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Biotechnology – Laboratories for research, development and analysis – Guidance for containment of animals inoculated with micro-organisms in experiments

The European Standard EN 12738:1999 has the status of a Swedish Standard. This document contains the official English version of EN 12738: 1999.

Swedish Standards corresponding to documents referred to in this Standard are listed in ”Catalogue of Swedish Standards”, issued by SIS. The Catalogue lists, with reference number and year of Swedish approval, International and European Standards approved as Swedish Standards as well as other Swedish Standards.

Bioteknik – Laboratorier för forskning, utveckling och analys – Vägledning för förvaring av försöksdjur inokulerade med mikroorganismer

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English version

Biotechnology - Laboratories for research, development and analysis - Guidance for containment of animals inoculated with microorganisms in experiments

Biotechnologie - Laboratoires de recherche, développement et analyse - Guide pour le confinement des animaux inoculés avec des microorganismes utilisés à des fins expérimentales

Biotechnik - Laboratorien für Forschung, Entwicklung und Analyse - Leitfaden für die Einschließung von Tieren, die im Rahmen von Experimenten mit Mikroorganismen beimpft werden

This European Standard was approved by CEN on 19 June 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 January 2000, and conflicting national standards shall be withdrawn at the latest by January 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.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

Introduction

The physical containment of inoculated animals for reasons of biological safety is based on the principles of the prevention and control of microbiological hazards to humans, animals, plants and the environment which may be caused by housing and experimenting with animals. These principles are a pre-requisite for the setting up and continued operation of an animal containment facility.

Those who use animals for experimental purposes have a moral obligation to avoid causing unnecessary pain or suffering.

> NOTE : Attention is drawn to existing European (see annex A [1], [2]) and national regulations and codes of practice relating to the protection of animals used for experimental and other scientific purposes and to the management of infected animals.

1 Scope

This European Standard, in order to protect the worker and/or the environment, gives guidance on minimum physical biosafety measures for the containment of animals deliberately inoculated with microorganisms, including genetically modified microorganisms, which can present a risk to human or animal health or the environment.

This European Standard does not apply to the containment of animals which have not been deliberately inoculated with microorganisms.

The containment level required is determined by assessment of the risk to humans and the environment (see annex A [3] [4]).

The European Standard does not address procedures or practices which are necessary for safe working with animals unless of particular relevance to the containment of animals, nor does it address requirements which are not primarily concerned with biological safety.

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 12128	Biotechnology - Laboratories for research, development and analysis - Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements
EN 12347	Biotechnology - Performance criteria for steam sterilizers and autoclaves
prEN 12469	Biotechnology - Performance criteria for microbiological safety cabinets

CR 12739	Biotechnology - Laboratories for research, development and analysis - Report on the selection of equipment needed for biotechnology laboratories according to the degree of hazard
EN 12740	Biotechnology - Laboratories for research, development and analysis - Guidance for handling, inactivating and testing of waste
EN 12741	Biotechnology - Laboratories for research, development and analysis - Guidance for biotechnology laboratory operations
CR 12894	Biotechnology - Microorganisms - Examination of the various existing lists of animal pathogens and production of a report
EN 61010-2-041	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-041 : Particular requirements for autoclaves using steam for the treatment of medical materials and for laboratory processes [IEC 61010-2-041:1996]
EN 61010-2-042	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-042 Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials and for laboratory processes [IEC 61010-2-042:1997]
EN 61010-2-043	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-043: Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials and for laboratory processes [IEC 61010-2-043:1997]
ISO 3864	Safety colours and safety signs
ISO 7000	Graphical symbols for use on equipment - Index and synopsis

3 Definitions

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

3.1 animal

Non-human vertebrate or invertebrate, including free-living larval forms.

3.2 animal containment level

Standard of accommodation suitable for the containment of animals deliberately inoculated with microorganisms.

3.3 animal unit

Building, or separate area within a building, for the housing of animals, which may contain facilities and other areas such as changing rooms, showers, autoclaves, food storage areas.

3.4 autoclave

Apparatus designed to make materials and/or equipment sterile by exposure to steam at a pressure above the atmospheric pressure [EN 12347].

3.5 genetically modified microorganism

Microorganism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

> NOTE : Within the terms of this definition, genetic modification occurs at least through the use of the techniques listed in the Directive 90/219/EEC or its appropriate Annexes (see annex A [3]).

3.6 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.

3.7 physical containment

System for confining a microorganism and/or organism or other entity within a defined space [EN 1620].

3.8 risk

Probability of occurrence of a hazard causing harm and the degree of severity of the harm.

4 Classification, animal containment levels (ACL)

Four levels of animal containment, namely ACL 1, 2, 3 and 4, are based primarily on the risk group assigned to the microorganisms being used. ACL1 is the lowest level and ACL4 the highest level of containment. It is recognized that other factors also influence the selection of an appropriate level of animal containment. With respect to microorganisms these factors include volume and concentrations to be used, the route of inoculation, infectivity and virulence, path of transmission (see CR 12894) and whether and by what route they may be excreted. With respect to animals they include the size and nature of the animals (aggressiveness, tendency to bite or scratch), their natural ecto- and endoparasites, the zoonotic diseases to which they are susceptible, or whether they are genetically modified. Methods of inoculation, sample taking, anaesthesia and post-mortems need to be considered.