SLOVENSKI STANDARD
SIST EN 12683:1999

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Biotehnologija - Spremenjeni organizmi za uporabo v okolju - Navodilo za ugotavljanje znaļ ilnosti gensko spremenjenega organizma z analizo molekularne stabilnosti spremenjenega genoma

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

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

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.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

modified organism by analysis of the functional expression of the genomic modification

3 Definitions

For the purposes of this standard, the following definitions apply :

3.1 control

Preparation of known characteristics used to standardize an analysis.

3.2 data signal

Output of a test system.

NOTE : Data signals can be characterized :

- by binary decision : presence/absence (+/-) ;
- in relative terms by ordering the data signal strength with respect to (a) defined control(s) ;
- quantitatively by giving their output strength in absolute terms ;
- by position or movement ;
- qualitatively by describing parameters not addressed by strength or position.

3.3 detection

Recognition of the presence of an organism or of a molecular structure within a sample.

3.4 gene probe

Specific nucleic acid sequence used to identify certain DNA or RNA fragments by means of hybridization.

3.5 genetic modification of interest

Conceptual design for altering the genetic material within an organism.

NOTE 1 : The genetic modification of interest can be described at different levels of molecular detail.

NOTE 2 : The conceptual design can include insertion, substitution or deletion of genetic material.

3.6 genetically modified organism

Organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

NOTE : Within the terms of this definition genetic modification occurs at least through the use of the techniques listed in the Directive 90/220/EEC or its appropriate annexes (see annex A [2]).

3.7 genomic modification

Actual physical structure of the genetic modification of interest as it exists in the genetically modified organism.

3.8 identification

Establishment of identity by comparison with a reference.

NOTE 1 : The reference could be an organism, a molecular structure or the genetic modification of interest.

NOTE 2 : The certainty of identification is affected by the types and/or number of characteristics investigated.

3.9 molecular stability

Maintenance of the integrity of the desired structure and/or the desired function of the genomic modification with respect to time and/or generation.

3.10 organism

Biological entity capable of replication or of transferring genetic material.

3.11 reproducibility

Precision under reproducibility conditions [ISO 3534-1].

NOTE 1 : Reproducibility conditions are conditions where test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment.

NOTE 2 : Results should be expressed as reproducibility standard deviation or reproducibility coefficient of variation.

4 Molecular stability testing

4.1 General considerations

The relative molecular stability of traits introduced by genetic modification, over time and generation, can be important in order to ensure the performance of the GMO under field conditions and/or for biosafety reasons. The design of an analysis for molecular stability should take into account the natural variations on the one hand and the experimental objective with respect to product performance and safety on the other.

Molecular stability analysis can be performed at either the structural or genomic level or at the functional or phenotypic level depending on the objective of experiment. Testing for molecular stability between generations should be carried out over an appropriate number of generations.

Molecular stability testing could be required at various points during the development and release of a GMO into the environment. This generally starts in contained systems, like the laboratory, microcosms, growth chambers, greenhouses, animal houses and can continue during the release into the environment.

4.2 Types of molecular stability

Molecular stability or instability of a genomic modification can be observed at any of the following levels :

- the structural or genomic level ;
- the transcriptional or RNA-level ;
- the level of functional expression ;
- phenotype such as morphology, resistance, host specificity, colour.

4.3 Factors influencing the molecular stability

Molecular stability of a genomic modification at the structural or genomic level can depend on factors which directly influence the genomic modification such as :

- mutation ;
- recombination and/or transposition ;
- gene transfer ;
- copy number of accessory genetic elements like plasmids ;
- methylation.

These factors influence mainly the genomic modification, the type of integration into, and/or the localization within the genome.