thermal actions

3.14
joint
junction of two or more pieces of material

[SOURCE: EN 1672-2:2005+A1:2009]

3.15
non absorbent material
material which, under intended conditions of use, does not retain substances with which it comes into contact so that it has no adverse influence on pumped products

3.16
non toxic material
material which does not produce or release substances injurious to health under intended conditions of use

[SOURCE: EN 1672-2:2005+A1:2009]

3.17
seal
component to prevent the unwanted entry or passage of any matter

3.18
self draining
design and construction of the shape and surface finish so as to ensure the evacuation by gravity of the pumped products

3.19
smooth
condition of a surface (with reference to surface finish) which satisfies operational and hygienic requirements

3.20
soil
any unwanted matter, including product residues, micro-organisms, residual detergent or disinfecting agents

[SOURCE: EN 1672-2:2005+A1:2009]

3.21
vermin
animals (including mammals, birds, reptiles and insects) which may adversely influence the pumped products

3.22
toxic/toxicity
toxicity of a material is defined by EU or local regulations.

Note 1 to entry: Toxicity depends on the quantity of material which can migrate either by wear or by diffusion in the pumped product under intended use.

3.23
compatibility (material)
compatibility means that the material is non absorbent and insoluble, and that the material surfaces do not deteriorate due to chemical, microbiological, mechanical or thermal action, as a result of contact with the pumped product

3.24
compatible (liquid)
compatible means that the liquid identified does not create toxic conditions or any other adverse influence when mixed with the pumped product

3.25
method of assembly
steps to assemble components or parts when they are in a dismantled state

3.26
auxiliary liquid
auxiliary liquid is a liquid provided for flush, pressure balance, or other similar purposes

3.27
barrier liquid
barrier liquid is an appropriate (that is clean, compatible, etc.) liquid inserted between two seals or barriers

4 List of hazards

The potential hazards which can be associated with pumps and pump units used for pumping agrifoodstuffs products can arise from:

— micro-biological causes such as pathogens, spoilage, micro-organisms or toxins resulting from their ingress to or retention by the product;

— chemical causes resulting from contamination such as lubricating, cleaning, or disinfection substances;

— foreign materials entering the product such as unwanted allergies, pests, metals, wear debris, etc., resulting from raw materials or other materials used in the construction of the equipment, or entry through unprotected openings;

— mechanical causes such as possible mis-assembly or mis-use resulting in opportunities for micro-biological, chemical or foreign material hazards;

— any deterioration resulting from thermal, chemical, or vibration effects on the pump or plant.

The micro-biological hazards which may arise in a pump or pump unit reflect the particular characteristics of the installation in which it is installed such as whether the pumped product can develop micro-organisms, or whether these are reduced to non-hazardous levels by subsequent stages of the process, or the operating pattern involving a change in the product being pumped.

For these reasons it is only possible to fully assess the hazards only by considering the whole production line. It is the responsibility of the user to consider the hazards and to carry out any tests deemed to be necessary to demonstrate the reduction of risks.

The manufacturer of the pump or pump unit assists in the reduction of risks by designing the pump or pump unit to avoid undesirable features known to create risks to hygiene, and to accommodate effective cleaning. The reduction of other non-biological hazards should also be considered during the design of the pump or pump unit.

The hazards can be generated at any time during the stages of installation, commissioning, adjustment, operation, maintenance, or disposal, from the normal usage or from foreseeable misuse of the pump or pump unit. The risks of hazards shall be assessed using the procedure described in EN ISO 12100 (see Figure 1) and steps taken to reduce the risks to an acceptable level using the safety requirements or methods, and means of verification given in this European Standard and indicated also in Table 1.

