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BIOTECHNOLOGY - GUIDANCE ON ASSESSMENT OF THE PURITY, BIOLOGICAL ACTIVITY AND STABILITY OF MICROORGANISM BASED PRODUCTS

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English version

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

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

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

This European Standard was approved by CEN on 1 July 1998.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.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.
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> NOTE 3 : Due to rapid evolution in this field, it is recommended that the user should consult existing applicable national, European and international standards.
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> NOTE 4 : Technical specification assessment is consistent with the need for protection of human health, animal and environmental safety.