

# Food processing machinery — Basic concepts —

Part 2: Hygiene requirements

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ICS 67.260

## National foreword

This British Standard is the UK implementation of EN 1672-2:2005+A1:2009. It supersedes BS EN 1672-2:2005 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by A1 A1.

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A list of organizations represented on this subcommittee 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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Nahrungsmittelmaschinen - Allgemeine Gestaltungsleitsätze - Teil 2: Hygieneanforderungen

This European Standard was approved by CEN on 14 February 2005 and includes Amendment 1 approved by CEN on 29 December 2008.

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## Foreword

This document (EN 1672-2:2005+A1:2009) has been prepared by Technical Committee CEN/TC 153 "Machinery intended for use with foodstuffs and feed", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by December 2009.

This document includes Amendment 1, approved by CEN on 2008-12-29.

This document supersedes <sup>A1</sup> EN 1672-2:2005 <sup>A1</sup>.

The start and finish of text introduced or altered by amendment is indicated in the text by tags <sup>A1</sup> <sup>A1</sup>.

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).

<sup>A1</sup> For relationship with the EU Directive(s), see informative Annexes ZA and ZB, which are integral parts of this document. <sup>A1</sup>

This document is complemented by prCEN/TR 1672-1 which deals with safety rules to protect operators.

This document includes a Bibliography.

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 United Kingdom.

## **Introduction**

This document is a type C standard as stated in EN ISO 12100-1.

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

Here it has to be distinguished between the hazards to the operator and the risks to the food (the product processed by the machinery).

This document addresses only those hazards which are commonly occurring on food processing machines and for which technical specifications can be set which will apply to all (or most) of the classes of machines within the scope of the standard which have that hazard.

In almost all cases at least one of the different methods of design, safeguarding or other safety measures can be chosen which will meet both safety and hygiene essential requirements and adequately control both risks. The option to satisfy both hygiene and safety risks may not be the most obvious option which would have been adopted had the risk only been to safety or to hygiene, but will have to be the one chosen to meet both.

The first choice is to select a design method which removes both hygiene and safety risks: if this is not within the state of the art then safeguarding options for both, or if not, one of the risks should be selected. Where no design or safeguarding options are within the state of the art to adequately control both hygiene and safety risks then one of the risks, or both, would have to be dealt with by safety measures, including instructions to the user. The assessment of the respective safety and hygiene risks will indicate their relative significance and the higher level of protection (i.e. safeguarding) should be implemented to deal with the severest risk and safety measures for the lesser risk.

The technical requirements given in the prCEN/TR 1672-1 and in this document permit both objectives to be met for those significant and common risks identified as justifying common requirements in this document.

Other hazards, for which such common requirements can not be set, remain to be covered in machinery specific type C standard and/or by reference to EN ISO 12100-2 and type A and type B standards.

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.

**NOTE** The essential requirements of the Machinery Directive should be met in respect of both safety risks to the operator of the machinery and hygiene risks to the food (product processed by the machinery). The Directive requirements and the safety and hygiene risks identified by the risk assessment process required by EN 1050 can each usually equally well be met by a range of safeguarding or hygiene design options.

## 1 Scope

This document specifies common hygiene requirements for machinery used in preparing and processing food for human and, where relevant, animal consumption to eliminate or minimise the risk of contagion, infection, illness or injury arising from this food. It identifies the hazards which are relevant to the use of such food processing machinery and describes design methods and information for use for the elimination or reduction of these risks.

This document does not deal with the hygiene related risks to personnel arising from the use of the machine.

This document applies to food processing machines – Examples of such groups of food processing machinery are given in the informative Annex B.

NOTE Separate hygiene requirements are contained in other EU Directives (see Bibliography).

In addition, the principles contained in this document can be applied to other machinery and equipment used to process food where similar risks apply.

Examples of hygiene risks and acceptable solutions are given in the informative Annex A.

This document is not applicable to machines manufactured before the date of publication of this document by CEN.

## 2 Normative references

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

EN ISO 4288, *Geometrical product specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture (ISO 4288:1996)*

EN ISO 12100-1:2003, *Safety of machinery — Basic concepts, general principles for design — Part 1: Basic terminology, methodology (ISO 12100-1:2003)*

EN ISO 12100-2:2003, *Safety of machinery — Basic concepts, general principles for design — Part 2: Technical principles (ISO 12100-2:2003)*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given EN ISO 12100-1:2003 and the following apply.

### 3.1

#### **food**

any product, ingredient or material intended to be orally consumed by human or animal

### 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

### 3.3

#### **adverse influence**

effect which gives a significant 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 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).

#### 3.4.1

##### **food area**

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 (see Figure A.1)

#### 3.4.2

##### **splash area**

area composed of surfaces on which part of the food may splash or flow along under intended conditions of use and does not return into the food (see Figure A.1)

#### 3.4.3

##### **non food area**

any area other than those specified above (see Figure A.1)

### 3.5

#### **cleaning**

removal of soils

#### **cleanable**

designed and constructed so that soils are removed by recommended cleaning methods (see 7.2.4)

### 3.6

#### **contamination**

presence of soils

### 3.7

#### **corrosion resistant material**

material resistant to normally occurring action of chemical or electrochemical nature. It includes food processing, cleaning and disinfection according to the instructions for use

### 3.8

#### **crevice**

surface defect e.g. crack, fissure, which adversely affects cleanability

### 3.9

#### **dead space**

space wherein a product, ingredient, cleaning or disinfecting agents or soils may be trapped, retained or not completely removed during operation of cleaning (see Figures A.15 and A.16)

### 3.10

#### **disinfection**

inactivation of all pathogens and a wide range of other micro-organisms to a level consistent with hygienic application of the equipment

### 3.11

#### **durable**

ability of a surface to withstand the intended conditions of use, for example: to resist to damage caused by the action of the process, contact with the food being processed, thermal actions, handling and contact with any cleaning or disinfecting agents specified

### 3.12

#### **joint**

junction of two or more pieces of material



**3.13**

**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 food

**3.14**

**non toxic material**

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

**3.15**

**seal**

closing of an aperture so as to effectively prevent the unwanted entry or passage of any matter

**3.16**

**self draining**

design and construction of the shape and surface finish so as to prevent liquid from being retained

**3.17**

**smooth**

condition of a surface which satisfies operational and hygienic requirements

**3.18**

**soil**

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

**3.19**

**vermin**

animals (including mammals, birds, reptiles and insects) which may adversely influence the food

## **4 List of significant hazards**

The significant hazards can arise from:

- biological causes such as pathogens, spoilage micro organisms, toxins or vermin;
- chemical causes including those from cleaning, disinfecting agents and lubricant substances;
- foreign bodies arising from raw materials, machinery or other sources.

For each of these hazards there can be a risk of contamination of the food and/or risks to the health of the consumer.

Microbiological hazards can cause spoilage of the food, food poisoning or other related illness in consumers.

Chemical hazards can cause contamination or leave residues in the food causing injury to health (e.g. burns) or illness.

Foreign bodies can contaminate food and cause physical injuries (e.g. choking, lacerations).

When considering the design of a machine it is necessary to consider the implications of any of the hazards and the measures necessary to eliminate or reduce the hazard. Informative Annex C gives examples.

## **5 Hygiene requirements**

### **5.1 Hygiene risk assessment**

#### **5.1.1 General**

The hazards shall be eliminated or the associated risks reduced by ensuring machinery is properly designed, constructed and capable of being properly installed, operated, cleaned and maintained.

The hygiene requirements of the different areas of the equipment depend upon the functions of the area, the type of food to be processed and the nature of hazards to the food.

In applying the design and construction criteria the primary objective shall be to eliminate or reduce the risks to an acceptable level (see Figure 1).

The hygiene risk assessment follows the methodology described in EN 1050.

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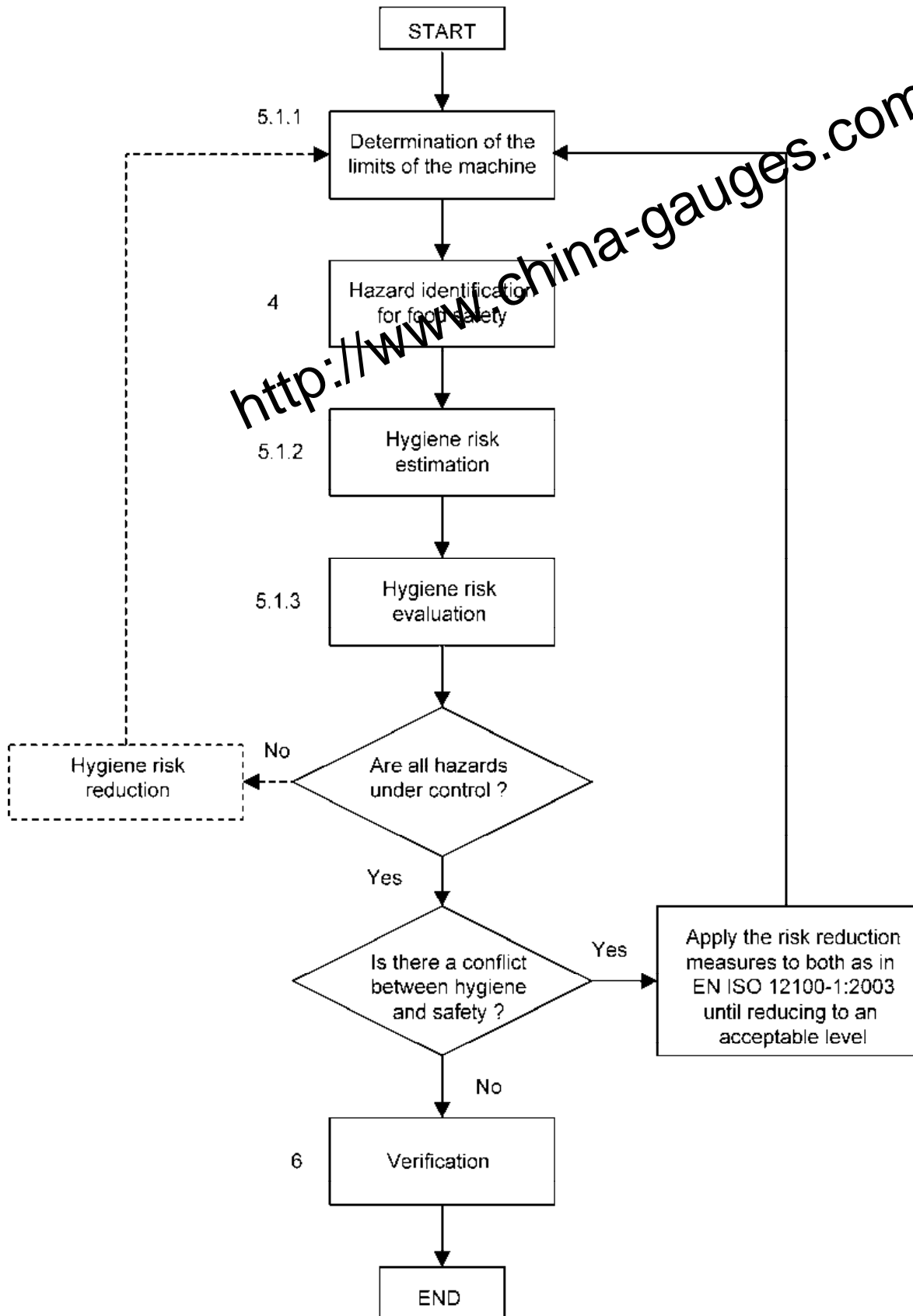


Figure 1 — Hygiene risk assessment

**5.1.2 Determination of the limits of the machine**

Risk assessment shall take into account:

- the phases of machine life;
- the limits of the machine (see 5.2 of EN ISO 12100-1:2003) including the intended use (both the correct use and operation of the machinery as well as the consequences of reasonably foreseeable misuse or malfunction) in accordance with 3.22 of EN ISO 12100-1:2003, for example: will the machine be used for one specific purpose only, for which hazards are readily identifiable, or could the machine be used for a wide range of food products in many industries (e.g. a pump)?;
- the full range of foreseeable uses of the machinery (e.g. industrial, non-industrial and domestic) by persons identified by sex, age, dominant hand usage and limiting physical abilities (e.g. visual or hearing impairment, size, strength);
- the anticipated level of training, experience or ability of the foreseeable users.

