COMMISSION OF THE EUROPEAN COMMUNITIES

COM(80) 467 final

Brussels, 28 July 1980

4412.381 - text
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O.J. C 314/80

DRAFT COUNCIL RECOMMENDATION

concerning the registration of

recombinant DNA (desoxyribonucleic acid) work

(submitted to the Council by the Commission)

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REASONS FOR PROPOSAL

I. INTRODUCTION

An analysis of the current situation and of results of work accomplished in the course of the last two years, in the United States as well as in Europe, to evaluate the importance of the dangers resulting from genetic engineering, has shown that the conjectural risks associated with the work involving the production or utilization of recombinant DNA are probaly non-existent or small.

It is apparent, moreover, that the voluntary measures of control and safety, such as have been recommended to research workers in the majority of western countries, function in a satisfactory manner, without excessive bureaucracy and in a way which allows continual adaptation in view of the rapid progress in knowledge and techniques in the area of fundamental and applied biology. It has been ascertained ultimately that national recommendations for the classification of work according to risk categories and safety measures do not radically differ from one Member State to another and indeed tend to converge to a certain uniformity.

However, certain questions can be raised concerning effects in the long term of possible contamination, which, although unlikely, remains possible. It is therefore highly desirable that a precise

inventory is at all times and everywhere available to allow the possible imposition of preventive measures of protection as well as to allow the origin of any contamination to be traced. It is nevertheless advisable in order to do this that each Member State be free to adopt adequate legislative regulatory or administrative measures and that national or regional authorities be entrusted with its execution.

Lastly, the adoption of a common definition of work involving recombinant DNA will help to facilitate a dialogue between Member States in order to pursue gradually a harmonisation of national dispositions.

II. NATURE AND OBJECT OF THE DRAFT RECOMMENDATION

The draft recommendation proposed by the Commission to the Council asks Member States to adopt a common definition of work involving recombinant DNA and to act in such a way that no laboratory can undertake this work without having previously notified the competent regional or national authority and deposited with them information defining the nature of the activity envisaged and which allows evaluation of the planned conditions of safety and protection in the execution of this activity.

The Commission deems, in taking account of present knowledge on the weak gravity of risk and on its purely conjectural nature, that this recommendation to Member States is both necessary and sufficient.

It is necessary because no experimental analysis has been able to be made on long term effects which work on genetic engineering could have on the adaptation and gradual evolution of microorganisms, carriers of foreign DNA. Microorganisms might be able to succeed in crossing laboratory barriers and to find a habitat in which to survive. The risk is small and unlikely since all the work carried out up to now shows that cells into which recombinant DNA has been transferred have a lower capacity for survival in natural conditions and that their infectivity, in the case of transfer undertaken with pathogenic microorganisms, is generally reduced. Nevertheless, it is desirable in the unlikely case of an unforeseen contamination that the Member States can have available at all times a precise inventory to enable the origin of contamination to be traced.

The draft Commission recommendation is considered sufficient since all data collected in the course of the last two years shows that the safety problem posed by genetic engineering is low and does not justify the adoption of detailed legislation of which the principal effect would be to slow down the development of research and prevent the adaptation and the continuous evolution of protection methods and the classification of work according to risk categories. In particular, three types of information, gathered in the course of the last two years, justifies the Commission in taking this position.

- the negative results of analyses undertaken in the USA and in Europe to establish the reality of certain risks which could result from genetic engineering;
- the absence, even though a great amount of work in genetic engineering has been conducted throughout the world, of a single case of contamination or accidental infection;
- the discipline of all european research workers who have immediately agreed to follow the safety and protection measures proposed by the consultative committees which have been created in each Member State to define and focus a national policy on the matter.

It is on the basis of these observations that the Commission has decided, after consultation of national experts nominated by the Committee for Research in Medicine and Public Health (CRM) and of representatives of the European Science Foundation (ESF) and of the European Molecular Biology Organization (EMBO), to present to the Council the present draft recommendation which replaces the draft directive submitted to the Council on 4th December 1978, justified at that time by the preoccupations and uncertainties on the gravity of risks linked with certain activities in genetic engineering.

