



EUROPEAN PARLIAMENT

Working Documents

1984-1985

4 December 1984

4412.221

DOCUMENT 2-1144/84

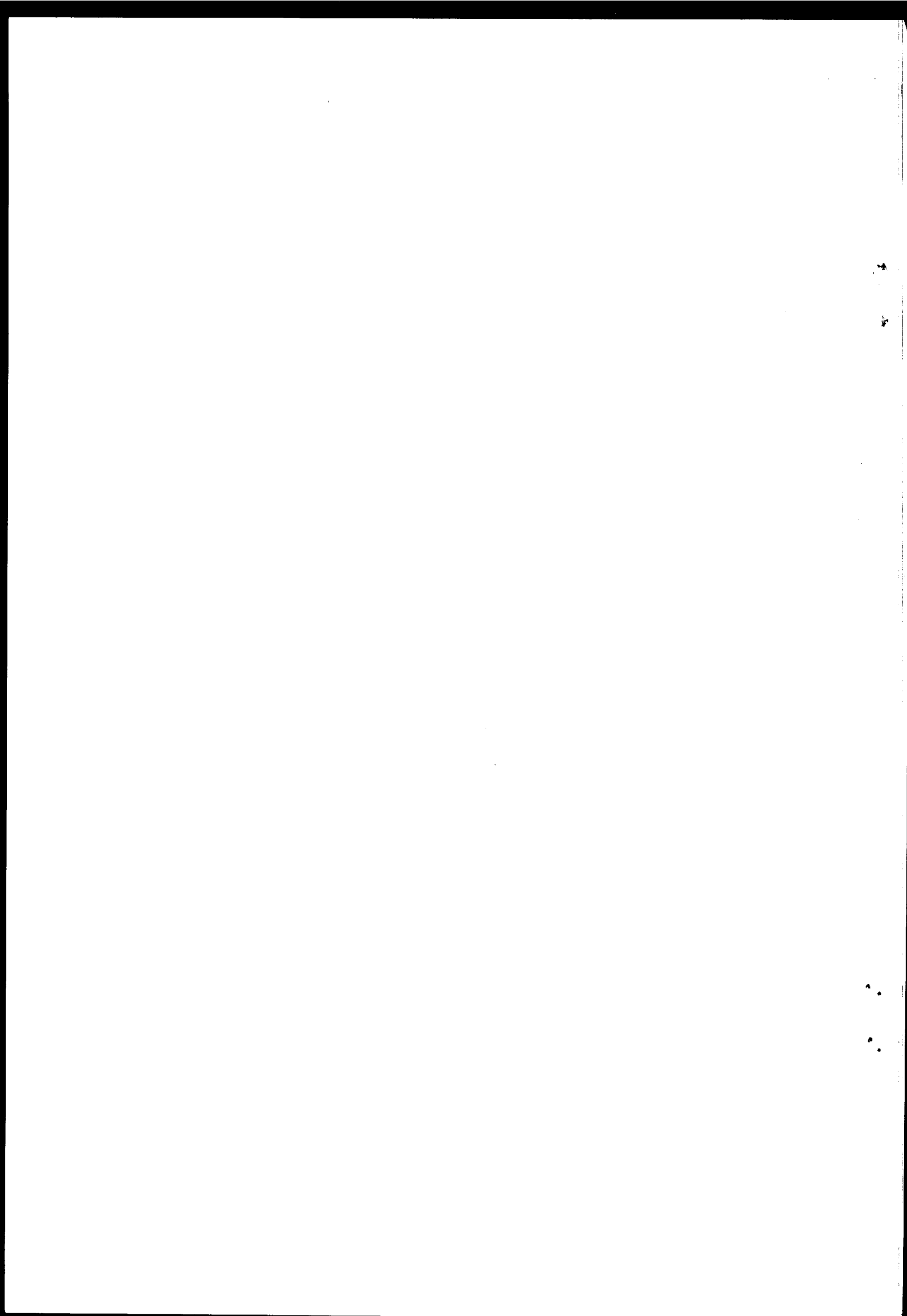
Report

drawn up on behalf of the Committee on Energy,
Research and Technology

on the proposal from the Commission of the
European Communities to the Council (COM(84) 230 final -
Doc. 1-335/84) for a decision adopting a multiannual
research action programme of the European Economic
Community in the field of biotechnology (1985-1989)

Rapporteur: Mrs P. VIEHOFF

PE 91.447/fin.



By letter of 29 May 1984, the President of the Council of the European Communities requested the European Parliament to deliver an opinion, pursuant to Article 235 of the EEC Treaty, on the proposal from the Commission of the European Communities to the Council for a decision adopting a multiannual research action programme of the European Economic Community in the field of biotechnology (1985-1989).

On 11 September 1984, the President of the European Parliament referred this proposal to the Committee on Energy, Research and Technology as the committee responsible and to the Committee on Budgets, the Committee on Economic and Monetary Affairs and Industrial Policy, the Committee on Agriculture, Fisheries and Food and the Committee on the Environment, Public Health and Consumer Protection for opinions.

The Committee on Legal Affairs and Citizens' Rights was also asked for an opinion on December 1984.

At its meeting of 11 September 1984, the Committee on Energy, Research and Technology appointed Mrs VIEHOFF rapporteur.

The committee considered the Commission's proposal and the draft report at its meetings of 20 September, 16 October and 28 November 1984.

At the last meeting, the committee decided unanimously to recommend to Parliament that it approve the Commission's proposal with the following amendments.

The Commission stated before the committee that it was prepared to accept Amendments Nos. 1-10.

The committee then adopted unanimously the motion for a resolution as a whole.

The following took part in the vote: Mr PONIATOWSKI, chairman; Mr SALZER and Mr ADAM, vice-chairmen; Mrs VIEHOFF, rapporteur; Mr CIANCAGLINI, Mr FICH (deputizing for Mr WEST), Mr GRIFFITHS (deputizing for Mrs LIENEMANN), Mr KILBY (deputizing for Mr MOLLER), Mr LINKOHR, Mr MEGAHY (deputizing for Mrs LIZIN), Mr METTEN (deputizing for Mr GLEZOS), Mr MUNCH, Mr PETERS (deputizing for Mr SMITH), Mr RINSCHÉ, Mr STAES, Mr TOKSVIG and Mr TURNER.

The opinions of the Committee on Budgets, the Committee on Agriculture, Fisheries and Food, the Committee on the Environment, Public Health and Consumer Protection and the Committee on Legal Affairs and Citizens' Rights are attached.

The report was tabled on 30 November 1984.

The deadline for tabling amendments to this report will be indicated in the draft agenda for the part-session at which it will be debated.

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The Committee on Energy, Research and Technology hereby submits to the European Parliament the following amendments to the Commission's proposal and a motion for a resolution together with explanatory statement:

I. Proposal from the Commission of the European Communities to the Council for a decision adopting a multiannual research action programme of the European Economic Community in the field of biotechnology (1985-1989)

Text proposed by the Commission of the European Communities

Amendments tabled by the Committee on Energy, Research and Technology

Preamble, recitals

1-10 unchanged

Amendment No. 1

Preamble, recital 11 to read as follows

(amend or add indents):

Preamble

Preamble

THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard

.....

- (unchanged)

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-
-

Whereas a Community research action programme is necessary for the development of biotechnology in the Community and, particularly for:

- the establishment of new methods for the synthesis of compounds with high added value,

Whereas a Community research action programme is necessary for the development of biotechnology in the Community and, particularly for:

- the establishment of new methods for the synthesis of compounds with high added value and for lowering production costs,

Text proposed by the Commission
of the European Communities

- more efficient land use through the design of new crops which can provide important feedstocks for the European industries,

- acceptability of the products of modern biotechnology through the use of new testing methods which render possible a more efficient and less costly evaluation of toxicity and biological activity

- new approaches in the detection, prevention and treatment of costly diseases,

- protection of health and environment against risks which may be associated to new developments in modern biotechnology,

- Whereas it is necessary to monitor developments in biotechnology, with a view to assessing their strategic significance for Europe, and to promote effective concertation between the Community and its Member States in matters affecting the development of biotechnology;

Amendments tabled by the Committee
on Energy, Research and Technology

- unchanged

- application of biotechnology to environmental protection,

- unchanged

- replacement of animal experiments with tests on cell cultures,

- new approaches in the detection, prevention and treatment of diseases

- protection of health and environment against risks which may be associated with new developments in and the application of biotechnology

Amendment No. 2

Preamble, twelfth recital, to be expanded as follows:
such monitoring is also needed to ensure that problems of a social, ethical and ecological nature, inherent in the application of this technology, may be recognized in good time and their adverse consequences prevented;

Rest of preamble
unchanged

Article 1(1) and (2)
unchanged

Amendment No. 3

ADD a new sub-paragraph 3:

(3) Encouragement and priority shall be given to contracts bringing together the technological resources of firms and institutions from different Member States, where possible.

Article 2
unchanged

Amendment No. 4

Article 3 to read as follows:

Article 3

The Commission will report to the Council and the European Parliament at the end of the third year of the programme and will propose, where appropriate, any amendments necessary. These amendments may lead to a revision of the programme in the course of the fourth year in accordance with the appropriate procedures.

Article 3

At the beginning of the third year the Commission shall submit to the Council an interim report on the results of the programme. On the basis of this report, the programme shall be evaluated before the end of the third year. This evaluation shall be carried out by experts not involved in the Committee referred to in Article 5 and who have themselves not received any appropriations under the research programme. A report on this evaluation shall be sent to the Council and to the European Parliament.

This evaluation may lead to the submission by the Commission of a proposal for a revision of the programme in accordance with the appropriate procedures.

Articles 4 - 6
unchanged

Amendment No. 5

Article 7, paragraph 1, to read as follows:

Article 7

(1) In accordance with Article 228 of the Treaty the Community may conclude Agreements with non-Member States participating in European Cooperation in the field of Scientific and Technical research (COST) with a view to ensuring cooperation between the Community concerted action projects referred to in the Annex and the relevant programmes of such States.

(2) The Commission is hereby authorized to negotiate the Agreements referred to in paragraph 1.

Article 7

(1) In accordance with Article 228 of the Treaty the Community may conclude Agreements with non-Member States participating in European Cooperation in the field of Scientific and Technical research (COST) or international organizations with a view to ensuring cooperation between the Community concerted action projects referred to in the Annex and the relevant programmes of such States or international organizations.

(2) unchanged

ANNEX

ACTION I - Sub-programme 1
- Bio-informatics

Amendment No. 6

Third indent

- Computer modelling of biological structures and systems

Add to the third indent:

- Computer modelling of biological structures, systems and processes.

Text proposed by the Commission
of the European Communities

Amendments tabled by the Committee
on Energy, Research and Technology

Amendment No. 7

Subprogramme 2, 2nd paragraph
'Enzyme engineering', add to the 1st
indent:

ACTION I, Sub-programme 2,
2nd paragraph

ACTION I, Sub-programme 2,
2nd paragraph

- Development and evaluation of bio-reactors (and particularly those which are multienzymatic, multiphase or co-factor requiring) for industrial applications, depollution and detoxification.

