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DOCUMENT 1-521/80

Report

drawn up on behalf of the Committee on Energy and Research

on the proposal from the Commission of the European Communities to the Council (Doc. 1-750/79) for a multiannual Community programme of research and development in biomolecular engineering (indirect action 1981-1985)

Rapporteur: Mr G. SCHMID

English Edition

PE 65.864/fin.

By letter of 12 February 1980 the Council of the European Communities requested the European Parliament to deliver an opinion on the proposal from the Commission of the European Communities to the Council (Doc. 1-750/79) for a multiannual Community programme of research and development in biomolecular engineering (indirect action 1981-1985).

The President of the European Parliament referred this proposal to the Committee on Energy and Research as the committee responsible, and to the Committee on Budgets, the Committee on Economic and Monetary Affairs and the Committee on the Environment, Public Health and Consumer Protection for their opinions.

On 21 February 1980 the Committee on Energy and Research appointed Mr Schmid rapporteur.

It considered the report at its meeting of 23 September 1980 and adopted the motion for a resolution unanimously.

Present: Mrs Walz, chairman; Mr Gallagher, Mr Ippolito and Mr Normanton, vice-chairmen; Mr Schmid, rapporteur; Mr Adam, Mr Beazley, Mrs Bonino, Mr Calvez (deputizing for Mr Pintat), Mr Croux, Mrs Dekker (deputizing for Mr Capanna), Mr Hoffmann (deputizing for Mr Fuchs), Mr Kellett-Bowman (deputizing for Mr Seligman), Mr Linkohr, Mr Moreland (deputizing for Sir Peter Vanneck), Mr Müller-Hermann, Mr Price, Mr Purvis, Mr Rinsche, Mr Sälzer, Mr Sassano and Mr Veronesi.

The opinions of the Committee on Budgets, the Committee on the Environment, Public Health and Consumer Protection and the Committee on Economic and Monetary Affairs are attached.

C O N T E N T S

The Committee on Energy and Research 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 multiannual Community programme of research and development in biomolecular engineering (indirect action 1981-1985)

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council (COM(79) 793 final),
- having been consulted by the Council (Doc. 1-750/79),
- having regard to the opinion of the Economic and Social Committee (CES 655/80)[1],
- having regard to the report by Mr N. BALFOUR on the communication from the Commission to the Council concerning convergence and budgetary questions (Doc. 1-136/80),
- having regard to the draft Council recommendation concerning the registration of recombinant DNA (deoxyribonucleic acid) work (Doc. 1-448/80),
- having regard to the report of the Committee on Energy and Research and the opinions of the Committee on Budgets, the Committee on the Environment, Public Health and Consumer Protection and the Committee on Economic and Monetary Affairs (Doc. 1-521/80),

1. Recognizes the possible value of the application of molecular biology in industry and agriculture but draws attention to the conjectural risks of genetic engineering;
2. Recognizes that increased research in this field brings closer the possibility of manipulating human genes and demands an early discussion of the consequences thereof;

[1] OJ No. C 230, 8.9.1980, p.11

3. Considers that it would be useful to have a Community research programme in the field of biotechnology as an indirect action with a view to:

   - the future position of Europe on the world market,
   - closing the gap between the varying levels of economic development in the Member States of the Community,
   - the contribution of a research programme to the harmonization of safety guidelines for recombinant DNA work,
   - the social demand for the medical application of biotechnology;

4. Demands however that by 1983 the Commission should clearly establish the economic and social demand and the social effects of the increased use of biotechnology;

5. Calls on the Commission to tighten up the programme, define clear goals and in so doing ensure:

   (a) that no projects are selected which have already been the subject of intensive work in the USA or Japan in order to avoid unnecessary duplication of work,

   (b) that practical projects are selected aimed at:

      - lowering production costs in agriculture,
      - lowering energy consumption in the chemical industry,
      - solving environmental problems,
      - solving medical problems,
      - using agricultural waste products,
      - the biological exploitation of solar energy,
      - more basic research to assess the safety problems raised by work with recombinant DNA and particularly with regard to its practical applications;

6. Demands that only one third of the members of the advisory committee should be appointed by the governments of the Member States with two thirds being appointed by the Commission;

7. Stresses that the advisory committee must include highly qualified scientists in order to guarantee a critical choice;

8. Expects the Commission in implementing the programme to:

   - publish invitations to tender for the projects not only in the Official Journal but also in technical publications,

- put the research units together in such a way that the proportion of scientists to technicians corresponds to conditions prevailing in practice,
- provide finance also for materials (chemicals, etc.),
- pursue a prudent information policy having regard to the aims of the programme and the competitive situation both on the world market and within Europe,
- carry out strict and continuous programme monitoring with the participation of scientific experts,
- link the provision of funds to the observance of the appropriate national safety guidelines when concluding contracts on research with recombinant DNA,
- demand observance of the strictest rule where the Member States' safety guidelines for certain experiments differ widely;

9. Demands that in negotiations for research contracts the Commission:

- shall not deviate from the principles laid down in Document XII-105/76 to the detriment of the Community,

- ensures that the Community has a say in the exploitation of patents,
- provides for the repayment of research costs where the contractor patents results obtained with Community money and the Commission does not wish to exercise influence over their exploitation;

10. States that three new A posts are necessary for the implementation of the programme and expects the remaining posts to be recruited from the staff;

11. Demands the opening of the conciliation procedure should the Council again intend to encroach upon the budgetary powers of the European Parliament by fixing appropriations and posts for the duration of the research programme in the text of the regulation and in the event of this legitimate request being ignored would find itself under certain circumstances compelled to freeze all the appropriations earmarked in the budget for this purpose;

12. Approves the Commission's proposal subject to these amendments.

B

Explanatory statement

I. Molecular biology and its possible uses

1. In the field of nuclear energy the essential implications and concepts are by now familiar to the layman. This is however not yet true of molecular biology and its technical application. If it is to be fully understood, the Commission's proposal for a research programme therefore requires some introduction.

2. It was unavoidable that the proposal itself should be formulated in technical language. But in future the Commission should in such cases automatically supply Parliament with a readable introduction. It is hard to see why Parliament should be treated worse than the press, which the Commission immediately provided with a more readily comprehensible description of the programme.

Biotechnology in the past

3. The principle of using the metabolism of microorganisms (bacteria, yeasts, moulds, etc.) to obtain useful products is well established. At a very early stage microorganisms were being used - although no one was aware of their existence - to make vinegar, beer, leavened bread, curdled milk products, cheese and alcohol. The breeding of better plant and animal varieties grew out of experience and in ignorance of the laws of heredity. Following Leeuwenhoek's discovery of microorganisms and after a first glimpse was gained in the mid-19th century of the metabolism of microorganisms, specific processes were devised for producing primary products and biomass by means of microorganisms, e.g. lactic acid, butanol, acetone, ethyl alcohol, citric acid, glycerin, nutritive and feeding yeasts. Mendel's discovery of the laws of heredity in 1865 permitted controlled breeding within the natural laws, which prevent transfers of genes between unlike species. The production of penicillin in the forties ushered in a new era. To make large quantities it was necessary to cultivate the mould free of foreign germs. The development of suitable processes for this purpose facilitated the production of many other antibiotics, other metabolic products and the isolation of enzymes on a large scale. The culture of improved varieties reached a further stage of development with the deliberate induction of genetic mutation (mutagenesis). This technique was used very successfully with microorganisms and in the last few years great strides forward have been made. The individual building blocks of the metabolic mechanisms, enzymes, can be isolated from the living cell, fixed on inanimate supports and in this way used in large-scale processes. The technique of genetic engineering, developed in 1973, permits

the combination of different kinds of genes across the natural barriers. This is the point of departure of the proposed research programme.

Basic principles of modern biotechnology

The following is a very brief summary of the more important concepts (underlined).

(a) Cells and molecules

4. Living organisms consist of cells. A living cell is composed of different inanimate molecules. The different classes of molecules have quite specific functions within the cell. But a cell is more than the mere sum of its components. Only the specific combination and arrangement of the molecules bring about the functions which characterize living organisms such as metabolism, the generation of energy and reproduction. Molecules can also perform their individual functions outside the combination that makes up the living cell.

(b) Enzymes and bioreactors

5. Most of the chemical reactions occurring in metabolism take place extremely slowly at normal temperatures and pressures in the absence of agents (catalysts) to speed up the reaction. In the living cell special protein molecules, the enzymes, increase reaction rates by a factor of 10,000 million and more. Enzymes are the most effective catalysts known to us. They act selectively, and in a mixture containing many possible reactants accelerate precisely one reaction. This property is most valuable in chemical processes.

Enzymes also retain their catalytic properties outside the living cell. They are isolated industrially from microorganisms (about 300 tonnes enzyme/year worldwide). An enzyme is unchanged by the chemical reaction which it catalyzes. Thus in principle it can be used over and over again. However, reactions take place in solution. Although it is theoretically possible to recover the enzyme from the solution, it is difficult and much too costly. One way of solving this problem is to bind the enzyme to a mechanical support such as cellulose or aluminium oxide (immobilization). When the reaction is over, the immobilized enzyme can then simply be removed from the solution together with the support. This method can be further refined if the reaction solution is pumped continuously past immobilized enzymes in a tank (bioreactor). The use of bioreactors substantially reduces the times required.

(c) Deoxyribonucleic acid (DNA) and protein synthesis

6. A living cell is a protein factory. It produces protein molecules by combining the components of proteins, i.e. the 20 different aminoacids in a particular sequence. The blueprint is contained in the molecule which carries the genetic information, deoxyribonucleic acid (DNA). DNA consists of a

backbone and four different DNA components, called bases, representing the genetic code. These are adenine (A), cytosine (C), guanine (G) and thymine (T). The bases are arranged along the DNA chain. A sequence of three bases in a row on the chain (base triplet) indicates a word in the genetic code. For example, the base triplet G-A-G stands for the aminoacid glutamate. Each word of the code stands for a particular aminoacid. The arrangement of the base triplets along the DNA chain thus determines the composition of a protein molecule. The genetic information contained in the DNA molecule is therefore translated in the cell into the protein structure, which by virtue of its quite specific form is able to perform its function, e.g. of an enzyme.

Because of its strategic importance for the cell, the genetic information is stored in a special way, in duplicate. However, two separate chains of a DNA double chain are not identical but complementary. Their relationship is one of lock and key.

The part of a DNA chain which encodes the composition of a protein is called the structural gene. In addition to the structural genes, DNA also carries operational orders, regulator genes which are also expressed in code by means of bases. The simplest of these orders are 'start' and 'stop'. But there are also more complex orders. They are necessary because the DNA of each cell contains all the information which may ever be needed. But only parts are needed at any one time. The regulator genes control which part of the information is read off when and 'expressed', i.e. translated into proteins.

The genetic code is universal. It is found in the cells of bacteria, algae, plants, animals and man. Thus a piece of foreign DNA introduced into a bacterium is reproduced by its metabolic mechanism when the bacterium reproduces by cell division. However, the regulator genes of bacteria are different from those of higher cells. For this reason animal DNA is not automatically expressed in bacteria. But there are processes by which these expression barriers can be overcome.