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**5.1.3 Hygiene risk estimation**

The estimation of the hygiene risk by the manufacturer shall be related to the three significant hazards defined in Clause 4 and restricted to the hazards caused by the intended use of the machine, as defined in 3.22 of EN ISO 12100-1:2003:

- estimate the severity of the possible harm from the considered hazard;
- estimate the probability of the occurrence of that harm from the considered hazard: see example below.

**EXAMPLE**

When all hygienic hazards are identified, they can be scored, one by one, with the help of the Figure 2.

The questions to raise are:

- 1 – Does the hazard have a low, medium or high impact if it occurs?
- 2 – Is the probability of occurrence that the hazard occurs low, medium or high?

	High	LH	MH	HH
Severity	Medium	LM	MM	HM
	Low	LL	ML	HL
		Low	Medium	High
		Probability of occurrence		

**Figure 2 — Example of tool for the risk estimation - Risk ranking diagram**

NOTE It is recommended to make or realise the estimation with a team rather than by one person only.

#### 5.1.4 Hygiene risk evaluation

After hygiene risk estimation, hygiene risk evaluation shall be carried out to determine if hygiene risk reduction is required or whether food safety has been achieved by reducing risks to an acceptable level. If hygiene risk reduction is required, then appropriate food safety measures shall be selected and applied, and the procedure repeated (see Figure 1). During this iterative process, it is important for the designer to check whether additional hazards are created when new food safety measures are applied. If additional hazards are identified, they shall be added to the list of identified hazards.

The achievement of the hygiene risk reduction objectives and a favourable outcome of risk comparison give confirmation that the machinery is safe.

#### 5.1.5 Hygiene risk reduction

Achievement of the following conditions shall indicate the satisfactory hygiene risk reduction process:

- the hazard has been eliminated or the hygiene risk reduced by:
  - a) design or by the substitution of less hazardous materials and substances;
  - b) safeguarding the hygienic conditions;
- the information on the intended use of the machinery is sufficiently clear (see Clause 7) when:
  - a) the operating procedures for the use of the machinery are consistent with the ability of personnel who use the machinery or other persons who can introduce hazards to the food;
  - b) the recommended hygienic working practices for the use of the machinery and the related training requirements have been adequately described;
  - c) the user is sufficiently informed about hazards occurring during the different phases of the life of the machinery;
  - d) the use of personal protective equipment is recommended, the need for such equipment and the training requirements for its use have been adequately described.

## 5.2 Materials of construction

### 5.2.1 General requirements

Materials shall be suitable for intended use.

Surfaces of materials and coatings shall be durable, cleanable and where required capable of being disinfected, without breaks, resistant to cracking, chipping, flaking and abrasion and prevent penetration of unwanted matter under intended use.

### 5.2.2 Food area

In addition to the general requirements (see 5.2.1), under intended conditions of use, the materials shall be:

- corrosion resistant;
- non toxic;
- non absorbent (except when technically or functionally unavoidable).

The materials shall:

- not transfer undesirable odours, colours or taint to the food;

— not contribute either to the contamination of food or have any adverse influence on the food.

### **5.3 Design**

#### **5.3.1 Food area**

##### **5.3.1.1 Surfaces**

Surface finish shall be suitable for intended use.

Surfaces shall be cleanable and where required capable of being disinfected. For this purpose they shall be smooth, continuous or sealed.

The surface design and finish shall be such that the product is prevented as far as possible from becoming accidentally separated from the food area and from returning to it, if that return would cause a hazard to the processed food.

Surfaces shall have a finish so that no particle of product becomes trapped in small crevices, thus becoming difficult to dislodge and so introduce a contamination hazard.

These above requirements also apply to dismountable parts, which are removable for cleaning.

**NOTE** Guidance for measurement of surface finish (roughness specification *Rz* and/or *Ra*) can be found in EN ISO 4288. Additional requirements for surface finish can be found in some machinery specific type C standards.

##### **5.3.1.2 Joints**

###### **5.3.1.2.1 Permanent joints**

Joints shall be sealed and hygienic. Recesses, gaps, crevices, protruding ledges, inside shoulders and dead spaces shall be avoided (see Figures A.3, A.4 and A.5). If technically impossible, adequate solutions (e.g. cleaning, disinfection, instructions, etc.) shall be given.

###### **5.3.1.2.2 Dismountable joints**

Dismountable joints shall present a true and hygienic fit (see Figures A.6, A.7, A.8 and A.9).

##### **5.3.1.3 Fasteners**

Fasteners such as screws, bolts, rivets and so on, shall be avoided. If technically impossible adequate solutions (e.g. cleaning, disinfection, instructions, etc.) shall be given (see Figure A.10).

##### **5.3.1.4 Drainage**

It shall be ensured that the machinery is preferably self draining, or that the residual liquid can be removed by other means (see Figures A.11, A.12 and A.13).

##### **5.3.1.5 Internal angles and corners**

Internal angles and corners shall be so constructed that they are effectively cleanable and where required capable of being disinfected (see Figure A.14).

Internal angles and corners shall comply with technical requirements which are given in machinery specific C standards.

#### 5.3.1.6 Dead spaces

Dead spaces shall be avoided unless technically impossible in the design, construction and installation of the machinery (see Figures A.15 and A.16).

Dead spaces, which are unavoidable, shall be constructed in such a way that they are drainable, cleanable and capable of being disinfected, where required.

#### 5.3.1.7 Bearings and shaft entry points

Bearings shall be either located outside of the food area except where this is technically unavoidable, or designed for and lubricated with food grade lubricant, cleanable and, where required, capable of being disinfected (see Figures A.17 and A.18).

Shaft seals and moving shafts in the food area shall be self (or product)-lubricated or should be designed for and lubricated with food grade lubricant, cleanable and, where required, capable of being disinfected.

NOTE Requirements for equipment used in aseptic processing may be found in specific C standards.

#### 5.3.1.8 Instrumentation and sampling devices

Instrumentation and sampling devices shall comply with the relevant sections of this Clause 5 (see Figures A.19, A.20 and A.21).

#### 5.3.1.9 Panels, covers, doors

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

#### 5.3.1.10 Control devices

If there is no manual contact with the food, these items or areas of machinery which are handled for control reasons by the operator, shall be considered as non food areas. In case of manual contact with the food, where cross contamination can occur these areas or items shall be covered by the definition of a food area (see 3.4.1).

### 5.3.2 Splash area

The splash area shall be designed and constructed following the same principles for the food area.

As the food does not return to the food area, the technical design criteria may be less stringent than in the food area in areas such as the following provided that there is no adverse effect on the food:

- technical requirements for surface finish may allow for higher  $R_z$  and/or  $R_a$  values;
- internal angles and corners may be of smaller radius, provided they are still cleanable and, where required, capable of being disinfected;
- bearings, seals, moving shafts, etc., located in a splash area, may be lubricated by non-food grade lubricants, provided there is no adverse influence on the food.

Regarding fasteners see the Figure A.22.

### 5.3.3 Non food area

In addition to the general requirements (see 5.2.1) exposed surfaces used in the non-food area shall be made of corrosion resistant material or material that is treated (coated or painted) so as to be corrosion resistant. These surfaces shall be cleanable and, where required, capable of being disinfected and shall not contaminate or have any adverse influence on the food.

Equipment shall be designed and constructed in such a manner to prevent the retention of moisture, ingress and harbourage 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.

**5.3.4 Services**

Services, pipes, connections and related devices forming an integral part of the machinery shall meet the requirements of 5.3.1, 5.3.2 and 5.3.3, according to the area where they are situated and not introduce any hazard as defined in Clause 4.

**6 Verification of hygiene requirements and/or measures**

Verification of compliance with hygienic requirements shall be undertaken using one or more of the verification methods given in Table 1.

**Table 1 — Hygiene requirements and verification**

Reference subclauses	Requirement	Verification
5.1	Hygiene risk assessment	Documentary evidence
5.2.1	Durable	Material specification (food, process and cleaning specifications, etc.) and/or practical or functional test
5.2.1 5.3.1.1 5.3.1.3 5.3.1.5 5.3.1.6 5.3.1.7 5.3.1.9 5.3.2 5.3.3	Cleanable and/or capable of being disinfected	Visual inspection (of technical drawing and/or machinery) and/or practical test, micro biological test or functional test
5.2.2 5.3.3	Corrosion resistant	Material specification (food, process and cleaning specifications, etc.) and/or practical or functional test
5.2.2	Non toxic	Material specification or practical test for materials and articles intended to come into contact with food
5.2.2	Non absorbent	Material specification or practical test for materials and articles intended to come into contact with food
5.2.2	Not transfer undesirable odours, colours or taint to the food	Material specification or practical test for materials and articles intended to come into contact with food
5.2.2 5.3.3	Not contribute either to the contamination of food or have any adverse influence on the food	Material specification or practical test for materials and articles intended to come into contact with food
5.3.1.1	Surface design	Visual inspection (of technical drawing and/or machinery)
5.3.1.1 5.3.2	Surface finish	Measuring e.g. according to EN ISO 4288 For criteria of acceptability see also machine specific C standards if available
5.3.1.2.1	Permanent joints	Visual inspection
5.3.1.2.2	Dismountable joints	Visual inspection
5.3.1.3	Fasteners	Visual inspection



Table 1 (concluded)

Reference subclauses	Requirement	Verification
5.3.1.4 5.3.1.6 5.3.3	Drainage	Visual inspection (of technical drawing and/or machinery) and practical tests
5.3.1.5 5.3.2	Internal angles and corners	Measurements
5.3.1.6	Dead spaces	Visual inspection
5.3.1.7	Bearings and shaft entry points	Visual inspection
5.3.1.9	Panels, covers, doors	Visual inspection
5.3.1.10	Control devices	Visual inspection
5.3.2	Splash area	Compliance with Reference subclauses in left-hand boxes
5.3.3	Non-food area	Compliance with Reference subclauses in left-hand boxes
5.3.4	Services	Compliance with Reference subclauses in left-hand boxes

## 7 Information for use

### 7.1 General

The intended use of the food machinery and its limits shall be specified in the information for use provided by the manufacturer.

In relation to risks that cannot be eliminated, users shall be informed of any measures that they shall comply with, including the need for any particular training.

Information for use shall meet the requirements of Clause 6 of EN ISO 12100-2:2003.

### 7.2 Instruction handbook

#### 7.2.1 General

An instruction handbook shall be provided by the manufacturer and meet the requirements and advice of 6.5 of EN ISO 12100-2:2003. It shall include specific additional information related to the following points:

#### 7.2.2 Information relating to installation

In particular:

- space needed for use and maintenance, for example measures to be taken when installing machinery. Care shall be taken to ensure that there is adequate access for servicing machinery and cleaning service systems and their adjacent areas so that the required level of hygiene can be maintained;
- permissible environmental operating conditions and in addition, where required, measures to be taken so that the food is not adversely influenced by for example air currents, dust or liquids derived from leakage, condensation or aerosols.

#### 7.2.3 Information relating to the machine itself

Specific instructions for the intended use (see 5.1.5) shall be included.

**7.2.4 Information relating to cleaning and disinfection**

The instruction handbook shall indicate the recommended cleaning and disinfecting agents and instructions for dismantling (if necessary), cleaning, disinfection, rinsing and inspection for cleanliness.

