



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 12683:1999

ICS 07.080

**BIOTECHNOLOGY - MODIFIED ORGANISMS  
FOR APPLICATION IN THE ENVIRONMENT -  
GUIDANCE FOR THE CHARACTERIZATION  
OF THE GENETICALLY MODIFIED  
ORGANISM BY ANALYSIS OF THE  
MOLECULAR STABILITY OF THE  
GENOMIC MODIFICATION**

National Standards  
Authority of Ireland  
Dublin 9  
Ireland

Tel: (01) 807 3800  
Tel: (01) 807 3838

*This Irish Standard was  
published under the  
authority of the National  
Standards Authority of  
Ireland  
and comes into effect on.  
January 22, 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 12683**

July 1998

ICS 07.080

Descriptors: biotechnology, genetics, modified organisms, environments, environmental protection, analysis methods, bioassay, experimental design

English version

**Biotechnology - Modified organisms for application in the  
environment - Guidance for the characterization of the  
genetically modified organism by analysis of the molecular  
stability of the genomic modification**

Biotechnologie - Organismes modifiés disséminés dans  
l'environnement - Guide pour la caractérisation de  
l'organisme génétiquement modifié par l'analyse de la  
stabilité moléculaire de la modification génomique

Biotechnik - Veränderte Organismen zum Einsatz in der  
Umwelt - Leitfaden für die Charakterisierung des  
gentechnisch veränderten Organismus durch Untersuchung  
der molekularen Stabilität der Genomveränderung

This European Standard was approved by CEN on 1 July 1998.

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  
EUROPAISCHES KOMITEE FÜR NORMUNG

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

## Contents

<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 Molecular stability testing .....</b>	<b>7</b>
<b>5 Materials .....</b>	<b>9</b>
<b>6 Considerations for experimental procedures .....</b>	<b>9</b>
<b>7 Validity of data analysis .....</b>	<b>13</b>
<b>8 Documentation of results .....</b>	<b>15</b>
<b>Annex A (informative) Bibliography .....</b>	<b>16</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 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.

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

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

This European Standard relates to part of the characterization of genetically modified organisms (GMOs). It is designed as a guideline for adaptation of experimental procedures to the requirements of the specific experimental design. The characterization of a GMO can include the analysis of :

- the genomic modification (see EN 12687) ;
- the functional expression of the genomic modification (see EN 12682) ;
- the molecular stability of the genomic modification.

This European Standard deals with the analysis of the molecular stability of the genomic modification of GMOs. In principle, this European Standard refers to the analysis of the molecular stability of GMOs during their prerelease evaluation and in monitoring of experimental releases. If specific questions concerning molecular stability occur during or after the release, especially if the release is scheduled for more than one generation, it is this standard that could apply (see annex A [3], [4]).

The analysis of the molecular stability can be based on :

- the physical analysis of the genetic modification of interest as it exists in the GMO (genomic modification) (see EN 12687); and/or
- the analysis of the functional expression of the genetic modification of interest (genomic modification) (see EN 12682).

## 1 Scope

This European Standard provides guidance for factors and criteria considered by the experimenter for the valid design, execution and evaluation of an analysis of the molecular stability of the genomic modification with respect to life cycle, heritability and external factors. It describes the steps in the characterization of a GMO that should be followed to ensure the validity of the analysis of the molecular stability of the genomic modification.

The type of molecular stability analysis is dependent on the objectives of the experiment.

## 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 12687:1998	Biotechnology - Modified organisms for application in the environment - <i>Guidance for the characterization of genetically modified organism by analysis of the genomic modification</i>
EN 12682:1998	Biotechnology - Modified organisms for application in the environment - <i>Guidance for the characterization of genetically</i>

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
-