(d) Genetic manipulation and DNA recombination

7. Genetic manipulation means deliberate interference with genetic information, i.e. with the chemical composition of the DNA. Until a few years ago it was only possible basically to change the bases of a chain present in nature (mutation). For some time now, it has been possible to incorporate genes of one type of cell into the DNA of another type. The new genes are reproduced together with the host cells as part of their genetic information. Under certain conditions the foreign DNA may also be expressed, i.e. translated into proteins, in which case the host cell acquires new characteristics.

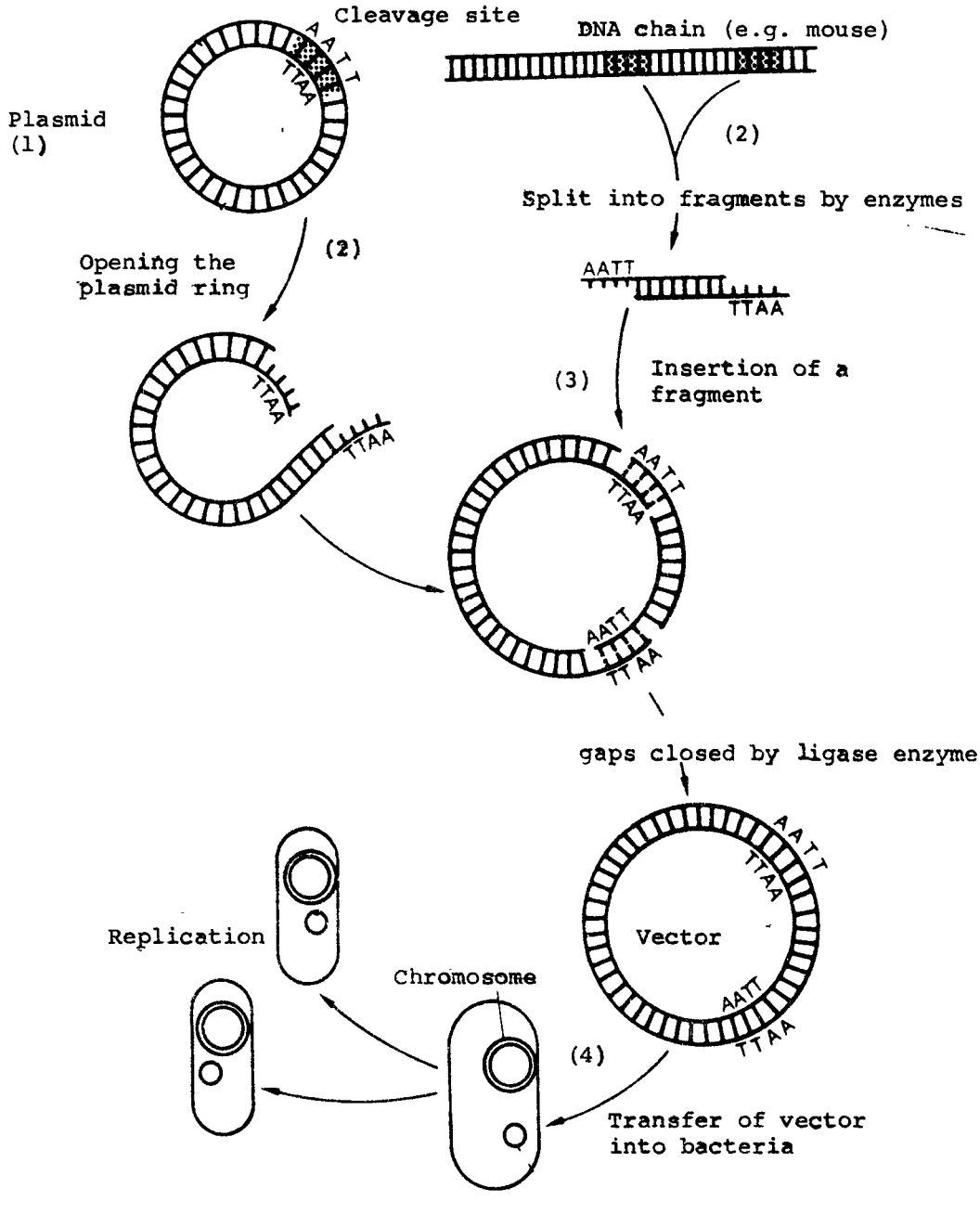


Figure 1: The process of gene transplantation (after Stanley N. Cohen, 'The Manipulation of Genes', Scientific American, July 1975, p.30.)

There are various methods for transferring genes to other cells. The method most frequently used for transfer into bacteria is briefly described below by way of introduction to genetic engineering and to the main principles of the technique. (See Fig. 1).

Phase 1:

8. The essential part of the genetic information in a bacterium is located in a large ring-shaped DNA molecule, the bacterial chromosome. Bacteria may also contain small DNA rings called plasmids. They carry special information such as resistance to antibiotics. Plasmids can be separated from the other cell components and isolated.

Phase 2:

9. Special restriction enzymes (of which there is a variety) cleave DNA molecules at specific sites. The enzyme recognizes these cleavage sites by specific base combinations. In the example illustrated, a cut is made after the base sequence TTAA (thymine-thymine-adenine-adenine). A plasmid generally contains only one cleavage site.
Restriction enzymes can be used not only to cleave plasmids of host cells. There are also cleavage sites along the chromosome of the cell from which genes are to be transferred. By skilful use of restriction enzymes individual genes can be cut out of the chromosome.

Phase 3:

10. The piece of DNA from the donor cell can be inserted into the segmented bacterial plasmid. Then the plasmid ring can be closed again in a further step. A plasmid which has been manipulated in this way is called a vector.

Phase 4:

11. The manipulated plasmid (vector) now containing the foreign DNA as an integral component can be infiltrated into the bacteria like a 'Trojan horse'. The whole process is referred to as 'cloning' the foreign gene into a bacterium cell. The plasmids are then reproduced with the bacterium and with them the foreign DNA. A colony of bacteria all containing the same fragments of foreign DNA is called a clone.

Application of molecular biology

12. In any discussion of the possible applications of molecular biology, a distinction has to be drawn between enzyme engineering and genetic engineering. Enzymes are already being used in industrial applications and their usefulness is therefore easier to define, whereas in the case of genetic engineering it is at present only possible to indicate potential areas of application.

(a) Use of bioreactors

13. This technology makes possible:

- chemical processes at low temperatures permitting energy savings,
- cheaper manufacture of products which can be obtained only with difficulty by conventional chemical processes,
- the use of bioreactors for controlled waste-water purification,
- the medical application of small bioreactors as replacement organs (e.g. compact artificial kidneys) or for treating congenital enzyme defects (e.g. phenyl ketonuria).

The advantage of bioreactors over conventional processes with enzymes is clearly shown by the following example.

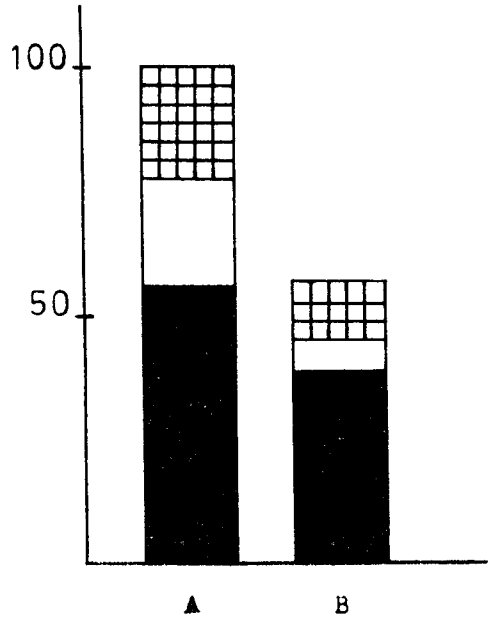


Fig. 2 : Comparison of costs of production of L-amino acids

A = conventional process
B = bioreactors

vertical axis : relative costs in %

black column : raw materials costs

white column : costs of the enzyme

chequered column: staff costs and energy

Source: Kula, R.M., Chemie in unserer Zeit 14 (1980) 61

(b) Possible uses of genetic engineering

14. For the moment the value of genetic engineering has only been demonstrated in the field of basic research. Important new results have been produced concerning hitherto unknown principles underlying the organization of genes and in particular those of higher organisms.

15. As far as application is concerned, however, the technology is still in its infancy. The following list therefore gives a few of the possible areas of application, although long periods of research may be required before they reach the stage of industrial application:

- large-scale production of hormones,
- production of interferon (a substance for combating virus diseases and perhaps also cancer),

- production of vaccines against infectious jaundice,
- production of vaccines against animal dysentery (up to 10% of new-born calves and piglets in the USA die from this disease),
- production of vaccines against contagious diseases without using infectious germs (greater safety in production),
- improvement of microorganisms used in the production of enzymes, antibiotics, etc.,
- replacement of energy-intensive nitrogen artifical fertilizers by an expansion of biological nitrogen fixation,
- production of vegetable proteins having the amino acid composition of animal protein (which may lead to a reduction of the energy input for essential proteins in human food to less than one tenth of the present figure),
- production of improved useful plants by somatic cell hybridization,
- replacement of chemical high-pressure and high-temperature processes into biochemical processes operating on a low energy input,
- biological processing of chemical by-products without fresh production of polluting waste (e.g. production from methanol of bacterial biomass which can be used for animal feed),
- biological conversion of solar energy.

16. Most of the extremely interesting areas of application mentioned here will however require considerable lead times. It is not possible to predict with any accuracy whether the practical difficulties will be solved satisfactorily. Some of them are already known:

- many genes from other organisms are not stable in the host bacterium used and therefore are destroyed when the bacterium reproduces;

- as in the immune system in higher organisms, there are also mechanisms in bacteria capable of distinguishing between their own and foreign proteins and which lead to the desired foreign protein being destroyed;

- a similar problem can occur with the overproduction of a substance which on its own is stable. One of the new possibilities of genetic engineering is to design high-efficiency strains of organisms for specific products. Where a bacterium produces large quantities of a substance it may happen that this substance is then decomposed. Thus in such a case there is a quantitative limitation.

Risks in genetic engineering

17. Shortly after the discovery of the technique of DNA recombination, American scientists pointed out the possible risks and dangers.

This topic was the subject of a report by Mr CERAVOLO (PE 64.494) on the proposal for a directive establishing safety measures against the conjectural risks associated with recombinant DNA work (Doc. 55/79). Your rapporteur will therefore confine himself to those aspects which are of direct relevance to the research programme.

Safety guidelines

18. Following the discussion referred to above, safety guidelines were issued in all industrialized countries classifying possible experiments. The inidvidual classes are then made subject to physical and biological safety measures.

19. The physical measures have been adopted from previous experience in work with infectious germs. They range from working with gloves and automatic pipettes through the destruction of experimental material by heat (autoclaves) to completely sealing off the laboratory from the outside. The different levels of physical precautions are referred to as L1 to L4 (also P1 to P4).

20. Biological safety measures include the use of crippled bacteria as host organisms which cannot multiply outside the laboratory or can only do so with difficulty. The different levels of biological protection are referred to as B1 and B2 (also EK1 and EK2). Although these measures can never completely exclude risk, they do help to reduce it substantially.

21. It is particularly relevant to the proposed programme that the strictness of the guidelines varies from one Member State to another. The following summary shows this clearly.

