SLOVENSKI STANDARD
SIST EN 12461:1999

01-december-1999

Biotehnologija - Procesi in proizvodnja v industrijskem obsegu - Navodilo za ravnanje z odpadki, njihovo inaktivacijo in preskušanje

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

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

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

Ta slovenski standard je istoveten z: **EN 12461:1998**

ICS:

07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology
13.030.01	Odpadki na splošno	Wastes in general

SIST EN 12461:1999 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12461

February 1998

ICS 07.080; 13.030.01

Descriptors: biotechnology, work safety, accident prevention, environmental protection, waste treatment, wastes, solids, effluents, gaseous effluents, sterilization, disinfection, incineration (waste), irradiation, hazards, contamination

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

This European Standard was approved by CEN on 31 January 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 12461:1998 E

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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

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 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 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, 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 hospital and 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

3 Waste management policy

The production of waste should be minimized and if possible, the recovery of materials should be attempted.

A documented waste management policy should be established describing the measures for prevention, minimization, segregation, handling, storage, treatment, reuse, transportation and disposal of waste from a large scale biotechnological process.

The waste management system and the responsibilities and duties allocated to managers, supervisors and employees should be specified. The arrangements for effective control of biohazardous waste should be integrated with general management and supervisory organization within the production process.

Documented operational procedures, describing the methods used for effective waste management should be established. These documents should be reviewed at regular intervals and updated, if necessary. Attention is drawn to international, European and national requirements for the control of waste.

A description should be given of the methods and procedures for handling, inactivation and treating waste for both normal conditions and deviations. It is also necessary to describe the commissioning, maintenance and use of plant and equipment in accordance with other appropriate biotechnological European Standards and guidelines.

Comprehensible information should be provided on the risks to health and safety arising from waste which contains pathogenic microorganisms together with details of its treatment and the prevention and control measures which are used in normal and emergency procedures. This information should be understandable to technical and non technical personnel alike.

The waste management plan together with the practical arrangements for the control, treatment and disposal for waste should be subject to a quality assurance and control programme or equivalent systematic monitoring and auditing programme. The quality of the waste management system should be assured by periodic checks and inspections of the various arrangements and procedures. These include operating conditions and control devices of plant and equipment, the composition and characterization of the waste loads and adherence to approved standard operating procedures. Test and inspection results should be documented together with details of any action taken to correct deviations from the intended operating conditions. The results and documentation of quality assurance or audit programme should be submitted to the internal supervising office.

4 Characterization of waste stream

The following are essential elements, which should be included and documented in a waste management plan :

- definition of the physical and chemical parameters which can affect the choice of treatment and testing methods such as the amount of suspended solids or pH ;

- methods for the segregation of biohazardous waste from non-biohazardous waste at the point of origin, if possible ;

- methods for the segregation of other categories of waste (such as hazardous chemical or radioactive products) which do not contain microorganisms when there is incompatibility with the biohazardous waste treatment methods.

A detailed statement should be given of the various activities, processes and the types of waste are subject to the waste management plan (see figure 1).

