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PREM 19/3154

The Advisory Council for Applied Research and Development (ACARD): Report of the Working Party on Biotechnology.

SCIENCE AND TECHNOLOGY

JANUARY 1980

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Published Papers

The following published paper(s) enclosed on this file have been removed and destroyed. Copies may be found elsewhere in The National Archives.

Biotechnology
Report of a Joint Working Party
Advisory Council for Applied Research and Development
Advisory Board for the Research Councils
The Royal Society
March 1980
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PREM Records Team

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cc CO

10 DOWNING STREET
LONDON SW1A 2AA

THE PRIME MINISTER

8 November 1990

Dear Sir Robin.

The formal Government response to ACOST's report on Developments in Biotechnology, promised in my letter of 6 February to Lord Tombs, is enclosed.

I look forward to discussion on it at the Council's meeting on 14 November.

Yours sincerely

Margaret Thatcher

Sir Robin Nicholson

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CC AT

Qd: 0548

File Ref: ST

FROM: ROY WALKER

MR POTTER (No. 10)

DATE: 5 NOVEMBER 1990

GOVERNMENT RESPONSE TO ACOST'S REPORT ON DEVELOPMENTS IN BIOTECHNOLOGY

file to AT.

I enclose the proposed Government Response to ACOST's report on Developments in Biotechnology for the Prime Minister to send to Sir Robin Nicholson; it has been cleared by EST Ministers and SoS, HO (subject to minor amendments, incorporated in this draft, which were suggested by DES, DOE and MAFF and copied to the other departments).

2. We briefly discussed the need for Sir Robin to receive the Response as soon as possible because it is scheduled for discussion at the 14 November ACOST Council meeting which the Prime Minister will chair.

3. I am copying this minute to Ms Phippard.

C

C R WALKER

GL pd 5/xi

DRAFT LETTER FROM THE PRIME MINISTER TO SIR ROBIN NICHOLSON

ACOST ADVICE ON S&T PRIORITIES 1990

The formal Government response to ACOST's report on Developments in Biotechnology, promised in my letter of ~~XX~~ 6 February to Lord Tombs, is enclosed.

at flap

I look forward to discussion on it at the Council's meeting on 14 November.

THE GOVERNMENT RESPONSE TO THE ACOST REPORT: DEVELOPMENTS IN BIOTECHNOLOGY

1. The Government welcomes the ACOST Report which provides a clear and succinct overview of some of the developments in biotechnology since publication of the 'Spinks Report' in 1980. The scope for application of biotechnology is vast and there is already significant commercial capitalisation of the new techniques in areas such as medical science and agriculture. The cross fertilisation of bioscience with electronics, materials science and engineering promises to transform whole sectors of industry; chemicals and food are two of the more immediately obvious candidates. Exploitation of biotechnology will also be crucial to the development of many of the cleaner technologies needed to reduce pollution and to rectify past environmental damage. The Government is encouraging action in all these areas.

2. The recommendations in the report deal with the core concerns of provision for the underlying science and for the enabling technologies themselves. On applications, they are not comprehensive, concentrating mainly on developments in agriculture.

3. The following paragraphs respond to ACOST's recommendations a. to k. as listed at the front of the report. As well as commenting on each recommendation, the responses note related activities which are already taking place or are in prospect.

Recommendation a.

Government Departments should take a more proactive role in biotechnology

4. It is for industry to exploit the opportunities arising from the rapid development of biotechnology. Government's role is to facilitate this by stimulating the science base, by creating an effective, yet flexible regulatory regime and by ensuring adequate public information. In this context Government

Departments are increasingly taking a proactive role on aspects of biotechnology which fall within their areas of responsibility. Annex A gives examples of the growing research effort financed by Departments and the Research Councils. Regulation is discussed in several places throughout the main text and public information is dealt with in paragraphs 21-28 and Annex B.

5. The Report highlights the importance of proper regulation, not least to ensure that the new technology achieves and retains public confidence. There has been a history of sensible regulation in respect of human health and safety under the Health and Safety at Work etc. Act 1974 (HSW Act) and specific regulations under the Act on genetic modification have been in force since 1978.

6. Proposals to implement EC Directives on the contained use and deliberate release to the environment of genetically modified organisms and to take account of the recommendations of the Royal Commission on Environmental Pollution (RCEP) in its 13th report are being considered interdepartmentally. Appropriate legislative powers to ensure protection of the environment are contained in Part VI of the recently enacted Environmental Protection Act (EPA). These will balance the powers that already exist in respect of human health and safety under the HSW Act. The developing structure will entail regulations on environmental aspects under the new EPA. These regulations will be administered and enforced under unified arrangements being developed by HSE and DOE. Under these arrangements HSE inspectors will enforce regulations to protect the environment on behalf of DOE.

7. Recommendation a. is so wide ranging that, for clarity, individual responses are also given below to related subsidiary recommendations in Appendix A.

Appendix A - Safety Aspects

It will be important for the UK to continue to have a strong voice in the EC in what will inevitably be a high profile political topic.

The UK government should press for this view [that the product should be evaluated for risk, and not the means used to produce it] to predominate in discussions in the EC.

8. The Government acknowledges the importance of EC discussions of regulation, both for the protection of the environment and consumer and for the climate of investment and competitiveness. UK has been particularly influential in international developments in biotechnology regulation, building upon the high regard for the Advisory Committee on Genetic Manipulation (ACGM) and strong interdepartmental coordination; the effort will continue in EC fora.

9. It is important to distinguish between products which contain genetically modified organisms (GMOs) and whose marketing therefore involves a release of such organisms to the environment and those which have been derived through techniques of genetic modification but where the marketed product does not itself contain GMOs. For products not containing GMOs, for example, human insulin and human growth hormone, the recommendation is eminently sensible. Products which contain GMOs are covered both by the EPA and by the EC Directive on deliberate release of GMOs to the environment and are identified for this purpose by the fact that a genetic modification technique was used to produce them. This is to ensure that they are adequately assessed for any risk they may present. The Government agrees that specific product controls should apply to products containing GMOs, as they apply to other products, where these controls are adequate to protect man and the environment against risk. The Deliberate Release Directive is structured to enable products to be removed from the scope of its clearance mechanism when product controls, good enough to make such clearance unnecessary, are in place.

MAFF and the Advisory Committee on Novel Foods and Processes must take a more proactive role. We recommend that MAFF consider appointing a consumer representative to the ACNFP.

10. As MAFF is both regulator and sponsor of research for the food industry, in many cases it would be improper to single out one form of technology as being more appropriate than another - and this can limit the scope for promoting a particular new product, process or technique. Given its role in the regulatory process, similar constraints apply to the Advisory Committee on Novel Foods and Processes (ACNFP). In these circumstances a proactive approach can ensure that industry has access to the latest techniques and that regulatory arrangements are updated to relate properly to new technology, particularly when considering the granting of product licences, consents, approvals etc.

11. The Food Safety Act 1990 has given powers under which irradiation can be authorised while maintaining controls which will provide reassurance to consumers and MAFF is now consulting on detailed regulations to permit irradiation of food for public consumption from 1 January 1991. The Act also gives specific powers to regulate novel foods or food sources so that, in the absence of EC legislation, statutory backing may be given to the present arrangements operated informally by ACNFP. ACNFP has also published the guidelines it proposes to apply, under which the data required of industry are restricted to the minimum required by the nature of the product or process.

12. Consideration is being given to the addition of a lay member to ACNFP. It is however essentially a committee of experts in all scientific disciplines relevant to the safety of novel foods and processes. Its advice is in any case considered by the Food Advisory Committee (FAC) which includes a number of people from consumer backgrounds and has a broad interest in novel foods and processes. FAC has developed guidelines to assist it in considering the labelling of novel foods; these are likely to be published shortly.

Appendix A - Environmental Aspects

We recommend that the Department of the Environment take due account of the recommendations made by the RCEP, both in drawing up the relevant sections of the Environmental Protection Bill and, in particular, the regulations which will follow from it. We further recommend that DOE consider ways of providing for increased lay representation in these and future decision processes.

13. Part VI of the EPA proposes a hierarchical system of controls for protecting the environment against the release of genetically modified organisms with more hazardous organisms requiring more comprehensive, consent-based controls. A general duty to prevent damage to the environment will apply to all operations involving genetically modified organisms. Assessment prior to the issuing of consents will, at the current state of knowledge, be on a case-by-case basis; this was one of the major recommendations made by the RCEP in its 13th Report on the "Deliberate Release of Genetically Engineered Organisms to the Environment", published in July 1989. It is also the approach adopted in the EC Directive on the Deliberate Release to the Environment of Genetically Modified Organisms which, together with the Directive on the Contained Use of Genetically Modified Micro-organisms, was agreed at a meeting of Environment Ministers in March 1990.

14. There are two ways in which provision has been made for increased lay representation in decision making processes. Firstly Mr Trippier, Minister for the Environment and Countryside, announced during the House of Commons committee stage of the EP Bill, that there would be widespread public consultation on the content of the regulations. Secondly, although the membership of the Advisory Committee on Releases to the Environment (ACRE) (see paragraph 15) includes scientific expertise, it also includes people from a wide range of backgrounds, eg industry, local authorities, farmers and environmental expertise.

We support the RCEP proposal for a reconstituted Committee within the HSE which will have the responsibility for advising the Secretary of State for the Environment on each release.

15. The Secretary of State for the Environment with the Health and Safety Commission has already established a new committee, ACRE. Its membership comprises experts from a broad range of disciplines and representatives, from both management and trade union sides of industry, and from other environmental interest groups; the secretariat is jointly provided by the Health and Safety Executive and the Department of the Environment. ACRE will advise the Secretary of State and the Health and Safety Commission on the human and environmental safety aspects of releases of all types of novel organisms into the environment. It has replaced the Intentional Introduction Sub-Committee of the ACGM and the DOE's Interim Advisory Committee on Introductions which advised Ministers on the ecological implications of introductions. One of its main tasks, apart from assessing the risks associated with particular releases, will be to prepare guidance, and to advise Government about which areas of research to support.

Appendix A - Ethical Aspects

16. Ethical aspects are dealt with in paragraphs 54-56.

Appendix A - Welfare Aspects

The Ministry of Agriculture Fisheries and Food should consider how to convey better to the public the advantages offered by genetic engineering for the improvement of animal welfare.

17. Biotechnology is increasingly contributing to the production of veterinary diagnostics and medicines and it is mainly in this

way that it benefits animal welfare. However it is the safety and efficacy of these products rather than their method of production that is important. Although MAFF could not be seen to favour one product compared to another because of the way it was produced, the Ministry is anxious that industry should take advantage of new developments which might bring about safer and more clearly targeted treatments and will feature the contribution which biotechnology can make along with other techniques in any future public information campaigns on animal welfare.

> **We recommend that the committees set-up to consider all license applications for animal experiments are kept fully informed of relevant issues that arise from developments in biotechnology, and that welfare aspects of transgenic animals and their progeny are given careful consideration.**

18. MAFF is responsible for assuring the welfare of all farm animals, including genetically modified ones, and for ensuring the same standards of welfare apply to all animals regardless of their origin. The Ministry does not anticipate any specific welfare problems compared with traditional breeding practices for farm animals. If any arise, they will receive comparable treatment.

19. The Home Office exercises the control of experimental animals under the Animals (Scientific Procedures) Act 1986 following advice given by the Inspectorate which is established under section 18 and the Animal Procedures Committee established under section 19. A growing number of applications for licences involve biotechnology, and a senior member of the Inspectorate coordinates the consideration of those applications.

20. The Animal Procedures Committee has also been increasingly interesting itself in these issues and intends to devote a meeting to discussing them early next year. Great attention is paid to the welfare aspects of animal procedures; and, in particular, it is well recognised that there can be serious

welfare hazards in the development of animals with potentially harmful genetic defects, although the problems which arise from biotechnological innovation are not in principle different from those arising from selective breeding.

Recommendation b.

A programme of balanced information should be provided to the public on major aspects of biotechnology, such as genetic engineering. This would be of interest to both the scientific community and to industry where the lack of such a programme contributes to a major market imperfection. The Inter-departmental Committee on Biotechnology (ICBT) should co-ordinate the interests of other Government departments in this area. Elements of such a programme should include:

- **the commissioning by Government of an independent body such as the Royal Society or a charity (for example The Leverhulme Trust or The Nuffield Foundation) to prepare a booklet providing reliable information and analysis for the public.**

- **in the longer term, increasing the general level of understanding of such matters through education in schools. The DES should consider how to achieve this.**

- **consideration by the ICBT of how to disaggregate those areas and industrial developments which have few or no safety and/or ethical considerations from those which have and to convey information on these divisions to the public.**

21. The Government agrees that there should be as much openness as possible on major developments in biotechnology, with objective information being made available to the public. Significant efforts have been made already - Annex B gives examples of information made available by Government. There is every intention to continue to maximise this.

22. There is a need to put across the key messages. Biotechnology can and does bring benefits. It is controllable. Risks can be foreseen and are being assessed. We are developing with our EC partners an appropriate and effective system of regulation to safeguard public health and the environment.

23. ICBT is an appropriate body to coordinate the Government's provision of public information. It is giving careful consideration to the Government role in making information available. For instance, it is Government's responsibility to provide information about the regulatory regime or departmental responsibilities, but it is for consumer interests and companies to supply information which relates to specific products.

24. Commissioning an independent body to provide a booklet providing reliable information and analysis could be useful in explaining the safety and ethical considerations underlying the Government's stance in regulating and supporting biotechnology. ICBT will explore this option carefully. A major step in independent assessment has already been taken with the publication of the 13th Report of the RCEP in 1989 which provided authoritative coverage of the environmental hazards which might arise from the new technology.

25. The control regime brought in under in the EPA will include provision for public access to information, with due protection for commercial confidentiality and for data whose disclosure might lead to damage to the environment. The intention is to set up public registers of information obtained under Part VI. In addition, the Act stipulates that applicants for consent to release genetically modified organisms advertise their proposals.

26. Government agrees with ACOST on the role of schools in increasing the general level of public understanding of biotechnology in the longer term. The programmes of study for key stage 4 in the science National Curriculum for schools include the basic principles of genetic modification in relation to drug and hormone production and awareness of ethical issues. This provides a starting point for teaching about new

developments in biotechnology. The programmes of study will be kept under review by DES and the National Curriculum Council and, if developments in biotechnology and experience in schools are such as to make amendment of the programmes of study appropriate, this will be done.

27. DTI has supported a three-year programme at the National Centre for School Biotechnology (University of Reading) providing resource material, advice and workshops for teachers.

28. The Government agrees on the need to isolate aspects of biotechnology that raise ethical issues and to make clear to the public that they are being addressed appropriately. (See paragraphs 54-56.) For instance the aims and ethical considerations surrounding human and animal embryonal stem cell biology are different and need to be treated separately. ICBT will continue to provide a focus for this activity.

Recommendation c.

Inter-research council co-ordination of biotechnology should be strengthened. For example, an opportunity exists for the AFRC and SERC to consider a co-ordinated programme of molecular, biochemical and physiological studies in the plant sciences

29. The Research Councils and ABRC recognise the need for close collaboration. ABRC has recently decided to set up a sub-committee to review responsibilities for current and prospective work and to draw up a development strategy for biotechnology. Its members will include AFRC, MRC, NERC and SERC.

30. The Biotechnology Joint Advisory Board (BJAB) was originally established by SERC and DTI. AFRC and NERC are now included and MRC is also represented. The Board will develop a strategic view of R&D and foster cross-Council programmes of basic science, technology transfer and collaborative R&D directed towards future UK industrial competitiveness.

31. AFRC and SERC are examining the scope for a joint programme in plant biochemistry. They have also recently announced a joint 'clean technology' initiative, which has a strong biotechnology input.

Recommendation d.

UK research institutions should explore ways of taking a more European perspective and should determine how they can gain greater added value for the UK from collaboration with European partners.

32. The Government supports this recommendation. The Research Councils are considering how they can contribute further to its implementation and have already established mechanisms for co-ordinating their input to EC programmes. Interested Government Departments (DES, DTI, MAFF and DH) are working with the Research Councils to sieze the new opportunities to be obtained from full UK participation in the Third EC Framework Programme

Recommendation e.