Summary: Safety provisions in the various countries
(by John TOOZE with the addition of the revised Germany guidelines)

DNA - source for a 'shotgun' experiment	USA (new)	France	Germany (new)	Germany (old)	Netherlands	United Kingdom
Primate (ape, man)	P4 EK1 P3 EK2	P3 EK1 P2 EK2	P3 EK1 P2 EK2	P4 EK1 P3 EK2	P4 EK2	P4 EK1 P3 EK2
Mammal	P3 EK1 P2 EK2	P3 EK1 P2 EK2	P3 EK1 P2 EK2	P4 EK1 P3 EK2	P3 EK2	P4 EK1 P3 EK2
Invertebrate	P2 EK1 P1 EK2	P2 EK1 P1 EK2	P2 EK1 P1 EK2	P2 EK1	P2 EK1	P2 EK1 P1 EK2

'Shotgun' experiment = cloning of all of one cell's segmented DNA.

1 = lowest safety level, 4 = highest safety level; P = physical safety, EK = biological safety

Source: H. Schultze: Nutzen und Risiken der Gentechnologie, 1979.

22. In practice the varying guidelines amount to a distortion of competition. In Europe there are no more than a few P4-level laboratories. The cost of

a P3 laboratory is about 100,000 EUA. The number of staff per place of work is lower in the case of a safety laboratory. In addition, experiments at level EK2 take longer because of the slower reproduction of the crippled bacteria strain.

23. With the exception of the United Kingdom, the safety guidelines are not legally enforceable. Compliance is either voluntary or more often ensured by making the provision of research funds conditional on the observance of the guidelines.

Three consequences flow from this:

- the harmonization of the guidelines must be taken further, this is what the Commission is aiming to achieve with its proposal for a Council directive (COM(78) 644 final);

- since with the exception of the United Kingdom there are no legally binding regulations, research contracts should stipulate that the provision of funds shall be conditional upon compliance with the national safety guidelines;

- in the event of excessive disparities between national safety guidelines for a specific project, the Commission should link the provision of funds to the strictest regulations.

Risk assessment

24. The risk in using certain technologies, e.g. nuclear energy, is ascertained by estimating the probability of harmful events. The events themselves are already known as are the possible consequences. But in genetic engineering the risks are conjectural because no harmful event has yet occurred. For this reason, possible incidents are postulated in the form of scenarios. Most of the scenarios are concerned with new synthetic germs and with the disturbance of the already endangered biological balance. Unlike industrial installations, the possible danger from sythetically produced living organisms is not merely local. Once released into the environment, microorganisms multiply and spread independently. They can never be recovered. For that reason special care is called for.

25. Current risk assessment and the associated safety measures relate to the scale of laboratory experiments. Thus there is a quantitative limit of 10 litres on almost all experiments involving bacterial cultures. But many problems only become evident when the experiment is scaled up to larger volumes e.g. 50 or 100 litres and later, in production, 1,000 litres. At that point, in the present state of the art, it is no longer economically feasible to ensure that microorganisms are securely contained.

26. Risk assessment is also difficult because there are still some gaps in our scientific knowledge. It is true that in the last few years, particularly in the USA and EMBO, experiments have been carried out in an effort to clear up unanswered questions. But some of the answers remain elusive. In addition, successful risk assessment requires the continuous collection, coordination and evaluation of the data acquired. Therefore in September 1979 the US National Institute of Health (NIH) submitted a programme for further research into the problem of safety. The Commission for its part produced a study by SARGEANT and EVANS on 'Hazards involved in the industrial use of microorganisms' (EUR 6349, 1979). But the study did not consider the problems of genetic engineering. The European Community should take prompt steps to promote the examination of questions of safety in its territory because if it does not do so they may prove to be a barrier to the industrial application of this technology.

Ethical problems

27. The proposed research programme evisages the genetic manipulation of microorganisms and plants. The knowledge thereby obtained could however lead to this technology being applied to human beings. At that point, if not before, ont only scientific and economic but also ethical problems will be raised. These questions are already being discussed by philosophers and in religious circles. In a speech to UNESCO in Paris on 2 June 1980, Pope John-Paul II said:

'Whereas the role of science is to serve mankind, it is all too often used for purposes which destroy the true dignity of man and human life. This is the case when scientific research sets itself aims or when its results are put in the service of aims which run counter to the welfare of mankind. This is true in the case of genetic engineering, biological experiments and the development of chemical, bacteriological and nuclear weapons' (quotation from: L'OSSERVATORE ROMANO, German weekly edition, 6 June 1980).

28. Parliament cannot evade the question of interference with human genetics. There must be some discussion on this subject before it becomes a practical possibility. The widespread view that in general pure scientific research precedes a second more practical phase of applied research, is not supported by the facts of the history of science and technology. Thus it can be shown that after the discovery of nuclear fission (i.e. at the basic research stage) the development of the atomic bomb was politically virtually inevitable. It follows that the social and political consequences and the ethical implications of recombinant DNA should be discussed at the basic research stage, and that means now.

II. The need for, possible uses and limitations of a Community research programme

29. As the Committee on Budgets, asked for its opinion, has rightly remarked, in terms of volume the proposed biomolecular engineering research programme falls into the category of large-scale programmes and is only exceeded in size by the JET programme, the energy research programmes and the radiation protection programme. For this reason alone, a strict examination of the need for the programme is called for.

Current European research

30. Research into biomolecular engineering is already being undertaken in Europe. It is therefore necessary to consider whether the Community's research programme overlaps with existing research programmes.

31. This is denied in a study on genetic engineering in applied biology (EUR 6078, 1978) carried out for the Commission. The author, Professor A. Rörsch (also Secretary-General of the European Molecular Biology Conference), stresses however that this is his personal and private opinion. Therefore careful attention has been given to examining this assertion. Your rapporteur was unable to find any element of competition between the Commission's proposal and existing European efforts provided the Community confines itself to promoting applied research.

European Molecular Biology Organization (EMBO)

32. EMBO was set up in 1963 by scientists in Geneva as a non-profit-making organization under Article 60 of the Swiss Civil Code. It was intended to advance the development of biomolecular research in Europe by exchange fellowships, refresher courses, the setting up of a European Laboratory for Molecular Biology and a programme for the promotion of research. To date, the first three aims have been achieved. In 1978 the organization included researchers from 18 countries, mainly from Europe but also from Israel (18), Australia (1) and the USA (4). Of 348 members in January 1978, 248 came from 8 countries of the Community (none from Luxembourg). Since 1970, following a period of financing by the Volkswagen Foundation, the finances of the EMBC have been administered by EMBO.

European Molecular Biology Conference (EMBC)

33. In 1970, 13 governments (Austria, Denmark, Federal Republic of Germany, France, Greece, Israel, Italy, Netherlands, Norway, Spain, Sweden, Switzerland and the United Kingdom; the Belgian Fonds National de la Recherche Scientifique is associated) signed an agreement setting up the European Molecular Biology Conference. This organization was intended to

ensure the long-term financing of EMBO fellowships and the planned European laboratory. Since then other countries have joined: Ireland (1975), Finland (1976) and Iceland (1977). The 1978 budget was DM 5,850,328 (2,333,914 EUA) and remains at the same level for 1980. The EMBC's plans for the eighties include inter alia:

(a) the award of 230 short-term and 155 long-term fellowships annually for exchanges of scientists;

(b) 20 workshops, 14 practical and 6 theoretical courses per annum;

(c) the award of 10 lectureships per annum;

(d) an annual EMBO symposium.

34. An analysis of the research topics of the recipients of exchange fellowships in 1979 showed that out of 243 short-term fellowships, 65 (i.e. 27%) related to genetic research. The working titles of projects, however, do not permit precise categorization so that the number may be even higher.

European Molecular Biology Laboratory (EMBL)

35. In 1973, at the instigation of the EMBC, 10 countries (Denmark, Germany, France, Israel, Italy, Netherlands, Austria, Sweden, Switzerland, United Kingdom) decided to build and run their own European laboratory in Heidelberg (Federal Republic of Germany). Since 5 May 1978 the laboratory's highly qualified staff has worked under the direction of Sir John Kendrew on basic research into molecular biology. The 1979 budget was DM 31,344,000 (12,504,290 EUA). At present 40 researchers work in the laboratory. In accordance with Article II of its statutes it serves no commercial purpose. There is a special department for research into recombinant DNA. At the end of 1978 four research groups were working in this field - now there are seven. Since recently the EMBL has offered scientists one of the few P4 top-level safety laboratories in Europe.

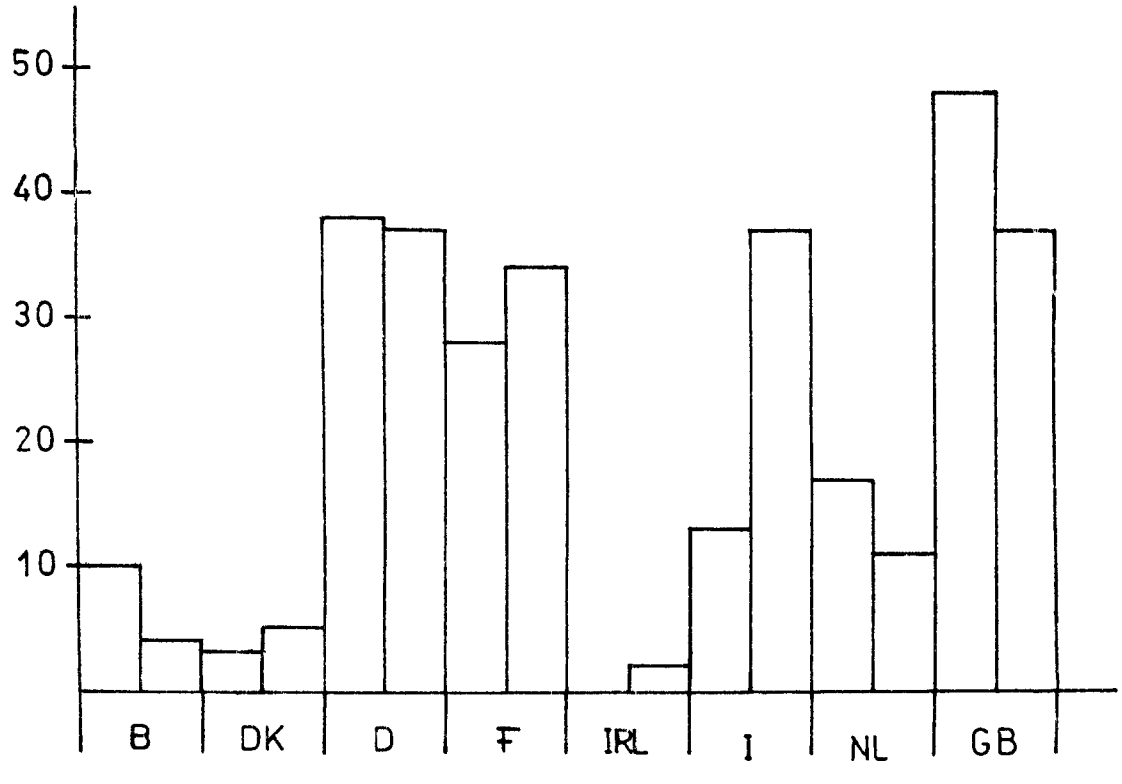
The situation and promotion of molecular biology research in the Member States of the Community

36. A Community project is only relevant when it does not compete with the existing efforts of the Member States. Another factor in the assessment of the need for a Community programme is the differing state of development of research and technology.

