SLOVENSKI STANDARD
SIST EN 12468:1999

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Biotehnologija - Spremenjeni organizmi za uporabo v okolju - Navodilo za strategije spremljanja in nadzora namernega sproġļ anja gensko spremenjenih rastlin

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

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

Biotechnologie - Organismes modifiés disséminés dans l'environnement - Guide des stratégies de surveillance pour les disséminations volontaires de plantes génétiquement modifiées

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English version

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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of an identical text or by endorsement, at the latest by June 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

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 behaviour of genetically modified plants is tested in an experimental field, it is important that a valid monitoring strategy is used, and that the monitoring strategy has been designed in accordance with the specific plant species and experimental requirements.

In this European Standard, monitoring refers both to the monitoring of the occurrence, persistence and/or spread of the genetically modified plant and/or the gene(s) involved in the modification.

This European Standard is intended to aid the experimenter in the design of a monitoring strategy appropriate to the monitoring objectives. Therefore, this European Standard gives the experimenter a list of points that should be considered in determining the validity of a monitoring strategy comprising valid design, review, execution and documentation of a monitoring protocol.

1 Scope

This European Standard gives guidance on factors and criteria considered for the determination of the suitability and validity of the design, development and execution of a monitoring strategy for genetically modified plants. Monitoring encompasses detection of genes and traits, as well as the identification of genetically modified plants in an experimental release.

This European Standard provides the person conducting a monitoring programme with factors and criteria that should be considered in determining the validity of the proposed monitoring strategy.

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 12305 Biotechnology - Modified organisms for application in the environment - guidance for the sampling strategies for deliberate releases of genetically modified plants

3 Definitions

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

3.1 analyte

Substance sought or determined.

3.2 behaviour

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

3.3 control

Preparation of known characteristics used to standardize an analysis.

3.4 detection

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

3.5 experimental field

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

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 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 [2]).

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 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 plant.

3.10 monitoring protocol

List of sequential steps and methods to be used for monitoring.

3.11 monitoring strategy

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

3.12 release site

Defined area which contains one or more experimental fields.

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

3.13 trait

Observable and/or measurable characteristic.

3.14 volunteer plant

Carry-over plant material growing as a weed in a subsequent crop.

4 General considerations

Monitoring is important in order to test predictions made with respect to the behaviour of the genetically modified plant released into a release site.

The design and execution of a valid monitoring strategy is therefore dependent on the particular objectives of the monitoring strategy. These can include the following.

a) Studies on the effect of the genetic modification of interest on the behaviour of the genetically modified plants released into the environment. The monitoring strategy can include studies on the presence of the genetically modified plant of interest in environmental samples, its performance in the environment and of its effects on the ecosystem considered.

b) Studies on the functioning of the genetic modification in the genetically modified plants released into the environment. The monitoring programme can include studies on

the molecular stability and functional expression of the gene(s) involved in the genetic modification of interest.

c) Studies on the transfer of the gene(s) involved in the genetic modification of interest. The monitoring programme can include studies on transfer to the indigenous plant population cultivated or not.

5 Monitoring strategy

5.1 General

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

a) design and review of the monitoring protocol ;

b) validation of the monitoring protocol ;

c) execution of the monitoring protocol ;

d) appropriate record keeping.

Responsibility for these steps should be assigned to a specific authority, organization or person. The monitoring strategy should be reviewed regularly, in the light of the field inspections, to ensure its continuing validity.

5.2 Criteria for the design of the monitoring protocol

The following key factors should be considered in the initial design of the protocol to ensure the design correlates with the monitoring strategy objectives as determined by the person designing the test :

a) sampling strategy appropriate to the objectives and needs of the monitoring strategy as described in EN 12305 ;

NOTE : 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.

b) extent of monitoring necessary to fulfil the requirements of the experiment such as timescale, scale and area of sampling ;

c) plant species, predicted behaviour of plant, particularly with respect to pollination and pollen dispersal, seed dispersal, dispersal by vegetative means, competitive ability and weediness ;

d) relevant area for monitoring in line with the monitoring objectives such as the release site and/or the potential dispersal area ;

e) particular features of the release site to monitor such as adjacent sites, streams, soil movement activities, meteorological parameters, wild relatives ;