Increased industrial support for biotechnology in UK universities and research institutes is required in order to enhance the transfer of the considerable scientific expertise into commercial success

33. The Government welcomes this recommendation which endorses the considerable efforts already made to increase private sector involvement. Departments and Research Councils, of course, have substantial experience of running collaborative programmes involving industry and HEIs - the PROSAMO programme is an example (see paragraph A6). A strong portfolio of LINK programmes in biotechnology has also been developed to facilitate the transfer of research knowledge from the science base to industry. Turning that knowledge into commercial success is for the companies themselves.

Recommendation f.

As a matter of priority UK strengths in plant biotechnology should be reinforced. Government, in conjunction with industry and the research community, should aim to provide guidance to those in universities and the research institutes on the balance between work of interest to industry and work to satisfy national requirements on environmental issues. Emphasis should be placed on stimulating research into isolating important genes and to learning how to manipulate them in plants of economic and of scientific importance. Further technical and economic assessment of the potential for producing chemicals from plants should be encouraged. The Priorities Board for Research and Development in Agriculture and Food might consider how to stimulate interaction between the agricultural and chemical industries.

34. Within the UK science base it is important to give particular attention to areas which have both the potential for scientific advance and long-term wealth creation. The Government, therefore welcomes the recommendation to reinforce UK strengths in plant biotechnology and agrees that emphasis should be placed on research into isolating and manipulating plant genes of economic and scientific importance. AFRC, the main publicly funded player in this field, has these areas, together with plant biochemistry and physiology as major elements in its Corporate Plan.

35. Annex A describes some of the Government funded research activities in plant biotechnology. BJAB will consider the need for further initiatives in this area.

36. There is a scope for further collaborations between industry and the science base in LINK programmes in Eukaryotic Genetic Engineering, the Control of Plant Metabolism and Crops for Industrial Use.

37. The Government agrees that the agenda of the Priorities Board for Research and Development in Agriculture and Food should include consideration of how best to stimulate interaction between the agricultural and chemical industries in relation to the use of plants as sources of chemical feedstocks.

Recommendation g.

A strategic decision by Government and industry to support embryonal stem cell biology will consolidate our strengths and will complement the UK initiative in the research on the mapping of the human genome. The MRC and the AFRC should consider how they might co-ordinate an initiative to provide increased support in this area of biological research, taking into account the strengths that exist in the cancer charity supported Institutes. They should also continue to give priority to work in genome mapping and automated sequencing techniques.

38. BJAB will consider the first part of this recommendation. On the second, AFRC and MRC are discussing the best way to co-ordinate the expansion of work on stem cell biology.

39. AFRC is diverting funds into embryonal stem cell biology where the current UK lead is under threat from USA and Britain's EC partners who have recognised its potential for wealth creation and are increasing support.

40. A major MRC initiative in the genetics of human disease will cover somatic gene therapy, requiring study of adult stem cells; the initiative will also involve training in techniques for the use of embryonal stem cells.

Recommendation h.

AFRC, MAFF and DTI should give consideration to the development of a programme in embryo multiplication in cattle; to applying biotechnology to the production of higher quality and healthier products; and to the funding of a programme to encourage the development of efficient methods for the construction of transgenic mice and other laboratory animals.

41. This recommendation will also be considered by AFRC and Departments involved, consulting BJAB as necessary. Funding is under consideration for a programme of research underpinning embryo multiplication techniques and for a joint industry/AFRC Institute programme on embryo cloning in cattle.

42. AFRC has a major programme of research on transgenic animals which offers considerable potential for UK industry. MRC also has a substantial interest in development research using transgenic rodent technology to provide models of human diseases and to investigate basic biological processes (eg gene expression in development) and their perturbation by toxins and teratogens. Collaboration already exists between MRC and AFRC in Cambridge and Edinburgh. Enhanced facilities for studying transgenic rodents are under construction at the MRC's National Institute of Medical Research. Under the Eukaryotic Genetic Engineering LINK programme, AFRC and SERC, together with DTI, are developing a major project in construction of transgenic rats.

Recommendation i.

Manpower shortages should be addressed. The DES, the Research Councils and DTI should consider how to establish a co-ordinated approach with industry for the future provision of manpower needs in the biotechnology related industries.

43. In recent years the Research Councils have provided some additional support for postgraduate training. Furthermore, the postdoctoral fellowship schemes of the Councils, the Royal Society and the Fellowship of Engineering have been expanded. There are, however, continued problems with the recruitment of high quality graduates to postgraduate studentships and postdoctoral positions in the biological sciences.

44. The Government will invite the ABRC to consider, in its review of co-ordination arrangements for biotechnology, how to improve the assessment of manpower needs and postgraduate provision in biotechnology. Manpower and training will also be considered by BJAB to ensure coordination of the approach with industry.

45. A major DES objective for Science Budget expenditure is to achieve a better match between support for postgraduate training and the needs of UK industry and the Science Base, in biotechnology as in other fields. The Research Councils' effectiveness in meeting this objective will be monitored closely. ABRC has recently established a sub-committee on postgraduate support. Its terms of reference include reporting on the scope for improvements across Councils in targeting studentships to meet identified needs in the science base and industry. It is intended that this sub-committee should subsequently have a wider remit addressing other issues concerning the supply and demand for scientific manpower.

46. The University Grants Committee's Biotechnology Initiative was recently reviewed by the Committee's successor, the Universities Funding Council. The Review concluded that the Initiative was successful and the Council decided to continue special funding to eight institutions. At the same time universities were invited to bid for support under a new tranche of the Initiative. As a result, the Council has allocated £66,000 a year to support 36 new posts in 14 institutions.

47. Paragraph 7.2.16 of the Report states that the Teaching Company Scheme (TCS) in biotechnology should be expanded and the Integrated Graduate Development Scheme (IGDS) should be extended to biotechnology. Neither scheme excludes biotechnology. Both can and will respond to proposals from industry in biotechnology.

> **Recommendation j.**
>
> **Increased support is required for the related skills in chemistry which UK industry will require to take full advantage of the initiatives in protein engineering. It will be important to sustain the UK's strengths in crystallography and to enhance support for 2-D NMR and molecular modelling. The Research Councils should consider this in conjunction with their funding of protein engineering. The DTI and SERC in their training role in for example the Teaching Company Scheme (TCS) and the Integrated Graduate Development Scheme (IGDS) should also take action in this respect.**

48. These topics will be amongst those considered by ABRC and BJAB, with additional advice from the Management Committee of the LINK programme in Protein Engineering.

49. The role of TCS and IGDS has been described in paragraph 47. Other schemes already in place are supporting general postgraduate training in the general area of biotechnology, including protein structure and/or engineering.

50. AFRC supports fundamental research on protein engineering and on molecular recognition in its institutes and in high education institutes. The Council has appointed a co-ordinator to maximise the effectiveness of its programme in protein engineering and has strengthened its expertise in x-ray crystallography and biomolecular computing.

51. The protein engineering interdisciplinary research centre that MRC has set up at Cambridge is already focusing on the need for crystallography, 2-D NMR and molecular modelling as part of the development of protein engineering. MRC's Corporate Strategy recognises the need to maintain the UK's strength in protein crystallography and enhance that in 2-D NMR.

52. A recent MRC strategic review emphasised the need for increased support for research on macro-molecular structure and function and for concentrating all the relevant techniques in a number of state-of-the-art centres. However, as the Report recognises, the general problems of recruitment to research apply to this field at least as much as to others.

53. In addition to support of LINK and underpinning programmes in protein engineering, SERC also funds work on protein structure and engineering through the molecular recognition initiative, with underpinning work supported through its Biological Sciences Committee.

Recommendation k

Consideration should be given to a detailed and systematic analysis of the ethical issues that relate to certain aspects of genetic manipulation. This could possibly be by means of ad hoc Committees along the line of the Warnock Committee.

54. Although most biotechnological applications do not raise ethical issues, certain aspects do give rise to strong views in areas of legitimate public interest and concern. The Government is reviewing the ethical implications arising from genetic modification.

55. The Government notes the initiative taken by the Nuffield Foundation in convening a conference on bioethics attended by distinguished scientists and senior members of professional

bodies, as well as lawyers, philosophers, theologians, representatives of the public and consumers. The Foundation is expected to pursue further consultations with official and unofficial bodies to consider the scope for new machinery to examine ethical issues that are chiefly but not exclusively related to genetic research in medicine and biology.

56. Some ethical issues have received substantial attention already. For example, the Medical Research Council has played a leading role in the preparation of the European Medical Research Councils' guidelines on human gene therapy. And in November 1989 the Government announced the establishment of a Committee on the Ethics of Gene Therapy under the chairmanship of Sir Cecil Clothier QC. Among other matters the Committee will draw up ethical guidance for the medical profession on the treatment of genetic disorders.

EXAMPLES OF GOVERNMENT FUNDED RESEARCH

A1. Government funded research specifically focused on biotechnology is underpinned by a wider programme of basic and strategic research in biology, chemistry, physics, process engineering, mechanical design, and materials, which all produce results and skills necessary for long-term exploitation of biotechnology by industry. The following examples illustrate how Departments and Research Councils are providing support for both these aspects in their respective areas of responsibility.

DEPARTMENT OF THE ENVIRONMENT

A2. DOE supports research in biotechnology in pursuit of its policy responsibilities in the prevention of environmental damage by GMOs and in preventing or abating pollution. The techniques of molecular biology which have been developed for biotechnology are also proving of great value in important environmental concerns such as biodiversity, adaption to environmental change, gene flow in populations and taxonomy.

A3. DOE's broadly based research programme on the impact of environmental releases of GMOs is expected to run at about £1m per year over the next two years. Contracts currently let and planned for the immediate future cover such areas as microbial ecology; organism dispersal; leakage of genetic material; releases into aquatic environments; the relevance of population genetics; the risks associated with introducing novel species into the UK and the use of models to predict the outcome. These projects are, in the main, targeted on assessing the risks which might be associated with the release of both genetically modified organisms and non-indigenous organisms.

A4. DOE and DTI have recently joined forces to launch an Environmental Technology Innovation Scheme (ETIS). ETIS aims to encourage innovation, improve environmental standards and help users or suppliers of environmental technology to become more competitive. Priority areas have been identified some of which provide scope for biotechnology applications.

DEPARTMENT OF HEALTH

A5. DH direct funding of research in biotechnology is limited, but it has, for example, agreed to contribute to the LINK Molecular Sensors programme.

DEPARTMENT OF TRADE AND INDUSTRY

A6. DTI innovation policy in biotechnology is reflected in significant research programmes and projects across the range of application, as illustrated by the following examples:

> The Plant Gene Tool Kit project drew 11 companies into co-funding with DTI a 3 year and £3m effort at research institutes and universities to reduce to practice the transfer of foreign genes into key crop plants;
>
> The PROSAMO programme (Planned Release of Selected and Modified Organisms) is a similar collaboration (£1.5m) with 8 companies and AFRC to provide a firmer scientific base for the objective assessment of the risks associated with genetic release;
>
> The UK contribution to the Eureka programme was strengthened when the Imperial Cancer Research Fund laboratories joined Amersham International and Bertin (France) in a project in the advanced automation of molecular biology;
>
> The SMART scheme (Small Firms Merit Award for Research and Technology) has encouraged academic researchers to set up companies to take their work forward commercially, including Polyclonal Antibodies Ltd (Professor Landon, St Bartholomew's Hospital) and Affinity Chromatography Ltd (Dr Lowe, University of Cambridge).

A7. The following list of LINK programmes, relevant to biotechnology gives Departmental and Research Council involvement in brackets:

Agrofood Quality (AFRC, DTI, MAFF)
Biochemical Engineering (DTI, SERC)
Biotransformations (DTI, SERC)
Control of Plant and Microbial Metabolism (AFRC, DTI, SERC)
Crops for Industrial Use (AFRC, DTI, MAFF, DAFS, SERC)
Eukaryotic Genetic Engineering (AFRC, DTI, SERC)
Food Processing Science (DTI, MAFF)
Molecular sensors (AFRC, DTI, SERC)
Protein Engineering (AFRC, DTI, MoD, MRC, SERC)
Selective Drug Delivery and Targeting (DTI, MRC, SERC)

MINISTRY OF AGRICULTURE, FISHERIES AND FOOD

A8. MAFF provides about £2m for research on novel animal and plant breeding techniques and very substantially more for research using biotechnological methods. It receives advice from the Priorities Board for Agricultural Research, which provides a forum for commercial advice on the most effective allocation of the Ministry's research priorities. In addition, the LINK Agro-Food Quality programme, which will provide a total of £16m (half from MAFF and DTI with probable involvement of the Research Councils) for research for applying biotechnology to the production of higher quality and more nutritious food products, has recently been approved.

HEALTH AND SAFETY EXECUTIVE

A9. Through its biomedical research programme HSE has funded research on the following:

hazards associated with large scale growth of rDNA organisms;

DNA repair and systems evaluation;

tumour risk from cloned oncogenes;

planned release of genetically modified plants.

AGRICULTURE AND FOOD RESEARCH COUNCIL

A10. Through grants to institutes and HEIs, AFRC supports a wide ranging programme of biotechnology and underpinning science involving plants, animals and food. The Plant Molecular Biology programme, costing £14m in total, has recently been launched and covers many aspects of plant genetics and development. Work in transgenic animal biology is being extended to include embryonal stem cells. The AFRC Institute of Animal Physiology and Genetic Research, a world leader in embryo multiplication, has applied with other bodies to DTI for funding for a possible programme on embryo cloning in cattle. In addition to its sponsorship of the LINK programme AFRC supports fundamental research on protein engineering and molecular recognition, and has strengthened its expertise in X-ray crystallography and biomolecular computing. The Council is a co-sponsor with DTI and industry of the PROSAMO programme, which is providing a firmer scientific base for objective assessment of the risks associated with genetic releases.

MEDICAL RESEARCH COUNCIL

A11. MRC supports basic research in several areas of relevance to biotechnology, including molecular biology, immunology, developmental biology and neurobiology. New Units have been established (eg Protein Function and Design) and IRCs (Cell Biology and Protein Engineering) as well as introducing new programmes into existing MRC Institutes (eg the setting up of a Laboratory of Eukaryotic Gene Expression at the National Institute for Medical REsearch (NIMR)). MRC does not have advisory or executive committees dealing specifically with biotechnology.

A12. Current support falls into four main categories: diagnosis and assay; genetic engineering; monoclonal antibodies; conventional vaccines, drugs and therapeutic reagents. Each category covers work with a clear intent to produce something of commercial value and basic underpinning research. Humanising rat monoclonal antibodies for cancer therapy and an extensive programme to develop vaccines against HIV infection are examples of research aimed at direct biotechnological advance.

A13. The Council takes direct responsibility for industrial exploitation of research carried out on its own establishments where a number of projects, fully funded by industry have been effective in the transfer of important technology. MRC played a key role in the development of Celltech and set up its own Collaborative Centre, adjacent to NIMR, to act as a bridge in the transfer of research to industry. More recently a new company, Cambridge Antibody Technology, set up with venture capital, will have close links with the Laboratory of Molecular Biology in Cambridge.

NATURAL ENVIRONMENT RESEARCH COUNCIL

A14. NERC has supported a Special Topic Programme on biotechnology and maintains programmes on the development of baculovirus expression vectors, the development of viral insecticides, and the risks of release, at its Institutes of Virology and Environmental Microbiology and of Freshwater Ecology.

SCIENCE AND ENGINEERING RESEARCH COUNCIL

A15. SERC funds through its Biotechnology Directorate a targeted programme of strategic research and enabling technologies in areas with potential for exploitation in the long-term. SERC has increased its conventional grant funding through the Biotechnology Directorate by 50% over the past two years, and recently announced a new Interdisciplinary Research Centre (IRC) in Biochemical Engineering at University College, London (UCL).