37. Despite the Commission's enquiries and efforts it was unable to obtain full information for a precise assessment. The best that can be done therefore is to try to clarify the research situation in the light of selected information.

38. International exchanges of researchers provide a good yardstick for research activities. Visiting researchers always seek out the more attractive laboratories. Conclusions may be drawn from their country of origin as to the countries in which the science is already well developed or still in its infancy. EMBO's short-term fellowships to Community countries were therefore analysed with regard to scientists' host countries and countries of origin (Luxembourg is not included as it is not a member of the EMBC). Figure 3 shows that research is most highly developed in the United Kingdom, the Federal Republic of Germany and France. Italy sends far more researchers than it receives - a clear indication that in Italy research is still in the development stage but very active.

Figure 3: Exchanges of scientists among the countries of the Community in the field of molecular biology (number of recipients of EMBO fellowships in 1979 by host country and country of origin)



vertical axis : number of exchange fellowships

horizontal axis : Member States in the following order: Belgium, Denmark, Germany, France, Ireland, Italy, Netherlands, United Kingdom

left-hand column : number of fellowships to a Member State (host country)

right-hand column : number of fellowships from a Member State (country of origin)

Source: European Molecular Biology Conference, Annual Report for 1979 17.3.1980, evaluation of Part II.

39. In relation to research into recombinant DNA no representative figures were available on research expenditure, publications, number of laboratories or research groups. The survey of laboratories concerned with genetic engineering on plant cells covers only a single field, albeit an important one for the Community.

Table 1: Genetic engineering on plant cells in the Member States (number of laboratories and research groups)

Member State	Laboratories	Research Groups
Belgium	10	15
Denmark	3	8
Germany	18	24
France	13	36
Ireland	6	9
Italy	8	20
Luxembourg	0	0
Netherlands	6	14
United Kingdom	9	26

Source: Analysis of a list of addresses supplied by the Commission (1979 situation)

The table gives the impression that development in this specialized field has reflected the general development of molecular biology in the Member States.

40. The best illustration is given by the field of enzyme immobilization. The study by THOMAS for the Commission on 'Production of biological catalysts, stablization and exploitation' (EUR 6079, 1978) also contains data on laboratories and companies although more in a descriptive than precisely comparative form. It is also unclear whether the information is complete - for example the author does not mention himself or his laboratory. The following table has been compiled in conjunction with an evaluation of a study of patents carried out for Directorate-General XIII of the Commission.

Table 2: The situation in the Member States in the field of enzyme immobilization

Member State	Companies	Universities	Inventions patented (1970-1978)
Belgium	1	2	-
Denmark	1	1	2
Germany	4	11	18
France	5	7	16
Ireland	-	1	2
Italy	1	4	1
Luxembourg[1]	-	-	1
Netherlands	-	2	5
United Kingdom	4	15	13
Total	16	43	58

Sources: Evaluation by: D. Thomas, 'Production of biological catalysts, stabilization and exploitation' EUR 6079, 1978;
J. Sigmond, patent report 'Immobilization of enzymes', 1979.

Companies: Number of companies concerned with the application of or research into enzyme immobilization.

Universities: Number of basic research groups.

Patents: Number of patents applied for by companies or individuals.

[1] This is a patent application by a Luxembourg national on behalf of a US company.

As far as industrial use is concerned, Germany, France and the United Kingdom have a clear lead over the other Member States.

41. The promotion of applied research in the field of biotechnology varies considerably from Member State to Member State. Information was available for Germany, France, the United Kingdom and Italy.

Federal Republic of Germany

42. The Ministry for Research has run a biotechnology programme since 1972. For the period 1979-1983 the 'Leistungsplan 04-Biotechnologie' provides for DM 313 million (125 million EUA) to be spent on projects. This does not include the activities of the big state research institutions. DM 57.4

million (23 million EUA) are earmarked for bioreactors alone. That corresponds to the amount which the Community plans to spend on its entire research programme. In 1979 altogether DM 15 million (6 million EUA) were spent on genetic research in the Federal Republic of Germany. These figures reflect the great importance which Germany attaches to biotechnology.

France

43. In France there is a biomass programme coordinated by the Commissariat à l'Energie Solaire on which 3.28 million EUA were spent in 1979. There is no special biotechnology programme. The report on 'Sciences de la vie et société' (Paris 1979) to the President of the Republic contains a number of recommendations for research projects including projects for the development of bioreactors and for nitrogen fixation. Expenditure on biotechnology is currently estimated at FF 20 million (3.4 million EUA).

United Kingdom

44. It is difficult to quantify how much is spent on research as there are no official statistics. The report 'Biotechnology - Report of a Joint Working Party' (March 1980) estimates government support at £5 million (8.2 million EUA) per annum. The report by Mr SPINKS contains practical proposals with costs estimated at £10 million per annum.

Italy

45. The National Research Council's (CNR) 24 applied research programmes include 6 on biotechnology:

- biomedical technology
- breeding
- virus research
- research into new protein sources
- genetics
- improvement of plants by genetic manipulation.

No figures are available because of the Italian government's failure to provide information.

Need for a programme

46. The Commission justifies the need for a programme by referring to the lead of the USA and Japan on the world market. In support of this argument it produces figures on patents. Since the importance of patents lies not in their number but in their quality, such information has only limited value.

47. Thus a number of Japanese patents relate to the production of glutamate and soy sauce ingredients. Your rapporteur is very fond of Asiatic cuisine but cannot see the relevance of these patents to the world market. The other data found after further research point more persuasively to the lead of Japan and the United States. This view is also expressed in the British, French and German studies on the importance of biotechnology. But in each case these are merely opinions rather than precise analyses.

48. The need for a Community programme can only be shown conclusively by a clear analysis of the economic and social demand and the consequences of the new technology. This must include comparable information from different countries on, for example:

- the number, size, turnover and earnings of companies in the field,
- companies' shares of the world market for specific products,
- the proportion of GDP in the different countries attributable to biotechnology,
- the importance of biotechnology for employment,
- the promotion of research in the individual countries,
- a conclusive analysis of the patent situation,
- an appraisal of the market for new products,
- the relationship of research costs to economic value,
- a determination of social demand,
- an estimate of the research costs for that demand,
- an analysis of the overall social consequences of introducing the technology (e.g. effects on employment).

There is no sign of any such information. The two studies on which the proposal was based, by RÖRSCH and THOMAS, were carried out by molecular biologists. They are known to be very competent in their field. They cannot however be expected to do the work of economists. Thus RÖRSCH's study contains no relevant information at all. THOMAS describes the enzyme technology situation in different countries qualitatively and not in such a way as to afford comparison.

49. The Commission's explanatory memorandum does not therefore disclose any pressing need for the programme from the point of view of foreign trade considerations. But the arguments put forward by the Commission and others cannot be dismissed out of hand.

50. The Commission puts further weighty arguments for a Community action which have nothing to do with Europe's competitive position on the world market:

(a) There are no trade barriers between the Member States of the Community, but they are at varying stages of economic growth which must be harmonized by Community efforts. Community actions in relation to important technologies can contribute to achieving this.

(b) the harmonization of safety guidelines for work with recombinant DNA is important if only on account of possible distortions of competition within Europe. A Community research programme can help to achieve this if the provision of funds is linked to compliance with uniform guidelines.

(c) There are less profitable areas which cannot be covered by industry, such as the very limited market for medical bioreactors which will require support from public funds. In such cases joint efforts by the Member States will save time and money.

For these reasons a Community action will in any event be useful, and so it should not be held up for want of a precise economic analysis. The social consequences of biotechnology are in any event the subject of the programme on 'Forecasting and Assessment in the field of Science and Technology' (Doc. XII/93/80) the first results of which should be available in 1982. For the evaluation of the research programme on biomolecular engineering in the meantime Parliament should therefore demand a study on the economic and social demand and their consequences. Approval of further funds from the budget will then depend on the results of this examination.

Form of Community action

51. Three forms of action have been developed for the Community's research policy:

- direct (Joint Research Centre)
- coordinated (coordination of national actions)
- indirect (award of research contracts by the Community).

It must now be considered which of these possibilities best suits a programme in the field of biomolecular engineering.

Direct action

52. Biotechnology does not feature in the multiannual programme of the Joint Research Centre 1980-1983 (COM(79) 121 final). On a visit to Ispra your rapporteur discovered that biological research is in fact carried out there, but it is essentially environmental research carried out under the auspices of DG XII. Two Ispra scientists are included on an address list of researchers concerned with genetic engineering on plant cells. It is significant that at the moment there is neither a safety laboratory nor the other necessary equipment for this type of research. At present it is not possible to carry out a biomolecular engineering research programme of the scope envisaged at the Joint Research Centre.

53. The Commission should however consider whether a research group could be put together at Ispra to take part in the programme. In fact most Member States lack institutes conducting research in the area between basic and applied research.

54. The setting up of such a group would be valuable also having regard to the need for safety measures in work with recombinant DNA. In drawing up such guidelines governments are advised by scientists whose wish it is to carry out their research as far as possible without interference and who are to some extent involved with industry through consultancy contracts or shareholdings. It would definitely be desirable to have experts not subject to these constraints.

Coordinated action

55. A coordinated action would in principle be possible. With this type of action the influence of the Commission, which is desirable for various reasons, would not be very strong.

Indirect action

56. The indirect action proposed by the Commission is the best way to carry out this research programme.

III. Difficulties in realizing the aim of the programme

57. The stated aim of the programme is to support European industry and agriculture. This formula is a thread running through the whole proposal and clearly forms part of the Commission's sales talk for this programme, but critical examination reveals flaws in the argument.

The concept of a European industry

58. Many large chemical and pharmaceutical companies in Europe are engaged in research and development in genetic engineering. The major companies in the Federal Republic of Germany are Boehringer of Mannheim, Hoechst of Frankfurt am Main, Schering of Berlin, and recently also BASF, while other pharmaceutical manufacturers are also active in this field. In the United Kingdom, ICI is involved in developments in genetic engineering while in France and Italy there are well known companies also operating in this field. Clearly the Commission has these companies in mind when it speaks of the European industry.

59. However the actual development of the application of genetic engineering does not take place in the conventional large company. In the USA small individual undertakings have been set up such as the Cetus Corporation of Berkeley, California and Genentech Inc. of San Fransisco, California. By virtue of their flexibility these two companies have succeeded in recruiting a large proportion of the competent scientists in this field either directly as employees or as consultants. The intellectual capital of these companies is valued so highly that a number of large companies such as Eli Lilly, in the case of Genentech Inc., and Standard Oil of Indiana, in the case of the Cetus Corporation, have gained access to their expertise through contracts or capital investments. None of these newly founded companies has any ambition one day to produce pharmaceuticals themselves on a large scale or to build up the necessary sales network. They prefer to sell their expertise to the giants of industry rather than compete with them. This form of organization will therefore make it possible in the future to retain the present flexibility and the associated high level of inventive output.

60. A company named 'Biogen' has been set up in Luxembourg and Geneva with the same ideas in mind. This is an international commercial company consisting of scientists about whom very little is known. Biogen S.A. of Geneva was registered in Luxembourg in 5 May 1978. The firm was set up with venture capital from International Nickel (INCO), a Canadian mining company. Its shareholders are companies on either side of the Atlantic (!).

