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DOCUMENT 1-810/81

REPORT

Drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the proposal from the Commission of the European Communities to the Council (Doc. 1-448/80) for a draft recommendation concerning the registration of work invclving recombinant desoxyribonucleic acid (DNA)

Rapporteur: Mr D. CERAVOLO

PE 74.522/fin.

English Edition

By letter of 26 September 1980 the President of the Council requested the European Parliament to deliver an opinion on the recommendation concerning the registration of work involving recombinant desoxyribonucleic acid (DNA).

The President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection on 13 October 1980.

On 26 September 1980 the Committee on the Environment, Public Health and Consumer Protection appointed Mr Ceravolo rapporteur. It considered the proposal for a recommendation at its meetings of 5 December 1980, 20 October 1981 and 10 November 1981. At the last of these meetings the motion for a resolution drawn up by Mr Ceravolo was discussed and rejected following adoption of the amendment tabled by Mrs Lentz-Cornette (PE 74.522/Am.1). The amendment was adopted by the committee by 9 votes to 8.

Present: Mr Collins, chairman; Mrs Weber, vice-chairman; Mr Ceravolo, rapporteur; Mr Bombard, Mr Clinton (deputizing for Mr Mertens), Mr Combe, Mr Ghergo, Miss Hooper, Mr Key (deputizing for Mr Muntingh), Mrs Lentz-Cornette, Mr Protopapadakis, Mrs Pruvot, Mrs Schleicher, Mrs Scrivener, Mrs Seibel-Emmerling, Mr Sherlock and Mrs Squarcialupi.

C O N T E N T S

A

The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following motion for a resolution together with explanatory statement:

MOTION FOR A RESOLUTION

embodying the opinion of the European Parliament on the proposal from the Commission of the European Communities to the Council for a draft recommendation concerning the registration of work involving recombinant desoxyribonucleic acid (DNA)

The European Parliament,

- having regard to the draft recommendation concerning the registration of work involving recombinant desoxyribonucleic acid (DNA),

- having been consulted by the Council (Doc. 1-448/80),

- having regard to the report of the Committee on the Environment, Public Health and Consumer Protection (Doc. 1-810/81),

Approves the draft recommendation proposed by the Commission of the European Communities.

B

EXPLANATORY STATEMENT

1. Background

As early as 4 December 1978, the Commission submitted a proposal for a directive establishing safety measures against the conjectural risks associated with recombinant DNA work (Doc. 55/79). This document set out 'six different sets of considerations' indicating the need for national laws to control the activity of genetic manipulation:

1.1. Harmonization between the Member States

In view of the different containment systems existing in Europe, it is necessary, in order to avoid wide discrepancies between research capacity and thus competitiveness, to adopt national laws harmonized around a core of Community principles.

1.2. The exemplary value of legislation on genetic manipulation technology

In the long term, the applications of molecular biology in agriculture and industry will inevitable transform life in society and will induce significant and, possible, irreversible changes to our environment. To request that the techniques which are to bring about these changes should be subjected, from the start, to statutory control and to legislation, does not constitute a curb on progress but recognition of the need to adapt society to new scientific developments.

The activity of genetic manipulation, even though the risk it represents is only conjectural has been well analysed in the Member States and is possibly not greater than the dangers associated with conventional research into pathogens, constitutes an exemplary field for testing compatibilities between legislation and the development of modern technologies.

1.3. Gravity of the hazards

The classification of a risk as conjectural does not imply that the risk under consideration is benign.

If the gravity of the dangers involved is such as to require the elaboration of expensive protection mechanisms, it must also be logical to draw up regulations to ensure their effective use as protection against the risks in question.

1.4. Expansion of recombinant DNA work

Assuming that a risk exists in connection with recombinant DNA, it will increase with time in proportion to the total number of sites where such work is carried on.

