DIRECTORATE GENERAL FOR
RESEARCH

COMMITTEE ON ENERGY, RESEARCH AND TECHNOLOGY

SYNOPSIS OF THE HEARING ON BIOTECHNOLOGY

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Contents

Foreword

The Committee on Energy, Research and Technology of the European Parliament organized a Hearing on Biotechnology on 20/21 November 1985 in Brussels. This hearing stressed the need for more cooperation in European research and development in order to strengthen the position of Europe vis-à-vis Japan and the United States and underlined the need for international regulations in biotechnology. Furthermore, the hearing aimed at highlighting complex problems relating to the possible consequences of biotechnology for agricultural policy in Europe and problems relating to the impact of biotechnology in the Third World.

The main objective, however, of this hearing was to collect further facts and information for the Committee's own-initiative report by Mrs. Phili VIEHOFF, MEP. Her report is to be debated in the Parliament during the first half of 1986. Mrs. VIEHOFF has already been the Committee's rapporteur (Doc. 2-1144/84 and Resolution of 14 December 1984, OJ C 12/85, pp. 144-146) on the current multiannual research action programme for the EEC in the field of biotechnology (1985 to 1989) (Council Regulation 85/195/EEC of 12 March 1985, OJ L 83/85, pp. 1-7).

The Directorate General for Research and Documentation has been asked to summarize this hearing. This document contains a short synopsis of statements made by experts on the different topics and a summary of the subsequent discussions.

Introduction

Mrs Phili VIEHOFF, Member of the European Parliament:

Biotechnology and the Rôle of the European Parliament

The tasks and the rôle of the European Parliament are limited and therefore cannot be compared with the rôle of Congress in the United States or with the rôle of national parliaments. The European Parliament does however have **three important tasks:**

— to advise the council and to control and advise the European Commission;

— to initiate studies and investigations;

— to influence and reflect public opinion and to raise public awareness.

These tasks can become powerful tools when used to instigate discussions on high technology in general and biotechnology in particular. Already in October 1980 the European Parliament discussed the potential, the usefulness, the limitations and the possible risks of biotechnology. A comprehensive report made by Mr Gerhard Schmidt (Working Document 1-521/80) formed the basis for this discussion which led to some changes in and modifications of the Commission proposal for the Biomolecular Engineering Programme. This Programme has proved successful and has laid the foundations for the multiannual European Biotechnology Action Programme, which started recently.

Before this Action Programme was accepted in December 1984, a second broad discussion took place in the Parliament. This discussion had a different character from the discussion in 1980. The rapid advancement in scientific progress and the growing interest of industry in applying biotechnology for the creation of new products and processes, as well as the steep rise in financial efforts made by the United States in this field and the Japanese guided joint approach, formed the background to the discussion this time.

Although it was agreed unanimously that a European Biotechnology Action Programme was necessary if Europe did not want to fall back to an uncompetitive position vis-à-vis the United States, Japan and even some newly industrialised countries, an attempt was made to take the discussion beyond this well-known statement.

Besides stressing the need both for international regulation of biotechnology and the importance of advanced European support industries for large-scale development of biotechnology, as well as the need for a policy that could prevent a brain drain from Europe to the United States, there were other and perhaps more complex problems in the medium and long term that should get more attention too.

There is one other new initiative I would like to mention. That is the proposal for the establishment of a **European Parliament Office for Scientific and Technological Option Assessment (OSTOA).** This office will assess science and technology policy and will formulate alternatives for the development and application of technologies and organisational structures. As far as biotechnology is concerned, I think this European OSTOA can function as an important resource base for Members of Parliament and help to prepare further discussions and to raise public awareness on a broader scale. Let me now move on to four issues that need more attention in the years to come.

First, the question of access to and distribution of biotechnology. Biotechnology offers an enormous potential for many different industries and countries, but it is obvious that the distribution of biotechnology is very unequal. This situation is aggravated by the fact that biotechnology research is often carried out in the private sector. One of the most problematic implications of this is the restriction on broad access to new agricultural and pharmaceutical biotechnology advances. This situation could easily lead to tensions and even political conflicts between states. An illustration of this is the limitation on the potential of biotechnology for Third World countries because of their inability to gain access to the technology. But on a more subtle level the same conflicts could occur between industrialised countries, particularly if we think about the possible effects of export control policy on high technology. Until now it seems that many European companies have not been aware of or have not wished to acknowledge the threat of being cut off from American high technology or from parts essential to their products. However, we should not underestimate the extraterritorial jurisdiction of the United States.

Secondly, the issue of regulation and risks. Genetic manipulation of micro-organisms and plants will undoubtedly result in enormous benefits for human health, crop production, veterinary medicine, and pollution control. But what about the risks?

As biotechnology is exploited by industry, commercial objectives will lead to increasingly varied uses and increasingly varied hazards. Entrepreneurs may become less cautious when they see high profits on the horizon. This can become particularly relevant in the case of large-scale industrial processes and in cases of the deliberate release of manipulated organisms into the environment. Field tests have already been made involving the deliberate release of genetically engineered organisms into the environment. What is at issue is whether a foreign organism will disrupt the ecosystem into which it is introduced. However, scientists have insufficient information to predict the ecological consequences of genetic engineering. Although the risks from genetic engineering so far appear to be low,

the consequences of an accident could be enormous. More basic research and testing in microcosm are necessary to reduce the uncertainties. Factors such as release, survival, multiplication, dissemination, and transfer should be included in new risk assessment methods. It is a pity that the international efforts at OECD level have failed to establish harmonious regulatory programmes because the American delegation could not accept the text of the proposed international guidelines. I am afraid that the American delegation's attitude has a strong political and economic background, namely to prevent a too strong regulation for the American firms at home and abroad. In the US there is intensive lobbying from industry to reduce regulation and to regard biotechnology products as normal chemical products. This would prevent new regulations and would save time. It would facilitate the marketing of American biotechnology products and would give these companies an advantageous position in the face of fierce international competition. We should prevent the realisation of such a policy in Europe. Here in Europe we should show a more responsibile attitude, to reduce the possible risks and avoid the misuse of national regulation policies. We should establish **European** regulation guidelines as soon as possible.

Thirdly, the restructuring of agriculture. Although until now biotechnology applications have been concentrated upon pharmaceuticals and diagnostics, the market for agro-food products is estimated to be much larger. Biotechnology and the increasing use of information technologies will change the existing structure of agriculture and food-processing. The traditional essential for growing things, still vitally important, are land, water and farmers. New ingredients include seeds, genes and chemical molecules. The importance of seeds is reflected in the buying-up of small seed companies by large pharmaceutical and (petro) chemical corporations. In addition, the seeds themselves have changed. Specific genes have been transferred from one species to another to increase crop yield, and to make plants resistant to diseases, insects and even drought.

Although these achievements are very promising, a drawback is that these advances in plant genetics are supported by the continued increased use of chemicals on the land, such as pesticides, herbicides and fertilisers. A serious danger is that producers will use even greater amounts of herbicides in the long run, because their seeds will be resistant to these increased amounts. This development is dangerous for public health and should be monitored much more closely. Also the growing dependency of farmers on the concentrated seed industry and their 'package-policy' should be given more attention.

It is unlikely that industry will stimulate research and development on seeds that no longer require agro-inputs, although theoretically this is possible. However, the profit-orientated thinking of industry and the high stakes in the existing agro-input market will prevent this. This illustrates the distinction between the full potential of biotechnology and the actual direction of private research carried out by companies.

If we look at the consequences of biotechnology and information technology for the farmers, then it becomes clear that the farmer of the future will spend less time on a tractor and more time at his computer, programming minute details about his crops, plugging into data gathered by satellites, and keeping up on the latest in genetic manipulation. This highly sophisticated business will give employment to only a few farmers. According to recent American research at least half of America's food will be produced by only 1% of the farms. The employment problem created by this could be serious in Europe too, particularly in the new EC countries like Portugal, Spain and Greece.

That is not all. Genetically manipulated seeds can change the whole **regional and international division of labour in agriculture.** Crops that used to be grown in the South can be shifted to the North when for example the resistance of plants to colder climates is increased.

The consequences for agricultural and related trade between industrialised countries and between Third World countries and industrialised countries could be far-reaching. Although it all sounds still very futuristic, and although much research has still to be done before this situation is reached, development towards this situation seems unavoidable. In the European Parliament all Committees involved in agriculture, technology, environment and industry have to consider these possibilities.

There is increasing recognition of the fact that the existing agricultural policy has become untenable. Nearly 70% of the budget is spent on agriculture and this limits the possibilities for many other useful initiatives and programmes. Biotechnology will lead to a restructuring of agricultural policy on a much broader scale and perhaps much faster than has been acknowledged until now. This restructuring in the sense of changing and cutting subsidies, changing price policy for agricultural products used for industrial production, and the retraining of farmers is essential if we want to make the most of this enormous transformation and if we want also to direct development in a socially and economically acceptable way. This issue will become very important in the next decade. The European Parliament started the discussion last year and will continue it because this is a complex problem that should be resolved on an international scale. The European Parliament is an excellent platform for the discussion of the different options at an early stage.

Fourth, and lastly, I would draw attention to the **socially useful products.** What do I mean by this? If we look at the direction of commercial research and at the new biotechnology products, commercial incentives clearly exist for high value added products and not for uses of biotechnology which have little commercial value, but high social value, like malaria vaccine. However, 150 million people catch malaria every year and biotechnology could lead to a new cheap vaccine. The same can be said for other common virus diseases. But industry is not interested in poor people's needs. Industry is not interested either in fighting rare diseases where there is no commercial interest. Investments in the so-called 'orphan drugs' are high and profits low, because the market is very limited. However, the potential of biotechnology is very promising in this field and should be developed further. This is also true for a terrible disease like AIDS. The European Parliament has asked for more biotechnology-related research to speed up the development of diagnostics and medicines.

If we look again at the potential of biotechnology for food production, it would be logical to stimulate the development of tissue culture or other biotechnology-

based techniques in areas near the starving populations of the Third World, instead of shipping our overcapacity to these countries. However, the protection of farmers in industrialised countries prevents this. Also the fact that we know very little about rice, the world's largest food crop, limits the horizons of companies.

