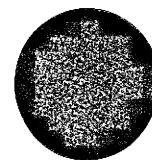




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REPORT

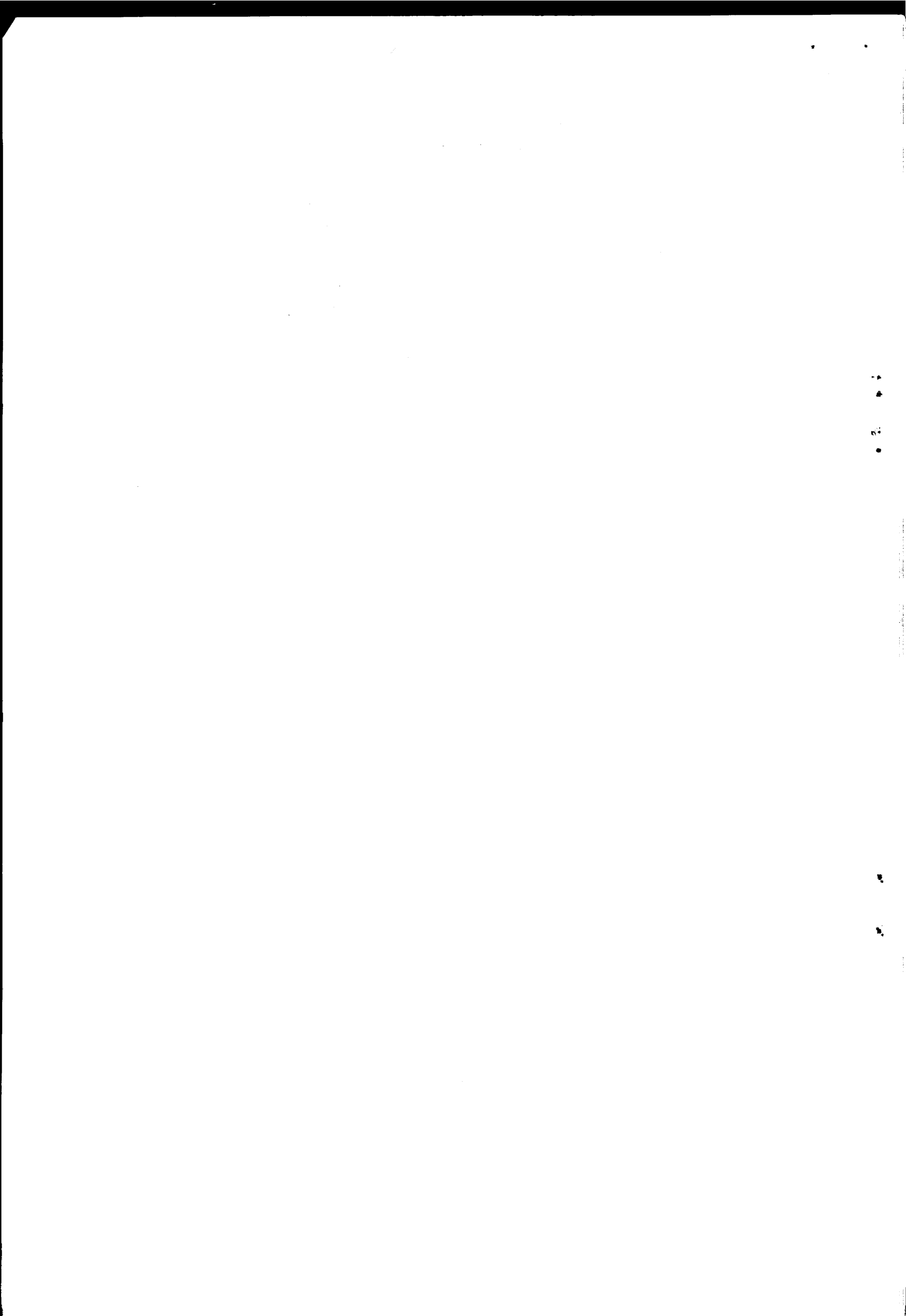
drawn up on behalf of the Committee on Energy, Research
and Technology

on biotechnology in Europe and the need for an integrated
policy

Rapporteur : Mrs P. VIEHOFF

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PE 105.423/fin.
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By letter of 20 November 1985 the Committee on Energy, Research and Technology requested authorization to draw up a report on biotechnology in Europe and the need for an integrated policy.

By letter of 10 December 1985 the Committee on Energy, Research and Technology was authorized to draw up a report on this subject. The Committee on Agriculture, Fisheries and Food, the Committee on Economic and Monetary Affairs and Industrial Policy, the Committee on Legal Affairs and Citizens' Rights, the Committee on Social Affairs and Employment and the Committee on the Environment, Public Health and Consumer Protection were asked for opinions.

On 23 April 1985 the Committee on Energy, Research and Technology also decided to include in its report all the motions for resolutions on biotechnology referred to it pursuant to Rule 47 of the Rules of Procedure, namely the motions for resolutions tabled by Mr ROUX and others (Doc. B 2-579/85), Mr TOLMAN and Mr EYRAUD (Doc. B 2-1087/86) and Mr PEARCE (Doc. B 2-1162/85).

The committee considered the draft report at its meetings of 24 February, 28 May, 22 June and 17 September 1986. The motion for a resolution as a whole was adopted on 14 October 1986 by 18 votes to 2 with 2 abstentions.

The following took part in the vote : Mr PONIATOWSKI, chairman; Mr SÄLZER, Mr ADAM and Mr SELIGMAN, vice-chairmen; Mrs VIEHOFF, rapporteur; Mr BLUM, Mrs d'ANCONA (deputizing for Mrs Lizin), Mr GAUTHIER, Mr HARLIN (deputizing for Mr TRIDENTE), Mr KOLOKOTRONIS, Mrs LIENEMANN, Mr LINKOHR, Mr MALLET, Mr METTEN (deputizing for Mr SMITH), Mr PETERS (deputizing for Mr WEST), Mr RINSCHÉ, Mr SCHINZEL, Mr SHERLOCK (deputizing for Mr TOKSVIG) and Mr WETTIG (deputizing for Mr SANZ-FERNANDEZ).

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

The opinion of the Committee on Social Affairs and Employment will be published separately.

The report was tabled on 24 October 1986.

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 motion for a resolution together with explanatory statement :

A
MOTION FOR A RESOLUTION

on biotechnology in Europe and the need for an integrated policy

The European Parliament,

- having regard to the communication from the Commission to the Council concerning the review of the multiannual research programme for the EEC in the field of biotechnology (1985-1989) (COM(86) 272 final),
 - having regard to the discussion paper of the Commission 'Biotechnology in the Community : Stimulating Agro-Industrial Development' (COM(86) 221 final),
 - having regard to the motions for resolutions by Mr ROUX and others on research in the field of biotechnology (Doc. B 2-579/85), by Mr TOLMANN and Mr EYRAUD on the use of agricultural products in biotechnology (Doc. B 2-1087/85) and by Mr PEARCE on developments in the manufacture of hormones (Doc. B 2-1162/85),
 - having regard to the report of the Committee on Energy, Research and Technology and the opinions of the Committee on Agriculture, Fisheries and Food, the Committee on Economic and Monetary Affairs and Industrial Policy, the Committee on Legal Affairs and Citizens' Rights, the Committee on Social Affairs and Employment and the Committee on the Environment, Public Health and Consumer Protection (Doc. A 2-134/86),
- A. whereas the complexity of biotechnology research requires a multidisciplinary and integrated approach which goes far beyond the financial and research potentials of the individual Member States of the Community,
- B. in view of the considerable success of the first European Biomolecular Engineering Programme (BEP) in stimulating transnational cooperation between European laboratories and the training of young scientists as well as coordinating research activities, although BEP had only a limited budget and concentrated mainly on research connected with agriculture and the food processing industry,
- C. recognizing that since the start of the Biotechnology Action Programme (BAP) in 1985 new and broader areas of research are covered and that this programme was received with overwhelming interest both from industry and research laboratories, resulting in more than 1 300 project applications, of which, however, more than 80% had to be turned down because of the restricted budgetary provisions of the four-year-programme,
- D. warning that further neglect of applications for highly promising projects may well make European laboratories less willing to cooperate,

