

**Biotechnology - Laboratories for
research, development and analysis -
Guidance for containment of animals in
experiments**

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development and analysis - Guidance for
containment of animals in experiments

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 12738:2000 sisaldab Euroopa standardi EN 12738:1999 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 11.01.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 12738:2000 consists of the English text of the European standard EN 12738:1999.</p> <p>This document is endorsed on 11.01.2000 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: This European Standard gives guidance on minimum physical biosafety measures to protect the worker and/or the environment for the containment of animals, including genetically modified animals, deliberately inoculated with microorganisms, which can present a risk to human or animal health.</p>	<p>Scope: This European Standard gives guidance on minimum physical biosafety measures to protect the worker and/or the environment for the containment of animals, including genetically modified animals, deliberately inoculated with microorganisms, which can present a risk to human or animal health.</p>
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ICS 07.080, 07.100.01

Võtmesõnad:

ICS 07.080; 07.100.01

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 ana-
lyse – Guide pour le confinement des
animaux inoculés avec des microor-
ganismes utilisés à des fins expéri-
mentales

Biotechnik – Laboratorien für For-
schung, Entwicklung und Analyse –
Leitfaden für die Einschließung von
Tieren, die im Rahmen von Experi-
menten mit Mikroorganismen beimpft
werden

This European Standard was approved by CEN on 1999-06-19.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

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 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.