
Stroji za predelavo hrane - Osnovni koncepti - 2. del: Higijenske zahteve

Food processing machinery - Basic concepts - Part 2: Hygiene requirements

Nahrungsmittelmaschinen - Allgemeine Gestaltungsleitsätze - Teil 2: Anforderungen an Hygiene und Reinigbarkeit

Machines pour les produits alimentaires - Notions fondamentales - Partie 2 : Prescriptions relatives à l'hygiène et à la nettoyabilité
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67.260	Tovarne in oprema za živilsko industrijo	Plants and equipment for the food industry
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English Version

**Food processing machinery - Basic concepts - Part 2:
Hygiene and cleanability requirements**

Machines pour les produits alimentaires - Notions
fondamentales - Partie 2 : Prescriptions relatives à
l'hygiène et à la nettoyabilité

Nahrungsmittelmaschinen - Allgemeine
Gestaltungsleitsätze - Teil 2: Anforderungen an
Hygiene und Reinigbarkeit

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European foreword

This document (prEN 1672-2:2019) 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 document is currently submitted to the CEN Enquiry.

This document will supersede EN 1672-2:2005+A1:2009.

The significant changes with respect to the previous edition EN 1672-2:2005+A1:2009 are listed below:

- The list of terms and definitions was upgraded;
- New methodology “Iterative hygiene risk reduction process”;
- All requirements regarding hygiene were upgraded, and new requirements regarding cleanability were added;
- Annex ZA was deleted to be in line with the HAS consultant recommendation.

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Introduction

This document gives general hygiene and cleanability requirements for machinery in the scope of this standard. It is intended to be referred by type-C machinery-specific standards. This standard can be used as a general guide for machinery without type-C-specific standards.

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 will distinguish 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.

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1 Scope

1.1 This document specifies common hygiene and cleanability requirements for machinery and machine components used in preparing and processing food for human (see informative Annex A) and, where relevant, animal consumption to eliminate or minimize 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.

Detailed hygiene and cleanability requirements may be given in applicable C-standards for specific machine or categories of machinery.

NOTE 1 Separate hygiene and cleanability requirements are contained in other EU-Directives or -Regulations (see the Bibliography).

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

NOTE 2 This document can also be used for machinery, components or other equipment used for other purposes than food preparing or processing, if cleanability is required.

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

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

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2 Normative references (standards.iteh.ai)

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100:2010)*

EN ISO 21469, *Safety of machinery — Lubricants with incidental product contact — Hygiene requirements (ISO 21469)*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1 food

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

Note 1 to entry: It includes food and feed according to Article 2 of Regulation (EC) No. 178/2002.

prEN 1672-2:2019 (E)**3.2****hygiene****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**access distance****P**

distance from the nearest free access point of the machine, according to the intended installation, to reach the furthest point of all areas to be cleaned

3.4**adverse influence**

effect which gives a significant reduction of the fitness for consumption of a food

Note 1 to entry: A food can be adversely influenced, in particular by microbial pathogens or other unwanted microorganisms, toxins, vermin and other contaminants.

3.5**areas of equipment**

food area, splash area and non-food area as following defined (see 3.5.1 to 3.5.3) and as illustrated in Figure 1

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).

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3.5.1**food area**

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

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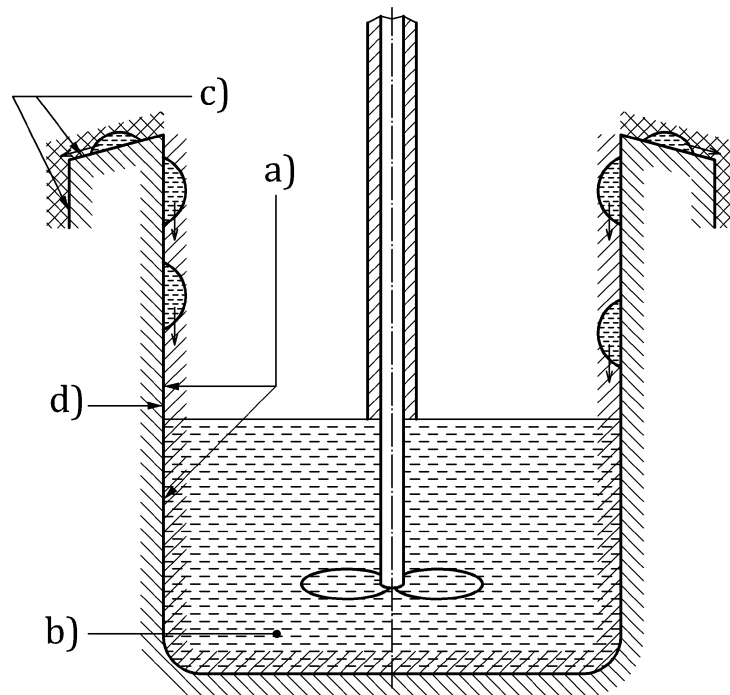
3.5.2**splash area**

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

Note 1 to entry: Part of the food in the splash area is no more food in the sense of 3.1.

