SLOVENSKI STANDARD
SIST EN 12689:1999

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Biotehnologija - Navodilo za ocenjevanje ļ istosti, biologķke aktivnosti in obstojnosti mikrobiologķih proizvodov

Biotechnology - Guidance on assessment of the purity, biological activity and stability of microorganism based products

Biotechnik - Leitfaden zur Bewertung der Reinheit, biologischen Aktivität und Stabilität von Produkten, die auf Mikroorganismen basieren

Biotechnologie - Guide pour l'évaluation de la pureté, l'activité biologique et la stabilité des produits a base de microorganismes

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English version

Biotechnology - Guidance on assessment of the purity, biological activity and stability of microorganism based products

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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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.

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

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

Microorganism based products (MBPs), such as fertilizer, growth promoter, pest and weed control agents, silage additive, probiotic for feedstuff additives, bioremediation agents and biodegradation agents are used in the environment.

MBPs can contain one or more microorganism strains including genetically modified microorganisms (GMMs). Purity, biological activity and stability of microorganism present are considered to be the technical specifications for evaluating MBP quality.

NOTE : During the development of a MBP that contains genetically modified microorganisms, attention is drawn to national and European (see annex A [5], [6], [12]) regulations, and related European Standards (see annex A [7], [8], [9], [10], [11]) concerning the handling of genetically modified microorganisms in contained or released conditions.

A large variety of MBPs exists and the choice of methods applied to assess technical specifications depends primarily on the characteristics of the microbial component of the product such as taxonomy, genotype, metabolism, growth environment, doubling time.

1 Scope

This European Standard gives guidance on assessment of technical specifications of microorganism based products (MBPs) for product quality evaluation. It is also applicable for purposes of product registration.

NOTE 1 : In this European Standard, the technical specifications are considered to be purity, biological activity and stability of microorganism based product.

This European Standard describes criteria and factors considered for the validity of the assessment of the technical specifications.

This European Standard only applies to the microbial components of a MBP as a whole and does not apply to any type of molecular components purified from the microorganism.

This European Standard applies to MBPs specifically manufactured to be used in agriculture and in the environment.

This European Standard does not apply to MBPs used either in food industry, for veterinary use or for human health.

NOTE 2 : This European Standard can be used by the manufacturer of MBPs or anyone interested in the evaluation of product quality.

NOTE 3 : Due to rapid evolution in this field, it is recommended that the user should consult existing applicable national, European and international standards.

NOTE 4 : Technical specification assessment is consistent with the need for protection of human health, animal and environmental safety.

2 Definitions

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

2.1 analyte

Substance sought or determined.

2.2 biocontaminant

Undesired microorganism.

2.3 biological activity of product

Intended performance of microorganism based products as related to the use.

2.4 control

Preparation of known characteristics used to standardize an analysis.

2.5 microbial component

Desired microorganism or mixture of desired microorganisms.

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 of 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 microorganism based product (MBP)

Product whose efficacy is dependent upon its microbial component.

2.8 product purity

Content of the microbial component in the microorganism based product.

NOTE : Depending of the type of microorganism based product, product purity can be expressed as one or more of the following :

a) proportion of microbial component to total viable microorganisms ;

b) a specified level of biocontaminants ;

c) identity of the microbial component to strains .

2.9 product stability

Preservation of biological activity and/or purity over time and under defined conditions.

2.10 reference data

Documentation of the characterization of microorganism including any methods which are state-of-art.

3 General considerations

3.1 Assessment protocol

The assessment of technical specifications should be consistent with the intended use of the product. This assessment refers only to the microbial component or the biological activity of the products.

Identification of microbial component should be provided by the manufacturer to the user. The manufacturer can use a wide range of procedures to characterize the microbial component, depending on the characteristics of the microorganism(s). The manufacturer should process the microbial component in such a way that its identity is ensured in the end product.

NOTE : Attention is drawn to EN 1619 regarding the strain conservation of microorganisms.

Validity of assessment of technical specifications is assured when specific criteria and factors are considered.

The technical specifications should be assessed using appropriate methods, depending on :

- the microorganism contained in the MBP ;
- the purpose and design of the assessment.

The method of assessment should be provided by the manufacturer. These methods should be used as the basis of the evaluation of product quality.

Regardless of the applied method, the following criteria should be considered to assure the validity of the assessment of product purity, biological activity of product, and product stability (see clauses 4, 5 and 6).

Considerations for assessment protocol to assess the technical specifications of a MBP should start with the definition and the statement of the objectives of the analysis either product purity, biological activity of product or product stability, followed by the design and documentation of an appropriate test method.

The major steps of assessment protocol are :

a) design and review of the assessment protocol (see 3.2) ;

b) execution of the assessment protocol (see 3.3) ;

c) record keeping (see 3.4).

3.2 Design and review of the assessment protocol

The design of the assessment protocol should be documented and reviewed for validity according the criteria in clauses 4, 5 and 6. The assessment protocol should include procedures for sampling and pre-treatment of samples.

The assessment of technical specifications is carried out on product samples as prepared for use.

The sampling should be consistent with the type of applied statistical analysis. The type of applied statistical analysis should provide representative data concerning production.

NOTE : Sampling methods and sample pre-treatment methods described by national and international standards for the type of product to be tested should be used.

Degradation and contamination of the MBP microbial component should be minimized during storage and transportation of samples. Conditions of storage and transportation of MBP samples, such as temperature, humidity and light, should be as close as possible to those of the storage of the whole product.

Pre-treatment of samples is usually necessary for the isolation of the microbial component of the MBP. Pre-treatment of samples is carried out after collection and storage if required. The choice of a pre-treatment procedure depends on :

- the nature and composition of the MBPs (e.g. liquid or solid samples) ;
- the applied method to assess product purity, biological activity of product and product stability.

Pre-treatment can alter the number and activity of microbial component of the MBPs. Therefore, it is essential that the pre-treatment procedure should be validated before being incorporated into assessment protocols.

3.3 Execution of assessment protocol

The assessment protocol should be carried out in accordance with the design as follows :

- collect samples and assay ;
- identify and label samples ;
- store the samples under conditions which minimize degradation of the analyte ;
- pre-treat the samples ;
- collect raw data and obtain results ;