SLOVENSKI STANDARD
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Stroji za predelavo hrane - Osnovni pojmi - 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 a l'hygiene

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

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

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 153 "Food processing machinery - Safety and hygiene specifications", 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of an identical text or by endorsement, at the latest by September 1997, and conflicting national standards shall be withdrawn at the latest by September 1997.

This European Standard 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).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

It has been prepared by two "ad hoc" working groups of CEN/TC 153 : "Basic concepts - Safety requirements" and "Basic concepts - Hygiene requirements".

Part 1 sets common requirements in respect of safety, for machinery used in processing food for human and, where relevant, animal consumption. It primarily covers general aspects of safety for the operator of the machinery.

Part 2 sets common requirements in respect of risks to hygiene arising from the use of the food machinery and food process. It primarily covers general aspects of hazards to the food created by the machinery in order not to introduce hazards to the consumer of the food (the product processed by the machinery).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

0 Introduction

This standard is a type C standard as defined in clause 0 of EN 292-1:1991 and is intended for use by food processing machinery manufacturers and by working groups preparing machinery specific C standards.

Parts 1 and 2 of EN 1672 have been prepared to be harmonised standards to provide one means of conforming with the essential requirements of the Machinery Directive and associated EFTA Regulations.

The extent to which hazards are covered is indicated in the scope of each part of this standard. In addition, machinery shall comply as appropriate with EN 292 for hazards which are not covered by this standard. 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 standard 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.

The essential requirements of the Machinery Directive have to 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 292 can each usually equally well be met by a range of safeguarding or hygiene design options.

In almost all cases at least one of the different methods of design, safeguarding or residual safeguards 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 residual safeguards, 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 residual safeguards for the lesser risk.

The technical requirements given in both parts of this standard permit both objectives to be met for those significant and common risks identified as justifying common requirements in this standard.

Other hazards, for which such common requirements can not be set, remain to be covered in machinery specific C Standard and/or by reference to annex A of EN 292-2:1991 and type A and type B Standards.

1 Scope

This part of EN 1672 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 infection, illness, contagion 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 standard does not deal with the hygiene related risks to personnel arising from the use of the machine, such as the use of cleaning agents, steam etc. which are dealt with in prEN 1672-1:1994.

This standard applies to food processing machines listed in the normative annex A used for batch, continuous, open and closed processing using any kind of energy for motive power, heating or control.

NOTE : Separate hygiene requirements are contained in other EU Directives (see annex E).

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

This standard applies primarily to machines which are manufactured after its date of issue.

In addition, the principles contained in this standard can be applied to other machinery and equipment used to process food where similar risks apply. Examples of such groups of food processing machinery are given in the informative annex C.

2 Normative references

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

EN 292-1:1991	Safety of machinery - Basic concepts, general principles for design - Part 1 : Basic terminology, methodology
EN 292-2:1991	Safety of machinery - Basic concepts, general principles for design - Part 2 : Technical principles and specifications

EN 292-2/A1:1995 Safety of machinery - Basic concepts, general principles for design - Part 2 : Technical principles and specifications

ENV 1070:1993 Safety of machinery - Terminology

ISO 468 Surface roughness - Parameters, their values and general rules for specifying requirements.

prEN 1672-1:1994 Food processing machinery - Safety and hygiene requirements - Basic concepts - Part 1 : Safety requirements.

3 Definitions

For the purposes of this standard, the definitions given in ENV 1070 and the following definitions apply.

3.1 food : Any product, ingredient or material intended to be orally consumed.

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 : An 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, domestic animals and other contaminants.

3.4 areas of equipment

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

3.4.1 food area : Area composed of surfaces in contact with food ; the food area also includes the surfaces with which the product may come into contact under intended conditions of use, after which it returns into the product (see figure B.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 product (see figure B.1).

3.4.3 non food area : Any area other than those specified above (see figure B.1).

3.5 cleaning : Removal of soils.

3.5.1 cleanable : Designed and constructed so that soils are removed by recommended cleaning methods (see 7.1.2).

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** : A 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 B.2 and B.3).

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 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** : The 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 hazards

The hazards can arise from :

- microbiological causes such as pathogens, spoilage micro-organisms or toxins ;
- 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 contaminate 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 D gives examples of design criteria.

5 Hygiene requirements and/or measures

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.

5.1 Materials of construction

5.1.1 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.

5.1.2 Food area

In addition to the general requirements (see 5.1.1), 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.

5.2 Design

5.2.1 Food area

5.2.1.1 Surfaces

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

Surface finish according to ISO 468 shall comply with technical requirements, limited to measuring methods R_z and R_a, given in the machinery specific C standards .

NOTE : In addition to these general requirements, surfaces in non food or splash areas should be considered as food areas where cross contamination occurs, for example : in cases where there is manual contact with the food.

5.2.1.2 Joints

5.2.1.2.1 Permanent joints

Joints shall be sealed and hygienic. Recesses, gaps, crevices, protruding ledges, inside shoulders and dead spaces should be avoided (see figures B.4, B.5 and B.6).

5.2.1.2.2 Dismountable joints

Dismountable joints shall present a true and hygienic fit (see figures B.7, B.8, B.9 and B.10).

5.2.1.3 Fasteners

Fasteners such as screws, bolts, rivets and so on, shall be avoided. If technically unavoidable, they shall be cleanable and, where required, capable of being disinfected (see figure B.11).

5.2.1.4 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 B.12, B.13 and B.14).

5.2.1.5 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 B.15).

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

5.2.1.6 Dead spaces

Dead spaces shall be avoided unless technically impossible in the design, construction and installation of the machinery (see figures B.16 and B.17).

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

5.2.1.7 Bearings and shaft entry points

Bearings shall be either located outside of the food area except where this is technically unavoidable, or lubricated by food grade lubricant, cleanable and where required capable of being disinfected (see figures B.18 and B.19)

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

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

5.2.1.8 Instrumentation

Instrumentation shall comply with the relevant sections of this clause 5 (see figures B.20 and B.21).

5.2.1.9 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.

5.2.1.10 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 occurs these areas or items shall be covered by the definition of a food area (see 3.2.1).

5.2.2 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 in the following areas provided that there is no adverse effect on the food :

- technical requirements for surface finish and materials may be less stringent and may allow for higher Rz and Ra values;

- internal angles and corners may be of smaller radius than specified for the food area, 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.

5.2.3 Non food area

In addition to the general requirements (see 5.1.1) 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.