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REPORT
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CR 12250:1995

December 1995

English version

**Biotechnology - Microorganisms - Further
examination of organisms in support of the
classification work carried out under directive
90/679/EEC**

**Biotechnologie - Microorganismes -
Examen des organismes appuyant
les travaux de classification
effectués dans le cadre de la
directive 90/679/CEE**

**Biotechnologie - Mikroorganismen -
Weitere Prüfung von Organismen zur
Unterstützung der im Rahmen der
Richtlinie 90/679/EWG
durchgeführten Einstufungsarbeiten**

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CEN

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

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Foreword

This report was prepared by the Technical Committee CEN/TC 233 "Biotechnology", the secretariat of which is held by AFNOR.

Introduction

The Directive 90/679/EEC (see annex A [1]) on the protection of workers from risks related to exposure to biological agents at work is the seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC (see annex A [3]) on the introduction of measures to encourage improvements in the safety and health of workers at work. The legal basis of this Directive 90/679/EEC (see annex A [1]) is the Article 118A of the Treaty which provides that the Council shall adopt, by means of Directives, minimum requirements in order to encourage improvements, especially in the working environment, so as to guarantee better protection of the health and safety of workers.

This Directive particularly includes definitions of biological agents and their classification into four groups according to their level of risk of infection, determines the rules for assessing the biological risk, for notifying to the competent authority the first use of hazardous biological agent and for preventing the biological risk.

The Article 18 of the Directive 90/679/EEC (see annex A [1]) states that the Council must adopt a first list of groups 2, 3 and 4 of biological agents for the annex III of that Directive within six months of the date of implementation.

Group 1 biological agent means one that is unlikely to cause human disease ;

Group 2 biological agent means one that can cause human disease and might be a hazard to workers ; it is unlikely to spread to the community ; there is usually effective prophylaxis or treatment available ;

Group 3 biological agent means one that can cause severe human disease and presents a serious hazard to workers ; it may present a risk of spread to the community but there is usually effective prophylaxis or treatment available ;

Group 4 biological agent means one that causes severe human disease and is a serious hazard to workers ; it may present a high risk of spreading to the community ; there is usually no effective prophylaxis or treatment available.

The European Council, after more than two years discussion at the European Commission level, has adopted a first list of biological agents of groups 2, 3 and 4 in the Directive 93/88/EEC (see annex A [2]) of 12 October, 1993.

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