EXAMPLES OF PUBLIC INFORMATION

B1. Government has been providing information to the public on subjects such as human and environmental safety in several ways: NERC held an open meeting on biotechnology, including risks of release of GMOs as early as July 1987. In October 1988 AFRC held a Workshop on Genetic Release for scientists from industry, institutes and universities as well as invited individuals from the press and organisations such as the RSPCA. A meeting in April 1990 on the 'Impact of New and Impending Regulations on Biotechnology' was sponsored by DOE and HSE together with the Bioindustry Association.

B2. The role played by the Advisory Committee on Genetic Manipulation in recent years in providing authoritative information to the public and guidance to industry and to the research community should also be recognised. The current level of public confidence in the UK owes much to the Committee's efforts.

B3. Public communication is an important component of many of the new initiatives eg the PROSAMO programme (see paragraph A6).

B4. Publication of the RCEP Report has already been mentioned in paragraph 13. An explanatory leaflet on 'Biotechnology and Genetically Modified Organisms: the Proposed New Controls' has been issued by HSE and DOE. It explains to the public, industry and others the new controls which the Government proposes to introduce on those using techniques of genetic modification or dealing with genetically modified organisms - and gives contact addresses for further information.

B5. The Advisory Committee on Novel Foods and Processes (ACNFP) has recently published its first annual report as a means of informing the public of its activities, including reviewing applications relating to foods from genetically modified sources made under the current voluntary scheme.

VC

Nasm

AT 5/11

copy

2 MARSHAM STREET
LONDON SW1P 3EB
01-276 3000

My ref P/PSO/39598/90

Your ref :

Ian Dixon Esq
S&T Secretariat
Cabinet Office
70 Whitehall
LONDON
SW1A 2AS

2 November

Dear Mr Dixon,

DRAFT GOVERNMENT RESPONSE TO ACOST REPORT ON DEVELOPMENTS IN BIOTECHNOLOGY

will request if required

You wrote on 29 October requesting Ministerial clearance of the above report. I must point out that paragraph 54 of the draft is not official Government policy, and has been overtaken by a statement made in the House of Lords on 15 October by Baroness Blatch. I suggest, therefore, paragraph 54 is reworded, as follows:

> "The Government appreciates the ethical issues of biotechnology are important and arouse strong views. The Secretary of State for the Environment is considering with colleagues the ethical implications of GMO activities, and will make a statement in due course. In addition, there are activities going on outside Government. The Nuffield Foundation has taken a welcome initiative in that area by convening a conference on bioethics attended by distinguished scientists and senior members of professional bodies, as well as lawyers, philosophers, theologians and representatives of the public and consumers. The Foundation is expected to pursue further consultations with official and unofficial bodies to consider whether there is scope for creating new national machinery to handle those ethical issues."

Otherwise, the Secretary of State is content for the draft to go forward to ACOST.

I am copying this letter to PS/E(ST) Ministers to PS/SoS Home Office, and to Barry Potter and Sonia Phippard.

Yours sincerely
Phillip Ward

PHILLIP WARD
Private Secretary

~~cc PU~~

n b. P.M.

2 M

From: THE PRIVATE SECRETARY

HOME OFFICE
QUEEN ANNE'S GATE
LONDON SWIH 9AT

2 November 1990

Dear Ian,

✓ [illegible]

Your letter of 29 October asked for Ministerial clearance of the Acost's Report. The Home Secretary is content with the document, so far as it concerns the Home Office.

I am copying this letter to Private Secretaries to E(ST) Ministers, to Barry Potter and to Sonia Phippard.

Yours sincerely,

MISS H J WILKINSON

Ian Dixon Esq
S&T Secretariat
Cabinet Office

cc PU ?

~~Mr Turnbull~~

NOFA
AT
29/10

CABINET OFFICE

70 Whitehall London SW1A 2AS Telephone 01-270 0391

Our Ref: Qe 0256

File No: ST 140/3

Mr S Crowne
PS/SoS
DES

29 October 1990

Dear Mr Crowne

DRAFT GOVERNMENT RESPONSE TO ACOST'S REPORT ON DEVELOPMENTS IN BIOTECHNOLOGY

Attached for Ministerial clearance is the third draft of the Government response to ACOST's report on Developments in Biotechnology.

ACOST have a Council meeting on 14 November which the Prime Minister is to chair. The Council's consideration of the response may be on the agenda. In order to allow time for the final response to be sent by the PM and distributed to Council members before the meeting I would be grateful for your Minister's clearance, if possible, by Friday 2 November. I apologise for the tight deadline.

Changes to the second draft have been made in response to Departmental comments at official level. Where the changes have been significant I have cleared them over the phone with officials in the Departments most directly concerned.

I am copying this letter to PS/E(ST) Ministers and to PS/SoS, HO for Ministerial clearance and to Barry Potter and Sonia Phippard for information.

Yours sincerely

Ian Dixon

Ian Dixon
S&T Secretariat

THE GOVERNMENT RESPONSE TO THE ACOST REPORT: DEVELOPMENTS IN BIOTECHNOLOGY

3RD DRAFT

1. The Government welcomes the ACOST Report which provides a clear and succinct overview of some of the developments in biotechnology since publication of the 'Spinks Report' in 1980. The scope for application of biotechnology is vast and there is already significant commercial capitalisation of the new techniques in areas such as medical science and agriculture. The cross fertilisation of bioscience with electronics, materials science and engineering promises to transform whole sectors of industry; chemicals and food are two of the more immediately obvious candidates. Exploitation of biotechnology will also be crucial to the development of many of the cleaner technologies needed to reduce pollution and to rectify past environmental damage. The Government is encouraging action in all these areas.

2. The recommendations in the report deal with the core concerns of provision for the underlying science and for the enabling technologies themselves. On applications, they are not comprehensive, concentrating mainly on developments in agriculture.

3. The following paragraphs respond to ACOST's recommendations a. to k. as listed at the front of the report. As well as

commenting on each recommendation, the responses note related activities which are already taking place or are in prospect.

Recommendation a.

Government Departments should take a more proactive role in biotechnology

4. It is for industry to exploit the opportunities arising from the rapid development of biotechnology. Government's role is to facilitate this by stimulating the science base, by creating an effective, yet flexible regulatory regime and by ensuring adequate public information. In this context Government Departments are increasingly taking a proactive role on aspects of biotechnology which fall within their areas of responsibility. Annex A gives examples of the growing research effort financed by Departments and the Research Councils. Regulation is discussed in several places throughout the main text and public information is dealt with in paragraphs 21-28 and Annex B.

5. The Report highlights the importance of proper regulation, not least to ensure that the new technology achieves and retains public confidence. There has been a history of sensible regulation in respect of human health and safety under the Health and Safety at Work etc. Act 1974 (HSW Act) and specific regulations under the Act on genetic modification have been in

force since 1978.

6. Proposals to implement EC Directives on the contained use and deliberate release to the environment of genetically modified organisms and to take account of the recommendations of the Royal Commission on Environmental Pollution (RCEP) in its 13th report are being considered interdepartmentally. Appropriate legislative powers to ensure protection of the environment are contained in Part VI of the recently enacted Environmental Protection Act (EPA). These will balance the powers that already exist in respect of human health and safety under the HSW Act. The developing structure will entail regulations on environmental aspects under the new EPA. These regulations will be administered and enforced under unified arrangements being developed by HSE and DOE. Under these arrangements HSE inspectors will enforce regulations to protect the environment on behalf of DOE.

7. Recommendation a. is so wide ranging that, for clarity, individual responses are also given below to related subsidiary recommendations in Appendix A.

Appendix A - Safety Aspects

It will be important for the UK to continue to have a strong voice in the EC in what will inevitably be a high profile

political topic.

The UK government should press for this view [that the product should be evaluated for risk, and not the means used to produce it] to predominate in discussions in the EC.

8. The Government acknowledges the importance of EC discussions of regulation, both for the protection of the environment and consumer and for the climate of investment and competitiveness. UK has been particularly influential in international developments in biotechnology regulation, building upon the high regard for the Advisory Committee on Genetic Manipulation (ACGM) and strong interdepartmental coordination; the effort will continue in EC fora.

9. It is important to distinguish between products which contain genetically modified organisms (GMOs) and whose marketing therefore involves a release of such organisms to the environment and those which have been derived through techniques of genetic modification but where the marketed product does not itself contain GMOs. For products not containing GMOs, for exaample, human insulin and human growth hormone, the recommendation is eminently sensible. Products which contain GMOs are covered both by the EPA and by the EC Directive on deliberate release of GMOs to the environment and are identified for this purpose by the fact that a genetic modification technique was used to produce them. This is to ensure that they are adequately assessed for

any risk they may present. The Government agrees that specific product controls should apply to products containing GMOs, as they apply to other products, where these controls are adequate to protect man and the environment against risk. The Deliberate Release Directive is structured to enable products to be removed from the scope of its clearance mechanism when product controls, good enough to make such clearance unnecessary, are in place.

> **MAFF and the Advisory Committee on Novel Foods and Processes must take a more proactive role. We recommend that MAFF consider appointing a consumer representative to the ACNFP.**

10. As MAFF is both regulator and sponsor of research for the food industry, in many cases it would be improper to single out one form of technology as being more appropriate than another- and this can limit the scope for promoting a particular new product, process or technique. Given its role in the regulatory process, similar constraints apply to the Advisory Committee on Novel Foods and Processes (ACNFP). In these circumstances a proactive approach can ensure that industry has access to the latest techniques and that regulatory arrangements are updated to relate properly to new technology, particularly when considering the granting of product licences, consents, approvals etc.

11. The Food Safety Act 1990 has given powers under which irradiation can be authorised while maintaining controls which

will provide reassurance to consumers and MAFF is now consulting on detailed regulations to permit irradiation of food for public consumption from 1 January 1991. The Act also gives specific powers to regulate novel foods or food sources so that, in the absence of EC legislation, statutory backing may be given to the present arrangements operated informally by ACNFP. ACNFP has also published the guidelines it proposes to apply, under which the data required of industry are restricted to the minimum required by the nature of the product or process.

12. Consideration is being given to the addition of a lay member to ACNFP. It is however essentially a committee of experts in all scientific disciplines relevant to the safety of novel foods and processes. Its advice is in any case considered by the Food Advisory Committee (FAC) which includes a number of people from consumer backgrounds and has a broad interest in novel foods and processes. FAC has developed guidelines to assist it in considering the labelling of novel foods; these are likely to be published shortly.

Appendix A - Environmental Aspects

We recommend that the Department of the Environment take due account of the recommendations made by the RCEP, both in drawing up the relevant sections of the Environmental Protection Bill and, in particular, the regulations which

will follow from it. We further recommend that DOE consider ways of providing for increased lay representation in these and future decision processes.

13. Part VI of the EPA proposes a hierarchical system of controls for protecting the environment against the release of genetically modified organisms with more hazardous organisms requiring more comprehensive, consent-based controls. A general duty to prevent damage to the environment will apply to all operations involving genetically modified organisms. Assessment prior to the issuing of consents will, at the current state of knowledge, be on a case-by-case basis; this was one of the major recommendations made by the RCEP in its 13th Report on the "Deliberate Release of Genetically Engineered Organisms to the Environment", published in July 1989. It is also the approach adopted in the EC Directive on the Deliberate Release to the Environment of Genetically Modified Organisms which, together with the Directive on the Contained Use of Genetically Modified Micro-organisms, was agreed at a meeting of Environment Ministers in March 1990.

14. There are two ways in which provision has been made for increased lay representation in decision making processes. Firstly Mr Trippier, Minister for the Environment and Countryside, announced during the House of Commons committee stage of the EP Bill, that there would be widespread public consultation on the content of the regulations. Secondly,

although the membership of the Advisory Committee on Releases to the Environment (ACRE) (see paragraph 15) includes scientific expertise, it also includes people from a wide range of backgrounds, eg industry, local authorities, farmers and environmental expertise.

> **We support the RCEP proposal for a reconstituted Committee within the HSE which will have the responsibility for advising the Secretary of State for the Environment on each release.**

15. The Secretary of State for the Environment with the Health and Safety Commission has already established a new committee, ACRE. Its membership comprises experts from a broad range of disciplines and representatives, from both management and trade union sides of industry, and from other environmental interest groups; the secretariat is jointly provided by the Health and Safety Executive and the Department of the Environment. ACRE will advise the Secretary of State and the Health and Safety Commission on the human and environmental safety aspects of releases of all types of novel organisms into the environment. It has replaced the Intentional Introduction Sub-Committee of the ACGM and the DOE's Interim Advisory Committee on Introductions which advised Ministers on the ecological implications of introductions. One of its main tasks, apart from assessing the risks associated with particular releases, will be to prepare

guidance, and to advise Government about which areas of research to support.

Appendix A - Ethical Aspects

16. Ethical aspects are dealt with in paragraphs 54 and 55.

Appendix A - Welfare Aspects

The Ministry of Agriculture Fisheries and Food should consider how to convey better to the public the advantages offered by genetic engineering for the improvement of animal welfare.

17. Biotechnology is increasingly contributing to the production of veterinary diagnostics and medicines and it is mainly in this way that it benefits animal welfare. However it is the safety and efficacy of these products rather than their method of production that is important. Although MAFF could not be seen to favour one product compared to another because of the way it was produced, the Ministry is anxious that industry should take advantage of new developments which might bring about safer and more clearly targeted treatments and will feature the contribution which biotechnology can make along with other techniques in any future public information campaigns on animal welfare.

We recommend that the committees set-up to consider all license applications for animal experiments are kept fully informed of relevant issues that arise from developments in biotechnology, and that welfare aspects of transgenic animals and their progeny are given careful consideration.

18. MAFF is responsible for assuring the welfare of all farm animals, including genetically modified ones, and for ensuring the same standards of welfare apply to all animals regardless of their origin. The Ministry does not anticipate any specific welfare problems compared with traditional breeding practices for farm animals. If any arise, they will receive comparable treatment.

19. The Home Office exercises the control of experimental animals under the Animals (Scientific Procedures) Act 1986 following advice given by the Inspectorate which is established under section 18 and the Animal Procedures Committee established under section 19. A growing number of applications for licences involve biotechnology, and a senior member of the Inspectorate coordinates the consideration of those applications.

20. The Animal Procedures Committee has also been increasingly interesting itself in these issues and intends to devote a meeting to discussing them early next year. Great attention is

paid to the welfare aspects of animal procedures; and, in particular, it is well recognised that there can be serious welfare hazards in the development of animals with potentially harmful genetic defects, although the problems which arise from biotechnological innovation are not in principle different from those arising from selective breeding.

Recommendation b.

A programme of balanced information should be provided to the public on major aspects of biotechnology, such as genetic engineering. This would be of interest to both the scientific community and to industry where the lack of such a programme contributes to a major market imperfection. The Inter-departmental Committee on Biotechnology (ICBT) should co-ordinate the interests of other Government departments in this area. Elements of such a programme should include:

- **the commissioning by Government of an independent body such as the Royal Society or a charity (for example The Leverhulme Trust or The Nuffield Foundation) to prepare a booklet providing reliable information and analysis for the public.**

- **in the longer term, increasing the general level of understanding of such matters through education in**

schools. The DES should consider how to achieve this.

- **consideration by the ICBT of how to disaggregate those areas and industrial developments which have few or no safety and/or ethical considerations from those which have and to convey information on these divisions to the public.**

21. The Government agrees that there should be as much openness as possible on major developments in biotechnology, with objective information being made available to the public. Significant efforts have been made already - Annex B gives examples of information made available by Government. There is every intention to continue to maximise this.

22. There is a need to put across the message that the new biotechnology can bring benefits and is controllable, that risks can be foreseen and are being assessed, and that there is an appropriate and effective system of regulation under development, in conjunction with our EC partners, to safeguard both the health of the public and the environment.

23. ICBT is an appropriate body to coordinate the Government's provision of public information. It will need to give careful consideration to the extent and departmental distribution of Government involvement and the best ways of making information available. For instance, it is Government's responsibility to

provide information about the regulatory regime or departmental responsibilities, but it is for consumer interests and companies to supply information which relates to specific products.