In the field of toxic waste treatment biotechnology seems to offer attractive possibilities. It might be possible to create special organisms that could digest toxic wastes. And enzymes in fermentation processes might catalyze a much more complete and rapid degradation of particular wastes.

Also in the field of local, small-scale energy production biotechnology can play an essential rôle, particularly in developing countries.

Biotechnology — if regulated properly — can offer many promising solutions for food, health, energy and waste problems in North and South. However, many of these developments offering important public benefits will be neglected by profit-seeking industry. Therefore, it is necessary to be selective in setting up biotechnological programmes. Industry knows where profits are to be found and will not invest if they are not sure of their returns. Now that the European Biotechnology Action Programme has begun, in parallel with many national government biotechnology programmes, we should reconsider our starting points. An important task for the European Parliament is to monitor useful applications of biotechnology that for commercial reasons will not be picked up by industry. The path the European Parliament should follow is that of public benefit. More funds should become available for research and development programmes that make qualitative contributions to the well-being of people, without concentrating on short-term profits. Close examination of the results of the European Biotechnology Action Programme and suggestions for new directions will be an important task of the European Parliament, together with the proposed European Parliament Office for Scientific and Technological Option Assessment.

Part I:
General overview on biotechnology

1. Prof. Dr. THOMAS (Université de Technologie de Compiègne):

The state of European research in biotechnology

1. The European biotechnology situation is unfavourable when compared with the USA and Japan. However, Japan is disadvantaged by not having direct access to agricultural raw materials.

2. No European country dominates the biotechnology market. West Germany and France possess specialised knowledge of microbiology. The UK leads in the field of protein-design. Belgium and Italy are leaders in plant conservation and gene technology.

The technology exists in Europe, but improved coordination of research etc. is vital.

3. Until now biotechnology applications in Europe have been concentrated in the pharmaceutical and diagnostic fields. This technology should be extended to European agriculture for the resolution of common problems.

4. Research collaboration must be encouraged. Little international research exchange existed in Europe in the past. However, there has been improvement since the introduction of the Biomolecular Engineering Programme (BEP) (1) which has a fund of 15 Mio ECU.

5. Europe-wide training is necessary, using an interdisciplinary scientific approach.

6. Collaboration between European industry should be encouraged. Legal barriers have caused delays. Therefore, a coordinated legal system is required.

7. Improved relations between research centres and industry is needed, so that biotechnology applications are deployed to maximum effect.

8. These are positive signs: the implementation of these measures could enable Europe to challenge the USA and Japan in the field of biotechnology research.

9. During the following discussion Dr. THOMAS was asked about training, finance and the extent of the proposed collaboration.

10. He believed that training should reflect the interdisciplinary nature of biotechnology, involving a teamwork approach by scientists, as 'one person alone cannot be a biotechnician'. It is also desirable that there should be an effective interchange between academic and industrial experience, allowing university-based scientists an opportunity to work in an industrial environment.

(1) Research and training programme for the EEC in the field of biomolecular engineering (indirect action April 1982 to March 1986), Council Decision (81/1032/EEC) of 7 December 1981, OJ L 375/81, pp. 1-4.

11. Countries which are at a disadvantage where biotechnology is concerned have a chance to work with countries which are more advanced, thus allowing for regional development.

Regarding plant molecular biology a small country like Belgium with intensive land use has certain advantages over a large agricultural country like France. Collaboration therefore is useful and already much compatibility exists in Europe.

12. Low investment restricts biotechnology development in Europe. On the other hand, in the USA it depends on private risk-capital which is more freely available and therefore government intervention is not required. Because in Europe investment of this type is not forthcoming, it is necessary to find alternative sources of capital. Dr. THOMAS believes that banks may be attracted to biotechnology as an investment option. The state function should be as an investment regulator.

EUREKA's role as a possible source was questioned. Dr. THOMAS stated that its function was merely to provide initial investment stimulus as a framework for the commercialisation of research. Important action programmes already exist in parts of Europe, such as West Germany. Overall, BAP (1) is the most important programme on a general European level, having financed 170 projects. But given that 800 requests have been made, many of which were perfectly viable, it is obvious that much more remains to be done.

13. International collaboration is hindered severely because individual companies are eager to maintain development and production confidentiality. Therefore Europe's patent system must be coordinated.

14. The European price structure is another major problem because the agricultural raw materials needed for biotechnology are over-priced. A price reduction in starch, for example would have no effect because there are more than 350 products required for starch-production, of which only one-third are sold on the food market.

2. Dr. POTTER (Science & Engineering Research Council (SERC), UK):

Project Management in Europe

How to define project management in biotechnology?

15. Broadly speaking project management in biotechnology is similar to project management in any branch of science. Where it differs from most other

(1) Multiannual research action programme for the EEC in the field of biotechnology (1985 to 1989), Council Decision (85/195/EEC) of 12 March 1985; OJ L 83/85, pp. 1-7

fields is in the way biotechnology affects project initiation and management. In particular biotechnology is highly multidisciplinary and the projects typically involve two or more disciplines. As many industrial sectors and government departments or public bodies have interests in biotechnology, there is a need for a very high degree of coordination and cooperation in biotechnology projects.

What is the optimal size in terms of personnel for a biotechnology project?

16. The minimum size for an effective multidisciplinary project is 3 post-doctoral fellows plus technician support. The maximum size is limited by the ability to manage a large group of people, sometimes in different laboratories.

17. The availability of suitable qualified people varies from country to country. Within the UK data exist for supply and demand and also for the loss of biotechnologists to other countries i.e. the 'Brain Drain'. The loss from the UK has occurred mostly to the USA and, to a lesser extent, Switzerland.

What is the most favourable environment for project management in biotechnology — industrial, academic, green-field or other?

18. In general, project management based outside of the sector(s) where the work will be undertaken is best. Within the UK the Biotechnology Directorate manages programmes involving both academia and industry. This central position involving a wide range of organisations without being part of them is the most effective environment for project management. International projects linking various countries within the Community are possible and desirable. The decisive first step would be to build confidence between the participating groups in the different countries. Where it is not clear that cooperation will benefit all the participants, projects will not succeed.

What are the difficulties in bringing biotechnology from the laboratory to commercial application?

19. Such a transition is easiest when the idea originates within the firm that subsequently exploits the results. The most effective transfer of technology from academia to industry is brought about by the movement of people from one to the other, at least for a short period of time if not permanently.

20. Most of the earliest biotechnology products to come onto the market will be in the health-care field. Many of these products will require acceptance by regulatory bodies and obtaining such acceptance is expensive and time-consuming. Some companies may even consider moving their operations to a country where obtaining regulatory approval is quicker than elsewhere. Current estimates suggest that it take five years for a product in the health-care field to move from the laboratory to the market. Products not requiring regulatory approval can be exploited quicker, although even here it could take at least 3 years.

Are project managers in biotechnology generally aware of the Community policy instruments available for project support?

21. Literature produced by the Commission describes these projects and the Vademecum of contract research in particular is a most useful document in this regard. If there is a weakness in the awareness of biotechnologists in regard to Community funding it is because of the way such literature is distributed within Member States. Perhaps more attention should be given to this.

The UK's Protein Engineering Programme

22. This managed Programme involves the funding by the Biotechnology Directorate and by four industrial companies of research projects in seven universities. The supported research is broadly divided between the production of new or improved proteins which can be used in health-care, as industrial enzymes or for other purposes. Together the companies concerned will provide about £0.5 million towards a £2 million programme over 4 years. Protein engineering is a multidisciplinary field with many potential applications. The programme being supported by the so-called 'Protein Engineering Club' includes not only basic research but also work that is of more immediate relevance to industrial needs.

Discussion

23. Dr. POTTER was asked, whether joint ventures were a way out of the problem of the 'missing link' in the application of biotechnological research which in Europe had fallen miles behind the USA. Dr. POTTER agreed that this was so and said that he would like to see a wider spread of companies and academic centres working together. However, he pointed out the difficulties in organising such ventures. Joint ventures exist already but the cooperation should start at a precompetitive level.

24. Is there a European basic research and, if so, can we use it to our benefit in competition with Japan and the USA?

25. Dr. POTTER answered in the affirmative and explained that European research is very strong with as high a quality as that in the US and Japan but research in these two countries is better organised.

26. Dr. POTTER was asked if there were any other programmes similar to the UK engineering programme which he had mentioned earlier, and whether the Commission's programme of some 55 million ECU could be compared to the ESPRIT programme. He replied that this could lead to something like ESPRIT, but the most important thing for the moment is to bring companies together. Companies have to gain the confidence to work together. In the UK there is a directorate developing this cooperation, and something like this is needed at European level. However, patience will be needed. The crucial thing is project selection and therefore the project manager is very important. If you want to create common research amongst universities and companies which is not leading to their particular benefit and profits you need special arrangements. Many companies do not have this aim.

27. One possibility for progress is the creation of a demand in the EC countries in some biotechnological areas such as the 'orphan drug' system, mentioned by Dr. THOMAS, where European money and research could be concentrated. This could be mobilised for basic and applied research. But there are many problems with this.

28. Concerning the Commission's proposal for the exclusion of small companies from anti-trust law, Dr. POTTER said that while some small firms were aware of this, many others were not.

29. There is an increase in research which is not published but if a company wants to go to an institute offering money for research, it would be difficult for the academic department to turn it down. This can lead to difficulties because there will be less publicity for the results, which is indeed a problem for the cooperation of universities and companies. Mr GAUTHIER who asked the question thinks that this problem is mainly a disadvantage for young doctors who need to publish.

30. Dr. POTTER's opinion about the brain drain from Europe to the USA is that the USA appears more attractive and offers research at a high level. During the discussion it was mentioned that the European language problem is a further obstacle for working together in Europe.

3. Prof. Dr. MARCONI (ENI, Italy): European companies and the marketing of biotechnology: the field of pharmaceuticals, and, Dr. VANDENDAEL (EFPIA), pharmaceuticals in Europe

31. The fields in which use is made of biotechnology may be divided as follows: 1) Food 2) Agriculture 3) Energy 4) Pharmaceuticals

32. After the discovery of recombinant DNA techniques in 1973 forecasts have been made in many quarters about the future development of this science. They converged on two points:

- biotechnology will be extensively developed
- initially the field in which this development will be most apparent is pharmaceuticals, or more generally human health care. In order to judge future developments in biotechnology one should pay attention to two different types of product:
  - products of 'classical' fermentation, such as antibiotics and enzymes for therapy and clinical diagnosis, and
  - products of 'new' biotechnologies, such as recombinant DNA techniques or cellular fusion.

