SLOVENSKI STANDARD

SIST EN 12686:1999

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Biotehnologija - Spremenjeni organizmi za uporabo v okolju - Navodilo za strategije vzorļ enja namernega sproġļ anja genetsko spremenjenih mikroorganizmov, vkljuļ no z virusi

Biotechnology - Modified organisms for application in the environment - Guidance for the sampling strategies for deliberate releases of genetically modified microorganisms, including viruses

Biotechnik - Veränderte Organismen zum Einsatz in der Umwelt - Leitfaden für Probenahmestrategien bei der absichtlichen Freisetzung gentechnisch veränderter Mikroorganismen, einschließlich Viren

Biotechnologie - Organismes modifiés disséminés dans l'environnement - Guide des stratégies d'échantillonnage pour les disséminations volontaires de microorganismes génétiquement modifiés, y compris de virus

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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.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

When genetically modified microorganisms including viruses (GMMs) are subject to an experimental release into the environment, it is important to ensure the validity of sampling strategies used to monitor the release.

The sampling strategy and the statistical analysis used will vary with the predicted frequency of occurrence and spatial distribution of the relevant GMMs or genes in the area studied. Since there are many different techniques available for the detection and the identification of GMMs, this European Standard is formulated as a recommendation to the experimenter to design a sampling strategy appropriate to the purpose of the field experiment, to the microorganisms and to the particular phenotypic and genotypic properties of the GMMs being used. This European Standard gives the experimenter a list of points that should be considered in determining the validity of a sampling strategy comprising valid design, review, execution and documentation of a sampling protocol.

1 Scope

This European Standard provides guidance concerning the procedures for setting up a valid sampling strategy to meet the objectives of a monitoring strategy for GMMs released into the environment. Since monitoring methods of microorganisms in environmental samples usually require pretreatment of the samples, for example the extraction and isolation of GMMs and/or their nucleic acid, this is included in scope of this European Standard. The sampling is to provide material to which subsequent analytical or biological methods for monitoring of GMMs can be applied (see EN 12685).

This European Standard is intended to address sampling of microorganisms, including viruses (and their relevant hosts), or their nucleic acid.

This European Standard does not cover :

- the sampling of virus-like entities or similar agents ;
- the sampling of GMMs in food, human health and veterinary applications.

  NOTE : Attention is drawn to national, European and international regulations, and relevant standards covering the sampling of GMMs in food, human health and veterinary applications.

This European Standard can be applied to sampling of GMMs in all habitats and micro-environments as required to meet the defined experimental objectives. The mode of sampling and the nature of the samples are dependent on the particular purpose.

Therefore this European Standard provides the experimenter with a list of guiding parameters that should be considered in determining the validity of the proposed strategy for sampling.

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 12685 Biotechnology - Modified organisms for application in the environment - Guidance for the monitoring strategies for deliberate releases of genetically modified microorganisms, including viruses

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 genetically modified microorganism

Microorganism 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 90/219/EEC or its appropriate annexes (see annex B [1]).

3.3 genotype

Genetic constitution of an organism.

NOTE : The genotype can be described with respect to particular genes.

3.4 host

Target species for virus replication as defined in the experimental design.

3.5 micro-environment

Defined location in the environment potentially occupied by an organism.

NOTE : This "micro-environment" can impart a degree of confinement on the dispersal of the organism.

3.6 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 microorganism.

3.7 monitoring strategy

Procedure for designing, reviewing, executing and documenting a monitoring protocol.

3.8 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.

3.9 release site

Defined area which contains one or more experimental fields.

NOTE : Several different trials can occur within a release site.

3.10 sample

Materials collected for analysis.

3.11 sampling protocol

Written document describing the manner in which samples are collected, transported, stored and their pre-treatment.

3.12 sampling strategy

Procedure for designing, reviewing, executing and documenting a sampling protocol.

4 General considerations

In order to evaluate the validity of a proposed sampling design, the following considerations should be taken into account.

The availability and use of adequate controls is essential for the validity of the results.

The design of most field trials with GMMs follows the same principles as applied to field trials with microorganisms which are not genetically modified.

Statistical analysis, required for quantitative evaluation, determines the sampling design and hence the validity of the results. The purpose of the experiment should be clearly defined in order to prepare a statistically adequate protocol for sampling.

Specific requirements of any subsequent detection and identification method, should be considered and can influence the utility of the results for monitoring purposes (see prEN 12685).

NOTE : The development of a monitoring and sampling valid strategy for deliberate releases of genetically modified microorganisms in the environment is summarized in figure A.1.

5 Sampling strategy

5.1 General

It is first necessary to determine the objectives of the sampling strategy. The main steps in the development of the sampling strategy are :

a) statement of experimental objectives ;

b) design and review of sampling protocol ;

c) execution of the sampling protocol ;

d) appropriate record keeping.

Responsibilities should be assigned for each step to a specific authority, organization or person. The sampling strategy should be reviewed regularly, for example in the light of the inspections of the release site and monitoring results, to ensure its continuing validity (see EN 12685).

5.2 Design criteria

The design of the sampling protocol should meet defined objectives as determined by the experimenter. The design can vary widely, given distinctive requirements for, for example, trials to study phenotypic properties of GMMs, gene transfer, or dispersal and/or persistence of GMMs in the environment. Depending on the objectives for which the sampling is carried out, the nature and composition of the samples which are collected, can be different. Sampling can involve host material, soil and water, but also air (e.g. dispersal of spores), animals or plant parts (e.g. roots harbouring symbiotic microorganisms).

The protocol for sampling should be part of the preparation and design of the experiment, keeping the flexibility that could be required by unexpected observations, and should therefore be supported by a clear design of the experiment. Parameters such as starting date or period, location(s) and site size, number of genotypes, are important in the development of the design.

When designing the sampling protocol a very important factor concerns the pretreatment of the samples which is required to allow subsequent detection and/or identification of GMMs. The choice of the pretreatment procedure is affected by the nature and composition of the samples and also by the demands of the detection and/or identification technique used for monitoring and\or characterization of the GMM. Many of these techniques require extraction of microorganisms, nucleic acid and/or gene products from the sample.

Examples of approaches for detection and isolation of GMMs from environmental samples are :