STANDARDISERINGEN I SVERIGE
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SVENSK STANDARD SS-EN 12685

Handläggande organ	Fastställd	Utgåva	Sida
Standardiseringsgruppen STG	1999-01-29	1	1 (1+10)

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

The European Standard EN 12685:1998 has the status of a Swedish Standard. This document contains the official English version of EN 12685:1998.

Swedish Standards corresponding to documents referred to in this Standard are listed in ”Catalogue of Swedish Standards”, issued by SIS. The Catalogue lists, with reference number and year of Swedish approval, International and European Standards approved as Swedish Standards as well as other Swedish Standards.

Bioteknik – Modifierade organismer för användning i miljön – Vägledning för övervakningsstrategier vid avsiktlig utsättning av genetiskt modifierade mikroorganismer, virus inkluderade

Europastandarden EN 12685:1998 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 12685:1998.

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ICS 07.100.00

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Tryckt i mars 1999

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12685

July 1998

ICS 07.100.00
Descriptors: biotechnology, genetics, modified organisms, environments, environmental protection, inspection, experimental design

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 dissé-minations 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

This European Standard was approved by CEN on 1998-07-01.

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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.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Ref. No. EN 12685:1998 E

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 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

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.

3.11
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 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.

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 12686;

NOTE The development of a monitoring and sampling valid strategy for deliberate releases of genetically modified micro-organisms 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) predicted behaviour of GMM, particularly with respect to competitive ability, dispersal, persistence and the ability to form spores, resting forms and other specialized structures;

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, soil properties;

f) presence of potential hosts, presence of potential microbial vectors;

g) appropriate choice of monitoring methods.