



SLOVENSKI STANDARD
SIST EN 13951:2004+A1:2008
01-december-2008

fdU_YnUHY_c]bY!'JUfbcgfbYnU HYj Y!'?a Yh'g_c!y]]]g_UcdfYa U!'DfUj]U
bU flcj Ub^UnUnU[ctcj `Ub^Y\][]YbYdf]i dcfUM]

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

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

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

<https://standards.iteh.ai/catalog/standards/sist/0a048c42-58c3-4e93-a13a-ae367549e5f2/sist-en-13951-2004a1-2008>

Ta slovenski standard je istoveten z: EN 13951:2003+A1:2008

ICS:

23.080	!] æ ^	Pumps
67.260	Tovarne in oprema za živilsko industrijo	Plants and equipment for the food industry

SIST EN 13951:2004+A1:2008 **en**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 13951:2004+A1:2008](https://standards.iteh.ai/catalog/standards/sist/0a048c42-58c3-4e93-a13a-ae367549e5f2/sist-en-13951-2004a1-2008)

<https://standards.iteh.ai/catalog/standards/sist/0a048c42-58c3-4e93-a13a-ae367549e5f2/sist-en-13951-2004a1-2008>

EUROPEAN STANDARD

EN 13951:2003+A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2008

ICS 23.080; 67.260

Supersedes EN 13951:2003

English Version

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

Pompes pour liquides - Prescriptions de sécurité - Matériel
agroalimentaire - 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 28 November 2002 and includes Amendment 1 approved by CEN on 14 August 2008.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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 and United Kingdom.

[SIST EN 13951:2004+A1:2008](https://standards.iteh.ai/catalog/standards/sist/0a048c42-58c3-4e93-a13a-ae367549e5f2/sist-en-13951-2004a1-2008)

<https://standards.iteh.ai/catalog/standards/sist/0a048c42-58c3-4e93-a13a-ae367549e5f2/sist-en-13951-2004a1-2008>



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents

	page
Foreword.....	3
Introduction.....	4
1 Scope	4
2 Normative references	5
3 Terms and definitions	5
4 List of hazards.....	8
5 Hygiene: safety requirements and/or measures	11
5.1 Materials	11
5.2 Design – Food areas.....	12
5.3 Design - Non-food areas	16
5.4 Auxiliary liquids, barriers and lubricants.....	16
5.5 Guards and shrouds.....	17
5.6 Legs.....	17
6 Verification of hygiene measures	17
6.1 Inspection of documentation.....	17
6.2 Inspection of the assembled pump or pump unit	17
6.3 Materials	17
6.4 Level of cleanability.....	17
6.5 Surface roughness test.....	18
7 Information for use	18
7.1 General.....	18
7.2 Instruction for use - Instruction handbook	18
Annex A (informative) Materials in contact with foodstuffs (EU regulations)	20
A.1 Metallic materials in contact with foodstuffs.....	20
A.2 Elastomeric materials in contact with foodstuffs.....	20
A.3 Plastic materials in contact with foodstuffs	20
Annex B (informative) Surface roughness.....	21
Annex C (informative) Design practices	22
Annex D (informative) Hygienic risk associated with types of pump inlet and outlet connections	24
D.1 Hazards sources	24
D.2 Criteria to be taken into account.....	24
Annex E (informative) Hygienic risk linked to the choice of shaft sealing system and to the characteristics of the pumped product	25
Annex ZA (informative) A1 Relationship between this European Standard and the Essential Requirements of EU Directive 98/37/CE A1.....	26
Annex ZB (informative) A1 Relationship between this European Standard and the Essential Requirements of EU Directive 2006/42/EC A1.....	27
Bibliography	28

Foreword

This document (EN 13951:2003+A1:2008) 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 April 2009, and conflicting national standards shall be withdrawn at the latest by December 2009.

This document supersedes EN 13951:2003.

This document includes Amendment 1, approved by CEN on 2008-08-14.

The start and finish of text introduced or altered by amendment is indicated in the text by tags $\boxed{A_1}$ $\boxed{A_1}$.

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).

$\boxed{A_1}$ For relationship with EU Directive(s), see informative Annexes ZA and ZB, which are integral parts of this document. $\boxed{A_1}$

iTeh STANDARD PREVIEW
(standards.iteh.ai)

This document deals with essential requirements 2.1 "Agrifoodstuffs machinery" of Machinery Directive.

The annexes A, B, C, D, E and F are informative.

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, 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 and the United Kingdom.

EN 13951:2003+A1:2008 (E)**Introduction**

This document is a type C standard as stated in EN 1070.

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.