  These two categories are not only the result of a historical development but also reflect the present situation.

33. While Europe holds quite a respectable position in the field of conventional fermentation, it lags behind the United States and Japan in the field of the new biotechnologies. This is also mentioned in the study of the US-OTA (Office of Technology Assessment).

34. One reason for the European weakness in new technologies can be seen in the lower expenditure in biotechnology. The sum spent by Europe on education is about 1.7% of GDP (as an average). US expenditure is 2.4%, and the Japanese spend 2.1% of GDP. Between the various Community countries the expenditure level ranges from 0.2% to 2.4%, the highest level being that of the Federal Republic of Germany, although even here it cannot be claimed that new biotechnology has been developed in the American way.

35. In 1972 the German BMFT (Ministry for Research and Technology) had already recognised biotechnology, together with data processing and telecommunications as one of the key technologies for the future. The investments were channelled mainly to the GBF (Gesellschaft für Biotechnologische Forschung) in Brunswick, one of the best equipped biotechnology research institutes. Heidelberg is the site of the EMBL (European Molecular Biology Laboratory), which has one of the largest data banks of nucleic acid chains, although commercial results have been slow to emerge. It is not the lack of investment but the rigidity and inflexibility of the German scientific system, which is responsible for the delay in the development of biotechnology in Germany. The reasons for Europe's delay in that field compared to the United States and Japan is clearly expounded by an American formula: lack of government interference, total commitment of staff, possibility of personal gain for academic staff.

36. The Japanese formula for success in biotechnology is completely different and based on extensive government intervention which encourages fruitful cooperation between universities and industry. This is the core of the problem: how to establish closer cooperation between academic and industrial research. The solution cannot be based on the models used in USA or Japan, because of the different socio-economic structure of the three systems. There are other measures which must be taken both at national and Community level. A frequently heard complaint is the lack of tax incentives for research in most Community countries, which has a detrimental effect on the availability of capital.

37. The incentive which induces American savers to invest is not a passion for new knowledge, but the lower rate of taxation for these forms of investment. To give an idea of the sums involved: the Federal Agencies in the US spent $511 million on biotechnnology research in the period 1982-1983, whereas the funds placed at the disposal of the UK Government for the same period amounted to $116 million.

38. At Community level, a solution must be found to another serious problem affecting biotechnology production in Europe: the cost of raw materials (often this amounts for 60% of total costs). Most products of biotechnology are based on the cultivation of micro-organisms which require large quantities of carbohydrates (sugars), as substrates. European producers are at a disadvantage compared to competitors from outside, since they must buy the substrates at the prices dictated by the Common Agricultural Policy instead of world prices, which are considerably lower.

39. Another difficulty faced by the European pharmaceuticals industry is the absence of harmonised rules on biotechnology research and on the approval of drugs. Unless these problems are resolved, it will be difficult for Europe to stay in the race, despite the strength of the pharmaceutical industry, which is able to penetrate international markets: on average between 50-70% of the output is sold outside Europe, as opposed to 30-40% for American industries and 2-7% for Japanese industries.

Dr. VANDENDAEL (EFPIA):

Pharmaceuticals in Europe

40. Despite ever-increasing advances made in the field of health, the diseases which remain after the first pharmaceutical revolution and which are not likely to be solved through traditional methods of research remain numerous.

41. Increased knowledge of the intricate mechanisms of cells gives some hope. Traditional pharmacology could be compared with trying thousands of different keys in the lock to an unknown mechanism.

42. There is a long-term interest in sustaining research in chemistry. In order to be successful in this field a certain number of conditions must be fulfilled. A serious lack of research applications in industry and of collaboration between industry and universities is felt in Europe. Moreover, there is a financial problem. The risk involved is too important for Europeans because of the absence of a uniform market. A prerequisite would be to give a European dimension to this industry; a dimension comparable in volume to that of the United States at least.

43. Dr. VANDENDAEL and Dr. MARCONI were answered questions about the position of the Soviet Union and Europe.

44. It is difficult to assess the position of the Soviet Union because they are very secretive and publications are few.

In comparison with Europe, the USA doubled and the Japanese tripled their industrial production during the last 15 years. During the last 20 years the rate of specialisation fell to 14% in Europe, but rose to 65% in Japan. The pharmaceutical industry although born in Europe could not escape this development. 60% of all medecines still come from Europe, but the actual market is the result of decisions taken during the last 20 years and this is inadequate for the future. Only 36% of the medecine which was developed in the 70's and which will determine the market till the year 2000 came from Europe. Obviously Europe is not sufficiently innovative in order to hold its position.

45. Opposing the view of Mrs VIEHOFF, Dr. VANDENDAEL mentioned that there are three companies which are researching into Malaria. Furthermore Dr. VANDENDAEL did not know of any interactions between companies which want to keep some discoveries secret. In general keeping such secrets is not possible.

46. He also stated that monoclonal antibodies are not only a luxury for an early pregnancy test but they are very important in the field of diagnosis and therapeutics.

47. Finally, some arguments were stated concerning the problems relating to patent laws:

- a 'periode de grâce en matière de brevet' was mentioned; this refers to a period of 6-18 months between the publication of research and the subsequent patent demand;
- there are big differences between the different types of patents, for example, in regard to whether a living organisms can be patented;
- the proposals of the EC are not perfect, but they can be an important element in allowing Europe fully to develop its potential on the international market.

4. Prof. Dr. VAN MONTAGU (University of Gent, Gent, Belgium):

European companies and the marketing of biotechnology:

the field of agriculture and food processing

48. He gave a detailed statement on the use of recombinant DNA techniques in plant genetic engineering and listed five fields of work, where there will be rapid developments.

49. Firstly, new plant cultivation derived from the new DNA techniques would have a higher nutritional value and be resistant to insect attack. In five years geneticalIy constructed plants could be a reality.

50. Secondly, the recent breakthroughs in the understanding of plant molecular structure could lead to 'diagnostic kits' for testing plants.

51. Thirdly, soil could be genetically improved to contain built-in features such as fungicides and insecticides and be more growth promoting.

52. Fourthly, recent breakthroughs in computer modelling (particularly in Belgium) would lead to enzyme engineering.

53. Fifthly, the propagation of plants would no longer be a 'hit-or-miss affair', new knowledge would mean plant propagation could be more certain and productive. European enterprises making biotechnological products have been successful but they have not enough capacity.

54. The problem for Europe in creating this 'Brave New World' was the interest being shown by European Industry. UNILEVER was a leading force in biology techniques but seemed not to be interested in recombinant DNA, already the US companies MONSANTO and DUPONT were dominating the field with vast resources being earmarked for developments. Whilst Dr VON MONTAGU admitted that BAYER had already invested in the Max Planck Institute in Cologne and BASF in the University of Heidelberg there was an urgent need for greater investment by European companies. Europe still dominated such areas as enzyme production through companies such as NOVO (Denmark) and GIST (Holland) but the Americans were catching up fast.

Conclusion

55. The problem for Europe was that research teaching was better in the US. Vast armies of graduate students were concentrated at STANFORD, MIT and other specialist centres and were not dispersed in small research teams such as in Europe. There was an overriding need to interest industry directly in the promotion of research on the widest possible scale.

Discussion

56. In the subsequent discussion Dr. VAN MONTAGU gave some information about the gene-banks. The gene-banks which are available at the moment concern a collection of seeds and organisms collected from all

over the world. For example there is a bank of 65,000 rice seeds in the Philippines which is sponsored by the World Bank and the FAO; another important bank is in Fort Collins in the USA. A problem for the international organisations could be private seed-banks. They should be available to every research institute or organisation.

57. The research done on recombinant genetics requires a lot of highly skilled know-how and much investment. Many parts of the genes have been chemically engineered and therefore it has to be considered as a chemical industry and the legislation should be the same as the legislation for chemical products.

58. If progress is to be made in that type of research the industry must have financial or other incentives for development. This could mean that genes would not be freely available as firms envisage breakthroughs which would give them a competitive advantage over similar firms.

59. Which products will soon be available for use on the market, particularly in the Third World? Once the relevant genes have been developed, techniques are such that the discovery can have a practical agricultural application within five years. Large plantations are to be set up in the US and the Third World, for tobacco and cotton production, for example. Unfortunately however, the number of current projects is limited.

60. The major problem which biotechnology has to solve is disease control and reorientation because of over-production in US and Europe. A lot of biotechnological material produced by agriculture will be used for new industries producing fine chemicals.

61. Two additional problems, which the Community has to solve were mentioned. 62. Firstly, in Germany, it is necessary to have special agreement for the release of micro-organisms into the environment because of the possible negative environmental impact. Hence Europe should try to harmonise conditions in the Community for plant molecular-biology and release of micro-organisms.. Dr. VAN MONTAGU stated that, while we have to ensure that regulations protect our society, this must be done as rationally as possible; institutions must ensure that bureaucratic delay is kept to a minimum.

63. Secondly, the problem of risk-assessment in research: Dr. VAN MONTAGU outlined the limits to current knowledge and appealed for the authorities to take account of scientific opinion. A solution can only come through experience and the universities and industries conducting research must be aware of the risks involved. The universities are responsible for most of the new discoveries in the field. However, stronger links must be developed between these research bodies and the production agencies. The universities and small companies are necessary but if the advantages of biotechnology are to be realised larger companies and institutions must become involved.

64. Finally Dr. VANDENDAEL made a statement concerning the problems encountered by smaller companies. Much of their research is duplicated and few will survive whilst they concentrate on the same projects. He pointed to the high risk nature of the industry and the length of time between investment and results which were far greater than in, for example, the electronics industry ('Silicone Valley n'est pas la même chose que Siliclone Valley'). The primary question here is one of finance.

5. Prof. Dr. BERENDSEN (University of Groningen, The Netherlands):

The relationship between biotechnology and information technology

Introduction

65. Dr. BERENDSEN began by speaking about theories on the use of engineered proteins to construct information processing devices, called biochips or molecular computers. These theories are still rather speculative.