The method and frequency of cleaning various surfaces including dismountable parts is dependant on the food product processed and the associated relevant hazard.

**7.2.5 Information relating to maintenance**

A scheme shall comprise a system of measures to ensure required level of hygiene is maintained for food machinery within specified intervals.

If food grade lubricants are required they shall be specified.

**7.3 Marking**

No specific marking within the scope of this document is necessary.

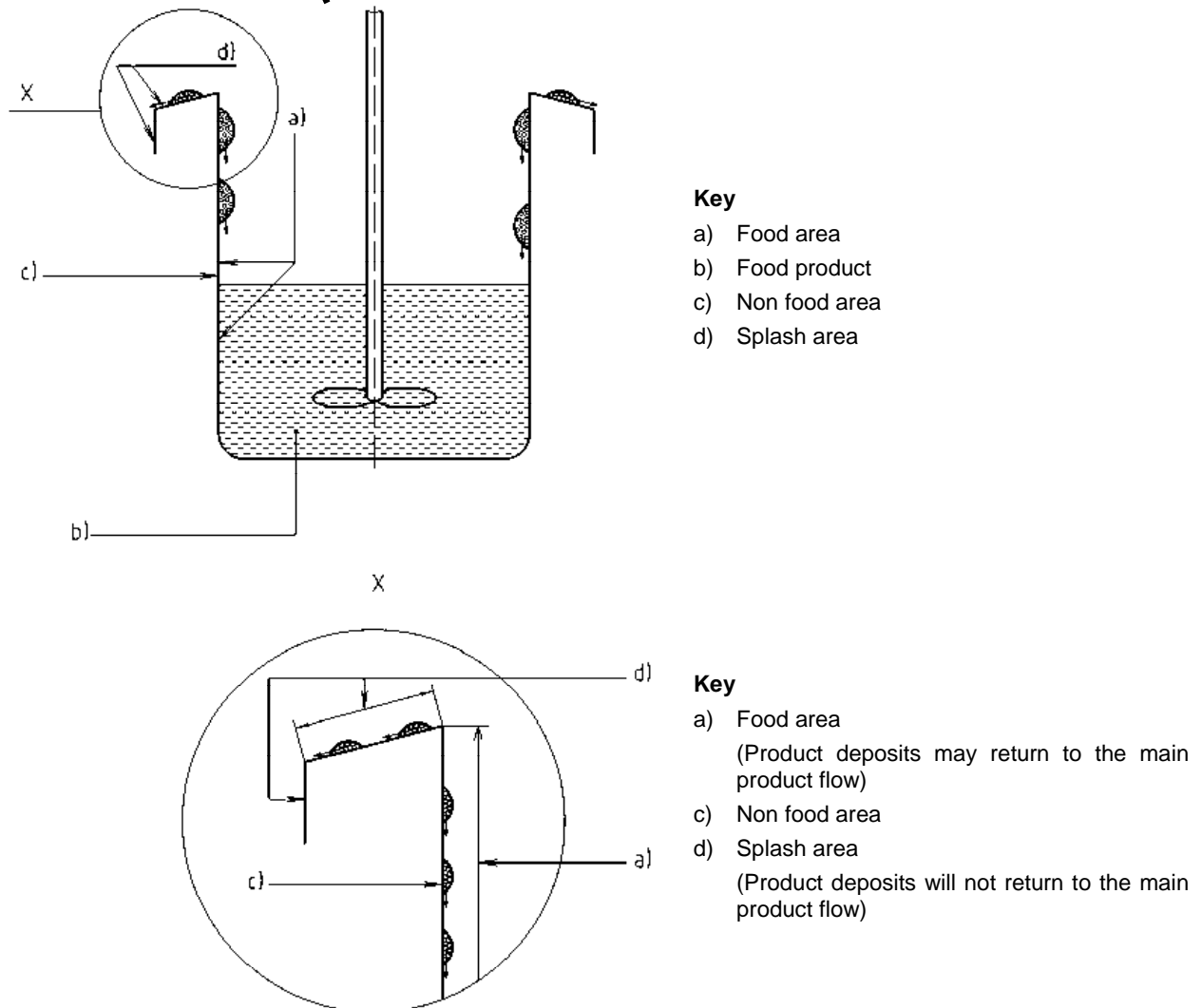
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**Annex A**  
(informative)

**Figures**

This informative annex contains:

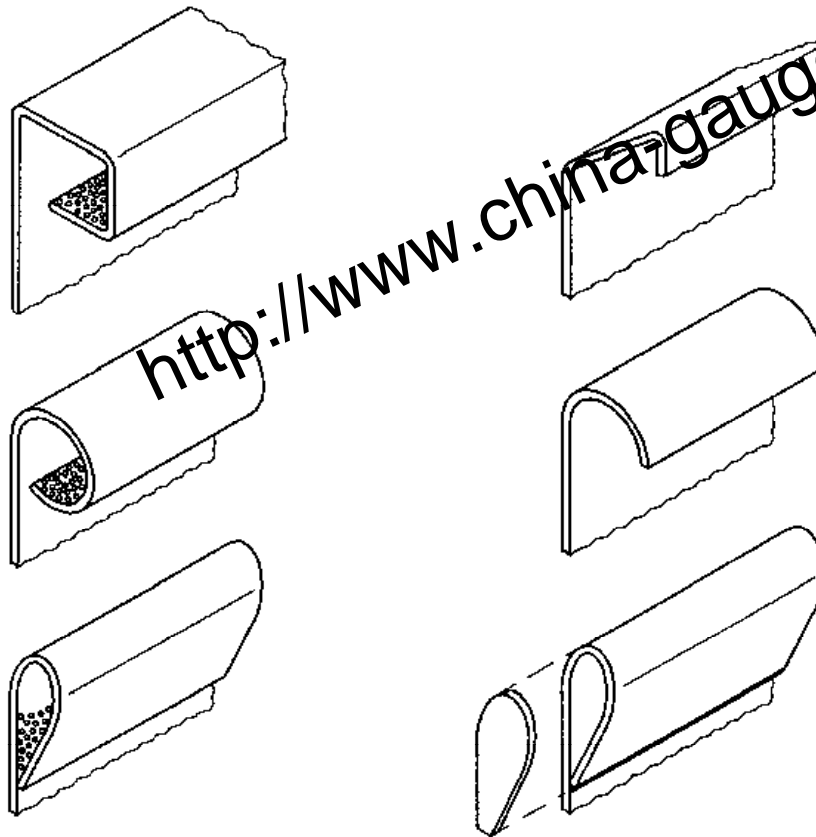
- Figure A.1 which illustrates food area, splash area and non-food area;
- Figures A.2 and those following, some of which give examples of "hygiene risks" and "acceptable" suggested solutions for the design and/or installation of food processing machinery. The "acceptable" figures only indicate a possible solution.



**Figure A.1 — Food area, splash area and non-food area**

HYGIENE RISK

ACCEPTABLE



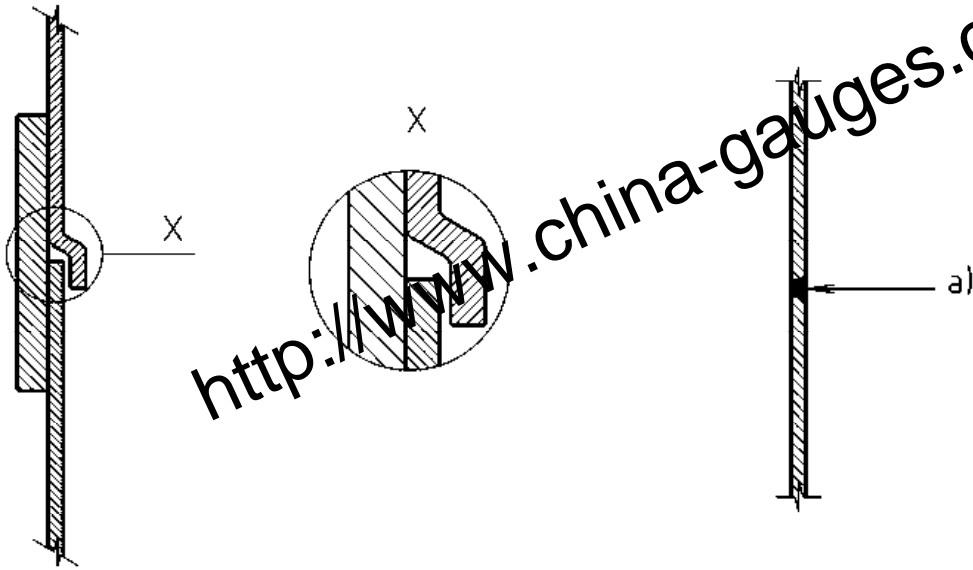
While all the designs for finishing off the top rim impart rigidity to the construction, they provide ledges where product debris can lodge and which are difficult to clean.

Where this method of construction is used, open ends should be "capped" to prevent debris being trapped. The weld should be ground and polished to give a smooth surface.

