SLOVENSKI STANDARD
SIST EN 13312-3:2002

01-januar-2002

Biotehnologija - Merila za delovanje cevne napeljave in pripomočke - 3. del: Naprave za vzorčenje in inokulacijo

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

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 3: Probenahme- und Beimpfungsvorrichtungen

Biotechnologie - Criteres de performance pour tuyauteries et instrumentation - Partie 3: Dispositifs d'échantillonnage et d'inoculation

Ta slovenski standard je istoveten z: **EN 13312-3:2001**

ICS:

07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology
23.040.01	Deli cevovodov in cevovodi na splošno	Pipeline components and pipelines in general

SIST EN 13312-3:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13312-3

February 2001

ICS 07.080; 07.100.01

English version

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

Biotechnologie - Critères de performance pour tuyauteries et instrumentation - Partie 3: Dispositifs d'échantillonnage et d'inoculation

Biotechnik - Leistungskriterien für Leitungssysteme und Instrumentierung - Teil 3: Probenahme- und Beimpfungsvorrichtungen

This European Standard was approved by CEN on 13 January 2001.

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 Management Centre 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 Management Centre 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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 13312-3:2001 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 2001, and conflicting national standards shall be withdrawn at the latest by August 2001.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This standard is one of a series of European Standards concerned with performance criteria for piping and instrumentation. These standards are:

EN 13312-1, *Biotechnology - Performance criteria for piping and instrumentation - Part 1 : General performance criteria.*

EN 13312-2, *Biotechnology - Performance criteria for piping and instrumentation - Part 2 : Couplings.*

EN 13312-3, *Biotechnology - Performance criteria for piping and instrumentation - Part 3 : Sampling and inoculation devices.*

EN 13312-4, *Biotechnology - Performance criteria for piping and instrumentation - Part 4 : Tubes and pipes.*

EN 13312-5, *Biotechnology - Performance criteria for piping and instrumentation - Part 5 : Valves.*

EN 13312-6, *Biotechnology - Performance criteria for piping and instrumentation - Part 6 : Equipment probes.*

This standard includes a Bibliography.

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

Sampling and inoculation devices are used to remove material from or add material to the closed system. In order to perform a safe operation the device should perform in such a way as not to breach the containment of the closed system.

NOTE Recommendations for safe operation with and maintenance of sampling and inoculation devices are given in EN 13092 (see [1]).

Use of this European Standard will aid the equipment manufacturer in the classification of sampling and inoculation devices with regard to safe performance in biotechnological processes. The classification is easily understandable and readily utilizable for the user and the regulatory authorities.

1 Scope

This European Standard specifies performance criteria for sampling and inoculation devices used in biotechnological processes with respect to the potential hazards to the worker and the environment from microorganisms in use.

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

Where the device is included as an integral part of other units of equipment or components of equipment, the manufacturer of that equipment has the responsibility to interpret the appropriate safety standard (relative to that equipment) as inclusive of a complete device.

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 (including amendments).

EN 13312-1:2001, *Biotechnology - Performance criteria for piping and instrumentation - Part 1: General performance criteria.*

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in EN 13312-1:2001 apply.

4 Hazards

The following hazards shall be taken into account.

a) Release of microorganisms caused by exhaust gases or liquid condensate.

b) Release of microorganisms caused by accidents.

c) Release of microorganisms caused by exposure to process fluids when breaching the containment of the closed system during sampling or inoculation.

d) Release of microorganisms caused by breakage or bursting of sampling or inoculum containers.

NOTE Additional information on hazards accompanying the usage of sampling and inoculation devices is given in Bibliography [1].

5 Performance classes

The sampling and inoculation devices shall be classified for leaktightness, cleanability and sterilizability in accordance with 5.1 to 5.4 of EN 13312-1:2001.

The selection of the appropriate class for performance of a sampling or inoculation device shall be made in accordance with 5.5 of EN 13312-1:2001.

6 Classification and verification of performance

The sampling or inoculation device shall conform to the general requirements given in clause 6 of EN 13312-1:2001.

7 Marking and packaging

The sampling and inoculations devices shall conform to the requirements given in clause 7 of EN 13312-1:2001.

8 Documentation

The sampling and inoculation device shall conform to the requirements given in clause 8 of EN 13312-1:2001.

Annex A (informative)

Guidance on design for sampling and inoculation devices

A.1 Devices for use where release of microorganisms is not limited

This clause concerns work with microorganisms that are regarded as likely to pose no risk or a negligible risk to people and/or the environment (for example group 1 of Directive 90/679/EEC ; see [2]). Hence, for work with these microorganisms any type of sampling device can be used, ranging from a ladle to a sampling into a receptacle, an example of which is shown in figure B.1. Proper cleaning of the parts that are in contact with microorganisms of the sampling device is recommended for obtaining representative samples but this is beyond the scope of this standard. Consequently, no requirements are necessary with regard to biosafety. The same assessment goes for inoculation devices.