- E. aware of the positive effects a more substantial financial endowment of the BAP would have as regards
- the development of socially useful products,
 - the extension of scientific exchange and training facilities especially for the less-advanced countries in the Community,
 - the expansion into those important research areas where Europe is lagging behind the USA and Japan, such as bioinformatics, protein design and plant biochemistry,
- F. determined that the social, economic and ecological aspects of new developments in the field of biotechnology should be evaluated and assessed at the research and development stage,
- G. recognizing that, since they did not participate in the first BEP programme, the new Member States of the Community should receive supplementary aid to enable them to participate in the Biotechnology Action Programme (BAP) under optimum conditions,
- H. aware that biotechnology may have some positive effects on the Third World but aware also of the predominantly negative effects of the use of biotechnology in the industrialized countries on agricultural areas in Third World countries,
1. Asks the Commission to review its biotechnology programme with a view to providing the Community with an effective strategic programme that affords Europe the means of increasing its competitiveness on world markets vis-à-vis Japan and the United States;
 2. Believes that the revised biotechnology programme should specify priority fields of action within which research projects will be conducted that allow for link-ups between laboratories and European companies;
 3. Believes at all events that the biotechnology programme should involve the industrial community as far as possible while remaining at the stage of precompetitive research;
 4. Calls on the Commission to include Parliament's recommendations in its proposal for the revision of the programme;
 5. Stresses the need to establish generally acceptable priorities and better coordination of the individual research activities of the Member States through more comprehensive discussions with interested parties (universities, medical authorities and profession, industry) and governments upon the instigation of the Commission, and to bring the BAP projects more in line with similar projects by other services of the Commission (e.g. parts of the Science and Technology for Development programme and activities of Directorate-General XIII);
 6. Stresses the importance of the Commission taking action to ensure that high priority is given to those projects which contribute to socially useful products with high development costs and relatively low profits such as 'orphan drugs';

7. Suggests that priority should be given to activities in the field of health in order to promote research concentrating on the main causes of death in Europe (cardio-vascular diseases and cancer);
8. Stresses the importance of research in the areas of medical biotechnology and environmental biotechnology (e.g. degradation of toxic substances), which are under-represented in the current programme;
9. Underlines the importance of medical research (in areas such as tropical diseases, vaccines, etc.) and the need for cooperation with Third World countries;
10. Calls for further and up-to-date consideration by interested parties (universities, industry and Member States government experts), under the aegis of the Commission, of the long-term competitiveness of European biotechnology vis-à-vis the USA and Japan and calls for the Commission to propose further remedial action;
11. Expects the Commission to give priority in future to instigating projects studying the massive release into the environment of genetically engineered natural micro-organisms ('deliberate release'), the standardization of varieties and the danger of cultivating the same varieties over large areas, which should be one of the topics of the FAST conference in March 1987;
12. Asks the Commission to be aware in a general sense of the repercussions of each research project on the 'environment' and suggests that for each research project a sum yet to be determined should be set aside in the overall financial package for an environmental impact study;
13. Calls for an assessment of the political and ecological repercussions of possible risks of epidemics or any restriction of gene resources and suggests a feasibility study for a European Institute for Ecology;
14. Demands that the principles and guidelines of good practice with regard to the safety of workers in laboratories, including university and research institutes, be strictly respected;
15. Welcomes the recent inventory by the Commission's Biotechnology Regulation Interservice Committee as an important step towards creating a European biotechnology regulation system and calls for harmonization of Member States' provisions with regard to safety and the environment to provide for common procedures for risk assessment and imposition of conditions at each stage of the development of projects involving micro-organisms carrying genetic material and suggests a step-by-step approach for regulating the various phases of biotechnology processes (laboratory, trials, limited production, mass production) and a case-by-case approach for approving new biotechnology products;
16. Underlines the need for intensive stimulation of research in the field of bioinformatics (bio-data banks, inter-laboratory information networks, etc.) by setting up intensive training and research facilities in cooperation with the ESPRIT-programme;
17. Calls for better and wider dissemination of biotechnological knowledge using advanced info-networks, via the BICEPS initiative, and welcomes therefore the planned cooperation of DG XII and DG XIII;

18. Underlines the possible major impact of biotechnology on the future development of agriculture, which will bring about important changes in agriculture and other related fields, such as the seed industry and international trade in commodities;
19. Calls for an investigation into pricing of agricultural raw materials that will be used in biotechnology industry;
20. Expects special consideration to be given to the possible regional disparities resulting from biotechnology especially concerning the less-favoured position of the Mediterranean countries and the Third World as regards the interface between biotechnology, agriculture and industry, as well as the effects of plant substitution on the future agricultural orientation of these countries and asks for a follow-up of the Athens conference;
21. Proposes that the BAP programme take into account the possible lower level of development attained in Portugal and Spain and grant those countries additional resources to enable them to reach the levels attained by those countries which have already benefited from the BEP;
22. Calls for greater coordination between the BAP programme and the Science and Technology for Development (STD) programme (1987-1990) in the area of tropical agriculture and health care and demands easier access to training facilities in the Community for scientists and technicians from the Third World to enable these countries to develop their own research facilities;
23. Stresses the need for harmonization of patent law to prevent unfair competition by ensuring patentability of micro-organisms and ensuring that biotechnological innovations receive equal treatment under the different systems of the Member States;
24. Demands adequate information of the public on opportunities, risks and possibilities of biotechnological research and its application;
25. Instructs its President to forward this resolution and the report of its Committee on Energy, Research and Technology to the Council and Commission.

B
EXPLANATORY STATEMENT

FOREWORD

Background to the report

1. Developments in biotechnology have been looked at on a number of occasions in recent years by the European Parliament. In the past it was mainly the Committee on Energy, Research and Technology which was responsible for drawing up reports but now that the results of biotechnology research are rapidly finding their way into commercial applications in many sectors of industry, agriculture and health care, other parliamentary committees are also being obliged to consider the various policy aspects of biotechnology more closely.
2. The fact that this multidisciplinary technology with such a wide range of applications has already received the attention of a number of parliamentary committees at a relatively early stage is extremely encouraging. The many facets and repercussions of biotechnology - from safety provisions to employment opportunities and from a policy to encourage research to the consequences for the developing countries - call for a specialist approach which can best be developed in parliamentary committees with the necessary facilities. However, to prevent the wide-ranging opportunities and consequences of biotechnology from being subdivided into artificial compartments of policy and thus losing sight of the overall dimension of biotechnology, the Committee on Energy, Research and Technology's rapporteur for biotechnology has taken the initiative of drawing up this joint report.
3. All the parliamentary committees which could be regarded as concerned by biotechnology were asked to deliver opinions making specific policy recommendations for the medium and long-term. This request was acted upon by the Committee on the Environment, Public Health and Consumer Protection, the Committee on Agriculture, Fisheries and Food, the Committee on Legal Affairs and Citizens' Rights, the Committee on Social Affairs and Employment and the Committee on Economic and Monetary Affairs and Industrial Policy. The Committee on Social Affairs and Employment had not delivered its definitive opinion when this report was being finalized. The Committee on Regional Policy and the Committee on Development and Cooperation unfortunately decided not to submit contributions but, in view of the political importance of biotechnology in these areas of policy, the rapporteur has included in the policy guidelines for the Committee on Energy, Research and Technology, recommendations in the area of regional development and development cooperation. The two committees have been notified of this decision.
4. It has thus been possible to combine in this report a large number of policy recommendations, opinions and views on biotechnology from various committees, as a basis for a wide-ranging debate in the European Parliament. As the various contributions demonstrate, there is sometimes conflict or overlapping. This can be explained firstly by the differing political persuasions of the draftsmen of the opinions and secondly by the fact that biotechnology often produces a number of different effects simultaneously which are relevant to the areas of policy covered by more than one committee.

5. This report does not aim to be exhaustive, partly because the necessary know-how is not yet available and partly because at the present early stage of biotechnology it is not yet possible to cover all its possible effects. In addition, there have been earlier reports, such as that by Mr Schmid of 1980 and the Viehoff report of 1984¹. The hearings held in November 1985 by the Committee on Energy, Research and Technology and by the Committee on Legal Affairs and Citizens' Rights also covered many aspects of biotechnology whose implications for the future of Europe were clarified by experts². Finally, the Commission of the European Communities, and in particular DG XII through its Concertation Unit for Biotechnology in Europe (CUBE) and the Division for Genetics and Biotechnology, have published comprehensive reports on developments in the area of biotechnology in recent years³. The contents of these reports will not be reproduced here. The aim is rather to highlight developments resulting from biotechnology which deserve closer study so that potential negative effects can be recognized at an early stage and the positive effects can be promoted; thus biotechnology presents a real challenge to European cooperation.

I. Introduction

6. Section II of this report will discuss the significance of biotechnology and the need for closer cooperation at European level if Europe is not to be left behind in the biotechnology race with the United States and Japan. It will be argued that although the Biomolecular Engineering Programme (BEP) and the current Biotechnology Action Programme (BAP) have laid a solid foundation for European cooperation, a massive increase in resources is required to allow new promising research projects to be started up and to encourage more activities in the area of socially useful but not immediately commercially attractive products using biotechnology.

Section III will then go on to describe what the Committee on Energy, Research and Technology regards as the most important policy considerations and issues in the medium and long term. Following on from this, Section IV summarizes the policy recommendations and research topics suggested by the other committees. The full text of the opinions of the various committees is given in an annex.