Figure A.2 — Cleanability

HYGIENE RISK

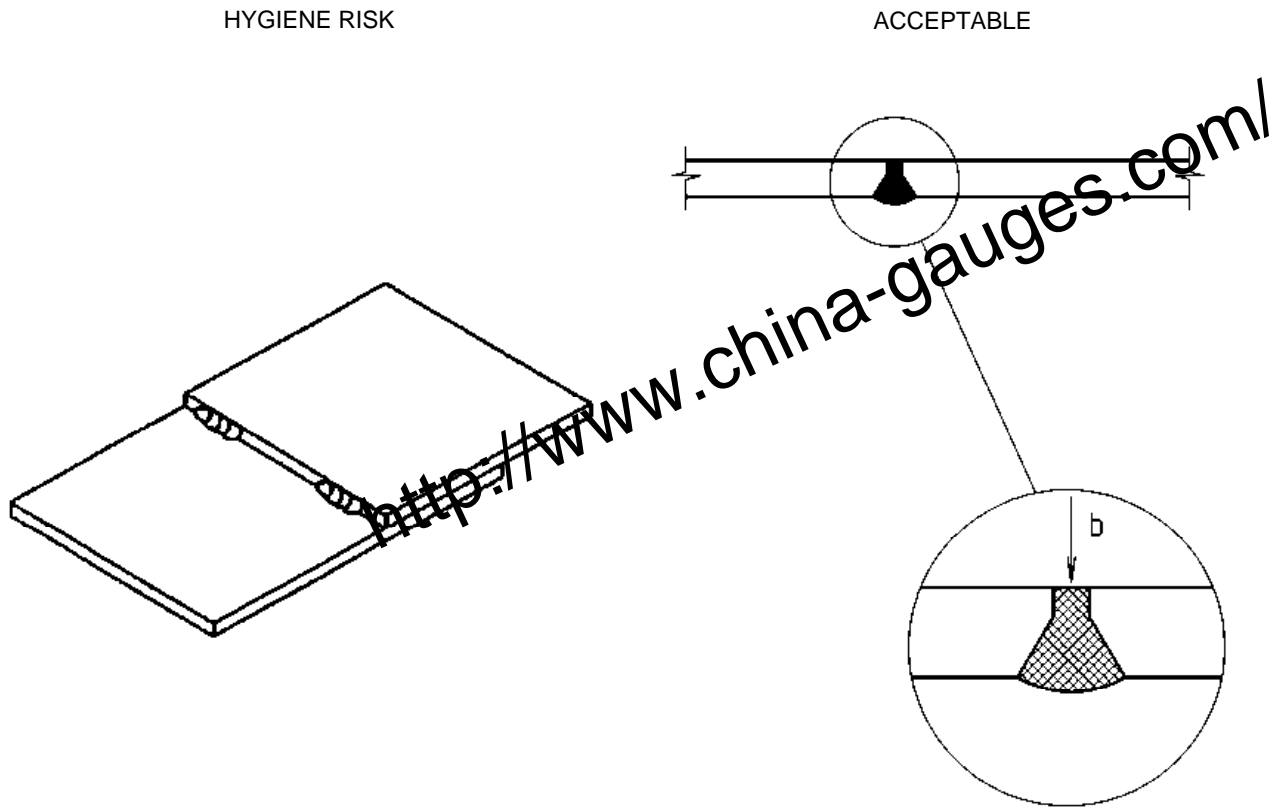
ACCEPTABLE



**Key**

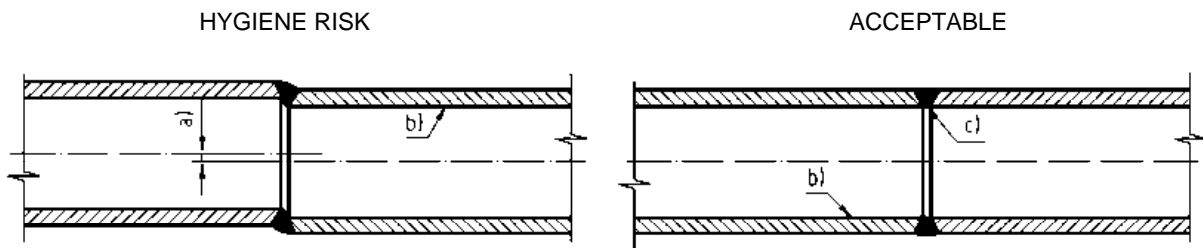
a) Welded

Figure A.3 — Joints



**Key**  
 b) Smooth surface

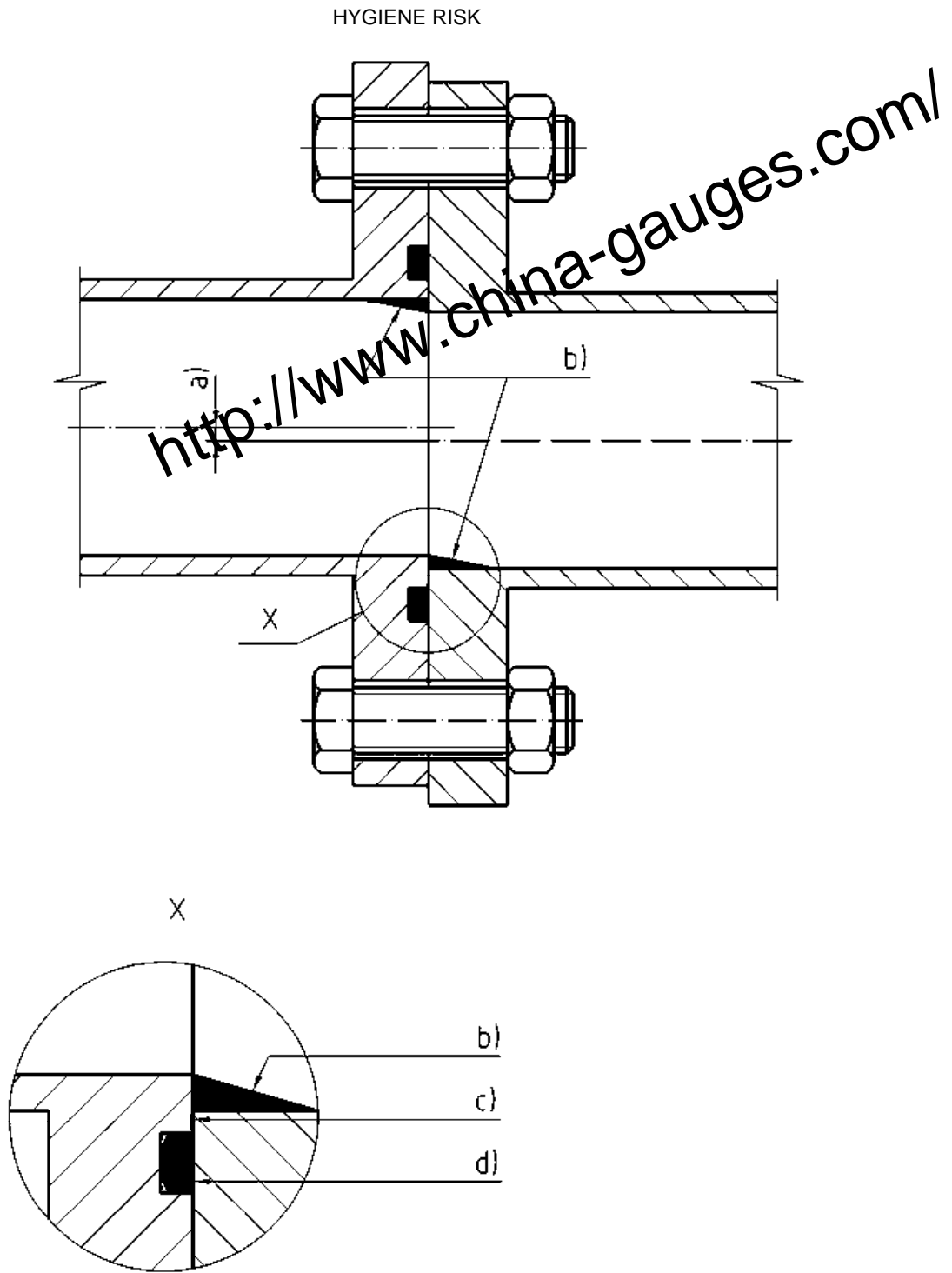
**Figure A.4 — Welded joints**



**Key**  
 a) Misalignment  
 b) Food area  
 c) Smooth welding

**NOTE** Values for maximum permissible misalignment may be found in specific standards.

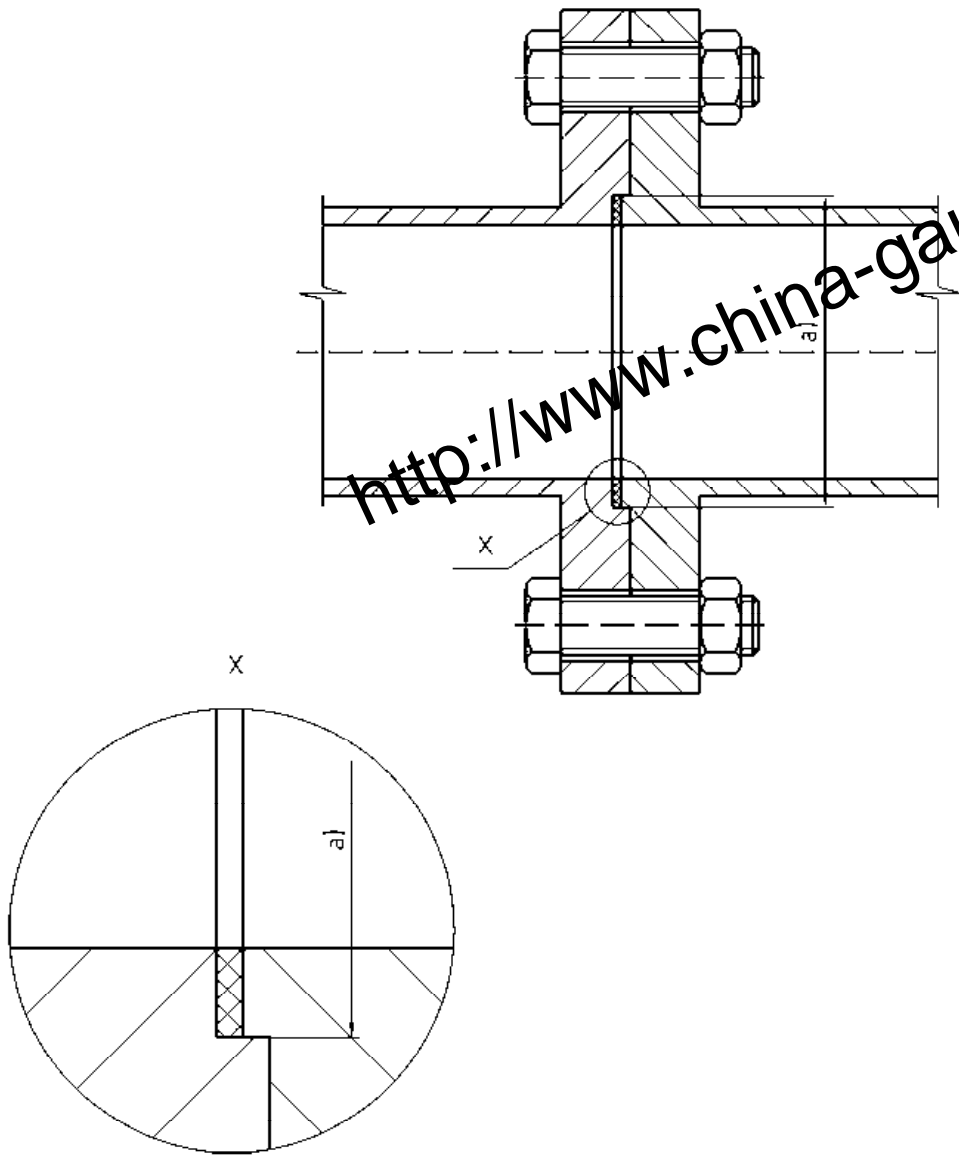
**Figure A.5 — Permanent joints - Welded pipes**



**Key**

- |  |   |
|--|---|
| <p>a) Misalignment</p> <p>b) Shadow areas may harbour product and are not easily cleanable</p> | <p>c) Metal to metal contact does not present a bacteria-tight joint</p> <p>d) Seal away from product flow presents uncleanable gap</p> |
|--|---|

**Figure A.6 — Dismountable joints**



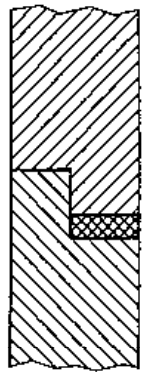
<http://www.china-gauges.com/>

Gasket compression is limited by flange construction

**Key**  
a) Location of flanges

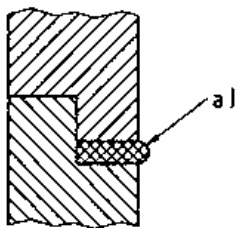
**Figure A.7 — Dismountable joints**



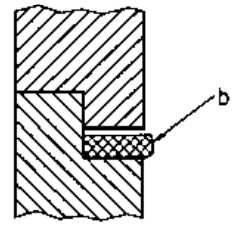


When compressed by 15 %, 70°shore hardness rubber gaskets will provide a bacteria-tight seal.

It is important to limit the compression to prevent damage to elastomer structure, resulting in loss of contact pressure.



Non-resilient gasket material "flow" under pressure. Temperature will cause permanent leakage due to large differences between thermal expansion rates of metal and plastic (e. g. P.T.F.E).



The same problem will occur when, due to ageing, resilience is lost.