- Development and evaluation of bio-reactors (and particularly those which are multienzymatic, multiphase or co-factor requiring) for industrial and medical applications depollution and detoxification.

- unchanged

- unchanged

Sub-programme 2
3rd paragraph
'Genetic Engineering'
1st to 3rd indents
unchanged

Amendment No. 8

Add the following indent:

3rd paragraph

3rd paragraph

- Genetic engineering

- Genetic engineering

- Production of vaccines, proteins
and hormones for human medicine.

Sub-programme 2
4th and 5th paragraph
1st to 4th indents
unchanged

Amendment No. 9

5th indent to read as follows:

5th paragraph, 5th indent

5th paragraph, 5th indent

- Study of cell biology applied to the prevention, detection and treatment of a few selected diseases which are particularly important from a socio-economic point of view.

- Study of cell biology applied to the prevention, detection and treatment of a few selected diseases.

Rest of Sub-paragraph 2
unchanged

ACTION II : CONCERTATION

First to seventh indents
unchanged

Amendment No. 10

8th indent

8th indent

- disseminating knowledge and increasing public awareness of the nature and potential of biotechnology and the life sciences, to raise the quality of public debate;

Insert the following in the 8th indent:

- disseminating knowledge and increasing public awareness of the nature, potential and risks of biotechnology and the life sciences, to raise the quality of public debate;

MOTION FOR A RESOLUTION

closing the procedure for consultation of the European Parliament on the proposal from the Commission of the European Communities to the Council for a decision adopting a multiannual research action programme of the European Economic Community in the field of biotechnology (1985-1989)

The European Parliament,

- having regard to the proposal from the Commission to the Council¹,
- having been consulted by the Council pursuant to Article 235 of the EEC Treaty (Doc. 1-335/84),
- having regard to its resolution of 20 November 1980 on a multiannual Community programme of research and development in biomolecular engineering (indirect action 1981-1985)²,
- having regard to the report of the Committee on Energy, Research and Technology and the opinions of the Committee on Budgets, Committee on Economic and Monetary Affairs and Industrial Policy, Committee on Agriculture, Fisheries and Food, Committee on the Environment, Public Health and Consumer Protection and of the Committee on Legal Affairs and Citizens' Rights (Doc. 2-1144/84),
- having regard to the result of the vote on the Commission's proposal,
 - A. recognizing the widespread application possibilities of biotechnology and its possible contribution to new economic activities, but bearing also in mind the far-reaching consequences of the use of biotechnology,
 - B. noting that many aspects of genetic engineering may lead to dangers for human society and for the environment,

¹ OJ No. C 182, 9.7.84, p. 7

² OJ No. C 327, 15.12.80, p. 38 (Doc. 1-521/80, SCHMID report)

- C. recalling the promising results of the Biomolecular Research and Training Programme and the growing willingness among the best European laboratories to cooperate within this framework that can also be considered as an important building block,
 - D. aware that R & D funding by governments for biotechnology in Europe lags behind the USA,
 - E. noting the fragmented market, the duplication of R & D efforts in the Member States, and therefore the need of a concertation unit to coordinate national and European research, training and information on biotechnology,
 - F. aware of the European competitive edge in several sectors and the promising chances for a European biotechnology industry,
1. Stresses the political importance and economic necessity for a European Biotechnology Action Programme;
 2. Calls, however, at the same time, for an adequate European biotechnology assessment programme - drawn up in close collaboration with national assessment programmes - which covers all political, economic, legal, ethical and environmental aspects and involves the participation of a broad spectrum of the social groups concerned;
 3. Welcomes the institution of a programme as a means not only to stimulate research, but also to bring together European expertise at present fragmented by Community internal frontiers, and by the lack of sufficient contracts between firms and universities in different Member States;
 4. Stresses the need to encourage small and medium-sized enterprises to participate in the implementation of the programme;
 5. Requests the Commission to stimulate research projects having regard to work already in progress in USA and Japan so as to create an indigenous European biotechnological capability based on international cooperation where this is appropriate and on independent actions where this is desirable;

6. Stresses the need for a stimulation programme for the downstream processing industry and for biomolecular software, not only with the larger firms which have access to risk capital, but also with innovative small and medium-sized firms, and for this purpose stresses the need for the adoption of the Community scheme to provide risk capital in the form of innovation loans to small and medium sized firms as called for by the Commission and Parliament in the draft budget 1985, line 757;
7. Recognizes the positive effects of cooperation with ESPRIT and other Community information/documentation programmes;
8. Urges measures to stem the European brain drain, in particular to the USA, by improving scientific cooperation and the exchange of scientists in the Community and by encouraging research by European industry;
9. Stresses the necessity of harmonization of patent law to prevent unfair competition by ensuring that biotechnological innovations are treated harmoniously by the legal systems of the European Community;
10. Underlines the need to harmonize safety guidelines in all Member States and demands that in case of big differences between national safety guidelines for all experiments, laboratory trials and production processes, the most far-reaching guidelines will be followed;
11. Calls therefore on the Commission to make proposals as soon as possible in the context of Action IV for common safety precautions, particularly for DNS recombinations;
12. Stresses the major impact biotechnology can have on agriculture, and thus urges for an urgent extension of (re)training facilities and on-the-job-training to anticipate the expected growing outflow in agriculture and the agro-food industry;
13. Demands extensive research on a restructuring of the agriculture policy of the Community (new prices and market regimes, e.g. starch and sugar and in the future also for other products);

14. Calls on the Commission to harmonize programme sections 2.2.2.4., 2.2.2.5. and 2.4 of the biotechnology research programme with Section 2b of the COST research action on the effects of processing and marketing on the quality and nutritional value of foodstuffs and in particular to investigate in this context the toxicological aspects of which no account was taken in the COST research action;
15. Stresses the pressing need for an adequate policy for the regions most affected through the application of biotechnology;
16. Recognizes the possible positive effects of biotechnology for the Third World;
17. Is aware, however, that the more likely negative effects necessitate protecting measures and guidelines to prevent the Third World countries being used as testing grounds, and stresses the need for international agreements on this;
18. Demands that scientists from Third World countries be given easier access to training facilities in the Community;
19. Calls upon the Commission to cooperate closely with the International Centers for Genetic Engineering and Biotechnology (ICGEB) of UNIDO in Trieste and in India;
20. Calls on the Commission to involve the trade unions in the implementation of this programme and, in particular, in the work of the Consultative Management and Coordination Committee (CMCC);
21. Asks its Committee on Energy, Research and Technology to hold a hearing of experts on all biotechnology related questions;
22. Calls on the Commission to adopt, on the basis of Article 149, second paragraph, of the EEC Treaty, the amendments which it has tabled to the Commission's proposal;
23. Instructs its President to forward to the Council and Commission, as Parliament's opinion, the Commission's proposal as voted by Parliament and the corresponding resolution.

EXPLANATORY STATEMENTI. INTRODUCTION

1. Biotechnology has become one of the most rapidly developing fields of science and technology. Although biological processes and organisms have been used throughout history, modern scientifically based interdisciplinary biotechnology has developed only since the early 1940's. As defined by the European Federation of Biotechnology:

"Biotechnology is the integrated use of biochemistry, microbiology and engineering sciences to achieve the technological application of the capabilities of micro-organisms, cultured tissue cells and parts thereof."(1)

2. In the past 10 years, dramatic new developments in the ability to select and manipulate genetic material have cumulated in a new technique called 'genetic engineering'. The novel techniques used in biotechnology like Recombinant DNA technology, Cell fusion, and Bioprocess technology, are extremely powerful because they allow a large amount of control over biological systems.(2) Biotechnology could potentially affect any current industrial biological process or any process in which a biological catalyst could replace a chemical one. The potential applications are numerous. Industrial applications will be found particularly in pharmaceuticals, animal and plant agriculture, speciality chemicals and food additives, waste treatment and environmental areas, commodity chemicals and energy production, and bioelectronics.(3)

3. The biotechnology-related market is substantial since almost 40% of the products manufactured by the industrial countries are of biological origin. Recent estimates speak of a market of US \$ 50-100 billion for biotechnology by the year 2000. For recombinant DNA alone, the Genex Corporation (USA) predicts a volume of about US \$ 40 billion.(4)

4. It seems that biotechnology can give an answer to some of the world's most pressing problems, such as disease, malnutrition, pollution and low-cost fuel, but expectations should not be exaggerated. Although exciting results of basic research emerge at an ever increasing rate, the prospects for the potential use of biotechnology will mainly depend on the economic, political, social, legal, and cultural conditions and risk assessment. These aspects have not got as much attention in the Commission's proposal as in other recent Commission papers. In this first report some of these aspects will be described shortly. In the final-report a more extensive elaboration of these and other aspects will follow.

II. THE POLITICAL IMPORTANCE AND ECONOMIC NECESSITY OF AN EUROPEAN BIOTECHNOLOGY PROGRAMME

5. According to the Commission "strength in biotechnology is of strategic importance for the competitiveness of industry and agriculture, and for enhancing the quality of human life and the natural environment."(5) Some theorists see biotechnology as a powerful tool for renewal and innovation of the socio-economic base of contemporary society that provides an incentive and a direction for new capital ac-

cumulation needed to re-establish a phase of economic growth.(6) Others assume that biotechnology is altering certain aspects of the international division of labour through increased competition between the industries to which it is relevant (agro-food, petrochemicals, pharmaceuticals etc.) and through increasing competition in domestic European markets as well as between Europe, the USA and Japan.(7) Perhaps biotechnology could also contribute to the easing of certain strategic constraints at world scale, which weigh particularly upon countries in the Third World; basic health, food production and storage, nutrition, energy and environmental problems.(8)

6. The importance of biotechnology as a key sector of future industrial development is reflected in the numerous national governmental initiatives to promote biotechnology.(9) In some sense one can speak of a 'biotechnology-race'. This can stimulate faster innovation, but it can also lead to unnecessary secrecy, parallel R&D efforts and duplication, wasting of money, and fragmented knowledge. Eventually it can lead to a situation in which one has to give the own market away to the strongest competitors, in particularly by signing joint ventures with American or Japanese firms.

7. It is obvious that a serious danger lies in the growing dependency of European firms that have concluded joint ventures or have obtained licences from American firms. The extraterritorial jurisdiction of the U.S.A. makes it possible that American technologies and products (or parts for production) that are already in Europe, still remain under the American jurisdiction. This means that the length of the American trade arm is much longer and this can have severe repercussions for the European counterparts. Furthermore, the American authorities can determine whether a high technology product (or parts of it) can be exported outside the USA. The list of products and parts that are non transferrable is growing 'for national security reasons'. Also the fact that Europeans are not always admitted anymore to congresses on high technology issues must be seen as a protectionist move of the U.S. The blockage of information can be the more serious the more dependent European companies are of their American counterparts.

