SLOVENSKI STANDARD
SIST EN 12307:1999

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Biotehnologija - Procesi in proizvodnja v industrijskem obsegu - Navodilo dobre prakse, postopkov, šolanja in nadzora osebja

Biotechnology - Large-scale process and production - Guidance for good practice, procedures, training and control for personnel

Biotechnik - Verfahren im Großmaßstab und Produktion - Leitfaden für gute Praxis, Arbeitsabläufe, Ausbildung und Überwachung des Personals

Biotechnologie - Procédé a grande échelle et production - Guide de bonnes pratiques, procédures, formation et contrôle pour le personnel

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ICS:

03.100.30	Vodenje ljudi	Management of human resources
07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology

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English version

Biotechnology - Large-scale process and production - Guidance for good practice, procedures, training and control for personnel

Biotechnologie - Procédé à grande échelle et production - Guide de bonnes pratiques, procédures, formation et contrôle pour le personnel

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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of an identical text or by endorsement, at the latest by April 1998, and conflicting national standards shall be withdrawn at the latest by April 1998.

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).

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Introduction

This European Standard supports industrial activities in the area of biotechnology covering operations with both non-genetically modified microorganisms and genetically modified microorganism (GMMs), with both non-pathogenic and pathogenic microorganisms (see annex A [1] [2]).

1 Scope

This European Standard gives guidance for good practice, procedures, training and control for the operation of large scale biotechnological processes.

NOTE : For laboratories associated with a large scale process, attention is drawn to prEN 12741 (see annex A [8]).

In addition, this European Standard gives recommendations for education and training of personnel involved in the large scale handling of microorganisms in plant building of containment levels 1, 2, 3 and 4 (see EN 1620).

This European Standard aims at the protection of the workers from biological hazards as well as the environment including plants and animals.

For operations using microorganisms only pathogenic for the environment (plant or some animal pathogens e.g. foot and mouth disease virus), this European Standard should be adapted according to the risk for environment and taking into account the recommendations of the national competent authorities.

This European Standard is complemented by :

- physical containment which requirements are given in EN 1620 ; and
- personal protective equipment which requirements are given in EN 143, EN 166, EN 374-1 and EN 374-3.

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.

EN 143 Respiratory protective devices - Particle filters - Requirements, testing, marking

EN 166 Personal eye protection - Specifications

EN 374-1 Protective gloves against chemicals and microorganisms - Part 1 : Terminology and performance requirements

EN 374-3 Protective gloves against chemicals and microorganisms - Part 3 : Determination of resistance to permeation by chemicals

EN 689 Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy

EN 1619 Biotechnology - Large-scale process and production - General requirements for management and organization for strain conservation procedures

EN 1620 Biotechnology - Large scale process and production - Plant building according to the degree of hazard

3 Definitions

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

3.1 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 [EN 1620].

3.2 hazard

Intrinsic potential property or ability of something (e.g. any agent, equipment, material or process) to cause harm [EN1620].

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

3.3 microorganism

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

NOTE : For the purposes of this standard, 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.

3.4 risk

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

3.5 workplace

The workplace is the defined area or areas in which the work activities are carried out [EN 689].

4 General considerations

Before handling, microorganisms should be classified with respect to human health and safety and hazard to the environment, according to national, European (see annex A [1] and [2]) or international rules of classification.

They should be handled in appropriate plant buildings of containment levels 1, 2, 3 or 4 as indicated by an assessment of risk. Plant building should be designed in accordance with EN 1620.

For any activity involving microorganisms in large scale process and production activities, the principles of Good Occupational Safety and Hygiene (GOSH) (see annex A [5]) Good Microbiological Techniques (see annex A [9]), and Good Industrial Large Scale Practice (GILSP) (see annex A [6]) should apply.

The basic recommendations for good microbiological practice are given in 5.1. Additional recommendations may be necessary in case of activities with potentially harmful microorganisms. Where appropriate, these additional recommendations are given in 5.2, 5.3 and 5.4.

When microorganisms are strictly pathogenic for plants and animals, specific recommendations aiming to limit or prevent their release into the environment via the workers, can be implemented on a case by case basis.

It is emphasized that good microbiological practice are fundamental to safety and cannot generally be replaced by specialized equipment which can only supplement it partly.

NOTE : In this European Standard, the term of good microbiological practice is used throughout. The term of good manufacturing practices (see annex A [7]) relates mainly to the pharmaceutical industries and is not referred to in this document.

5 Recommendations for handling microorganisms in large scale process and production activities

5.1 Basic recommendations for good microbiological practice

The following should be observed for handling all types of microorganisms :

a) workplace and environmental exposure to microorganisms should be kept as low as reasonably practicable ;

b) animals not involved in the work should not be permitted in or near the workplace ;

c) the workplace should be kept neat, clean and free of materials that are not pertinent to the work ;

d) pipetting by mouth should be prohibited ; materials should not be placed in the mouth ;

e) all technical procedures should be performed in a way that minimizes the uncontained formation of aerosols and droplets ;

f) control methods should be set up with engineering at source and these should be supplemented with appropriate personal protective equipment where necessary ;

g) control measures should be carried out and equipment should be tested and maintained ;

h) eating, drinking, smoking, storing of food and applying cosmetics should not be permitted in any area where infectious materials are handled ;

i) workers should be provided with appropriate and adequate washing and toilet facilities ;

j) hands should be washed before leaving the workplace ;

k) workers should be provided with suitable work clothing and if necessary, additional personal protective equipment ;

l) local rules for the safety and hygiene of personnel should be formulated and implemented ;

m) adequate written instructions should be available to keep exposure to any microorganism to the lowest level that is reasonably practicable ;

n) training of personnel should be provided and recorded (see clause 6).

5.2 Additional recommendations for handling microorganisms in a containment level 2

The following should be observed in addition to 5.1 for handling microorganisms in plant building of containment level 2 :

a) access to the workplace should be limited to nominated personnel ;

b) whilst work is in progress access to the controlled area should be restricted and clearly indicated. Entry points to the area (e.g. doors and windows) should be closed ;

c) in the event of spillage, the contaminated areas should be disinfected by validated procedures ;

d) all materials (liquid, solid and gas) should be made safe by validated means before leaving the controlled area ;

e) material, equipment and work clothing awaiting decontamination should be stored and transported in a safe manner in robust leakproof containers ;

f) workplaces and equipment should be made safe prior to maintenance work. A system of formal authorization such as permit-to-work, should be instituted for maintenance personnel ;

g) effective disinfectants should be available for routine disinfection ;

h) hands should be immediately disinfected and then washed when contamination is suspected, after handling infectious materials and also before leaving the workplace ;