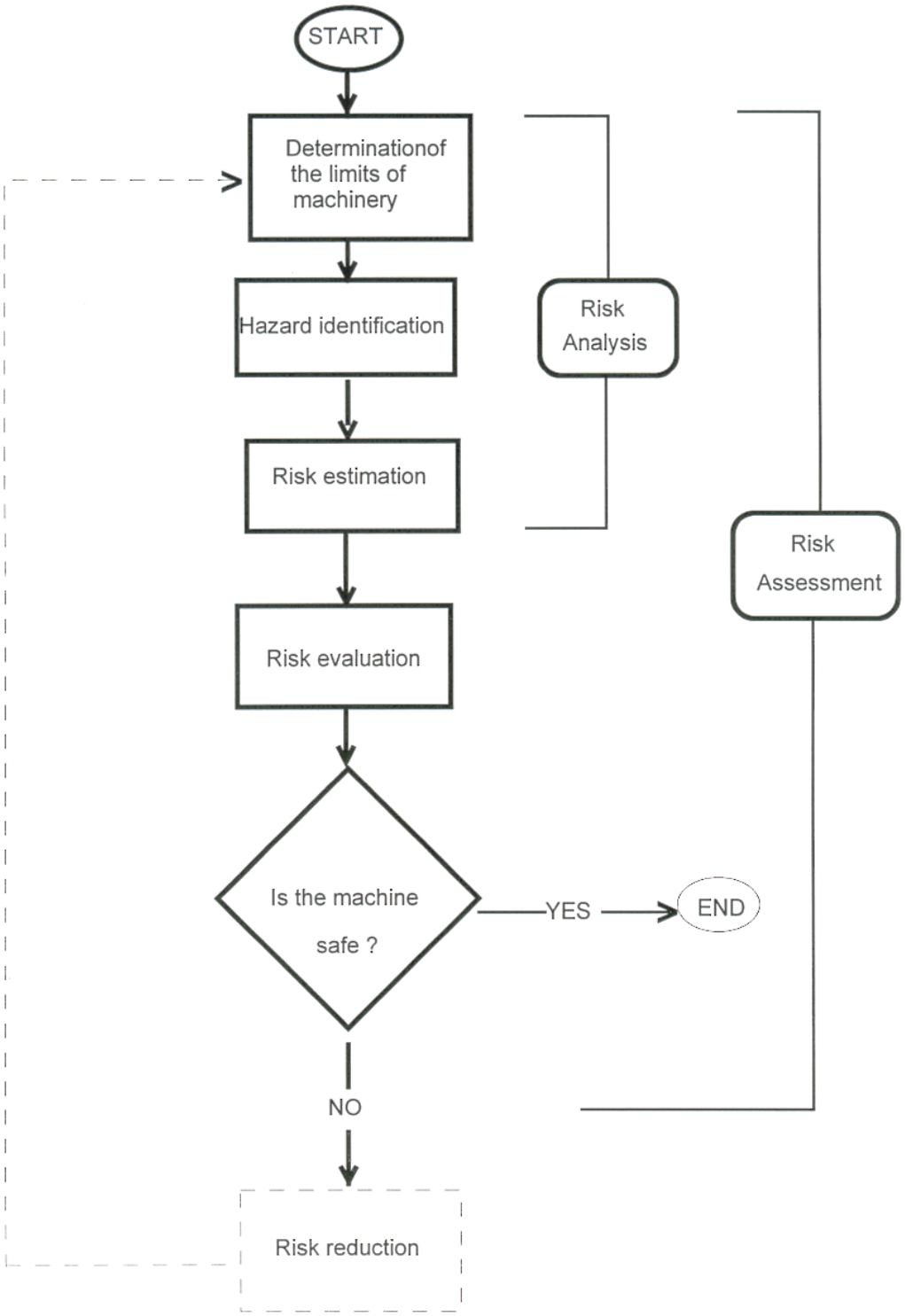


Figure 1 — The iterative process to achieve safety

Table 1 — List of hazards related to hygiene which are addressed in this European Standard

Significant hazards to hygiene	EN 13951	
	Reference to sub-clause	
	Measures to reduce the hazard	Means of verification
Hazards arising from the ingress of foreign matter	**Clause**	**Clause**
- wear debris	5.2.1, 5.2.2.1	6.4
- sealing of openings and joints	5.3.6, 5.3.11, 5.3.12, 5.4.1	6.3
- sealing around shafts	5.3.9	6.3
- spillage of product	5.4.1	6.3
- vermin	5.4.1, 5.7	6.3
Hazards arising from microbiological causes		
- retention of product.		
- general	5.3.1, 5.3.2, 5.4.1	6.5
- cleaning	5.3.2, 5.3.3	6.5
- draining	5.3.2, 5.3.3.1, 5.3.11	6.3
- surface finish/texture	5.3.5	6.6
- obstructions/protrusions	5.3.2, 5.3.7	6.3
- bearings	5.3.8, 5.4.2	6.2, 6.3
- shaft seals	5.3.9	6.3
- fasteners	5.3.10, 5.4.3	6.3
- sensors	5.3.12	6.2, 6.3
- lubricants	5.5	6.2, 6.3
Hazards arising from chemical causes		
- material compatibility	5.2	6.4
- general	5.2.1, 5.2.2.1, 5.3.9	6.4
- metals	5.2.2.2	6.2, 6.4
- non-metals	5.2.2.3	6.2, 6.4
- non-food areas	5.2.3	6.4
- soldering	5.3.6	6.3
- cleaning fluids	5.3.3.1	6.3, 6.5
- sensors	5.3.12	6.3
- auxiliary liquids	5.3.8, 5.5	6.2, 6.4
- barrier liquids	5.5	6.2, 6.3
Hazards arising from mechanical causes		
- material finishes	5.2	6.3, 6.6
- joints	5.3.6	6.2, 6.3
- fasteners	5.3.10	6.2, 6.3
- mis-assembly	5.4.3	6.2, 6.3

5 Hygiene: safety requirements and/or measures

5.1 General

The operating conditions and features required of every pump unit covered by this European Standard shall be either defined by the user in a specification or by the manufacturer's description which includes limits of operation.

