Biotehnoloogia. Suuremahuline protsess ja suurtootmine. Juhised sisseseade valimiseks ja paigaldamiseks vastavalt bioloogilisele ohule

Biotechnology - Large-scale process and production - Guidance on equipment selection and installation in accordance with the biological risk

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12460:1999 sisaldab Euroopa standardi EN 12460:1998 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 12460:1999 consists of the English text of the European standard EN 12460:1998. 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 standard annab juhendi biotehnoloogilise seadmestiku valimiseks ja ohu analüüsiks ning seadmete edasiseks komplekteerimiseks rajatisse, et saavutada vastavad bioloogilise ohutuse ettevaatusabinõude tasandid.	**Scope:**

ICS 07.080

Võtmesõnad: biotehnoloogia, kaitsepiirded, keskkonnakaitse, klassifikatsioonid, laborivarustus, mikroorganismid, ohud, saastumine, transgeensed organismid, tööohutus, õnnetuste vältimine

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Descriptors: Biotechnology, processes, equipment selection, biological risk.

English version

Biotechnology – Large-scale process and production
Guidance on equipment selection and installation in accordance with the biological risk

Biotechnologie – Procédé à grande échelle et production – Guide pour la sélection et l'installation des équipements en fonction du risque biologique

Biotechnik – Verfahren im Großmaßstab und Produktion – Leitfaden zur Auswahl und Installation von Geräten und Ausrüstungen entsprechend dem biologischen Risiko

This European Standard was approved by CEN on 1998-01-31.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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
Europäisches Komitee für Normung

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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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

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.

1 Scope

This European Standard gives guidance on the selection and risk analysis of biotechnological equipment and the subsequent assembly of these into a plant in order to attain the appropriate biosafety containment levels. This includes verification of installation, operation and maintenance. It also applies when a new process or significant changes are introduced into an existing plant.

This European standard applies if the biotechnological process includes the use of hazardous or potentially hazardous microorganisms and/or if the emission of such microorganisms into the working place and/or environment are restricted.

However this should be considered only as a part of the total safety approach required. Attention is drawn to relevant European and national regulations.

2 Definitions

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

2.1 ancillary unit of equipment

Unit of equipment that is not in direct contact with the product, but which is nevertheless necessary to perform a process.

NOTE : Examples of ancillary units of equipment are solvent recovery units for reuse of solvents, Cleaning In Place (CIP) units for preparation and storage of cleaning solutions.

2.2 component of equipment

Technical entity which forms part of a unit of equipment.

NOTE : Examples of components of equipment are vessels, valves and sensors.

2.3 hazard

Intrinsic potential property or ability of something (e.g. any agent, equipment, material or process) to cause harm [EN 1620].

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

2.4 microorganism

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

NOTE : For the purpose 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.