8. In a recent report of the Office of Science and Technology Policy for the US-Government it is stated that "(...)it has been a matter of concern that the transfer of biotechnology abroad might jeopardize America's scientific and commercial leadership and national security interests. This has engendered pressures for the implementation of government policies and regulations to control such transfer."(10) Although there is a common knowledge base in biotechnology that can be applied to the development and manufacture of military useful products (biological warfare-type agents) (11), the danger that other countries will be faster in commercial biotechnological appliances seems to be of more interest. Export controls will be an attempt of the US Government to "balance national security and economic objectives."(12) It is recommended to control better the channels for transferring those technologies, which range from exchanges and visits of scientists, trade shows, transfer of data bases, publications, licenses to patents, and industrial and military espionage.(13)

9. A joint European biotechnology programme can provide a better international coordination of efforts between ministries, disciplines, governments, consumers, international bodies, university and industry. A concertation unit as proposed by the Commission seems to fulfill these tasks.

The very promising results of the research and training programme in biomolecular engineering (1982-86), in which many of the best laboratories of Europe cooperate, can be seen as an important building for a more extensive biotechnology programme. There is a strong growing willingness among laboratories and biotechnologists to do international joint research and to train foreign scientists in the framework of the programme. Another reason to support a European biotechnology programme - and this is perhaps even more crucial - is that it can stimulate the creation of an internal European market and a common European legislation in biotechnology. In this context also the markets of Sweden, Switzerland, and Austria should be taken into account as they are participants of the European Molecular Biology Laboratory (EMBL) in Heidelberg (FRG). The dimension of a European market is a prerequisite for a competitive position of individual European firms.

III. THE POSITION OF THE EUROPEAN BIOTECHNOLOGY IN COMPARISON WITH THE UNITED STATES AND JAPAN

10. The recent report of the Office of Technology Assessment (OTA) of the Congress of the U.S.A., Commercial Biotechnology, an International Analysis, has made a thorough comparative analysis of the perspectives for commercialisation of the new biotechnologies by the USA, Japan and four European countries, the Federal Republic of Germany, France, the UK and Switzerland. (14) The main conclusions can be summarised as follows:

- The USA has at present a competitive advancement in the commercialisation of biotechnology owing to a well-developed life science base, the availability of financing for risk ventures and an entrepreneurial spirit. More attention should be directed to research problems associated with scale-up of bioprocesses for production
- Japan is likely to be the leading competitor to the USA for two reasons: a broad range of industrial sectors have extensive experience in bioprocess technology and the Japanese government has targeted biotechnology as a key technology of the future, is funding its commercial development and coordinates interactions among representatives from industry, universities and government.
- The European countries (West-Germany, France, the UK and Switzerland) are not moving as rapidly to commercialisation of biotechnology and are not expected to be as strong competitors as the USA and Japan. The European countries generally do not promote risk taking, either in industry or in government policies and they have fewer companies commercializing biotechnology. In markets for specific products, including some pharmaceuticals, speciality chemicals and animal agriculture products, some European companies will undoubtedly be strong international competitors.

11. The OTA Report only deals with four European countries. In a recent publication of the European Federation of Biotechnology, A Realistic View on Biotechnology, (September 1984) a portfolio chart of biotechnology is composed for 17 European countries. (15) A distinction is made between high-tech biotechnology (fermentation industry, pharmaceutical industry, fine chemicals, food/feed, biotechnological equipment/plants and waste water treatment) and low-tech biotechnology

(food, alcoholic beverages, waste water treatment, fermentation technology as ethanol, and biotechnological equipment). According to these data the European competitive edges are fermentation products, pharmaceuticals, alcoholic beverages and food/feed. It seems that exporting countries with a broad representation in the high-tech biotechnologies are Denmark, Belgium, West Germany, France, the Netherlands, Switzerland and the U.K.

In the low-tech field of the more traditional biotechnologies the following countries with strong export positions are noted to have a broad coverage: Denmark, France, Italy, the Netherlands, Switzerland and the U.K.

The total picture indicates that in addition to West Germany, France, Italy and the U.K., the smaller countries which have a strong overall position are: Denmark, the Netherlands, Switzerland and Belgium.

12. In several fields European companies have a leading position, particularly in pharmaceuticals and in the fermentation industry (enzymes, antibiotics).(16) However, some of the European pharmaceutical firms have transferred parts of their biotechnological research to the US.(17) This itself can be seen as an indicator of the weakness of the European market. In a recent study by Frost and Sullivan it is stated that Europe's position in international pharmaceutical markets is likely to deteriorate over the next five years because of the higher level of regulation of drug companies and prices by European governments.(18) The position in Europe contrasts sharply with the US where recent legislation will help to extend patent life for drugs, thus protecting drug prices for the major drug innovators.

Although the first industrial applications of biotechnology are expected to occur in pharmaceuticals, the Community should give more attention to the applications on the medium and long term in (animal) agriculture and speciality chemicals. An important reason for the latter priority is that the potential in the second cluster is much larger and that the pharmaceutical industry is a strongly concentrated, multinational industry with enough resources to fund research for its own purposes. The legal, regulatory and ethical aspects in the development of biotechnology for pharmaceuticals, however, should get the full attention of the Community. (See further paragraph VII.39).

13. The lack of European competitiveness results from serious deficiencies and weaknesses affecting the entire training-research-development-production-distribution-network upon which modern technologies need to be based. They can be ascribed to scale and structural factors, which are, themselves, the direct consequences of fragmentation into isolated national policies.(19)

14. Two other recent American studies arrived independently at the conclusion that Europe's biotechnology is lagging behind the US and Japan.(20) In one it is said that "(...)The US faces the stiffest challenge from Japan." And further: "(...)In general, the lack of qualified scientists and engineers (particularly in process and purification technologies), inadequate industry/university cooperation, and belated and insufficient R&D funding by industry and government, are probably the biggest barriers to commercial competitiveness in these countries." In both reports Japan is seen as the most serious competitor to the United States in biotechnology.

15. The Commission of the European Communities claims that Europe has the scientific knowledge, the industrial capacity and the agrarian basis to be "the world's number one" in biotechnology.(21) This optimistic outlook is based on the following factors of strength:(22)

- a strong position in basic research
- a strong chemical and food industry
- a strong position in 'classical' biotechnology (brewery and dairy industries)
- increasing public spending (see paragraph IV)
- a strong agricultural base; the surpluses (sugar yeast, milk) can be used as industrial inputs for biotechnological processes, - if the price level is attractive enough to the industry. (see also paragraph VII)

IV. GOVERNMENT FUNDS FOR BIOTECHNOLOGY. A COMPARISON BETWEEN THE UNITED STATES, JAPAN AND THE EUROPEAN COMMUNITY

16. The multi- and interdisciplinary character of biotechnology and its wide spread applications make it particularly difficult to obtain a clear and quantitative picture of biotechnology R&D activity in the Member States and in the USA and Japan for comparison. The different figures reflect definitions varying from very narrow, to very comprehensive, including agriculture and medical research. Therefore the figures presented cannot give any more than a rough indication of the situation in 1982/83.(23)

17. In the UNITED STATES the main federal support for activities related to biotechnology is channelled through two sources: the National Science Foundation (NSF), which is the principal federal agency for the support of basic research across all fields of science, and the National Institutes of Health (NIH), which are responsible for basic research in medicine and health care, and are also responsible for the registration of federally funded research work on recombinant DNA.(24) The US Department of Agriculture (USDA) is also funding basic research related to agriculture, some of which involves projects and techniques which may be described as biotechnology; similarly the Department of Energy's studies of biomass-based energy sources involve basic biology and biotechnology.

18. In fiscal year 1980, the NIH supported 717 basic research projects involving recombinant DNA at a cost of \$ 91.5 million. At the request of OTA, the NIH recently estimated what proportion of their budget might be classified as "biotechnology": for FY 1982, approximately \$ 380 m., versus \$ 170 m. in 1980.(25) "Biotechnology-relevant" research supported by the NSF in FY 1980 amounted to \$ 66 m.(26) USDA's Competitive Grants Programme (1982: \$ 16.5m.) supports new research directions in plant biology. But here also, the biotechnology-relevant research is overshadowed by the total budget of the Agricultural Research Service (\$ 458m. proposed for 1984). The ARS budget itself forms only part of the Dept. of Agriculture's total R&D spending (\$ 839m. estimated outlays in FY 1983), and including state programmes the total is over \$ 1.5 billion a year.(27)

19. Combining the figures suggests U.S. federal expenditure of at least \$ 200 m. p.a. in areas directly relevant to biotechnology. But

of equal or greater relevance to the country's strategic capability. are the much larger sums referred to which indicate that 10% of the total budgets of NIH, NSF and USDA may be viewed as biotechnology-relevant. Hence one can arrive at the following estimate on this broader basis:

ESTIMATION GOVERNMENTAL R&D IN THE UNITED STATES

NIH	: 10% of \$ 3.7 bn/NIH estimate - Biotechnology resource Program	\$ 380 million 20
NSF	: (1980, careful estimate)	66
USDA	: 10% of ARS \$ 426 m. (1982) = + biotechnology elements of State Agricultural Experiment Stations (50% federal, 50% State)	40 30
Dept. of Energy and other agencies		10-20
TOTAL ESTIMATE		<u>\$ 550 million</u>

20. In JAPAN, Government support for biotechnology dates from the beginning of the 1970's. The Science and Technology Agency initiated the new government biotechnology programmes by establishing a Committee for the Promotion of Life Science in 1973.(28) Support has increased steadily since then. Support in 1981 for Life Science in general is estimated at a minimum of ¥ 50.000 million (\$ 195 m.) and if one considers only the more restricted areas which are currently referred to as biotechnology the support was of the order of ¥ 5.600 million (approximately \$ 22 million). Government financial support has increased in 1982 with the announcement of the Ministry of International Trade and Industry's (MITI) biotechnology national projects. These projects are the Biomass Development Project concerned with alcohol production (1980-1987, total budget approximately \$ 48 m.) and the Next Generation Industries national project which has three biotechnology themes (1981-1991, total budget in biotechnology sector is approximately \$ 116 m.).(29) MITI is coordinating its strategy through the Bio-industry office and the Research Association for Biotechnology. The work is mostly done by industry though paid for by the government.