1.5. Transnational nature of the risk

The fact that genetic engineering work usually involves bacteria and viruses, which, in the event of their escaping from the laboratory, may spread across frontiers, limits the legislative independence of the individual states.

The agreements and guarantees to be established between neighbouring states must be based on a core of jointly agreed principles.

1.6. Research in laboratories of private undertakings

In the absence of legal measures, it is extremely difficult to compel laboratories in private industry to adhere to national guidelines on recombinant DNA. It may happen that different laboratories working at the same level of risk do not observe the same rules in respect of safeguards and containment. (In the interests of brevity the rapporteur has confined himself to reproducing and often quoting the main points of the former proposal for a directive which was subsequently withdrawn. As regards remaining points, he would refer the committee to the full text.)

2. As regards this proposal for a directive, the Economic and Social Committee, after undertaking a balanced analysis of both sides of the argument, unanimously declared itself in favour of a directive. Moreover, the Economic and Social Committee, in order to take account of all the available information, and not to create excessive barriers to research or neglect the protection of the citizens of the Member States, had also decided to prepare a study to deal, in particular, with the following problems: the extent to which specific physical (e.g. particular laboratory equipment) and biological (e.g. selected vectors and receivers) safety standards are adequate in the light of presumed risks, the importance of the establishment by the Member States of a uniform position on these questions, particularly as regards the industrial application of this new technolgoy; the need to harmonize provisions in force at national level which is particularly important in cases where, as in the area under consideration, the legal force and substance of such provisions diverge. Such disparities may make themselves felt particularly at the industrial application stage.

On the basis of this study, the Economic and Social Committee organized a seminar in May 1981 to consult experts from the world of science, agriculture, industry, the trade unions and representatives of the public interest.

3. Seminar held by the Economic and Social Committee

It cannot be said that the discussion led to unanimous conclusions, though it was of considerable interest. In particular, as regards the basic premise of the Commission's draft recommendation that, in the light of past experience, possible risks should be considered 'non-existent or small', certain statements contain views which clearly leave the matter open to doubt:

3.1. Brian M. Richards: while maintaining that few scientists now consider the initial fears to be justified, stated that there was still a certain amount of concern at the fact that appropriate criteria for assessing conjectural dangers had not yet been formulated.

3.2. Professor P. Puglisi: considered that two factors should be considered above all others, namely the need to prevent the introduction of excessively restrictive standards for the structure of laboratories which might restrict research possibilities to given industrial activities; and the possibility that, if all the necessary ingredients for pursuing DNA technology were sold freely, uncontrollable and uncontrolled experiment might be carried out.

3.3. William Bruce: whereas he accepted, in the case of laboratories undertaking work falling within risk level groups 1 and 2, the principle of control by safety committees which required only the notification of experiments, in respect of those falling withn risk categories 3 and 4, given the complexity of measures and the higher standards required, highly qualified national teams should keep the work under review.

4. In order to demonstrate further that what your rapporteur considers the central question, namely that of conjectural risks, remains unanswered, he has recorded below certain extracts from an interview with Professor Sgaramella, lecturer in molecular biology at the university of Pavia and well-known expert in genetic engineering, who, although not one of the rapporteurs, has

perhaps been the highest authority most active in playing down supposed dangers and fears.

The interview appeared shortly before the seminar in the April 1981 edition of 'Scienza e vita'.

Question: 'What could be the consequences of this lack of precise directives which affects all laboratories?'

Reply: 'There is a danger that foreign colleagues might undertake work in Italy which they could not do abroad. For example, if someone wished to clone the B hepatitis virus, which is notoriously dangerous, the decision whether or not to allow the experiment to take place in a given laboratory would be left exclusively to the discretion of the director of the institute concerned.

Question: 'What justifies the general tendency in the world today to relax certain safety standards governing genetic engineering?'

