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IRISH STANDARD

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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

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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 Genomveranderung

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

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Contents

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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.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 - Guidance for the characterization of genetically modified organism by analysis of the genomic modification
EN 12682:1998	Biotechnology - Modified organisms for application in the environment - Guidance for the characterization of genetically