3.5.3**non-food area**

any area other than those specified above

**Key**

-  a) food area (3.5.1)
-  b) food
-  c) splash area (3.5.2)
-  d) non-food area (3.5.3)

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Figure 1 — Areas of equipment

3.6**cleaning**

removal of soils

3.6.1**cleanable**

designed and constructed so that soils can be removed

3.6.2**easily cleanable**

designed and constructed to be cleanable by a simple cleaning method, where necessary after removing easily dismantled parts

Note 1 to entry: Simple cleaning methods could be, e.g. vacuum cleaning, cleaning in place (CIP) or cleaning after dismantling parts without the need of tools (e.g. spanner) for dismantling.

3.6.3**wet cleaning**

cleaning with the use of liquids

3.6.4**dry cleaning**

cleaning without the use of liquids

prEN 1672-2:2019 (E)**3.7****consumer**

human and/or animal

3.8**contamination**

presence of soils

3.8.1**cross contamination**

transfer of soil from one location to another location

3.9**corrosion-resistant material**

material resistant to normally occurring action of chemical or electrochemical nature

Note 1 to entry: It includes food processing, cleaning and disinfection according to the instructions for use.

3.10**crevice**

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

3.11**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 example given in Figure B.14)

3.12**disinfection**

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

3.13**durable**

ability of a surface to withstand the intended conditions of use, except for unavoidable wear and tear

Note 1 to entry: Damage, for example, can be 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;
- recommended or required utensils.

3.14**easily accessible**

designed and constructed to permit removal, visual inspection and replacement, where necessary after removing easily dismantled parts

3.15**hazard**

potential source that can lead to health harm

[SOURCE: EN ISO 12100:2010, 3.6, modified]

Note 1 to entry: Hazard means food safety hazard which can lead to unsafe food.

3.15.1**hazardous event**

event that can cause health harm

[SOURCE: EN ISO 12100:2010, 3.9, modified]

Note 1 to entry: A hazardous event can occur over a short period of time or over an extended period of time.

3.15.2**hazardous situation**

circumstance in which at least one consumer is exposed to at least one hazard

[SOURCE: EN ISO 12100:2010, 3.10, modified]

Note 1 to entry: The exposure can result in health harm immediately or over a period of time.

3.16**health harm**

physical injury and/or infection, sickness or contagion caused by unwanted components in or of food and/or food contaminants alone

3.17**hygienic equipment / hygienic machinery**

design and construction of equipment/machinery that can be easily freed from soil by cleaning with or without dismantling

3.18**joint**

junction of two or more pieces of material

3.18.1**joined surfaces**

surfaces between which no particle of product becomes trapped in small crevices, thus becoming difficult to dislodge and so introduce a contamination hazard

3.19**lubrication point**

place where the lubricant fulfills its function

3.19.1**lubricant outlet**

discharge for lubricant drainage (e.g. for pressure relief)

prEN 1672-2:2019 (E)**3.20****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

3.21**non-toxic material**

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

3.22**portable**

manually liftable and movable

3.23**open process**

process in which food has contact with the environment

3.23.1**closed process**

process in which food has no contact with the environment (except inlet and outlet of food, if relevant)

[SOURCE: EN ISO 12100:2010, 3.5, modified]

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3.24**rinsing**

removal of residues or any other matter after cleaning or disinfection by flowing liquid

3.25**seal**

component or assembly of components used for sealing

3.26**sealing**

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

3.27**self draining**

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

3.28**smooth**

condition of a surface which satisfies operational, hygiene and cleanability requirements

3.29**soil**

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

3.30**supply circuits**

service devices and/or transporting devices (e.g pipes, tubes, cables) for power, supports (air, water, etc.), data and ancillary substances which are integral parts of the machine

3.31**unsafe food**

adversely influenced (see 3.4) food or feed

Note 1 to entry: Machines which do not fulfill the requirements of this standard may produce unsafe food.

3.32**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:

a) microbiological causes, e.g.:

- 1) pathogens (e.g opportunistic pathogens like salmonella, enterobacter, coliform bacteria);
- 2) microbiological toxins (e.g. *Bacillus cereus*, *Staphylococcus aureus*) and biogenic amines of pathogens;
- 3) antibiotic-resistant microorganisms;
- 4) other biological causes, e.g.:
 - i) mono- and multicellular vermin (e.g. toxoplasms, tapeworm);
 - ii) bovine spongiform encephalopathy (BSE).

b) Chemical causes, e.g.:

- 1) cleaning and disinfection agents;
- 2) lubricants;
- 3) veterinary drugs;
- 4) agricultural pesticides;
- 5) contaminants (like dioxins, PCBs, mycotoxins, heavy metals);
- 6) substances released by materials.

c) Foreign bodies, contaminants and radiation arising from raw material, machinery or other sources, e.g.:

- 1) bone fragments;
- 2) metal parts and broken glass;
- 3) radioactive elements.

