SLOVENSKI STANDARD
SIST EN 1620:1999

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Biotehnologija - Procesi in proizvodnja v industrijskem obsegu - Gradnja objektov glede na stopnjo nevarnosti

Biotechnology - Large-scale process and production - Plant building according to the degree of hazard

Biotechnik - Verfahren im Großmaßstab und Produktion - Gebäude entsprechend dem jeweiligen Gefährdungsgrad

Biotechnologie - Procédé a grande échelle et production - Installation industrielle selon le niveau de danger

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English version

Biotechnology - Large-scale process and production - Plant building according to the degree of hazard

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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 233 "Biotechnology", the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by January 1997, and conflicting national standards shall be withdrawn at the latest by January 1997.

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.

Introduction

This European Standard covers a wide area of application of biotechnology, both areas which are not subject to "biotechnology legislation" and those which are regulated. This European Standard supports industrial activities in the area of biotechnology covering operations with including non-genetically modified microorganisms and genetically modified microorganism (GMMs) and with both non-pathogenic and pathogenic microorganisms (see annex B [1], [2]).

NOTE : Non-genetically modified microorganisms include natural microorganisms and microorganisms improved by traditional techniques.

The plant buildings used for biotechnological processes vary widely. The characteristics of each plant building will be dictated by the physical containment to be used at each stage of operation based on risk assessment. This assessment can indicate that some requirements in a given situation are not necessary or that a higher level is needed.

For animal and plant pathogen microorganisms, a case by case analysis should be done.

1 Scope

This European Standard specifies design requirements for plant buildings used for the safe handling of microorganisms and the product itself if it presents a biohazard.

NOTE 1 : When applying this European Standard, attention is drawn to the existing national regulations such as regulations concerning genetic engineering, water and environmental emission concerning the design requirements.

Plant buildings include buildings intended, if necessary, to contain all the fermentors and downstream processing apparatus. Plant building design includes design of equipment linked to the building itself and excludes specific production equipment.

NOTE 2 : Equipment implementation is covered by a standard "Equipment implementation according to the degree of hazard" is being prepared (see annex B [3]).

This European Standard is not applicable to design requirements which affect good manufacturing practice (see annex B [6]) or product quality, for which attention is drawn to relevant codes of practice and national regulations. It would be advisable to consider both aspects simultaneously.

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 or revision. For undated references the latest edition of the publication referred to applies.

prEN 12075 Biotechnology - Large scale process and production - Procedures for fermentations and downstream processes

prEN 12307 Biotechnology - Large scale process and production - Personnel : Guidance for good practice, procedures, training and control

3 Definitions

For the purposes of this standard, the following definitions apply :

3.1 biohazard

Intrinsic potential property or ability of microorganisms/organisms, and/or biologically active substances to cause harm.

3.2 closed phase

Period during which the microorganisms/organisms are separated by a barrier from the environment.

3.3 closed system

System where a barrier separates microorganisms/organisms from the environment.

3.4 controlled area

Area constructed and/or operated in such a manner as to limit contamination of the other areas by microorganisms/organisms from within the controlled area.

3.5 hazard

Intrinsic potential property or ability of something (e.g. any agent, equipment, material or process) to cause harm.

NOTE : Harm is an injury or damage to health of people and/or to the environment.

3.6 inactivation

Destruction of microorganisms.

3.7 microorganism

Any microbiological entity, cellular or non cellular, capable of replication or of transferring genetic material [EN 1619].

NOTE : The term microorganism covers the term of biological agent, according to the Directive 90/679/EEC : microorganisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity.

3.8 open phase

Period during which the microorganism/organism is not separated by a barrier from the environment.

3.9 open system

System where there is no barrier between the microorganism/organism and the environment.

3.10 physical containment

System for confining a microorganism/organism or other entity within a defined space.

3.11 primary physical containment

System of physical containment which limits the escape of a microorganism/organism into the working environment.

NOTE : This can involve the use of closed containers or appropriate equipment together with secure operating procedures.

3.12 risk

Probability of occurrence of a hazard causing harm and the degree of severity of the harm.

3.13 secondary physical containment

System of physical containment which limits the escape of a microorganism/ organism into the environment or into other working areas.

NOTE : This can involve the use of rooms with specially designed air handling, the existence of airlocks and/or sterilizers for the removal of materials and secure operating procedures. In many cases it can add to the effectiveness of primary physical containment.

4 General considerations

As a preliminary, a risk assessment shall be carried out on the process to determine the likely containment levels.

The following safety aspects shall be taken into consideration, where appropriate, when handling microorganisms :

- protection of personnel ;
- protection of the environment ;
- protection of the product.

Buildings shall be designed to prevent the potential risks by taking into account :

- the degree of biohazard ;

  NOTE : Annex A gives a common basis for classification.

- the route of exposure to the biohazard ;
- the mode of handling : open or closed system, open or closed phase.

The result shall be the establishment of controlled areas giving the required levels of containment.

5 Design requirements

5.1 Plant building in general

Table 1 gives a combination of measures which may be combined to give necessary levels of containment. However, it is emphasized that it may be appropriate to select and combine requirements from different containment levels on the basis of risk assessment related to any particular process or part of a process. Particularly, plant design which is intended for secondary physical containment shall be adapted to the level and reliability of primary physical containment. It is also necessary to comply with national and European regulations.

For microorganisms pathogenic only to plants or animals, but not to humans, requirements for building design shall be adapted, case by case according to the type and the degree of hazard of this microorganism. These considerations shall include the epidemiological situations of the plant or animal pathogens (e.g. endemic area).

Plant buildings should be designed to permit effective application of the principles of good occupational safety and hygiene (GOSH) (see annex B [4]) and good industrial large scale practice (GILSP) (see annex B [5]).