61. The object of Biogen is to develop commercial products in the pharmaceutical, chemical and energy fields using modern microbiological methods and in particular genetic engineering. Biogen's scientific consultants include eight scientists from the USA and various European countries: Professor W. Gilbert, chairman, Harvard University (USA); Professor B. Hartley, Imperial College of Science & Technology (London, England); Professor P.H. Hofschneider, Max-Planck-Institut (Munich, Germany); Professor B. Mach, University of Geneva (Switzerland); Professor K. Murray, University of Edinburgh (Scotland); Professor H. Schaller, University of Heidelberg (Germany); Professor P. Sharp, Massachusetts Institute of Technology (USA); Professor C. Weissmann, Institute of Molecular Biology (Zürich, Switzerland).

62. In relation to Biogen, it should be noted that there is a missing link in the development of genetic engineering for industrial processes. Basic research institutions are interested in looking at the principle of genetic expression in order to show the circumstances under which genetic expression of the structural proteins of the hepatitis-B-virus can be obtained. But it is not in the interest of such institutions, nor is it their purpose, once they have established the principle, to develop high-output strains

for use in industrial production. Conversely, many of the large established pharmaceutical companies, particularly in Europe, are interested only in buying high-output strains. There is therefore a development gap between the basic research institutes and the established pharmaceutical companies. This gap is now filled in Europe by Biogen.

Three things follow from this:

(a) Support for Biogen means supporting US industry by virtue of the mixed European/American character of the company;

(b) Support for basic research has the disadvantages mentioned above and in the following section;

(c) Support for research in the conventional chemical/pharmaceutical industry may entail financing 'finger-exercises' for scientists in industry who have been recruited now in preparation for the day when high-output strains and expertise will be bought. The pharmaceutical industry says this quite openly: 'Virtually all the large pharmaceutical companies in the Federal Republic of Germany have decided to devote attention to this technology. They are in the process of setting up working parties to collect know-how and to design projects with the established groups to some extent as insiders (who will in the meantime familiarize themselves with the special problems of industry) ... In order to become reasonably active in this field it is necessary - I hope that the scientists agree with me - to engage at least two and I would say more realistically four or five scientists to practise their finger-exercises on such projects'. (Professor Dr. W. Frommer, Federal Association of the Pharmaceutical Industry, Minutes of the BMFT hearing, Bonn, 19-21 September 1979).

Scientists and patents

63. Basic researchers and industry have different goals. The reputation and career of an academic scientist are dependent on the publication of his work in the scientific literature. It is therefore important for him to be the first in the field. This aim is not always consistent with the aim of securing a patent because the additional work necessary to obtain a patent can take a long time. A claim will not be allowed where its subject matter has already been disclosed in a prior publication. Without patent protection the knowledge obtained is accessible not just to the European industry but to anyone.

Problems of patenting microorganisms

64. Patenting microorganisms presents a special problem in biotechnology. According to the European Patent Convention of 7 October 1977 and the patent law of most of the countries signatory to the Convention, it is possible to

patent new microorganisms not occurring in nature. This however requires a sample of the microorganism to be deposited with a recognized institution. The Convention provides that the culture must be available to third parties on the publication of the European patent application. Account was taken of the interests of the person depositing the microorganism in that anyone who wishes to obtain such a culture must give the applicant or proprietor of the patent an undertaking not to make the culture available to other persons and, where appropriate, only to use the culture for experimental purposes until the European patent has been granted.

65. In some ways this protection is not sufficient for the industry. As a consequence no applications for patents are filed and microorganisms are kept strictly secret. How far the ratification of the Budapest treaty of 28 April 1977 on the international recognition of the deposit of micro-organisms can remedy the situation still remains to be seen. But in any event secrecy is incompatible with the objects of the programme.

Effects of American patent applications on projects 3, 4 and 5

66. On 6 November 1978 GENENTECH INC. filed three patent applications with the European Patent Office in Munich. They cover the field of projects 3, 4 and 5 with a very wide claim. The view of specialist patent attorneys is that the patents will be granted. This could mean that inventions made in connection with projects 3, 4 and 5 might be patentable but that the patents granted would be dependent on master patents.

The underlying reason for the lack of development of biotechnology in Europe

67. In the explanatory statement to its proposal the Commission states that the level of development of biotechnology in Europe is behind that in the USA and Japan. It does not however state the reasons. In particular it does not explain why European industry has hitherto shown so little interest. The lack of applied research is only the symptom and not the cause. One conclusion can be deduced from this: from the point of view of private industry, there was hitherto no market for this technology in Europe!

The question is whether this has changed to the extent that a Community research programme could promote industrial development and, if so, why. The question is very important for the aim of the programme. Unless there is strong demand, private enterprise will not take the results of basic research forward to the stage where they are ready for application.

68. It should be noted that the large-scale industrial application of biotechnology in the USA and Japan was in response to demand for cheap food. The production of isoglucose from maize starch is an excellent example of the application of bioreactors using immobilized enzymes. This is a way of replacing sugar from conventional sources (sugar cane, sugar beet). The protectionism of the Community's agricultural policy has effectively prevented the development in Europe of isoglucose production using biotechnology. One company in the United Kingdom which was interested in this process has since had to drop its plans.

IV. The plan for six research projects

69. It is not the task of Parliament to judge the quality of the proposed projects, but rather to concern itself with the objectives of the applied research. In this connection the Commission's proposal calls for some critical remarks (Annex I of Doc. 1-750/79).

The proposed programme is very ambitious. The proposed subjects embrace everything which is conceivable at the moment. Some of the subjects are still a long way from the application stage. The draft is less a programme of specific objectives than a collection of all possible research interests designed to open up additional sources of finance. Close examination reveals that the funds proposed will be insufficient for all the research topics mentioned. It also remains unclear how many research units will be used on each project.

70. This being so, the Commission or the advisory committee has a completely free hand in setting the objectives of an applied research programme. Parliament must decide whether it is willing to be fobbed off with rather general aims such as supporting European industry, agriculture and environmental protection. Your rapporteur recommends that the Commission be asked to tighten up the programm and define clear goals. A reminder of Parliament's budgetary rights in relation to non-compulsory expenditure should lend the necessary emphasis to this demand.

71. It is not the task of Parliament to submit a detailed proposal for a tighter programme. But it should give the Commission some guidelines. In view of the Community's needs and the problems outlined in Sections I(17) and III, your rapporteur would submit the following proposal:

1. No projects should be chosen which have already been the subject of intensive work in Japan and the USA. The lead of those countries can only be reduced in other as yet new fields.

2. The Commission should choose practical projects aimed in particular at:

   - lowering agricultural production costs (e.g. nitrogen fixation, somatic cell hybridization),
   - lowering energy consumption in the chemical industry,
   - solving environmental problems,
   - solving medical problems,
   - using agricultural waste products,
   - the biological exploitation of solar energy.

3. A number of experts consider that the research subjects proposed in project 6 are covered by projects 3, 4 or 5. Everyone working in this field must be concerned with genetic stability. Project 6 should therefore be deleted.

4. In its place a new project should be included with a view to extending knowledge in the assessment of safety problems in research, and in particular in relation to applied research.

V. The Commission's proposal for implementing the programme

72. The programme is to be implemented in the form of an indirect action (1981-1985) by means of cost-sharing contracts with private and state organizations. There will be a public invitation to tender. The maximum participation from the Community will be 26 million EUA. The Member States are expected to provide 23.5 million EUA. The Commission is asking for six posts (three A, one B and two C). In selecting projects and evaluating the results, the Commission will be assisted by an advisory committee whose composition is to be determined by the governments of the Member States. The results of the programme will be made available to European industry and property in inventions will pass to the contractor if he so wishes.

73. The Commission's proposals therefore contain nothing unusual. In spite, or perhaps because of this, they call for some comment.

Organization of research work

74. The Commission proposes a research unit of three researchers, two technicians, one laboratory assistant and secretarial assistance. Only the most well endowed universities can afford a ratio of one researcher to one technician. In industry, one researcher normally works with two or three technicians. The Commission should therefore bring its proposal into line with practice.

75. The Commission's proposal says nothing about money for materials (chemicals, etc.). In biolmolecular engineering, operating costs can be as high as staff costs. This is shown clearly by the example of the European Molecular Biology Laboratory.

Table : Structure of costs at EMBL, Heidelberg

Year	Staff costs	Running costs
1977	DM 5,989,000	DM 4,625,000
1978	DM 8,529,000	DM 7,889,000
1979	DM13,234,000	DM12,342,000

Source : European Molecular Biology Laboratory, Annual Report 1978

76. The EMBL figures are confirmed by the structure of costs at five German universities chosen at random for special areas of biolmolecular engineering as defined by the German Society for the Promotion of Research. Clearly, materials costs are a problem.

The Commission should therefore spell out in its invitation to tender that it accepts responsibility for both staff and materials costs.

Public invitation to tender

77. The Commission always publishes invitations to tender in the Official Journal of the European Communities, although this has only limited circulation. Scientists who have not previously worked for the Community will certain not be among the readers of the Official Journal (and your rapporteur even doubts whether anyone reads it willingly).

78. The Commission should therefore ensure that the invitation to tender is really public by advertising in newspapers and technical journals, not merely to meet the formal requirement of a public invitation to tender but in order to attract scientists who are not already in close contact with the Commission or the national research agencies.

Finance

79. The total cost will be 47 million EUA over five years. According to the Commission's proposal, its participation in the programme for the period 1981-1985 should not exceed 26 million EUA. The money is to be used for the part-financing (generally 50%) of the research projects and will cover the cost of management, programme coordination and a limited number of posts for Commission staff.

	Approximate number of research units	Total costs m EUA/5 years	Maximum Community participation m EUA/5 years
Contract research	43	47	23.5
Management and coordination			
Expenditure on experts, fees, meetings, seminars, etc.			0.7
Commission staff (3A, 1B, 2C)			1.8
			26.0

80. The Commission assumed 57,000 EUA per researcher/year and a 6% inflation rate for research costs. Apart from that, it does not disclose how it arrived at its figures. Further calculation on the basis of three researchers (composition of one research unit according to the Commission proposal) produces a figure for total costs of 41.5 million EUA rather than 47 million EUA. The Commission should state what it intends to use the difference for. (Note: explained by an inflation rate of 6.5% instead of 6%.)

81. 43 research units and 47 million EUA/5 years give an average cost per research unit of 218,600 EUA/year. Your rapporteur has calculated the cost

of one research unit on the basis of information on research spending provided confidentially by the industry. Taking salaries at 1980 levels, the result is 176,000 EUA/year for staff costs alone. If a 6% cost inflation rate is included in the computation, the Commission's programme will only cover staff costs. It has already been pointed out that the cost of materials in biomolecular research is very high. Therefore if the Commission is to remain within its financial limits, it must change either the number of research units or, preferably, their composition (57,000 EUA per employee per year in industry corresponds to a ratio of one researcher to three technicians!).

Posts requested by the Commission

82. The Commission is requesting three A posts, one B post and two C posts. The Committee on Budgets has demanded careful scrutiny of this request.