21. A more recent report quotes 7.471 m. ¥ for government expenditure on biotechnology R&D in 1982, and 7.906 m. ¥ (approximately \$ 32.2m.) budgetted for 1983, apparently including all ministries and agencies; if this omits the national projects cited above, the total must be well over \$ 50 million p.a. for 1983.(30)

22. In the EUROPEAN COMMUNITY we have to do with a fragmented market and with national initiatives of the Member States. The last years show a growing tendency for joint Community R&D policy in biotechnology. An example is the Biomolecular Engineering Programme, which started in 1982 after several years of extensive consultations and reports.(31) Although the scope of the programme is very broad, the size of this programme is modest: only 4 mio. ECU p.a.; however, the results are impressive and can be seen as a first big step towards a European biotechnology research programme. The general objectives of the programme are to promote and stimulate the development of new technologies leading to:

a. the manufacture of improved agricultural and bio-industrial products,

b. the determination of more efficient and safer production methods. Also in other related areas (e.g. agriculture research programme) biotechnological research is done.(32)

23. The efforts of the Member States on national level give the following rough indication:(33)

SUMMARY ESTIMATES BY COUNTRY OF PUBLIC EXPENDITURE
ON BIOTECHNOLOGY R&D (in m. ECUS; 1982/1983)

	<u>BIOTECHNOLOGY</u>	<u>"BIOTECHNOLOGY- RELEVANT"</u>
<u>West-Germany</u>		
(BMFT): DM 63 m. (projects) + 20 m. (institutional support) = DM 83 m.:	36	
Alternatively, estimate 10% of medical, agro-food and life- sciences research as "biotechnology relevant", i.e. "broad basis":		132
<u>France</u>		
FF 200 m. on education and research in biotechnology in 1982:	31	
Alternatively, "broad basis":		84
<u>United Kingdom</u>		
£ 28.8 m. (Research Councils, UGC, Dept. of Industry):	46	
Alternatively, "broad basis":		56
<u>Italy</u>		
CNR 5-year programmes on genetic engineering and biomedical/industry programme:	13	
Alternatively, "broad basis":		34
<u>Netherlands</u>		
Hfl. 70m. for biotechnology programme ('82-'88) plus university research 10-20 Hfl. p.a.: about 25 m. p.a.:	10	
Alternatively: "broad basis":		26
<u>Belgium</u>		
SSPS (molec.biol.etc.): FB 200 m. p.a.) plus ISRIA (100): at least FB 300 m. p.a.:	7	
Alternatively, "broad basis":		14
<u>Denmark, Greece, Ireland, Luxembourg: †</u>	3	6
	<hr/> 146	<hr/> 355
(US \$ m.):	<hr/> 130	<hr/> 320

24. For publicly supported R&D in biotechnology and related areas the following figures can give a rough indication for the position of the European Community, the USA and Japan.

European Community: 146 million ECU on narrow basis, up to 335 million ECU on broad basis (\$ 130 m. - \$ 320 m. p.a.)

United States: at least \$ 200 million p.a.; up to \$ 550 million p.a. on broad basis.

Japan: at least \$ 50 million p.a.

How tentative these figures are, they show at least that the R&D efforts of Europe in biotechnology are less than in the US, but much higher than in Japan. However, the size of the R&D expenditures is not so important. As we have learned from the Japanese efforts in microelectronics and computers the organization and coordination of research and development, as well as the interaction and training efforts are crucial. Some of these tasks can be fulfilled by a European concertation unit, as proposed by the Commission.

It should be noted that the R&D expenditures of the governments are only a fraction of the R&D expenditures on biotechnology of the companies concerned. In 1982 the total industrial research expenditure in Japan was approximately \$ 203 million and was rapidly rising.(34) Industrial funding in the US is probably at least 10 times that of federal expenditure, between \$ 2 and 5.5 billion per annum.(35) For the European Community no estimation was available as this first report was written.

V. THE IMPORTANCE OF SUPPORT INDUSTRIES FOR LARGE SCALE DEVELOPMENT OF BIOTECHNOLOGY

25. A major restraint on future large-scale development in the biotechnological industry forms the limited range process operations that is available for the handling of fermentation broths and for subsequent processing.(36) The main conclusion of two recent FAST-reports on "Technological forecasting for downstream processing in biotechnology" is that there is a number of pressing needs for improved performances and innovations in the downstream processing industry in Europe. Downstream processing includes all stages subsequent to the fermentation stage of microbiological processes. Improvements are critical if the European biotechnology industry is to be competitive, and if biotechnology is to extend its range of application into bulk production via multi-stage processes or into products of moderate value and scale of production.(37) A European effort is required to stimulate cooperation among users and suppliers, because "the range of problems and possibilities is too wide for any one organisation to pursue more than a fraction of those relevant to even one process sequence."(38) In this respect the potential role of the Downstream Working Party of the European Federation of Biotechnology and their national counterparts is mentioned.

26. The European position in downstream processing is less strong in specialised instrumentation and in consumables such as adsorbants and membranes. Much of the parent technology and manufacturing capacity is not European based.(39) Consequently developments are not made available for evaluation as early as they would be in the parent countries and - although the delay in application is quite short (40)- this can lead to a further slow down and a dependent development of the European biotechnology industry.

27. BIOPROCESS TECHNOLOGY is a crucial technology. Bioprocesses are systems in which complete living cells or their components (e.g. enzymes, chloroplasts, etc.) are used to effect desired physical or chemical changes.(41) The advent of new biotechnology has sparked renewed interest in the industrial use of bioprocesses, because in most cases they are the only practical way in which a desired product can be formed.(42) In particular, the development of techniques for the immobilization of biocatalysts has greatly expanded the possibilities for continuous bioprocesses and more effective bioprocessing.(43)

28. The Japanese companies are known for their experience in large-scale bioprocessing, especially in the field of plant biotechnology and enzyme technology.(44) This will provide them competitive strengths in many future biotechnology markets, although it must be kept in mind that the Japanese companies are particularly strong in the older techniques.

29. The United States, with an assortment of companies supplying biochemical reagents, instrumentation, and software, has the strongest biotechnology support sector in the world.(45) According to the authors of Commercial Biotechnology this is due to two factors:(46)

- a. The United States is a recognized leader in basic biomedical research, and over the years, public funds, notably from the National Institutes of Health, have created a large well-defined market for speciality products used in biological research.
- b. Because so many large and small U.S. companies are currently applying biotechnology, the speciality research product needs are greater in the U.S. than in any other country, and opportunities exist for many small manufacturers.

30. In a recent report on "Emerging Membrane Separation Technologies" by International Resource Development, the importance of the bioprocessing separation and purification (filtering) technologies is stressed. The market for separation products will be worth \$ 100 m. by the end of the decade.(47) As large-scale production draws closer, the ability to isolate and purify large quantities of desired products will be a determinant in how fast companies can reach international products markets. Those countries that possess the most advanced technology to separate and purify commercially important compounds might gain some commercial advantages in the early stages of production. In the US, Japan and Europe there is an intense competition in R&D to develop more advanced separation and purification methods as well as for monitoring and controlling a bioprocess itself. In particular in automated synthesis and the use of sophisticated instrumentation to monitor and control, the US companies hold a strong competitive position. The only European firm that has a strong posi-

tion in this field is Pharmacia, a Swedish firm.(48)

31. This illustrates the weak position of the European Community and stresses the need for a joint European effort in the entire field of downstreaming process equipment since it is the crucial chain of identifying promising new products and services. European support will be needed since the research (and investments) needed are beyond the resources of most of the (smaller and medium-sized) firms. Furthermore, the European market for downstream processes is a growth market and can lead to many new, high qualified jobs and to many new small specialized firms. In the Commission's proposal more attention should be paid to the potential of this sector.

32. The development of BIO-INFORMATICS, a term which is used to refer to the various topics at the interface between information technology and biotechnology, is essential. The volume of information becoming available is such that it demands automated, high-speed reading instruments and methods.(49) In the Proposal of the Commission it is stated that for the support of bio-informatics more research is needed in the field of: (50)

- data capture technologies
- data banks
- computer models
- advanced computer software systems.

These efforts are closely linked to other information gathering working groups in the Community (e.g. ESPRIT, The Task Force on Biotechnology Information and the European Molecular Biology Laboratory).

The creation of European databanks and European molecular software implies concentration and centralisation. The information should be made available to users throughout the Community (and perhaps also to other European countries) to stimulate a faster diffusion of knowledge and research results and to build up a supporting infrastructure. Such an information system can only be successful if the big private companies collaborate. Therefore negotiations with these companies should be undertaken. Another problem that should be discussed further, in particularly with reference to paragraph II.6, is the guaranteed global access to databanks and biotic collections.

33. The development of SOFTWARE designed for molecular biology and bioprocessing is almost entirely concentrated in the United States.(51) Software is very important, because it controls all the automated processes. The US company Intelligenetics is specializing in the application of data processing and artificial intelligence techniques to biological problems and this company has created specific software packages to assist researchers with molecular genetics analysis.(52) A growing dependence on American software suppliers can lead to an insufficient exploration of possible, specific European applications of biotechnology.

VI. HOW SERIOUS IS THE BIOTECHNOLOGY BRAIN DRAIN FOR THE EC?

34. In recent years concern has been expressed at the movement of European biotechnologists (especially from the United Kingdom and West-Germany) to other countries. Although we can speak of an internal brain drain inside the European Community (especially from the United

Kingdom to the continent), the problem of the brain drain to the United States and Switzerland seems to be more serious.

35. In 1983 the Institute of Manpower Studies (IMS) made a study on this subject for the situation in the United Kingdom. A rough estimate suggests that there may be some 250 UK biotechnologists who have left since the mid-1970's and are working overseas, if young post graduates on short term contracts are included. This is about 15 per cent of the total number currently employed in the UK. The annual outflow could have been of the order of 30 per annum in the last two years.(53) While this loss has not had a significant impact on many individual organisations, it was seen as an important reduction of the UK's pool of biotechnology expertise. The main reason for leaving the UK was the non-availability of 'suitable' opportunities and jobs in the UK. At senior levels it was the attraction of new opportunities that led them to move overseas.(54) The majority did not expect to return to the UK. The Research Councils, the UK's public research institutes, have adopted an active policy of encouraging scientists from the United Kingdom who have spent time in industry abroad to return home. (55)

36. The Federal Republic of Germany has sufficient personnel to compete with the United States and other countries in biotechnology. The training of people in rDNA and hybridoma technology is now a high priority in West Germany. Like the United Kingdom, West Germany is concerned about a brain drain of biotechnology R&D personnel, because of the increasing need of high qualified people in this field. Shortages of suitable qualified workers in West Germany are partially due to brain drain to the United States. The problem, however, appears here to be less serious than in the UK.(56)

37. France has a serious shortage of qualified personnel that could well undermine the country's basic and applied science base and prevent France and its industries from competing successfully in the world biotechnology marketplace, despite the fact that France has some isolated centres of expertise.(57)

38. To prevent a further brain drain the European Community has to build up a biotechnology industry. An internal European "brain flow" should take place, e.g. from the universities to the industry and vice versa. In Europe, there is a serious shortage of trained biotechnologist with a multidisciplinary background. It is positive that the European Commission has stressed the training aspect very strongly, because without enough qualified personnel biotechnology has no future in Europe. In particular for the smaller countries, where the lack of trained manpower is sometimes more evident, the training facilities will be welcome. However, the training programmes should have an additional character and should be substantially different from the training programmes in the Member States. The industry should also contribute (in a financial way and also with staff) to the establishment of these programmes, because it is largely in their interests. The training should also contribute to further basic research. To concentrate on the short term applications of biotechnology and to neglect further basic research could hamper applications in the medium- and long run. Also more attention should be paid to on-the-job training and various scientific exchange systems.(58)