66. A somewhat related development is the biosensor in which, for example, engineered enzymes or monoclonal antibodies, can be used in field effect transistors to produce sensors for biochemical and medical use. Here biotechnology can have its impact on information technology.

67. What Dr. BERENDSEN concentrated on in this report, however, is the impact of information technology on biotechnology.

Biotechnology and information technology

68. The basic question here is: can a protein be designed for a specific purpose? This depends on whether we can make a reliable prediction on the basis of all the knowledge already available. If we can predict from a sound theoretical basis the property of a protein it would be possible to go a step further. Then it would be possible to design proteins for very specific purposes, for example for catalysts with specific reactions in different industries.

69. The next decade will show us what is possible and the prediction of functions and structures of biological molecules on theoretical grounds will require computer powers much more powerful than those presently available. The United States is pushing its computer industries (especially the supercomputers) because it is worried about falling behind Japan.

Recommendations

70. In the future biotechnicians will have no need for supercomputers with general powers. Actually, a new kind of 'specialist' computer is beginning to be developed. In biotechnology specialised computers are needed which work very fast and here Europe could take the lead.

71. A rational design of biotechnology processes (i.e. structure-function relations, molecular structures) requires advanced user-computer interaction: biotechnology needs extensive data bases with high-level supporting software, intelligent biomolecular work-stations, and super-computers with specialised software.

72. Innovations in information technology required for biotechnology include, in order of priority:

(i) special purpose computation devices that exceed the capabilities of super-computers, for prediction of macromolecular properties;

(ii) advanced fast high-resolution graphics with stereo imaging;

(iii) expert systems related to data bases,

(iv) man/machine interfaces including 'feeling' (touch with force response).

73. The position of European expertise on graphics and computational software on biomolecular problems is comparable to that in the US and Japan. There are excellent research centres in the UK, Germany, France, the Netherlands, Belgium, Sweden and other countries; some have leading positions in the world. For centralised facilities and for organisational purposes the European Molecular Biology laboratory (EMBL) in Heidelberg is a suitable choice. However, the lack of financial aid necessary for modern laboratory equipment will cause Europe to fall behind the US. On the other hand, while European industries are not able to catch up in the super-computer market, Europe could strengthen its position in the still open market of special purpose devices.

74. It is necessary for the European manufacturers of computers to be independent of the operating system and network standards of the large American computer firms (notably IBM, DEC), if they want to play a central role in the future. Furthering the active participation of Sweden, Norway and Switzerland would lead to a lowering of dependency on the USA

Considerations

75. The success of innovative biotechnological developments is dependent on advances in the theory of the functional properties of biomolecules. Products of this advanced technology can be applied in the meantime leading to unprecedented new products and processes in the chemical and pharmaceutical industries.

76. The basic problem of biotechnological designers in predicting the properties of a possible new product in advance. This can only be solved if the vast amount of information, obtained by advanced computer methods, is readily available to research bodies (universities, institutes etc.).

77. Until now, the necessary technology for biotechnological predicting functions has only been available in American and Japanese super-computers. A concerted European effort, however, could bring about the development of special integrated hardware/software machines with more specialised abilities for biotechnology along with reduced production costs. Design should be rationalised and the application of these designs must be reliable.

78. The creation of the EMBL in Heidelberg is a step forward but it is only one of many possible options for the development of a biotechnological infrastructure.

Discussion

79. Dr. BERENDSEN said that there are already European facilities for developing special computers and once again he stressed that Europe should not develop supercomputers because the US and Japan have been developing them for 10 years.

30. It was mentioned that in Toulouse, French and other European specialists are organising a European computer centre in order to make a new European supercomputer. Dr. BERENDSEN did not agree with this. He added that specialised computers can also have a large variety of uses.

81. Modern sciences need interdisciplinary workings but cooperation is rather difficult, because those people who have to work together are not used to this cooperation and to bring them together needs a special effort.

82. The Commission asked for the views of Dr. BERENDSEN on the scale of resources needed for the construction of special purpose computers and whether Europe should work together with the USA. Dr. BERENDSEN answered that these activities should not be on a worldwide scale. At the moment Europe is still ahead in specialised computers and in software development. There is no reason to fall behind the rest of the world. We should cooperate all over the world but we should not become dependent. The supercomputers we have in Western Europe come from the USA. At the moment we have about ten. In Delft, NL, a specialised computer for nuclear questions is being developed, others are under development in Italy and Paris, and for biotechnological purposes one is being developed in the United States. In Heidelberg research is not concentrated on the development of computers. However, the present director intends to develop this field.

6. Dr. YOXEN (University of Manchester, UK): Changes in industrial structure — and biotechnology assessment.

83. Policy for biotechnology may be considered and developed at regional, national and international levels. International activity, such as that carried on within the European Economic Community, tends to be concerned with the harmonisation of regulations and the creation of a unified market, support for pre-competitive collaborative development programmes and the selective support of strategic research areas.

84. With the development of biotechnology one has a choice between three different kinds of policy — the laissez-faire policy, a dirigiste policy, and a social environmentalist policy.

85. The first of these is most evident in the United States, where the emphasis has been on creating the right fiscal conditions for research-based entrepreneurship. This has led not only to the creation of a significant number of small new biotechnology firms, but also to radical restructuring of large, well established companies, with the economic ability to invest heavily in strategic research centres.

86. An advantage of this approach is its dynamism: it does certainly promote change. The disadvantages lie in what is taken for granted. It can cause the decline of much existing, inefficient industry, which may have severe effects in particular regions. It does not lead to the pre-competitive collaboration pioneered so effectively in Japan.

87. Many countries have preferred a more interventionist approach to innovation, with a greater degree of planning and directed investment. The emphasis is much more on sectoral planning and on the coordination of effort, nationally or internationally, and much less on small research-intensive companies and on tax relief for venture capital. The advantages here are more highly organised programmes of research and investment plans which allow a degree of technology assessment. The disadvantages could be that the whole exercise

can become very bureaucratic. Similarly, the discussion and technology assessment can be rather pointless, without the means or the political will to act on them.

88. The 'socialist-environmentalist' approach is clearly intended to alter the balance of economic power and to introduce new values, such as those of the environmentalist movement. Probably it is at the regional level that it is likely to work best.

89. Its disadvantages are that it is relatively new and untried; it is obviously politically contentious and not easy to apply in a field that clearly depends on entrepreneurship in one form or another.

90. Dr. YOXEN'S conclusion from the above would be that we need in the European context is a **diversity of approaches to innovation,** even though his own preference is for the 'specialist-environmentalist' approach.

91. There is a clear need for a large 'home' market for the products of European companies. Since relatively few biotechnology products are actually on the market as yet, there is still time to act here.

92. But innovation is as much a process of selection and rejection as it is of the invention of new ideas. All kinds of product ideas fail or are abandoned because they do not fit the commercial priorities of major producers. A common example is 'orphan drugs'. This suggests the idea of soliciting from researchers in Europe ideas which have fallen by the wayside, or from unprofitable areas, like vaccines or occupational medecine, for support within a special Community funded programme.

93. Need for TA (Technology Assessment):

(i) TA is performed by an prudent company when it assesses a product for a market;

(ii) TA as a general economic and social evaluation of a particular technology, — this is what is meant by the term here in biotechnology;

(iii) TA being done by groups of workers and trade unions who want to assess the product and production strategy of the company they are working for.

The European Foundation for the Improvement of Living Conditions, based in Dublin, is involved with the second point. They are developing a research plan for TA and Dr YOXEN's group in Manchester is linked with this Foundation.

94. The pharmaceutical and seed industries are typical examples of technologies which need TA. There is little data on the potential impact of products based on biotechnology in Europe, so Dr YOXEN concludes with these points:

(i) Industrial involvement and university research would be improved by having stricter rules on the disclosure of commercial involvement by those who are involved. The effects of universities taking equity ownership in companies in the biotechnology field have to be considered carefully. This practice already exists among some British universities but its benefits are disputed.

(ii) Products of great social value might fail in some people's economic assessment. It is clear that there are, within the field of biotechnology, a number of products of this kind, but if you consider innovation as a highly selective process you have to choose the which ideas should be retained and have their development subsidised. In that particular area something like an 'orphan drug' system has to be employed.

(iii) There are a number of areas, such as the effects of economic concentration in the seed industry, which need much more study. Whilst some commentators have tried to predict the effect of 'new seeds' being marketed by large agrochemical concerns, much of this comment is somewhat speculative, and based on US or non-European agriculture. This question is exactly the kind of thing that an Office of Technology Assessment attached to the European Parliament could examine. This shows that an 'OTA' for the European Parliament would be a very positive development.

Discussion

95. Concerning the role of FAST and Technology Assessment on the national level, Dr. YOXEN thinks that the new European Institution has to complement the activity of FAST. It is difficult to say how an Office of TA should work. Governments have preferences for national questions and interaction has to be considered at the European level.

96. Dr. LINKOHR who reported on TA in Europe, considers that the development of a European TA necessitates a common European culture, i.e. agreement on a common technology assessment can only stem from common values and aims. So he is of the opinion that we should strengthen national TA, but we should make it more transparent in order to initiate a discussion on the European level which would lead to the development of a European view of new technologies.

97. Dr. YOXEN also recognises that national differences exist and that there must be a forum to stimulate debate and create an overview of national situations. The impact of the FAST teamwork on biotechnology was raised by Mr CANTLEY, speaking on behalf of the Commission; he emphasises that the work of the FAST team has been integrated into the programmes, which are now being implemented. In fact, three members of staff had been transferred from the FAST team into the concertation unit of biotechnology precisely to help with that implementation. The FAST recommendations had to be integrated with the new research programmes.

98. Concerning the seed industry within the new FAST programme, there is a specific subprogramme on the use of the renewable natural resource system. On this specific topic of genetic diversity, and of course the seed industry, FAST intends to organise a major world conference on biological diversity and property which perhaps should be co-financed by the European Parliament.

99. At the end of the discussion some questions about the negative impacts of biotechnology were raised. Mr. HÄRLIN asked for a list of criteria concerning negative effects of biotechnology which are accepted by the scientists. As regards the time needed for technology assessment there exists no average time lag. Some evaluations are done briefly and some need a long time.