**Key**

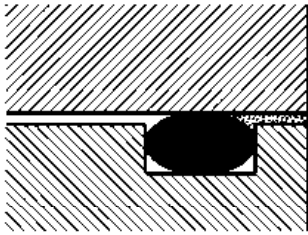
a) High temperature

b) Low temperature (Gap is not shown to scale)

**Figure A.8 — Dismountable joints**

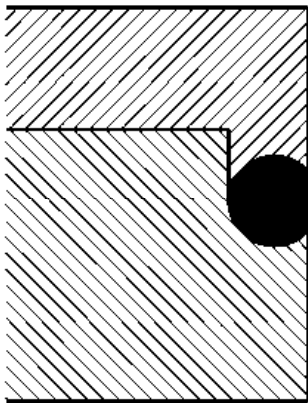
STATIC SEALS

O-rings



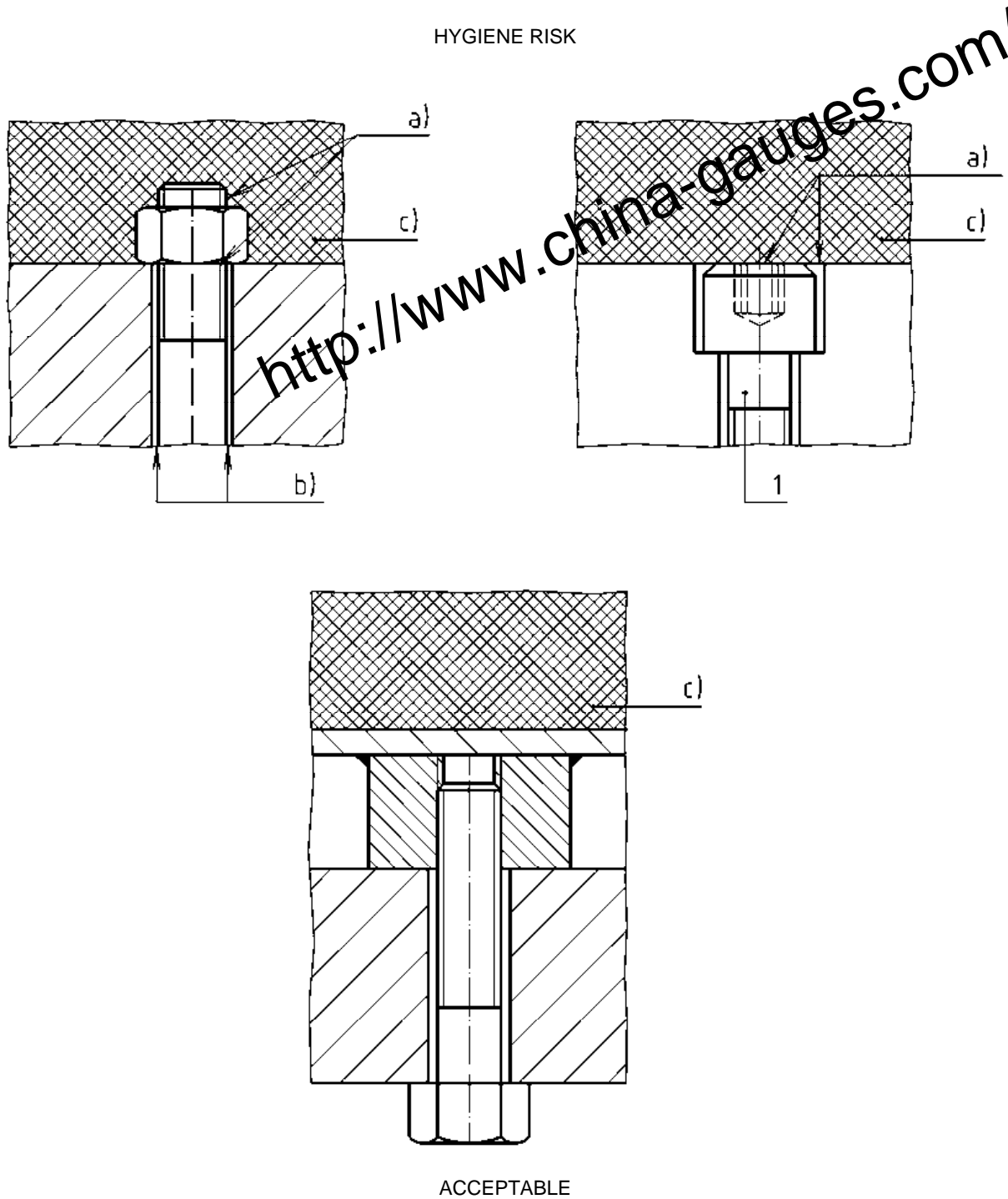
O-ring seals usually require a narrow gap which is very difficult to clean.

Moreover temperature variations will cause a pumping effect.



As a rule the seal should be as close to food product as possible to provide acceptable cleanability.

Figure A.9 — Dismountable joints



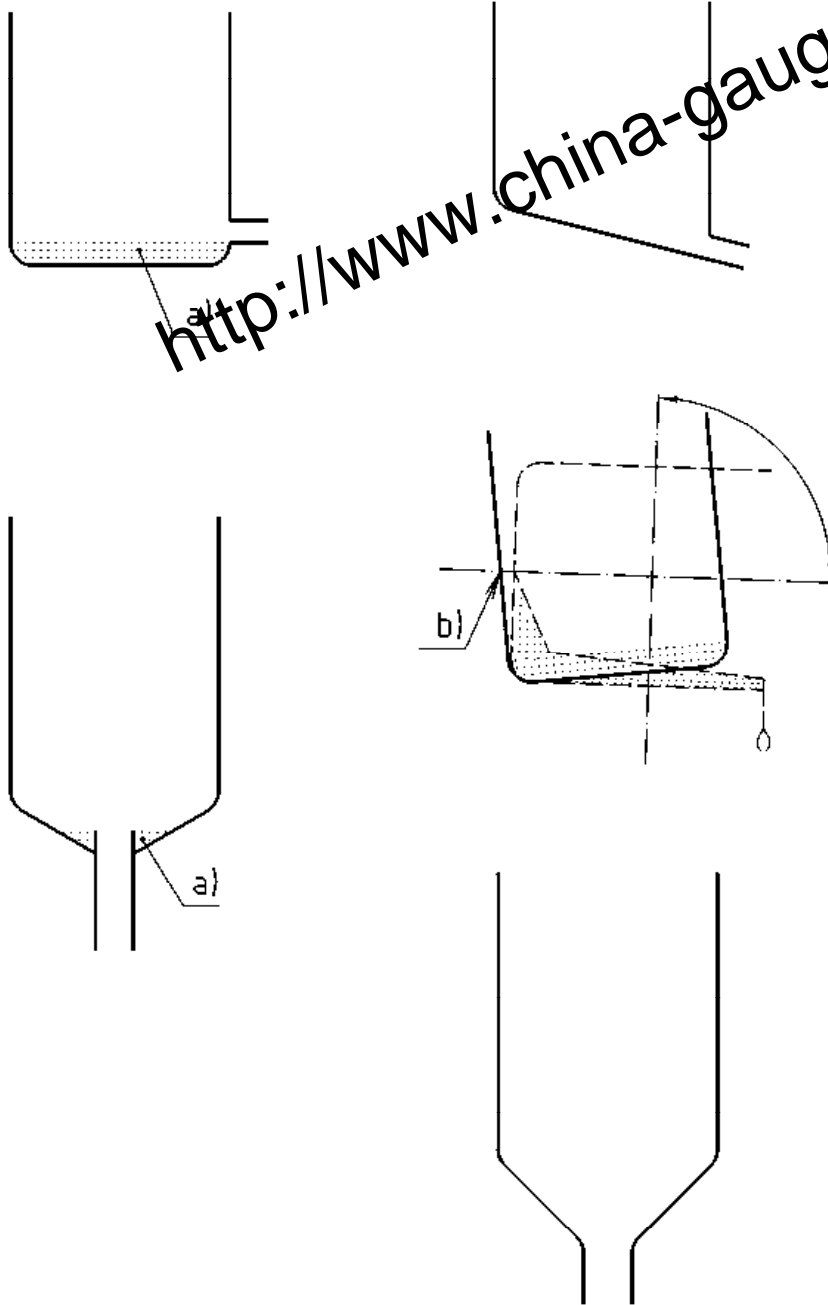
**Key**

- a) Exposed threads, crevices and/or metal to metal contact are not easily cleanable and will provide sources of infection
- b) Clearance between threaded part and hole is uncleanable
- c) Food area
- 1 Hexagon socket head screw

**Figure A.10 — Fasteners for food area**

HYGIENE RISK

ACCEPTABLE

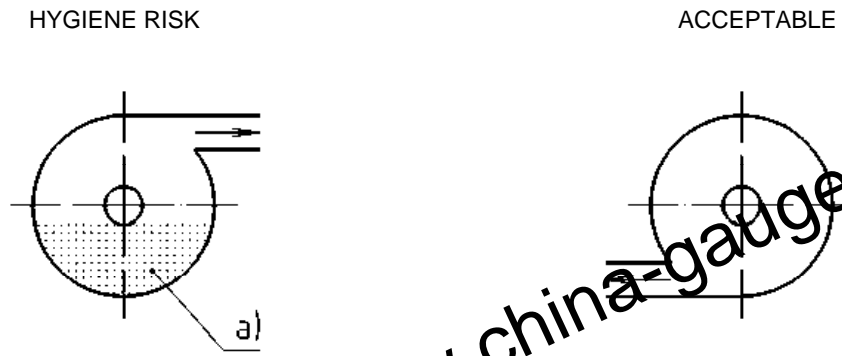


**Key**

a) Not self-draining

b) Vessel can be emptied by tilting

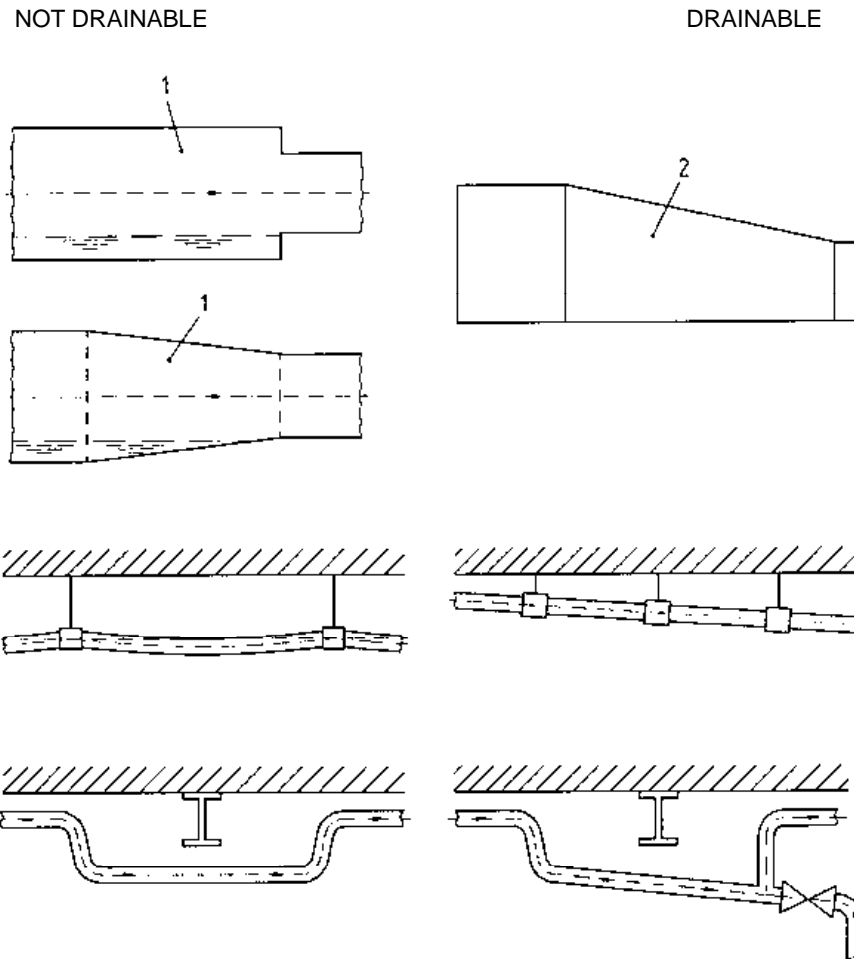
**Figure A.11 — Drainage of vessel**



**Key**

- a) Not self-draining

Figure A.12 — Drainage of pump



**Key**

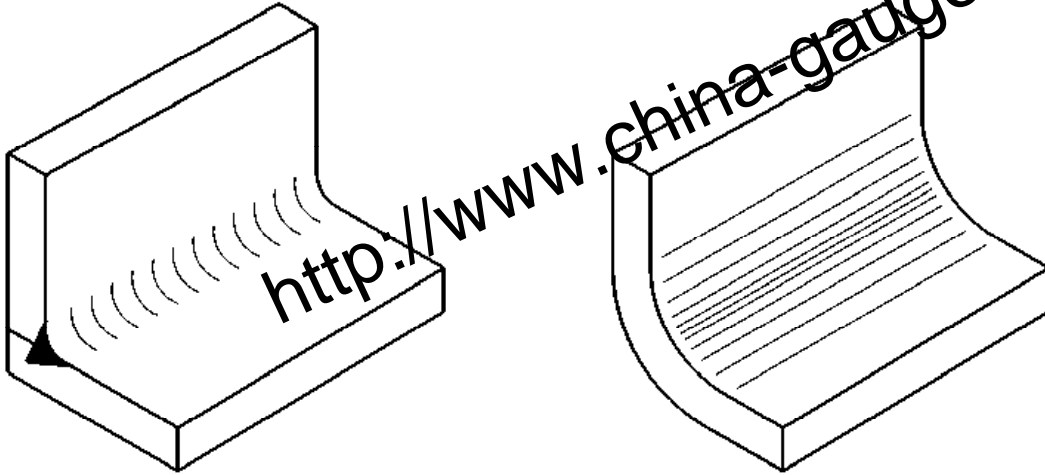
- 1 Concentric reducer
- 2 Eccentric reducer

