



NSAI
Standards

Irish Standard
I.S. EN 13095:1999

Biotechnology - Performance criteria for off-gas systems

I.S. EN 13095:1999

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN 13095:1999 is the adopted Irish version of the European Document EN 13095:1999, Biotechnology - Performance criteria for off-gas systems

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EUROPEAN STANDARD

EN 13095

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 1999

ICS 07.080; 07.100.01

English version

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.



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of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.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

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