



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 12682:1999

ICS 07.080

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

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*This Irish Standard was  
published under the  
authority of the National  
Standards Authority of  
Ireland  
and comes into effect on:  
January 22, 1999*

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

EN 12682

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 functional  
expression of the genomic modification

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

Biotechnik - Veränderte Organismen zum Einsatz in der  
Umwelt - Leitfaden für die Charakterisierung des  
gentechnisch veränderten Organismus durch Untersuchung  
der funktionellen Ausprägung 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  
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 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 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 ;
- the molecular stability of the genomic modification (see EN 12683).

This European Standard deals with the analysis of the functional expression of the genomic modification of GMOs. In principle, this type of analysis can be used to correlate the functionality to the genomic modification. With respect to an intended application it is the predicted modification of the phenotype according to the intended design which should be analysed. This European Standard deals with types of analysis performed during prerelease evaluations of GMOs. Most types of testing performed in the laboratory are also suited for a monitoring of the GMO and its novel traits in field samples.

## 1 Scope

This European Standard provides guidance on the design and execution of experiments for the analysis of the functional expression of the genomic modification.

It gives criteria for the setup of an experimental design and the determination of the validity of its execution. The main factors influencing the specificity, reliability and limits of detection for an analysis are given for the following categories of experiments :

- analysis of the expression of a genomic modification within GMOs (or clones of) or any specified part of them, including its response to internal (developmental stage, growth, organ or tissue location) and external factors (temperature, humidity, pH, other) ;
- establishment of identity of a desired product resulting from the expression of a genomic modification in comparison with a reference ;
- characterization of the novel trait(s) of a GMO.

This European Standard does not cover procedures for the analysis of pleiotropic effects of a genomic modification or the act of generating the GMO (e.g. somaclonal variation) on the phenotype of modified organisms, which cannot be predicted from the knowledge of the type of the genomic modification.

However, the principles stated in this European Standard are applicable for the execution of any analysis of gene functions.

## 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

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