Figure A.13 — Drainage of pipelines

HYGIENE RISK

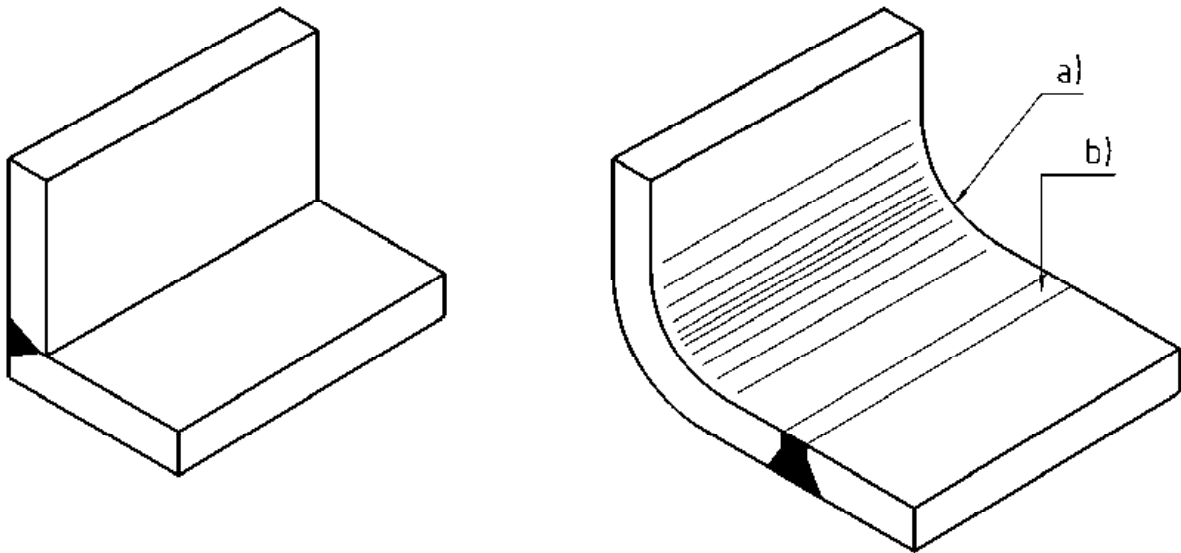
ACCEPTABLE

Only acceptable if weld is smooth and surfaces are free from crevices.



HYGIENE RISK

ACCEPTABLE



**Key**

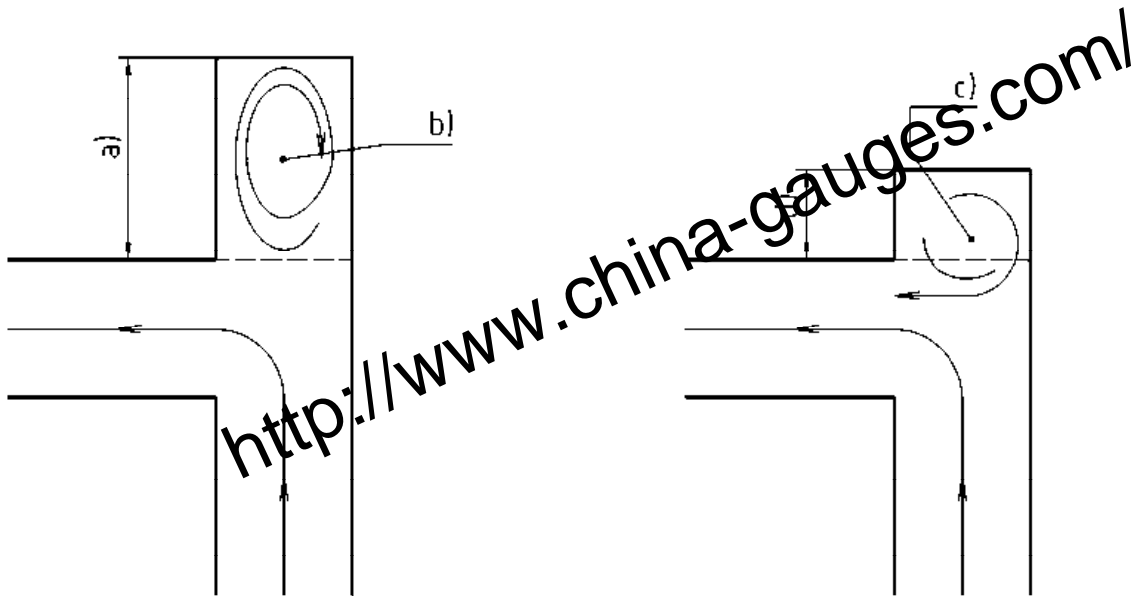
a)  $R_{min} = 3 \text{ mm}$

b) Smooth surface

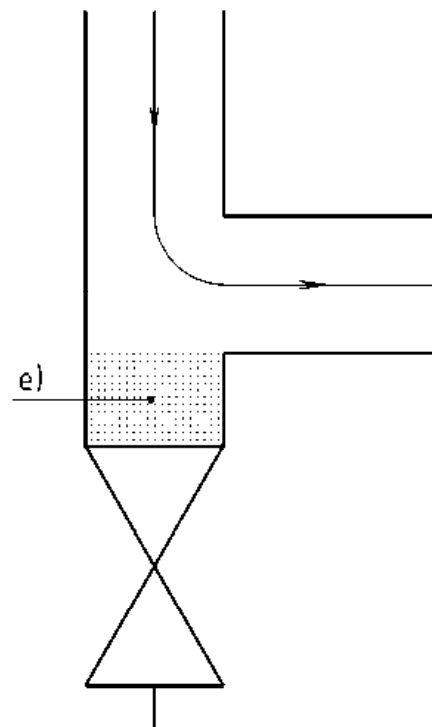
Cleanability improves up to  $R = 20 \text{ mm}$

**Figure A.14 — Internal angles and corners**

ONLY ACCEPTABLE IF UNAVOIDABLE



NOTE Acceptable length of deadleg mainly depends on viscosity and flow velocity and direction of flow.



**Key**

- |   |                              |
|---|------------------------------|
| a) Too long                                       | d) Short                     |
| b) Dead space insufficient exchange with mainflow | e) Dead space can be drained |
| c) Sufficient exchange with main flow             |                              |

Figure A.15 — Dead space

The Figure 16 illustrates how product on a conveyor, which has been trapped in a "Back-water" for some time, deteriorates and becomes discoloured but subsequently can be pushed back into the main product flow by fresh material. This should be avoided.

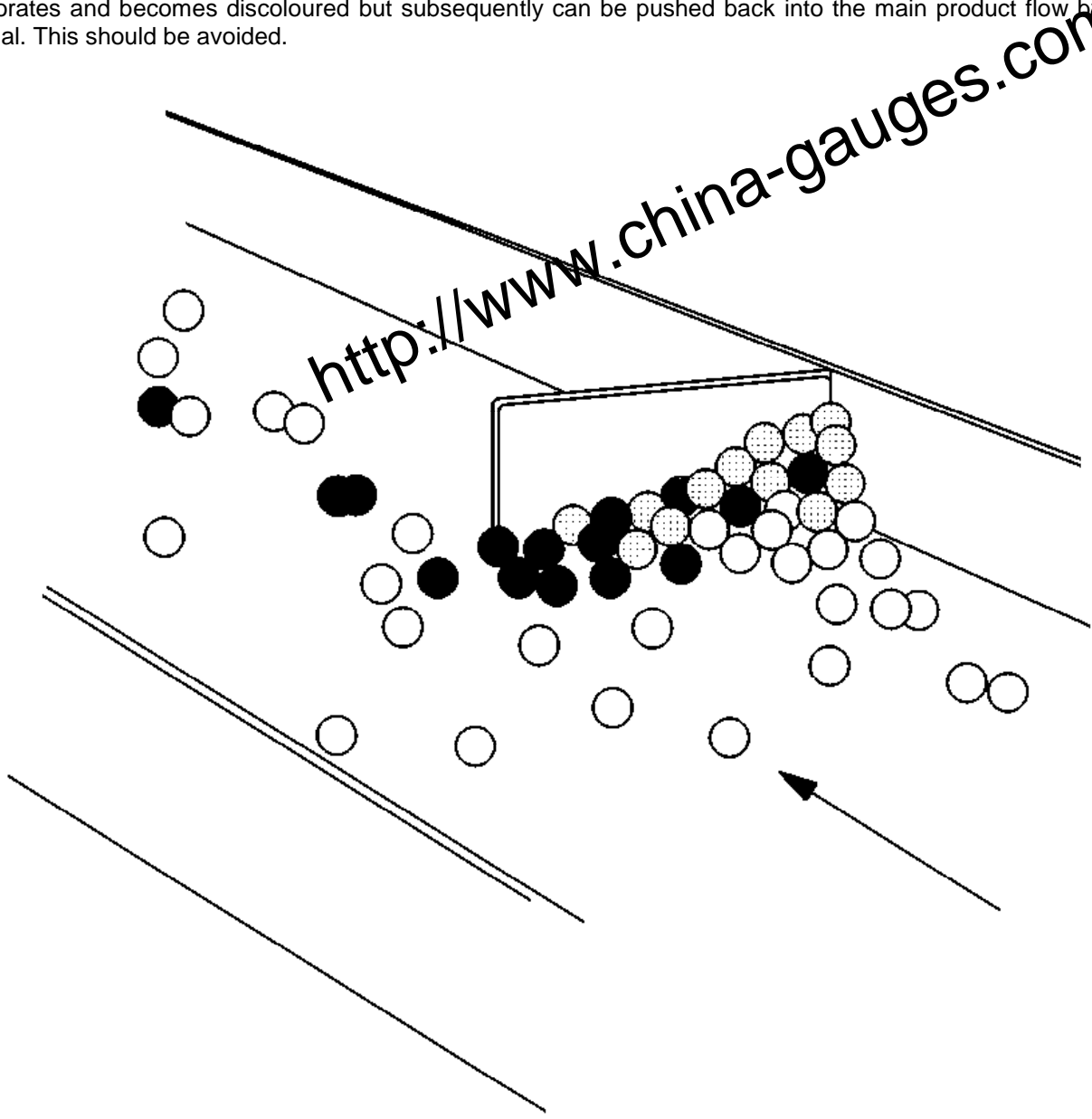
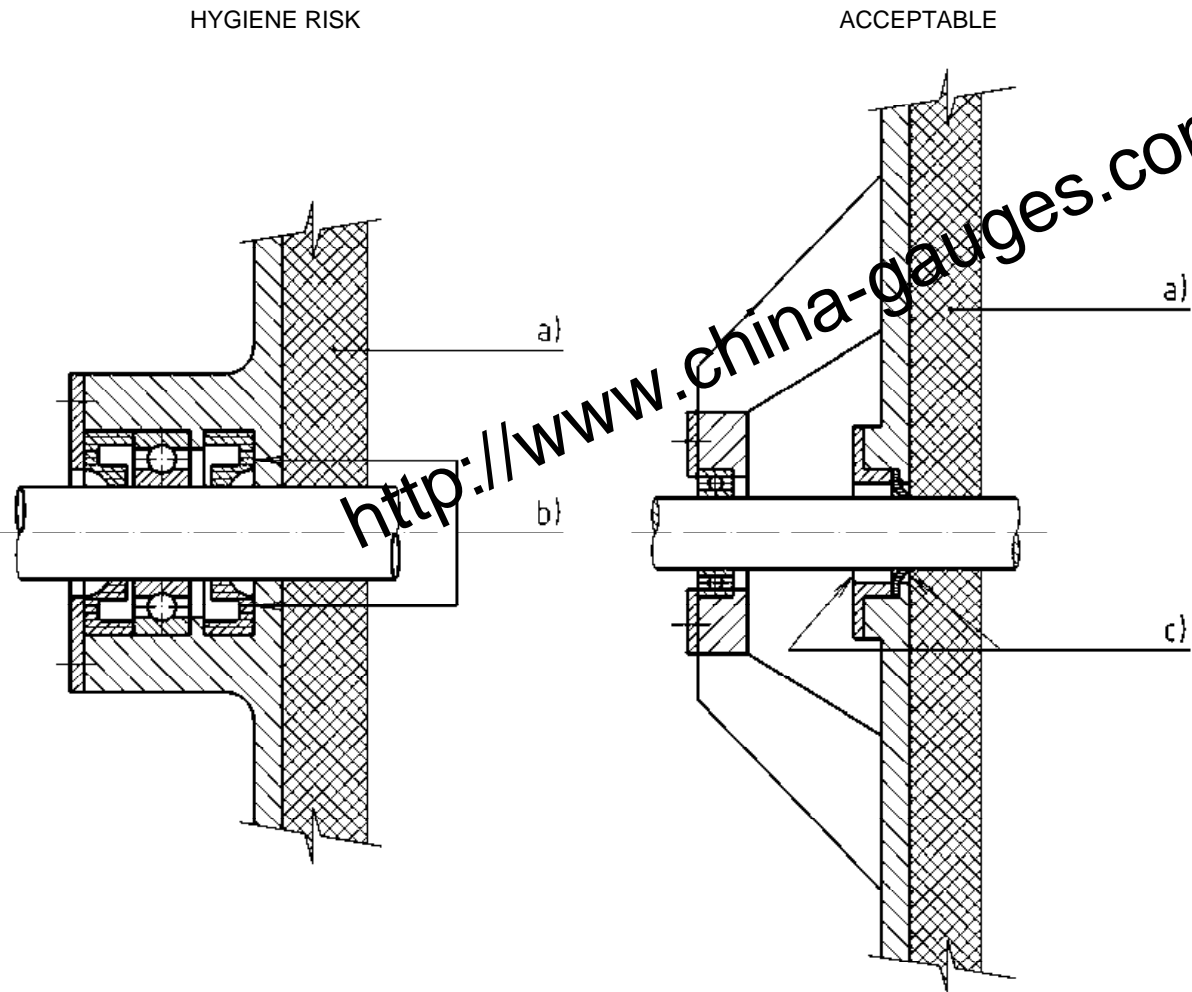