Part II:
The impact of biotechnology

1. Dr. MAHLER (NOVO, Denmark):

Risks and dangers involved in research and application of biotechnology — efforts to harmonize legislation

100. There are already a lot of institutions which are working for safety and regulation in biotechnology:

— WHO, which held a meeting in Dublin;

— OECD, which is preparing a report;

— Coordination Committee between the chemical industry (represented by SEFIC), the food industry (represented by CIIA), enzyme manufacturers (represented by EMFEP), the pharmaceutical producers (represented by FPI) and the agrochemical industry (represented by KIFAB).

They want to present to the EC Commission a uniform approach to biotechnology from their point of view at the end of 1985.

Risk assessment and guidelines

101. Europe needs conceptual information and here it can learn from the US experience in biotechnology. Competition and safety have to be seen in the content of this being a question of efficient decision-making where you accept new products and applications of biotechnology knowledge without incurring unacceptable risks.

102. The risk of the unknown is always there and we deal with it by unspecific testing. In risk assessment it is important to involve all the relevant experts and by using headlines and distributing documents the risks can be avoided. If the various experts involved in preparing the guidelines or 'Points to Consider' type documents for the particular kind of genetic transfer have done their job, these documents will reflect all the risks which have to be recognised as potential or objective risks even if they are not novel. Each point to consider corresponds to a risk, and by using the document as guidance, all risks can be avoided. It should be mentioned that only the transfer of genetic material across species barriers is considered here as new biotechnology, since by definition only such transfers do not already produce fertile hybrids in nature. Risk assessment means moving forward with caution: potential danger will either disappear or become controllable, that is able to be evaluated and handled. While the science may not be revolutionary, some of its applications may yet be.

103. Ten years ago some 140 scientists met in Asilomar (USA) for a moratorium to discuss guidelines for biotechnology. The call for a moratorium was followed in 1976 by the first version of the NIH guidelines, which were mandatory for NIH funded research and voluntarily followed by everybody else. The principles of containment and scale limitations stated in the NIH guidelines were soon adopted in other countries, and when the NIH guidelines were subsequently relaxed, these relaxations were, for the most part, adopted too. The stepwise approach to less restrictive NIH guidelines has now been taken to a point where the majority of recombinant DNA experiments in the US only require local committee approval, and where the original and somewhat arbitrary 10 litre-scale limitation has been removed, permitting NIH to authorise large-scale manufacture. This development from very strict to more relaxed guidelines can be seen as a sequential approach, each step being the result of accumulated experience which did away with the fears expressed at Asilomar.

104. Certainly there was some over-optimism in the USA which resulted from not paying enough attention to research risks. Ten years of experience tell us that the guidelines developed combined with existing legislation are adequate for occupational health, safety and environmental protection. Further, the majority of research is applied research with an empirical base and not fundamental research without empirical datas of risk assessment.

105. An important aspect in risk analysis is the differentiation:

— between kinds of organisms and micro-organisms: for example, plant elements and human elements are less well understood from a genetic expression and control point of view;

— by the level of understanding, because the only real risks are that we do not know what we are doing;

— between contained and released users, on the production basis;

— between a use of the organism itself and of a part of it;

— between an extract and a compound from the organism.

106. A differentiated risk analysis could imply that some recombined DNA uses are considered as belonging to traditional old biotechnology so that they can be used routinely.

Legislation and harmonisation

107. So far very little legislation has taken place in Europe or anywhere else. The UK and Sweden have expanded their occupational safety and health legislation to cover specifically notification of recombinant DNA work, and the Netherlands has similar intentions. In Denmark enabling legislation has been drafted, which may result in Denmark becoming the first country to regulate agricultural and industrial applications of new

biotechnology. Sweden on the other hand may abolish some of its present legislation. Apart from this, it would seem that the European countries have followed the recommendations by the European Science Foundation, the Council of Europe and the Council of the European Community to use NIH type guidelines, a notification procedure and refrain from introducing legislation at this stage of development. It would still seem possible to save Europe from divergence.

The competitive position of a country in regard to legislation is determined by its ability to keep pace with its industry in all phases of recombinant DNA development. When companies are ready for large scale production, national authorities should be ready to assess and approve the production plans. For plants, one has today according to international convention to choose between patent protection and plant variety rights protecting only the seeds. In the European Patent Convention, however, plants and animals are exempted from patentability. Plants can be patented in the US, Germany and France. Plant variety rights are found in many countries, but they will not serve the purpose of protecting recombinant DNA plants effectively. Harmonisation would seem to be possible in an area where no significant national legislation exists, and where the contents of the guidelines for recombinant DNA work were essentially the same everywhere. The main bottlenecks are to be found in European countries without such a tradition for harmonisation. With good reason Europe is often seen and dealt with by the US and Japan as a number of separate and different countries. It should be understood of course that harmonisation must be global in order to satisfy the purpose of effectively advancing the new biotechnology. Consequently European harmonisation is only one step, although a most important one, towards this goal. OECD harmonisation seems the most likely higher level attainable in the near future and a global harmonisation would involve the UN and the WHO in the final phase. The EEC directive on information procedure for technical standards and regulations may also promote harmonisation.

108. A final remark: Human gene splicing will be a problem in the future, but the only real risk may be the irrevocable reduction of the genetic diversity within and among us.

Discussion

109. During the discussion the question of the risks of biotechnology was raised. There is a danger that far-reaching changes caused by biotechnology may also involve irreversible damage such as happened with hydrochlorides. Through ever-increasing understanding Technology Assessment may be continuously reformulated. This does not mean that existing rules should be totally altered. Improvements can be achieved by the inclusion of specialists and the public in the consultation process. This also involves ethical aspects of biotechnology. Thus philosophers and theologians have participated in a report on the splitting of genes in the US. Furthermore it would be better to determine what are the needs and then speak of investment.

110. Concerning the problem of harmonisation of regulations, Dr. MAHLER referred to the advantages and disadvantages of acting at different levels (EEC, OECD). It is felt that harmonisation is a favourable development and should be as widespread as possible.

111. Concerning sanctions imposed on firms which ignore guidelines, it was stated that these guidelines are in general mandatory for government-sponsored research, but they are usually adhered to by the industry too. To conclude Mr FAIRCLOUGH (Commission) spoke about the introduction of legislation which was considered by Dr. MAHLER 'as a result of application pull rather than science push'. But the basic problem of how to reach harmonisation remains. The question is whether we should proceed in this direction at EEC or OECD level. Do we adopt voluntary guideliness or should a general framework be introduced quickly?

112. Dr. Mahler, in reply, considered that a formal framework for consultation might be useful, but that informal discussions are now taking place. The Commission should be aware of developments in this area. Consensus is necessary before any legislation is proposed. This building of consensus may take place at various levels. In order to stimulate a balanced development in the various OECD countries, the national governments should introduce regulations in this field. This would prevent the establishment of a diversity of rules set up by by the industry itself.

2. Prof. Dr. PAPAMATHEAKIS (Research Centre Crete, Greece):

Future developments in biotechnology

113. Addressing the issue of the future development of biotechnology (B.T.) is extremely difficult unless one defines a narrow time range for projected and likely developments in this dynamic field. The impact of the new biotechnology is just starting to become apparent and it is expected to be significant. This is indicated by intensive public and private investment of capital and reorientation of research and development activities in many cases. Major rate-limiting factors in large scale applications are:

— process engineering;

— genetic and metabolic stability of engineered microorganisms or their products;

— containment steribility and ecological effects.

This implies that a vigorous further development of the biotechnology industry will rely on solving the above problems. Funding for supporting training and research and development projects in fields related to fermentation and engineering technologies is of key importance towards effective solutions.

114. Concerning **health care**, particular emphasis is given to hormones (endorphines, insulin, human growth hormone, somatostatin) and other bioactive substances. DNA insulin is a good follow-up case for market studies, since it is now commercialised. Developing vaccines for malaria etc., is a promising area for disease control and two major new markets are monoclonals and interferon. Another interesting aspect of future development in disease control is the introduction of molecular diagnostics.

Chemicals

115. Although the traditional organic chemicals will be difficult to displace (for example, petrochemicals) biotechnology-based production is expected to have a visible effect on the chemical industry by the turn of the

century, contributing 10-15% to the overall market. In the longer run the dwindling global reserves of feedstock will necessitate the development of renewable sources. High-scale fermentation, using microorganisms boosted by genetic engineering, is an obvious solution to the future shortages. Key features in a strategic approach regarding biotechnology and its role are:

— fundamental knowledge in cell metabolism and kinetics;

— process engineering;

— immobilisation and affinity techniques to increase efficiency of production;

— effective means for securing genetic and phenotypic stabilities of the organisms in use.

Agrofood

116. Recent advances in gene isolation and transfer, suggest that important developments may appear soon. More than 90% of the human diet is based on 29 crop species, 15 major vegetable and 15 fruit crop species. These crops are obvious targets for DNA approaches to solving problems of plant physiology, development or physical factors. Main lines of activity in agrofood biotechnology are:

— pest, disease and stress control;

— enhancement of yield;

— upgrading products;

— animal production and protection.

Classical approaches to these problems will probably become obsolete, for example, the chemical pesticides market will be superseded by the microbiological metabolic products. In the long run biomass utilisation and chain-bioreactors will be of major importance. Pollution control and waste treatment will be most beneficial for society.

Conclusion

117. Biotechnology is steadily going to increase its share of the overall high-scale production in health, chemical and agrofood products including energy. This intervention is slow but cumulative. The anticipated social effects are significant although the time range for many achievements is hard to evaluate.

Defining the role of Europe vis-à-vis this process is vital. Thus the determination or re-evaluation of strategies for a vigorous response at this transitional stage has a critical political and social bearing for the future.

During the following discussion the importance of biotechnology for the energy sector was raised. There are a lot of problems which could be solved by biotechnology but which are not yet recognised as being significant, for example, the tertiary extraction of oil. Interest should be taken in investment for disadvanced sectors such as for specific problem areas in the Third World.

Part III:
Biotechnology and international political implications

1. Prof. Dr. JUNNE (University of Amsterdam, the Netherlands):

Biotechnology and consequences for changing relations between EC-USA, EC-Japan and USA-Japan

118. Of the relations between the major trade blocks inside the OECD area, relations between the European Community (EC) and the United States will probably be the most affected by the application of biotechnology. The effects on the relations between the USA and Japan are less clear-cut and the effects on relations between the EC and Japan probably are only marginal.

