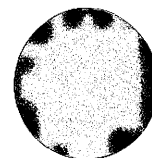


Brussels, 24 February 1982



127/82

4412.221

Note on Community action and national legislation  
concerning recombinant DNA work

I. Introduction

When it was suddenly realized at the beginning of the 1970's what extraordinary possibilities were opening up through the practical application of new genetic, biochemical and molecular biological knowledge, scientists and (informed members of) the public alike were taken by surprise. As a result, genetic engineering was considered by some sectors of popular opinion as a great break-through and condemned as a lethal threat by others.

Initial experiments with the new technology and intensive discussions within the world of science and between scientists and members of the public have reduced both expectations and fears to a reasonable level. Genetic engineering promises many new discoveries and may help solve many medical and biological problems; initial applications are already being made in the medical and industrial fields.

There is more awareness of the safety issues involved and many largely practical proposals to increase safety are being made.

Genetic engineering makes it possible to combine genetic information from different sources into new viable units. In this way the genetic information of an organism can be expanded either at random or for a specific purpose. Host organism can thus acquire new capabilities or characteristics. If these are characteristics that turn harmless organism into pathogens or cause undesirable changes in our environment through whatever mechanism, then man and his environment can be endangered if organisms escape to the environment.

These factors led in 1973/74 to voluntary restrictions in the application of this technology by scientists and to the issue of national rules for recombinant DNA work.

The conceivable or conjectural risk of genetic engineering range from a danger to the experimenter or other parties to a life-threatening change in the environment.

On the basis of an analysis of special experiments to assess the risks and a re-evaluation of longstanding experience and knowledge, the actual risks are today considered to be very slight. While it was initially assumed that practically all DNA introduced at random by genetic engineering would lead to a change in the characteristics of the host organism, the numerous genetic engineering experiments carried out so far have shown that this in fact happens in very few cases only.

## II National safety measures

The development of recombinant DNA techniques has caused intense public and scientific debate in many countries which involved such issue as the definition of the field covered by recombinant work, the classification of this work in categories of risks and in levels of containment, the necessity for state control, the type of control (voluntary or statutory) to be involved and the protection of intellectual property.

The present situation in different countries, both inside and outside the Community, in respect of the regulation of these activities is extremely diversified but essentially is contained between two poles : one represented by some form of self-regulation by the researchers themselves on the basis of an agreed code, and the other which exists in those countries where ad hoc legislation has been introduced laying down certain rules and corresponding administrative and penal sanctions for their infringement.

In the USA, the National Institute of Health (NIH) released very detailed guidelines providing an accurate classification of research activities in categories of risks and of assigned containment levels. Only the laboratories sponsored by the NIH are compelled to follow these guidelines, which have recently been revised and made less stringent. Guidelines somewhat similar to those of the NIH have been prepared or are in preparation, outside the Community, in all countries with advanced technologies but, as yet, no compulsory order have been issued on the matter in these countries.

Within the European Community, the United Kingdom has rendered compulsory advance notification of genetic manipulation work by all those who intend to carry out such work on the national territory. A code of practice, which differs from that of the NIH on essential points dealing with classification procedures and containment methods, is at the moment operated under a voluntary basis but with the understanding that the inspectors of the Health and Safety executive have extensive powers to enforce duties as well as precautions recommended by the British Advisory Group.

The other Member States have also prepared or adopted guidelines to research with recombinant DNA which in some cases adhere to either the British or the American system and in others represent a compromise between the two sets of guidelines.

In France, the Netherlands, Denmark and Belgium, the National Advisory Committees have been assigned the task to register the work at hand and to review research proposals. While a declaration of agreement has been drafted in France under which governmental, academic and industrial laboratories will submit to review and approval any project for recombinant DNA work, only two Member States (the Federal Republic of Germany and the Netherlands) have, in addition to the United Kingdom, clearly indicated an intention to introduce regulations on recombinant DNA research. In Germany, the compulsory orders will first be restricted to research financed by national funds; at a later stage, they will be extended to activities supported by the "Länder" and by private sources.

The elaboration or adoption of guidelines in the Member States and in other European countries has been greatly facilitated by the critical reviews and recommendations which were issued by the ad hoc committee on recombinant DNA research of the European Science Foundation and by the Standing Committee of E.M.B.O. (European Molecular Biology Organisation) on recombinant DNA.