VII. THE NEED FOR A PROFOUND RESTRUCTURING OF AGRICULTURE

39. One of the goals of the Research Action Programme Biotechnology (=the Commission proposal) is the promotion of agricultural competitiveness by research and training, concertation and by promoting closer relations between industry and agriculture. Other goals closely related are "improving the management of raw materials" and "reinforcing development aid", in which basic research for agriculture is stimulated. (59) Several reasons can be given for the strong emphasis on the (medium- and longterm) prospects of biotechnology for agriculture:

- a. although biotechnology applications are now more concentrated in pharmaceuticals, the market for agro-food products is estimated to be much bigger than the market for pharmaceuticals. (In the US the market for agricultural products is "close to ten times the size of the market for all pharmaceutical health care products").(60)
- b. biotechnology can also allow improved land use, and, in particular the replacement of surplus production by products of which there is now a shortage such as wood.(61)
- c. the implementation of new biotechnology methods opens up prospects for the upgrading of agricultural products and can lead to some degree to a reduction of national and Community support for agriculture;(62)

40. The second reason will demand a reappraisal of the use of land. Some traditional agricultural products risk to become superfluous, which will make it both highly expensive and ultimately wasteful to continue subsidising or encouraging their production.(63) This will cause serious conflicts between various interest groups in the Community. A carefully balanced restructuring policy towards the regions (and agricultural products) concerned is necessary to prevent disintegrating and to avoid further unequal regional development inside the Community. Regions that will be negatively affected should be informed in time and must be stimulated to switch to other higher value-added products. This demands a well organized informations policy, not only towards industry, but especially towards farmer organizations and other direct involved interest groups.

41. In its Communication on the Common Agricultural Policy (COM(83)500 final, 2.10) the Commission has underlined the necessity "to provide Community raw materials for biotechnology on the same conditions of competition as for external competitors."(64) In its Proposal the Commission suggests new regimes for sugar and starch for industrial use which will attain these objectives.(65) The system of lower prices for agricultural products that are used as industrial inputs is already applied in Belgium and Ireland. The reason behind these new regimes is that European industry is reluctant to buy Community agricultural surpluses, because prices are much higher than the world market prices for sugar, starch, milk). Some companies in the Community accordingly set up production units in countries such as Austria or Spain, where the prices of primary commodities are based on world market prices, and not primarily oriented on the producers (as are subsidized prices). The processed products are then re-imported into the Community. For the Community these practices worsen the agricultural situation substantially: support for the farmers remains and the surpluses grow. Lower prices for agricultural products can stimulate new industrial processes and can help to decrease surpluses. It is possible that lower prices will stimulate

farmers to switch production. It is likely, however, that this will not be a smooth process. The lower prices can also contribute to substantial lower income on farm level. In fact the farmers are in a dilemma. This is especially the case for sugarbeet-farmers: they have to sell their sugarbeets against far lower prices (otherwise they have an enormous production surplus), but the biotechnology makes it possible to produce other sweeteners, like isoglucose, fructose and aspartam, which are many more times sweeter than sugar and sometimes much cheaper.

42. The further development of industrial biotechnology in a commercially sound manner will require changes in the 'protectionist' attitude of particular sector interests. In particular, when agro-products are used as feedstocks, tariffs for commodity chemicals and the associated feedstocks will have to reflect world market prices and cannot be based on sourcing.(66) This demands a profound change of agricultural policy. In this context only some of the arising problems can be mentioned. They should be studied far more extensively than hitherto done to prevent a second 'steel-debacle' in the nearby future. Subjects for further study (e.g. in the frame work of the "SYRENA" - FAST-research programme)(67) are a.o.:

- The time-horizon of the application of biotechnology on a large scale to agriculture, and consequences for regional development and employment (regional inequalities, uneven adaption of new technologies, income inequalities at the farm level, increased scale, labor displacement, rising land prices, genetic erosion, etc.)
- An analysis of agro-products that will have a multi-purpose use (food, chemical feedstock, energy) and the possibilities for switching production in the different regions of the Community.
- The possibilities of starch as a feedstock for chemical and fuel production and the consequences for food production. Will starch be produced in large enough quantities to be used both as a source of food and a source of energy?
- An analysis of the effects of biotechnology on the organizational and social relations of 'traditional' farming towards 'bio-management'.
- Political constraints will arise as a result of the unequal development and diffusion of biotechnology in the different Member States and regions. To what extents will political conflicts hamper the restructuring of agriculture policy in the Community?

43. In this limited context one subject for further research must receive more attention. This is the strategical position of the seed-industry. Many of the corporations investing heavily in biotechnology are those that have been active in acquiring seed companies over the last decade. In particular, petrochemical and pharmaceutical transnational corporations have important agrochemical interests. These companies are well situated to dominate the gene revolution in agriculture. Apart from a few vegetatively propagated crops, there is no other way to bring bioengineered plant varieties to market except via the seed. Few of the remaining small, independent seed firms have the same possibilities and capabilities as the transnationals. These small companies will disappear or, as is more likely, be absorbed by larger firms. A serious danger lies in the fact that seed companies, and by extension their transnational parents, are capable of setting their

own breeding agendas according to their own commercial criterion.(68) It is very well possible that agricultural research, which is a public sector activity in most countries, will become dependent more and more on these seed companies. This should be prevented, because it implies the loss of an important institutional mechanism for the exertion of social control over the development and deployment of biotechnology.(69)

VIII. BIOTECHNOLOGY AND PROSPECTS FOR REGIONAL DEVELOPMENT AND EMPLOYMENT

44. The development of biotechnology will certainly change many existing social, economic and political structures. It is beyond the scope of the report to assess the possible impact of biotechnology. More research is needed on the changing international division of labour and on the practical consequences for the people directly involved.

45. The combination of biotechnology and microelectronics makes it possible that regions will develop more autonomously and less dependently. A quick diffusion of microelectronics (computers, telecommunication networks, flexible automated systems) makes decentralisation on a large scale possible. This also implies that backward regions will be able to compete with more developed regions. The use of biotechnology makes it possible to use renewable resources and to use them for several purposes. They can be used for food production, for energy, for the chemical industry, for pharmaceuticals etc. With less material an ever increasing result can be reached ("dematerializing of products"). (70) Improved logistics can prevent surpluses and deficiencies. This means that regions can become less dependent on imports in general and that a more balanced development is achieved.

46. The above described positive scenario implies equal access for regions to the new technologies and the wish of industry and services to decentralize. In reality, however, the political strength of the different regions (and countries) is not equal, and, therefore it is foreseeable that some regions will profit more than other regions. It is likely that the developed agricultural regions in the Northern part of the Community will switch faster to new, more value-added agricultural products. These regions can build up strong ties with the arising biotechnology-industries, which also will mainly develop in the Northern part. The Southern part of the Community has less access to the new technologies and has less possibilities of application. The necessary infrastructure (informatics) is also less developed and this will be an additional disadvantage. In the most positive case, these regions will produce less value-added agricultural products for a less developed biotechnology-industry. It is a political challenge to develop a balanced regional policy in the Community that explicitly pays attention to the impact of unequal (bio)technological diffusion.

47. Biotechnology will not lead to an important increase in EMPLOYMENT. The major technological trajectories of the future (biotechnology and microelectronics) are all labour saving. As a consequence, employment in almost all sectors of the economy will decrease, and Europe will at best know a situation of jobless growth. The impact of the jobless growth situation will be different for the

various regions.(71) A strong (further) decrease of job opportunities in agriculture is likely to occur.(72) The new trajectories have also an influence on the type of labour required and on the quality of labour. In general one may say that the lower skilled workers are replaced by new machinery and equipment, and that it will notably be the highly qualified staff for all types of computer related activities that will dominate the demand of the labour market in the future. This implies that it will also be the availability of highly qualified personnel that in the future will determine the location of economic activity (whereas it was the number of semi-qualified workers that dominated location patterns in the past).(73)

48. Biotechnology will generate only a modest increase in employment opportunities for highly specialised scientists (R&D, education & training, consultancy) and for biomolecular software writers.(74) However, highly computerized sophisticated instrumentation (biosensors, computer-coupled bioprocesses, software packages) will facilitate fast automation, which reduces the labor intensity of laboratory tasks.(75) The same can be said about the employment prospects for bio-informatics. Here also, much of the work will be highly automated.(76)

IX. THE POSSIBLE IMPACT OF BIOTECHNOLOGY ON THE THIRD WORLD

49. There has been widespread recognition of the potential value of biotechnology to the developing countries (=LDC's). Many of the possible applications of biotechnology are laid down in a recent FAST-study.(77) In the "Plan by Objective. Biotechnology", it is stated that "Europe's biotechnology can offer know-how, hardware and genetic material, which can improve "bio-system management" in the LDC's. Europe could also contribute to biomass energy production and to biomedical science.(78) It could be asked, however, how far these ideas are expressions of wishful thinking. One must recognize that the improvements in agriculture and industry as a result of biotechnology will be accompanied by strains and dislocations, both economical and social. For example, the development of biotechnology has heightened conflicts between industrial and less developed countries over access to and control over germplasm resources.(79) Biotechnology processes threaten to undermine export markets for raw materials (e.g. sugar). It is also possible that the bio-revolution will extend the process of displacement to heretofore marginal areas where subsistence and petty commodity production has persisted.(80) And, although bioengineered crop varieties adapted to low levels of fertility or tolerant of saline ground could raise food production in vast areas of the Third World, it is also clear that no commercial seed firm is interested in developing plant varieties for those who cannot pay for them.(81) The transnational agribusiness is, however, interested in the Third World, but for other reasons: here they find a source of much needed genetic diversity.(82) A serious danger might arise when LDC's become a testing ground for humanly engineered bacteria that are banned elsewhere. Another danger lies in the genetic erosion (the loss of valuable genetic plant information) as a result of monopolizing activities of large seed companies.(83)

50. Analyzing the distributional character of the new technologies becomes crucial if a serious effort is to be mounted to shift the distributional patterns of biotechnology in an equity-enhancing (or at least, less inequitable) direction.(84) Therefore we have to pose the basic questions involved in technological assessment: Who gets what, when, where, why, how, and how much. This is a political task.

51. Biotechnology in turn offers the possibility of bringing about dramatic changes in human health through new drugs and in human nourishment through vastly increased agricultural production. But access to the knowledge about biological systems should be guaranteed. It is a very positive development that the UNIDO has set up two International Centers for Genetic Engineering & Biotechnology (ICGEB) (in Trieste and in India) to aid developing countries.(85) Cooperation between these institutes and the Community's Biotechnology Programme should be stimulated, e.g. in the framework of the sub-programme medicine, health and nutrition in the tropics. Also, scientists from LDC's should get more access to training centers in Europe in order to establish (informal) networks or other forms of collaboration (information collection, data banks, cell banks, grants, seminars, etc.). The Community should support the development of networking financially.