83. Obviously the Commission needs properly trained staff to carry out a research programme, otherwise it cannot be expected to accept responsibility. The Commission is asking not for permanent posts but for temporary contracts. The Commission's proposal for the programme was prepared by the staff of the biology and health protection (radiation protection) research programme, which in fact has other duties.

84. It is however questionable whether three new A posts are needed. One enzyme specialist and one genetic engineering specialist should suffice. The one B and two C posts call for no special technical knowledge. Parliament should approve these requests for new posts only if the Commission can show conclusively that the staff cannot be recruited from existing staff.

Choice of projects (advisory committee)

85. For the purpose of selecting the research units and their integration in research groups, the Commission proposes to set up an advisory committee for programme management. The advisory committee would consist of three representatives per Member State appointed by their governments and three representatives from the Commission. The committee's duties would be advisory in nature with the Commission retaining formal responsibility for implementation. This arrangement corresponds to the practice introduced between 1969 and 1975 by Council decisions. The terms of reference of the advisory committee on research programme management were laid down in 1977 (OJ No. C 192, 11.8.1977).

86. It is clear that the Commission requires advice concerning the implementation of such programmes. However, there are both political and practical arguments against the present advisory committee structure.

(a) Political reasons

87. In theory the committee has only an advisory capacity. But in practice it assumes the role of the Council of Ministers despite the Commission's denial of this to Parliament's Committee on Budgetary Control. The present programme provides a good example of this. Since 1977 it has been submitted to the Scientific and Technical Research Committee (CREST) several times, in various forms, although CREST in theory has only advisory status. This has resulted in considerable delay to the proposal.

88. The role of advisory committees is being given careful consideration in the Committee on Budgetary Control on the basis of a report by Mr Marcel COLLA. The question is whether by this practice the Council is in breach of Article 205 of the EEC Treaty, which provides that the Commission shall have sole responsibility for implementing the budget.

89. The committee's chairman, Mr Heinrich AIGNER, has already indicated to the Commission that Parliament attaches great importance to this point. Mr RYAN, the Committee on Budgets co-rapporteur on the draft programme has also expressed doubt about the role of the advisory committee.

(b) Practical reasons

90. This structure does not suit the programme. Every scientist consulted (see annex) answered without hesitation that the programme would only contribute to the rapidly expanding area of research into recombinant DNA if the projects were selected by top scientists on the strictest criteria. And the keynote should be quality rather than a fair share-out between Member States.

91. In practice, the governments of the Member States do not fill posts on the advisory committees on research programme management according to these criteria. A 1977 survey on a number of such committees shows this clearly :

Table : Composition of advisory committees (1977)

State	Government Representative	State research establishment	Industry	University	Status unknown	Total
Belgium	22	20	6	5	2	55
Denmark	-	14	2	12	4	32
France	7	38	8	2	1	56
Germany	21	20	9	14	1	65
Ireland	5	13	1	6	2	27
Italy	2	29	16	5	2	54
Luxembourg	4	1	-	-	-	5
Netherlands	11	27	8	7	2	55
United Kingdom	13	30	8	2	-	53
TOTAL	85 (21%)	192 (48%)	58 (14%)	53 (13%)	14 (3%)	402 (100%)

Source : House of Lords, Select Committee on the European Communities Research and Development in the EEC, Session 1977-1978, Sixth Report, HMSO, London, 1977

92. The clause which enables the Member States to appoint their experts according to the criteria which they consider most appropriate has led to a situation in which the committees are dominated by the representatives of ministries and state research establishments.

93. The specialist officials of the national governments and scientists in state research establishments are no doubt qualified for their specific duties, but it is open to question whether many of them have an adequate scientific grasp of the areas which the programme covers. This is particularly true of Member States which do not yet have state programmes for the promotion of biomolecular engineering. Obviously the level of knowledge within national research agencies depends on their particular field of activity.

94. In the case of efforts to promote research in the Member States (see the study by the ESC on organization and management in Community research and development, Doc. CES 91/80) there are very good reasons why the various advisory committees are constituted differently. In the Federal Republic of Germany, substantial funds are provided by the DFG (Deutsche Forschungsgemeinschaft) which is an autonomous body under the direction of scientists chosen by election of the members of the committees of the CNRS (Centre National de Recherche Scientifique),an autonomous corporation under public law in France, half are appointed and half elected by scientists. Of the total of 140 members on the 11 advisory committees of the CNR (Consiglio nazionale delle ricerche) in Italy, 106 are scientists. 12 experts are appointed from industry and 12 further members are co-opted.

In Denmark the members of advisory committees are appointed by the Minister for Education, not arbitrarily but on a proposal from institutions.

(c) Alternatives to the Commission's proposal

95. The advisory committee for this programme must be constituted differently from previous committees because the conventional structure could jeopardize the success of the projects.

One possible solution might be as follows :

(a) The government of each Member State would appoint one representative to represent its interests;

(b) The Commission would appoint freely four representatives drawn from industry, five applied research scientists and three representatives of the Commission;

(c) On a proposal from EMBO the Commission would appoint nine basic research scientists.

There are other possible solutions. But the important thing is to ensure the influence of the scientists and reduce the element of national representation.

Programme evaluation

96. Properly run research programmes must include a system for evaluating their results. The Commission proposes a system of written interim reports and a final report. These reports would be evaluated by Commission officials and the advisory committee. This method calls forth the same objections as those made under the section 'Choice of Projects'. It cannot be expected to produce an efficient evaluation of results and, considering the level of estimated expenditure, would be highly irresponsible. It is another reason for calling for a different composition of the advisory committee. Alternatively, it might be possible to delegate the task of evaluation to small committees of scientists appointed by the Commission after consultation with the advisory committee and EMBO. In Section 5 on Diffusion (page 14), the Commission itself suggests the possibility of bringing in scientific experts.

Dissemination of information

97. The Commission considers that the proper implementation of the programme and its harmonious evolution require a continuous flow of information between the contractors, the Commission and third parties (for example, the industries not directly involved in contracts).

For this purpose :

- the Commission will establish 'permanent relationships with representatives of industries in the Member States and will seek permanent guidance and advice for the preparation of programmes and the evaluation of results';
- the Commission will 'encourage through symposia, summer schools, travel grants and research grants the establishment of permanent contact between its contractors and researchers from non-participating industries';
- the Commission proposes 'that publicly supported laboratories participating in the Commission programme open their doors widely to industrial research scientists and invite them to participate for short periods of time in the work of the research groups'. New techniques and methods such as those dealing with molecular cloning or somatic cell hybridization could be transferred in this manner to the European industries.

98. The requirement for the widest possible dissemination of knowledge about biomolecular engineering is reasonable in the context of basic research. In any case, academic scientists exchange information without assistance from the Commission. However, the purpose of an applied research programme prohibits the sort of open information policy proposed, because it would mean that the main competitors on the world market would have easy access to such knowledge.

99. The proposed information policy is only meaningful insofar as it aims to familiarize biochemists in industry with techniques which have long been standard practice in the USA and Japan. But this is not stated as one of the aims of the programme and it would be wrong for the Community to finance it.

100. Moreover, the Commission's proposal underestimates the competition existing at present between the industrial companies within Europe. The proposed measures should be re-examined carefully to take account of these objections.

Property in inventions and repayment clause

101. The object of the research programme is to make European industry more competitive. If this is to be achieved, two requirements must be met :

(a) inventions must be protected by patents

(b) the Commission must have a say in how the patents are exploited.

102. To prevent the premature disclosure of information which in the interests of the contractor should remain secret, it is proposed to apply for the execution of the programme Council Regulation (EEC No. 2380/74), which adopts provisions for the dissemination of information relating to research programmes for the European Economic Community. A set of general

rules based on the Council Regulation has been drawn up (XII/105/76) and is used in other Commission programmes.

Document No. XII/105/76 sets out the rights of both the contractor and the Commission.

The Commission may :

- with certain limitations disseminate, publish and use information for its own purposes,
- require the contractor to obtain its consent before passing on information to third parties,
- where patentable information is passed on, require the contractor to refrain from any action which might adversely affect the patentability of the invention,
- apply for patents in the name of the Community where the contractor renounces that right,
- require that inventions be exploited subject to conditions favouring the interest of the Community,
- require licences to be granted to other contractual partners of the Commission which have carried out related research work under the programme.

The contractor may :

- subject to giving satisfactory reasons prevent the publication of information from the final report where he himself renounces the right to publish,
- use information and reports for his own purposes,
- when passing on patentable information to the Commission require that the Commission refrain from any action which might adversely affect the patentability of the invention,
- claim as his own property both patentable and non-patentable inventions produced or developed under the contract.

This produces a balanced relationship between the interests of the Community and those of the contractor. By providing finance for the research, the Commission acquires a right to influence its exploitation. In Chapter 5 of its proposal the Commission indicates a possible relaxation of the requirements in the form of individual contracts within the framework of the Council Regulation. It should only deviate from the rules laid down in Document XII/105/76 where there is no danger to its influence over exploitation. The Commission must be able, for example, in order to safeguard the aim of the programme, to prevent the sale of a patent produced with Community money to American or Japanese industry.

103. On the other hand, it is possible to imagine cases in which patents may be exploited expeditiously and smoothly in Europe in any event. In such cases the Commission's capacity to influence exploitation has little practical value.

104. In such cases the Community would be better served if the Commission gave up its influence and demanded the repayment of research costs. Depending on the particular circumstances, it might require repayment of part or all of such costs. In its opinion the Committee on Budgets demands consideration of this possibility, not least in the interests of economy. Which leads to an important consideration : where they extend beyond the provision of risk capital, subsidies to industry are irreconcilable with the concept of an ordered market economy.

105. At an early stage the Commission indicated its objections to repayment clauses, saying that they were difficult to apply in practice. Your rapporteur therefore points out that repayment clauses are the standard procedure in various Member States for the promotion of applied research and technology :

(a) The Italian Fund for Applied Research gives loans with repayment contingent on technical success. The contractor can choose between paying the money back and keeping the results for himself or not paying the money back and handing over the results and exploitation rights;

(b) In the event of success, 'development loans' from the Dutch Ministry for Economic Affairs are repayable with 5% interest;

(c) The Fund for Scientific and Technical Research in France provides industrial aid covering 50% of project costs but repayable in the event of economic success.

106. Admittedly the examples given relate to support for projects in an advanced state of development where it is easier to forecast economic success than in the case of more long-term research. The Italian procedure described under (a) above, however, avoids problems of establishing proof of success in that the decision lies with the contractor. The Commission should incorporate in the research contracts a repayment arrangement along these lines.

VI. Infringement of Parliament's budgetary powers by the Council

107. In its opinion the Committee on Budgets expresses concern at the Council's practice in its decisions of fixing the scope of research programmes and the number of posts required. This constitutes a gross infringement of Parliament's budgetary rights. The Committee on Energy and Research endorses the objections of the Committee on Budgets. It therefore demands the use of the conciliation procedure,should the Council again decline to follow Parliament in this matter.