The manufacturer shall assess any foreseeable hazards to hygiene arising from operating conditions where specified of the pump or pump unit. The pump or pump unit shall be designed in such a way as to reduce hazards identified by this European Standard to an acceptable level. Specifications shall classify the pumps and units, including auxiliary equipment, according to the levels of cleanability required. It is the purchaser's responsibility to select the levels of cleanability appropriate to the application, taking into account the risks arising from the pumped product, the placement of the pump in the process and the cleaning regime anticipated.

Where the means of reducing the risk is by a safe system of working the machinery, the manufacturer shall include in the information for use details of the systems of the element of training required by the operating personnel.

5.2 Materials

5.2.1 Common requirements

Materials shall be suitable for intended use.

Surfaces of materials and coatings shall be durable, cleanable, undamaged and without breaks, resistant to chipping, flaking, erosion, corrosion and abrasion, and prevent penetration of unwanted matter during intended use.

The pump components intended to be dismantled for cleaning shall not be painted.

5.2.2 Food areas

5.2.2.1 Additional requirements

In addition to the common requirements set out in 5.2.1, materials used in the food contact area shall be compatible with the pumped product under all foreseeable conditions of use. The compatibility shall not be compromised by the cleaning solutions nor by any disinfection and sterilization treatments specified by the customer.

The materials shall be non-absorbant, except where this is technically or functionally unavoidable in which circumstance it shall not reduce the level of safety intended.

Operation at intended pressures and product velocities shall not be detrimental to the performance of the materials nor shall temperature give rise to risks from thermal expansion or contraction nor any other thermal degradation.

The materials shall be non-toxic and not deleterious to health, and incapable of being dissolved or broken down into elements or compounds. Where coatings (metallic or non-metallic) and/or adhesives are used to meet these requirements, the bond shall be and remain continuous.

The pumped product shall remain non-toxic.

Where parts within the pump are subject to wear (for example, mechanical seal rings or close-fitting, rotating rubber components), any wear debris shall be of a size and quantity which is not deleterious to health or to the quality of the pumped product.

If abrasive (for example, crystalline or fibrous) foodstuffs will be pumped, the possibility of abrasive wear of the surfaces should be considered and the choice of material subject to agreement between customer and supplier.

The manufacturer shall define the safe working value of *NPSHR*/*NPIPR*, (i.e. net positive suction head required/net positive inlet pressure required) to avoid damage to the material surfaces from cavitation erosion.

Any specific hygienic hazards which can appear because of a misuse e.g., dry running, poor *NPSHA* (i.e. net positive suction head available), poor *NPIPA* (i.e. net positive inlet pressure available) shall be clearly specified in an instruction handbook.

NOTE Definitions of NPSHR, NPIPR, NPSHA and NPIPA are available in ISO 17769.

5.2.2.2 Metals

Product contact surfaces shall be of stainless steel of a type appropriate to the application, or of other metals (including solder) suitable for the conditions of intended use.

NOTE 1 General experience has shown that the varieties of austenitic stainless steel complying with the following specifications is compatible with the majority of food stuff:

— C ≤ 0,08 %

— Cr ≥ 13 %

— Ni ≥ 8 %

Other stainless steels such as duplex stainless steels are often used in pumps.

A typical specification for duplex stainless steel is: Cr 22 % Ni 5 %.

NOTE 2 Consideration should be given to designating stainless steels in accordance with EN 10088-1.

5.2.2.3 Plastics and elastomers

All plastic materials used shall be produced only from monomers according to EU regulation (see Annex A) and shall conform to the general requirements of this European Standard.

All elastomeric materials used shall conform to the general requirements of this European Standard and take into account the information provided in Annex A.

5.2.3 Non-food areas

In addition to the common requirements set out in 5.2.1, materials used in the non-food contact areas shall not react chemically with the product in its pumped condition nor any cleaning solutions nor by the disinfection and sterilization treatments specified by the customer, in such a way as to reduce the suitability of the material for its intended use in the non-food area.

Pump components in non-food areas shall be made from corrosion resistant materials or rendered corrosion resistant by an appropriate treatment or coating. If a coating is used it shall be well bonded and act as part of the component to which it is bonded. The materials shall be non-absorbent, durable and washable.

Solid or laminated plastic or rubber materials shall present a visually continuous surface finish and shall be non-porous. All surfaces shall be free from cracks and indents, unless, as in the case of castings, cleanability can be demonstrated.

5.3 Design – Food areas

5.3.1 General design criteria

A pump shall be designed to reduce to the minimum possible the opportunities for hazardous conditions arising in the product during the operation of the pump.

Examples of construction to take into account hygienic risks are given in EN 1672-2:2005+A1:2009, Annex A and in Annex C of this European Standard.

All areas within the pump, particularly those with restricted access by the pumped liquid, shall be designed to ensure circulation.

5.3.2 Avoidance of product retention

Pumps should be designed in such manner as to reduce product retention as far as is practicably possible.

It should be ensured that the pump/pump unit is self draining, or that the residual product can be removed by other means.

Where product retention cannot be avoided, or self-draining cannot be fully assured, reference to the areas concerned shall be identified in the operating instructions including methods for cleaning, draining and disinfecting. Dismantling for cleaning shall be permitted.