X. PATENT PROTECTION IN BIOTECHNOLOGY

52. In 1982 the OECD distributed a questionnaire on "Patent Protection and Biotechnology". In July 1984 a synthesis report was presented. This report was based on the replies given by 19 OECD-Member countries.(85) The major reason to focus on patent protection in biotechnology is that the starting material, the microorganism, is living and self-replicating, which separates microbiological from other inventions. The central question in the discussion is the form in which patent claims could be granted for microorganisms, if at all, and the availability of so-called per se claims, as well as those commonly described as "product by process" claims.(86)

53. In no other field of technology do national laws vary on so many points and diverge so widely as they do in biotechnology. It appears that United States law and Japanese law are on the whole more open and flexible towards new developments in biotechnology than are the laws of many other OECD countries.(87) International investors in biotechnology prefer those countries which afford strong and effective patent protection, i.e. the United States and Japan.(88) The same can be said for inventors.(89) The new Drug Bill adopted by the U.S. House of Representatives on September 6, 1984, provides up to five more years of patent protection for new brand-name drugs.(90) This can be an extra incentive for European firms to patent in the US and to transfer research and production as well.

54. Considering the international dimension of biotechnology activities and the ease and speed with which the main starting material of the new industry can be taken away and cultivated, a harmonisation of patent protection is needed. An agreement on harmonisation should be established at OECD level, because an agreement at Community level alone implies differences with our main competitors. However, this can take a long time. Therefore, the efforts of the Commission to draw up a document on the situation in the Community on

intellectual property rights in the field of biotechnology (91) have to be enforced.

XI. LEGAL AND ETHICAL PROBLEMS RELATING TO GENETIC ENGINEERING

55. It is expected that in the nearby future tensions will arise between "pure scientific and economic" interests (freedom to do research) and more ethically inspired interests. This will especially occur in research relating to human genetics such as the manipulating of embryos. In the Committee of experts on Ethical and Legal Problems relating to Human Genetics (CAHGE) it was accepted that this should be restricted to therapeutical use and that it would be useful to draw up guidelines.(92) We have to ask what is meant by "therapeutic". It seems that this still leaves enough room for less desirable manipulating. Also the problem of embryos should be studied further. In general, we have to ask, whether everything that is technically possible is also desirable. A discussion on this question should not be restricted to a small group of experts and representatives of governments and industry (who often discuss restricted papers). The implications of biotechnology and genetic manipulation are such that a much broader public should discuss these problems.(93)

56. In the various Member States of the Community different norms and regulations are applied to work involving recombinant DNA. From an updated picture on the situation of legal regulations in Council of Europe Member States it appeared that the United Kingdom is the only Community Member State which possesses a legislation covering DNA research. In the other Member States other provisions are made, but not in all countries. Sometimes safety of recombinant DNA research is only provided by guidelines that are followed on a 'voluntary' basis (Ireland). To safeguard workers a common legislation (guidelines) should be established. It is said sometimes that working with DNA involves less hazards than was expected. Therefore, the earlier mentioned CAHGE-committee added a paragraph just before the Principles of the Recommendation (82/472/EEC, concerning registration of work involving recombinant DNA), stating that these Principles apply only to work involving recombinant DNA which may present a bio-hazard of a category which will be determined by each State (i.e. the work having a bio-risk less than this minimum or no risk will fall outside the application of the Recommendation).(94) This is a very regrettable development. Who determines the minimum risk-level? Is enough known about the possible hazards? Does such a multi-interpretable text protect workers (and others) sufficiently? As long as we do not know all the possible consequences of working with recombinant DNA no deregulating steps may be taken. This is a political responsibility.

57. Laboratory risks and risks in 'scaling-up' or testing in 'open field' are not comparable. Technology assessment of the latter is extremely difficult, because beside biological risks, social, economical, environmental, legal and ethical impacts should be considered. Before this assessment is made (it should be a part of the biotechnology proposal) NO manipulated microorganisms should be allowed to leave laboratories for testing or scaling up.

XII. THE PROPOSAL OF THE EUROPEAN COMMISSION FOR A MULTIANNUAL RESEARCH ACTION PROGRAMME: THE MAIN CRITICAL POINTS.

58. In its preparatory studies the Commission has clearly shown the need for a European biotechnology action programme. In the last few years many important aspects have been dealt with. It is hard, however, to find a reference to all these aspects in the Commission Proposal COM(84)230. The Proposal is more or less a summarized "task list". The central task is the effective management and use of information. Therefore the Commission suggests the establishment of a concertation unit on biotechnology (CUBE) that has a monitoring task and has contacts with other policy areas, and national and international organisations. A too strong concentration on organised interests (especially in industry and agriculture) can lead to an involvement of Community that goes far beyond 'pre-competitive' research. An important task of CUBE should be to inform in particularly those sectors (e.g. small- and middle sized firms, trade unions, regional and local politicians) in the Community that are less aware of the transformation biotechnology is likely to provoke.

59. In the Resolution of the Report of G. SCHMID on biomolecular engineering (Doc 1-521/80) it is stated that the Commission should prove an economical and social need for biotechnology and should make clear what the implications of intensive use of biotechnology are for society. The Commission succeeded in the first, but although some attempts where made in the FAST-programme- did not succeed in the latter.

60. In all its reports and analyses the Commission stresses the multidisciplinary character of biotechnology and the diversity of applications. Less attention is paid, however, to the assessment of biotechnology and genetic engineering. The pervasiveness of biotechnology is such that almost every economic activity will be affected. The combination of microelectronics and biotechnology will speed up this process. This implies that assessment problems will occur much faster than is foreseen. Therefore the Commission should develop an extensive Biotechnology Assessment Programme with respect to all problems relating to political, economic, regional, legal, environmental, and ethical impacts.

61. The necessity for restructuring of agriculture policy in the Community as a result of biotechnological development is not elaborated enough in the proposal. This, however, will be of crucial importance for the development of biotechnology in the Community. As suggested earlier more research has to be done. This can provide a basis for political discussion.

62. The Biotechnology Action Programme cannot be more than a catalyst to stimulate the development of biotechnology and to assess the possible risks. The Commission should seek support by national authorities, institutions and industry that could act as co-financers. Duplication of research (that already take place in the Community or in the US) should be avoided.

63. It is a very positive development that a cooperation will be established between the Biotechnology Action Programme and the ESPRIT project (information technology), and CIDST (=Committee on Information and Documentation for Science and Technology). It is unclear, however, how the collaboration will take place and how overlap will be avoided.

64. The need for multidisciplinary trained scientists has been stressed. The experiences with the training programme in biomolecular engineering confirm this. However, it is questionable whether the Commission can provide enough training facilities to train substantially more scientists than will be trained in the national Member States anyhow, this will largely depend on the willingness of the Member States to cooperate financially. European training facilities, how limited they are, should also be accessible for scientists of the developing countries.

65. Only those middle and long term projects should be financed by the Community that would not have been set up by the industry and agriculture itself without the financial support of the Biotechnology Action Programme.

66. In the Programme the Commission should build in a condition that contractants will have to repay (partly) research costs, if they successfully commercialize the results of research that is carried out within the framework of the Programme.

FOOTNOTES

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- 2 Commercial Biotechnology: An International Analysis (Washington, D.C.: U.S. Congress, Office of Technology Assessment, OTA;BA-218, January 1984, p. 4.
- 3 Commercial Biotechnology, p. 5.
- 4 Commission of the European Communities, COM(83)328 final, Biotechnology: The Community's Role, Brussels, June 1983, p. 2.
- 5 Commission of the European Communities, COM(84)230 final, Proposal for a Council Decision, Brussels, April 1984, p. 1.
- 6 Commission of the European Communities, COM(83)672 final/2-annex, Biotechnology in the Community, Brussels, October 1983, p. 12.
- 7 COM(83) 672 final/2-annex, p. 13; E.H. Houwink/EFB, 1984, p. 117.
- 8 COM(83) 672 final/2-annex, p. 13; E.H. Houwink/EFB, 1984, p. 117.
- 9 M. Cantley, Plan by Objective. Biotechnology, Brussels 1983, p. 14-51; Commission of the European Communities, National Initiatives for the Promotion of Biotechnology. A comparative assessment of the United States, Japan, and the Member States of the European Community (Background information document), Complement to COM(83)328 for the European Summit in Stuttgart, June 1983.
- 10 Biobusiness World Data Base, Draft Report by a U.S. Government Interagency Working Group on Competitive and Transfer Aspects of Biotechnology, distributed for McGraw-Hills Biotechnology NEWSWATCH, McGraw-Hills, Washington D.C., May 1983, p. A-1.
- 11 Idem, p. C-1.
- 12 Idem, p. A-10: "(...)Clarification is needed on export control regulations pertaining on biotechnological equipment, materials, microorganisms, and technical data. As the number of biotechnology-related applications increases, there will be an increased need for licensing officers trained in biotechnology relevant fields."
- 13 Idem, p. A-5; For more examples see: "Restrictions on the transfer of scientific information and technology from the United States to other countries". Study prepared for Centrale Organisatie TNO (The Netherlands) by INTERDEVELOPMENT, Inc.,

- Arlington, Virginia/USA, December 1982.
- 14 Commercial Biotechnology, 1984, p. 7-8 and p. 21.
- 15 E.H. Houwink/EFB, 1984, p. 92-95.
- 16 idem, p. 122-123; Commercial Biotechnology, 1984, p. 74.
- 17 Cf. The Journal of Commerce (New York), 31 January 1983; Commission des Communautés Européennes, EUROPE 1995 - Mutations Technologiques & Enjeux Sociaux. Rapport FAST, Futuribles, Paris, 1983, p. 23-24.
- 18 Strategies for Marketing Ethical Pharmaceuticals in Europe, Frost and Sullivan, September 1984, New York.
- 19 COM(83)672 final/2-annex, p. 18.
- 20 Competitive and Transfer Aspects of Biotechnology; Commercial Aspects of Biotechnology; Policy Option Papers. Report delivered to George A. Keyworth, Science Adviser to the President, 27th May 1983; U.S. Office of Technology Assessment, "Biotechnology: Commercialization and International Competitiveness", October 1983. Cited in: COM(83)672 final/2-annex p.17 and COM(84)230 final p. 1.
- 21 COM(84)230 final, p. 1.
- 22 The Journal of Commerce (New York), 11 August 1983; Commercial Biotechnology, 1984, p. 110; The Economist, 3 September 1983; The Economist, 1 September 1984.
- 23 Commission of the European Communities, National Initiatives for the Promotion of Biotechnology, complement to COM(83)328, p. 23.
- 24 M.F. Cantley, Plan by Objective. Biotechnology, 1983, p. 14.
- 25 Complement to COM(83)328, p. 1. Also \$ 20 m. for equipment in "biotechnology resources programme" should be added.
- 26 Information derived from paper by Oscar Zaborsky (US National Science Foundation), at Eastbourne, April 1981 (Second European Congress on Biotechnology); Complement to COM(83)328, p. 1.
- 27 Complement to COM(83)328, p. 2.; M.F. Cantley, Plan by Objective. Biotechnology, 1983, p. 14-16.
- 28 Complement to COM(83)328, p. 3-6.
- 29 M.F. Cantley, Plan by Objective. Biotechnology, 1983, p. 20-21.
- 30 McGraw-Hill "Biotechnology Newswatch", 21 March 1983: "Japan's R&D biobudget jumps 5.8%."
- 31 More information on the progress of the European Biomolecular Engineering Programme (1982-1986) can be found in recent

publications of the Commission of the European Communities: a) Research and training programme in biomolecular engineering, Progress report 1983, Vol. I: Research (EUR 8967); b) Research and training programme in biomolecular engineering, Catalogue of contracts with classification of activities. Phases one and two, Brussels, August 1984; and c) BEP, Genetic engineering of plants and microorganisms important for agriculture. Book of abstracts for the meeting of contractants in Copenhagen, 9-10 October 1984.