24. Commissioning an independent body to provide a booklet providing reliable information and analysis could be useful in explaining the safety and ethical considerations underlying the Government's stance in regulating and supporting biotechnology. ICBT will explore this option carefully. A major step in independent assessment has already been taken with the publication of the 13th Report of the Royal Commission on Environmental Pollution in 1989 which provided authoritative coverage of the environmental hazards which might arise from the new technology.

25. The control regime brought in under in the EPA will include provision for public access to information, with due protection for commercial confidentiality and for data whose disclosure might lead to damage to the environment. The intention is to set up public registers of information obtained under Part VI. In addition, the Act stipulates that applicants for consent to release genetically modified organisms advertise their proposals.

26. Government agrees with ACOST on the role of schools in increasing the general level of public understanding of biotechnology in the longer term. The programmes of study for key stage 4 in the science National Curriculum for schools

include the basic principles of genetic modification in relation to drug and hormone production and awareness of ethical issues. This provides a starting point for teaching about new developments in biotechnology. The programmes of study will be kept under review by DES and the National Curriculum Council and, if developments in biotechnology and experience in schools are such as to make amendment of the programmes of study appropriate, this will be done.

27. DTI has supported a three-year programme at the National Centre for School Biotechnology (University of Reading) providing resource material, advice and workshops for teachers.

28. The Government agrees on the need to isolate aspects of biotechnology that raise ethical issues and to make clear to the public that they are being addressed appropriately. (See paragraphs 54 and 55.) For instance the aims and ethical considerations surrounding human and animal embryonal stem cell biology are different and need to be treated separately. ICBT will continue to provide a focus for this activity.

Recommendation c.

Inter-research council co-ordination of biotechnology should be strengthened. For example, an opportunity exists for the AFRC and SERC to consider a co-ordinated programme of

molecular, biochemical and physiological studies in the plant sciences

29. The Research Councils and ABRC recognise the need for close collaboration. ABRC has recently decided to set up a sub-committee to review responsibilities for current and prospective work and to develop a development strategy for biotechnology. Its members will include AFRC, MRC, NERC and SERC.

30. The Biotechnology Joint Advisory Board (BJAB) was originally established by SERC and DTI, AFRC and NERC are now included and MRC is also represented. The Board will develop a strategic view of R&D and foster cross-Council programmes of basic science, technology transfer and collaborative R&D directed towards future UK industrial competitiveness.

31. AFRC and SERC are examining the scope for a joint programme in plant biochemistry. They have also recently announced a joint 'clean technology' initiative, which has a strong biotechnology input.

Recommendation d.

UK research institutions should explore ways of taking a more European perspective and should determine how they can gain greater added value for the UK from collaboration with

European partners.

32. The Government supports this recommendation. The Research Councils are considering how they can contribute further to its implementation and have already established mechanisms for co-ordinating their input to EC programmes. Interested Government Departments (DES, DTI, MAFF and DH) are working together with Research Councils which have interests in biotechnology to encourage UK participation in the new opportunities within the Third EC Framework Programme

Recommendation e.

Increased industrial support for biotechnology in UK universities and research institutes is required in order to enhance the transfer of the considerable scientific expertise into commercial success

33. The Government welcomes this recommendation which endorses the considerable efforts already made to increase private sector involvement. Departments and Research Councils, of course, have substantial experience of running collaborative programmes involving industry and HEIs - the PROSAMO programme is an example (see paragraph A6). A strong portfolio of LINK programmes in biotechnology has also been developed to facilitate the transfer of research knowledge from the science base to

industry. Turning that knowledge into commercial success is for the companies themselves.

Recommendation f.

As a matter of priority UK strengths in plant biotechnology should be reinforced. Government, in conjunction with industry and the research community, should aim to provide guidance to those in universities and the research institutes on the balance between work of interest to industry and work to satisfy national requirements on environmental issues. Emphasis should be placed on stimulating research into isolating important genes and to learning how to manipulate them in plants of economic and of scientific importance. Further technical and economic assessment of the potential for producing chemicals from plants should be encouraged. The Priorities Board for Research and Development in Agriculture and Food might consider how to stimulate interaction between the agricultural and chemical industries.

34. Within the UK science base it is important to give particular attention to areas which have both the potential for scientific advance and long-term wealth creation. The Government, therefore welcomes the recommendation to reinforce UK strengths in plant biotechnology and agrees that emphasis should

be placed on research into isolating and manipulating plant genes of economic and scientific importance. AFRC, the main publicly funded player in this field, has these areas, together with plant biochemistry and physiology as major elements in its Corporate Plan.

35. Annex A describes some of the Government funded research activities in plant biotechnology. BJAB will consider the need for further initiatives in this area.

36. There is a scope for further collaborations between industry and the science base in LINK programmes in Eukaryotic Genetic Engineering, the Control of Plant Metabolism and Crops for Industrial Use.

37. The Government agrees that the agenda of the Priorities Board for Research and Development in Agriculture and Food should include consideration of how best to stimulate interaction between the agricultural and chemical industries in relation to the use of plants as sources of chemical feedstocks.

Recommendation g.

A strategic decision by Government and industry to support embryonal stem cell biology will consolidate our strengths and will complement the UK initiative in the research on the

mapping of the human genome. The MRC and the AFRC should consider how they might co-ordinate an initiative to provide increased support in this area of biological research, taking into account the strengths that exist in the cancer charity supported Institutes. They should also continue to give priority to work in genome mapping and automated sequencing techniques.

38. BJAB will consider the first part of this recommendation. On the second, AFRC and MRC are discussing the best way to co-ordinate the expansion of work on stem cell biology.

39. AFRC is diverting funds into embryonal stem cell biology where the current UK lead is under threat from USA and Britain's EC partners who have recognised its potential for wealth creation and are increasing support.

40. A major MRC initiative in the genetics of human disease will cover somatic gene therapy, requiring study of adult stem cells; the initiative will also involve training in techniques for the use of embryonal stem cells.

Recommendation h.

AFRC, MAFF and DTI should give consideration to the development of a programme in embryo multiplication in

cattle; to applying biotechnology to the production of higher quality and healthier products; and to the funding of a programme to encourage the development of efficient methods for the construction of transgenic mice and other laboratory animals.

41. This recommendation will also be considered by AFRC and Departments involved, consulting BJAB as necessary. Funding is under consideration for a programme of research underpinning embryo multiplication techniques and for a joint industry/AFRC Institute programme on embryo cloning in cattle.

42. AFRC has a major programme of research on transgenic animals which offers considerable potential for UK industry. MRC also has a substantial interest in development research using transgenic rodent technology to provide models of human diseases and to investigate basic biological processes (eg gene expression in development) and their perturbation by toxins and teratogens. Collaboration already exists between MRC and AFRC in Cambridge and Edinburgh. Enhanced facilities for studying transgenic rodents are under construction at the MRC's National Institute of Medical Research. Under the Eukaryotic Genetic Engineering LINK programme, AFRC and SERC, together with DTI, are developing a major project in construction of transgenic rats.

Recommendation i.

Manpower shortages should be addressed. The DES, the Research Councils and DTI should consider how to establish a co-ordinated approach with industry for the future provision of manpower needs in the biotechnology related industries.

43. The Government will invite the ABRC to consider, in its review of co-ordination arrangements for biotechnology, how to improve the assessment of manpower needs and postgraduate provision in biotechnology. Manpower and training will also be considered by BJAB to ensure coordination of the approach with industry.

44. Recent increases in the Science Budget have allowed the Research Councils to provide some additional support for postgraduate training. In addition, the postdoctoral fellowship schemes of the Councils, the Royal Society and the Fellowship of Engineering have been expanded. There are, however, continued problems with the recruitment of high quality graduates to postgraduate studentships and postdoctoral positions in the biological sciences. These recruitment problems need to be speedily addressed by ABRC. While the Government expects the Councils to target postgraduate support towards areas of skill shortages, it accepts that, particularly in biotechnology, where the initial training is common to a range of careers in the biological sciences, forecasting and planning of postgraduate numbers will be imprecise.

45. A major DES objective for Science Budget expenditure is to achieve a better match between support for postgraduate training and the needs of UK industry and the Science Base, in biotechnology as in other fields. The Research Councils' effectiveness in meeting this objective will be monitored closely. ABRC has recently established a sub-committee on postgraduate support. Its terms of reference include reporting on the scope for improvements across Councils in targeting studentships to meet identified needs in the science base and industry.

46. The University Grants Committee's Biotechnology Initiative was recently reviewed by the Committee's successor, the Universities Funding Council. The Review concluded that the Initiative was successful and the Council decided to continue special funding to eight institutions. At the same time universities were invited to bid for support under a new tranche of the Initiative. As a result, the Council has allocated £66,000 a year to support 36 new posts in 14 institutions.

47. Paragraph 7.2.16 of the Report states that the Teaching Company Scheme (TCS) in biotechnology should be expanded and the Integrated Graduate Development Scheme (IGDS) should be extended to biotechnology. Neither scheme excludes biotechnology and both can respond to proposals from industry in biotechnology.

Recommendation j.

Increased support is required for the related skills in chemistry which UK industry will require to take full advantage of the initiatives in protein engineering. It will be important to sustain the UK's strengths in crystallography and to enhance support for 2-D NMR and molecular modelling. The Research Councils should consider this in conjunction with their funding of protein engineering. The DTI and SERC in their training role in for example the Teaching Company Scheme (TCS) and the Integrated Graduate Development Scheme (IGDS) should also take action in this respect.

48. This topic will be considered by the ABRC and BJAB, with additional advice from the Management Committee of the LINK programme in Protein Engineering.

49. The role of TCS and IGDS has been described in paragraph 47. Other schemes already in place are supporting general postgraduate training in the general area of biotechnology, including protein structure and/or engineering.

50. AFRC supports fundamental research on protein engineering and on molecular recognition in its institutes and in high education institutes. The Council has appointed a co-ordinator

to maximise the effectiveness of its programme in protein engineering and has strengthened its expertise in x-ray crystallography and biomolecular computing.

51. The protein engineering interdisciplinary research centre that MRC has set up at Cambridge is already focusing on the need for crystallography, 2D NMR and molecular modelling as part of the development of protein engineering. MRC's Corporate Strategy recognises the need to maintain the UK's strength in protein crystallography and enhance that in 2-D NMR.

52. A recent MRC strategic review emphasised the need for increased support for research on macro-molecular structure and function and for concentrating all the relevant techniques in a number of state-of-the-art centres. However, as the Report recognises, the general problems of recruitment to research apply to this field at least as much as to others.

53. In addition to support of LINK and underpinning programmes in protein engineering, SERC also funds work on protein structure and engineering through the molecular recognition initiative, with underpinning work supported through the Biological Sciences Committee.

Recommendation k

Consideration should be given to a detailed and systematic analysis of the ethical issues that relate to certain aspects of genetic manipulation. This could possibly be by means of ad hoc Committees along the line of the Warnock Committee.

54. Although certain aspects of genetic modification raise questions of legitimate public interest and concern, most biotechnological applications do not raise ethical issues. The Government's view is that where ethical issues arise from genetic modification, these should not be dealt with in a general way, but case-by-case. Ad hoc Committees may often be the best way of obtaining informed comment and advice.

55. Some ethical issues have received substantial attention already. For example, the Medical Research Council has played a leading role in the preparation of the European Medical Research Councils' guidelines on human gene therapy. And in November 1989 the Government announced the establishment of a Committee on the Ethics of Gene Therapy under the chairmanship of Sir Cecil Clothier QC. Among other matters the Committee will draw up ethical guidance for the medical profession on the treatment of genetic disorders.

ANNEX A

EXAMPLES OF GOVERNMENT FUNDED RESEARCH

A1. Government funded research specifically focused on biotechnology is underpinned by a wider programme of basic and strategic research in biology, chemistry, physics, process engineering, mechanical design, and materials, which all produce results and skills necessary for long-term exploitation of biotechnology by industry. The following examples illustrate how Departments and Research Councils are providing support for both these aspects in their respective areas of responsibility.

DEPARTMENT OF THE ENVIRONMENT

A2. DOE supports research in biotechnology in pursuit of its policy responsibilities in the prevention of environmental damage by GMOs and in preventing or abating pollution. The techniques of molecular biology which have been developed for biotechnology are also proving of great value in important environmental concerns such as biodiversity, adaption to environmental change, gene flow in populations and taxonomy.

A3. DOE's broadly based research programme on the impact of environmental releases of GMOs is expected to run at about £1m per year over the next two years. Contracts currently let and planned for the immediate future cover such areas as microbial ecology; organism dispersal; leakage of genetic material; releases into aquatic environments; the relevance of population genetics; the risks associated with introducing novel species into the UK and the use of models to predict the outcome. These projects are, in the main, targeted on assessing the risks which might be associated with the release of both genetically modified organisms and non-indigenous organisms.

A4. DOE and DTI have recently joined forces to launch an Environmental Technology Innovation Scheme (ETIS). ETIS aims to encourage innovation, improve environmental standards and help users or suppliers of environmental technology to become more competitive. Priority areas have been identified some of which provide scope for biotechnology applications.

DEPARTMENT OF HEALTH

A5. DH direct funding of research in biotechnology is limited, but it has, for example, agreed to contribute to the LINK Molecular Sensors programme.

DEPARTMENT OF TRADE AND INDUSTRY

A6. DTI innovation policy in biotechnology is reflected in significant research programmes and projects across the range of application, as illustrated by the following examples:

> The Plant Gene Tool Kit project drew 11 companies into co-funding with DTI a 3 year and £3m effort at research institutes and universities to reduce to practice the transfer of foreign genes into key crop plants;
>
> The PROSAMO programme (Planned Release of Selected and Modified Organisms) is a similar collaboration (£1.5m) with 8 companies and AFRC to provide a firmer scientific base for the objective assessment of the risks associated with genetic release;
>
> The UK contribution to the Eureka programme was strengthened when the Imperial Cancer Research Fund laboratories joined Amersham International and Bertin (France) in a project in the advanced automation of molecular biology;

The SMART scheme (Small Firms Merit Award for Research and Technology) has encouraged academic researchers to set up companies to take their work forward commercially, including Polyclonal Antibodies Ltd (Professor Landon, St Bartholomew's Hospital) and Affinity Chromatography Ltd (Dr Lowe, University of Cambridge).

A7. The following list of LINK programmes, relevant to biotechnology gives Research Council involvement in brackets:

Biochemical Engineering (DTI, SERC)
Biotransformations (DTI, SERC)
Control of Plant and Microbial Metabolism (AFRC, DTI, SERC)
Crops for Industrial Use (AFRC, DTI)
Eukaryotic Genetic Engineering (AFRC, DTI, SERC)
Food Processing Science (DTI, MAFF)
Molecular sensors (AFRC, DTI, MOD, MRC, SERC)
Selective Drug Delivery and Targeting (DTI, MRC, SERC)

MINISTRY OF AGRICULTURE, FISHERIES AND FOOD

A8. MAFF provides about £2m for research on novel animal and plant breeding techniques and very substantially more for research using biotechnological methods. It receives advice from the Priorities Board for Agricultural Research, which provides a forum for commercial advice on the most effective allocation of the Ministry's research priorities. In addition, the LINK Agro-Food Quality programme, which will provide a total of £16m (half from MAFF with possibly further support from other Government Departments) for research for applying biotechnology to the production of higher quality and more nutritious food products, has recently been approved.

HEALTH AND SAFETY EXECUTIVE

A9. Through its biomedical research programme HSE has funded research on the following:

hazards associated with large scale growth of rDNA organisms;

DNA repair and systems evaluation;

tumour risk from cloned oncogenes;

planned release of genetically modified plants.

AGRICULTURE AND FOOD RESEARCH COUNCIL

A10. Through grants to institutes and HEIs, AFRC supports a wide ranging programme of biotechnology and underpinning science involving plants, animals and food. The Plant Molecular Biology programme, costing £14m in total, has recently been launched and covers many aspects of plant genetics and development. Work in transgenic animal biology is being extended to include embryonal stem cells. The AFRC Institute of Animal Physiology and Genetic Research, a world leader in embryo multiplication, has applied with other bodies to DTI for funding for a possible programme on embryo cloning in cattle. In addition to its sponsorship of the LINK programme AFRC supports fundamental research on protein engineering and molecular recognition, and has strengthened its expertise in X-ray crystallography and biomolecular computing. The Council is a co-sponsor with DTI and industry of the PROSAMO programme, which is providing a firmer scientific base for objective assessment of the risks associated with genetic releases.