Reply: 'Our knowledge of the micro-organisms which we are dealing with is much greater today than it was some years ago. We now know that certain hypotheses suggestive of science fiction that were once put forward are unlikely to be fulfilled. It is important to observe certain precautions, for example, such as not using the DNA of vectors of viral illnesses. That does not mean, however, that the chance propagation of dangerous agents such as unknown or oncogenic viruses may not occur.

5. Further considerations

5.1. Claims as to the virtual certainty of the harmlessness of the experimental practices adopted hitherto are based on the considerable experience gained with the bacteria Escherichia coli, the most common microbic agent used in genetic engineering. This information would now appear incomplete, as we know today that certain other less well-known microbic agents are being used.

5.2. A recent report from Washington states that genetic engineering techniques have made possible the creation of a new bacteria capable of destroying di oxin gas (well-known following the Seveso tragedy and its use by the Americans in Vietname for 'defoliation' purposes). This micro-organism apparently belongs to the Pseudomonas genus.

5.3. The same genus contains the micro-organism created some years ago by General Electric which is able to feed itself on hydrocarbons and can thus be used in operations to eliminate sea pollution following oil spills.

5.4 It is worth pointing out that, after all the initial enthusiasm, everything has remained blocked, despite the granting of the patent, owing to the possible risk that such a micro-organism might spread in an uncontrolled manner, for example in the fuel tanks of planes.

5.5. A further point to consider is the use of DNA originating from tumoral viruses. It should be remembered that any oncogenic consequences for human begins as a result of these experiments, which are already being carried out, will come to light only after several years, when the damage may prove irreversible.

5.6. In addition, genetic engineering is not an exact technique. Even today, genes are never transplanted in their pure state. The transplant of genes is usually accompanied by unwanted fractions of other genes, which may represent as much as 20% of the total.

(In the interests of brevity, the general theme of genetic engineering will not be dealt with here; reference should be made to the draft report submitted previously on the Commission's proposal for a directive (See PE 64.494).

6. Submission of a draft recommendation

On 28 July 1980 the Commission submitted a draft recommendation concerning the registration of work involving recombinant desoxyribonucleic acid (DNA). The European Parliament was asked for its opinion on the new proposal on 26 September 1980. The draft recommendation replaced the proposal for a directive submitted earlier.

7. General observations on the draft recommendation
(rapporteur's views supported by a minority)

7.1. The draft recommendation is based on the assumption that, in the light of the information acquired, 'the conjectural risks associated with the work involving the production or utilization of recombinant DNA are probably non-existent or small'.

In this connection, it should be recalled that the text of the preceding proposal for a directive, which was subsequently withdrawn, was based on a similar premise expressed as follows: 'the classification of a risk as conjectural does not imply that the risk under consideration is benign'. The entire approach of the directive avoided any tendency to entertain excessive fears or over-dramatization.

It is surprising that this reasoning, if valid a short time ago, should no longer be so today.

7.2. The recommendation maintains that control and safety measures applied voluntarily in most Western countries are satisfactory and can be continuously adapted to new developments. It would appear that this conviction may be based on information derived exclusively from laboratories operating in the public sector.

The preceding directive contains the following text: 'While it is possible to conceive, in the absence of national legislations regulating work with recombinant DNA, that the governmental funding agencies maintain a certain level of control over these research activities of universities and national institutes, it is far more difficult to envisage, in the absence of legal dispositions, a system compelling the laboratories from private industries to adhere to the terms of national guidelines on recombinant DNA'.

This consideration would seem self-evident and the rapporteur fails to see why today it should be abandoned.

7.3. The recommendation maintains that certain problems may arise as regards the long-term effects of possible contamination which, although improbable, nevertheless remains a possibility. In this connection, the recommendation adds that '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 micro-organisms, carriers of foreign DNA. Micro-organisms might be able to succeed in crossing laboratory barriers and to find a habitat in which to survive.'

It is hard to understand, faced with a risk about which there is so little knowledge, and which cannot therefore be described as 'non-existent or small', why the recommendation confines itself to providing for a system of inventorizing work undertaken with a view to being able to trace the origin of contamination and hence acting after the event.