32

A short description of other research programmes set up by the European Commission are found in: M.F. Cantley, Plan by Objective. Biotechnology, p. 54-66.

33

Complement by COM(83)328, p. 25. The figure for The Netherlands is modified (was estimated on Hfl. 75 mio. for period '82-'88, but is Hfl. 70 mio.), see: Beleidsvoorzicht Technologie 1984-1985, Tweede Kamer der Staten-Generaal, 18608, nr. 1-2, september 1984, p. 44.

34

Complement by COM(83)328, p. 7. Figure derived from JETRO-report.

35

M.F. Cantley, Plan by Objective. Biotechnology, p. 16.

36

B. Atkinson and P. Sainter, Technological Forecasting for Downstream Processing in Biotechnology. Phase 2: Process and Unit Operation Needs. Series FAST 7, EUR 8549, Brussels, 1983, Preface, p. V.

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idem; and Phase I: Intermediate forecast report. Series FAST 6, EUR 8041, Commission of the European Communities, Brussels, 1982. Another interesting study in this context is done in the United Kingdom by Peter Dunnill and Martin Rudd, Biotechnology & British Industry, A Report to the Biotechnology Directorate of the Science and Engineering Research Council, London, 1984.

38

idem, Phase 2, 1983, p. 78.

39

idem, Phase 2, 1983, p. 75.

40

idem, Phase 2, 1983, p. 75.

41

Commercial Biotechnology, 1984, p. 44. The term "bioprocess" is used in preference of the more familiar term "fermentation", because it more correctly identifies the broad range of techniques discussed. A fermentation process strictly speaking refers only to an anaerobic bioprocess.

42

Commercial Biotechnology, 1984, p. 45.

43

idem, p. 47.

44

idem, p. 83. The Japanese companies have already reported repeated success in growing plant cells in 15.000 liter batches. The upper limit in the United States is only 300 liter.

45

idem, p. 84.

- 46 idem, p. 84.
- 47 International Resource Development, "Emerging Membrane Separation Technologies", Norwalk, Connecticut, March 1984.
- 48 Commercial Biotechnology, 1984, p. 88.
- 49 M.F. Cantley, Bio-Informatics in Europe. Foundations and Visions, in: Swiss Biotech, 2(1984) nr. 4, p. 7-14.
- 50 COM(84)230 final, p. 14-16.
- 51 Commercial Biotechnology, 1984, p. 89.
- 52 idem, p. 89-90.
- 53 Richard Pearson and David Parsons, The Biotechnology Brain Drain, A Report prepared for the Biotechnology Directorate of the Science and Engineering Research Council (SERC) by the Institute of Manpower Studies, p. 6.
- 54 idem, p. 7.
- 55 Commercial Biotechnology, 1984, p. 338.
- 56 idem, p. 338.
- 57 idem, p. 339.
- 58 Allan T. Bull, Geoffrey Holt, Malcolm D. Lilly, Biotechnology. International Trends and Perspectives, OECD, Paris, 1982, p.59.
- 59 COM(84)230 final, p. 6-7.
- 60 Complement to COM(83)328 final, p. 2; See for figures e.g. the above mentioned OECD study on Biotechnology, appendix 2, tabel 1, p. 68.
- 61 COM(83)328 final annex, p. 6.
- 62 COM(83)328 final annex, p. 6.
- 63 M.F. Cantley, Plan by Objective. Biotechnology, 1983, p. 11.
- 64 COM(83)500 final, 2.10, p. 6.
- 65 COM(83)672 final, p. 9; COM(84)230 final, p. 3.
- 66 D.F. Gibbs and M.E. Greenhalgh, Biotechnology, Chemical Feedstocks and Energy Utilization. A Report from the FAST Programme of the Commission of the European Communities, Frances Pinter, Londen & Dover, 1983, p. 98.
- 67 "SYRENA" is the acronym for a programme of activities focussed upon the integrated development of Europe's renewable natural

resource system. A description of this programme can be found in: Commission of the European Communities, FAST 1984-1987. OBJECTIVES AND WORK PROGRAMME, Brussels, February 1984, p. 143-183.

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Ken Sargeant, Biotechnology, Connectedness and Dematerialisation: The Strategic Challenges to Europe, and the Community Response. Paper presented at "Biotechnology '84", 1-2 May 1984 organised in Dublin by the Royal Irish Academy and the Society for General Microbiology.

69

Jack Kloppenburg, Jr., The Social Impacts of Biogenetic Technology in Agriculture: Past and Future, (draft), p. 20-21, in: G. Berardi and C. Geisler (eds.), The Social Consequences of New Agricultural Technologies, Boulder, Colorado: Westview Press.

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idem, p. 25.

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I.J. Boeckhout and W.T.M. Molle, Technological Change, Location Patterns and Regional Development, FAST Occasional Papers, no. 16, Brussels, June 1982, p. 148.

72

Paul Hanappe en Augustin Antunes, Technologie, Emploi et Regions. Trois scenarios finalisés pour l'Europe, FAST Occasional Papers, no. 56, Brussels, March 1981, p. 71 and 87.

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74

Paul Hanappe and Augustin Antunes, 1981, p. 87-88; E.H. Houwink/EFB, 1984, p. 123-124.

75

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76

M.F. Cantley, Bio-Informatics (...), 1984, p. 7-14.

77

Jean-Jacques Salomon (ed.), L'Impact des Biotechnologies sur le Tiers-Monde, FAST-Occasional Papers, no. 55, Brussels, 1983.

78

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- 82 Fulfillment of Human Rights in the Third World, New York, March 1984, p. 5.
- 83 Jack Kloppenburg, Jr., The Social Impacts (...), 1983, p. 27.
- 84 Scott Armstrong, How Biotech Will Impact Third World, in: The Christian Science Monitor, September 27, 1983; Milieudefensie, (The Netherlands) July/August 1984, p. 24-25.
- 85 Ward Morehouse, Biotechnology and the Fulfillment (...), 1984, p. 3.
- 86 OECD, Committee for Scientific and Technological Policy, Patent Protection in Biotechnology: An International Overview, (Restricted), Paris, July 1984, p.ii and p. 96, paragraph 323.
- 87 idem, Chapter II, p. 49-58. Per-se claims means that every microorganism will be patented.
- 88 idem, p. iv and p. 96.
- 89 idem, p. 95, paragraph 319.
- 90 idem, p. 97, paragraph 329.
- 91 Congressional Record - Senate, August 10, 1984, S.2926; The Washington Post, 7 September 1984.
- 92 Inter-Directorate Working Party Industrial Property and Biotechnology, A Community Approach to intellectual property rights in the field of biotechnology, Luxembourg, 25 November 1983, III/D/919/84-EN.
- 93 According to information available to the rapporteur.
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- 95 European Communities Council Recommendation of 30 June 1982 (82/472/EEC) concerning registration of work involving recombinant DNA.

OPINION OF THE COMMITTEE OF BUDGETS

Letter from the chairman to Mr PONIATOWSKI, chairman of the Committee on Energy, Research and Technology

Luxembourg, 1 October 1984

Subject: Proposal from the Commission for a decision adopting a multiannual research action programme of the European Economic Community in the field of biotechnology (1985-1989) (COM(84) 230 final - Doc. 1-335/84)

Dear Mr Chairman,

The Committee on Budgets considered the abovementioned Commission proposal at its meeting of 20 September 1984.

The committee welcomed the fact that the Commission proposes to take an initiative in this important field. It noted that the planned volume of expenditure chargeable to the budget of the Communities would be 88.5 m ECU over a five-year period and 26 additional posts would be required in that same period. It was also noted that this research programme fitted in closely with the guidelines laid down in the framework programme of Community scientific and technical activities for 1984-1987, which was endorsed by Parliament in June 1983. In particular, the biotechnological component of the programme for the period 1985-1987, and the biomolecular engineering component for the period 1984-1986, would be covered in the total appropriations of 80 m ECU set aside for biotechnology under the framework programme.

The committee applauded the emphasis placed on rationalizing the organization of research within the Community, especially as regards the avoidance of duplication between national research efforts. It agreed with the Commission's view that cooperation at Community level would make budget spending more effective.

The Committee approved the principle whereby third countries could participate in the programme provided that they bore a portion of the related costs.

The Committee on Budgets wishes to draw particular attention to the following points:

1. The appropriations entered in the 1985 budget, needed to finance studies, pilot projects and similar activities, can be implemented immediately after 1 January 1985, even if the Council has omitted to lay down the corresponding legal basis, given that the budget provides a sufficient legal basis for the implementation of appropriations.
2. The precise volume of appropriations for this programme can be determined only by the budgetary authority when it lays down the budget for 1985, and will largely depend on what resources are available.

3. The role of the management and consultative committee must be confined purely to consultation: in particular, its responsibilities must not encroach on the budgetary powers of Parliament, nor must they restrict the Commission's responsibilities with respect to management, as provided for by the Treaty.

The committee also stressed how important it was to coordinate all the Community policies having a bearing on this sector, to prevent conflict from arising between them. It questioned in particular whether the organization of the market in sugar would be compatible with the action proposed.

Yours sincerely

(sgd) Jean-Pierre COT

The following were present: Mr COT, chairman; Mr CURRY, vice-chairman; Mr ARNDT, Mr BARDONG, Sir Fred CATHERWOOD, Mr CHAMBEIRON, Mr CHRISTODOULOU, Mr CORNELISSEN, Mr DANKERT, Mr DEPREZ, Mr ELLES, Mrs FUILLET, Mr HABSBURG (deputizing for Mr PFENNIG), Mr LANGES, Mr NORMANTON, Mr SCHREIBER (deputizing for Mr ABENS), Mr VARFIS and Mr de VRIES (deputizing for Mr ROSSI).

