SLOVENSKI STANDARD
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Stroji za predelavo hrane - Osnovni koncepti - 2. del: Higienske 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 COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 1672-2:2020) 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of an identical text or by endorsement, at the latest by June 2021, and conflicting national standards shall be withdrawn at the latest by June 2021.

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

This document supersedes 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.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This document gives general hygiene and cleanability requirements for machinery in the scope of this document. It is intended to be referred by type-C machinery-specific standards. This document 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.

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.

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 feed processing to eliminate or minimize the risk of contagion, infection, illness or injury arising from this food to an acceptable level. It identifies the hazards which are significant to the use of such food processing machinery and describes design methods and information for use for the elimination or reduction of these risks.

Additional and/or deviant hygiene and cleanability requirements may be given in applicable C-standards for specific machines or categories of machinery.

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

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

This document may 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 operators 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.

2 Normative references

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 21469:2006, *Safety of machinery — Lubricants with incidental product contact — Hygiene requirements (ISO 21469:2006)*

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: The definition means food according to Article 2 of Regulation (EC) No. 178/2002 and feed.

3.2
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

Note 1 to entry: Access points are given in Figure 21.

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 machinery and machine components
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

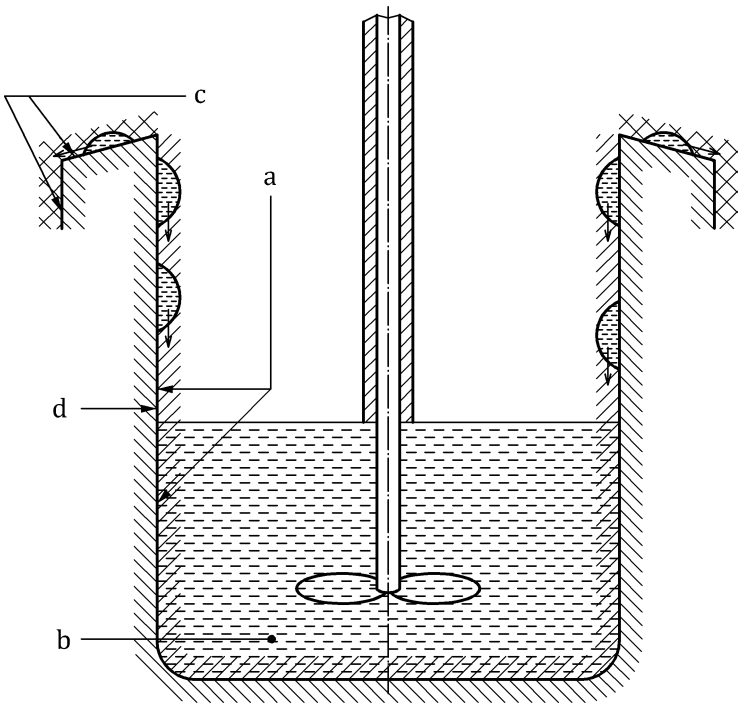
Note 1 to entry: These areas are not to be confused with any others amongst those defined in other standards (e.g. electro-technical standards).

3.5.1
food area
machine and machine components surfaces which are exposed to food or from which food or other materials can drain, drip, diffuse or be drawn into the food

3.5.2
splash area
area composed of surfaces on which part of the food can 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 food area or splash area



Key

a food area (3.5.1)
b food (3.1)
c splash area (3.5.2)
d non-food area (3.5.3)

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 dismountable 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

3.7
consumer
human and/or animal

3.8
contamination
presence of soils

3.8.1
cross contamination
transfer of soil from one part of the machine into the food during use of the machine

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
unaccessible space wherein a product, ingredient, cleaning or disinfecting agents or soils can be trapped, retained and not removed during operation or operation of cleaning

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 of the surfaces can be caused by e.g.:

— the action of the process;

— contact with the food being processed;

— thermal actions;

— handling and contact with any cleaning or disinfecting agents specified;

— utensils and supplies for cleaning.

3.14
easily accessible
designed and constructed to permit removal, visual inspection and replacement, where necessary after removing easily dismountable parts

Note 1 to entry: Easily dismountable means without the need of tools (e.g. spanner).

3.15
hazard
potential source that can lead to health harm

[SOURCE: EN ISO 12100:2010, 3.6, modified – Note 1 to entry has been added]

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 has been added]

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 has been added]

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

3.16
health harm
physical injury, infection, sickness or contagion caused by unsafe food

[SOURCE: EN ISO 12100:2010, 3.5, modified – "health" and "infection, sickness or contagion caused by unsafe food" have been added]

3.17
joint
junction of two or more pieces of material

3.17.1
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

3.18
lubrication zone
place where the lubricant fulfills its function

3.18.1
lubricant outlet
discharge for lubricant drainage (e.g. for pressure relief)

3.19
non-absorbent material
material which, under intended conditions of use, does not retain substances with which it comes into contact

3.20
non-toxic material
material which does not produce or release substances in quantities injurious to health under intended conditions of use

3.21
portable
manually liftable and movable

3.22
open process
process in which food has contact with the environment

3.22.1
closed process
process in which food has no contact with the environment (except inlet and outlet of food, if relevant)

3.23
rinsing
removal of residues or any other matter by flowing liquid

3.24
seal
component or assembly of components used for sealing

3.25
sealing
closing of an aperture so as to effectively prevent the unwanted entry or passage of soil

3.26
self draining
design and construction of the shape and surface finish so as to prevent liquid from being retained

3.27
smooth surface
surface which satisfies operational, hygiene and cleanability requirements

3.28
soil
any matter which can make food unsafe; including but not limited to product residues, micro-organisms, residual detergent, chemicals or disinfecting agents, except substances migrating (or released metallic ions) from food contact materials into the food

