

Biotehnoloogia. Suuremahuline protsess ja suurtootmine. Protseduurid fermentatsiooni- ja järelprotsesside jaoks

Biotechnology - Large-scale process and production - Procedures for fermentation and downstream processes

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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English version

**Biotechnology - Large-scale process and
production - Procedures for fermentation and
downstream processes**

Biotechnologie - Procédé à grande échelle et
production - Procédures pour les procédés de
fermentation et de traitement aval

Biotechnik - Verfahren im Großmaßstab und
Produktion - Vorgehensweise für die Bereiche
Fermentation und Aufarbeitung

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of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.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

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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 microorganisms (GMMs), with both non-pathogenic and pathogenic microorganisms (see annex A [1], [2]).

Fermentation processes vary widely in their nature and design. Generally prokaryotic or eukaryotic microorganisms, plant cells, mammalian cells or insect cells are cultivated and processed in such a way as to produce a desired end-product such as biomass, pharmaceuticals, additives, metabolites and foodstuffs.

1 Scope

This European Standard specifies the principles for the assessment and selection of fermentation and downstream operations so that they are carried out in a manner which ensures the safety of personnel, the environment and product and contributes to product quality.

This European Standard is intended for use by those designing and/or operating processes and by other interested parties.

Unit operations are not described in detail and individual production processes can require specific equipment or unit operations which are not described here.

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 12460 Biotechnology - Large-scale process and production - Equipment implementation according to the degree of hazard

prEN 12461 Biotechnology - Large scale process and production - Guidance for the handling, inactivating and testing of waste

3 Definitions

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

3.1 bioaerosol

Colloid dispersed solid or liquid particles in a gaseous environment presenting negligible gravitational settling, containing microorganisms.