MEDICAL RESEARCH COUNCIL

A11. MRC supports basic research in several areas of relevance to biotechnology, including molecular biology, immunology, developmental biology and neurobiology. New Units have been established (eg Protein Function and Design) and IRCs (Cell Biology and Protein Engineering) as well as introducing new programmes into existing MRC Institutes (eg the setting up of a Laboratory of Eukaryotic Gene Expression at the National Institute for Medical REsearch (NIMR)). MRC does not have advisory or executive committees dealing specifically with biotechnology.

A12. Current support falls into four main categories: diagnosis and assay; genetic engineering; monoclonal antibodies; conventional vaccines, drugs and therapeutic reagents. Each category covers work with a clear intent to produce something of commercial value and basic underpinning research. Humanising rat monoclonal antibodies for cancer therapy and an extensive programme to develop vaccines against HIV infection are examples of research aimed at direct biotechnological advance.

A13. The Council takes direct responsibility for industrial exploitation of research carried out on its own establishments where a number of projects, fully funded by industry have been effective in the transfer of important technology. MRC played a key role in the development of Celltech and set up its own Collaborative Centre, adjacent to NIMR, to act as a bridge in the transfer of research to industry. More recently a new company, Cambridge Antibody Technology, set up with venture capital, will have close links with the Laboratory of Molecular Biology in Cambridge.

NATURAL ENVIRONMENT RESEARCH COUNCIL

A14. NERC has supported a Special Topic Programme on biotechnology and maintains programmes on the development of baculovirus expression vectors, the development of viral insecticides, and the risks of release, at its Institutes of Virology and Environmental Microbiology and of Freshwater Ecology.

SCIENCE AND ENGINEERING RESEARCH COUNCIL

A15. SERC funds through its Biotechnology Directorate a targeted programme of strategic research and enabling technologies in areas with potential for exploitation in the long-term. SERC has increased its conventional grant funding through the Biotechnology Directorate by 50% over the past two years, and recently announced a new Interdisciplinary Research Centre (IRC) in Biochemical Engineering at University College, London (UCL).

EXAMPLES OF PUBLIC INFORMATION

B1. Government has been providing information to the public on subjects such as human and environmental safety in several ways: NERC held an open meeting on biotechnology, including risks of release of GMOs as early as July 1987. In October 1988 AFRC held a Workshop on Genetic Release for scientists from industry, institutes and universities as well as invited individuals from the press and organisations such as the RSPCA. A meeting in April 1990 on the 'Impact of New and Impending Regulations on Biotechnology' was sponsored by DOE and HSE together with the Bioindustry Association.

B2. The role played by the Advisory Committee on Genetic Manipulation in recent years in providing authoritative information to the public and guidance to industry and to the research community should also be recognised. The current level of public confidence in the UK owes much to the Committee's efforts.

B3. Public communication is an important component of many of the new initiatives eg the PROSAMO programme (see paragraph A6).

B4. Publication of the RCEP Report has already been mentioned in paragraph 13. An explanatory leaflet on 'Biotechnology and Genetically Modified Organisms: the Proposed New Controls' has been issued by HSE and DOE. It explains to the public, industry and others the new controls which the Government proposes to introduce on those using techniques of genetic modification or dealing with genetically modified organisms - and gives contact addresses for further information.

B5. The Advisory Committee on Novel Foods and Processes (ACNFP) has recently published its first annual report as a means of informing the public of its activities, including reviewing applications relating to foods from genetically modified sources made under the current voluntary scheme.

file Kb

10 DOWNING STREET

From the Private Secretary

7 February 1984

BIOTECHNOLOGY COMMITTEES

The Prime Minister has seen your Secretary of State's minute of 1 February and, in the light of his further explanation, accepts that the Inter-Departmental Committee on Biotechnology should be allowed to continue and that Mr. Baker should continue to hold meetings with industrialists. She feels it would be useful to consider in about a year whether the continued existence of these two groups is justified.

I am copying this letter to those who received a copy of your Secretary of State's minute dated 1 February, and to Dr. Nicholson.

ANDREW TURNBULL

Callum McCarthy, Esq.,
Department of Trade and Industry.

10 DOWNING STREET

①

Prime Minister

Mr Tebbit has returned arguing the case for retaining the Inter Departmental Committee on Biotechnology and Mr Baker's group of businessmen.

Robin Nicholson is content provided both committees are looked at again in a year or so.

Agree?

AT
6/2

W.0104 6 February 1984

PRIME MINISTER

BIOTECHNOLOGY COMMITTEES

I have seen a copy of the minute to you of 1 February on this subject from the Secretary of State for Trade and Industry. In it Mr Tebbit expands on the case made in his minute of 23 December last for the Interdepartmental Committee on Biotechnology (ICBT) to be retained and a consultative committee of industrialists to be set up.

2. As I pointed out in my minute to you of 5 January, biotechnology is an extremely pervasive subject and the expertise in Government is broadly spread amongst a number of Departments. In these circumstances there is real value in having a co-ordinating committee such as ICBT, and I believe Mr Tebbit is right in wishing to retain it.

3. In considering the value of consultative committees of industrialists, I would make a distinction between mature industries with a well-established structure, and industries based on new technologies. An example of the latter group is space, where the Space Consultative Committee (chaired by Mr Baker) has been a valuable forum in which to bring together representatives of diverse industries with space interests. Information Technology is another area where special arrangements have had to be made. I believe that a consultative group in Biotechnology will be of value both to Government and, as Mr Tebbit suggests, to the industrialists themselves.

4. The best course of action might be for you to approve

both groups but to ask for a report on their activities in a year's time, at which stage the need for their continued existence could be reviewed.

5. I am copying this minute to Sir Robert Armstrong.

RBN

ROBIN B NICHOLSON
Chief Scientific Adviser

Cabinet Office
6 February 1984

Science & Technology: Acard report on biotechnology Jan. 1980.

JF5511

cc DP
cc D. Nicholson C.O.

PRIME MINISTER

BIOTECHNOLOGY COMMITTEES

Your Private Secretary wrote to mine on 9 January concerning my proposal to disband the Official Committee but to retain the Inter-departmental Committee on Biotechnology and the proposed consultative committee of Industrialists. I am sorry if my minute of 23 December did not make the case for my proposals clear.

2 The Inter-departmental Committee on Biotechnology (ICBT) was set up following publication of the White Paper on Biotechnology (Cmnd 8177) in 1981 and in response to a recommendation in the ACARD/ABRC/Royal Society report on Biotechnology (the Spinks Report). The need for such a Committee arises from the extremely pervasive nature of the technologies involved, with applications which span a whole range of industries including manufacturing, services and agriculture. Additionally it provides a format to co-ordinate the activity of Government Departments and bodies such as the Reserch Councils, as well as being contact point on biotechnology for those outside Government, in industry and the academic world. The Committee does not meet frequently but one of the major benefits has been the

establishment of a network of contacts in Departments and other bodies, enabling better co-ordination and effectiveness at the informal level as well as formally. There is unanimous agreement among other Departments concerned that ICBT is doing a useful job. The Education, Science and Arts Select Committee on Biotechnology was critical of the arrangements for co-ordinating Government activity in biotechnology and the Government's response in January 1983 laid particular emphasis on the role of ICBT in bringing together the wide range of interests in Departments and related bodies.

3 The proposal that a group of senior industrialists should continue to meet under Kenneth Baker's chairmanship stems from a successful exploratory discussion held last year. This was attended by very senior industrialists from the key companies in the field and the industrialists themselves expressed a wish for further meetings. I am confident that those key people would continue to attend. There is much to be gained from discussion with representatives from the wide range of sectors involved in biotechnology - food, chemicals, pharmaceuticals, process plant, agriculture and waste treatment. The meeting would not be held frequently, but I, and Kenneth, are convinced that they would be of real value.

They would!

4 I agree that it would be useful for ACARD to review this topic from time to time but I do not think that it can be a substitue for the more specific and immediate activities on which I consider ICBT and the industrial group should be engaged.

5 I hope that on the basis of this further explanation you can agree to the proposals in my minute of 23 December. I am copying this minute as before.

NT

N T

1 February 1984

Department of Trade and Industry

Sc & Tech Jan 80
Biotechnology

File

10 DOWNING STREET

From the Private Secretary

9 January 1984

OFFICIAL COMMITTEE ON BIOTECHNOLOGY

The Prime Minister has seen your Secretary of State's minute of 23 December on Committees in the area of biotechnology. She is concerned about the proliferation of Committees in this area, which she feels may absorb the time and energies of Ministers and officials and deflect them from the real decisions which have to be taken. She agrees that the Official Committee on Biotechnology should be wound up and feels that the Interdepartmental Committee on Biotechnology could also be dispensed with. She also questions the need for a Consultative Committee of industrialists. She doubts whether we need such a Committee in this area any more than in other areas of modern industrial development and she doubts whether industrialists would really send their best people to such a group.

She suggests that ACARD be asked to keep a watching brief and at some appropriate time Sir Henry Chilver could be asked to review the UK's performance and standing in biotechnology.

I am sending copies of this letter to John Kerr (HM Treasury), Ellen Roberts (Department of Health and Social Security), Brett Bonner (Departmnet of Employment), Alan Davis (Department of the Environment), Michael Reidy (Department of Energy), John Graham (Scottish Office), Colin Jones (Welsh Office), Derek Hill (Northern Ireland Office), Ivor Llewelyn (Ministry of Agriculture, Fisheries and Food), Richard Hatfield (Cabinet Office) and Dr. Nicholson (Cabinet Office).

MR. A. TURNBULL

Callum McCarthy, Esq.,
Department of Trade and Industry.

10 DOWNING STREET

①

Prime Minister

To see Mr Tebbit's recommendations and Dr Nicholson's comments

Agree

(i) that Official Committee be wound up? Yes

(ii) that the Interdepartmental committee be retained? No

(iii) that Kenneth Baker's informal consultative group be retained? No

(iv) that ACARD / Sir Henry Chilver be asked to keep a watching brief and to review UK performance in biotechnology at some future date? Yes ✓

AT
6/1

CC NO

W.015 5 January 1984

PRIME MINISTER

I am appalled at the committees that DTI a) has b) wants to retain c) wants to set up. They take an immense amount of time + divert energies away from the real decisions which DTI has to take. We do NOT need a committee on this any more than on other aspects of modern industrial development. We have ACARD. I agree with Robin Nicholson MT

OFFICIAL COMMITTEE ON BIOTECHNOLOGY

I have seen a copy of the minute to you of 23 December 1983 on Biotechnology from the Secretary of State for Trade and Industry. In it Mr Tebbit proposes first that the Official Committee on Biotechnology be dissolved leaving the lower level Interdepartmental Committee on Biotechnology in existence, and secondly that an industrial consultative committee be set up under the Chairmanship of Mr Kenneth Baker.

2. Whether or not this is the right approach depends on what future role Ministers see for Government in Biotechnology. Unfortunately Mr Tebbit's minute gives little indication of DTI's thinking on this point.

3. Biotechnology is one of those technologies (Space, and Information Technology are other examples) which cut across the current industrial structure. There are no major 'biotechnology companies' in the UK at the moment although many industries, eg brewing, pharmaceuticals, chemical plant and food, have skills and expertise which will be essential parts of a biotechnology company.

4. Clearly it is for industry itself, through new companies, joint ventures etc, to create an appropriate structure which will ensure that UK industry is able to become technically and commercially competitive in biotechnology so as to be able to take advantage of the many new business opportunities which are thought to be coming in the future.

5. I suggest that Government's role must be first to ensure that it does not obstruct the necessary changes in the relevant industries, and secondly that it uses its considerable powers of public purchasing, regulation and R & D funding to reinforce the commercial judgement of industry.

6. The problem for Government is that expertise in biotechnology is widely spread around Whitehall with there being no obvious reason for DTI to be in the lead other than its role as "sponsor" of many of the private sector companies that should be leading the way in biotechnology. Other Departments such as MAFF, DoE, DHSS and (through the Research Councils) DES could claim expertise and responsibilities at least equal to those of DTI.

7. Thus while Mr Tebbit's proposals will provide a welcome focus for Biotechnology in Whitehall, there must be some concern whether the fora proposed are certain to meet the needs I outline in paragraph 5 above. You may feel that Biotechnology is too important for the performance of Government to be left entirely in the hands of one Department with limited skills and responsibilities in this area. An annual report to Ministers, effectively a 'watchdog activity', could also become a piece of bureaucracy of limited value.

8. My advice is to use ACARD which did, of course, set the whole subject going with the Spinks report in 1980 and which continues to have both industrial and scientific expertise which is appropriate to advise on the development of biotechnology. You could ask Sir Henry Chilver to review the UK's performance and standing in biotechnology at an appropriate time. It would then be appropriate to mention this request to Sir Henry and ACARD in your reply to Mr Tebbit.

9. I am copying this minute to Sir Robert Armstrong.

ROBIN B NICHOLSON
Chief Scientific Adviser

SCIENCE & ~~EDUCATION~~ Tech JAN. 80

REPORT ON BIOTEC.

JP

10 DOWNING STREET

From the Private Secretary

DR. NICHOLSON

OFFICIAL COMMITTEE ON BIOTECHNOLOGY

Before putting the Secretary of State for Trade and Industry's minute of 23 December into the Prime Minister, I would be grateful for your advice.

(ANDREW TURNBULL)
23 December 1983

CT

OW

B/F with
Dr Nicholson's advice. cc NO
AT 23/12

[redacted]

JH 472

PRIME MINISTER

OFFICIAL COMMITTEE ON BIOTECHNOLOGY

You agreed in June last year 1982 that the Official Committee on Biotechnology (BT) should continue for a further year. It was the intention to report to you in June but the Election intervened. The Official Committee itself has met four times over the past 18 months and has dealt primarily with policy matters and questions which called for confidential discussions amongst Government Departments. These have included the Government's response to the Interim Report on Biotechnology by the House of Commons Select Committee on Education, Science and the Arts; the proposed reconstitution of the Genetic Manipulation Advisory Group; my own Department's programme "Biotechnology in Industry"; and policy towards international collaboration in biotechnology, notably the proposals arising from the Versailles Summit and a proposal made by the United Nations Industrial Development Organisation for an international biotechnology centre. Officials have also considered the need for the various Committees in the biotechnology field.

2 In addition to the Official Committee on Biotechnology there is a second Committee - the Interdepartmental Committee on

Biotechnology (ICBT) - which meets under the chairmanship of the Government Chemist. It has wider representation, including some from outside Whitehall, and it provides the main focus for action in Government. It serves as a contact point on biotechnology for those outside Government, it tackles specific problems and it provides co-ordination between Departments and with the Research Councils.

3 Neither BT nor ICBT has industrial representation and since the Election consideration has been given to the need for a consultative committee of industrialists to guide Ministers and officials in the industrial development of biotechnology. An exploratory meeting chaired by Kenneth Baker has confirmed a strong interest from senior industrialists in such a forum and it is therefore proposed that a consultative committee of industrialists should continue to meet under Kenneth Baker's chairmanship. It is also proposed that ICBT should continue alongside the industrial committee to deal with matters requiring interdepartmental action and co-ordination.

This is for industry.

To which they will send their third eleven. We already have ACARD

4 There remains the question of the Official Committee. As the past 18 months has demonstrated policy matters arise from time to time on which Ministers require co-ordinated policy reviews and advice and which require confidential discussion amongst departments. These have not arisen frequently, however, and continuation of the Official Committee is not, in my view, justified. I therefore propose that the Official Committee

should be disbanded. If any interested party wishes to raise policy matters which require confidential discussion amongst Departments, the Department of Trade and Industry would be happy to convene an ad hoc meeting.