119. Biotechnology will have a far-reaching impact on agricultural production. This will affect trade relations between the USA and EC in two ways: it will affect **bilateral** trade as well as **competition in third markets.** The USA has never really accepted the Common Agricultural Policy (CAP). The EC, however, can point to the fact that in spite of CAP, the EC is the largest importer of US agricultural products, and that the USA realises a considerable trade surplus in agricultural trade with Western Europe (of about $6 billion annually).

120. The EC is trying to limit the import of animal feed. About half the European imports of agricultural products from the US fall under this category. EC policy aims at the development of new plants which are rich in protein and can be produced at acceptable costs in Europe to replace imports.

121. In order to stimulate this development, the EC tried to put on a ceiling on imports of maize gluten from the US and started negotiations with the American Government in 1984.

122. The US Government strongly opposed such a measure. The reason for the strong reaction can be better understood if the impact of biotechnology on food processing in the US itself is taken into account. (In the US, large quantities of sugar have been replaced by High Fructose Corn Syrup (HFCS) produced from maize, and HFCS replaces more than 2 million tons of sugar per year.)

Effects on competition in third markets

123. Besides being the largest importer of US agricultural products, the EC is, at the same time, also the world's second largest exporter of agricultural products after the US. In many markets of the world, the US and the EC compete directly with each other.

124. As a consequence, biotechnology will contribute to increase surplus production both in the US and Europe.

125. This happens at a time when the application of biotechnology, in many importing countries, may eventually help to reduce their food imports in the long run. This will take a long time in many developing countries. However in the Soviet Union and China, who have been major importers in the past, this application can be realised somewhat sooner. This would have consequences for relations between the EC and the USA in two ways: (a) it would increase surplus stocks that would have to be sold in other markets, thus increasing international competition, and (b) it would have an impact on the differing interests in East-West trade of the US and the EC respectively.

126. Biotechnology will probably contribute to a considerable increase of productivity in agriculture. As a consequence for agricultural policy, surplus production would increase to such a degree that it could no longer be financed.

Consequences for technology transfer and scientific cooperation

127. The US Government has suggested putting many biotechnology products on the COCOM list of strategically sensitive goods that must not be exported to socialist countries. Since biotechnology can be used to produce biological weapons as well as detecting agents, sensors, vaccines and strategically interesting new materials, it is classified as of special relevance to the military. This may also have a negative consequence on technology transfer from the United States to **Western** Europe and on international free scientific communication.

128. A large area of potential European exports might fall under an expanded list, if the United States were to get their proposals accepted. American and European interests clearly diverge in this area.

Consequences for relations between the USA and Japan

129. The US and Japan are also involved in a long-standing conflict on agricultural trade. Japan is the country that is the single largest importer of American agricultural products (the EC imports more only **as a group**). Japan receives 15% of American agricultural exports, which constitute 40% of Japan's agricultural imports.

130. The United States, however, is insisting on a further liberalisation of Japanese agricultural imports. An expansion of agricultural exports is expected to reduce the tremendous deficit in bilateral trade with Japan. What role does biotechnology play in this regard?

131. As in the case of the EC, a large amount of Japanese agricultural imports from the US consists of feed grain. Developments in the field of biotechnology may help to substitute some of these imports by domestic products (such as high-protein feed made from rice, straw or algae). Biotechnology will also help to develop higher-yielding rice varieties. It may also lead to some export of rice which would compete with American exports and lead to additional tensions in the relationship with the US.

132. However, agricultural products will increasingly be used as industrial raw materials. This will increase the demand for agricultural imports. A reduction of imports as a consequence of substitution by local production will therefore be compensated for.

133. In the long run, the rather complementary character of the United States' and the Japanese economies may even be strengthened by this development.

134. Tensions may result more from applications of biotechnology in fields other than agriculture. In biotechnology, a pattern similar to that which developed in microelectronics may occur; in this case, whilst the US economy excelled in the invention of new products, Japanese companies succeeded in optimizing production processes for these very same products and then competed very successfully in the world market.

Consequences for relations between the EC and Japan

135. The relationship between the EC and Japan will probably be little more than marginally affected by developments in biotechnology. Those areas in which biotechnology may have an important impact on trade flows (raw materials, agricultural products) do not play a large role in bilateral trade between Japan and European countries.

136. More than the field of bilateral trade, the export of capital equipment for biotechnological production processes to third countries may become an area of increasing competition. The EC and Japan are the most important capital goods exporters to developing countries. The more biotechnological production processes are introduced, the larger the demand for equipment in this field will be. Given the considerable experience of Japan in this field and the fact that it has every reason to boost research and development in this area, the European market share in capital goods may come under an even greater threat in the future.

Problems raised by the questions:

— Dr. JUNNE said that despite the difficulty of predicting the real impact of biotechnology on agriculture and world trade, some prognoses can be made, for example, on the increase of productivity,

— The most serious problem is overproduction. This can only be solved by reducing the amounts produced since the surplus cannot be exported. The USSR will, in the future, come to be more independent of cereal imports. The USA will probably insist that Europe reduces production because Europe's production costs are higher than those in the USA. All this would cause new conflicts because there would be no further interest in the USSR and differences of interest between the EC and the US would become less acute.

— Dr. JUNNE gave some information about the US defense department and its programme to advance research in the field of biotechnology. Most of the uses of biotechnology are not in the field of armaments, but in the development of new sensors, new material for aircraft, etc. or for vaccines for overseas personnel. There is no danger of biotechnology being used for weapons at the moment, but the possibility that it may have this capacity has led to much secrecy in development. The US defense department would like to include a lot in the COCOM list, because it is difficult to say which aspect of biotechnology may have military applications.

— Concerning secrecy, it is difficult to keep secret information about biotechnological research because of the different forces which are working in this field, for example:

  — the patent rules which are important for competition,

  — the commercialisation of research,

  — the military potential,

  — the tendency to keep subsidised research in one country.

  Information control should be regulated at an international level. The OECD would be the best body for this.

2. Dr. KUIPER (University of Amsterdam, Netherlands):

US-European joint ventures: consequences for European export policy

137. How do European companies in the field of biotechnology come within the ambit of US export controls? This question is a great problem now and will be in the future, as internal US regulations on biotechnology may also have consequences for European biotechnology firms as well. In order for this question to be answered it must be divided into three parts:

(i) certain goods of US origin;

(ii) certain US technical data;

(iii) corporate (or personal) links to a company incorporated in the USA.

138. In the first case, chemical and biological agents which have weapons applications are listed in the US Munitions List. Their exportation to all destinations is controlled under the US Arms Export Control Act. Since these controls are coordinated through COCOM they should not cause any serious problems to EC Member States, which normally apply these same controls.

139. Secondly, certain chemical substances and most bacteria, fungi and protozoa figure on the US Commodity Control List (CCL). A so-called 'validated license' is required for their export to the USSR, its East-European allies, North Korea, Laos, Kampuchea, Vietnam, Libya and Latin American countries. This means that an individual export license has to be obtained for every export transaction above a certain value. Some of these controls are unilateral i.e. not coordinated through COCOM.

140. Unilateral controls of exports to non-EC countries may have repercussions for European companies,

because re-exports from Europe to controlled destinations are also controlled. In the most extreme situation this may lead to a European company having to request a re-export authorisation from the Office of Export Adminstration (OEA) in Washington D.C.

141. In spite of the offensive aspects of US export and re-export controls, the actual problems with respect to these controls may well remain limited, as long as the number of **unilateral** US export controls in the field of biotechnology is restricted. It seems that some biotechnological products and processes are going to be, or have already been, placed on the COCOM watchlist, which may lead to their ultimate inclusion the COCOM prohibited list. As long as multilateral agreement is reached on restrictions on biotechnological exports, trans-Atlantic friction can be minimized.

Export controls on technical data

142. Although virtually all Western countries have some kind of legislation which enables the government to classify patent applications which show a links with national security, the US is the only country in the Western alliance to have, in addition, a regulatory system for the restriction of technology exports and re-exports. Other countries merely restrict the export of the products embodying the technology; the US also restricts the 'technical data' itself, insofar as it is 'directly and signficantly related to the design, production or utilisation in industrial processes' and not 'generally available' to the public.

143. Export and re-export of technical data are defined so broadly in the Export Administration regulations that if, for example, a Dutch engineer were to tell the participants in the biotechnology hearing some technical details about a biotechnology plant he had seen in Amsterdam and which was built with some technical help from the US, he would be re-exporting controlled technical data. Formally he would need a validated license for that.

144. If one takes into account that more and more biotechnological know-how probably will be brought under the export restrictions of technical data, it is not fanciful to assume that serious problems might develop between the US and its European allies, if such restrictions do not obtain multilateral agreement. In the past the EC has protested strongly against US measures, for example during the pipeline controversy in 1982 and also criticised at that time the attempt to extend US jurisdiction over persons handling technical data by requiring specific clauses in private contracts.

Persons subject to the jurisdiction of the United States

145. The principal provisions of the Export Administration Act of 1979, (as amended in 1985), which serve as legal basis for the regulations partly described above, give the President authority to prohibit or curtail the export of 'any goods and technology subject to the jurisdiction of the United States' or exported by 'any person subject to the jurisdiction of the United States'.

146. Although at present this standard definition is of little importance, since the obligations relating to the re-export of controlled goods and technical data are incumbent on **any person** inside and outside the US, it may come back to haunt European corporations at any moment. The habitual regulatory definition includes companies incorporated outside the US which are 50% or more US-owned (in certain cases even 25% or more US-owned if the other share blocks are less than 25%). This would make a normal 50-50 joint venture between a US and a European company, even if it were incorporated in an EC Member State, into a 'person subject to the jurisdiction of the United States' for the purposes of US export controls. During the pipeline controversy this way of bringing companies incorporated in EC Member States within the ambit of US jurisdiction was roundly condemned as contrary to international law.

Conclusion

147. Although at present US export controls on biotechnological products and know-how may not cause grave problems to the European industry in this field which has technological or corporate links with the US, there is a considerable potential for conflict if the US carries out its intention to introduce more sophisticated controls on these products and related technology and does so unilaterally. Indeed, if more sophisticated restrictions on exports to 'unfriendly' countries are needed, an effort should be made to achieve agreement within a multilateral framework.