II. Biotechnology - a challenge to European cooperation

7. Biotechnology, one of the new key technologies which will radically alter existing agro-industrial structures, has received increasing attention at national and international level in recent years. Governments in virtually all the industrialized countries have set up special biotechnology programmes to encourage research and development, with the ultimate goal of improving their competitive position. Parallel to this, numerous general measures have been taken with the same aim of strengthening the technological base. Looking at all these efforts, one can therefore speak of a real biotechnology race. However, the participating countries do not all have equal chances in this race since their starting positions as regards know-how, industrial base and financial resources differ widely. The vast financial input by the US Government alone in the area of biotechnology research - a total budget of some \$2 billion in 1985, with a slight rise to almost \$2.1 billion in 1986 and 1987 - bears no relation to what can be spent by individual European countries. Although the available financial resources give some indication of the relative strengths of individual countries, other factors also play an important role as the example of Japan shows. The Japanese Diet has, for example, set up a special commission composed of more than 100 members, the

Society of Diet Members for the Development and Protection of Biotechnology⁴. The group is chaired by the Minister of Finance, which underlines the importance that the Japanese Government attaches to biotechnology. Such a broad-based commission also promotes coordination of relevant areas of policy and helps to ensure a broad stream of information down to the lower levels. Effective regulation and coordination of research and the active promotion of selective cooperation between laboratories and industrial firms are further examples of Japan's innovative management style.

8. In the Commission of the European Communities in recent years there has been some sign of policy measures to promote biotechnology, although not always in a flexible way. Although initially a number of Member States were somewhat reluctant to embark on a coordinated European approach, they now seem to have reconsidered their position since it has become clear that it is virtually impossible to create rapidly at national level the necessary scientific base to cover the wide-ranging aspects of biotechnology. The complexity of biotechnology in fact requires a multidisciplinary and integrated approach. Insistence on a national approach means that there is a grave risk that it will only be possible to carry out research in a few specific areas or that in an attempt to cover everything the results will be superficial.

9. European cooperation in the field of biotechnology research and training is essential to build up Europe's competitive potential. The first European biotechnology programme (BEP, which stands for Biomolecular Engineering Programme) concluded in March 1986 has shown how over a period of only four years it was possible to achieve a great deal despite an extremely modest budget of only 15 m ECU. Almost 300 proposals from the leading laboratories in Europe have been submitted since 1982 but owing to the meagre financial resources less than one-third could be taken up. In the area of training, 84 contracts were concluded for periods varying from 6 to 24 months. Exchanges of young scientists between leading laboratories laid the basis for what has rightly been called 'a European multidisciplinary training institute without walls'. The trans-national character of the programme was further underlined by the 63 cooperation contracts between 103 European laboratories. Such cooperation would not have been possible without European coordination, nor could the research results have been achieved in such a short period.

10. As well as giving a great deal of praise to the BEP programme now completed, the European Parliament has also voiced a number of criticisms. The range of topics covered by the BEP programme was extremely limited since the research concentrated on areas connected with agriculture and the food-processing industry. Regrets were expressed on various sides that industry had taken virtually no part and that projects were carried out only by universities and government laboratories. The limited budget, the pre-competitive area in which the research had to be carried out and the wide diversity of the biotechnology industry can be cited as the reasons for the lack of participation by industry.

11. In 1985, the BEP programme was followed up by the Biotechnology Action Programme (BAP). The budget is 55 m ECU over four years. In BAP efforts are being made to extend the areas of research covered by BEP and to tie them in better with the needs of European industry and agriculture. High priority has been given to cooperation with industrial laboratories. New areas, such as bio-informatics, are also covered to some extent by BAP. In order to expand international exchanges, preference has been given to proposals for training and research involving cooperation between a number of European institutes. Support for the BAP programme has been overwhelming. Proposals for more than

1 300 projects were received by the European Commission. Since here too the budget is extremely modest for such an ambitious programme, it has only been possible to approve one in seven of the projects submitted. There is a danger that, particularly in view of the extremely high calibre of the projects submitted, this may have a discouraging effect and may stifle the new spirit of European cooperation. In order to prevent a situation in which promising projects cannot be carried out, thus attacking the competitive potential of Europe at its roots and increasing the threat of a brain-drain to the United States in particular, emergency budget measures are required at least to double the present financial resources.

12. An increase in financial resources is necessary to even out geographical disparities. Countries such as Greece, Spain and Portugal now have a raw deal when they could in fact make an important contribution to research and benefit from extension of the training and exchange programme. A larger budget is also necessary to finance projects resulting in socially useful products (such as orphan drugs) or to expand sections of the BAP such as bio-informatics (BICEPS), protein design and plant biochemistry. These sectors are still not highly developed in Europe whereas in the United States and Japan major efforts are being made in these promising fields.

13. An increase in the budget is also necessary to enable greater attention to be paid to research into the socio-economic impact of biotechnology; a start has been made with a recent study by the Dublin Foundation but more studies and projects are required. Possible topics include the regulation of biotechnology, risk-assessment studies, studies into the ecological effects of the spread of micro-organisms on a large scale, studies of public attitudes and information, research into the effect on employment, the intellectual property aspects of biotechnology and the patentability of living organisms, studies of the effects on the competitive position of Europe vis-à-vis the United States and Japan, of the advantages and disadvantages of biotechnology for the developing countries and of cooperation projects with non-Community countries, etc. Money is not only necessary to implement these projects but above all to establish and coordinate all these activities. As regards coordination, it should be pointed out that even within the institutions of the European Community (e.g. the various Directorates-General, such as the activities of DG XII/CUBE and DG XIII where a special biotechnology task force has also been set up), a great many more activities need to be coordinated and geared to one another. Coordination is extremely important in ensuring that information is passed on rapidly and in preventing duplication and fragmentation of efforts. Moreover, better coordination can reduce conflicts between different organizations as regards the areas within their jurisdiction and can help to replace such conflicts with cooperation.

14. The problem of European cooperation does not really appear to lie in stimulating research proposals either in the area of scientific research or in the social and economic fields. There are plenty of ideas and there no longer appears to be any reluctance to cooperate at European level, at least in the scientific field. Even industry is proving much more willing to give practical consideration to European cooperation, as shown by the setting up of the European Biotechnology Coordination Group (EBCG). However, the political will of the Member States to transfer more resources to European projects is still a serious stumbling block. The extent to which joint European efforts are required to meet the challenge of biotechnology is still gravely underestimated. Lack of harmonization in the internal market and the political divisions within Europe undermine its position in competition against the United States and Japan. However, the major changes to be expected

particularly in the agro-industrial field in the next few years require joint efforts. Similarly, many areas of policy connected with biotechnology, such as control of deliberate releases, require harmonization of national policy. Political backing for cooperation is required if Europe is to maintain a strong scientific base in the coming decades and be able to establish new agro-industrial structures which will help to create new employment opportunities and to promote an acceptable environment in the broad sense.

III. Medium- and long-term policy recommendations for research and technology

15. During the past two years, the Committee on Energy, Research and Technology has taken a number of initiatives in connection with developments in biotechnology and their effects. Since basic research and training provide the foundations for the advancement of biotechnology, the Committee on Energy, Research and Technology feels it has a special role to play in the coordination and monitoring of parliamentary activities connected with biotechnology. This report is a first step in that direction. A conceivable follow-up to the report would be the setting up of an interparliamentary committee for biotechnology, like that created by the Japanese Diet. Intensive interaction and coordination of biotechnology policy between the various committees is likely to be of vital importance in the coming years.

16. The following summary lists possible topics for discussion and areas of policy which could be put on the agenda for the Committee on Energy, Research and Technology in the next few years.

(a) Biotechnology should be given greater priority in the Committee on Energy, Research and Technology and consequently a greater share of the budget since biotechnology must be regarded as a crucial, and key technology on which the future development of numerous industrial, agricultural and medical activities will hinge in the coming decades.

The results of the Biomolecular Engineering Programme (BEP) and the vast flood of applications for the multi-annual Biotechnology Action Programme (BAP) which began in 1985 demonstrate the success of incentives for joint research, training and development projects at European level. However, more than 80% of the applications for the current BAP programme have already had to be rejected owing to lack of funds and there is a real fear that this will have an adverse effect on motivation and possibly escalate the brain drain. There is a danger of a further nationalization of research and development instead of progress in the Europeanization now under way.

17. (b) An increase in the BAP budget only makes sense if clearer priorities can be established than has hitherto been the case. This requires further coordination between the Member States. However, not everything has to be financed at European level, only those aspects of research, development and possible applications which cannot be carried out by individual Member States on economic grounds, or where there is insufficient manpower and know-how at national level. Greater consideration should also be given to training, particularly for the less-developed countries in the Community such as Greece, Spain, Portugal and Ireland so as to prevent biotechnology undermining integration. Moreover, with the aid of biotechnology these countries have the potential to become the 'California of Europe' in agricultural terms. It should be seen, in conjunction with the Committee on Regional Policy, how such a goal could be achieved.

18. (c) Top priority should be given to research and development projects which contribute to socially useful products. These might be in the area of 'orphan drugs' which have extremely high development costs and low profits. It should be seen how the Science, Technology and Development (STD) programme can be coordinated with the BAP programme in the area of medical biotechnology (tropical sicknesses, vaccines). In the area of environmental biotechnology (e.g. degradation of toxic substances), a more detailed study should be made, in conjunction with the Committee on the Environment, of how sections of the BAP programme or its successor can be developed in this direction. Coordination between BAP and the DG XI environmental programmes should also be encouraged. In the area of local, small-scale energy production, particularly for backward rural areas and for developing countries, projects should be set up in cooperation with the Committee on Regional Policy and the Committee on Development and Cooperation.