5 I am copying this to the Chancellor, to the Secretaries of State for Health and Social Security, Employment, Environment, Energy, Scotland, Wales and Northern Ireland, to the Minister of Agriculture, Fisheries and Food, and to Sir Robert Armstrong.

NT

N T

23 December 1983

Department of Trade and Industry

29/1

CHIEF SECRETARY TO THE TREASURY

Treasury Chambers, Parliament Street, SW1P 3AG

Mrs I Wilde
Private Secretary to the
Rt Hon Sir Keith Joseph MP
Secretary of State
Department of Education and
 Science
Elizabeth House
York Road
London SE1 7PH

24 January 1983

Dear Imogen

BIOTECHNOLOGY: GOVERNMENT RESPONSE TO SELECT COMMITTEE REPORT

The Chief Secretary has seen a copy of your Secretary of State's minute of 11 January to the Prime Minister, with which he enclosed a draft response to the Select Committee's Report.

The Chief Secretary is content with the draft proposed.

I am sending copies of this letter to the Private Secretaries to the Prime Minister and the other recipients of Sir Keith Joseph's minute.

Yours sincerely

JSt. Gieve

JOHN GIEVE
Private Secretary

Science & Tech.

Working Party on Biotechnology.

Jan 83

Science, Tech Bp
file

10 DOWNING STREET

From the Principal Private Secretary

SIR ROBERT ARMSTRONG

Thank you for your minute of 20 January (A083/0207) about the Select Committee on Education, Science and the Arts.

I share your concern at the suggestion that the Prime Minister should appear in front of this Committee. But I do not think that it is likely to happen. On a previous occasion when the suggestion was made, it was made clear to the Chairman that the Prime Minister would not be willing to accept such an invitation: if the invitation was repeated, I have no doubt that it will get the same answer.

E E R BUTLER

21 January 1983

10 DOWNING STREET

~~Robin~~

No cause for alarm.

This is very much a unilateral operation by Christopher Price, who is chairman of the Select Committee. He has tried this previously and was firmly told by Ian Gow that it wasn't on. I drew Sir Keith's prediction to the PM's attention; Mr Price's request would get the same dusty answer this time.

TF 2/1

Ref: A083/0207

MR. BUTLER

Mr. Flesher
I strongly agree
with Sir R. Armstrong's comment.
FERB 21.1.

Dr. Nicholson has minuted you direct about the draft Government response to the interim report by the Select Committee on Education, Science and the Arts, on the protection of the research base in biotechnology. I have nothing to add to Dr. Nicholson's comments on the draft.

2. But I am concerned by the suggestion in the first paragraph of the minute which the Secretary of State for Education and Science sent to the Prime Minister on 11th January that the Select Committee may wish to request the Prime Minister to appear in front of them to ask questions about her declared role as the ultimate co-ordinator of science policy within central Government. I hope that the Prime Minister will be very reluctant indeed to accept any suggestion that she should undertake to give evidence to the Select Committee. If once she gives evidence to one Select Committee, she will certainly be called to give evidence to others, including particularly the Select Committee on the Treasury and the Civil Service; and, once having agreed to go to one it would be very difficult not to go to others.

3. If the Committee insists on having a Minister, I suppose the Secretary of State for Education and Science, or possibly the Permanent Under Secretary of State with special responsibilities for science (I am not sure whether it is Mr. Shelton or Mr. Waldegrave), might be asked to give evidence. The alternative is that Dr. Nicholson and I should go; and, little as I want to go, I should be prepared to offer myself up in order to protect the Prime Minister's position.

RtA

Robert Armstrong

20th January 1983

Science & Tech.
Jan '80,
Report on Biotechnology

Science + Tech. Ind

c. MAFF
Env.
Scotland
Wales
Industry

Social Servic
CS-HMT
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10 DOWNING STREET

From the Private Secretary

18 January 1983

The Prime Minister has seen your Secretary of State's minute of 11 January covering the Government's response to the Education, Science and Arts Select Committees Report on the Protection of the Research Base on Biotechnology. She has agreed that your Secretary of State and the Secretary of State for Industry may publish the response as proposed, subject to the comments of other colleagues.

I am sending a copy of this to the Private Secretaries of the recipients of your Secretary of State's minute.

(TIMOTHY FLESHER)

Mrs. Imogen Wilde,
Department of Education and Science.

10 DOWNING STREET

From the Private Secretary

DR. NICHOLSON

Thank you for your minute of 17 January about the Government response to the Education, Science and Arts Select Committees Report on the Protection of the Research Base on Biotechnology. The Prime Minister was grateful for your comments and she has approved the draft response submitted by the Secretary of State for Education and Science.

(TIMOTHY FLESHER)

18 January 1983

Prime Minister: 1

You asked for Dr Nicholsons comments on this report. Agree that Sir Keith should publish his response as proposed?

Yes mt

W.029

17 January 1983 TF

cc: Sir Robert Armstrong
Mr Sparrow
Dr Davies
Mr Courtney
Mr King

17/1

TO: MR FLESHER, No 10

FROM: DR NICHOLSON

BIOTECHNOLOGY: GOVERNMENT RESPONSE TO EDUCATION, SCIENCE AND THE ARTS COMMITTEE'S INTERIM REPORT ON THE PROTECTION OF THE RESEARCH BASE

In assessing the draft Government response to the Select Committee's Interim Report, I should first comment that the Report is pretty awful. Much of the comment and many of the recommendations are not specific to biotechnology and could equally well have been made about information technology, for example. In addition there is a strong flavour of solving problems by throwing money at them throughout the Report.

2. In these circumstances I think the draft response adopts the only sensible line of reporting comprehensively and somewhat painstakingly on the activities of each of the bodies which are receiving Government funds for biotechnology.

3. In total this adds up to quite an impressive activity, bearing in mind that the United Kingdom spends less than 10 per cent of the total world spend on fundamental research. It would have been helpful for some estimate of the total UK expenditure to be made for easier comparison with the national expenditures quoted for France and Germany. I presume the reason this has not been done is the difficulty of defining what is biotechnology research. However, an approximate figure, both in sterling and in manpower terms, would be a valuable addition to the data in the Report.

4. In terms of research at universities, the response indicates how the Government is limited in telling the universities exactly what to do by the mechanisms it has to employ, eg the UGC, but it is also clear that the system of earmarking is being extensively used to promote biotechnology.

5. The response also makes it clear that additional resources for biotechnology can come in the main only from reducing the resources supplied to other areas. The Select Committee's Report conveniently ignored this problem.

6. There are some areas in the Report where the response has had to be that the matter is under consideration. These include potentially controversial areas, like the role and rights of BTG and the use of Porton Down. Inevitably this response looks a little weak and it will be desirable for the Government to make its decision known in these areas as quickly as possible.

7. The main criticism of the response is likely to be a perceived lack of an adequate response to the sections of the Report on a national strategy on biotechnology (paragraphs 4.14 to 4.17). The arrangements presented in the response could be seen as spreading a limited amount of money around very thinly and with an inadequate strategic framework against which the various committees distribute the resources allocated to them. Paragraph 13 of the response, which confirms the Department of Industry's lead position in biotechnology, is unlikely to be seen as an adequate response to this criticism. The yearning for a national strategy exists more widely than in biotechnology alone, and is favoured by sectors of the community who would prefer the more dirigiste approach adopted in France and Japan.

8. If, as the Secretary of State suggests, the Committee try to persuade the Prime Minister to appear before them, I imagine that they will want to question her on this point. The arguments for and against a more centralised approach were of course well rehearsed in the House of Lords Select Committee on Science and Government and the Government response was made known in Cmnd 8591. I believe it is possible to make an excellent case for the arrangement adopted by the Government and to indicate that it is now working quite well in the field of biotechnology.

RBN

ct

Prime Minister:

I imagine that you will give the proposal at X the same reply as previously

4

PRIME MINISTER

Please ask Dr. Nicholson to go through it for me. 12/1

BIOTECHNOLOGY: GOVERNMENT RESPONSE TO EDUCATION, SCIENCE AND THE ARTS COMMITTEE'S INTERIM REPORT ON THE PROTECTION OF THE RESEARCH BASE

The House of Commons Select Committee on Education, Science and the Arts produced an interim report on the protection of the research base in biotechnology in July. Patrick Jenkin and I propose that the Government response should be made in the terms of the attached draft. He and I have co-operated in its production and we propose to issue the response over our joint signatures. As X we have heard unofficially that the Select Committee may wish to use the occasion of the publication of the response as a reason for requesting you to appear in front of them to ask questions about your declared role as the ultimate coordinator of science policy within central Government, we feel that it is right that you should see, and have a chance to comment on, the draft response before we issue it. We envisage that the response should be in the form of a letter from us jointly to the Select Committee's Chairman, Christopher Price, rather than a White Paper.

You will note that the response is reasonably full. We believe that the sort of account which it provides of public sector activities in biotechnology is a necessary part of any response, given the flavour in the report of some dissatisfaction with public sector activity, a flavour which needs correcting. The Interim Report was published on 27 July 1982; it is therefore necessary to issue the response before 27 January 1983. It would be very helpful therefore if you, and the colleagues to whom I am copying this letter, could kindly approve, or let me have comments as soon as possible.

Copies of this minute go to the Minister of Agriculture, Fisheries and Food, the Secretaries of State for the Environment, Scotland, Wales, Industry and Social Services, to the Chief Secretary and to Sir Robert Armstrong.

KJ

11 January 1983

A1209SCE2B

ESAC : SIXTH REPORT : SESSION 1981/82

BIOTECHNOLOGY : INTERIM REPORT : 29 JULY 1982

REVISED DRAFT OF GOVERNMENT RESPONSE: 8 DECEMBER 1982

INTRODUCTION

1. The Government is grateful to the Select Committee for producing its interim Report in such a short time and has considered carefully the recommendations therein. This response is intended as a coherent account of Government support for research and development in biotechnology and does not therefore consist solely of a list of responses to the individual recommendations in the report. Rather, passages which bear particularly on individual recommendations are immediately followed by the number of the recommendation concerned in parentheses. All the recommendations have been covered with the exception of Recommendation 17 which is for action by the Universities concerned. The table at Annex I correlates the paragraph numbers of this response with the recommendations in the report.

2. The basis for the Government's policies in biotechnology was stated in Cmnd 8177 which was presented to Parliament in March 1981:

> "At this stage, the need is to participate fully enough in fundamental and applied scientific research to understand all the possibilities, and to create the climate in which selective development can be undertaken by those best able to perceive needs and assess the possibilities and risks".

3. Biotechnology embraces a wide range of activities at differing stages and with different rates of development. Its emergence results, amongst other things, from developments in continuous fermentation, enzyme and cell immobilisation, cell fusion and recombinant DNA. These developments offer the potential to produce new ranges of pharmaceutical products and medical diagnostic reagents; protein for human and animal food; micro-organisms that will extract metals from ore, purify waste or produce liquid fuel; and new plant varieties with improved growth characteristics, disease resistance and higher food value.

4. Biotechnology is built on many different disciplines. In all of them our basic science is good. The UK is well placed to exploit biotechnology, which while not itself an industry is of interest to many different and strong sectors of UK industry. In many of these sectors substantial opportunities are arising, albeit at different rates. Biotechnology consists of a range of possible processes, process aids, routes to new products and devices, which fit into existing industries - food, agriculture, chemical, pharmaceutical and medical. Each aspect of the field has been moving at a different rate.

5. Private investors in collaboration with the British Technology Group and the Scottish and Welsh development Agencies have been active in applying appropriate university and Research Council basic research.

It is generally agreed that the pharmaceutical and health care field is moving fastest in that it is the first sector to bring new products to the marketplace.

Next are developments in food and agriculture, waste treatment, energy production, metal extraction, enhanced oil recovery and the provision of fine chemicals. Perhaps last of all will be the large scale productions of basic organic chemicals using a biological route.

6. In health care the development of a number of new products such as human insulin, human growth hormone, interferons and some vaccines is already well advanced. Other therapeutic products are likely to be developed. The ease with which these products can be approved for human use varies and depends on how closely they are related to the human-derived material for which they are replacements. In general, however, therapeutic products involve considerable investments of money and time in research, development and testing to ensure safety and suitability for human use and early financial returns cannot be expected. On the other hand, diagnostic reagents for laboratory use and some veterinary products do not require such extensive testing and profits may therefore be realised sooner, often making them more attractive propositions for smaller firms.

7. The UK has been active in research and development of new and modified foods but the costs are high, even for large companies, and the benefits are not likely to be realised in the short term. The development of new biological processes will also require a reappraisal of the traditional links between food and agriculture and will open up the possibility of agricultural raw materials being used as feed stocks for non food products. Other important areas where there are opportunities for the UK include enhanced oil recovery and process plant (particularly overseas where biomass as a feed stock for liquid fuel or the chemical industry is a more likely possibility than in the UK).

8. This outline of the opportunities is by no means comprehensive. Many developments are only now beginning to emerge from the research phase and the direction of development for commercial exploitation remains uncertain. In addition, new biotechnological techniques and processes may well emerge over the next twenty years with benefits as yet unforeseen.

9. The Government fully recognises the potential of biotechnology. As set out in the White Paper on biotechnology (Cmnd 8177) the main responsibility for turning biotechnological opportunities into products must rest with industry. But the Government recognises it has a role both in ensuring that there is sufficient trained manpower and an adequate research base upon which industry can build and in encouraging industry to take advantage of the opportunities which biotechnology presents. The Government believes that these needs can best be met through the steady and evolving programmes of support being developed by bodies such as the Research Councils, the University Grants Committee (UGC), the British Technology Group (BTG), the Scottish and Welsh Development Agencies and by Government departments.

GENERAL THRUST OF REPORT: DUAL SUPPORT SYSTEM

10. In commending certain public sector activities in this and succeeding paragraphs, the Government does not wish to imply that the private sector is any less active or innovative; but in a response such as this the Government can only speak knowledgeably of the public sector. The Government takes the view that, having regard to present and planned activities and expenditure, the public sector's awareness of biotechnology and its provision to promote biotechnology in its many aspects is broadly right in scale and nature. It does not accept that the UK is in danger of missing the opportunity to be a world leader in this area. As this response will seek to show, there is much relevant work of which the UK, and in particular the public sector, can be proud.

11. The Report emphasises the Committee's concern over pressure on the dual support system and recommends priority for the restoration of support for scientific and technological research within that system (R.7). The Report of the Joint ABRC/UGC Working Party on the Support of University Scientific Research (The "Merrison Report", Cmnd 8567) was concerned with arrangements for the most effective use of likely future resources and made a number of recommendations designed to meet that situation and to enable effective research to be undertaken at the lower level of resources planned for the universities. The Working Party in particular recommended first that "As a longer term objective ... Universities should channel more of their funds into research" and secondly that "Universities will need to concentrate research funds into selected areas". It is too early to assess the response of Universities to these longer term recommendations (which have been commended to the Universities by the Department of Education and Science and the UGC) but taken together they would make a considerable impact.

12. The Merrison Report also recommends that the Government should "weigh the damage to research that is now precipitously close against the provision of a relatively modest amount of new money which could be used to mitigate this". The Secretary of State for Education and Science shares this concern and has recently announced that he has been able to make available to the UGC extra funds in 1983/84 which will enable the universities to recruit an additional 230 young lecturers. In discussion with the UGC and the ABRC it has been agreed that 200 of these "new blood" posts will be in the natural sciences and a proportion of that 200 will be in disciplines which underpin biotechnology. The "new blood" posts are seen as being important for scientific research and there is an understanding that the lecturers will in their early years spend most of their time on research, thus strengthening the dual support system. Also the Secretary of State for Education and Science is making available an additional £2.5m for the Science Budget in 1983-84. This sum will be distributed between the four natural science Research Councils and is intended to be spent on research grants to back up the "new blood" appointments. He expects, subject to the annual reviews of public expenditure, to provide further funds to the UGC and the Research Councils in 1984/85 and 1985/86 for these purposes.

