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Biotechnology - Large scale process and production - Control procedures for raw materials

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Bioteknik - Storskalig process och produktion - Kontrollrutiner för råmaterial

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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN 1826

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Descriptors: biotechnology, raw materials, definitions, storage, quality, inspection

English version

Biotechnology - Large scale process and production - Control procedures for raw materials

Biotecnologie – Prodédé à grande échelle et production - Procedures de contrôle pour les matières premieres

Biotechnik – Verfahren im Großmaßstab und Produktion – Verfahren zur Überwachung von Rohrstoffen

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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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of an identical text or by endorsement, at the latest by March 1997, and conflicting national standards shall be withdrawn at the latest by March 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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0 Introduction

The use of raw materials is strongly related to quality and safety aspects to prevent potential hazards, especially harmful microbial contaminants :

- during storage ;
- in the process ;
- of the final products.

The proper use of the raw materials is determined by these aspects. The intrinsic properties of the raw materials should be taken into consideration and a generalization of these aspects is not possible. At any time when a raw material is introduced or changed, a list of specifications and verification assays should be created to guarantee the quality of the end-product and to limit risk for human health, safety and environment.

1 Scope

This European Standard gives guidance on control procedures for raw materials used in biotechnological processes.

This European Standard does not list individual materials, but provides criteria against which raw materials used in industrial biotechnology processes can be checked.

This European Standard is applicable to all materials used during production of products by means of a biotechnological process. It is not applicable to equipment.

NOTE : Use of raw materials is covered in the European Standard “Procedures for fermentation and downstream operations” (see annex A [4]).

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.

ISO 11014-1 Safety data sheet for chemical production - Part 1: Content and order of sections

3 Definitions

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

3.1 process

Totality of unit operations involved in the production of a defined product and of waste,

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3.2 quarantine

Isolation of materials by physical or other effective means whilst awaiting a decision on their release or rejection.

3.3 raw material

Material used during production of products by means of a biotechnological process,

3.4 raw material control

Procedures for assuring the acceptability of raw materials used in the biotechnological process.

3.5 specification

Document stating requirements.

NOTE 1: A qualifier should be used to indicate the type of specification, such as "product specification", "test specification".

NOTE 2: A specification should refer to or include drawings, patterns or other relevant documents and indicate the means and the criteria whereby conformity can be checked. [ISO 8402]

3.6 supplier

Party that is responsible for the product, processor service and is able to ensure that quality assurance is exercised.

NOTE 1: The definition may apply to manufacturers, distributors, importers, assemblers and service organizations. [EN 45020]

NOTE 2: The term product in EN 45020 definition is understood as raw material.

NOTE 3: The supplier is in general a different party from the user. However, users can, in certain cases, be their own suppliers of equipment and materials, for example utilities.

3.7 user

Manufacturer responsible for the biotechnological process who uses equipment and materials as input.

3.8 validation record

Proof relying on documentary evidence.

3.9 verification assay

Assay used to determine whether the material meets the specifications.

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4 Raw material control

4.1 General

The purchase of raw materials should involve personnel who have experience or knowledge of the product and suppliers.

A list should be established that guarantees control of the properties and the handling of the raw materials before use in and during the process. Figure 1 shows the procedure for raw material control.

NOTE 1: Attention is drawn to the protective measures for workers to be applied, where appropriate, when handling raw materials (see annex A [5]).

The relevance of every point on the list should be decided on a case by case basis dependent on the application and the use of the finished product. The control procedures for each raw material used for each process should be established and followed.

It is recommended that a validation record is kept by documenting all important facts concerning the raw materials.

Amongst the raw materials that should be taken into consideration are the following :

- water;
- carbon and nitrogen sources ;
- additional nutrients (e.g. minerals, vitamins) ;
- additives, acid, base, antifoam ;
- auxiliary materials (e.g. enzymes, filtration adjuvants) ;
- culture media for microorganisms ;

NOTE 2: The inoculum is not covered as a raw material in this standard. It is covered in prEN 12075 (see annex A [4]).

- process air;
- process steam condensed into the fermenter during sterilization by direct steam;
- cleaning materials.

NOTE 3: Cleaning materials as well as materials used in lubrication and surface treatment of equipment should be subject to specific procedures.

The specifications established by the user for raw materials should be followed by the suppliers. The receiving company should be informed in writing about any deviations. It is also recommended that complaints and rejection procedures are agreed upon by the user and the supplier. This includes verification assays.

NOTE 4: Attention is drawn to national, European and international regulations concerning the control of raw material for food and pharmaceutical products.