Mr. DOROUGH, Counsellor for Science and Technology of the U.S. Mission to the European Communities:

EC-US Relations in biotechnology

148. On 31 December 1984, the United States proposed a coordinated national framework for the regulation of biotechnology.

149. As an integral part of the proposal, US regulatory agencies committed themselves to seeking international harmonisation on a whole range of scientific and technical issues such as test guidelines and good laboratory practices. Much of the harmonisation which has already occurred in these areas is applicable to biotechnology. The EC commented favourably on this commitment.

150. Mr. DOROUGH called for a regulatory structure 'which should be of sufficient transparency and clarity to avoid the creation of technical barriers to trade and draw to the maximum extent possible on existing national regulatory practices'. Members of the committee were disappointed that Mr DOROUGH could not speak more widely on his Government's attitude to other points raised in the hearing. Unfortunately, Mr. DOROUGH also gave no reply to the speeches of Dr. JUNNE and Dr. KUIPER.

3. Prof. Dr. Salomon (Conservatoire national des Arts et Matières, Parin, France):

Consequences of biotechnology for Third World countries

151. Despite the similarities amongst problems facing the Third World, there are great disparities in the situation of different countries. The possibilities offered by biotechnology, together with the attendant risks of distortion, must therefore be seen in the light of these disparities.

152. Unfavourable effects of biotechnology in Third World countries may be expected for the following reasons:

(i) Because of its cost, its technical complexity, the scientific personnel it requires and the scale of the markets which undertakings must aim at, this research field is likely to increase the technological gap which exists between most Third World countries and the industrialised nations. In this field, the future seems unlikely to differ greatly from that of the pharmaceuticals industry. In addition to the difficulty of competing with multinational undertakings or smaller firms dependent on large-scale finance connected with risk capital, there will be the further handicap of the growing privatisation of research findings.

(ii) The new products and processes developed in the industrialised countries will inevitably come into competition with the traditional products and processes used in the less-developed countries, rendering existing qualifications and practices obsolete and, above all, displacing or even eliminating from the market products which constitute the only currency of exchange for many Third World countries — hence the threat of an increased balance of payments deficit, higher unemployment and even worse food shortages than at present.

(iii) Concerning sugar, it must be feared that the growing consumption of fructose syrups and the replacement of sucrose for industrial purposes and in food will lead to an increase in sugar cane stocks and this will lead to a crisis in the sugar industry in the tropical producer countries.

(iv) Few Third World countries would be able to participate extensively in projects in the first category (genetic engineering or bio-engineering, recombinant DNA techniques, cloning, etc.) whereas most of them would be able to contribute to the transfer of the various applications of biotechnology. Developing countries which can master production processes are described as the new industrialised countries and include Brasil, Mexico, South Korea, Taiwan.

153. The selection and the transfer of biotechnologies are clearly going to play a crucial role. This is a problem which is both economic and political. Genetic engineering involves costs as disproportionate as and disadvantages of the same kind as those involved for instance in robotics. On the other hand, the techniques connected with traditional biotechnology (fermentation in solid and liquid media, compostage and recycling of waste, production of biogas, hydrolysis of cellulose and decomposition of lignite, etc.) could be substantially improved through research progress. For example, smaller and therefore less expensive production chains, introducing small-scale techniques as opposed to those aimed at the large-scale manufacture of amino acids, would also have the advantage of protecting soils, reducing deforestation and monitoring the population of rural areas.

154. How can the industrialised countries help to reduce some of the most urgent problems facing the Third World by means of their research in biotechnology?

— By paying attention to the conditions governing the selection, transfer and adaptation of the new technologies.

- By providing and seeking to reduce the unfavourable effects produced by the widespread dissemination of new products and processes likely to increase the economic vulnerability and dependence of developing countries.

155. If a proper equilibrium is to be achieved between North and South it is in the interests of the industrialised world and the EC to ensure that the repercussions of biotechnology are not going to be exclusively negative for the Third World.

Discussion

156. In a statement Mr. SELIGMAN (MEP) proposed to organize a special conference on the specific problems of developing countries with the participation of the countries concerned.

157. Data banks could be developed for information on animal and plant species. There is a need for highly qualified people in recipient countries who can make the most of this information.

158. In answer to a question on racial engineering Dr. SALOMON said that although some work had been carried out in the United States this really could not be taken seriously.

159. Finally Dr. SALOMON emphasised that in the Third World skilled technicians are more important than scientists who may be trained in recent

techniques of biotechnology.

4. Dr. MUNCK (Carlsberg Research Laboratories, Copenhagen, Denmark):

Industrial use of agricultural products in Europe and the principle of agricultural refineries

160. The increasing surplus of cereal grains (except maize) in the EEC causes a mounting economic problem with regard to financing export restitutions. Emergency aid to starving developing countries is one of the outlets for this surplus.

161. The current situation of EEC tariffs and restituion payments for cereals, related raw materials and industrial products manufactured from them, is somewhat chaotic.

162. However, for the citizens in the EEC many good reasons exist for maintaining a common agricultural policy. It gives us a basic self-sufficiency in many classes of food production, and contributes directly and indirectly in the order of 20-30% to the gross national products of our countries. Furthermore, fluctuations due to varying weather conditions etc. make it difficult to maintain the EEC's policy for self-sufficiency without some overproduction.

163. A surplus of 58 million tons of cereals in the EEC is forecast for the year 2000 providing present trends prevail. Limitations on imports of cereal substitutes and maize from third countries will reduce the surplus to 38 million tons. However, through genetic and plant husbandry improvements and by introducing quotas in animal production an even larger surplus can be expected.

164. But there are a large number of possibilities to utilise cereal seed and straw in industry. The technical possibilities seem promising enough to absorb cereal surplus in industry, but the realisation of this depends mainly on raw material prices and on the fundamental problem of how to link together agriculture and industry.

165. Installing new types of local harvesting and treatment centres called 'agricultural refineries' could increase profit per hectare considerably compared to the conventional technique. In principle, biotechnology offers the developing countries great scope for improving the food situation. However, the existing balance of power will prevent the developing countries profiting from the benefits of biotechnology to the same extent as the industrialised countries. It is more likely that the negative aspects of biotechnology will more rapidly become apparent to the developing countries than the possible positive aspects. The negative aspects include still greater dependence on the Western agrochemical industry and seed trade, fewer opportunities for exporting raw materials to Western countries because biotechnology offers Western countries the possibility of substituting raw materials with agricultural crops.

166. In order to achieve this goal, a new system for harvesting, drying and transporting the whole range of agricultural raw materials must be designed. The necessity for a more rational utilisation of machinery in agriculture has today been recognised in the formation of machine pools. However, a further development of the machine-pool concept is required. The introduction of a whole-crop harvesting system, which in contrast to existing systems enables full utilisation of machinery throughout the whole vegetative growing season (6-8 months), could bring down the capital costs per ton of a harvested product drastically. A local plant for harvesting, extended with equipment for preservation and pretreatment of whole-plant crops, i.e. an 'agricultural refinery', will not only permit collection and drying of material for traditional use, but also add the option of industrial use for components now discarded.

167. Although contract farming can undoubtedly secure significant improvement of margins when applied optimally, one should not fail to see that this structure opens up the possibility of further marginal improvements when implemented as a whole-crop harvesting system. However, the experience so far indicates that the economic attraction of whole-crop harvesting is dependent upon the total crop utilisation; i.e. some degree of preparation for the industrial application of the crop has to take place. Provided that outlets can be found for the additional straw derived from whole-crop harvesting, trials have shown very promising results in respect to marginal improvements. It is suggested that straw should be used in increased amounts for paper and fibre boards to substitute for import and to make up for the decreasing productivity of Central European forests.

168. The suggested measures can compensate for any unavoidable reduction of grain prices. Community self-sufficiency in feed substitutes, feed protein, vegetable oil and cellulose fibres would be increased as a consequence of the measures described.

169. With the exception of marginal agricultural areas which are not suitable for mechanisation and which should be used for speciality food production, forestry and recreation, it seems quite feasible that by far the greater proportion of land now under the plough could be used for diversified agriculture, producing food, feed, fibre, building materials, industrial chemicals and polymers. The key to that development is to redesign the interface between agriculture and industry enabling us to extract economically the raw materials from dispersed agriculture to industry.

170. In order to avoid a surplus of cereals in the year 2000, it is recommended:

(i) that the EEC stimulate cooperation between agriculture and industry starting by establishing agricultural refineries as demonstration units in various EEC countries;

(ii) that the EEC revise its present tariff system regarding cereals and cereal products and change it to a coherent, simplified set of rules designed to stimulate efficiency in cereal production and in the industrial use of cereals, thus creating the basis for an international competitive biotechnology industry in the EEC;

(iii) that the use of straw as a fibre source be stimulated by supporting a modernisation of the present industrial process to obtain competitiveness with the wood-based industries;

(iv) that the production of agricultural commodities in which the EEC is deficient — maize for starch, feed protein, vegetable oil and cellulose fibres — be stimulated by quality related premium prices of present commodities and development of new crops;

(v) that significant basic research programmes be established in the industrial manufacture of cereal based products including genetic engineering of plants and micro-organisms, the purification of cereal components and their processing and modification into final products.

Discussion

171. In the discussion it was said that Dr. MUNCK's ideas would be difficult to realise. Were they not utopian?

172. Dr. MUNCK commented that a limiting factor will be the price of cereals. This has to go down if his ideas are to succeed. What the politicians can do is to ask themselves what the business climate here is going to be and decide on a certain policy, for example, a pricing system based on quality. By increasing production, the price of cereals will be greatly reduced. By kilo the farmer will get less, but per acre he will get more.

173. Concerning overproduction Dr. MUNCK forecasts an annual productivity increase of about 5% and a three-fold increase in cereal production in the year 2000. By then we will be able to develop new possibilities for using these commondities so that the surplus will not prevail. This is the only way forward according to Dr. MUNCK because if we have quotas, farming efficiency will go down and in 20 years we will be in the same situation as the Eastern European countries.