3.29
unsafe food
adversely influenced (see 3.4) food

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

3.30
vermin
animals (including mammals, birds, reptiles and insects) which can adversely influence the food

3.31
tilting
raising one end of the machine for accessibility

4 List of significant hazards

The significant hazards can arise from:

a) microbiological causes, e.g.:

1) pathogens (from e.g. opportunistic pathogens like salmonella, enterobacter, coliform bacteria);

2) microbiological toxins (from e.g. *Bacillus cereus, Staphylococcus aureus*) and biogenic amines of pathogens;

3) microorganism;

4) other biological causes, e.g.:

— mono- and multicellular vermin (e.g. toxoplasms, tapeworm);

— unconventional transmissible agents.

b) Chemical causes, e.g.:

1) cleaning and disinfection agents;

— lubricants;

— veterinary drugs;

— agricultural pesticides;

— contaminants, e.g. allergens, dioxins, polychlorinated biphenyl (PCB), mycotoxins, heavy metals;

— substances released by materials.

c) Physical causes:

1) foreign bodies (e.g. bone fragments, metal parts and broken glass);

— contaminants and radiation arising from raw material, 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.

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

Chemical 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.

5 Hygiene and cleanability requirements

5.1 Iterative hygiene risk reduction process

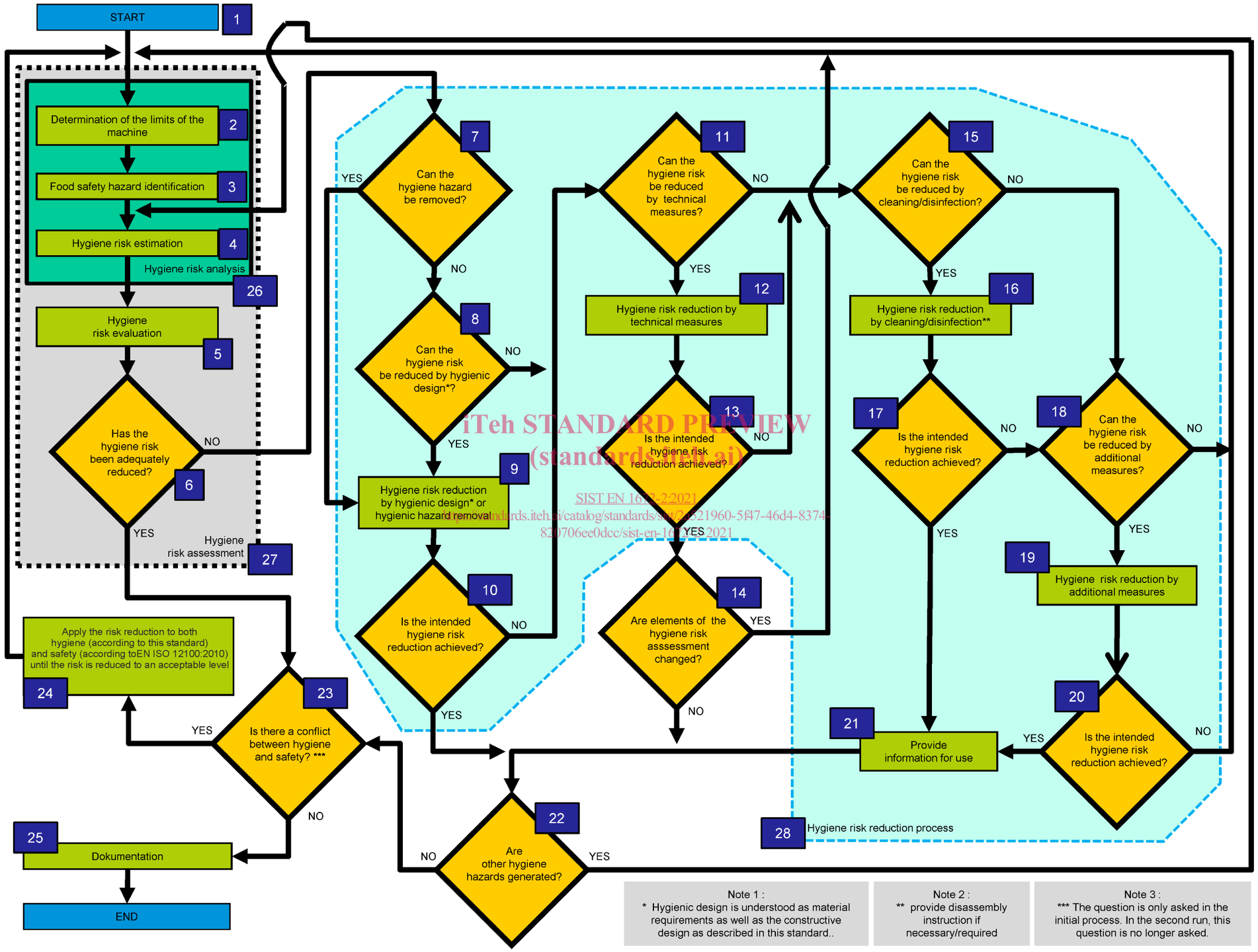
5.1.1 General

The hygiene and cleanability requirements of the different areas of equipment are described in 5.2. They depend upon the significant hazards as described in Clause 4, the functions of the areas of equipment.

The primary objective is to eliminate or reduce the risks to an acceptable level. The hygiene risk assessment and hygiene risk reduction process 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, the steps and answer to questions shall be followed in the order shown in this figure.

This iterative risk reduction process shall be carried out separately for each hazard, hazardous situation, under each condition of use.

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



NOTE Explanations to numbers 1 to 28 are given in 5.1.2 to 5.1.4.

Figure 2 — Iterative hygiene risk reduction process