19. (d) Developments in the area of bioinformatics, as announced in the provisional proposals for the BICEPS programme, should be expanded to ensure that Europe does not lose ground to US and Japanese competition in the border area between biotechnology and informatics. Bioinformatics is a vital link in the development of biotechnology and for both informatics and health care. Bioinformatics is extremely important in passing on know-how - even at secondary school level. Access to computerized data banks can forge links between university institutions, schools and industrial laboratories. A great deal of thought should also be given to training in the area of bioinformatics which is likely to provide skilled job opportunities. One could mention here the development of artificial intelligence, expert systems, advanced computer software, biochips, data banks, etc. Close cooperation between BICEPS and DG XIII's task force for biotechnology should be encouraged so as to make the best possible use of the available resources. In the area of data banks and the dissemination of high quality information in particular, there should be a clear division of tasks between DG XII and DG XIII.

20. (e) It is important to ensure that the BAP programme continues to act as a catalyst. The Commission should not take on an entrepreneurial role and with it the risks run by industry. It would therefore appear to be advisable for funds not to be allocated direct to firms but rather to joint ventures between university researchers and industrial laboratories to ensure continued consolidation of the research base and to give a greater guarantee of public access to the research findings. On the last point - access to the results of research funded partly by public bodies - continuous monitoring will be required in the next few years.

21. (f) In the short term, it is important to clarify the potential damaging effects of experiments in the environment with genetically engineered and exotic organisms. In this area, the Committee on Energy should cooperate closely with the Committee on the Environment, Public Health and Consumer Protection, the Committee on Legal Affairs and Citizens' Rights and BRIC (Biotechnology Regulation Interservice Committee) of the European Commission as well as with the Information Service. The planned European Office for Technology Assessment will provide a vital link in this chain. In its work, the European OTA should give priority to providing unbiased information on biotechnology for the general public since it has emerged that the further development of biotechnology will be determined largely by information campaigns and the role of public opinion.

- 8 Kees van den Doel and Gerd Junne, Product substitution through biotechnology: Impact on international relations, a report published as part of a research project financed by the Community into the social and economic effects of biotechnology and coordinated by the European Foundation for the Improvement of Living and Working Conditions, Dublin, May 1986. See also Kees van den Doel and Gerd Junne, 'Product substitution through biotechnology: impact on the Third World', in: Trends in Biotechnology, April 1986, p. 88-90.
- 9 See footnote 5. The American Office of Technology Assessment calculates that the number of farmers in the United States will fall by half to 1.2 million in about a decade. Only 50 000 of these farms will provide 75% of total agricultural output. As a result, traditional family farms will disappear and only part-time farmers with small plots and extremely large farms will remain.
- 10 Commission of the European Communities, BRIC, The Commission's approach to the regulation of biotechnology, Brussels, February 1986; Commission of the European Communities, BRIC, The European Community, and the regulation of biotechnology: an inventory, Brussels, March 1986; Annemieke Roobeek, 'Biotechnology and regulation: different perspectives in the United States and the European Community', in: Trends in Biotechnology, April 1986, pp. 75-78
- 11 Guiseppe Lanzavecchia, The impact of biotechnology on living and working conditions, Rome, April 1986. This report appeared as part of the research project financed by the Community into the social and economic impact of biotechnology and coordinated by the European Foundation for the Improvement of Living and Working Conditions, Dublin.
- 12 Joseph G. Perpich, 'A Federal Strategy for International Industrial Competitiveness', in: BIO/TECHNOLOGY, Vol. 4, June 1986, pp. 522-525.

MOTION FOR A RESOLUTION

DOCUMENT B 2-579/85

tabled by Mr ROUX, Mr MARLEIX, Mr CARIGNON, Mr FITZSIMONS and Mr LALOR
on behalf of the Group of the European Democratic Alliance
pursuant to Rule 47 of the Rules of Procedure
on research in the field of biotechnology

The European Parliament

- A. having regard to the application of new technology to living organisms and various materials, known as biotechnology,
- B. having regard to the growing and crucial importance of the biotechnology sector in the future, on a par with data processing, micro-electronics, etc.,
- C. having regard to the wide-ranging effects of research in this area on such different sectors as :
 - o agri-foodstuffs,
 - o health (antibiotics, more reliable and new vaccines, substitute hormones),
 - o energy (obtaining synthetic petrol from vegetable matter)
 - o chemicals (enriching low-grade ores),
- D. whereas, after 1990, it is estimated that more than 250 billion francs will be invested in biotechnological research every year,
- E. having regard to the lead built up by the USA and Japan in this new sector,
- F. having regard to the efforts made in the field of research by the FRG and France in order to gain a foothold in this market (2.5 billion FF have been invested in biotechnological research in France),
1. Considers it vital that the Community and Member States take coordinated action in this area, particularly in order to :
 - o take up the American and Japanese challenge,
 - o occupy what is, in view of their intellectual, technological and financial capacities, their rightful place in this sector,
 - o avoid overlap and financial loss, arising from the compartmentalization of the public and private markets in the Community.
2. Considers the drawing up of a large-scale European biotechnology programme along the lines of the ESPRIT programme, to be urgent;
3. Considers that the Community must not lag behind in this very promising sector, as it did in data processing, micro-electronics, etc.;
4. Points out that the biotechnology sector opens up great prospects in terms of jobs,
5. Believes more than ever that here as in other activities, the need for Community action is closely linked to the parallel creation of a huge internal market,
6. Instructs its President to forward this resolution to the Commission of the European Communities and the Council.

MOTION FOR A RESOLUTION
DOCUMENT B 2-1087/85

tabled by Mr TOLMAN, chairman and Mr EYRAUD, first vice-chairman,
on behalf of the Committee on Agriculture, Fisheries and Food
pursuant to Rule 47 of the Rules of Procedure
on the use of agricultural products in biotechnology

The European Parliament,

- A. having regard to the need to step up efforts to increase outlets for agricultural products other than for use as food,
 - B. having regard to the Community's efforts to develop biotechnology in the very near future,
 - C. having regard to the excellent opportunities for using a large number of agricultural products in biotechnology,
 - D. whereas the use of agricultural products in biotechnology may have consequences for the future of European agriculture,
 - E. whereas biotechnology has been included in the EUREKA project,
1. Calls on the Commission to submit a study on the impact of the use of biotechnology on European agriculture;
 2. Invites its competent committee to draw up a report on the subject;
 3. Instructs its President to forward this resolution to the President of the Council.

MOTION FOR A RESOLUTION
DOCUMENT B 2-1162/85
tabled by Mr PEARCE
pursuant to Rule 47 of the Rules of Procedure
on developments in the manufacture of hormones

The European Parliament,

- A. having regard to the motion for a resolution on dwarf-tossing tabled on 29 August 1985 by Mrs Squarcialupi (Doc. B 2-784/85),
- B. being led to believe that developments in the manufacture of hormones may soon provide new means of treating dwarfism at an early stage,
 - 1. Urges the Commission of the European Communities to produce a brief report on research in the Community into this matter so that application of public and private funds to such research may be carried out in the fullest knowledge of current developments and may come speedily to a successful conclusion;
 - 2. Instructs its President to forward this resolution to the Commission of the European Communities.

OPINION

(Rule 101 of the Rules of Procedure)

OF THE COMMITTEE ON AGRICULTURE, FISHERIES AND FOOD

Draftsman : Mr T. TOLMAN

At its meeting of 5 February 1986, the Committee on Agriculture, Fisheries and Food appointed Mr Graefe zu Baringdorf draftsman.

The committee considered the draft opinion at its meetings of 2/3 April and 22/23 April 1986 and adopted the conclusions thereof at the latter meeting by 19 votes to 6 with 2 abstentions.

In the light of the result of the vote, the draftsman, Mr Graefe zu Baringdorf, stood down in favour of the committee chairman, Mr Teun Tolman.

The following took part in the vote :

Mr TOLMAN, chairman and draftsman; Mr EYRAUD, Mr GRAEFE ZU BARINGDORF, Mr MOUCHEL, vice-chairmen; Mr ABENS (deputizing for Mr Woltjer), Mr ADAMOU, Mrs ANDRE (deputizing for Mr Nielsen), Mr BARRETT (deputizing for Mr MacSharry), Mr BORGO, Mr CHIABRANDO (deputizing for Mr F. Pisoni), Mr CLINTON, Mr DEBATISSE, Mr ELLES (deputizing for Mr Battersby), Mr FILINIS (deputizing for Mr Gatti), Mr GARCIA, Mr MAHER, Mr MARCK, Mrs MARTIN, Mr MERTENS, Mr MORRIS, Mr MÜHLEN (deputizing for Mr Früh), Mr NAVARRO VELASCO, Sir Henry PLUMB (deputizing for Mr Simmonds), Mr PRANCHERE, Mr PROVAN, Mr RAFTERY (deputizing for Mr Dalsass) and Mr ROSSI.

