SLOVENSKI STANDARD
SIST EN 12687:1999

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

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

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

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

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English version

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.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 the 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 ;
- the functional expression of the genomic modification (see EN 12682) ;
- the molecular stability of the genomic modification (see EN 12683).

This European Standard relates to the specific characterization of the genomic modification of GMOs. This characterization is implicit for use during environmental releases and should be applied, if required, during assessment of product quality.

1 Scope

This European Standard gives guidance on the steps that should be followed during the analysis of the genetic modification of interest :

- to analyse and describe the genetic modification of interest as it exists in the GMO (genomic modification) ;
- to detect and/or identify the GMO accurately.

This European Standard gives guidance on the factors and criteria considered by the experimenter for the selection of the appropriate method(s) and the validity of experimental results for the analysis of the genetic modification of interest.

The procedures described in this European Standard are applicable to testing the genomic modification. They include techniques of biochemistry, immunology or molecular biology.

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 12682	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
EN 12683	Biotechnology - Modified organisms for application in the environment - Guidance for the characterization of 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 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 can be affected by the types and/or number of characteristics investigated.

3.9 organism

Biological entity capable of replication or of transferring genetic material.

3.10 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.

3.11 sample

Materials collected for analysis.

3.12 trait

Observable and/or measurable characteristic.

4 Testing for genomic modification

4.1 General considerations

A genetic modification in general is intended to modify the expression of genetic traits of an organism or to produce a new gene product in a GMO, in order to modify the phenotype of that organism. The presence of the genetic modification of interest as it exists in the GMO

can be deduced from the presence or absence of an insert of specific DNA or gene product(s) such as RNA or protein, of a specific biochemical reaction, or of a specific phenotypic trait (see EN 12682). Only the analysis at the level of genetic material provides information about the structure of the genetic modification of interest within the GMO.

The methods described in this European Standard relate to the detection and identification of a particular GMO by determination of the presence of nucleic acid molecules which specifically characterizes the GMO.

Usually the genetic modification of interest is a DNA sequence. However, in some special cases, the genetic modification of interest can be a RNA sequence (e.g. RNA-viruses).

Not all of the methods described in this European Standard are necessarily applicable for every analysis of the genetic modification of interest as it exists in the GMO. This standard provides the criteria by which a suitable method or combination of methods is found for the analysis of the genomic modification, depending on the purpose of the analysis.

The methods described in this standard can be appropriate to test GMOs provided that the genetic modification of interest is available either as cloned DNA, or as complete or partial nucleotide sequence data or other relevant data. They refer to techniques that are based on :

a) restriction pattern analysis (see 4.2) ;

b) DNA- or RNA-hybridization (see 4.3) ;

c) DNA- or RNA-fragment amplification (see 4.4) ;

d) DNA- or RNA-sequencing of the genomic modification (see 4.5).

Examples of the application of such methods can be used to :

- qualitatively establish the presence of the genomic modification ;
- estimate the copy number ;
- estimate the number of integration sites and their relative position in the genome of an organism ;
- compare the genetic modification of interest with the actual genomic modification.

4.2 Restriction enzyme method

Restriction pattern analysis provides the means to construct a primary physical map of a DNA-segment.

4.3 Hybridization method

Hybridization (molecular hybridization) is the sequence-dependent pairing of complementary single-stranded nucleic acid molecules resulting in a double-stranded hybrid. The detection of a genomic modification within an organism is visualized by hybridization with a labelled gene probe.