SLOVENSKI STANDARD
SIST CR 12250:1999

01-december-1999

Biotehnologija ï Mikroorganizmi - Nadaljnji pregled organizmov kot pomoļ pri razvrģļ anju v skladu z direktivo 90/679/EGS

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

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

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

Ta slovenski standard je istoveten z: **CR 12250:1995**

ICS:

07.080 Biologija. Botanika. Zoologija Biology. Botany. Zoology

SIST CR 12250:1999 **en**

REPORT
RAPPORT
BERICHT

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English version

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This CEN REPORT has been prepared by Technical Committee CEN/TC 233 "Biotechnology" and has been approved by CEN on 1995-10-18.

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CEN

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

Rue de Stassart 36, B - 1050 Brussels

Ref. no. CR 12250:1995 E

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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.

As stated at the Article 19 of the Directive 90/679/EEC (see annex A [1]), purely technical adjustements to the annexes in the light of technical progress, changes in international regulations or specifications and new findings in the field of biological agents shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC (see annex A [3]) : the Commission is assisted by a Committee of Member States delegates and chaired by the Commission representative.

This Directive 93/88/EEC (see annex A [2]) sets up a first list of bacteria, viruses, parasites and fungi of groups 2, 3 and 4 to be included in annex III of the Directive 90/679/EEC (see annex A [1]). This list of hazardous biological agents is introduced through particularly important notes which specify that :

- only agents which are known to infect humans are to be included ;

- the list of classified biological agents is based on the effect of these agents on healthy workers. No specifiic account is taken of particular effects on those whose susceptibility may be affected for one or other reasons such as pre-existing disease, medication, compromised immunity, pregnancy or breast feeding ;

- biological agents which have not been classified for inclusion in group 2 to 4 in the list, are therefore not implicitly classified in group 1. When a whole genus is mentioned in the classified list of biological agents, it is implicit that the species and strains known to be non-pathogenic are excluded ;

- where a strain is attenuated or has lost known virulence genes, then the containment required by the classification of its parent strain need not necessarily apply ;

- all viruses which have already been isolated in humans and which are not allocated in a group in the list are to be classified in group 2 as a minimum ;

- the classification of parasites and the resulting requirements as to containment apply only to stages in the life cycle of the parasite in which it is liable to be infectious to humans at the workplace.

Moreover, it is stated that for certain specified not airborne biological agents classified in group 3, the application of containment measures to these agents shall be subject to evaluation by Member States. This is the case for some *Mycobacteria*, *Rickettsia*, *Salmonella typhi*, *Shigella dysenteriae*, hepatitis B, C and D viruses and some other viruses.

Annex A

(Informative)

Bibliography

[1] Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 of Directive 89/391/EEC). OJEC n° L 374, 31.12.1990, p 1.

[2] Council Directive 93/88/EEC of 12 october 1993 amending Dirctive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 of Directive 89/391/EEC). OJEC n° L 268, 29.10.1993, p 71.

[3] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work. OJEC n° L 183, 29.06.1989, p 1.

[4] Council Directive 90/219/EEC of 23 April 1990 on the contained used of geneticallly modified microorganisms. OJEC n° L 171, 08.05.1990, p 1.

Conclusion

Such a list represents a broad consensus at EEC level. This list will soon have to be implemented in all EEC Member States following the implementation of the Directive 90/679/EEC [1] and constitutes a valuable scientifically based list of biological agents pathogenic to humans for all CEN countries.

This first EEC list of biological agents pathogenic to humans both with the introductory notes which will be implemented at national level in all EEC Member States is considered as a first reference list by CEN.

On the other hand, the CEN would be ready for preparing and proposing improvements of this list when considering further reviews if such proposals are allowed to be taken into account by the European Commission.

Among these proposals it is suggested to examine and try to combine the definitions of the risk groups and the classification criteria for microorganisms pathogenic for humans as described in the Directives 90/679/EEC (see annex A [1]) and 90/219/EEC (see annex A [4]).