COORDINATION

13. Coordination of national opportunities, which by the nature of the subject cover a diverse range of industries, activities and interests, is of course essential and has been much strengthened. Coordination is not the main key to success but it is an essential element if maximum benefit is to be derived from the combined efforts of industry and government. The Government reiterates that within central government the Department of Industry is the 'lead' department for biotechnology with overall responsibility for fostering industrial developments and ensuring exploitation for the maximum benefit of UK industry. Other departments which are closely involved with areas such as health, energy, environment, agriculture and food will, within government, continue to take the lead in these sectors, DOI will provide the necessary overall coordination and promotion within the UK and internationally (Recommendation 6).

14. The Committee recommended (Recommendation 5) that the present spread of committees concerned with biotechnology should be reviewed. This has been done in consultation with the Advisory Board for the Research Councils. Biotechnology embraces a wide range of industries and departmental interests and it is inevitable that there will be a spread of committee activities covering these. It is clearly important that the various activities are adequately but not excessively coordinated and that in so doing scarce scientific manpower resources are not diverted from research and development work.

15. The main government committees concerned with biotechnology, their function and inter-relationships are set out in the table at Annex II. The existing arrangements for coordinations were strengthened earlier this year by the establishment of the Interdepartmental Committee on Biotechnology (ICBT) which provides the main focus for biotechnology in government and coordinates the interests of government departments and related bodies. It also provides a point of contact for those outside government. The Committee has a core of members covering the major departmental interests and bodies such as the Research Councils, BTG and the Public Health Laboratory Service, but other departments and bodies receive papers and attend as necessary. The membership of the Committee is flexible so that those directly concerned with a particular topic may attend as appropriate.

16. ICBT has cross membership with the Inter Research Council Coordinating Committee on Biotechnology (IRCCCOB) and with the SERC Biotechnology Directorate. In addition the Chairman of ICBT attends the Department of Industry's Materials and Chemicals Requirements Board. There are links between ICBT and relevant sector Working Parties of the National Economic Development Office. Outside government there are several committees concerned with biotechnology set up by bodies such as the Confederation for British Industry, the Society for Chemical Industry and the British Coordinating Committee for Biotechnology and there are links between these and main committees listed in the table. The government believes that the existing committees adequately meet the various functions for which they were set up and that there is sufficient cross membership and linkage to ensure a coordinated effort. Bearing in mind the wide range of interests involved the present spread of committees is not considered to be excessive.

17. The UGC, which while excluded from the table at Annex II because of its much wider remit nevertheless concerns itself with biotechnology, also recognises the importance of departmental or inter-departmental committees and is very willing to provide assessors provided it is clear that their business directly concerns the UGC; but in view of the considerable reductions made in its Secretariat it cannot afford the staff time to attend committees of only indirect relevance. In the light of the Select Committee's recommendation that the UGC should be represented on the Inter-Departmental Committee on Biotechnology (R.2) the Department of Industry has undertaken to give notice whenever a relevant item appears on the agenda, so that the UGC may be represented when it is discussed.

18. Advice on desirable new developments is provided to the UGC through its Sub-Committees. In making their contribution to a Sub-Committee's work, members are not limited by the extent of their own specialisted knowledge because they can draw on extensive contacts with colleagues working in cognate fields, with professional bodies and with employers. The Sub-Committees have assessors from the Research Councils and Government Departments and this also extends the expertise to which they have access: for example the Technology Sub-Committee has an assessor from the Department of Industry.

19. Formal representation by assessors is not the only means by which Government Departments communicate with the UGC. Departments are free to express their views on relevant matters at any time and contacts between the UGC and several Departments are growing. In the light of the Select Committee's recommendation for the establishment of a formal channel of communication with the Department of Industry (R.1) the UGC has made it clear that it is willing at any time to receive the views of that Department on any relevant matters, and not only on those covered by the DOI assessor on its Technology Sub-Committee.

20. Having taken a strategic decision such as identifying a particular area for support, Sub-Committees are faced with the difficult task of identifying the centres where additional funds should be deployed, and providing guidance as to their use. There is no single right way to do this. In some cases all the expertise required already exists within the Sub-Committee or a combination of Sub-Committees. In others it may be necessary to establish a separate panel or working party to make a special investigation. It is often best to supplement the expertise of the Sub-Committee with that available from the extensive and specialist committee structure within the Research Councils. In biotechnology, Research Councils had not only been individually active in establishing their own programmes, but they had also formed an Inter-Research Council Coordinating Committee. The UGC believed that the combined expertise of its own Biological Sciences and Technology Sub-Committees, including the assessors, supplemented by that of the Research Councils would enable a proper selection of centres to be made rapidly. It is satisfied that this arrangement has worked satisfactorily and that the development in the universities of biotechnology, as of other areas, is more likely to be promoted by such means than through the creation of new specialist machinery as recommended by the Select Committee (R.3).

DEVELOPING SUPPORT FOR BIOTECHNOLOGY (Recommendations 8 and 9)

Agricultural Research Council (ARC)

21. Much of the ARC's research programme lies within the broad definition of biotechnology adopted in the Spinks Report. For planning and descriptive purposes, however, the Council has adopted a narrower definition, limiting the term to work on the application of molecular biology to the agricultural, horticultural and food industries.

22. Recognising the great potential for agriculture if it were possible to manipulate the genes of crop plants, the ARC initiated in 1978 a coordinated programme to investigate the application of recombinant DNA technology and other methods of gene transfer to arable crops. The programme is now the major component of ARC's work in biotechnology. It involves 40 scientists at four ARC institutes and about 15 at several universities. It is in effect a national programme and to foster collaboration and achieve coordination the ARC convenes an annual discussion meeting for the participants.

23. ARC also support genetic manipulation in other areas. There is work on the synthesis in E. coli of molecules important in animal health, on recombinant DNA cloning systems in bacteria of special interest to agriculture and food, and on bacteria which play a part in the biodegradation of animal and crop waste materials. For instance, the Council's Food Research Institute is working on the handling of food processing wastes and at Rothamsted Experimental Station there is a programme of commercial significance on the conversion of animal waste into protein in the form of worms. Most recently, plans have been drawn up for new work on animal genetic manipulation with the ultimate objective of improving farm animals. In 1981 ARC set up a monoclonal antibody centre at its Institute of Animal Physiology to encourage the use of monoclonal antibodies as research tools in agricultural research and to develop veterinary diagnostic reagents.

24. Immobilised cells or multienzyme systems are the third main field of the ARC biotechnology programme. There is work on the role of blue-green algae in ammonia production and on the synthesis of high value flavour compounds by immobilised plant cells cultures.

25. In 1981-82 the total cost of these agricultural biotechnology programmes, including work in Scottish agricultural research institutes funded by the Department of Agriculture and Fisheries for Scotland (DAFS), was £2.4 million. 110 scientists and assistants are involved at institutes and a further 25 in universities; almost half of the institute staff have been redeployed from other, lower-priority work. Additionally, the ARC and DAFS spent a further £2.7 million in 1981-82 on studies of plant micropropagation, biological control of crop pests and diseases, photosynthesis and biomass, and animal vaccine production, all of which are frequently included within a biotechnology portfolio.

26. There are further scientific opportunities in agricultural biotechnology and ARC has designated the entire topic as a special priority area. The Council's forward plan calls for expansion in selected fields and further new initiatives. With the prospect of a static budget in coming years, this policy will require retrenchment in areas of lower priority to release resources for new work in institutes and universities. The rate of further expansion in biotechnology will thus depend largely on the extent to which existing lower priority work in institutes can be reorganised.

Medical Research Council (MRC)

27. The Medical Research Council's responsibilities relate to the application of biotechnology in medicine, although wider industrial applications can sometimes be identified. Major contributions have been made, and continue to be made, in relation to two areas of biotechnology which have lead to the recent increase of interest in the field, ie genetic engineering and monoclonal antibodies. A substantial amount of work also continues on the development of vaccines and new drugs, and on the synthesis, isolation and assay of substances (such as hormones) important in medicine, by more traditional biotechnological methods. The scope of the projects involved ranges from basic 'underpinning' research (eg on the chemistry, organisation and function of genes) on which the Council spend £17 million in 1980-81, to more directly biotechnological objectives (eg the production of a monoclonal antibody for the purification of interferon) on which expenditure was £1.7 million in the same year.

28. A significant proportion of the MRC's support for biotechnology is through the provision of grant support to university scientists. The MRC has indicated to universities that it is willing to consider applications for bridging support to cover temporary resource difficulties; university scientists have been reminded of the MRC's senior award schemes and of the provisions that can be made to retired workers, that can be extended to those taking premature retirement. A new MRC Research Group scheme is to be introduced on a limited scale whereby the UGC arm of the dual support system is complemented and reinforced by the MRC's provision of items not normally allowable under grant schemes, in order to safeguard high quality biomedical research in universities.

29. As well as funding work in the field through making grants to universit[illegible]s the Council finances programmes of work in its own establishments. It also promotes the field through special schemes such as research studentships and fellowships for training in recombinant DNA techniques: 30 studentships and 14 fellowships have so far been awarded, and 6 more fellowships have been made available for award in the current session. The MRC's contribution to training must be seen as significant. In addition the Council has extended its existing project grant scheme to encourage joint applications from university departments and industrial collaborators and introduced a scheme, similar to SERC's CASE scheme, to provide awards to MRC establishments wishing to collaborate with industrial laboratories; both these schemes could, of course, involve proposals for research in biotechnology. (Recommendation 14).

30. The Council is fully aware of the potential importance of biotechnology, both in relation to the diagnostic, prophylactic or therapeutic possibilities, and the accompanying commercial opportunities for British industry. Expenditure for both research and training in this field has accordingly been increased, and it is likely to be increased further when suitable opportunities are identified. There are however, existing mechanisms for monitoring, with the aid of expert advice, expenditure within the grant-in-aid, which seek to reconcile the competing claims of the wide range of subjects which the MRC covers. At present there is earmarked provision for biotechnology in that part of the Council's programme which deals with training, but not in other parts; nor does the Council propose any (R.8). The Council's intention is to try to hold a balance between maintaining a continued strength in basic research and exploiting opportunistically those discoveries with potential health care applications. A major concern must be that the response to the pressure to support short-term commercial development does not cut off the flow of innovations by diverting money and skills from the fundamental research. The MRC's support of fundamental research is acknowledged by the Committee to have paid off handsomely by creating a number of the present opportunities.

Natural Environment Research Council (NERC)

31. The role of NERC is relatively minor as far as biotechnology is concerned when compared with the activities of the ARC, MRC and SERC. A preliminary award for the acquisition of technologies and the training of personnel in plant cell manipulation has been made under NERC's Special Topic System (earmarked funds)

and relates to the selection and development of improved tree stocks in the UK. NERC underwrites the Culture Centre for Algae and Protozoa (CCAP) and discussions between CCAP and other bodies on possible join projects on cryopreservation and plant cell culture are already in progress.

32. NERC's CASE and grants awards systems are open to developments in biotechnology relevant to NERC and NERC's Grants Committee have been made aware of the Council's desire to support biotechnology, especially in collaboration with industry and research institutions (Recommendation 14).

33. None of the advanced training courses currently supported by NERC can be associated closely with biotechnology. However the Council is aware of several new courses being developed by the Universities and is very willing to consider for approval those options which provide training in aspects of biotechnology relating to environmental impacts; forestry, fisheries, biomass production, culture maintenance, pest and algal control, minerals exploitation and land reclamation. Considerations will also be given to any courses which offer conversion or specialist training in the techniques of biotechnology to environmental scientists.

Science and Engineering Research Council (SERC)

34. Biotechnology in various guises has been supported by SERC since the late 1960s. The Council formed a Directorate for Biotechnology in November 1981 and provided that Directorate with earmarked funds to support research and studentships for exclusive use to support biotechnology. In addition, the Council recognised the need to provide a national focus for interests in biotechnology, together with coordination and leadership to ensure the most effective implementation of the Council's research and training programme. SERC's expenditure on biotechnology in 1982-83 Financial Year is likely to be £1.6m and already the Directorate has awarded grants to a total value of nearly £4m. Of this total commitment about 24% of the grants are in the field of fermentation/microbiology, and 21% are concerned with recombinant DNA techniques. The Council will continue with its policy of giving full support to the Directorate and hopes to meet the target of an expenditure of about £2.5m on biotechnology by 1985-86.

35. Against this background the Directorate has drawn up a strategy for its support of biotechnology which is developed at three levels. Firstly at the level of basic underpinning the Directorate will play its part in the support of national culture collections, and fundamental research which may be of a highly speculative nature, but which may, if successful, lead to significant advances in the field. It will also provide earmarked support for postgraduate students through the Council's studentship schemes.

36. At the second level of strategy, the Directorate has identified sectors of biotechnology where it is essential to maintain a national capability. Such a capability would, typically, be in an academic department and would be a national resource which industry could tap. Six areas of biotechnology are proposed where at least one and hopefully two academic centres will be established and these areas have been selected to ensure that the UK maintains essential expertise or creates new concentrations of essential skills. The priority sectors are:

i. Immobilized enzymes and cells
ii. Plant genetics and biochemistry
iii. Large scale growth of mammalian and plant cells
iv. Fermentation technology and microbial physiology
v. New reactor design and new concepts in downstream processing
vi. Sensors and biolectronics.

37. The third level of strategy involves the identification of specific target products or processes. Directorate support here will be provided through its joint funding of research with companies in the Cooperative Grant Scheme. At the time of giving evidence to the Select Committee, three Cooperative Grants existed under this scheme, but the Directorate has now increased the number of Cooperative Grants to 14, with a total industrial contribution of £1.7m contrasted with an SERC contribution of £0.9m. This development clearly shows the importance industry places on academic work at this stage of development in biotechnology.

UGC

38. The universities have been at the forefront of the recent advances in biotechnology. The block recurrent grants provided through the UGC under the dual support system fund a considerable amount of work in this area, as they

do in other subject areas of immediate or potential importance to the national interest. Because the level of university funding is being reduced, institutions are now finding it increasingly difficult to provide adequate finance from their block grants for deserving new developments, and the UGC accepts the need to consider whether earmarked grants should be made for special purposes. Such grants have to be limited, because they can only be found at the expense of the general funding of the university system for which the UGC is responsible. The UGC has recently decided to give exceptional treatment to biotechnology by deciding to commit itself to expenditure of up to £1.2m a year as a first claim, alongside the costs of redundancy compensation, on the funds which it has set aside for restructuring from 1981-82.

39. The biotechnology initiative of the UGC is designed to provide a specific injection of funds to strengthen particular centres, notably through the provision of new permanent posts. The funds are earmarked for three years, but in the longer term responsibility for decisions on the support for biotechnology (as in other areas) is a matter for universities themselves. The Select Committee recommended that the UGC should monitor the expenditure allocated to create new posts to ensure that it was used for the purpose (R.4). It is normal practice for the UGC to monitor the use made of earmarked funds during the period of earmarking through annual reports submitted by the receiving institutions, and this will be done for the biotechnology grants. In confirming the award of a grant, the UGC is reaffirming its understanding with the universities that they will create genuinely new posts, and not simply retain posts which would otherwise have been cut.

40. The initiative has been in two stages. Stage I is now complete; awards of £100,000 pa for three years have been confirmed to University College, London, to the University of Birmingham, and to the University of Manchester Institute of Science and Technology. Submissions have also been received from all the universities invited to make proposals under Stage II, and grant is being offered to Cambridge, Leicester, Sheffield, Glasgow and Strathclyde. It is hoped that decisions on the remainder will be made in the very near future.

41. It is not intended that the initiative should formally be extended beyond Stage II, but this does not necessarily mean that no more biotechnology proposals will be supported. The UGC has issued a general invitation to universities to inform them of developments in any academic area which might be worthy of special support, with the intention of assisting some of them from

the funds set aside for restructuring after prior claims have been met. [illegible] number of proposals which have been received concern biotechnology. These will be eligible for consideration for earmarked grants as recommended by the Select Committee alongside all other proposals received for initiatives of other kinds.