Dead spaces should be avoided unless technically impossible in the design, construction and installation of the pump/pump unit.

Dead spaces, which are unavoidable, shall be constructed in such a way that they are drainable/cleanable and capable of being disinfected, where required. The instruction handbook shall mention theses areas.

All surfaces as well as the point at which they are joined shall be free from any protrusion or cavities capable of retaining product.

Wherever possible, internal angles smaller than 135° between adjacent surfaces should be rounded off with a radius 3,5 mm min.

Where a smaller radius is necessary due to space and functional requirements, this should be compensated by CIP (NEP) circulation velocities or cleaning procedure, to ensure cleanability.

Fillets should be used wherever practicable.

Where used, grooves shall be wider than their depth.

Grooves shall be so constructed that they are effectively cleanable.

5.3.3 Cleanability

The manufacturer of the pump or pump unit shall declare in the instruction handbook the level(s) of cleanability achievable in accordance with the present standard or otherwise agreed with the purchaser. Verification shall be demonstrated by the appropriate method described in 6.5 applied by the manufacturer of the pump or pump unit alone, or applied by the purchaser to the complete plant into which the pump is installed.

The manufacturer shall specify if the pump is not suitable for manual cleaning (COP, NHP) or mechanical cleaning (CIP, NEP).

5.3.3.1 Pump designed for mechanical cleaning (CIP, NEP)

The pumps intended to be cleaned in place shall be designed to ensure good circulation and removal of retained product subject to the level of cleanability specified. Care shall be taken to ensure that the cleaning fluid can be adequately drained or adequately diluted to prevent any risk of a hazard resulting from retained cleaning fluid.

Where inspection is required following mechanical cleaning (CIP, NEP), components shall be easily accessible or removable to expose all places where product retention could possibly occur.

In the instruction handbook, the manufacturer shall specify the procedure to be used when cleaning.

5.3.3.2 Pump designed for manual cleaning (COP, NHP)

Product contact areas in pumps not designed for mechanical cleaning (CIP, NEP) shall be accessible for cleaning and inspection during the cleaning process whether removed or remaining in situ. Parts that can be dismantled shall be readily removable.

The design detail shall be determined in order to assist in the process of cleaning. This may be by partial or full dismantling, and cleaning by washing or immersion of individual parts or sub-assemblies. All places where product retention could possibly occur shall be exposable.

Cleaning methods and cleaning materials shall not cause deterioration to those characteristics of the parts being cleaned which were the reasons for their selection.

5.3.3.3 Level of cleanability

Pumps complying with this European Standard shall achieve one of the specified levels of cleanability which shall be identified by the manufacturer in the instruction handbook, and may be related to specific types of processes and cleaning procedures (test procedures). This shall be described also in the instruction handbook.

— Level 1: the pump shall comply with 5.2.1, 5.3.8 and 5.5 and permit soils visible to the naked eyes after in-plant cleaning.
The level of micro-organisms remaining is not defined.

— Level 2: the pump shall comply with all applicable clauses of this European Standard and permit soils visible to the naked eye after in-plant cleaning.
The level of micro-organisms remaining is not defined.

— Level 3: the pump shall comply with all applicable clauses of this European Standard and permit no soils visible to the naked eye after cleaning.
The level of micro-organisms remaining is not defined.

— Level 4: the pump shall comply with all applicable clauses of this European Standard and permit no soils visible to the naked eye after cleaning.
A defined level of micro-organisms remaining shall be achieved.

NOTE If the micro-organisms test includes a visible soils test, it is not necessary to conduct a separate visible soils test.

5.3.4 Sterilization

In the instruction handbook, the manufacturer shall declare, any limitation on the method of sterilization which may apply.

5.3.5 Surface texture

The surface texture shall be such as to avoid retention of the product.

For materials used in food area, the surface texture shall be such as to favour a satisfactory cleanability (for metallic materials see Annex B).

5.3.6 Permanent and dismantleable joints – General criteria

All joints shall be designed in such a way as to reduce to a minimum any protrusion, edges and recesses.

Permanent metal to metal, metal to non-metal and non-metal to non-metal joints shall be continuously bonded (see Figure C.1). Soldering, press-fitting or shrink-fitting may be employed, only in cases where welding or bonding is impractical and where necessary for essential functional reasons. In all cases, appropriate treatments shall be applied to fill any clearance or crevice.

Soldering alloy and the material used for impregnation shall meet all requirements of 5.2.1.

Dismantleable joints used for normal operation or for maintenance shall be designed as far as is possible to prevent incorrect re-assembly where this may give rise to a hygiene hazard or may adversely affect measures taken to reduce hygiene hazards.

Dismantleable joints including joints where pipelines or other appendages enter the equipment shall be cleanable and designed to prevent the ingress of contamination or to be the sources of other hygiene hazards.

The pumps shall be designed so that any incorrect re-assembly leading to a hazardous operating condition is not possible. A hygienically safe seal shall be achievable. Over-tightening shall be prevented or shall not cause any reduction in the efficacy of the seal. The pumps shall carry permanent notices warning operators of hazards from incorrect use.