ANNEX

The rapporteur wishes to thank the following people for their information and advice

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Beauchamp, Dr K., Boehringer GmbH, Biochemicawerk Tutzing

Binder, Dr N., Federal Ministry for Research and Technology, Bonn

Böck, Prof. Dr A., Professor of Microbiology, University of Munich

de Nettancourt, Dr D., Commission of the European Communities

Flämig, G., Member of the German Bundestag

Gautier, Dr F., MEP, Gesellschaft für Molekularbiologische Forschung, Braunschweig

Goebel, Prof. Dr W., Professor of Microbiology, University of Würzburg

Hirth, Prof. Dr J., Institut de Biologie Moléculaire et Cellulaire, Strasbourg

Kendrew, Sir John, Director-General of the European Molecular Biology Laboratory (EMBL), Heidelberg

Lüdemann, Dr H.D., Professor of Physical Biology, University of Regensburg

Murray, Prof. Dr K., European Molecular Biology Laboratory, Heidelberg

Obermair, Prof. Dr G., Professor of Theoretical Physics, University of Regensburg

Perrota, Dr V., European Molecular Biology Laboratory, Heidelberg

Schmitt, Prof. Dr R., Professor of Genetics, University of Regensburg

Schöne, Dr H.H., Hoechst AG, Frankfurt

Tanner, Prof. Dr W., Professor of Botany, University of Regensburg

Vosberg, Dr H.P., Max-Planck-Institut für Medizinische Forschung, Heidelberg

Weber, B., Member of the European Parliament

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OPINION OF THE COMMITTEE ON BUDGETS

Draftsman: Mr R. RYAN

On 28 April 1980 the Committee on Budgets appointed Mr Ryan draftsman of an opinion on a multiannual Community programme of research and development in biomolecular engineering (indirect action : 1981 - 1985) (Doc. 750/79).

It considered the draft opinion at its meetings of 28 and 29 May and 11 and 12 September 1980 and adopted it unanimously at the latter meeting.

Present : Mr Lange, Chairman; Mr Aigner, Mr Arndt, Mr Colla, Mr d'Angelosante (deputizing for Mr Spinelli), Mr Forth, Mr Howell, Mr R.V. Jackson, Mr Newton Dunn, Mr Simonnet, Mr J.M. Taylor, and Mr Tuckman.

I. INTRODUCTION

1. The programme proposal presented by the Commission covers an area of research in which Europe is lagging behind Japan and US and in which no research has so far been conducted at Community level i.e. using joint resources and finance.

2. As there is sufficient basic knowledge available in Europe, but European industry is nevertheless in danger of falling behind in growing competition with Japan and the USA, the Commission regards the present moment as particularly opportune for the introduction of a successful trans-frontier research and development project at Community level.

3. A research programme covering two areas, enzyme and genetic engineering, is planned. The Commission has established the basis for joint cooperation at a series of in-depth seminars and by means of other contacts with European industry culminating in the present proposal for a medium-term programme to be implemented as an indirect action.

II. The substance of the Commission programme

4. The Commission proposal covers the field of biomolecular technology and is aimed specifically at the control of genes and their products. The Commission has suggested six integrated projects, the scope, technical content and application of which can be best judged by experts of the relevant specialist committee. All the projects are in the field of applied research. While they are of considerable interest to industry and agriculture, they involve medium and long-term research which will mainly be carried out in university laboratories. The Commission expects these projects to lead, in particular, to

- a better patents balance-sheet for the Community,
- reductions in costs and improvements in the quality of goods,
- lower energy consumption and, finally,
- improved environmental protection.

The **general aim** is to revitalize the existing innate innovatory capability in Europe.

5. The Commission hopes to achieve these objectives by means of a research programme which will

- bring together expertise and development opportunities in the Community,
- coordinate and provide for the joint planning of various existing projects and
- integrate protective measures against bio-hazards.

The purpose of these measures is to optimize the productivity of the research activities of European industry and agriculture.

III. Funding of the research programme

6. The Commission estimates the total costs for the entire foreseeable life of the programme at just under 50 million EUA, of which 26 million EUA is to be met from the Community budget.

7. More specifically, the programme is an indirect action to be carried out on the basis of cost-sharing agreements with private and public organizations. This means that the Community will pay up to 50% of the cost of the projects listed in Annex I of the Commission document. Past experience has shown, however, that there are occasional exceptions to this in practice and that much higher subsidies are also approved by the Commission[1]. The latter has already indicated that a study is being carried out on its behalf into the establishment of stricter criteria.

8. The financial record in the Commission document gives a detailed analysis of the payment and commitment appropriations for staff, administration and technical management and contracts over the period 1981-1985.

The Commission believes that coordination and secretarial work will require the creation of six new posts, three in category A, one in category B and two in category C.

9. The Commission will be fully responsible for implementing the programmes but will also have the support of an advisory programme committee to help ensure that the research and development programme is carried out as efficiently as possible. The committee will be a purely advisory body with particular responsibility for

- the selection of research units,
- the integration of these research units,
- the appointment of project coordinators,
- the coordination of the activities of the six research groups,
- the regular evaluation of the progress of the research and, if necessary, the modification of programmes,
- contacts between the Commission and European industry for the purpose of defining new research objectives and making the optimum use of the results obtained.

The committee will consist of three Commission representatives and three representatives of each Member State.

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[1] see the relevant discussion of the Committee on Budgetary Control concerning the granting of a discharge for the 1978 financial year in the field of research, PE 62.880

IV. Comments of the Committee on Budgets

10. In the light of the above remarks, a comparison between the new research programme and existing indirect actions is called for. The table in Annex I lists all current indirect actions, the total funding for the duration of the programme and the number of posts created in each case. This list shows that, in terms of size, the new research programme in the field of biomolecular technology proposed by the Commission would fall into the larger programme category and that in fact only the JET and fusion programme, the energy research programmes and the radiation protection programme are larger. It would account for almost 5% of the total appropriations for indirect actions. The numbers of staff required to coordinate and administer the programme, are commensurate with this.

Considerable research efforts are also being made in some cases in the Community Member States. It is, however, very difficult to determine the total amount of research expenditure in the Member States for the purpose of comparison with the proposed Commission programme.

11. It is not for the Committee on Budgets to assess the need for and usefulness of a programme of the kind suggested by the Commission. The programme is in any case so complex and specialised that it requires the assistance of experts to judge it. The Committee on Budgets proposes, therefore, to concentrate only on the financial aspects and administrative problems.

Consideration of the financial, administrative and organizational aspects nevertheless implies some assessment of the effectiveness and viability of the programme and of the staffing implications. The comments of the Committee on Budgets are set out below:

(a) Concentration and efficient use of resources

12. As a general rule, any pooling of both financial and intellectual resources in the European Community is to be welcomed. As the Commission itself points out, 'the budget needed for initiating and bringing to term a detailed and important research action in molecular biology tends, nowadays, to exceed the possibilities of single institutes and, in certain cases, those of small nations'.[1]

[1] Doc. 1-750/79, page 7

13. In the light of the information given above, it is possible to situate the level of expenditure proposed by the Commission in the overall context of other existing research projects. As the Committee on Budgets must always ensure that appropriations are used as efficiently as possible and that they are not spread too thinly over a wide range of different activities, the question of the order of priorities for Community research must be considered. The Commission advances arguments of a general nature such as 'the optimization of food production', 'optimization of the competitiveness of European industries', 'improvement of life in society', and finally 'coordinating and stimulating research directly applied to ... health protection, preservation of the environment and the use of solar energy'[1] to justify launching the new research project.

14. Finally, there are economic arguments and the Commission attempts to cover this aspect by drawing up a patents balance-sheet. The figures relating to patents in individual countries given on page 8 of the Commission document must be treated with caution as it appears that these individual patent applications are not comparable and the Community is well placed in the middle ranks of the comparable countries when the patent applications of individual Member States are added together.

15. It is primarily for the Committee on Energy to say whether further expansion of Community research in this area is desirable. Even if the answer to this question is in the affirmative, there is still the matter of whether the six projects proposed by the Commission actually represent the best possible focus of research and optimum use of available Community funds. According to the Commission, the projects are designed to take account of the specific objectives of agriculture and industry. In this context care must also be taken to ensure that European industry is not indirectly subsidized with the Community financing projects which would otherwise be carried out by industry acting on its own initiative. In other words, only those medium and long-term programmes should be promoted which, as well as having some prospects of success, would not be carried out by industry or agriculture without appropriate encouragement or incentives.

(b) Savings on expenditure, repayment

16. The possibility of industry repaying subsidies in cases where the results of research are successfully applied should therefore be considered.

On page 13 of the proposal the Commission states that 'the invention, patentable or not, shall belong to the contractor if he so desires'.

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[1] Commission proposal, paragraph 3.2.4, page 10.

17. In pursuing the aim of a repayment approach, detailed criteria would have to be laid down specifying under what circumstances and at what time repayment would be made. The Commission is asked to incorporate a repayment clause in the regulation and in individual contracts to be concluded by it in cases where the results of the research are used for industrial or commercial purposes and earn profits. This aspect should be dealt with independently from the lodging of patent applications.

18. The Committee on Budgets realizes that it is extremely difficult to define criteria in a legally water-tight manner and to ascertain the possible benefits of a project. However, the Commission should do everything possible to benefit ultimately from any commercial exploitation of the results of Community organised research by way of payment of royalty fees by commercial interests benefitting from such research, which income could be used to finance new research programmes. If the Commission is unable to obtain refunds on payments corresponding to commercial profits, because of a lack of authority to enforce the corresponding decisions, it would be appropriate to consider whether sufficient pressure could be brought to bear by refusing to conclude further contracts with those companies.

Concerning this idea of refund or share of royalties, the ECSC General Provisions applicable to research agreements give a suitable precedent, as laid down in Annex IV of the Internal Provisions on the execution of the operational budget in Articles 8-12. Particularly in Article 12, a detailed definition of "share of royalties" is made. The Commission is asked to provide for a royalties clause in the regulation in order to lay down, where appropriate, provisions in individual contracts.

(c) Coordination

19. A further very important aim of this programme and indeed of any pooling of Community activities, must be to coordinate in a useful way the research activities of the Member States. Your draftsman does not believe that this must always necessarily result in a corresponding concentration of research centres. The general idea should be to promote or organize a system of cooperation within the Community so as to improve the overall effectiveness or optimize the productivity of research. This, if it were achieved, would help the Community to compete more successfully with countries such as the USA and Japan.

(d) Administration and organization - advisory programme committee

20. As far as the administration and organization of the work is concerned, it has already been pointed out that the Commission would assume full responsibility for implementing the projects. The Committee on Budgets can agree to the setting up of an advisory committee containing representatives of the Member States provided such body would be purely consultative.

21. This raises once again the question of the real role of programme committees. The Committee on Budgetary Control has already dealt extensively with the problem of administrative committees and advisory programme committees in the course of its work on preparing the discharge for the 1978 financial year. It feels that 'these bodies are useful and important, particularly for ensuring scientific advice and coordination between the Community and the Member States'.[1]

22. Nevertheless, it must be re-emphasized that the Commission should resist any pressure from these committees aimed at influencing decisions for which the former is competent. It must also decisively oppose the disruption of programmes by Member States withdrawing once interesting results begin to emerge and continuing the research at national level. The Commission should be urged to report such occurrences immediately to the Parliament or its Committee on Budgetary Control.