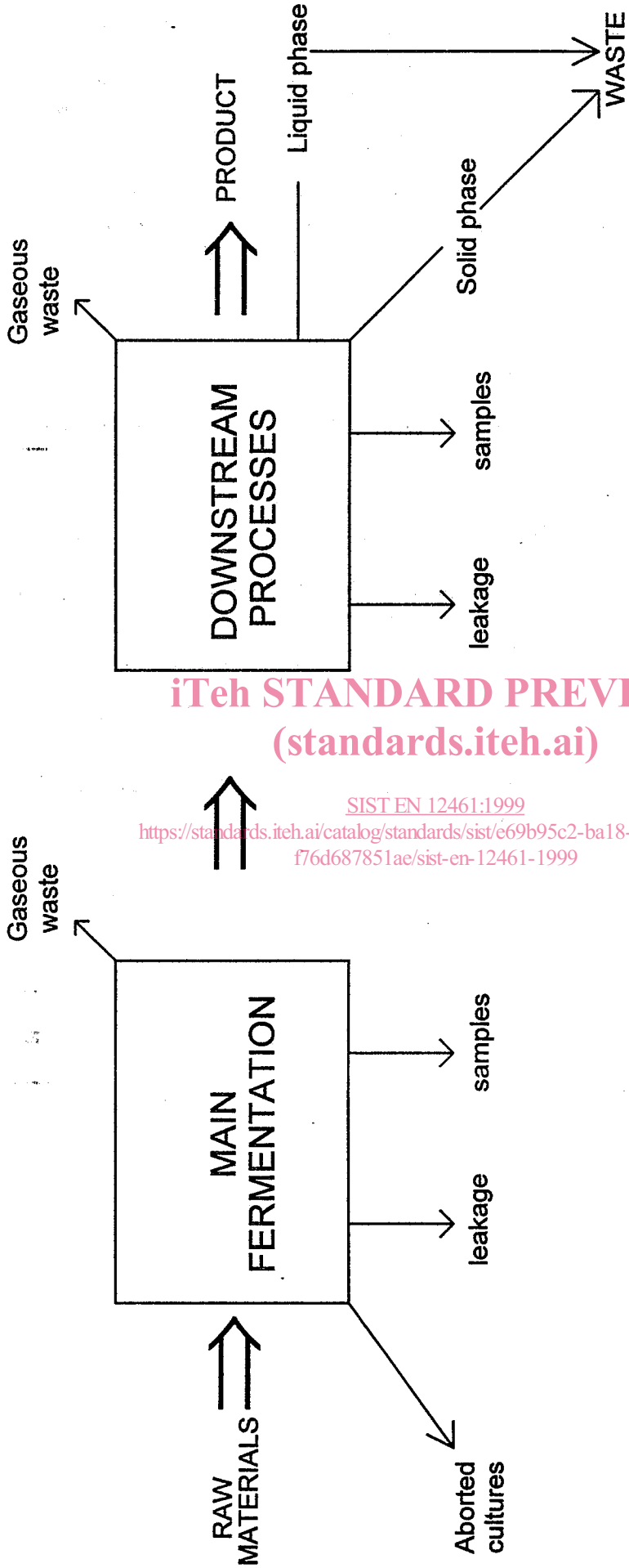

Figure 1 : Identification of waste streams.

5 Establishment of procedures

The procedures for appropriate treatment of waste stream should be developed. Figure 2 shows the main steps to be considered to guide the choice of waste treatment procedures.

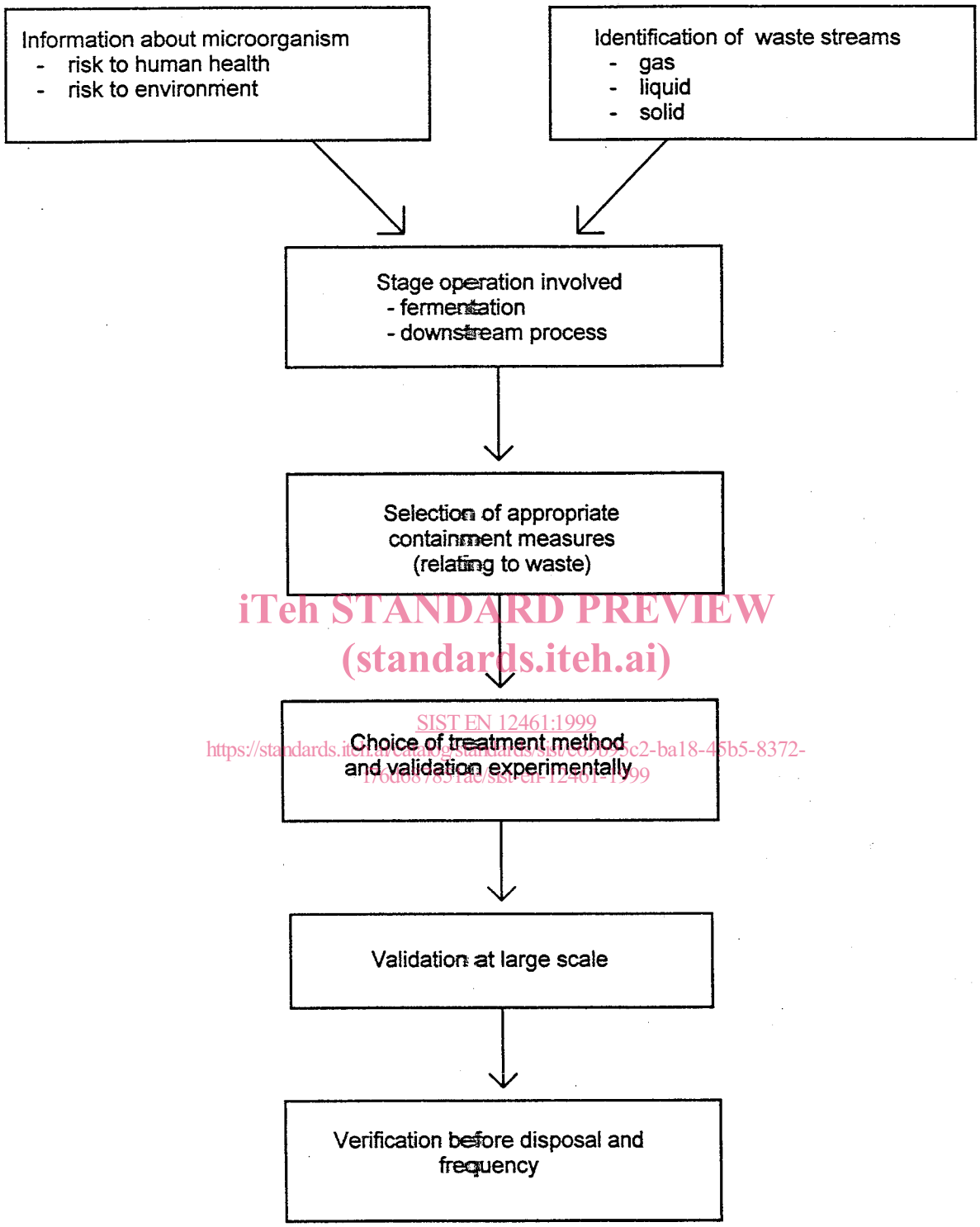

Figure 2 : Establishment of procedures.