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**BIOTECHNOLOGY - MODIFIED ORGANISMS
FOR APPLICATION IN THE ENVIRONMENT -
GUIDANCE FOR THE SAMPLING
STRATEGIES FOR DELIBERATE RELEASES
OF GENETICALLY MODIFIED
MICROORGANISMS, INCLUDING VIRUSES**

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English version

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

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

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

This European Standard was approved by CEN on 1 July 1998.

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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.

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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.

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.

Introduction

When genetically modified microorganisms including viruses (GMMs) are subject to an 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 will vary with the predicted frequency of occurrence and spatial distribution of the relevant GMMs or genes in the area studied. Since there are many different techniques available for the detection and the identification of GMMs, this European Standard is formulated as a recommendation to the experimenter to design a sampling strategy appropriate to the purpose of the field experiment, to the microorganisms and to the particular phenotypic and genotypic properties of the GMMs being used. 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 provides guidance concerning the procedures for setting up a valid sampling strategy to meet the objectives of a monitoring strategy for GMMs released into the environment. Since monitoring methods of microorganisms in environmental samples usually require pretreatment of the samples, for example the extraction and isolation of GMMs and/or their nucleic acid, this is included in scope of this European Standard. The sampling is to provide material to which subsequent analytical or biological methods for monitoring of GMMs can be applied (see EN 12685).

This European Standard is intended to address sampling of microorganisms, including viruses (and their relevant hosts), or their nucleic acid.

This European Standard does not cover :

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

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

This European Standard can be applied to sampling of GMMs in all habitats and micro-environments as required to meet the defined experimental objectives. The mode of sampling and the nature of the samples are dependent on the particular purpose.

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

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