

Biotechnology — Modified organisms for application in the environment — Guidance for the monitoring strategies for deliberate release of genetically modified micro-organisms, including viruses

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ICS 07.080; 07.100.01

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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 micro-organisms, including viruses

Biotechnologie — Organismes modifiés disséminés dans l'environnement — Guide des stratégies de surveillance pour les disséminations volontaires de micro-organismes 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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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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.

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Introduction

When genetically modified micro-organisms 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 micro-organisms, 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 micro-organism

micro-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 90/219/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