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English version

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

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

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

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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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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ANNEX A (informative)

Relationship between a sampling and monitoring valid strategy

Annex B (informative)

Bibliography

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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.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

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Introduction

When genetically modified microorganisms including viruses (GMMs) are subject to experimental release into the environment, it is important to ensure the validity of a monitoring strategy for testing their behaviour.

In this European Standard, monitoring refers both to the monitoring of the occurrence, persistence and/or spread of the GMM and/or the gene(s) involved in the modification and its performance in the environment.

This European Standard is intended to aid the experimenter in the design of a monitoring strategy appropriate to monitoring objectives. The development of a monitoring valid strategy is directly linked to the development of the sampling strategy as described in EN 12686). 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 provides 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 GMM. Monitoring encompasses detection of genotypic and phenotypic properties, as well as, detection of viral material and/or symptoms specific for the infected host, for the identification of GMMs in an experimental release.

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

This European Standard is specifically aimed at monitoring experimental release of GMMs or their nucleic acid.

This European Standard however does not cover :

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

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

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 12686 Biotechnology - Modified organisms for application in the environment -
Guidance for the sampling strategies for deliberate releases of genetically
modified microorganisms, including viruses

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 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 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]).

3.7 genotype

Genetic constitution of an organism.

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

3.8 host

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

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 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. (standards.iteh.ai)

3.11 monitoring

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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.

3.12 monitoring protocol

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

3.13 monitoring strategy

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

3.14 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.

3.15 release site

Defined area which contains one or more experimental fields.

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

4 General considerations

Monitoring is important in order to test predictions made with respect to the behaviour of the GMM in a release site.

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

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

- a) Studies on the functioning of the genetic modification in the GMM, released in 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.
- b) Studies on the effect of the genetic modification of interest on the behaviour of the GMM, released in the environment. The monitoring strategy can include studies on the presence of the GMM of interest or its hosts in environmental samples or its performance in the environment including effects on the ecosystem considered.
- 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 microbial population.

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) 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 inspections of the release site, to ensure its continuing validity.