1 Scope

This European Standard is concerned with the special technical safety requirements for liquid pumps and pump units operating with agrifoodstuffs. It augments EN 809 and contains a list of the additional significant hazards which can arise from the pump and pump units used with substances intended for human and domestic animal consumption.

In drafting this standard it was assumed that the pumps falling within its scope will conform to all relevant requirement of EN 809.

It also establishes requirements and/or measures which lead to a reduction of the risks.

This 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 can exist.

Conformity to this standard aims to ensure that the pump, if used in accordance with the instruction handbook, will remain safe and, provided it is adequately cleaned, will not cause contamination of the pumped product. Although it is the responsibility of the manufacturer to ensure that the pump can be cleaned, due to the influence of the product, the process and the cleaning regime adopted, the hygiene of the pump should ultimately be the responsibility of the end-user.

The pumps and pump units which fall within the scope of this standard are described as:

- rotodynamic pumps;
- rotary positive displacement pumps;
- reciprocating positive displacement pumps.

Pumps handling agrifoodstuffs which do not fall within this scope should comply with EN 1672-2.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

EN 1050, *Safety of machinery – Principles for risk assessment*.

EN 1070, *Safety of machinery – Terminology*.

EN 1672-2:1997, *Food processing machinery – Basic concepts – Part 2: Hygiene requirements*.

EN ISO 4287, *Geometrical Product Specifications (GPS) – Surface texture: Profile method – Terms, definitions and surface texture parameters (ISO 4287:1997)*.

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 1070 together with the following apply.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

3.1

food/agrifoodstuffs products

any product, ingredient or material intended to be orally consumed at any stage of its production process

[SIST EN 13951:2004+A1:2008](https://standards.iteh.ai/catalog/standards/sist/0a048c42-58c3-4e93-a13a-ae367549e5f2/sist-en-13951-2004a1-2008)

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

(Definition in accordance with EN 1672-2:1997)

<https://standards.iteh.ai/catalog/standards/sist/0a048c42-58c3-4e93-a13a-ae367549e5f2/sist-en-13951-2004a1-2008>

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

(Note in accordance with EN 1672-2:1997)

3.4.1

food area

area composed of surfaces in contact with food. The food area also includes the surfaces with which the product may come into contact under intended conditions of use, after which it returns into the product

(Definition in accordance with EN 1672-2:1997)

3.4.2

non-food area

any area other than those specified above

(Definition in accordance with EN 1672-2:1997)

EN 13951:2003+A1:2008 (E)**3.5****product/pumped product**

all products passing through the pumps as a result of process, testing, cleaning, rinsing, or disinfecting products

3.6**cleaning**

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 The term CIP corresponds to the abbreviation of the English wording "Cleaned In Place". In French language the following term NEP is the abbreviation of the wording "Nettoyage En Place". In German language it is the term CIP which 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 The term COP corresponds to the abbreviation of the English wording "Cleaned Out of Place". In French language, the following term NHP is the abbreviation of the wording "Nettoyage Hors Place". In German language it is the term CIP which is used.

3.7**contamination**

presence of soils

(Definition in accordance with EN 1672-2:1997)

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**

any 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 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
(Definition in accordance with EN 1672-2:1997)

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
(Definition in accordance with EN 1672-2:1997)

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
(Definition in accordance with EN 1672-2:1997)

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.

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 13951:2004+A1:2008
<https://standards.iteh.ai/catalog/standards/sist/0a048c42-58c3-4e93-a13a-ae367549e5f2/sist-en-13951-2004a1-2008>

EN 13951:2003+A1:2008 (E)**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**

all 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 be considered also 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 1050 (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 standard and shown also in Table 1.