Annex D gives recommendations in order to reduce hygienic risks in pumps connections.

5.3.7 Process flow obstructions and intrusions

Process flow obstructions and intrusions (e.g. springs, openings, perforations, integral relief valve, valves and poppets) should be avoided except where functionally necessary.

Where functionally necessary, such process flow interruptions and intrusions should be cleanable in place or readily accessible for cleaning and inspection.

They shall be installed to avoid dead spaces and to be capable of being drained.

5.3.8 Product contact bearings

Bearings in contact with the product shall be avoided wherever possible. When technically necessary, these bearings shall be cleanable (see Annex B).

5.3.9 Shaft seals

The assessment of specific hazards associated with a dynamic sealing system in a pump shall take into account the following criteria:

— that the sealing system shall present a barrier between the interior of the pump and its exterior, which could be a passage for micro-organisms;

— that the sealing system can produce local overheating;

— that the product circulation speed may be low;

— that a hidden product retention area, difficult to clean, may be created.

The parts comprising the shaft seal when assembled in a pump shall meet the same requirements as the pump into which they are fitted with regard to the materials and cleanability.

Shaft seals shall be hygienically designed and be readily accessible for cleaning and inspection. If necessary for technical reasons, a full cleaning procedure shall be described in the instruction handbook.

Where a shaft passes through a product contact surface, the portion of the opening surrounding the shaft shall be protected to prevent the entrance of contaminants.

Packed gland or other type of seals (O-ring, lip seal, etc.) which can retain product shall be avoided in pumps for processes and systems which can develop pathogenic micro-organisms and for which the stages of the process after the pump does not assure their reduction to an acceptable level.

Single mechanical seals can give low risk levels of hazards where there is no micro-organisms involved and effective cleaning can be carried out. Such arrangements shall be assessed for the acceptability of the residual levels of hazards and, if appropriate, information shall be included in the Instruction book. Double mechanical seals, or single mechanical seals in tandem or fitted with an external quench can give low risk levels of some hazards. The seal arrangement shall be assessed for the acceptability of the residual risks of hazards taking into account the nature and characteristics of the pumped product and, where appropriate, information shall be included in the Instruction book.

NOTE The hygienic risk level linked to the choice of sealing system and the characteristics of the pumped product is indicated in informative Annex E.

5.3.10 Fasteners

Fasteners (e.g. screws, bolts, rivets) should be avoided. Where technically unavoidable, fasteners shall be cleanable (see Figure C.2). There shall be no exposed screw threads or recesses in the food area.

Exposed surfaces shall have the same surface finish requirement and other contact surfaces shall be free of markings.

5.3.11 Access and drainage ports

These shall be designed so that they avoid any adverse influence (e.g. entry and/or accumulation of any soil). They shall be cleanable and, where required, capable of being disinfected.

5.3.12 Sensors and sensor connections

All sensors and sensor connections having product contact surfaces shall conform to all the requirements of this European Standard and shall be installed to avoid crevices, dead spaces and be drainable and cleanable if necessary.

5.4 Design - Non-food areas

5.4.1 General criteria

Equipment should be designed and constructed in such a manner as to prevent the retention of moisture, ingress and harbouring of vermin and accumulation of soils, and to facilitate inspection, servicing, maintenance, cleaning and, where required, disinfection. Tubular framing shall be totally closed or effectively sealed.

Pumps and pump units shall be designed such that any product which comes in contact with a non-food area shall be drained and shall be prevented from returning to the mass of product being processed or shall require manual intervention to over-ride the means of prevention. Where return of product may occur as a result of normal use or of foreseeable misuse the area contacted shall be considered to be a food area.

Non-food areas shall be washable and shall be angled to prevent the retention of washed product.

5.4.2 Bearings

Bearings, including the permanently sealed type, shall be located outside the product contact surface with adequate clearance for inspection between the bearing and any product contact surface (see EN 1672-1:2005+A1:2009, Annex A).

5.4.3 Quick-release fasteners

Warning of the hazards associated with fasteners not requiring the use of a tool shall be mentioned in the instruction handbook.

Incorrect re-assembly of such fasteners shall not lead to a hazardous operating condition. Over-tightening which causes distortion, or otherwise prevents the achievement of a hygienically safe seal, shall be prevented. If this is by the use of a special tool, it shall be supplied with the pump.

5.5 Auxiliary liquids, barriers and lubricants

If an auxiliary liquid, barrier substance or lubricant comes into contact with the pumped product, either during normal operation or as a result of a failure, no toxic condition shall result. The machinery which supplies an auxiliary liquid, shall be equipped with a system which informs the user of migration of liquid into the pumped product.

Any auxiliary liquid, barrier substance or lubricant shall be non toxic and compatible with the pumped product.

The residual risk depends on the process and the pumped product. The user shall be informed of this in the instruction handbook.

5.6 Guards and shrouds

The guards and shrouds are in non-food areas, consequently all requirements for non-food areas apply.