7.4. The recommendation states that 'each Member State (must) be free to adopt adequate legislative, regulatory or administrative measures'.

Whereas in the preceding directive priority was given to the need to harmonize legislation at Community level in order to avoid distortions of competition, the recommendation has simply reversed this position.

7.5. The recommendation '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 to 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'.

If the intention is truly to achieve this result, a suitable legislative instrument is required that provides for adequate control measures. If there is an effective case for it, it should not be the subject of a mere recommendation.

It is maintained that the recommendation is justified by the negative results of analyses undertaken in the USA and Europe to establish the significance of dangers which might result from genetic engineering. Generally speaking, reference is made to numerous experiments carried out at the higher level (III and IV) and the recommendation omits to mention, in particular, information on the closed world of private laboratories.

7.6. It is also maintained that the draft recommendation makes adequate provision for the safety problems encountered hitherto, and that the principal effect of a solution through the adoption of detailed legislation would be to slow down the development of research and prevent the adaptation and the continuous evolution of protection methods and the classificaton of work according to risk categories. But the Commission itself, in the preceding directive, stated that 'to request that the techniques which are to bring these changes (. . . significant and possibly irreversible changes to our environment) are subjected from the start to statutory control and to legislation does not constitute an aggression to progress but, on the contrary, a recognition of the need to adapt society to new scientific developments . . . for establishing compatibilities between legislation and the development of modern technologies . . . to protect man against his own achievements . . . .

Provided that the legislation adopted is tolerant, flexible, and associated to a stimulation of research through funding, the opportunity should not be missed'.

If it were true that legislation had the effect of slowing down research, then environmental strategy as a whole would have to be reversed, starting with that devised for new chemical products to be placed on the market, in respect of which the adoption of an 'identity card' is planned in order to prevent the uncontrolled distribution of substances dangerous both for the environment and for hum an health, as has occurred in the past and still occurs today.

7.7. The draft recommendation has been given a threefold justification:

(a) the negative results of the analyses undertaken in the USA and Europe to establish the reality of certain risks;

(b) the absence of even minor cases of contamination or accidental infection, even though a great amount of work has been carried out throughout the world;

(c) the discipline of all European research workers who have immediately agreed to follow, on a purely voluntary basis, the protection and safety measures proposed by the consultative committees.

These justifications are not convincing. In respect of certain risks, for example, those connected with long-term effects, the Commission itself has stated (see above) that 'it is not possible to undertake an experimental analysis'. Furthermore, no mention has been made of the fact that genetic engineering has only just got underway and a vast and unknown field of experimentation, which may, however, be defined theoretically, has yet to be covered, with all the possible advantages and dangers which may arise.

Sound legislation should precisely be formulated to allow for possible subsequent developments.

As regards points (a) and (b), it would seem extremely hazardous for the Commission to make generalizations on the basis of information which excludes all private research.

7.8. Finally, the Commission states that 'certain' experts - without defining them further - appointed by the Member States will meet at regular intervals to:
- undertake a general analysis of the situation;
- examine all possible measures 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 cases where unforeseen developments require it, modify the terms of the present recommendation or prepare the text for a draft Council directive.

The best that can be said of this commitment on the part of the Commission is that it reveals an awareness of the difficulties involved in solving the problems at issue by means of a mere recommendation. In reality, however, the tackling of long-standing problems, such as the list of dangerous experiments which are already subject in various Member States to certain controls or prohibitions, has been postponed.

And on what basis can an analysis be made of the situation if, as seems likely, a mere recommendation fails to provide the expected and desired results, and if the greater part of research, namely private research, remains outside the scope of effective control?

8. The rapporteur's viewpoint was supported only by a minority in the committee. The majority view was that, on the basis of the considerations outlined by the Commission and in the light of data that had become available in the past two years, the draft recommendation, as submitted by the Commission of the European Communities to the Council, should be approved.