COUNCIL OF EUROPE
COMMITTEE OF MINISTERS

RECOMMENDATION No. R (84) 16

OF THE COMMITTEE OF MINISTERS TO MEMBER STATES CONCERNING NOTIFICATION OF WORK INVOLVING RECOMBINANT DEOXYRIBONUCLEIC ACID (DNA)

(Adopted by the Committee of Ministers on 25 September 1984 at the 375th meeting of the Ministers' Deputies)

The Committee of Ministers, under the terms of Article 15.*b* of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members by common action in economic, social, cultural, scientific, legal and administrative matters, in particular through harmonisation of laws on matters of common interest ;

Having regard to the Consultative Assembly Recommendation 934 (1982) on Genetic Engineering ;

Considering and welcoming the great progress realised in recent years as to the safety in recombinant DNA work ;

Being informed that not all member states possess legislation or regulations concerning safety in DNA work ;

Considering that the European Communities Council Recommendation of 30 June 1982 (82/472/EEC) concerning the registration of work involving recombinant deoxyribonucleic acid, which is applicable only to the ten member states of the European Communities, is a good basis for the harmonisation of the rules on notification and registration of recombinant DNA work ;

Convinced that this result should be extended to all the member states of the Council of Europe,

Recommends that the governments of the member states, if they have not yet done so :

a. adopt, by the means they consider appropriate, a system of notification in accordance with the principles contained in the appendix to the present recommendation ;

b. provide, in order to safeguard scientific and industrial secrecy and to protect intellectual property, that each notification, its contents and accompanying documents shall be kept confidential unless the notifying laboratory agrees otherwise.

Appendix

The following principles apply to work involving recombinant DNA which may present a biohazard of a category which will be determined by each state. The use of recombinant DNA techniques for transfer into human subjects shall be dealt with by specific provisions.

I

Any laboratory wishing to undertake, in the territory of a member state, work involving recombinant DNA notifies the competent national or regional authority.

II

Such notification is given, for each of the research projects envisaged, before the date on which it is begun or, where the competent authorities so decide and in the case of work falling within a category of very low risk potential, if possible within six months and not later than twelve months after the date on which the project is begun.

III

Such notification is accompanied, for each of the projects which is subject to prior notification, by the following documents :

— the portion of the experimental protocol which is required for the evaluation of safety at the site where the proposed activities are to be carried out,

— a list of the protective and supervisory measures to be applied throughout the duration of the experimental work,

— a description of the general education in recombinant DNA research and of the training received by the members of the team which will participate in the proposed activities or will be responsible for supervision, monitoring or safety.

IV

Each notification and the accompanying documents are classified and stored by the national authorities or regional authorities for safety and health protection to which they have been submitted.

V

Each notification and its accompanying documents may be consulted by national experts authorised to that effect by the national authorities.

VI

Work involving recombinant DNA is defined as the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

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