5.7 Legs

Legs shall be of a sufficient length to provide a minimum clearance between the lowest part of the base, pump, motor or drive and floor no less than 100 mm on pumps with legs designed to be fixed to the floor or pumps having a horizontal base area or more than 0,1 m^2. If the area is less than 0,1 m^2 the minimum clearance shall be 50 mm.

6 Verification of hygiene measures

6.1 General

Verification of compliance with the hygiene requirements is undertaken by using one or more of the methods set out below. The appropriate measures for a particular requirement is indicated in Clause 4, Table 1.

6.2 Inspection of documentation

Examination is made of the specifying documents, drawings, and of the pump data as indicated in the instruction handbook to establish conformity.

Reference may also be made to material certificates or other supplier documentation.

6.3 Inspection of the assembled pump or pump unit

Visual examination is made of the pump or pump unit and its nameplate, and where appropriate, comparison with its documentation and instruction handbook, to demonstrate conformity with a particular requirement.

6.4 Materials

Assessment of a material against the requirements of this European Standard shall be made by the manufacturer using appropriate tests, or field experience. Details of the assessment shall be recorded.

The manufacturer shall apply verification measures defined in 6.2 and 6.3 to assure that a specified material has been used in the construction of the pump.

6.5 Level of cleanability

The verification, that the level of cleanability of the pump is satisfactory for its purpose, shall be carried out either on the pump itself or on a test pump which is identical to or sufficiently similar to, the pump to be purchased, or on the process plant in which it is installed.

Any test to be carried out on the pump shall demonstrate cleanability either under a standard or agreed cleaning regime, or by a method which demonstrates cleanability compared with that of a standard component (e.g. a length of pipe prepared to standard conditions). General practice indicates that requirements for cleanability are more or less stringent, depending on the product being pumped and the placing of the pump within the (overall) process (i.e. raw foodstuff/ingredients or finished product).

The cleanability of pumps shall be verified by a method which is adapted to the level of cleanability required by its use.

NOTE The verification proves a level in cleanability but not an absolute cleanability.

Where a test is required, the procedure can vary. It shall be written and published by a laboratory or by the manufacturer. It shall include:

— soil definition;

— cleaning procedure;

— inspection method and acceptance criteria.

6.5.1 Cleanability levels 1 and 2

The cleanability shall be assessed by applying verification measures defined in 6.2 and 6.3.

6.5.2 Cleanability level 3

The cleanability shall be assessed by applying verification measures defined in 6.2 and 6.3 together with tests for visible soils established by the manufacturer or by a laboratory.

6.5.3 Cleanability level 4

The cleanability shall be assessed by applying verification measures defined in 6.2 and 6.3 together with tests established by the manufacturer or by a laboratory which shall comprise:

— visible soil test;

— micro-organisms test.

See note of the 5.3.3.3.

For levels 3 and 4 the non conformance from these requirements which do not adversely affect the level of cleanability shall be permitted. In that case, the manufacturer shall mention it in the technical documentation.

6.6 Surface roughness test

Surface roughness tests shall be carried out in accordance with EN ISO 4287.

7 Information for use

7.1 General

The requirements of EN 809 shall be applied.

7.2 Instruction for use - Instruction handbook

The requirements of EN 809 and the following additional requirements shall be applied:

— instructions relating of hygiene whilst handling, putting into service, operating, and maintaining the pumps;

— any special instructions relating to cleaning, disinfection or sterilisation of the pump;

— specifications of lubricants, auxiliary liquids, etc., where hygiene is implicated;

— relevant guidance on hygienic requirements for any auxiliary equipment supplied by the user;

— safeguards to be provided by the user as part of the installed arrangements;

— information on safe systems of working and the elements of training required to be given to the operators.

During the maintenance and the replacement of parts or components supplied by the manufacturer, the integrity of material and the original level of hygiene and safety shall be maintained.

Annex A
(informative)

Materials in contact with foodstuffs (EU regulations)

A.1 Metallic materials in contact with foodstuffs

There is experience of the successful use of a wide range of metallic materials used in contact with a pumped product. The choice of a particular material is made to be suitable for the product with which it will come into contact.

The selection process needs to consider the chemical interaction of the metal and the pumped product, its solubility in whole or in part, and any other mechanism which may lead to loss of material to the pumped product.

In some European countries, this experience has been codified into local regulations listing acceptable metals or prohibit others to take into account in selecting materials for use with a pumped product. A European Directive on the use of metals with foodstuff applications is in preparation.

The responsibility of a manufacturer to supply components in metals meeting the requirements set out in this European Standard is not reduced by any local regulation.

A.2 Elastomeric materials in contact with foodstuffs

At the moment, there are different acceptance criteria regarding the use of elastomeric materials for contact with foodstuffs.

There are a large number and amount of additives, oils, reinforcements used to formulate rubbers. Elastomers are also manufactured through a chemical crosslinking reaction called vulcanization. This latter process can both generate and remove various chemicals (or various chemical products) during the curing.

Thus, the various chemicals in the mixture or in the cured elastomer all require analysis including the original products and the newly created ones.