174. We must have reasonable food prices for urban dwellers. Modern biotechnology is very beneficial for the environment if it is applied in the right way. We can even correct old mistakes with it. Genetic engineering is making more options possible and we have to eliminate

the negative parts and to profit from the positive elements.

175. Furthermore, we have to help the developing countries to produce their raw materials themselves. Their cereal production should be based on their own products such as millet and what we should do is to help them with our technology, (see, for example, the installation of agricultural refineries as described above).

176. Some of Dr. MUNCK's ideas will not be applied because they are not in the interests of the industry. For example, in the Philippines a very simple and cheap apparatus was developed in order to economise on the use of fertilisers in rice fields. The fertiliser industry would not recommend it.

177. Dr. MUNCK does not consider straw as a waste product. He mentioned that straw is already used in Danish factories but the pollution problems affects small companies and has to be solved, perhaps by giving financial aid to such companies.

178. Regarding the problem of input and output of energy (for example, driving a car run on ethanol) Dr. MUNCK stressed that he wants to show in his book all the existing possibilities.

179. All economic calculations and important information concerning the new cereal circle are explained in the book of Dr. MUNCK and Dr. REXEN, 'Cereal Crops for Industrial Use in Europe'.

5. Dr. FEILLET (JNRA, Montpellier, France): Biotechnology and European agricultural policy

180. Three main points:

— supplementary technical clarification to what was already said in the Hearing,

— implications on the level of production,

— implications on the level of transformation.

Remarks on the technical aspect

181. There is a major difference today between biotechnology and traditional genetics: the impact in the field of agriculture.

182. Scientists do not know everything about how genes behave, it is a major technical blockage which is not yet sufficiently clarified. Efforts are necessary to develop the most traditional genetics and agronomics because such a knowledge is indispensable for the new technology

183. The first application will appear in the animal production sector and afterwards in the plant production. The food industry which was more an art than a science will change completely owing to biotechnology and because of a better knowledge of micro-organisms.

184. Biotechnology is not only genetic engineering. Other aspects of biotechnology should be discussed more. Industrial progress will be seen in many other sciences and technologies and not only through the 'génie génétique'.

The effect of recent progress on the production sector

— The increasing influence of seed industries in agriculture:

  (i) agriculture from the farmer's side;
  seed production will be increasingly difficult to operate directly from the fields (hybrid seeds for example);

  (ii) industry supplying products to agriculture;
  for example the industry of fertilisers must be reorganised.

— Agriculture will become more biological, plants will have more 'autonomy', for example they will be able to adapt better to different climates. Fertilisers and pesticides will be more biological.

  Positive effects:
  less fertilisers required.

  Negative effect:
  stronger resistant plants usually tend to lead to an increasing use of herbicides because plants are less likely to be affected.

— Agricultural production better adapted to the needs of the consumers:

  (i) biotechnology leads to the possibility of creating more rapidly new species, the composition of which will fulfil greater industrial needs of the animal feed industries,

  (ii) these techniques will make possible the introduction into the plants themselves of the characteristics necessary for subsequent transformation (for example the industrial alterations of tomatoes)

  (iii) Transfer of production zones:
  Will biotechnology make possible the cultivation in temperate climates of tropical plants and vice-versa? Agricultural production will develop under better conditions in the Third World countries. But one should not draw conclusions too quickly because one must for example allow genes to adapt fully in their environment.

Implications for the level of industrial transformation

Four elements:

— the sector of the food industry is the primary concern;

— the major sector of the food industry are rendered more independent by biotechnology;,

— agricultural products become more like chemicals and this widens competition on the market;

— industry, which although originating from agriculture, produces no more food.

Conclusions

185. The CAP (Common Agricultural Policy) has made possible the development of an intensive agriculture within the area of food industry.

186. The unique relationship between agriculture and the food industry disappears. As a consequence of this policy one should consider agricultural and industrial policies together.

187. The multinational companies of pharmaceutical and petro-chemical products will control the market in the future.

188. The fundamental problem of regulation will have to be solved.

Discussion

189. During the discussion Dr. FEILLET was asked some technical questions about ethanol on the basis of agricultural raw material. Dr. FEILLET recommended the American OTA report for information. Furthermore he mentioned the French Government which has developed plans for adding 6% ethanol to petrol, replacing the lead. In order to achieve this aim 5% of French wheat production would be needed. However it must be emphasised that biotechnology cannot in any way solve the surplus problem. Dr. FEILLET did not believe that outlets of a size capable of solving the over-production problem can be envisaged. On a macro-economic level biotechnology cannot be regarded as a solution to this question. No great change is foreseen in the immediate future.

190. The role of the EC States: all biotechnological sectors are important to the Member States; so if all Member States wish to have their own individual strategies, they must still be prepared to share a certain number of strategic areas so that resources can be exploited at the optimum level. It is absolutely necessary to found European expertise centres in certain sectors.

191. As to the whole crop harvesting system, mentioned by Dr. MUNCK, Dr. FEILLET thinks that the harvest of tomorrow will consist of proteins. glucides, lipides and wheat straw which will perhaps come to be used as a source for glucides. If it were economically feasible to transform cellulose into glucose there would be no need to grow cereals in order to extract starch. With today's technology this transformation is possible, but extremely expensive. At the moment the question of finding the cheapest method of producing sugar is more important.

192. In the future biotechnology will fall increasingly under the control of multinationals as it becomes too expensive for smaller concerns to stand alone.

6. Dr. VON WEIZSÄCKER (Institute for European Environmental Policy, Bonn, Federal Republic of Germany):

Biotechnology and European integration and its impact on the environment

193. At first glance, biotechnology does not seem to have much to do with European integration. Biotechnology is a science and European integration is a political issue. Biotechnology would no doubt thrive in many research laboratories and industries in Europe even without any European integration. Nevertheless, a closer look reveals a number of interesting connections, past, present and future. Some of these connections should be of concern to the European Parliament.

Basic research and training

194. Since the first FAST programme of 1978 the Commission has emphasized the importance of biotechnology. In many research laboratories in Europe, the Community initiatives in biotechnology have been welcomed as an important encouragement at a critical time. The European initiatives have triggered, or at least reinforced, national efforts in the same direction. In most European countries the lion's share of both basic research and training is provided by the universities. The universities traditionally do not need any support or guidance from international organisations. However, as biotechnology is becoming 'Big Science', duplication ought to be avoided and international collaboration has to be sought. Hence, the European Molecular Biology Laboratory in Heidelberg is regarded by many as an excellent example of a useful concentration of forces and financial means. Also, the Biomolecular Engineering Programme, launched in 1981, has already achieved important progress in its main goals, to remove, through mission-orientated research and specialised training actions, the bottlenecks which prevent applications in the Community of modern biochemistry and molecular genetics to agriculture and industry.

Common Agricultural Policy

195. The Common Agricultural Policy is in a phase of change. Productivity gains, which can be attributed to traditional 'biotechnology', have led to an economically intolerable situation. The 'Green Paper' of the EEC on the reform of the Common Agricultural Policy (CAP) places considerable emphasis on the possibility of non-food crops and other land-use possibilities to reduce the pressure of food overproduction. In as much as biotechnology is involved in opening new alternatives, e.g. the production of economically viable fuel for cars, biotechnology has, by implication, a highly important European dimension.

Environmental concerns

196. Some writers including notably Jeremy RIFKIN have expressed concern about environmental and social dangers from certain new developments in biotechnology, notably genetic engineering. It is indeed true that both the construction and the release of genetically-engineered new organisms demands our close concern. When Stanley COHEN and others announced in 1974 the successful use of the restriction enzymes for the insertion into bacteria of alien genetic material, a wave of alarm went across the globe. But, in the wake of the Asilomar Conference which addressed these problems it became increasingly clear that the manipulated micro-organisms lacked the vitality to proliferate to any significant degree in natural environments. Hence, safety regulations were relaxed, and the public support for genetic engineering is now stronger than ever before. Leaving out the entire military sector, Dr. VON WEIZSÄCKER shares the views of most biotechnologists that the fears of a doomsday bug were greatly exaggerated, and that normal biotechnological routines under the observation of existing safety regulations do not pose any particular environmental problems.

197. On the other hand, Dr. VON WEIZSÄCKER feels that a different category of dangers needs to be taken much more seriously. He is referring to the 'dangers of success'. One automobile, one barrel filled with dioxine or one nuclear reactor would not be termed an environmental problem even if major health hazards were involved. Only the successful introduction of the

automobile in many millions of copies has created an environmental problem.

198. To repeat the point with regard to agriculture: small scale agriculture has for thousands of years improved rather than damaged the environment of the European continent. It is only for about 35 years that agriculture has been 'successful'. Biotechnology will be perfectly acceptable from the environmental point of view as long as it is applied locally and in small scale. As said in the preceding chapter, it may even play a beneficial role. However, if one imagines a functioning Common Market with comparable economic incentives to introduce biotechnological routines into all farms, one will encounter very serious environmental problems.

Regulations

199. One aspect of the regulation is patent law. Evidently, the process of harmonisation has to be completed soon.

200. Equally important is the harmonisation of safety standards, a task that was left with an ad hoc working group of the Science and Technology Committee of OECD. Contrary to earlier expectations, however, that ad hoc group is quite unlikely to come to a final conclusion in 1985, because the United States has, in a surprise move, blocked the earlier consensus. At the moment, it is hoped that the European Community will formulate the existing consensus of the OECD working group as a European framework for regulations.

Discussion

201. Concerning the 'dangers of success' Dr. VON WEIZSÄCKER stated that at the moment it is rather premature to speak concretely about risks to the environment as the application area of biotechnology is only 1% of total land area. However, one must proceed with caution. He noted that chequer-board application is a more favourable approach to that of homogeneous application of biotechnology.

202. It is difficult to declare that the risks of biotechnologies are being ignored. There may be areas where knowledge is inadequate and where more research is necessary for risk assessment.

203. But what we are going to regulate is different. In the Community the essential question to be tackled is that of regulating the production process and the 'success' itself.

204 Biotechnology can be considered as a new form of technology which introduces the new ethical question of the relationship between man and nature. This requires a different approach. The Commission has produced a new paper on agricultural policy, 'The Green Paper'. There is a kind of 'industrial enthusiasm' in agriculture with regard to land use and alternative forms of agriculture We should be aware of these alternatives.