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

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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. The informative Annex C gives examples.

5 Hygiene and cleanability requirements

5.1 Iterative hygiene risk reduction process

5.1.1 General

The hygiene and cleanability requirements of the different areas of equipment are described in Clause 5. They depend upon the significant hazards as described in Clause 4, the functions of the area of the machinery and machine components

In applying the principles of design (see 5.3) the primary objective is to eliminate or reduce the risks to an acceptable level. The risk assessment and risk reduction follow the methodology described in EN ISO 12100:2010. In order to deal with hygiene risk and cleanability, the process has been modified as shown in Figure 2. To apply this method, follow the steps and answer to questions in the order shown in this figure.

It is recommended to do the iterative hygiene risk reduction process by a team rather than by one person only.

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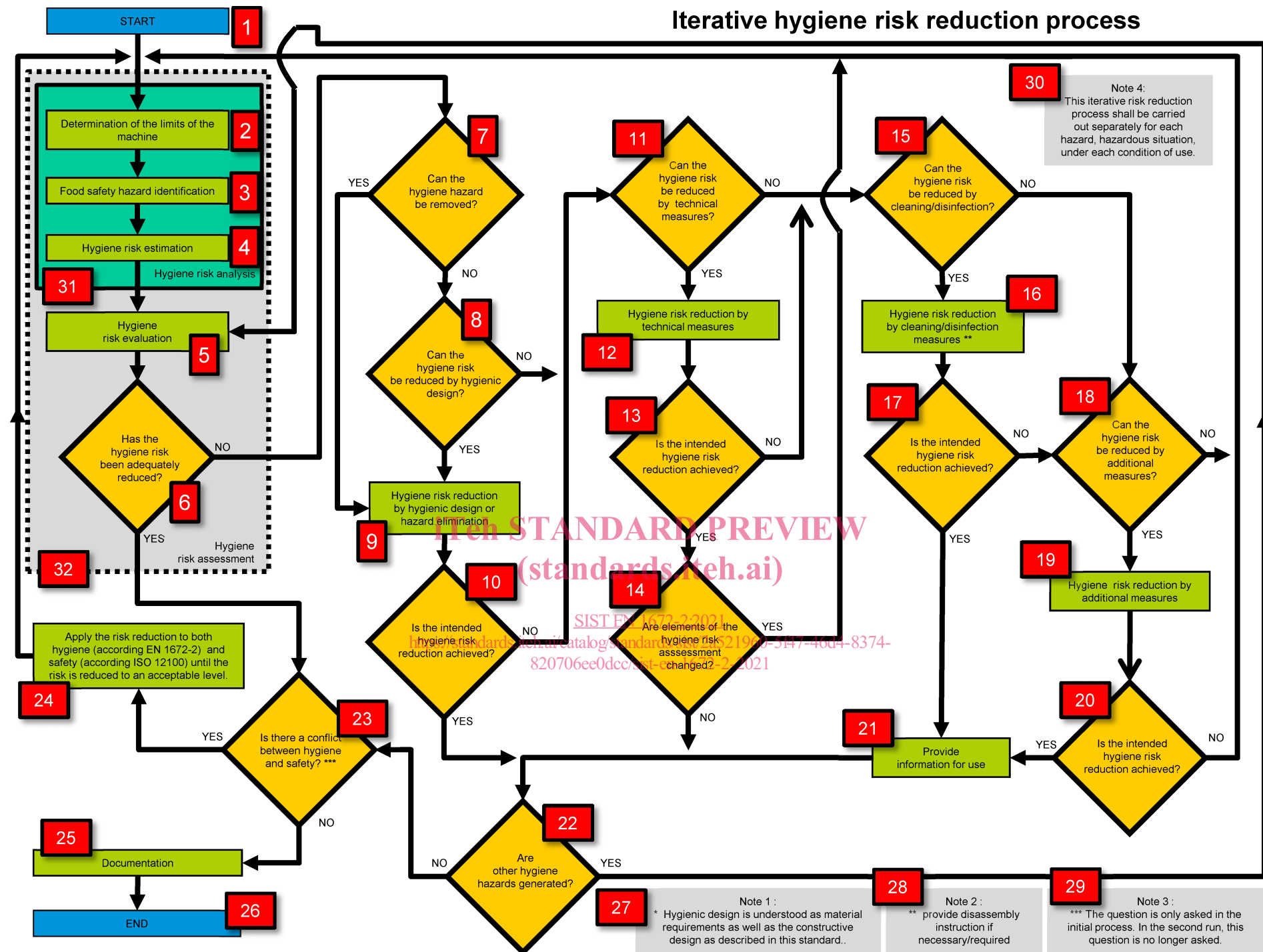


Figure 2 — Iterative hygiene risk reduction process