According to exposure and contact duration, classes are established presenting different severity levels.

A.3 Plastic materials in contact with foodstuffs

The European regulation in this field is based on European Directive, n° 89/109/EEC dated 1988/12/21.

In this field of plastic materials, a list of monomers and substances allowed in manufacturing plastic materials or plastic material products which could be in direct contact with foodstuff, has been established. The list which is still subject to amendment is found in the European Regulation 90/128 dated 1991/08/1 modified 92/39 dated 1992/05/14.

Special requirements deal with frequently used pigments and colouring in plastic materials, and content of heavy metals is particularly checked.

Annex B
(informative)

Surface roughness

Surface finishes can be determined by what is required to satisfy hygienic criteria according to pump application and selection by the user.

The cleanability of metallic surfaces has been shown to be influenced by:

- the topography of the surface (profile, roughness,…) see EN ISO 13565-2;
- local fluid velocities;
- pump type;
- application;
- cleaning process.

Of these, the first three are closely related and are often dictated by practice and previous successful experience.

Application covers the product itself (viscosity/effective viscosity and tenacity of residues) and the position of the pump within the process (i.e., handling of the raw, semi-processed or final product).

When specified, surface finish should be related to one of the classification bands set out in EN ISO 4287 and to the method by which it is obtained (e.g., for the same Ra, the topography of the surface is different between a mechanically or electro-chemically polished surface).

Systematic cleanability tests using typical modern cleaning regimes have been conducted by a laboratory on X2CrNiMo17-12-2 stainless steel. The sample surface finishes have been obtained by turning, countersinking, die casting, mechanical and electrolytic polishing, tribo-finishing and impact treatment: the values of Ra are 0,4 μm - 0,8 μm – 1,6 μm – 3,2 μm (see references of this test in bibliography).

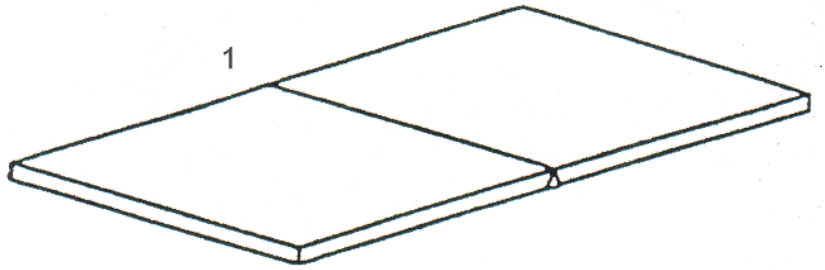
It was shown that the differences of cleanability observed could not be explained with the Ra (or Rz) in the conditions of this study (0,4 μm ≤ Ra ≤ 3,2 μm).

Usual industrial manufacturing practices allows the attainment of these values.

The ultimate responsibility for selection of the correct surface roughness lies with the end-user of the pump, in consultation with the manufacturer.

Annex C
(informative)