Figure A.16 — Dead space

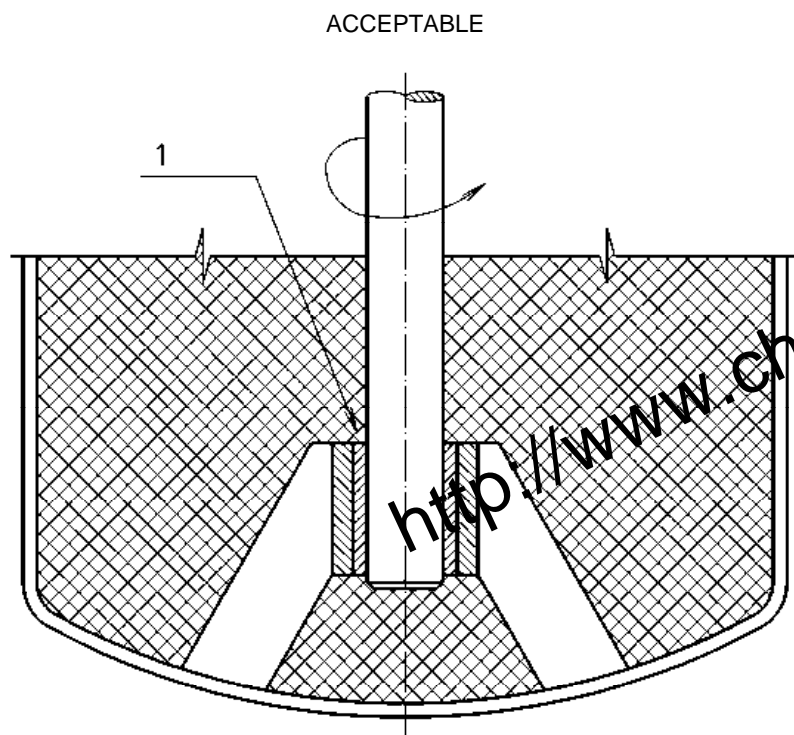




**Key**

- a) Food
- b) Food product can enter bearing. Lubricant can contaminate food
- c) Seal is cleanable from both sides