The Committee on Agriculture, Fisheries and Food requests the Committee on Energy, Research and Technology to take account of the following conclusions when it draws up its report:

The Committee on Agriculture, Fisheries and Food,

1. Applauds the comprehensive and lucid approach adopted by the rapporteur, Mrs Viehoff, to the subject of biotechnology;
2. In view of the potential impact of biotechnology on food production and processing, decides to draw up a separate own-initiative report on biotechnology in the agricultural sector;
3. The uses of genetic manipulation and plant tissue culture techniques will greatly accelerate scientists' ability to generate more genetic diversity which, in turn, will offer more opportunities to produce varieties suitable for a wider range of soils and climates. This will also offer increased opportunities to select for characteristics such as disease and pest resistance, higher protein levels with better milling and baking quality, in the case of wheat, and lower protein levels with higher starch content for malting barleys, etc.

In the short and medium term, genetic engineering of Rhizobia may increase the efficiency of nitrogen fixations in legumes. In the longer term, it may be possible, using genetic manipulation of plants and genetic engineering of bacteria, to enable plants of the Gramineae family, such as cereals and grass, to fix atmospheric nitrogen;

4. Developments in reproductive physiology (particularly in the case of cattle and sheep) such as artificial twinning, non-surgical transfer of fertilized ova, predetermination of sex, etc., will help to enhance genetic merit, increase fecundity and reduce production costs;
5. While recognizing that biotechnology may reduce the need for fungicides, bactericides, pesticides and nitrogenous fertilizer by producing crops which are more resistant to disease and more efficient in nitrogen fixation from the atmosphere, we must also recognize that genetic manipulation and plant tissue culture may also give crops more resistance to chemicals such as weedkillers;
6. Developments of biotechnology in the Community will require certain conditions to be met, including :
 - (a) the laying down of European safety rules and standards for products derived from biotechnology;
 - (b) the provision of extra research funds, and the placing at the disposal of researchers, particularly in the field of genetics, of information technologies geared to the needs of biotechnology, both for the collection of data (lasers, X-rays, enzymatic electrodes and remote sensing by satellite for agriculture) and for their storage (data banks for biotechnical research, etc.). It is, therefore, very important to develop the field of application of the ESPRIT programme in these areas of bio-informatics, otherwise there is a danger that the information networks developed will be incompatible with each other and that the dependence on centres outside the Community, especially in the US and Japan, will grow;

- (c) the development of significant exchange programmes, involving not only exchanges of researchers between universities and research institutes but also exchanges with agri-foodstuffs industries and pharmaceutical companies which also make an important contribution to research in this field;
- (d) measures to provide the Community with more flexible and more effective protection for inventions (periods of grace of six months to a year for a patent application to be lodged after disclosure of the invention, admissibility of patent applications for micro-organisms per se, possible extension of the length of patents, etc.).

The flow of investment for innovation depends to a large extent on the effectiveness of the protection offered by patents and upon the means available to combat infringements;

7. Recognizes that biotechnology could enable the agri-foodstuffs and other industries to use substantial quantities of agricultural produce and also enable some of the environmentally hazardous by-products, such as whey and animal wastes, to be converted to useful and valuable products such as potable alcohol and methane gas;

8. The success of biotechnological industries which use raw materials from agriculture (e.g. the drinks industry) depends, amongst other things, upon a reliable supply of raw materials of the correct quality and at prices satisfactory to both producers and processors.

OPINION

(Rule 102 of the Rules of Procedure)

Draftsman : Mr RAFTERY

On 29 January 1986, the Committee on Economic and Monetary Affairs and Industrial Policy appointed Mr Raftery draftsman.

The committee considered the draft opinion at its meetings of 19-21 March 1986 and 21-23 May 1986 and at the latter meeting adopted it by 21 votes to 0 with 2 abstentions.

The following took part in the vote : Mr SEAL, chairman; Mr BEAZLEY, vice-chairman; Mr RAFTERY, draftsman; Mr ALVAREZ DE EULATE, Mr BAILLOT, Mr BEIROCO, Mr BRITO APOLONIA (deputizing for Mr Filinis), Mr BUENO VICENTE, Mr CASSIDY, Mr GARCIA PAGAN, Mr GASOLIBA i BOHM, Mr GAUTIER, Mr HERMAN, Mr KILBY (deputizing for Mr DE FERRANTI), Mr LATAILLADE, Mr MARQUES MENDES, Mrs TOVE NIELSEN, Mr PATTERSON, Mr PEGADO LIZ (deputizing for Mr Mancel), Mr ROSA (deputizing for Mr Rogalla) and Mr STAUFFENBERG (deputizing for Mr von Wogau).

I. INTRODUCTION

1. The importance of biotechnology

Recent progress in the life sciences has provided us with an increasingly extensive knowledge of biological structures and functions. The new biotechnologies, the science of the use of biological processes, which have resulted from these developments will lead to an ever-increasing number of applications over a wide range of different sectors of economic activity.

In agriculture, biotechnology will make it possible, through the application of new genetic technologies, to improve existing species and create new ones with quicker reproduction potential. This will result in improved yields and reduced costs, mainly as a result of lower consumption of fertilizers and pesticides. The large-scale production of new enriched protein foodstuffs can also be envisaged.

Most chemical products manufactured in the world derive from hydrocarbons. However, thanks to biotechnology, it is possible to develop new chemical raw materials (micro-organisms, intensive culture of algae, use of lineocellulose). Fermentation technology and enzyme technology are also opening up countless possibilities in the chemical sector, using raw materials derived from agriculture. New possibilities are also being opened up for agriculture, particularly through the development of the agri-foodstuffs industries.

Biomedical technology has already made great strides, offering prospects for significant progress in the field of diagnosis (monoclonal antibodies), the inventory of human proteins and the production of vaccines and hormones by means of genetic engineering - progress which will reduce the cost of health expenditure while improving the effectiveness of treatment. The second pharmaceutical revolution is opening up prospects for significant progress. The annual savings which could be achieved from only a 1% reduction in health expenditure in the Member States would be substantial, not to mention the benefits produced by improved medicines derived from biotechnology.

Finally, without mentioning the possibilities of the biological processing of minerals (lixiviation) or the recycling of waste, biotechnology applied to biomass also offers prospects for alternative sources of energy.

Given that 40% of manufacturing production in the industrialized countries is already biological in nature and origin, economists believe that biotechnology will be a driving force for innovation leading to the beginning of a long new cycle which will sustain the Western economies.

2. The characteristics of biotechnology

Biotechnologies also have specific characteristics. They involve numerous scientific disciplines and require considerable back-up in terms of informatics. Their applications cover a wide range of products or services and overlaps and conflicts can therefore be expected both between different sectors and different countries. Finally, they will continue to require substantial financial resources. The range and scale of the economic, social and ecological impact of biotechnology inevitably make it an international undertaking, requiring the introduction of a Community strategy as a matter of the utmost urgency, especially in view of the lead already enjoyed by the United States and Japan in this field.

The conclusions which follow reflect the priorities which should be set from the economic point of view in order to create a climate favourable to a successful Community strategy for biotechnology.

II. CONCLUSIONS

In conclusion, the Committee on Economic and Monetary Affairs and Industrial Policy believes that :

1. Biotechnology is a source of new growth, particularly in the agri-foodstuffs, chemical and pharmaceutical sectors and it can also contribute to the process of reforming the common agricultural policy by offering Community agriculture new possibilities, it can help with reducing health expenditure, the decentralization and convergence of economic activity, the development of SME, especially those with capacity for innovation, and increasing the Community's energy independence, though it must be stressed that bio-ethanol has no economic justification in the current state of the world energy market;
2. The range of the possible applications of biotechnology, particularly in the sectors of agriculture, foodstuffs, medicine and pharmaceuticals, energy and the environment, together with the international and interdisciplinary nature of the research and the scale of the resources required, make it a vital undertaking for the economic future of the Community. Hence the need for an extensive Community strategy and programme for biotechnology, taking account also of the lead enjoyed by the United States and Japan in these sectors;
3. In this respect, it is essential to pursue the programmes undertaken by the Commission, particularly the research action programme in the field of biotechnology (1985-1989 BAP) adopted by the Council on 12 March 1985. Nevertheless, this programme, which was devised at the precompetitive stage and on the basis of shared-expenditure contracts, seems too restricted both in its field of application and the resources at its disposal (55 m ECU). Consequently, too many projects have been rejected and abandoned for lack of finance, despite their undoubted value;
4. The Commission should therefore consider drawing up a new research programme in the field of biotechnology. In short, it is vital for the Member States to coordinate and develop their research activities on a European scale in the field of biotechnology, so as to avoid unnecessary duplication of research and assemble the concentration of transnational resources without which our research cannot achieve genuine success, given the need for an interdisciplinary approach and the cost of research in this sector. Collaboration and synergy between national programmes and activities should be promoted both through implementation of Commission research contracts and through concerted action;
5. Consideration must be given, as a matter of urgency, to the possibilities for breeding or switching cultivation to crops with new properties and potential uses outside the foodstuffs sector, to enable farmers to react to market developments by making the appropriate modifications to their production ranges;
6. The development of biotechnology in the Community will require numerous conditions to be met in order to create a favourable climate, including :