III. ANALYSIS, REVISION AND ADAPTATION OF NATIONAL AND COMMUNITY GUIDELINES.

The state of knowledge, research techniques and methods of risk evaluation have evolved considerably during the last few years and will continue to progress in the future.

The Commission will follow closely problems related to work in genetic engineering and will take, if circumstances require it, all necessary and useful measures to maintain or reinforce arrangements for safety and risk evaluation in the Community of Member States. To this end, experts, mandated by Member States, will meet at regular intervals and at least once a year, under the aegis of the Commission to :

- undertake a general analysis of the situation in the Member States with regard to the production and utilization of recombinant DNA,

- examine all measures as elaborate as required, leading to harmonization,

- establish, should the case arise, according to progress in knowledge, the list of work which, in all Member States, should be forbidden or subject to compulsory safety measures,

- in the case where unforeseen developments require it, modify the terms of the present recommendation or prepare the text for a draft Council directive.

— Council Decision 77/804/EEC of 20 December 1977 concerning European Social Fund aid for women (1)

expiring on 31 December 1980;

Whereas the imbalance of employment within the Community has made apparent the necessity to follow joint specific action for people employed in the textile and clothing sectors, migrant workers and their families, persons affected by employment difficulties (young people under 25) and women,

DECIDED:

Article 1

1. In Article 5 of Council Decision 75/459/EEC the date 1 January 1981 is replaced by 1 January 1983

2. In Article 3 of Council Decision 76/206/EEC the date 1 January 1981 is replaced by 1 January 1983

3. In Article 4 line 2 of the Council Decision 77/803/EEC the date 1 January 1981 is replaced by 1 January 1983

4. In Article 3 line 2 of the Council Decision 77/804/EEC the date 1 January 1981 is replaced by 1 January 1983.

Article 2

This Decision is to be published in the *Official Journal of the European Communities* and shall enter into force on 1 January 1981.

(1) OJ No L 337, 27. 12. 1977, p. 14.

Draft Council Recommendation concerning the registration of recombinant DNA (desoxyribonucleic acid) work

(Submitted by the Commission to the Council on 4 August 1980)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the draft Recommendation submitted by the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas the development of fundamental and applied biological research is such as to contribute to the economic expansion of the Member States, and whereas this implies, in several sectors, that recombinant DNA work will be performed on certain organisms;

Whereas the risks associated with work involving recombinant DNA are of a conjectural nature; whereas a permanent inventory within each Member State is necessary to allow the possible imposition of protection measures and, in the very unlikely event of conjectural hazards proving real, to trade the origin of any deleterious effects that may arise;

Whereas a continual analysis of the situation in each Member State must be undertaken in order to promote progressively the harmonization of national provisions and, in the case where unforeseen

developments require it, to establish lists of work which ought to be banned or subjected to compulsory safety measures in all Community countries;

Considering the complexity of the problem posed by the conjectural risks of certain type of work involving recombinant DNA, the rapid developments in the understanding of this problem, the extension of the research sector concerned and the importance that must be attached to the consideration of local circumstances when assessing the hazards involved in performing scientific work;

Whereas it is necessary, in order to safeguard scientific and industrial secrecy and to protect intellectual property, to minimize the dissemination of the terms of experimental protocols prepared for the execution of the work as well as the dissemination of the substance of research projects based on the production and utilization of recombinant DNA;

HEREBY RECOMMENDS TO THE MEMBER STATES:

that they adopt the laws, regulations and administrative provisions in order that:

Notification by laboratories

1. Any laboratory wishing to undertake, in the territory of a Member State, work involving recombinant DNA notifies the competent national or regional authority;

Supplementary information

2. Such notification is accompanied, for each of the research projects envisaged, 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 staff who will participate in the proposed activities or will be responsible for supervision, monitoring or safety;

Classification of files

3. 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;

Consultation of files

4. Each notification and its accompanying documents may be consulted by authorized national experts;

Definition of work involving recombinant DNA

5. Work involving recombinant DNA is defined as the formation of new combinations of heritable 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.