A.2 Devices for use where release of microorganisms should be minimized

This clause concerns work with microorganisms that are regarded as posing no (or a negligible) risk or a low risk (for example group 1 and group 2 of Directive 90/679/EEC ; see [2]) to people and/or the environment. For work with these microorganisms sampling should be performed either by special sampling probes, an example of which is shown in figure B.2, or by pipes or tubes with a special combination of valves and couplings, an example of which is shown in figure B.3 and in figures B.7.1 and B.7.2. Other types of sampling devices are acceptable if a comparable safety level is obtained, e. g. sampling from an external loop of a vessel via a barrier for microorganisms (for example used with on-line analytical equipment) or via a septum that can be pierced by a syringe. In the latter example the receptacle should form a containment of the sample, the perforated septum should be closed after sampling and the outer surface should be disinfected properly after sampling.

The design of the sampling devices of figures B.2, B.3, B.7.1 and B.7.2 represent two possibilities of a large variety of designs. The design of the sampling device should ensure to limit egress of microorganisms to the environment in all modes of operation, despite the egress into a sampling receptacle. The sampling receptacle should form a containment of the sample.

NOTE For example, pouring the sample into a standard beaker is not an acceptable sampling device for group 2 microorganisms according to Directive 90/679/EEC (see [2]).

One possibility out of a large variety of designs for sampling receptacles is shown in figure B.4. The sampling receptacle should be closed during transportation and should be protected against damages such as breaking. Before removing or dismantling of the sampling receptacle or the sampling pipes or the sampling probe, the parts of the sampling device that are in contact with microorganisms and that are not separated from the process (e. g. in the bioreactor) by a barrier (e. g. by a valve) should be inactivated e.g. by steam or by disinfection if appropriate.

Release of microorganisms into the environment should be also limited when using inoculation devices. Hence, the inoculation device should be closed during transportation and should be protected against damages such as breaking. Connection of an inoculation device to a closed system (e.g. to a bioreactor) can be performed by pipes or tubes with a special combination of valves (analogous to the above expositions for sampling devices) or

by other means, e.g. via a septum that can be pierced by a syringe. In the latter example the syringe can be retained and fixed at the septum or it can be removed after the inoculation procedure. An appropriate method should be established for disinfection and inactivation of microorganisms. This method should to be used if necessary for example when a syringe is pulled out of the inoculation port and not immediately put by a sleeve to cover the spots in contact with microorganisms up to inactivation e.g. in an autoclave.

Figure B.5 and B.6 show two examples out of a large variety of designs for inoculation devices, one using tubes, valves and couplings and the other using the septum and syringe technique. Other types of inoculation devices are acceptable if a comparable safety level is obtained. The inoculation procedure is not a concern with respect to the scope of this European Standard. Proper handling and methodology for sampling and inoculation are described in Bibliography [1].

A.3 Devices for use where release of microorganisms should be prevented

This clause concerns work with microorganisms that are regarded as posing medium or high risk (for example group 3 and group 4 of Directive 90/679/EEC ; see [2]) to people and/or the environment. For work with these microorganisms sampling should be performed either by special sampling probes or by pipes or tubes with a special combination of valves, examples of which are shown in figures B.7.1 and B.7.2. Other types of sampling devices are acceptable if a comparable safety level is obtained, e. g. sampling from an external loop of a vessel via a barrier for microorganisms.

Sampling devices used for work with these microorganisms should allow a secure and permanent closure of the sampling device in case of malfunction of the sampling device itself or of associated equipment e. g. for sterilization or for reception of the sample.

The design of the sampling devices of B.7.1 and B.7.2 represent one possibility of a large variety of designs. The design of the sampling device should ensure to prevent egress of microorganisms to the environment in all modes of operation, despite the egress into a sampling receptacle. The sampling receptacle should form a containment of the sample and should be protected against damages such as breaking, except for the special situation that the sampling device is operated entirely inside a microbiological safety cabinet conforming to EN 12469 (see [3]), that allows work with microorganisms of medium and high risk.

The sampling receptacle should be closed and should be protected against damages during transportation. The sampling receptacle should not be opened again until :

- an appropriate transfer of the sample into a contained area fitted for working with microorganisms of medium or high risk is provided (e. g. transfer to an inoculation device of appropriate containment level, or transfer to analytical devices or filling machines operating in a microbiological safety cabinet that allows work with microorganisms of medium and high risk) ; or

- the risk group of the sample is reduced to a negligible or low risk using appropriate and validated inactivation steps inside an appropriate contained area.

Before removing or dismantling of the sampling receptacle or the sampling pipes or the sampling probe, the parts of the sampling device that are in contact with microorganisms and that are not separated from the process (e. g. in the bioreactor) by a barrier (e. g. by a valve) should be inactivated by appropriate and validated methods.