SLOVENSKI STANDARD
SIST EN 12682:1999

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Biotehnologija - Spremenjeni organizmi za uporabo v okolju - Navodilo za ugotavljanje znaḷ ilnosti gensko spremenjenega organizma z analizo funkcionalne ekspresije spremenjenega genoma

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

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

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

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English version

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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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.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 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 pleïotropic 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

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 the genetically modified organism by analysis of the genomic modification
EN 12683:1998	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

3 Definitions

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

3.1 analyte

Substance sought or determined.

3.2 background noise

Output of a test system formed by controls lacking the data signal-giving component(s) under investigation.

3.3 control

Preparation of known characteristics used to standardize an analysis.

3.4 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.

3.5 detection

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

3.6 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.

3.7 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]).

3.8 genomic modification

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

3.9 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.

3.10 monitoring

Regular or continuous observation or collection of data with respect to an organism, process or procedure.

NOTE : In this standard, monitoring applies to the progress of a released genetically modified organism.

3.11 organism

Biological entity capable of replication or of transferring genetic material.

3.12 phenotype

Sum of the traits of an organism.

NOTE 1 : The phenotype can be described with respect to one or more traits under a given set of conditions.

NOTE 2 : In the case of a virus, the phenotype can be described by one or more traits manifested in the infected host.

3.13 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.

3.14 trait

Observable and/or measurable characteristic.

4 Testing for functional expression

4.1 General considerations

The expression 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 functional expression 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.

Data signal processing from biochemical and molecular analysis or observation of phenotypic traits is used to determine the expression caused by a genomic modification including its regulation, to establish the identity of products, and to differentiate the phenotype of a GMO from that of the unmodified recipient or parent-organism.

4.2 Data signal processing by methods of biochemistry, immunology and molecular biology

The synthesis of gene products can be assayed by a variety of methods(see annex A [5], [6]) including :

- testing for sequence dependent data signal generation of primary gene products (RNA) ;