OPINION OF THE COMMITTEE ON
ECONOMIC AND MONETARY AFFAIRS AND INDUSTRIAL POLICY

Letter from the committee chairman to Mr PONIATOWSKI, chairman of the Committee on Energy, Research and Technology

Luxembourg, 18.10.1984

Subject: Multiannual research action programme of the European Economic Community in the field of biotechnology (1985-1989)

Dear Mr Poniatowski,

In its framework programme for Community scientific and technical activities 1984-1987(1) the Commission, fully supported by the Parliament, assigned a high degree of strategic importance to biotechnology as a means to improve European industrial competitiveness.

Biotechnology has major implications in such fields as agriculture, food, the environment and health.

Our committee, therefore, welcomes and approves the Commission's proposal adopting a multiannual research action programme of the EEC in the field of biotechnology (1985-1989)(2).

Our committee, however, underlines the need for the following:

1. proposals by the Commission covering the other four actions mentioned in the September 1983 communications (3);
2. adequate financial resources in order to permit a thorough development of the programme;

(1) Doc. 1-395/83

(2) Doc. 1-335/84

(3) COM(83) 672 fin./2

3. adequate staff and an increased use of informatics in the administration of the programme;
4. the inclusion of medical subjects in the research programme;
5. a fair and adequate diffusion of the results of research, duly taking into account regional disparities and problems faced by SME.

This letter should be considered as the opinion of the Committee on Economic and Monetary Affairs and Industrial Policy (1).

Yours sincerely

Barry SEAL

(1) Members present:

Mr SEAL, chairman; Mr BEAZLEY, vice-chairman; Mr BONACCINI, Mrs BRAUN-MOSER (deputizing for Mr von BISMARCK), Mr CHRISTODOULOU (deputizing for Mr ERCINI), Mr CRYER (deputizing for Ms QUIN), Mr GAUTIER, Mrs van HEMELDONCK, Mr HERMAN, Mrs de MARCH, Mr METTEN, Mr MUHLEN (deputizing for Mr STARITA), Mr NORDMANN (deputizing for Mr WOLFF), Mrs T. NIELSEN, Mr RAFTERY, Mr ROMUALDI, Mr ROGALLA, Mrs van ROOY (deputizing for Mr ABELIN), Mr WAGNER, Mr WE. EKIND and Mr von WOGAU

OPINION OF THE COMMITTEE ON AGRICULTURE, FISHERIES AND FOOD

Letter from Mr TOLMAN, chairman of the Committee on Agriculture, Fisheries and Food to Mr PONIATOWSKI, chairman of the Committee on Energy, Research and Technology

Brussels, 26 September 1984

Dear Mr Chairman,

At its meeting of 26 September 1984, the Committee on Agriculture, Fisheries and Food (1) examined the proposal from the Commission for a Council decision adopting a multiannual research action programme of the European Economic Community in the field of biotechnology (1985-1989).

The committee sees the present proposal as a logical development in the Community's programme of research in the field of biotechnology.

In the opinion by Mr GAUTIER of 30 May 1983 (PE 84.311/fin.) on a European scientific and technical strategy, my committee welcomed the possibilities offered by biotechnological research for improving the competitiveness of agriculture and fisheries. It was however, pointed out that conflicts may arise between agricultural policy on the one hand, and research in biotechnology on the other, since most agricultural raw materials for biotechnology are subject to market organizations whereas the biotechnological end products are not and may therefore be imported either duty-free or at fixed rates.

The Committee on Agriculture, Fisheries and Food fully supports the present proposal and urges the committee responsible to monitor implementation of the decision closely.

Yours sincerely

T. TOLMAN

(1) The following took part in the vote: Mr Tolman, chairman; Mr Eyraud, Mr Graefe Zu Baringdorf, Mr Mouchel, vice-chairmen; Mr Battersby, Mr Bocklet, Mr Borgo, Mr Christensen, Mr Clinton, Mr Crawley, Mr Dalsass, Mr Ducarme (deputizing for Mr Maher), Mr Ebel (deputizing Mr Debatisse), Mr Fanton, Mr Fruh, Mr Gatti, Mr Guarraci, Mr Guermeur (deputizing for Mr MacSharry), Mrs Jepsen, Mr Klinkenborg (deputizing for Mr Sutra), Mr Linkohr (deputizing for Mr Woltjer), Mr Marck, Mrs S. Martin, Mr Mertens, Mr Musso, Mr B. Nielsen, Mr F. Pisoni, Mr Provan, Mr Romeos, Mr Rothe, Mr Stavrou, Mr Stirbois, Mr Taylor (deputizing for Sir Henry Plumb) and Mr Wettig.

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH

AND CONSUMER PROTECTION

Draftsman: Mr G. SCHMID

At its meeting of 20 September 1984, the Committee on the Environment, Public Health and Consumer Protection appointed Mr SCHMID draftsman of the opinion.

The committee considered the draft opinion at its meetings of 30 October and 21 November 1984. On 21 November 1984, it adopted unanimously the draft opinion and its conclusions.

The following took part in the vote: Mrs Weber, chairman; Mrs Schleicher and Mr Collins, vice-chairmen; Mr Schmid, draftsman; Mr Alber, Mr Avgerinos (deputizing for Ms Tongue), Mrs Banotti, Mr Cottrell, Mr Dalsass (deputizing for Mr Mertens), Mr Falconer (deputizing for Mr Vittinghoff), Mrs C. Jackson, Mr Lambrias (deputizing for Mr Parodi), Mrs Lentz-Cornette, Mr Muntingh, Mr Pearce, Mrs Peus (deputizing for Mr Michelini), Mr Roelants du Vivier, Mrs Rothe (deputizing for Mr Bombard), Mr Sherlock, Mrs Squarcialupi, Mrs Van Hemeldonck (deputizing for Mr Hughes), Mrs van den Heuvel (deputizing for Mr Tognoli) and Mr van der Lek.

A. INTRODUCTION

The European Parliament has already given its approval in principle to a Community biotechnology programme in its 1980 opinion on the biomolecular research programme (Doc. 1-521/80). The proposed expansion of this programme must, however, be examined to see whether it takes due account of the following aspects:

- the risks of genetic engineering for man and the environment,
- applications in medicine,
- contribution to environmental protection,
- lower production costs with resultant drop in consumer prices.

The Commission proposal takes only limited notice of these points. The Commission describes the main aim of the programme as the promotion of agricultural and industrial competitiveness and asks industrial enterprises to submit their research projects. Industry, however, makes its decisions on the basis of expected profit and not of social needs. Promoting the application of biotechnology in the above areas does not follow from the logic of the market but requires a political decision. The Commission proposal therefore needs to be supplemented.

B. SUGGESTED AMENDMENTS TO THE COMMISSION PROPOSALS

To the Preamble:

Amendment No. 1:

Complete first indent as follows: '... and for lowering production costs'

Amendment No. 2

After second indent insert new indent to read as follows:

' - Application of biotechnology to environmental protection'

Amendment No. 3

After third indent insert new indent to read as follows:

' - Replacement of animal experiments with tests on cell cultures'

Amendment No. 4

In the fourth indent delete the word 'costly'

Amendment No. 5

Amend fifth indent to read as follows: ' ... associated with the application of biotechnology.'

Amendment No. 6

Complete the antepenultimate recital as follows:

'and these developments must also be monitored so that problems of a social, ethical or ecological nature which may arise from the use of such technology may be recognized in time and the adverse consequences prevented.'

To ANNEX I:

Amendment No. 7:

Sub-programme 2, in the paragraph 'Enzyme engineering', add to the 1st indent:

'.... for industrial and medical applications'

Amendment No. 8:

In the paragraph 'Genetic engineering' add the following indent:

- Production of vaccines, proteins and hormones for human medicine

Amendment No. 9:

In the paragraph 'technology of cells and tissues cultured in vitro' delete the words 'from a socio-economic point of view'.

Amendment No. 10

To Action II: in the eighth indent insert the following:

' ... on the nature, potential and risks of biotechnology ...'

C. SUGGESTED AMENDMENTS TO THE MOTION FOR A RESOLUTION

Amendment No. 11:

Add the following points to the motion for a resolution:

- calls on the Commission to harmonize programme sections 2.2.2.4., 2.2.2.5. and 2.4 of the biotechnology research programme with Section 2b of the COST research action on the effects of processing and marketing on the quality and nutritional value of foodstuffs and in particular to investigate in the context of the biotechnology research action programme the toxicological aspects of which no account was taken in the research action,
- calls on the Commission to make proposals as soon as possible in the context of Action IV for common safety precautions, particularly for DNS recombinations.

D. CONCLUSION

The Committee on the Environment, Public Health and Consumer Protection requests the committee responsible to adopt the above amendments which seek to clarify the points made in the introduction. Subject to the adoption of these amendments, the committee fully approves the proposals submitted.

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS AND CITIZENS' RIGHTS

Letter from the chairman of the committee to Mr PONIATOWSKI, chairman of the Committee on Energy, Research and Technology

Subject: Proposal for a Council Decision adopting a multiannual research action programme of the European Economic Community in the field of biotechnology (1985-1989) (Doc. 1-355/84 - COM(84) 230 final)

Dear Mr Poniatoski,

At its meeting of 29/30 November 1984 in Brussels, the Committee on Legal Affairs and Citizens' Rights considered the Commission proposal referred to above.

The Committee on Legal Affairs and Citizens' Rights notes that the Commission is proposing to put forward 'general or specific proposals appropriate to create a regulatory framework suitable for the development of the activities of the bio-industries and for the free circulation of goods produced by biotechnology', and that it has already set up a working party to investigate the problems associated with intellectual property rights in the biotechnology field, especially as regards patents, for which improvements in current legislation are planned.

Given that no firm proposals with regard to the two measures referred to above are included in the proposed multiannual programme, the Committee on Legal Affairs and Citizens' Rights has decided to reserve its position on these two measures until formal proposals from the Commission are referred to Parliament.

It considers, however, that paragraph 9 of the motion for a resolution in Mrs Viehoff's draft report (PE 91.447/fin.), on the need to harmonize patent law in this field, is just as likely to prejudice the position of Parliament and the Commission in a very complex field, particularly as discussions and negotiations are to be organized in the near future on the basis of a detailed study carried out by the OECD.

In addition to these comments on the proposed multiannual programme, my committee has instructed me to inform you that it intends to draw up an own-initiative report on the legal (and ethical) problems to which developments in biology may give rise; this report may cover some of the aspects referred to by the rapporteur in paragraph 2 of her motion for a resolution.

Yours sincerely,

Marie-Claude VAYSSADE

The following were present: Mrs Vayssade, chairman; Mr Evrigenis and Mr Gazis, vice-chairmen; Mr Andrews, Mrs Fontaine, Mr Pordea, Mr Price, Mr Tortora, Mr Ulburghs, Mr Wijsenbeek and Mr Zagari.

30 November 1984