SLOVENSKI STANDARD
SIST EN 13095:2000

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Biotehnologija - Merila za brezplinske sisteme

Biotechnology - Performance criteria for off-gas systems

Biotechnik - Leistungskriterien für Ablufteinrichtungen

Biotechnologie - Criteres de performance pour les systemes de traitement des effluents gazeux

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Biotechnology - Performance criteria for off-gas systems

Biotechnologie - Critères de performance pour les systèmes de traitement des effluents gazeux

Biotechnik - Leistungskriterien für Ablufteinrichtungen

This European Standard was approved by CEN on 17 September 1999.

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.

This European Standard exists 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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

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

The different treatment methods of off-gases can be divided into two main categories depending on the mode of action on microorganisms :

- removal of droplets, foam or microorganisms from the gas stream by centrifugal separation or scrubbing ;

- destruction or inactivation by heat, chemical(s) or irradiation.

An off-gas system can be composed of only one device, for example one filtration assembly or one incinerator, or of several devices in series. Criteria for selecting an off-gas system are given in annex B. For the removal of microorganisms from off-gases by filtration reference is made to EN 13091 (see Bibliography [1]). More information on the other treatment methods is provided in annex A.

Use of this European Standard will aid the equipment manufacturer in the classification of off-gas systems with regard to biosafety performance in biotechnological processes. The classification is easily understandable and readily utilizable for the user and the competent authorities.

1 Scope

This European Standard specifies performance criteria for off-gas systems used in biotechnological processes with respect to the potential risks of microorganisms in use for the worker and the environment.

This European Standard applies where the intended use of the off-gas system includes hazardous or potentially hazardous microorganisms used in biotechnological processes and/or where exposure of the worker or the environment to such microorganisms is restricted for reasons of safety.

This European standard does not apply to off-gas systems that use filtration assemblies to remove microorganisms and to off-gas systems used to avoid contamination of processing areas or equipment.

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 1672-2	Food processing machinery - Basic concepts - Part 2 : Hygiene requirements
EN 12296	Biotechnology - Equipment - Guidance on testing procedures for cleanability
EN 12297	Biotechnology - Equipment - Guidance on testing procedures for sterilizability

EN 12298	Biotechnology - Equipment - Guidance on testing procedures for leak tightness
EN 12460	Biotechnology - Large-scale process and production - Guidance on equipment selection and installation in accordance with the biological risk
EN ISO 4287	Geometrical Product Specifications (GPS) - Surface texture: Profile method - Terms, definitions and surface texture parameters (ISO 4287:1997)
EN ISO 4288	Geometrical Product Specifications (GPS) - Surface texture: Profile method - Rules and Procedures for the assessment of surface texture (ISO 4288:1996)

3 Terms and definitions

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

3.1
arithmetical mean deviation of the profile (R_a)

the arithmetical mean of the absolute values of the profile departures within the sampling length [EN ISO 4287].

3.2
hazard

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

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

3.3
leakage

egress from equipment.

3.4
log reduction value L_{rv}

logarithm to the base 10 of the ratio of the concentration of target microorganisms in the feed and the concentration of target microorganisms in the permeate, expressed as :

$$L_{rv} = lg \frac{C_f}{C_p}$$

where :

- C_f is the concentration of target microorganisms in the feed, expressed in numbers per millilitre ;
- C_p is the concentration of target microorganisms in the permeate, expressed in numbers per millilitre.

NOTE Sometimes the term titer reduction value T_r is used instead of L_{rv}.

3.5
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.

3.6
off-gas system

combination of devices for treatment of effluent gases from biotechnological processes.

3.7
process microorganism

microorganism used for production purposes in a biotechnological process or constituting (part of) the product itself.

3.8
reduction efficiency

efficiency of a device (for example a filter element) to decrease the number of viable microorganisms passing it measured by the log reduction value L_{rv}.

NOTE In practice the term removal efficiency is also used.

3.9
risk

a combination of the probability and the degree of the possible injury or damage to health in a hazardous situation [EN 1070].

3.10
soil

any unwanted matter (including product residues, microorganisms, dust and debris) [ISO/DIS 14159].

3.11
sterile

state of being free from viable microorganisms.

NOTE 1 In practice no such absolute statement regarding the absence of viable microorganisms can be proven. However, sterile conditions can be regarded as established by using an accepted or recognized method of sterilization.

NOTE 2 The process of inactivation of viable microorganisms during a sterilization procedure is usually described by an empirical mathematical function, commonly an

exponential function. By their mathematical nature, such functions can be reduced to very low numbers, but not to zero. However, these empirical functions can be applied to control or assess the process parameters of a sterilization procedure to realize a desired degree of inactivation of viable microorganisms.

3.12
sterilizability

ability of components of equipment, units of equipment or plants to be made sterile.

3.13
sterilization

process used to reach a sterile state.

3.14
target microorganism

process microorganism and/or other microorganisms relevant for a specific process.

NOTE For safety testing procedures, non-pathogenic microorganisms should be used where possible.

3.15
validation

documented procedure for obtaining, recording and interpreting the results needed to show that a process will constantly yield a product complying with predetermined specifications.

4 Hazards

The following hazards shall be taken into account :

- release of microorganisms by leakage through connections in the off-gas system ;
- insufficient inactivation or removal ;
- release of microorganisms after operation due to insufficient inactivation and/or removal of microorganisms when the off-gas system is opened or dismantled.

5 Performance classes

5.1 General

The off-gas systems shall be classified for the following performance criteria with regard to the contained use of microorganisms :

- leaktightness ;
- cleanability ;
- sterilizability ;