SLOVENSKI STANDARD
SIST EN 12305:1999

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Biotehnologija - Spremenjeni organizmi za uporabo v okolju - Navodilo za strategijo vzorčenja namernega sproščanja gensko spremenjenih rastlin

Biotechnology - Modified organisms for application in the environment - Guidance for the sampling strategies for deliberate releases of genetically modified plaints

Biotechnik - Veränderte Organismen zum Einsatz in der Umwelt - Leitfaden für Probenahmestrategien bei der absichtlichen Freisetzung gentechnisch veränderter Pflanzen

Biotechnologie - Organismes modifiés disséminés dans l'environnement - Guide des stratégies d'échantillonnage pour les dissémination volontaires de plantes génétiquement modifiées

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Biotechnology - Modified organisms for application in the environment - Guidance for the sampling strategies for deliberate releases of genetically modified plants

Biotechnologie - Organismes modifiés disséminés dans l'environnement - Guide des stratégies d'échantillonnage pour les dissémination volontaires de plantes génétiquement modifiées

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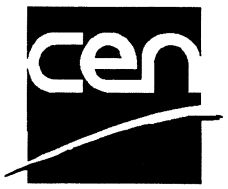

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

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of an identical text or by endorsement, at the latest by April 1998, and conflicting national standards shall be withdrawn at the latest by April 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

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 the genetically modified plants are subject to 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 in deliberate release of genetically modified plants depend on the frequency of occurrence and spatial distribution of the relevant genetically modified plants and/or introduced gene in the experimental field studied. Since there are many different techniques available for the detection and the identification of genetically modified plants, this European Standard is intended to give guidance to the experimenter on the design of a sampling strategy appropriate to the field trial, to the plants and to the particular traits being used. Not all of the points are necessarily relevant to a particular experiment.

The principles can also be applied to sampling of plants grown in greenhouses.

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 gives guidance for setting up a valid sampling strategy to meet the objectives of a monitoring strategy for genetically modified plants. The sampling is to provide material to which subsequent analytical methods for monitoring genetically modified plants of interest can be applied (see prEN 12468).

This European Standard deals only with providing statistically valid samples from the experimental field as identified in a field trial design.

The mode of sampling is dependent on purpose. Sampling may be carried out to meet the objectives of the investigator and/or statutory requirements.

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.

prEN 12468	Biotechnology - Modified organisms for application in the environment - Guidance for the monitoring strategies for deliberate releases of genetically modified plants

3 Definitions

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

3.1 behaviour

Interaction of the organism(s) with abiotic and biotic environments, its (their) occurrence, persistence and spreading abilities.

3.2 control

Sample or preparation of known characteristics used to standardize the analysis.

3.3 experimental field

Area within a release site which contains the plots necessary to standardize the analysis.

3.4 field trial design

Specifications for the planting of a trial, i.e. number and layout of plots in the field.

NOTE : The field trial design influences the type of statistical analysis that can be performed and vice-versa.

3.5 genetically modified plant

Plant 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 B [1]).

3.6 monitoring

Regular or continuous supervision and checking of an organism, process or procedure.

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

3.7 monitoring strategy

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

3.8 plot

Area where individual experimental unit or treatment is carried out.

3.9 release site

Defined area which contains one or more experimental field.

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.

3.13 trait

Observable and/or measurable characteristic.

4 General considerations

To ensure that the design of a sampling strategy is valid, the samples collected from a release should be representative of each experimental field. The number of samples required for representative sampling depends on the field trial design and experimental aims. The field trial design also determines the types of statistical analysis that can be performed. The following types of field trials can be used.

a) Trials to study the impact of an introduced trait in a genetically modified crop or to obtain lines containing the introduced trait. Typically such trials require a relatively small number of samples, since the plants tested are supposed to be similar.

b) Trials to study the transfer of a gene between plants. Typically such trials require a larger number of samples for analysis to detect rare events.

c) Trials to investigate the behaviour of an introduced trait in the genetically modified plants. In these trials, the sampling strategy depends on the trait studied. The stability of the trait is an important consideration.

NOTE 1: Guidance for points to consider for the analysis of the stability of an introduced trait is given in prEN 12683 (see annex B [2]).

The presence of adequate control samples is essential for the validation of results.

The design of most field trials with genetically modified plants will follow the same principles as applied to field trials with plants which are not genetically modified.

Statistical analysis required for quantitative evaluation influences the sampling strategy and hence the validity of the results. The purpose of the experiment should be defined in order to prepare an adequate protocol for sampling.

Specific requirements of any subsequent detection and identification methods, should be considered and will influence the utility of the results for monitoring purposes (see prEN 12468).

The sampling strategy should be re-evaluated periodically to ensure its validity.

NOTE 2: The development of a valid monitoring and sampling strategy for deliberate releases of genetically modified plants 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 person. The sampling strategy should be reviewed regularly, in the light of field inspections, to ensure its continuing validity.

5.2 Design criteria

The design of the sampling protocol should meet defined objectives as determined by the investigator and/or by statutory requirements. The design can vary widely, for example, requirements for trials of introduced traits (see 4.a), for studies of gene transfer (see 4.b) or gene behaviour (see 4.c) can differ.

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. The sampling protocol should be documented. Parameters such as when sampling will take place, location(s) and/or site size, number of genotypes, number of plots and means of plot identification, number of treatment(s), are important in the development of the design.