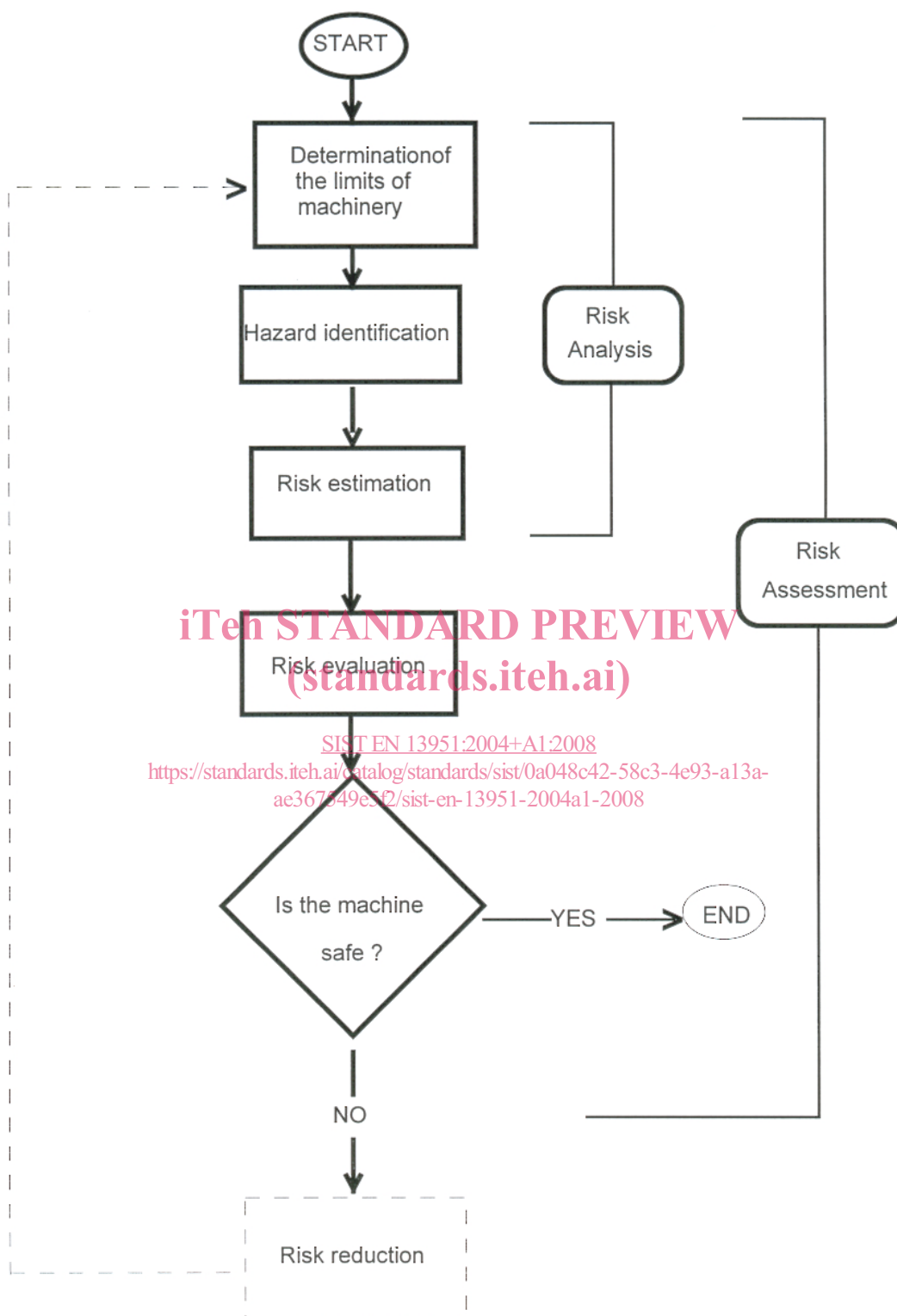


Figure 1 — The iterative process to achieve safety

Table 1 — List of Hazards related to Hygiene which are addressed in this 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.....	5.1.1, 5.1.2.1	6.3
- sealing of openings and joints.....	5.2.6, 5.2.11, 5.2.12, 5.3.1	6.2
- sealing around shafts.....	5.2.9	6.2
- spillage of product.....	5.3.1	6.2
- vermin.....	5.3.1, 5.6	6.2
Hazards arising from microbiological causes		
- retention of product.		
- general.....	5.2.1, 5.2.2, 5.3.1	6.4
- cleaning.....	5.2.2, 5.2.3	6.4
- draining.....	5.2.2, 5.2.3.1, 5.2.11	6.2
- surface finish/texture.....	5.2.5	6.5
- obstructions/protrusions.....	5.2.2, 5.2.7	6.2
- bearings.....	5.2.8, 5.3.2	6.1, 6.2
- shaft seals.....	5.2.9	6.2
- fasteners.....	5.2.10, 5.3.3	6.2
- sensors.....	5.2.12	6.1, 6.2
- lubricants.....	5.4	6.1, 6.2
Hazards arising from chemical causes		
- material compatibility	5.1	6.3
- general.....	5.1.1, 5.1.2.1, 5.2.9	6.3
- metals.....	5.1.2.2	6.1, 6.3
- non-metals.....	5.1.2.3	6.1, 6.3
- non-food areas.....	5.1.3	6.3
- soldering.....	5.2.6	6.2
- cleaning fluids.....	5.2.3.1	6.2, 6.4
- sensors.....	5.2.12	6.2
- auxiliary liquids.....	5.2.8, 5.4	6.1, 6.3
- barrier liquids.....	5.4	6.1, 6.2
Hazards arising from mechanical causes		
- material finishes.....	5.1	6.2, 6.5
- joints.....	5.2.6	6.1, 6.2
- fasteners.....	5.2.10	6.1, 6.2
- mis-assembly.....	5.3.3	6.1, 6.2