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Foreword

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

Introduction

From the beginning of the application of genetic modification of microorganisms there has been concern among users as well as authorities about the potential dangers of this new technique, especially with respect to the creation of new strains that could be hazardous to man, animals, plants or the environment in general. Many national authorities, advisory committees and also the European Commission, set up a legal framework to ensure the safe application of techniques of genetic modification. In order to be able to determine what, if any, safety precautions should be taken in individual biotechnological operations, safety criteria were set up to supplement the legislation. The NIH (see annex B [1]) and the OECD (see annex B [2]) were among the first to publish widely accepted safety criteria. Both publications have been regularly updated. They have had an important harmonizing impact and also strongly influenced the European Directive 90/219/EEC on contained use of genetically modified microorganisms (GMM's), issued in 1990 (see annex B [3]). This Directive aims at regulating the use of GMM's in such a way that no untoward effects are to be expected for man and environment.

Many microorganisms currently in use in modern biotechnology, whether it be research, development or production, have a long record of safe use. They have been employed for centuries in classical biotechnology without creating untoward effects to the environment and they have not been seen to be hazardous to humans. Therefore, in giving safety guidelines on how to use GMM's in general, making a distinction between safe and potentially unsafe organisms is logical.

Directive 90/219/EEC classifies GMM's into two groups : those that are considered to be intrinsically safe because they meet predefined safety criteria (Group I) and those that do not meet these criteria (Group II).

General safety criteria for hosts, vectors and inserts that can be used to construct Group I GMM's and criteria for such GMM's themselves are given in an annex of the Directive. These criteria were somewhat detailed originally but were amended into more general terms later (see annex B [4]).

At present Directive 90/219/EEC is being revised in which the distinction of the two groups of microorganisms is abandoned. However, assessment of the risks that GMM's may pose to man and environment will stay obligatory and, as a consequence thereof, the need for biological safety criteria for microorganisms.

Given the rather general quality of the Group I safety criteria, guidelines on their interpretation were issued (see annex B [5], [6]). These leave room, however, for different decisions on whether hosts, vectors, inserts and GMM's qualify for Group I or not. As a consequence, and also because European Union Member States differ in the kind of activities with GMM's that are carried out, national interpretations of the safety guidelines and the accompanying lists of Group I hosts and vectors have diverged to some extent.

1 Scope

This CEN Report reviews the safety criteria for hosts, vectors, inserts and genetically modified microorganisms (GMM's) used by the competent authorities of Member States of the European Union to classify GMM's as intrinsically safe, i.e. as Group I GMM's. The report

may assist both users and regulatory authorities in classifying GMM's, including mammalian and plant cells, as safe for human health and the environment.

This CEN Report covers Group I GMM's that are applied in research and development activities and those applied in industrial applications, which are frequently activities on a larger scale. Although most of the information available relates to GMM's that are to be used for research and development, the safety criteria for GMM's to be used for the latter kind of activities show much overlap. No listings of hosts and vectors are given, because such lists are readily available and are inevitably incomplete due to the continuous addition of newly classified biological agents.

2 Safety criteria for Group I GMM's

The safety criteria used by authoritative bodies of several European countries to classify hosts, vectors, inserts and GMM's as Group I are summarized in table I. The table relates them to the general safety criteria given in Directive 90/219/EEC and the most recent official guidelines thereof (see annex B [6]). More detailed information on the national criteria can be found in the publications of the respective authoritative bodies (see annex A).

Several national authoritative bodies also publish lists of Group I hosts and vectors or host-vector systems classified as such. These lists however are rather incomplete because of infrequent updates and, of far more importance, because they do contain only those microorganisms of which a notifier requested official recognition. In many cases such a request is not made because of reasons of confidentiality, which means that the hosts and vectors are only mentioned in the notification, but not incorporated in the lists of Group I microorganisms.

Not all countries where activities with Group I GMM's occur do have predefined specific national safety criteria available.

In Sweden for several Group I hosts and vectors used in industrial applications simply the relevant criteria of the NIH Guidelines were used (e.g. for hosts like K12 strains of *Escherichia coli* and Chinese Hamster Ovary cells and vectors like pBR322-derivatives , pKGE327 and pKGE439) (see annex B [14]).

In Belgium the still rather general guidelines of Directive 96/134/EEC are an integral part of the national legislation with some minor modifications. Although their scope is broadened to encompass animals and plants as well, no additional specifications are available (see annex B [7]).

Also in Norway these guidelines, as well as those on the general safety criteria given in the original Directive are the only official criteria available (see annex B [15]).

For several countries, notably Germany, it is difficult to represent the national safety criteria used in table I, because their legislation gives comprehensive safety criteria for microorganisms, but not specifically for Group I. Points that need to be considered when carrying out the risk assessment to decide on the relevant containment level are given instead, sometimes differentiated into risk assessment made for research applications and industrial applications. A guide to such risk assessment including typical examples has been issued by the German Occupational Safety and Benefit Organization of Chemical Industry (see annex B [8]), while in the United-Kingdom for large scale applications at the lowest containment level several criteria are available (see annex B [10]).