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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: Hygieneanforderungen

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

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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

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

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Contents

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of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by December 2009.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 ⟨A1⟩ EN 1672-2:2005 ⟨A1⟩.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟨A1⟩ ⟨A1⟩.

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).

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

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 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.

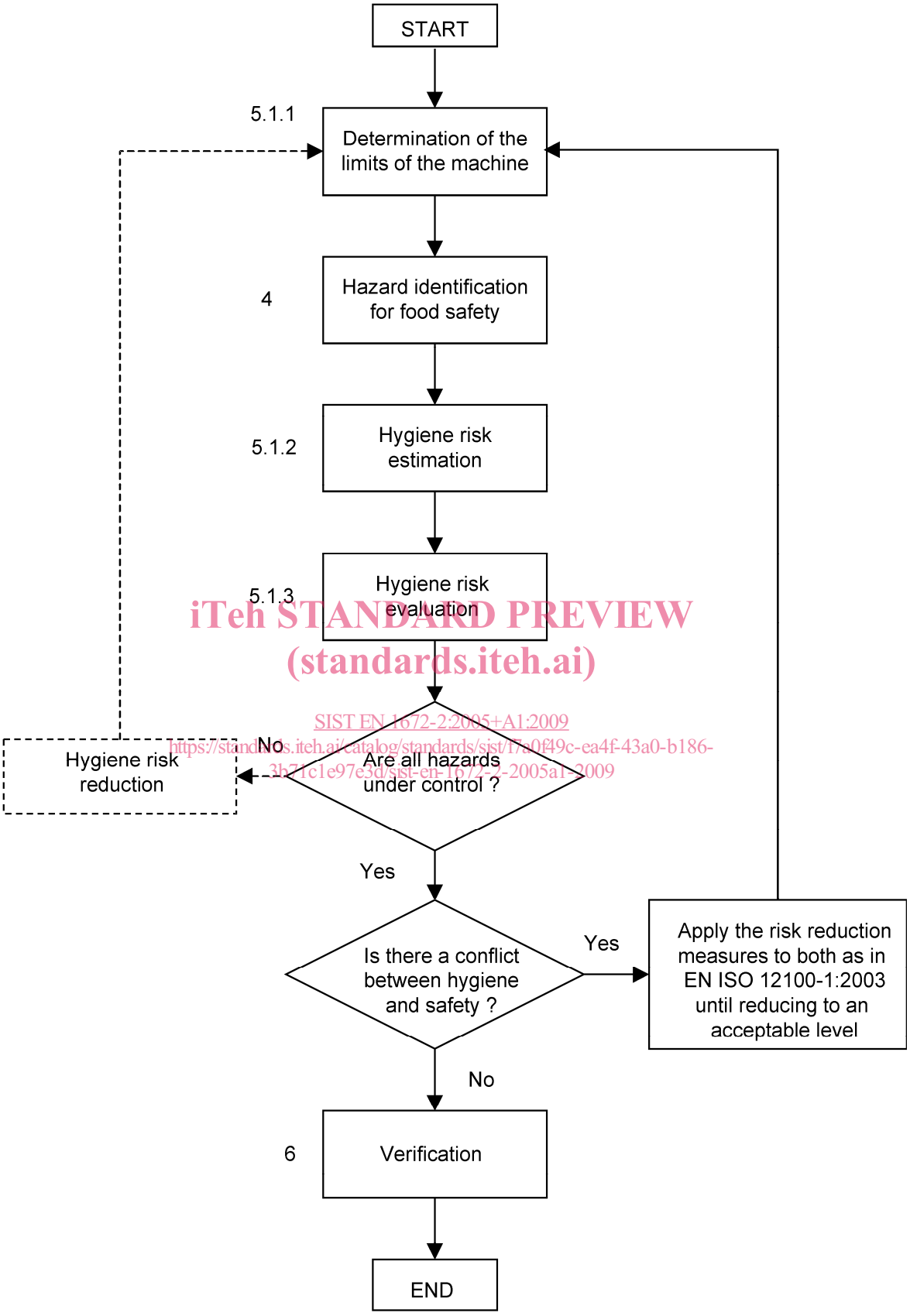

Figure 1 — Hygiene risk assessment

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, or limiting physical abilities (e.g. visual or hearing impairment, size, strength);

— the anticipated level of training, experience or ability of the foreseeable users.

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?

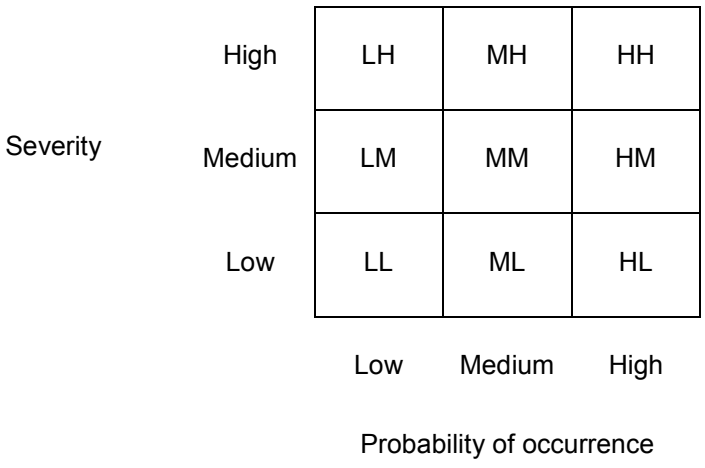

Figure 2 — Example of tool for the risk estimation - Risk ranking diagram

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;