- (a) the laying down of European safety rules and standards for products derived from biotechnology (recombinant DNA technologies, for example). The Commission is requested to provide Parliament's appropriate committees with immediate information on the work being carried out in the OECD;
- (b) placing at the disposal of researchers, particularly in the field of genetics, information technologies geared to the needs of biotechnology, both for the collection of data (lasers, X-rays, enzymatic electrodes, remote-sensing by satellite for agriculture) and for their storage (data banks for biotic research, genetics and macromolecules and for cells, plants and animal tissues). It is therefore vital to develop the field of application of the ESPRIT programme in these areas (bio-informatics), otherwise there is a danger that the information networks developed will be incompatible with each other and that dependence on centres of expertise outside the Community will grow;
- (c) providing the pharmaceutical and agri-foodstuffs industries in particular with a satisfactory supply of raw materials;
- (d) a significant increase in European exchange programmes, involving exchanges of researchers and teachers between university institutes and large pharmaceutical and agri-foodstuffs companies, which also make a substantial contribution to research in this field;
- (e) measures to provide the Community with more flexible and more effective protection for inventions in the field of biotechnology, as regards patent law, the law on the protection of new varieties of live plants and other legal provisions (periods of grace of six months to a year making it possible for a patent application to be lodged after disclosure of the invention, admissibility of patent applications for micro-organisms per se; possible extension of the length of patents and speeding up of procedures). These problems must be resolved because the flow of investment depends to a large extent on the quality and effectiveness of the protection offered by patents and on the means available to combat infringements. The Commission should encourage the necessary cooperation within the OECD;

7. Given the cost of research, which can often be very long and speculative, the success of a Community strategy for biotechnology depends in the final analysis on an appreciable increase in Community finance for research, which is required to play an important role as a stimulus, together with the kind of financial project development (risk capital) which is sadly lacking in the Community.

8. It is important also to promote research programmes to investigate the socio-economic implications of the application of genetic engineering and biotechnology.

OPINION

of the Committee on Legal Affairs and Citizens' Rights

Draftsman : Mr A.E. TURNER

At its meeting of 27 February 1986 the Committee on Legal Affairs and Citizens' Rights appointed Mr A.E. Turner draftsman.

The committee considered the draft opinion at its meeting of 18-19 June 1986 and adopted it unanimously.

The following took part in the vote : Mrs VAYSSADE, chairman; Mr DONNEZ, vice-chairman; Mr TURNER, draftsman; Mr ALBER, Mrs BONINO, Mr CASINI, Mr GARCIA AMIGO, Mr HOON, Mr LUCAS PIREZ, Mr MEGAHY, Mr PEGADO LIZ, Mr PRICE, Mr PROUT, Mr ROTHLEY and Mr VERDE I ALDEA.

INTRODUCTION

1. This opinion is directed to the various legal aspects on development of biotechnology in Europe, from the time of conception and invention through research, development, commercial exploitation and, finally, exporting.

PATENTING PROBLEMS

2. It is necessary in patent law to provide a description of the nature of the invention sufficiently clear to enable the public to carry out the invention. The reason for this is that the consideration for protection is knowledge given to the public. In the case of micro-organisms, it is impossible at the present time to define in words a micro-organism sufficiently clearly to be reproduced by an expert. Thus it is necessary to deposit examples of micro-organisms. The problem with this however, is that a member of the public could then take the micro-organism from the deposit and reproduce it without carrying out any original work of his own. Thus a deposit goes much further than is required in patent law.

Identification of micro-organisms for patent protection

3. In the United States and Japan deposited micro-organisms cannot be obtained by the public until after grant of the patent. Under the Munich Patent Convention, such deposits would be available immediately, that is before grant, and thus the public would be enabled to take the invention before the applicant had received protection for it. It would be difficult at the present time to amend the Munich Patent Convention. The European Patent Office has proposed a system whereby an independent expert can be requested by members of the public to examine a deposited micro-organism without allowing it into their hands. It would be a condition of independent inspection that it should be for the purpose solely of providing a proper identity of the micro-organism and sufficient information to repeat the invention as required by patent law. This appears to be a very practical method of dealing with the problem. However, not all Member States of the Convention have accepted the concept. It would, therefore, be desirable for all Member States to agree in common that they will accept this procedure. Although it is very impractical to amend the Munich Convention, perhaps at a later stage the American and Japanese provision whereby deposits are not available until after grant could be adopted.

4. Even after grant, the micro-organism deposited could be misused by members of the public who could use the exemplification to reproduce micro-organisms themselves. It has therefore been proposed that there should be restrictions on the use of such deposits preventing their transfer to other parties, and preventing their removal from the country of deposit. However, it would appear that the best solution would be to maintain the use of the independent expert after grant as well as before grant.

Protection of plants and animals

5. Under existing patent law, plants, animals and biological processes for their reproduction are excluded from patent protection: however, there is protection for plant materials in various national laws on plant breeders' rights. The latter are limited in that only the propagative material of a plant is protected: this means that one can sell the produce of a protected plant. Until recently, the principle thus set out had been accepted generally; however, in the United States very recently case law has held that plants can be protected by patent right as well. This, of course, is a very

probably best to leave the system as it is. Other methods should be employed to encourage university circles to build up close links with industry, and this can probably best be done by encouraging universities themselves to take out patents.

REGULATIONS FOR SAFETY AND THE ENVIRONMENT

Introduction

9. A good deal of work has been done in Europe, the United States and Japan on the question of regulation for the safety of biotechnological processes and products. There appears to be developing general consensus that biotechnology should not be treated as a different problem in kind from other questions of safety of humans, animals, industrial processes, agriculture and the environment. It is pointed out that many biotechnological processes (most notable in fermentation) had been used for very many years and furthermore that new strains have been produced in animals and plants by haphazard methods of breeding for many years and without special provisions for safety. This general conclusion appears to be correct. Furthermore, it is clear that there is not sufficient knowledge at the present stage as to how the biotechnology industries will develop to be able to lay down general provisions equally applicable and suitable to all developments. It also appears, amongst interested circles, that this has led to the belief that a specific case-by-case procedure should be applied to the regulation for safety and the environment for purposes of biotechnology. For instance, one case will involve organisms capable of very fast reproduction, whereas others will involve organisms with very slow reproduction. This conclusion also appears to be reasonable.

10. Thus there is no need or desirability for preferential treatment to biotechnology, that is in the form of different principles to be applied to biotechnological processes and products from other foodstuffs, pharmaceuticals, animal foodstuffs, agricultural regulations or environmental measures: the requirement is for an appreciation that when standards are being applied and procedures followed the special features of biotechnology shall be fully taken into account in the manner set out below. Thus to give an example, directives or national laws on agro-chemicals would be applied similarly to biotechnological as to other materials, with the proviso that where there have been low limit exemptions permitting small-scale field trials, outside the safety laboratory conditions, these exemptions would not apply in the case of biotechnological materials, because of the need to ensure that there is no escape of reproducible material into the environment. Furthermore, more research is required into the conditions of release and behaviour of rDNA organisms when released.

Harmonization

11. It is desirable, in the first place, that developments in the United States, Japan and Europe should go along parallel lines with application of the same general principles and procedures where possible. It is exceedingly important that in Europe itself, there should be a common set of requirements and procedures, that they should be applied by authorities in the Member States under Community directives where necessary, and that there should be mutual recognition of consents given by one Member State in the others. All these objectives are in fact being recognized insofar as bodies, such as the OECD, are bringing together informed and interested opinions and there is a very large measure of agreement. CUBE¹, BRIC² and BSC³ in the Commission are much involved in these objectives.

¹CUBE = Concertation Unit on Biotechnology in Europe

²BRIC = Biotechnology Regulation Interdepartmental Committee

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much broader right because it protects not only the plant, but all its produce and a patent claim would undoubtedly protect many variants on any particular strain patented. The reason in the past for the exclusion of plants and animals created by biological means from patent protection was that the means were haphazard, based upon the application of genetic breeding concepts hardly in keeping with the principles of industrial invention.

6. It could well, however, be said that with biotechnological development of new species by means of gene manipulation such work falls within the natural principles of patent law protection as it is based upon deliberate application of scientific principles. It is certainly the case that there is insufficient protection for biotechnological development by reason of recombinant DNA (rDNA) and that this is a serious drawback to the development of biotechnology. It would be possible to overcome this drawback if the Member States of the Munich Convention declared in common that rDNA was not a biological process. This would mean that processes for the production of new organisms would be protected, and at the same time Member States should agree that the inclusion of claims to micro-organisms per se (permitted in the Convention but not recognized clearly in all Member States' legal systems) should be acceptable. In this way shortcomings in the present patent system in the EEC could be overcome without having to end the Munich Convention at the present stage; while at the same time greater protection could be afforded to biotechnology, as is now the case in the USA. The absence of such protection is naturally a serious disadvantage to European industry.

