

Biotechnology — Guidance on sampling and inoculation procedures

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ICS 07.080; 07.100.01

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National foreword

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 15 and a back cover.

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This British Standard, having been prepared under the direction of the Sector Committee for Materials and Chemicals, was published under the authority of the Standards Committee and comes into effect on 15 March 2000

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ISBN 0 580 35458 X

Amendments issued since publication

Amd. No.	Date	Comments

English version

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

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of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.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