EESTI STANDARD EVS-EN 12307:1999

Biotehnoloogia. Suuremahuline protsess ja suurtootmine. Juhised heaks ametialaseks tegevuseks, töövõteteks, personali väljaõpetamiseks ja kontrollimiseks

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12307:1999 sisaldab Euroopa standardi EN 12307:1997 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12307:1999 consists of the English text of the European standard EN 12307:1997. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev Euroopa standard annab juhendi heaks ametialaseks tegevuseks, töövõteteks, väljaõpetamiseks ja suuremahuliste biotehnoloogiliste protsesside toimimise kontrollimiseks. Lisaks annab käesolev Euroopa standard soovitused sellise personali hariduse ja väljaõpetamise osas, kes on kaasatud suuremahulisse mikroorganismide käitlemisse tootmishoones ettevaatusabinõude tasanditel 1, 2, 3 ja 4.	**Scope:**

ICS 07.080

Võtmesõnad: biotehnoloogia, head laboritavad, kahjulikud mikroorganismid, keskkonnakaitse, klassifikatsioonid, mikroorganismid, ohud, personal, saastumine, tehnilised andmed, tööohutus, väljaõpe, õnnetuste vältimine

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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

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

This European Standard was approved by CEN on 1997-08-21.

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
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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).

Users of this European Standard, prepared in the field of application of Article 118A of the EC Treaty, should be aware that standards have no formal legal relationship with Directives which may have been made under Article 118A of the Treaty. In addition, national legislation in the Member states may contain more stringent requirements than the minimum requirements of a Directive based on Article 118A. Information on the relationship between the national legislation implementing Directives based on Article 118A and this European Standard may be given in a national foreword of the national standard implementing the European Standard.

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

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].