**Figure A.17 — Bearing and shaft entry point**



Bearings in food contact area

**Key**

- 1 Product lubricated bearing

**Figure A.18 — Bearing and shaft entry point**

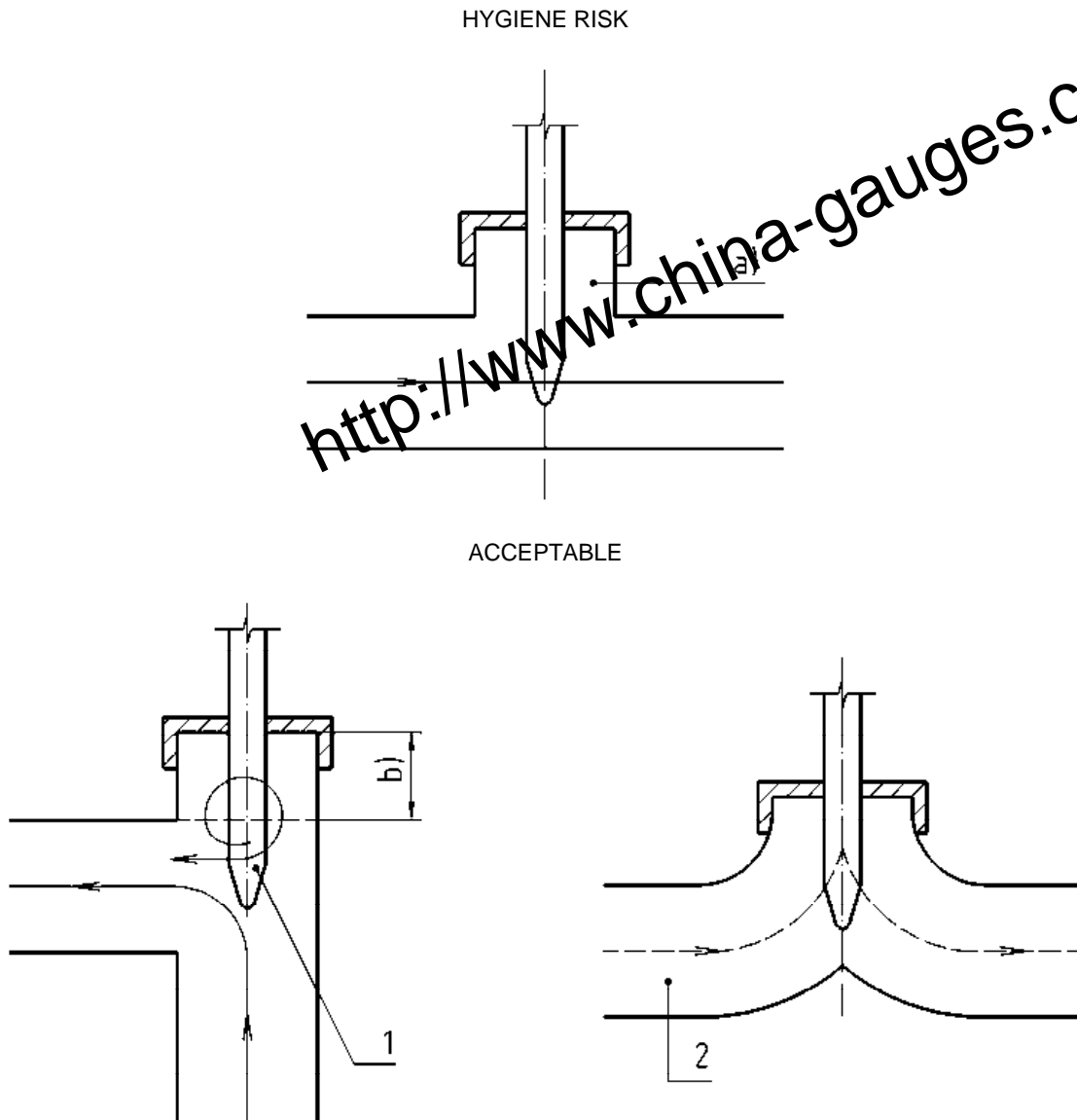


Figure A.19 — Instrumentation

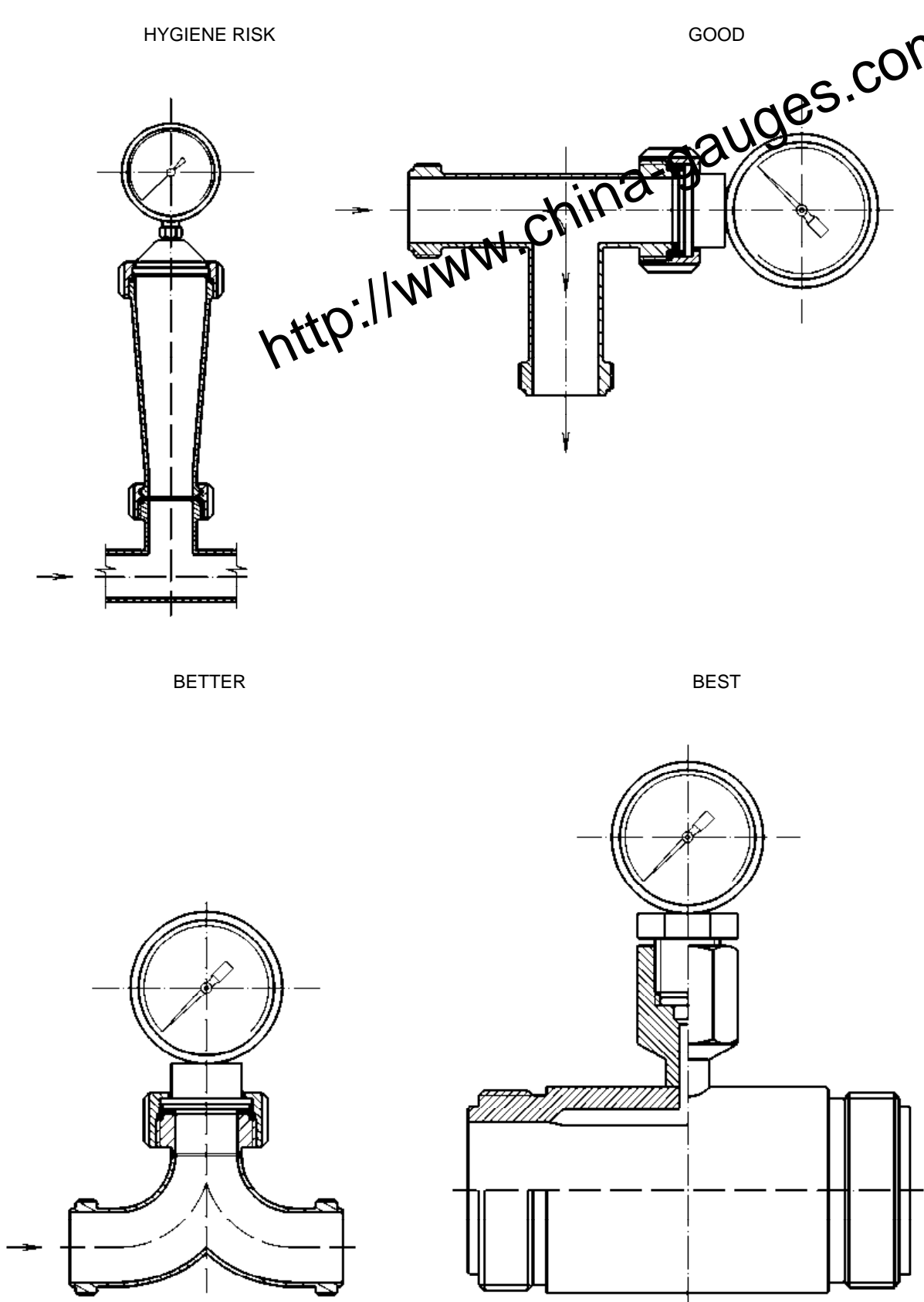
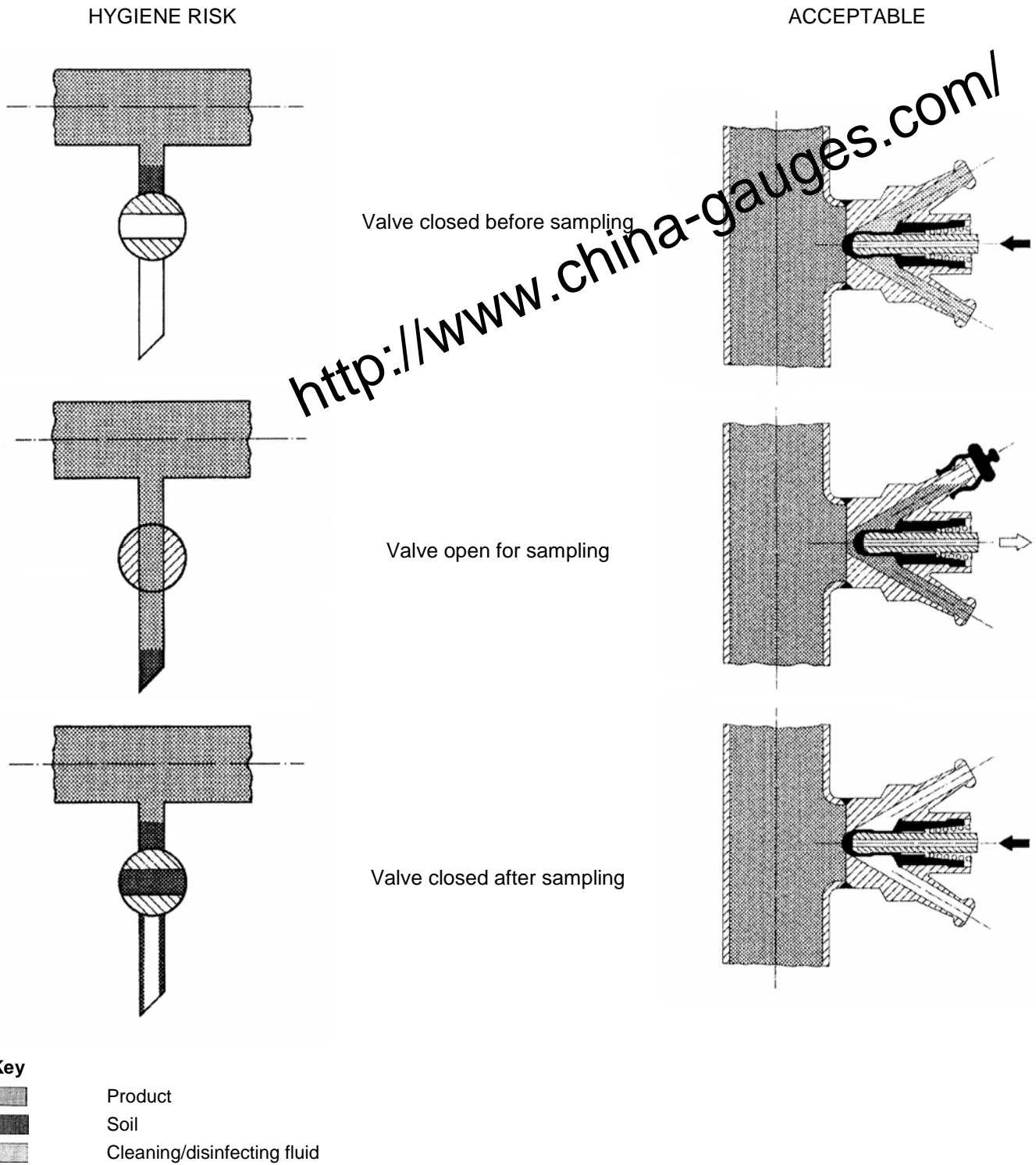


Figure A.20 — Instrumentation (pressure gauges)



NOTE The sampling device is not recommended for aseptic product.

Figure A.21 — Sampling devices

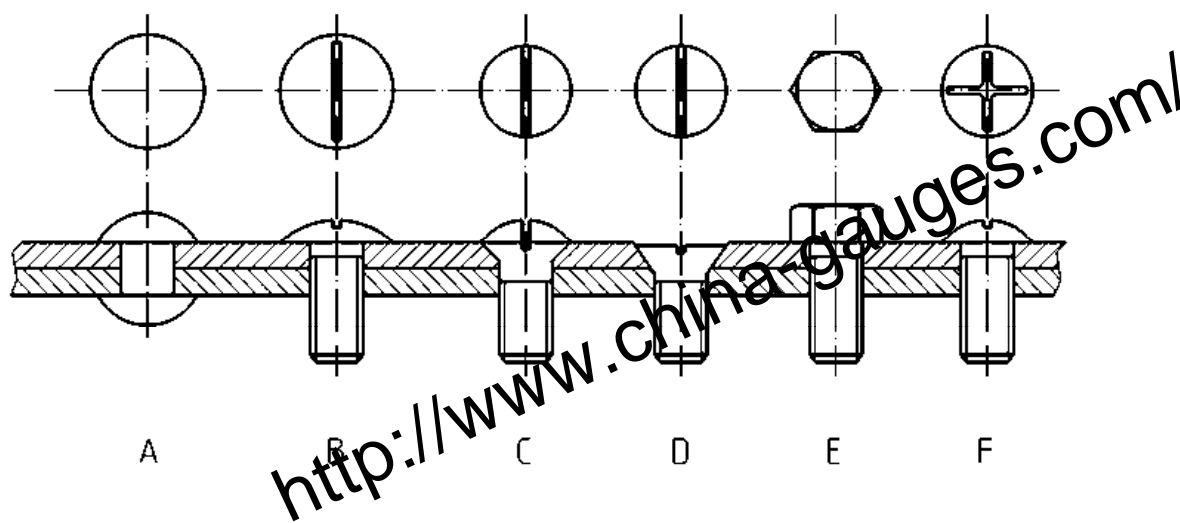


Figure A.22 — Fasteners for splash area

## Annex B (informative)

### Examples of machinery which may be covered by this document

Examples of groups of food processing machines:

- bakery machines, baking ovens, pasta machines:
  - machinery for the manufacture and processing of bakery products, confectionery and pasta;
  - ovens and baking machinery;
- machinery for processing cereals and animal feed;
- machinery for slaughter-houses and processing of meat products:
  - butchers machines;
  - slaughter-house machines;
  - cooking vessels;
  - smoking installations;
- seafood processing machines;
- machines for fruit and vegetable processing:
  - autoclaves
- machinery for catering and large kitchens;
- machinery for alcoholic and non alcoholic drinks;
- machinery for milk industry;
- machinery for dairy products;
- whipped cream machines and ice cream machines;
- machines for processing edible oils and fats;
- machines for confectionery and chocolates;
- machines for coffee and processing roasting machines;
- machinery and plants for sugar industry;
- machines for tobacco processing;
- coolers and freezers;
- egg sorting machinery.

**Annex C**  
 (informative)

**Summary of main hygiene aspects for food processing machinery**

Factors for consideration of each hazard	Information required	Design criteria
Intended use of the food machinery	<ul style="list-style-type: none"> <li>— single food type;</li> <li>— more than one food type;</li> <li>— food type not specified.</li> </ul>	Specify the intended use of the machine and its limits
Nature of the food	<ul style="list-style-type: none"> <li>— raw material;</li> <li>— part processed;</li> <li>— ready for consumption.</li> </ul>	Consider hazards associated with the food
Stage of processing	<ul style="list-style-type: none"> <li>— will the machine only handle raw materials?</li> <li>— is the machine intended to reduce or eliminate any of the identified hazards?</li> <li>— is the machine producing the final product?</li> </ul>	<p>Design according to food.</p> <p>Design according to control measures required.</p> <p>Designed to require of final food use.</p>
State of food	<ul style="list-style-type: none"> <li>— will the food be consumed immediately?</li> <li>— will the food have a defined shelf-life?</li> <li>— will the food be stable?</li> </ul>	Establish design criteria relating to food produced
Consumer of the food	<ul style="list-style-type: none"> <li>— healthy;</li> <li>— vulnerable group (i.e. elderly or infant)</li> </ul>	<p>No additional measures.</p> <p>Additional measures may be required.</p>
Market	<ul style="list-style-type: none"> <li>— local;</li> <li>— national;</li> <li>— international.</li> </ul>	Design according to intended throughput and use of the machine.



**Annex ZA**  
(informative)

**Relationship between this European Standard and the Essential  
Requirements of EU Directive 98/37/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 one means of conforming to Essential Requirements of the New Approach Directive Machinery 98/37/EC, amended by 2001/27/EC.

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 Essential Requirement 2.1 of the 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.**

**Annex ZB**  
(informative)

**[A1] Relationship between this European Standard and the  
Essential Requirements of EC 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.

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 Essential Requirement 2.1 of the Directive and associated EFTA regulations.

**WARNING** — Other requirements and other EC Directives may be applicable to the product(s) falling within the scope of this standard. [A1]

## Bibliography

- [1] 73/23/EEC, Council Directive of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits
- [2] Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 relating to materials and articles intended to come into contact with food
- [3] 93/43/EEC, Council Directive of 14 June 1993 on the hygiene of foodstuffs
- [4] EN 1050:1996, *Safety of machinery — Principles for risk assessment*
- [5] EN ISO 4287:1998, *Geometrical Product Specifications (GPS) — Surface texture: profile method — Terms, definitions and surface texture parameters (ISO 4287:1997)*
- [6] EN ISO 14159:2004, *Safety of machinery — Hygiene requirements for the design of machinery (ISO 14159:2002)*
- [7] prCEN/TR 1672-1, *Food processing machinery — Safety and hygiene requirements — Basic concepts — Part 1: Safety requirements*

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