

Biotechnology — Performance criteria for off-gas systems

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British Standard

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National foreword

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 18, an inside back cover and a back cover.

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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

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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of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.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 [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 $\log_{10}$ 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:

$$L_{rv} = \log_{10} \frac{C_f}{C_p}$$

where:

C_f is the concentration of target microorganisms in the feed, expressed in numbers per millilitre;