



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 12738:1999

ICS 07.080  
07.100.01

**BIOTECHNOLOGY - LABORATORIES FOR  
RESEARCH, DEVELOPMENT AND ANALYSIS -  
GUIDANCE FOR CONTAINMENT OF ANIMALS  
INOCULATED WITH MICROORGANISMS IN  
EXPERIMENTS**

National Standards  
Authority of Ireland  
Glasnevin, Dublin 9  
Ireland

Tel: +353 1 807 3800  
Fax: +353 1 807 3838  
<http://www.nsai.ie>

**Sales**  
<http://www.standards.ie>

*This Irish Standard was  
published under the authority  
of the National Standards  
Authority of Ireland  
and comes into effect on*

*December 17, 1999*

**NO COPYING WITHOUT NSAI  
PERMISSION EXCEPT AS  
PERMITTED BY COPYRIGHT  
LAW**

© NSAI 1999

**Price Code G**

Údarás um Chaighdeáin Náisiúnta na hÉireann



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN 12738**

July 1999

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 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.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Central Secretariat: rue de Stassart, 36 B-1050 Brussels**

## Contents

	<b>Page</b>
<b>Foreword</b> .....	<b>3</b>
<b>Introduction</b> .....	<b>4</b>
<b>1 Scope</b> .....	<b>4</b>
<b>2 Normative references</b> .....	<b>4</b>
<b>3 Definitions</b> .....	<b>5</b>
<b>4 Classification, animal containment levels (ACL)</b> .....	<b>6</b>
<b>5 Animal containment level 1 (ACL1)</b> .....	<b>7</b>
<b>6 Animal containment level 2 (ACL2)</b> .....	<b>8</b>
<b>7 Animal containment level 3 (ACL3)</b> .....	<b>11</b>
<b>8 Animal containment level 4 (ACL4)</b> .....	<b>12</b>
<b>Annex A (informative) Bibliography</b> .....	<b>15</b>

## **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

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
  - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-