7. However, before this step is taken, it would be necessary to make a political decision that protection of plant and animal materials and their products is desirable. In patent law, at present, there has always been a certain degree of exception given to foodstuffs and medicines in many of the national laws on the grounds of social policy. This has normally taken the form of the provision that the patentee may not prevent the production of such products but can be compelled to licence the production if there is a need that he is not fulfilling. The Munich Patent Convention ended the provisions for compulsory licensing, and generally speaking it would appear that it is accepted that the supply of pharmaceuticals, for instance, had not been adversely affected by this change in the law.

Premature publication of new inventions

8. There have been complaints in the biotechnology field in Europe recently that Europeans suffer from disadvantages in that in Japan and the United States there is a 'grace period' after an invention has been made during which the inventor can publish the invention and yet not destroy his right subsequently to apply for a patent. The period of grace is not recognized in European law, where any publication before application for patent renders the patent invalid. It is true that the 'grace period' does render it much easier for university research to be transferred to industry rapidly because the university is not deterred from publishing its results by the need to keep secrecy until a patent has been applied for. It is said that universities set such high importance on early publication that the European system is a disincentive to transfer technology from academic to industrial circles. However, the concomitant disadvantage of the American system is that there is far less certainty as to the ownership of an invention, because it is possible in the United States to have very expensive proceedings to determine who was the originator of the invention subsequently applied for. In Europe this lack of certainty cannot exist, because the first applicant (except in very limited cases of theft of a confidential document) is regarded as the appropriate patentee. Thus, despite the disincentive that the lack of a 'grace period' is said to give in Europe to transfer from academic to industrial circles, it is

12. Types of biotechnological procedures and products

- (a) In many biotechnological processes live organisms containing rDNA will be employed in the production process but the product sold will comprise no living or reproducible materials. In this case the special biotechnological hazard is confined to the place of manufacture and here, therefore, containment safety regulations will relate to methods of manufacture.
- (b) Live organisms which will be used by the final user as such outside places of manufacture and which are capable of reproduction will require special consideration when they carry foreign genes or gene components introduced intentionally by genetic engineering techniques. Here the products of rDNA must be had in mind. This heading does not include organisms (viruses, bacteria, algae, animals, plants, etc.) naturally occurring, or the subject of natural or induced mutation, unless foreign genetic material has been introduced by biotechnological processes.
- (c) Manipulation of human genes : this is an ethical and moral question, which is relevant only in the case of certain pharmaceuticals, so far as industry is concerned and should be considered entirely separately. It is beyond the scope of this opinion and is being considered by the Committee on Legal Affairs and Citizens' Rights in the report currently prepared by Mr ROTHLEY.

The requirements of competitive industry in Europe

13. It is very necessary for industry in Europe to have a degree of cost certainty as to the procedures required to bring a proposed development for a commercial production onto the market : at the present time it is probably the case that a good deal of biotechnological developments are deterred by fear as to doubts as to what hurdles have to be overcome and what will be their costs and the impracticability of setting up new plant in the face of such uncertainties.

Use of existing Community and national regulations

14. Existing Community and national regulations already cover all fields of commercial exploitation with requirements for safety of humans, animals, agricultural processes and the environment, though of course these are constantly being updated and developed and environmental standards are raised. All these controls and the general requirements for safety and environmental amenity should be applied to biotechnological procedures and products in the same way that they are applied to other laboratory operation, manufacturing plant and operations, experimental testing outside controlled conditions and final release upon the open market. In other words, there should not be different standards of safety and amenity merely because a process or product involves biotechnology. A process of manufacture should be as safe to those involved with it and a product should be as safe for the public and as appropriate to the environment, however it is obtained and whatever its chemical or biological make-up may be. However, as mentioned in paragraph 10, the low limit exemptions normal in existing legislation (to permit small-scale trials in the open environment) should not be permitted in the case of paragraph 12(b) above.

Special features for biotechnological processes and products

15. However, in view of the relative newness of biotechnological products, and uncertainty as to their possible consequences, it is necessary to superimpose upon existing regulatory procedures special assessment of the risks which may be involved in order that special conditions may be laid down to take them fully into account. However, because of the great variety of types of biotechnological processes and products that may be developed over the next few years, it is desirable to treat each proposal on its own merits setting out special conditions when required on a case-by-case basis. In order to make sure, however, that in each case full consideration is given to all possible aspects raised by biotechnological issues it is necessary to lay down a framework of procedure for risk assessment. This is being considered by industrial representatives in Europe and it would appear that the sort of procedure that they have proposed is appropriate⁴. It would appear, however, that the same type of risk assessment should be applied in all biotechnological procedures and products, wherever they are carried out in the Community, whether industrial or not. This would, therefore, apply to universities and other such institutes.

16. The proposed risk assessment programme for any particular case would comprise certain stages at which risk assessments should be made and certain questions asked and answered. The steps proposed are :

- (i) project initiation,
- (ii) contained laboratory experiments (in vitro and in vivo),
- (iii) small-scale experiments (closely monitored, non-contained),
- (iv) field application, and finally
- (v) commercial application.

17. At the first stage, characterization of the organisms must be made for the purpose of the procedures to be carried out and an assessment made of the containment level that will be required for adequate safety. In each subsequent stage, assessment must be made as to that next stage only of :

- (a) the risks and types of exposure to humans,
- (b) assessment of the capability of the organism to survive, multiply and spread,
- (c) the risk and type of exposure of animals (insects, wild animals, farm animals) and on various plants,
- (d) interaction with other relevant components of the eco-system, and
- (e) contingency measures.

These assessments will, at each stage, lead to a definition for the purposes of carrying out that stage of the safety precaution measures necessary for workers, experimental design and monitoring systems, definitions of safety and precaution measures, estimation of the potential consequences on release and measures for risk minimization in the case of unforeseen events. Quite clearly, each of these risk assessments and required steps to meet them will have a different significance according to the stage that is being considered.

⁴The European Committee on Regulation Aspects of Biotechnology which considered guidelines laid down by the OECD

Procedures

19. If the above form of uniform reporting by proposed users of biotechnological processes or products were adopted, this would lead to a common system of consideration and grant of consent to carry out biotechnological processes or to produce products throughout the EEC. A common form of reporting would also make it easier for the relevant authorities to monitor the assessment of risks and lay down the necessary conditions for meeting them. It would also mean that mutual recognition of the consent given by one authority would be readily comprehensible to the authorities in other Member States.

Labelling

20. Existing labelling regulations in the EEC should be equally applicable to biotechnological as to other products, any special conditions required in the final stage, or any necessary previous stage, could be established during the risk assessment set out above.

Transport

21. Regulations for the safety of transport of dangerous substances would be the same as for any other dangerous chemical substances. Though here again, if there were requirements for special conditions at the last or any intermediate stage of risk assessment, these should be laid down by the authority considering the risks.

Frontier controls

22. There should be no necessity for any frontier controls other than those that exist for other inherently dangerous products within the EEC, and ideally these controls should not be based upon the existence of frontiers but on reporting and monitoring of the starting point, route and destination of the journey with appropriate reports on monitoring by the authorities geographically involved. Clearly it is important to ensure that barriers to trade within the EEC are not set up under the guise of safety requirements for biotechnological reasons.

Exports

23. Conditions laid down in the final stage of the risk assessment to meet release of a product to the public, should apply also to exports to other parts of the world, most notably, of course, the under-developed world in order to avoid exploitation of possibly more lax safety and environmental regulations in Third World countries.

CONCLUSIONS

24. Two major legal aspects of the development of biotechnology (excluding the moral and ethical problems of manipulation of human genes) exist : patent problems and safety and environment regulatory problems.

25. Patent problems : greater certainty in patent protection to biotechnology is vital for European industry :

- (i) there is doubt as to the patentability of micro-organisms, firstly because the practical difficulty of sufficiently identifying a micro-organism in words renders obtaining valid patent rights doubtful. Therefore, the Member States and the Community should adopt the mechanism of deposit of micro-organism by the patent applicant as sufficient for patent purposes together with access to the deposit by the public through the intermediary of an independent expert for the purposes of obtaining sufficient identification and information to be able to repeat the invention.
- (ii) there is, secondly, doubt as to the patentability of micro-organisms because of the exclusion from patent protection of plants and animals created by biological means. In view of the clear inventiveness of recombinant DNA gene engineering the Member States and the Community should accept that such gene engineering does not fall within the exception to patents for plants and animals created by biological means, and that micro-organisms per se can be the subject of patent protection.
- (iii) although the European rule that publication of an invention before application for a patent invalidates the patent (unlike in the USA and Japan, where a period of grace after publication is permitted before application), and although this is possibly a disincentive to academic disclosures to industry, it is not clear that the USA/Japanese system should be adopted, because of the costly disputes that this system creates with regard to who first made an invention.

26. Regulation for safety and the environment concerning processes of production and products involving micro-organisms carrying foreign genes or gene components introduced intentionally by genetic engineering techniques. Clarity and certainty in the regulatory procedure are vital for European industry.