### III UK recent developments

The above-mentioned compulsory notification of the Health and Safety Executive and the Genetic Manipulation Advisory Group is contained in Health and Safety (Genetic Manipulation) Regulations from 1978. However, this regulation has been extensively modified by administrative action (by the Health and Safety Executive) due to changing circumstances.

It is now only the "upper-level" risk experiments which have to be notified to the Health and Safety Executive. "Lower" risk experiments may be notified up to 12 months in arrears. For these no approval is necessary. For the "upper-level" risk experiments there is an administrative understanding that research will not proceed prior to approval.

What is now of concern is not the research itself, but rather the use made of the products. That is, it is the industrial scale-up which is the concern. This is not subject to any national legislation, as it is not genetic engineering as defined by the statute.

Thus, British legislation, rather than increasing the number of restrictions, is reducing the number of areas where notification is required and approval necessary. British Health and Safety Executive has moved away from the control of all genetic engineering since introduction of regulations in 1978. Moreover, regarding the proposed control of the use made of the products of research (i.e. industrial scale-up) its view is that "it would rather not have its hands tied, but wait and see what develops".

### IV Community action

On the basis of the knowledge of that time about the risks and possibilities concerning the new technology the Commission in December 1978 drew up a "proposal for a Council Directive establishing safety measures against the conjectural risks associated with recombinant DNA work" basing itself on six main considerations, which underline the necessity of a national legislation in this field :

- Harmony between Member States
- The exemplary value of legislation on recombinant DNA technology
- Gravity of the hazards
- Expansion of the new techniques
- Transnational nature of the risk
- Research in laboratories of private undertakings

While stipulating that recombinant DNA considered to be associated to conjectural hazards cannot be performed if it is not first registered and authorized by the National Authority, the proposed directive leaves entire liberty to this National Authority in each Member State to establish the categorization and containment levels which it deems most appropriate. Special provision is taken for work tabulated as low risk and attempts are made to reduce at a minimum the amount of scientific information which is to be disclosed for registration and authorization purposes. Finally, full reference is made in the text of the directive to the fact that the terms of the present orders will have to be reviewed regularly at short intervals and revised, when necessary, at the light of new developments and scientific progress. In addition, the Commission intended to study the special case, covered at that moment by the terms of the directive, which concerns the use of recombinant DNA material for large scale industry production; if necessary, the Commission would propose additional directives adapted to such case.

The European Parliament was consulted by the Council on the proposal in April 1979.

A report was drafted on 14 April 1980 by the Committee on the Environment, Public Health and Consumer Protection basically approving the directive.

The Economic and Social Committee adopted unanimously an opinion for the issuing of a Directive.

"Taking account of present knowledge on the weak gravity of risk and on its purely conjectural nature" the Commission deemed in July 1980 that a recommendation to Member States instead of a Directive is both necessary and sufficient. It therefore, on 28 July 1980, put forward a "Draft Council Recommendation concerning the registration of recombinant DNA work" which replaces the above-mentioned Draft Directive.

Unlike a Directive a Recommendation shall have no binding force, cfr. Art. 189, 5, of the EEC-Treaty.

The Economic and Social Committee and the European Parliament have been consulted on the proposal.

As the culmination of lengthy preparatory work, including a hearing organized in the form of a colloquy which took place on 14 and 15 May 1981, the ESC adopted a final position on recombinant DNA work in December 1981. Though the risks are now regarded as being small, the Committee still considers the following points to be essential :

- continued priority to be given to risk assessment studies
- training in microbiological safety
- maintenance of safety standards geared to the safety needs of the general public
- harmonization of national provisions in order to ensure fair competition and equal safety in all Member States.

The Committee has concluded that for genetic research it is necessary to have a Community legal instrument in the form of a Directive covering all the above points. (It should be noted that the industrial scale-up aspect is not included.)

The European Parliament's Committee on the Environment, Public Health and Consumer Protection voted to approve the Commission's proposal for a draft recommendation at its meeting on 9-10 November 1981.

A suggestion in the report by Domenico Ceravolo (It, COM) that the Commission go back to the idea of a Directive on this matter was rejected when the Committee adopted, by a narrow margin (9 to 8) an amendment tabled by Mrs Lentz-Cornette (Lux, EPP).

The above report was discussed in Plenary on 18 February 1982. The Commission's proposal being approved through an adoption of the report the proposal is now pending before the Council. The next Environmental Council will take place in June 1982.