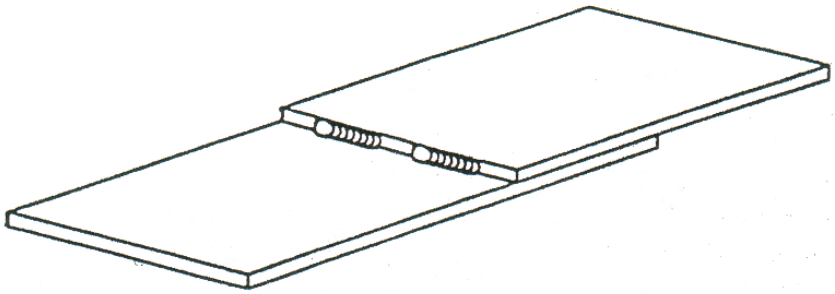
Design practices



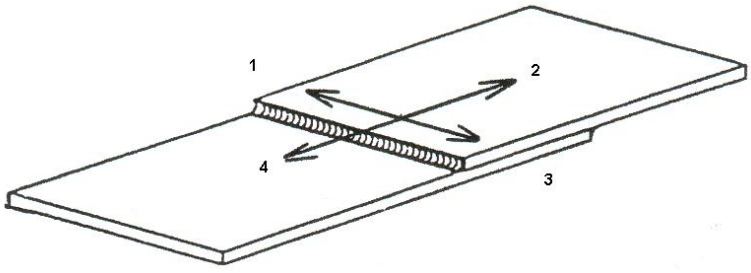
Key

1 food area

Acceptable when used as shown



Hygienic risk



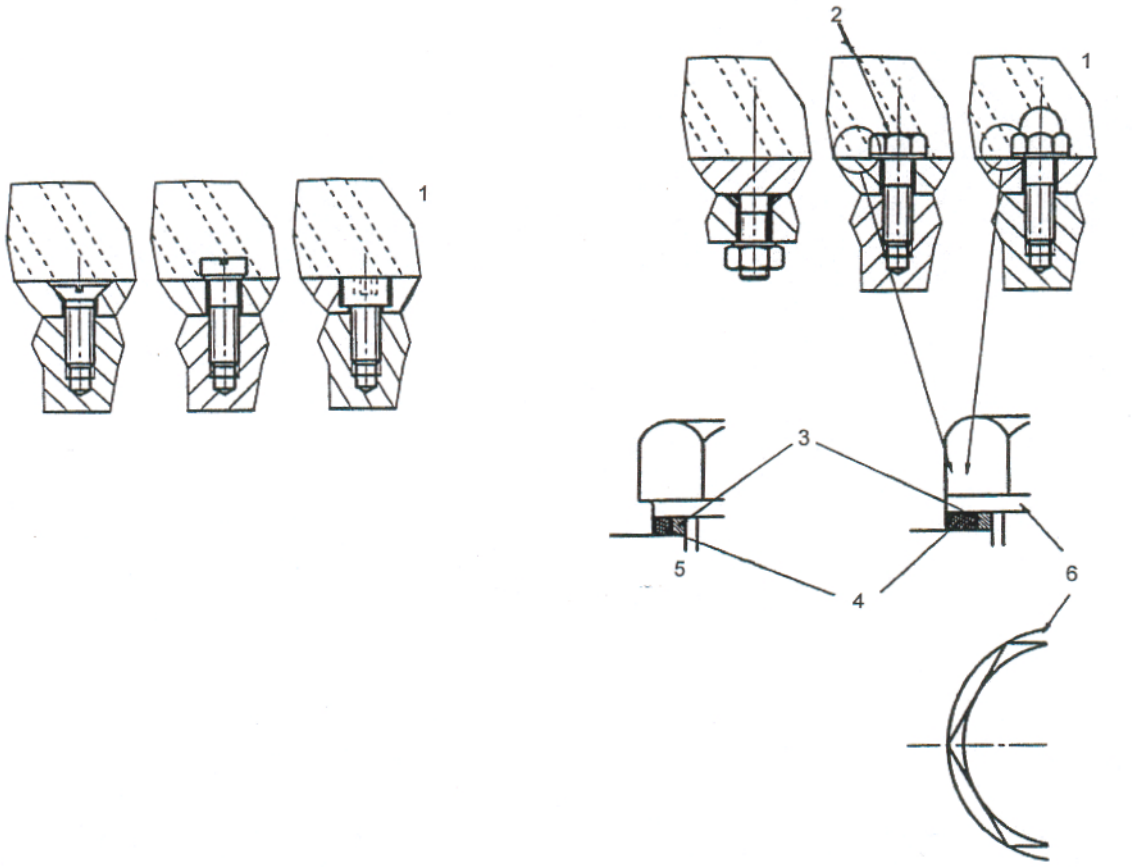
Hygienic risk

Key

1, 2, 3 acceptable direction of flow
4 flow with hygienic risk

Figure C.1 — Welded joints

Hygienic risk **Acceptable**



Key

1 pumped liquid
2 surface without marking
3 metallic part
4 elastomeric and plastic part
5 alternative design
6 circular collar

Figure C.2 — Design of fasteners

Annex D
(informative)

Hygienic risk associated with types of pump inlet and outlet connections

D.1 General

A pump is very often offered with a choice of connections and the selection is made together with the user.

Hazards can arise from selection, installation, and operation of these connections. The connections should be assessed in order to reduce the hazards.

D.2 Hazards sources

- Design of connections
  - retention of product due to misalignment;
  - retention of product due to physical change from thermal or chemical effects;
  - retention of product due to presence of gaps and cavities;
- installation of connections (leakage in and out / retention of product)
  - forces and moments from the pipework system;
  - retention due to means of installation (welding, shrink fitting, …);
    - incorrect installation (over and under-tightening, ...);
    - ...
- operation of connections
  - unscrewing due to thermal cycling;
  - ease of mis-assembly (omission of parts, incorrect position of parts, …);
  - parts exposed to mechanical shocks;
  - chemical attacks;
    - thermal degradation;
  - …

D.3 Criteria to be taken into account

- Hygienic level associated with the product;
- frequency of disconnection;

— methods and products used for cleaning;

— access for installation and operation;

— …

Annex E
(informative)

Hygienic risk linked to the choice of shaft sealing system and to the characteristics of the pumped product

Hygienic risk level linked to the choice of sealing system which is usually acknowledged is indicated in Table E.1.

Table E.1 — Hygienic risk level in accordance with the choice of the pumped product and the shaft seals

	Single mechanical seal	**Single mechanical seal + Quench or tandem or double arrangement** [a]	**Soft packing**
Hazard related to a low viscous product without bacteriologic risk	A	A	A
Hazard related to a low viscous product with bacteriologic risk	B	A	C
Hazard related to a viscous product without bacteriologic risk	B	A	A
Hazard related to a viscous product with bacteriologic risk	C	A	C

Where
A = low hygienic risk
B = medium hygienic risk
C = high hygienic risk

[a] The barrier substance shall be in accordance with 5.5.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 2006/42/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 2006/42/EC on machinery.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements 2.1 of that Directive and associated EFTA regulations.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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