- (i) The criteria in existing regulations on safety and the environment should apply to biotechnological processes and products as they do to chemical processes and products.
- (ii) At present a case-by-case examination and granting of approval should be applied to biotechnological processes and products in view of the very varying issues arising in different fields.
- (iii) Low limit exemptions for small-scale field trials common in regulations on chemical processes and products should not be permitted for biotechnological processes and products.
- (iv) All regulations should be harmonized in the Community, they should be implemented by Member States with mutual recognition by the others of consents and conditions given by one Member State.
- (v) Special risk assessment on a case-by-case basis shall be made at each stage of development of projects (initiation, contained laboratory experiments, small-scale non-contained experiments, field application, commercial application) and safety and environmental conditions should be established for each step again on a case by case basis based on such assessments.

- (vi) The risk assessment procedure should also apply to non-industrial projects in universities, research establishments, etc.
- (vii) Further research is particularly necessary at a Community level on the problems of release and containment of micro-organisms.
- (viii) Labelling, transport and export activities should be subject to conditions laid down in the risk assessment procedure.
- (ix) The nature of biotechnological products should not be used as a means of perpetuating internal frontier barriers : the safety of transport should be monitored at start and destination of journey and along the route, not specifically at internal frontiers.

OPINION

(Rule 101 of the Rules of Procedure)

of the Committee on the Environment, Public Health and Consumer Protection

Draftsman : Mr G. SCHMID

At its meeting of 22 March 1985, the Committee on the Environment, Public Health and Consumer Protection appointed Mr SCHMID draftsman.

The committee considered the draft opinion at its meeting of 25 June 1986 and adopted its conclusions unanimously.

The following took part in the vote : Mrs SCHLEICHER, acting chairman; Mrs BLOCH von BLOTTNITZ, vice-chairman; Mr VITTINGHOFF, replacing the draftsman Mr Schmid; Mr GARCIA (deputizing for Mr Pereira), Mr van der LEK, Mrs LENTZ-CORNETTE, Mrs S. MARTIN (deputizing for Mr Nordmann), Mr MERTENS, Mr PEARCE, Mr SHERLOCK, Mrs VEIL and Mr VERNIER.

A. Definition of the problem

1. Viewed from the perspective of the Committee on the Environment, Public Health and Consumer Protection, any discussion on the future of biotechnology must answer the following questions :

- (a) Is the growth in our knowledge of the possible risks of biotechnology keeping pace with the growth in the use of that technology?
- (b) Does biotechnology entail risks which, going beyond localized accidents, could adversely affect the environment and evolution overall?
- (c) Will the underlying rationale of business and research automatically allow biotechnology to be developed in areas where the social need is great but the economic interest scant?

This opinion will not discuss whether it is ethically defensible to apply genetic engineering to human beings. The committee will give its detailed views on that subject when Mr ROTHLEY draws up his report.

2. Knowledge of the risks of biotechnology has not progressed very far to date. Since the Asilomar Conference in 1974 only a few studies have been conducted to evaluate the possible risks and consequences of gene manipulation for human, animal and plant life and the environment in general. Once positive evidence had begun to emerge that genetic engineering was 'feasible', interest in questions of safety subsided dramatically. As a result, there is an increasingly yawning gap between the development of biotechnology and knowledge of its risks.

3. Environmental problems associated with the release of genetically manipulated organisms

Basically, there are three questions which have either not yet been fully answered or else cannot be answered at all :

- (a) Could the course of evolution be influenced by small quantities of genetically engineered organisms that had been deliberately released?
- (b) What, if anything, might be the consequences of the massive application of such organisms?
- (c) Could organisms which had inadvertently found their way into the environment, i.e. as the result of an accident, influence the course of evolution?

The experimental release of plants or animals appears relatively safe. The question here is whether the artificial organisms would be capable of finding their way independently into the environment and eliminating potential natural rivals. That would throw entire ecosystems out of balance. Theory and practice both seem to rule out this possibility. The new properties created in plants and animals will be geared to human food requirements. Yet what is beneficial to man is beneficial to neither the plants nor the animals - if anything, quite the reverse. The properties acquired through gene manipulation are unnecessary for, or even a hindrance to, survival in the harsh natural environment. On the other hand, the situation as far as micro-organisms are concerned is still completely unclear. Yet of all things, the release of micro-organisms is currently being tested. Naturally occurring bacteria, for instance *Pseudomonas syringae* and *Pseudomonas fluorescens*, are

to be suppressed by genetically manipulated species. The natural bacteria secrete proteins which, because of an affinity between their crystal lattices and those of frost, can act as crystallization centres the 'premature' formation of ice on plants (e.g. strawberries). The genetically manipulated species do not have this property. If sprayed on strawberry fields, the artificial bacteria could drive out the natural ones and thereby protect plants from frost. However, it is feared that the effect cannot be confined to the sprayed fields. If that were the case, then weeds - hitherto maintained in natural balance by prevailing temperatures - might also be protected from frost.

4. The mass application of genetically manipulated organisms raises even more problems. The following distinctions need to be made between this and experimental release :

The purpose of massive applications is economic. The genetically manipulated organisms are there to produce a profit. The presence of natural rivals runs counter to the economic interests of the persons who released the artificial organisms.

- Massive applications lead to the standardization of varieties. Large tracts of land which used to house many varieties are being made over to a single variety.
- Massive applications, as opposed to experiments, increase the probability that organisms will escape into the neighbouring environment.
- In crop breeding, independence from artificial fertilizers and resistance to pests are the most desirable properties to aim for. With massive applications, an 'epidemic' spread beyond the areas under cultivation can no longer be ruled out.

The unintentional release of dangerous micro-organisms was the subject which sparked off discussions on the possible risks of genetic engineering. The discussions on safety in recent years have partly dispelled such doubts. Yet certain imponderables remain :

- a micro-organism cannot be equally harmful in a large number of fundamentally different biotopes. A general risk to the environment is therefore excluded. In contrast, mankind, with its culturally acquired independence from environmental conditions, affords a uniform ecological niche for potential new pathogens.
- Naturally occurring gene transfers could pass on dangerous characteristics to what were previously harmless bacteria.
- In theory, a mass release could alter the above view : nature can cope with mutations and sudden variations in individual genes, but not with anything on such an immense scale.

5. Tampering with genetic potential may also lead to species becoming extinct. The danger here stems from two causes :

- The gene pool might be fatally impoverished, owing to a lack of knowledge.
- If biology, with its hitherto autonomic system of laws, is made subject to the laws of human society, the 'rules of the game' obtaining in human society will be imposed on nature.

These outstanding problems must be clarified before genetic engineering is applied on a large scale. As far as medical research is concerned, the experience acquired in the Community research programme will be the best guide.

6. Community action to date

In the debate on the multiannual research action programme in the field of biotechnology (1985-1989), the European Parliament called for emphasis to be placed on health, environmental protection and risk research, as well as on reducing production costs. The Council has adopted all Parliament's amendments to that effect. There is thus already a broad basis for action.

A discussion on the future course of biotechnology must therefore consider :

- how the programme is being implemented by the Commission and
- whether it is proving capable of solving the problems referred to above.

Application of biotechnology to health

In the cloning of vaccines and hormones, it is veterinary medicine which is the main focus of activity. Nevertheless, 13 out of the 22 research projects also have potential applications in human medicine (e.g. the blood clotting factor). Cell culture research too has medical applications.

Risks to man and the environment :

Only 24 out of 788 research projects (3%) touched on this subject. The release of genetically manipulated micro-organisms is the main problem under consideration in the research.

Practical experience with the programme so far points to a heavy bias towards industry, while the socially important areas of health and the environment are not being given their due. The Commission, however, cannot be blamed for this. Apart from the programme advisory committees, the priorities selected by researchers themselves carry a good deal of weight. Safety research does not enjoy a very high reputation within the scientific community and is no passport to an academic career. This is a view also shared by researchers themselves. According to the well known genetic engineering specialist Prof. Dr. Werner Gobel, bacterial ecology is relatively neglected because 'you don't win Nobel prizes for it these days'. What is more, in medical applications of biotechnology, the logic of the market does not necessarily reflect the social need.

B. Conclusions

7. The efforts made by the Community so far are not sufficient to close the newly widening gap between the growing spread of biotechnology and an adequate knowledge of the associated risks.

8. The Community's activities are less than fully effective in encouraging socially desirable medical and environmental applications of biotechnology, although the legal basis for such applications already exists.

9. The weaknesses observed in the case of the Community also apply, for the same reasons, to the activities of the Member States.

10. Solving safety problems is an eminently suitable task for the Community. Given that offers to sponsor research are clearly not enough (other subjects are 'more attractive'), more direct approaches will have to be employed. The same applies to the fields of medicine and the environment. As means to this end, the Community could :

- set up a separate R & D unit at ISPRA,
- invite tenders for practical projects and organize project teams,
- commission studies where expedient and
- sponsor demonstration projects.

Moreover the European Parliament has recently set up an office for the assessment of scientific and technological options, abbreviated as 'STOA'. It would seem particularly appropriate to consult this body which is directly answerable to Parliament on the effects on public health and the environment of the use of biotechnology.

11. The instruments required are neither especially original nor new for the Community. They have long been applied in the energy sector. What is important is rather to use them for biotechnology as well.