(e) Staff

23. As far as staff are concerned, the Committee on Budgets recognizes its limited capacity to judge whether the Commission has sufficient experts to cope with such a specialized field and supervise the research work or whether three new A category officials are indeed essential. It points out, however, that a sufficient number of experts were available to draw up the programme in the first place and conduct the preparatory seminars and contacts with industry. The Committee on Budgets therefore calls on the relevant expert committee and on the Commission to consider carefully whether any experts already on its staff could be seconded to this project. The Committee on Budgets consequently takes note of the request for posts subject to the usual provisos.

(f) Fixing of expenditure

24. The Committee on Budgets is once again forced to point out that it cannot agree to the Council fixing a ceiling on expenditure for the duration of the five-year programme.

(1) PE 62.880/rev., page 22

25. Although a satisfactory arrangement was reached some time ago with the Commission regarding the expenditure estimates in Article 2 of the regulations (the present proposal for a regulation also contains this text), the Council persists in regularly 'fixing' the volume of appropriations and the number of posts for research programmes in the regulations it adopts[1]. This constitutes a presumptious but illegal violation of the budgetary powers of the European Parliament in its capacity as one of the two arms of the budgetary authority, and shows the Council's disregard for budgetary procedures. A provision which satisfies the Parliament as far as the research field is concerned is to be found in the Commission's proposal for a regulation amending the Financial Regulation of 21 December 1977[2] but the Council excluded this aspect from its decision[3]. This problem must be solved as a matter of urgency in the proposed revision of the Financial Regulation to be carried out this year. But even before that, the Council should at last agree to such an arrangement when adopting this new research programme. The Committee on Budgets urges the Committee on Energy to request that the conciliation procedure be initiated, if the Council refuses yet again to go along with Parliament in this matter. If the Council refuses such conciliation, the Committee on Budgets may find itself reluctantly compelled to recommend that Parliament use the budget procedure to block all appropriations for a research programme of this kind (non-compulsory expenditure).

CONCLUSIONS

The Committee on Budgets approves the Commission proposal for a regulation while urging the committee responsible, the Committee on Energy and Research, to make final approval by Parliament conditional on clarification of the following points:

(a) Does the expansion of Community research in this field not mean that resources are being too thinly spread, or in other words that a programme of this type upsets the Community's research priorities?

(b) Would it be possible for the Commission to use existing specialized staff for this research project, thus in effect reducing the requirement for new staff?

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[1] See the latest Council decisions on research programmes for radiation protection, the management and storage of radioactive waste and medicine and public health, OJ L 78, 25 March 1980, pages 19-25

[2] See amendments to Article 88 in the Commission proposal, OJ C 160, 6 July 1978, page 11

[3] OJ L 160, 28 June 1979, page 1

In this matter the Committee on Budgets favours:

- efficient and concentrated use of all the research appropriations available to the Community,
- meeting staff requirements by transfer of existing personnel.

If the Committee on Energy and Research also decided to approve the proposal, the Committee on Budgets would like to see the following points included in the resolution:

- Approves the Commission proposal, particularly with a view to achieving the efficient coordination of individual national research activities at Community level and hence arrive at a sensible concentration of research expenditure in this field;
- Urges the Commission in this connection to give first priority to promoting or financing those medium and long-term research projects which, despite their likely success, would nevertheless not be carried out by industry and agriculture without appropriate encouragement or incentives;
- Calls for the conciliation procedure to be initiated if the Council presumes, once again, to infringe the budgetary powers of the European Parliament by 'fixing' the level of appropriations and number of posts in the text of the regulation for the duration of this research programme and gives notice that Parliament may find itself compelled, if this legitimate wish is ignored, to block all the appropriations entered for this purpose in the appropriate budget.
- Reiterates its view that all the advisory committees active in the research sector, including the advisory programme committee provided for in this particular programme, should have a purely advisory role and calls upon the Commission to inform the Parliament without delay of any overstepping of this authority which has already taken place or is liable to occur;
- Requests the Commission to incorporate a royalties clause in the research contracts planned with industrial undertakings;
- Requests the Commission to incorporate the following amendments in its proposal in accordance with Article 149, second paragraph, of the EEC Treaty.

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES	AMENDED TEXT

Preamble and recitals unchanged

Article 1 unchanged

n e w Article 2

1. The Community shall promote the research projects described in Annex A as an indirect action by means of cost-sharing contracts. Provision shall be made for repayment of a part of the contribution if the research proves successful and is utilized industrially or commercially and/or leads to the lodging of a corresponding patent application and the subsequent award of licences.

2. The average contribution shall not exceed 50%. In calculating the Community's contribution towards a particular project, account shall be taken of all other subsidies which have been granted or are expected.

3. The Commission shall negotiate and conclude the necessary contracts. For this purpose, it shall draw up a standard contract defining the rights and obligations of each party, including where appropriate conditions and procedures for the possible repayment of amounts contributed.

Article 2 becomes Article 3

Article 3 becomes Article 4

Article 4 becomes Article 5

Article 5 becomes Article 6

1979 BUDGET - PROGRAMME OF INDIRECT ACTIONS

Item	Heading	Staff for 1979					Programme Decision				
		A	B	C	D	Total	Date	Effective from	Duration	Ceiling: EUA	Staff approved
3350	Training	2	2	2	-	6	21.12.76	1.01.77	4 years	4.600.000	6
3351	Fusion and plasma physics	74	35	3	-	112	25.03.76	1.01.76	5 years	124.000.000	113
3351	JET	70	44	11	-	125	30.05.78	1.01.78	12 years	102.400.000	150
3352	Biology and health protection	41	12	10	1	64	15.03.76	1.01.76	5 years	39.000.000	68
3353	Reference materials and methods	8	1	4	-	13	9.10.79	1.01.79	4 years	10.300.000	14
3354	Environment	6	1	3	-	10	15.03.76	1.01.76	5 years	16.000.000	10
	Amendment	"	"	"	-	"	9.10.79	"	"	20.800.000	"
3355	The plutonium cycle	2	1	-	-	3	17.12.74	1.01.75	4 years	4.500.000	3
	Amendment	"	"	-	-	"	10.10.78	1.01.75	5 years	4.750.000	"
3356	Management and storage of radioactive waste	2	1	1	-	4	26.06.75	1.01.75	5 years	19.160.000	4
3357	Energy research and development	12	7	8	-	27	22.08.75	1.07.75	4 years	59.000.000	27
	1st programme										
	2nd programme	17	7	10	-	34	11.09.79	1.07.79	4 years	105.000.000	34
3359	Decommissioning of nuclear power stations	2	-	-	-	2	27.03.79	1.01.79	5 years	4.700.000	3
3361	Primary raw materials	5	1	2	-	8	6.03.78	1.01.78	4 years	18.000.000	8
3362	Long-term forecasts and evaluations	6	1	3	-	10	25.07.78	17.08.78	5 years	4.400.000	10
3363	Water-cooled thermal reactor safety	2	-	-	-	2	27.03.79	1.01.79	5 years	6.300.000	3
3364	Uranium ore prospecting and processing	2	-	1	-	3	6.03.78	1.01.78	3 years	3.000.000	3
3365	Recycling of wastepaper and board	1	-	1	-	2	17.04.78	1.01.78	3 years	2.900.000	2
3370	Council resolution on nuclear safety	4	2	2	-	8	22.07.75	-	-	-	8
3380	BR2 reactor	8	16	2	-	26	27.11.73	-	-	-	30
3381	Other research staff made available	17	4	-	-	21	24.04.74	(C.E.A.)	-	-	13
							21.03.74	(G.F.K.)	-	-	6
							25.04.74	(Luxatom)	-	-	1

Item	H e a d i n g	Staff for 1979					Programme Decision				
		A	B	C	D	Total	Date	Effective from	Duration	Ceiling: EUA	Staff approved
3371-0	Processing and utilization of sewage sludge	-	-	-	-	-	27.09.77	19.10.77	3 years	140.000	-
3371-1	Growth of large urban concentrations	-	-	-	-	-	7.02.78	17.02.78	2 years	200.000	-
3371-2	Medical research I -	-	-	-	-	-	13.02.78	1.01.78	3 years	850.000	-
	- abnormalities										
	- cellular ageing	-	-	-	-	-	13.02.78	1.01.78	4 years	400.000	-
	- oxygenation	-	-	-	-	-	13.02.78	1.01.78	4 years	360.000	-
3371-3	Food technology I	-	-	-	-	-	20.02.78	25.02.78	3 years	250.000	-
3371-4	Analysis of organic micro-pollutants in water	1	-	-	-	1	9.10.78	4.11.78	4 years	480.000	1
3371-5	Physicochemical behaviour of atmospheric pollutants	1	-	1	-	2	9.10.78	4.11.78	4 years	500.000	2
									Total :	551.990.000	

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND CONSUMER PROTECTION

Letter from the chairman to Mrs WALZ, chairman of the Committee on Energy and Research

25 April, 1980

Dear Mrs Walz,

At its meeting of 25 April 1980[1] the Committee on the Environment, Public Health and Consumer Protection considered the proposal from the Commission of the European Communities to the Council for a multiannual Community programme of research and development in biomolecular engineering (indirect action: 1981-1985)(Doc. 1-750/79) on which it was asked for its opinion on 12 February 1980.

It was emphasised that a Community biotechnology programme could fill some of the gaps in the scientific field in the Community and boost the Member States' efforts in this sector.

The programme is concerned in particular with the stimulation and coordination of a range of applied research for the development of enzyme technology of suitable host-vector systems and also for the solution of important practical problems which prevent the control of expression of foreign DNA.

The Community is to make provision in the 1981 budget for about half the estimated financial requirement of this indirect action, which is based on Article 235 of the EEC Treaty, and which provides for the setting up of an Advisory Committee to assist the Commission in its management task. With the harmonious development of regulations and protective measures which new techniques should always be accompanied by as soon as they are introduced, it offers innovative potential as regards application in agriculture and industry and the protection of mankind and his environment.

Considering that the biomolecular engineering programme actually meets a need and as such has been favourably assessed by the Scientific and Technical Research Committee (CREST), the Committee on the Environment, Public Health and Consumer Protection hereby expresses its complete approval with one abstention.

Please regard this document as the opinion of the Committee on the Environment, Public Health and Consumer Protection.

Yours sincerely,

(sgd) Kenneth COLLINS
Chairman

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[1]Present: Mr Alber, Vice-Chairman; Mr Adam , Mr Ceravolo, Mrs Fuillet, Mr Forth, Mr Ghergo, Mrs Maij-Weggen, Mr Muntingh, Mr Newton Dunn, Mrs Scrivener, Mr Sherlock, Mrs Spaak, Mrs Squarcialupi

OPINION OF THE COMMITTEE ON ECONOMIC AND MONETARY AFFAIRS

Letter from the chairman to Mrs WALZ, chairman of the Committee on Energy and Research

27 February 1980

Dear Mrs Walz,

At its meeting of 21 February 1980 the Committee on Economic and Monetary Affairs considered the proposal from the Commission to the Council for a multiannual Community programme of research and development in biomolecular engineering (indirect action 1981-1985).

While acknowledging the undeniable economic importance attaching to the implementation of such a research programme in this field, the members of the committee felt that they lacked the technical resources needed for making a worthwhile appraisal of the quality of the programme envisaged.

Consequently, the committee decided it would be preferable not to offer an opinion on the document in question.

I therefore ask you to regard this letter as formal notification of the committee's decision to decline to deliver an opinion in this instance.

(sgd) Jacques L. J. DELORS