National Standards Authority of Ireland

IRISH STANDARD

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BIOTECHNOLOGY - MODIFIED ORGANISMS FOR APPLICATION IN THE ENVIRONMENT - GUIDANCE FOR THE MONITORING 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 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

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.

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.

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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.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