

Biotechnology — Large-scale process and production — Guidance for the handling, inactivating and testing of waste

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ICS 07.080; 13.030.01

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English version

Biotechnology — Large-scale process and production — Guidance for the handling, inactivating and testing of waste

Biotechnologie — Procédé à grande échelle et
production — Guide pour la manipulation,
l'inactivation et le contrôle des déchets

Biotechnik — Verfahren in Großmaßstab und
Produktion — Leitfaden zur Handhabung,
Inaktivierung und Prüfung von Abfall

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Comité Européen de Normalisation
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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.

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Introduction

This European Standard supports industrial activities in the area of biotechnology covering operations both non-genetically modified and genetically modified microorganisms and with both non-pathogenic and pathogenic microorganisms (see annex C [1], [2]). International, national and local rules, guidelines, safety regulations and instruction manuals that deal with the handling of microorganisms in all steps of fermentation and downstream processes, as well as those used in environmental biotechnology, should be considered.

1 Scope

This European Standard gives guidance on the assessment and the selection of procedures for treatment of waste process microorganisms from biotechnological plant to ensure the safety of people and the environment.

This European Standard applies to wastes and effluents (solid, liquid and gaseous) emitted from biotechnological processes which include traditional processes such as brewing or food processing, and fermentation for pharmaceutical and chemical products, as well as biotechnological processes for environmental and agricultural application.

This European Standard for biotechnological processes is only applicable until gas, liquids and solids are ready for safe transfer to normal industrial or municipal waste handling units.

This European Standard is not applicable to the waste from hospitals, nor to the treatment of chemical and physical hazardous waste.

NOTE Attention is drawn to relevant national regulations.

2 Definitions

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

2.1

biohazardous waste

biological waste which can cause a hazard

2.2

cell culture

in vitro growth of cells derived from multicellular organisms

2.3

disinfectant

chemical agent which is able to reduce the number of viable microorganisms

2.4

disinfection

process of reducing the number of viable microorganisms by various physical and chemical methods

2.5

hazard

intrinsic potential property or ability of something (e.g. any agent, equipment, material or process) to cause harm

[EN 1620]

NOTE Harm is an injury or damage to health of people and/or to the environment.

2.6

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.

2.7

inactivation

process used to reach a state free of a viable process microorganism

2.8

physical containment

system for confining a microorganism or organism or other entity within a defined space

[EN 1620]

2.9

process microorganism

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

2.10

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.

2.11

sterilization

process used to reach a sterile state

2.12

validation

documented procedure for obtaining, recording and interpreting the results needed to show that a process will constantly yield a product complying with predetermined specifications

2.13

verification assay

assay used to determine whether material meets the intended specifications

2.14

waste

by-product arising from a process, or unwanted substance or article derived from any activity

NOTE Examples of waste are scrap material, effluent, unwanted residue or surplus arising from any process or activity, or any substance or article which is discarded or to be disposed of as being broken, contaminated, spoiled, or worn out.