SLOVENSKI STANDARD
SIST EN 13092:2000

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Biotehnologija - Oprema - Navodila za vzorčenje in postopke inokulacije

Biotechnology - Equipment - Guidance on sampling and inoculation procedures

Biotechnik - Geräte und Ausrüstungen - Leitfaden für Probenahme- und Beimpfungsverfahren

Biotechnologie - Equipement - Guide de procédures pour l'échantillonnage et l'inoculation

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Biotechnology - Equipment - Guidance on sampling and inoculation procedures

Biotechnologie - Equipement - Guide de procédures pour l'échantillonnage et l'inoculation

Biotechnik - Geräte und Ausrüstungen - Leitfaden für Probenahme- und Beimpfungsverfahren

This European Standard was approved by CEN on 25 September 1999.

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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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

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of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

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

This European Standard provides a framework to ensure that sampling and inoculation procedures meet workplace and environmental safety requirements with respect to microorganisms. Such procedures may need to be carried out in parallel with other requirements such as prevention of process contamination.

Samples from a biotechnological process often need to be taken for off-line analysis thus breaching the integrity of a closed system. The most common example is taking samples to monitor the status of the process or to verify the specifications of the product.

In a comparable way the integrity is breached when an inoculum is introduced into a closed system from the outside. Both situations have potential for release of microorganisms into the environment.

Selection of appropriate sampling and inoculation devices is one factor in the overall safety. In this respect, well designed and manufactured sampling and inoculation devices are most important factors to safety. However, the operation and maintenance of a sampling or inoculation device have a significant influence on the overall safety. This is particularly because the consequences of release due to poor operation or maintenance are often greater than the consequences of incidental release due to the design of the sampling and inoculation devices.

1 Scope

This European Standard gives guidance to the manufacturer of sampling and inoculation devices on providing instructions in the manufacturer's documentation accompanying his products in accordance with prEN 13312-3. It has the purpose of pointing out to him, which hazards can occur during operation, so that he can take these into account in an adequate way during construction and will be in a position to formulate information for use giving adequate consideration of safety.

This European Standard can also provide a framework for the user of sampling and inoculation devices to assess new or existing sampling or inoculation devices to implement a safe operation and maintenance regime by restricting release, as necessary, of microorganisms into the workplace and the environment.

Sampling and inoculation include the transfer of microorganisms from one closed system into another closed system like collection of sample or inoculation of a fermenter with a starter culture.

This European Standard applies where the sampling or inoculation procedures include hazardous or potentially hazardous microorganisms used in biotechnological processes and/or where exposure of the worker or the environment to such microorganisms is restricted for reasons of safety.

This European Standard is not applicable to transport to and from a safe place and final analysis of a sample, nor is it applicable to sampling of raw materials and air sampling devices used to determine microbial air quality in the workplace.

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.

prEN 13312-3 Biotechnology - Performance criteria for piping and instrumentation - Part 3: Sampling and inoculation devices

3 Terms and definitions

For the purposes of this standard, the following definitions apply :

3.1
accidental release

unexpected release of process material to the environment during normal operation of equipment and the process.

3.2
closed system

system where a barrier separates microorganisms or organisms from the environment [EN 1620].

3.3
incidental release

expected release of process material during normal operation of the equipment and process.

3.4
inoculation

addition of inoculum to a process.

3.5
inoculation device

device for adding microorganisms to a process.

3.6
inoculum

microorganisms added to a process as seed material.

3.7
leakage

egress from equipment.

3.8
leaktightness

ability of component of equipment or unit of equipment to limit egress.

3.9
manufacturer

organization that designs, constructs, supplies and usually tests the equipment and materials.

NOTE By agreement with the purchaser the tests can be carried out by a third party.

3.10
microorganism

any microbiological entity, cellular or non cellular, capable of replication or of transferring genetic material [EN 1619].

NOTE For the purposes of this standard, the term microorganism covers the term of biological agent, according to the Directive 90/679/EEC : microorganisms, including those which have been genetically modified, cell cultures and human endoparasites which may be able to provoke any infection, allergy or toxicity.

3.11
non-representative material

material not representing the properties of process material.

3.12
process microorganism

microorganism used for production purposes in a biotechnological process or constituting (part of) the product itself.

3.13
risk

a combination of the probability and the degree of the possible injury or damage to health in a hazardous situation [EN 1070].

3.14
sample

material collected for analysis.

3.15
sampling device

device for taking samples from a component of equipment and/or a unit of equipment.

3.16
sterile

state of being free from viable microorganisms.

NOTE 1 In practice no such absolute statement regarding the absence of viable microorganisms can be proven. However, sterile conditions can be regarded as established by using an accepted or recognized method of sterilization.

NOTE 2 The process of inactivation of viable microorganisms during a sterilization procedure is usually described by an empirical mathematical function, commonly an exponential function. By their mathematical nature, such functions can be reduced to very low numbers, but not to zero. However, these empirical functions can be applied to control or assess the process parameters of a sterilization procedure to realize a desired degree of inactivation of viable microorganisms.

3.17
user

organization responsible for the biotechnological process who uses equipment and materials as input.

3.18
workplace

the workplace is the defined area or areas in which the work activities are carried out [EN 689].

4 Hazards

4.1 General

To limit the contact of microorganisms with persons and/or the environment the release of microorganisms during sampling or inoculation should be restricted. To control the contact of microorganisms with the workplace and the environment, the potential routes of release from the sampling or inoculation device should be identified and assessed. These routes of release should be assessed against operating criteria which take into account the hazardous nature of the microorganism.