COMMERCIAL EXPLOITATION OF THE RESULTS OF RESEARCH (Recommendations 10 and 11)

42. Following a recommendation on similar lines by ACARD in its report on Exploiting Invention (May 1981) a working party of officials under DES chairmanship with DOI, the Research Councils and BTG (NRDC) in membership, was convened early in 1982 to examine future arrangements for collaboration between the Research Councils and BTG (NRDC). The Working Party has completed its work and its recommendations are under consideration by the bodies and Departments concerned. Any new arrangements would be announced publicly.

43. As to R.11 (in which the Committee recommends an urgent review of the relationship between MRC and Celltech Ltd), arrangements already exist for both parties to the MRC/Celltech agreement to review it in late 1983, two years before it expires. The exclusivity aspect will be one of the issues considered when the planned review takes place. The Government considers that any earlier review would be based on inadequate experience; and believes that, provided the proposed agreement between the ARC and an intended agricultural biotechnology company also contains provision for early review, there is no need to delay the conclusion of that agreement in the way that the Committee recommends. Informal communications between the two Councils have already taken place to ensure that ARC has access to any relevant MRC experience when considering the detailed terms of the agreement.

THE CENTRE FOR APPLIED MICROBIOLOGY AND RESEARCH (Recommendation 12)

44. A study on the lines proposed by the Committee has, in fact, been undertaken. In 1979, when the Department of Health and Social Security took over from the Ministry of Defence responsibility for the Microbiological Research Establishment (now the Centre for Applied Microbiology and Research) the then Secretary of State for Social Services asked the Public Health Laboratory Service Board - which was to administer CAMR on behalf of DHSS - to examine and report on the Centre's potential for commercial development.

Of particular importance was the contribution the Centre would be able to make to the work of British industry and what the Centre might itself produce for commercial exploitation. The request for such a report was repeated by the succeeding Secretary of State.

45. A detailed report was presented by the Public Health Laboratory Service Board, and this was circulated to officials in all other Government Departments with an interest in CAMR and the views obtained were taken into account in a submission put to DHSS Ministers in 1982. The Board's report demonstrates both the importance of collaborative links between CAMR and university departments, and the valuable support it receives in determining its policies from its expert Scientific Review Committee, on which representatives of the universities and industry have been in a majority. CAMR is one of the centre of expertise being supported by the DOI under its new programme of support for biotechnology in industry (see paragraph 47 below). Ministers are currently considering the report and a further study at this time would not seem to be necessary.

BIOTECHNOLOGY AND INDUSTRY (Recommendations 13, 14, 15, 16 and 20)

46. The improvement of links between industry and higher education institutions is seen by all the bodies principally concerned (the Departments of Education and Science and of Industry, the Scottish Office, the UGC, the National Advisory Body for Local Authority Higher Education (NAB) and the Research Councils) as a policy objective, and has been so seen for some time. Activities in this area have not been restricted to the field of biotechnology but have been aimed more generally at trying to increase the extent to which the work carried out in universities and polytechnics and the kinds of training that they produce, are relevant to the present and expected requirements of industry. There are slight differences of emphasis in the thrust of each body's policy in this area, reflecting their respective overall aims and responsibilities. Specifically, the Department of Industry sees as its objectives:

a. to assist the use by industry of the research facilities and results available in universities and polytechnics;

b. to improve the usefulness to industry of the teaching given at these institutions.

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Some of the initiatives in this field which are relevant to biotechnology are set out below.

"Biotechnology in Industry": A new Department of Industry programme

47. The Secretary of State for Industry launched on 24 November a new long term programme of support for biotechnology in industry. The programme will comprise the following elements; grants for consultancies and feasibility studies to create greater industrial awareness; increased support for innovation and assistance with demonstration plants to increase the volume of biotechnology R & D in industry; support for programmes (jointly with industry) at centres of expertise such as the PHLS CAMR and AERE Harwell; and strengthening of the biotechnology infrastructure through, for example, industrial development of culture collections and improved access to information on biotechnology. The cost of the programme is expected to be £16 million over the next 3 years.

DOI has set up a new Biotechnology Unit at the Laboratory of the Government Chemist which will promote and monitor these initiatives. The Unit will in addition identify gaps in existing programmes and commission contractors to carry out the necessary work to fill these. The majority of the staff in the Unit will be seconded full-time from industry to provide expertise not currently available in the Department. The new programme will complement other public sector programmes in this area and the Department will work closely with other Departments and the Research Councils. A leaflet setting out the details of the programme is at Annex III.

Teaching Company Scheme

48. The DOI and the SERC jointly fund the Teaching Company Scheme. This Scheme encourages cooperation in research and training activities between higher education establishments and industrial firms. Graduates are seconded to work in joint academic/company teams; and senior academic staff arrange supporting courses, seminars, etc. More than 80 Teaching Company programmes have been set up, and the scheme has proved to be very successful. The scheme has so far operated mainly in the production engineering field but it is now being extended into other areas including biotechnology.

Awards Schemes

49. A number of schemes have been aimed at encouraging practical, commercial collaboration between industry and higher education establishments and increasing awareness of the possibilities in such collaboration. The DOI's 'EPIC Award' offers cash prizes for teams that can demonstrate examples of successful partnership with industry. The British Technology Group's 'Academic Enterprise Competion' awards prizes to academic researchers who set up or intend to set up new businesses based on their research results.

Industry-Related R & D at Universities

50. The Committee has acknowledged (paragraph 6.3 of its report) that the Department and the SERC's Biotechnology Directorate keep in close touch so that research at universities takes account of the needs of industry, and is carried out in close collaboration with industry.

51. The Department of Industry has already initiated work on whether the present tax rules affect the willingness to invest in research and development, and whether it might be desirable to consider changes in the rules in order to promote greater investment in R & D (R.13). Although this work was not begun with the specific issue of research into biotechnology in mind, its conclusions will clearly be relevant in that field. The work has not however yet reached a conclusion.

Industrial Units at Higher Education Establishments

52. In 1968, the then Ministry of Technology financed the launching of a number of University Industrial Units, which provide a consultancy service for industry. The DOI is currently providing financial assistance for the expansion of some of these.

Industrial Liaison Officers and Regional Brokers

53. Many universities have appointed Industrial Liaison Officers whose job is to discover the needs of industry and to guide firms to appropriate parts of the university. The University Directors of Industrial Liaison produce a directory of university industry liaison services. The DOI has received requests of support for data bases in this area and has agreed to support a

feasibility study by Manchester University in the Manchester area. SERC has, within a pilot scheme, appointed a small number of Regional Brokers who are complementary to ILOs and who will work closely with the latter and regional staff of the DOI.

Innovation Centres

54. Innovation Centres, or Science Parks, consist of a group of small firms, dealing with high technology products, which may be linked with R & D facilities of a higher education institution. The DOI and Shell jointly sponsored a study by Job Creation Limited of these developments. The Department of Industry is currently considering the report's findings.

BTG University Coordination Department

55. The BTG have a University Coordination Department whose function is to foster university/industry contacts. Among the BTG's activities in this field has been a programme of university/industry conferences held at a number of centres throughout the country to bring together academics, entrepreneurs and others concerned with promoting new technology based firms.

New Training Courses

56. The Secretary of State for Education and Science, on 15 July 1982, wrote to the Chairman of the UGC about key issues relating to the reshaping of the university system. He endorsed the principles underlying the UGC's allocations of grant to universities which proposed that "important new developments in biological sciences should be supported, including those with a high potential value for the economy". The Secretary of State's letter sought the views of the UGC regarding longer term priorities in the universities in specific areas of science and technology of particular relevance to industry, especially in matters such as: the length and intensity of courses; the balance between undergraduate, taught postgraduate and research provision; and subject balance.

57. As foreshadowed in the Secretary of State's letter of 29 July to the Royal Society in response to their Report "Biotechnology and Education", the Department of Education and Science will be asking the NAB to consider, in the light of its planning exercise for advanced further education provision in 1984-1985, how biotechnology might best be promoted in polytechnics and colleges (the department is aware that several such institutions are involved in biotechnology teaching and research). The Secretary of State has also sought advice upon how cooperation and the exchange of information between the UGC and the NAB can best be pursued.

58. Although the initiative in providing new courses in higher education rests with institutions (subject to UGC targets or, in the Local Authority sector, advice from the NAB and the power of the Secretary of State for Education and Science to approve courses), the DOI recognises that it has a role to play in representing the views of industry and other relevant bodies regarding the allocation of resources in higher education and progress in the adoption of new technology. (R.20)

Research Council Activities

59. The MRC have been continuing and developing their policy of promoting the transfer of technology to industry through collaborative agreements and consultancies as well as by the arrangements for the exploitation of inventions through BTG and Celltech. In total, the MRC currently have 27 collaborative agreements and 18 'know-how' agreements (on non-patentable discoveries) arranged by the Council direct: of these 15 and 17 respectively were signed last year. Members of the Council's staff hold some 35 industrial consultancies with companies other than Celltech. The MRC is willing to consider suggestions for any other ways in which links between industry and the Council's establishments might be increased. In particular in relation to the Committee's recommendation that fellowships should be founded to provide the opportunities for contact between biotechnologists in industry with universities, MRC establishments might provide an alternative academic arm to universities.

60. Throughout all of the levels of strategy identified by SERC strenuous efforts will be made to develop academic/industrial interaction through use of the Council's schemes. In addition to the Cooperative Grant Scheme, SERC's Biotechnology Directorate will use as appropriate the Royal Society/SERC

Industrial Fellowship Scheme as well as the CASE and Teaching Company Schemes. The Directorate plans to increase the number of CASE awards offered next year, as well as the number of Quota Research Studentships. It also maintains its willingness to support about six well-designed Advanced Courses, each of one year's duration, for which it would hope to provide perhaps 5-10 studentships per course. In addition, it is likely that there will be a number of short courses required to provide specific skills, such as gene cloning, and the Directorate is ready to support the mounting of these courses whenever the need for them has been established.

BIOTECHNOLOGY IN SCHOOLS (Recommendation 18)

61. On 2 June the Department published its consultative paper "Science Education in Schools", which raises a number of significant issues concerning the teaching of science in schools. Consultations are taking place within and beyond the education service on the basis of the paper, and the Secretaries of State for Education and Science and for Wales intend to issue a national statement of policy in due course. The view that the application of science should play a larger part in schools science courses has been widely expressed, and the Committee's recommendation that attention should be paid to applied aspects of biology, including biotechnology, will be taken into account. In the context of the current development of national criteria for examinations at 16+, the DES is also drawing the attention of the Joint Council of GCE and CSE Boards to this recommendation and to the Royal Society's Report "Biotechnology and Education". In addition, HM Inspectorate are preparing a new edition of the pamphlet for teachers entitled "The Use of Micro-Organisms in Schools". They are advised by a working group which includes representatives of the Microbiology in Schools Advisory Committee (MISAC), the Institute of Biology and the Royal Society. It is intended that the pamphlet should take a positive approach to microbiology, and seek to overcome the apprehensions of teachers by offering practical advice on safety.

TRAINING QUOTAS AND FUNDING OF STUDENTS' RESEARCH ACTIVITIES

62. The Committee's reference to training quotas (R.19) is difficult to understand in the context of the way in which the Research Councils operate their postgraduate training schemes. In broad terms each Council decides, within the total sum that it has allocated to studentships (from its total grant-in-aid) for the year in question, how to distribute the available

resources (a) between academic disciplines and (b) between higher education institutions (and its own institutes). (Councils do not operate national competitions in the same way that DES does for postgraduate studentships in the humanities.) As has been indicated earlier, all Research Councils are planning to increase their provision for postgraduate studentships in fields relevant to biotechnology. The Advisory Board for the Research Councils' Postgraduate Training (P) Committee monitors the postgraduate training plans of the Research Councils, and also of a few other award-making bodies. With the Committee's recommendation in mind, the Government is asking the Advisory Board to invite its P Committee to keep a particularly close eye on this aspect of the Research Council plans.

63. As to the funding of students' research activities (R.21), the Government assumes that the Committee is referring to the research training support grants. which are paid by the Research Councils to academic departments for the support of those departments' expenditure on items such as equipment and consumables needed by postgraduate students in the sciences in the course of their research work. The DES has, with agreement of the Treasury, recently increased the rate of research training support grant from £300 per student per annum to £400.

Annex I

CORRELATION OF PARAGRAPH NUMBERS IN RESPONSE WITH RECOMMENDATIONS IN ESAC SIXTH REPORT

RECOMMENDATION NO	PARAGRAPH NO
1	19
2	17
3	20
4	39
5	14
6	13
7	11
8	21-41
9	21-41
10	42
11	43
12	44
13	51
14	29,32
15	46
16	59-60
17	-
18	61
19	62
20	58
21	63

GOVERNMENT COMMITTEES CONCERNED WITH BIOTECHNOLOGY

COMMITTEE	ABBREVIATED TITLE	TERMS OF REFERENCE	CHAIRMAN/ MEMBERSHIP	LINKS WITH OTHER COMMITTEES
Inter-departmental Committee on Biotechnology	ICBT	To assist DOI in planning and executing action in those areas of biotechnology that do not fall clearly in specific Departmental responsibilities by providing the necessary coordination within the UK and internationally. To stimulate the exploitation of biotechnology in UK industry by actively identifying and encouraging support for specific projects. To provide biotechnology in Government with a visible focus for outside enquiries and suggestions	CH Government Chemist Membership flexible including DOE; MAFF; DEn; DHSS; HSE; MRC; ARC; SERC; PHLS/CAMR; PHLS; MOD(PE); BTG; Scottish Office. Others attend as necessary.	Cross membership with IRCCCOB; MRCB; Links with UGC; BCCB; SCI; CBI
Inter Research Council Coordinating Committee on Biotechnology	IRCCCOB	To advise the Heads of the Research Councils on - the development of biotechnology research programmes within the Research Council system - any coordination or rationalisation that may be desirable between the programmes of different councils	CH MRC Membership: MRC; ARC; SERC; NERC	Cross membership

COMMITTEE	ABBREVIATED TITLE	TERMS OF REFERENCE	CHAIRMAN/ MEMBERSHIP	LINKS WITH OTHER COMMITTEES
		_ any new work that should be initiated as a consequence of inadequate coverage of recent discoveries		
Materials and Chemicals Requirements Board (and its Chemical Manufacture and Biotechnology Executive Committee)	MCRB (CMBEC)	The DOI's research and development requirements boards determine the objective, composition and balance of the DOI research and technology programme. The MRCB covers mineral resources, mineral processing, metals extraction, chemical manufacture, biotechnology process plant, reclamation and engineering materials. CMBEC covers chemical manufacture and biotechnology	CH Dr B C Lindley, Dunlop Ltd, Membership made up of senior industrialists, academics and government	Chairman of ICBT sits on MCRB and CMBEC. Director of SERC Biotechnology Directorate sits on CMBEC.
SERC Biotechnology Directorate Management Committee	BTMC	To advise and report to the SERC's Engineering and Science Boards on the development of the Biotechnology programme. To approve expenditure within the powers delegated to it. To oversee the programmes and encourage the participation of industry, academic institutions and government in both the research and training aspects of the programme.	CH: Dr A T James (Unilever) membership senior industrialists and academics and Government Chemist.	Director of SERC Directorate sits on ICBT, CMBEC and IRCCCOB. Government Chemist

COMMITTEE	ABBREVIATED TITLE	TERMS OF REFERENCE	CHAIRMAN/ MEMBERSHIP	LINKS WITH OTHER COMMITTEES
		To guide the Director on the content; balance; implementation and exploitation of the programme.		
Genetic Manipulation Advisory Group	GMAG	To advise research workers and others on the risks involved with recombinant DNA experiments and the appropriate safety and containment precautions	CH: Sir R Williams; (Formerly Director of PHLS). Memb made up of senior industrialists; academic; and government	Contacts with HSE and Advisory Committee on Dangerous Pathogens

ANNEX III

Department of Industry

BIOTECH

Biotechnology in Industry

a long-term programme of support

Support for consultancy
Support for innovation
Support for centres of expertise
Support for major facilities
Demonstration projects
Firmer foundations

Like Information Technology, Biotechnology will have a profound effect on all our lives, through its impact on a wide range of industries during the next ten to twenty years.

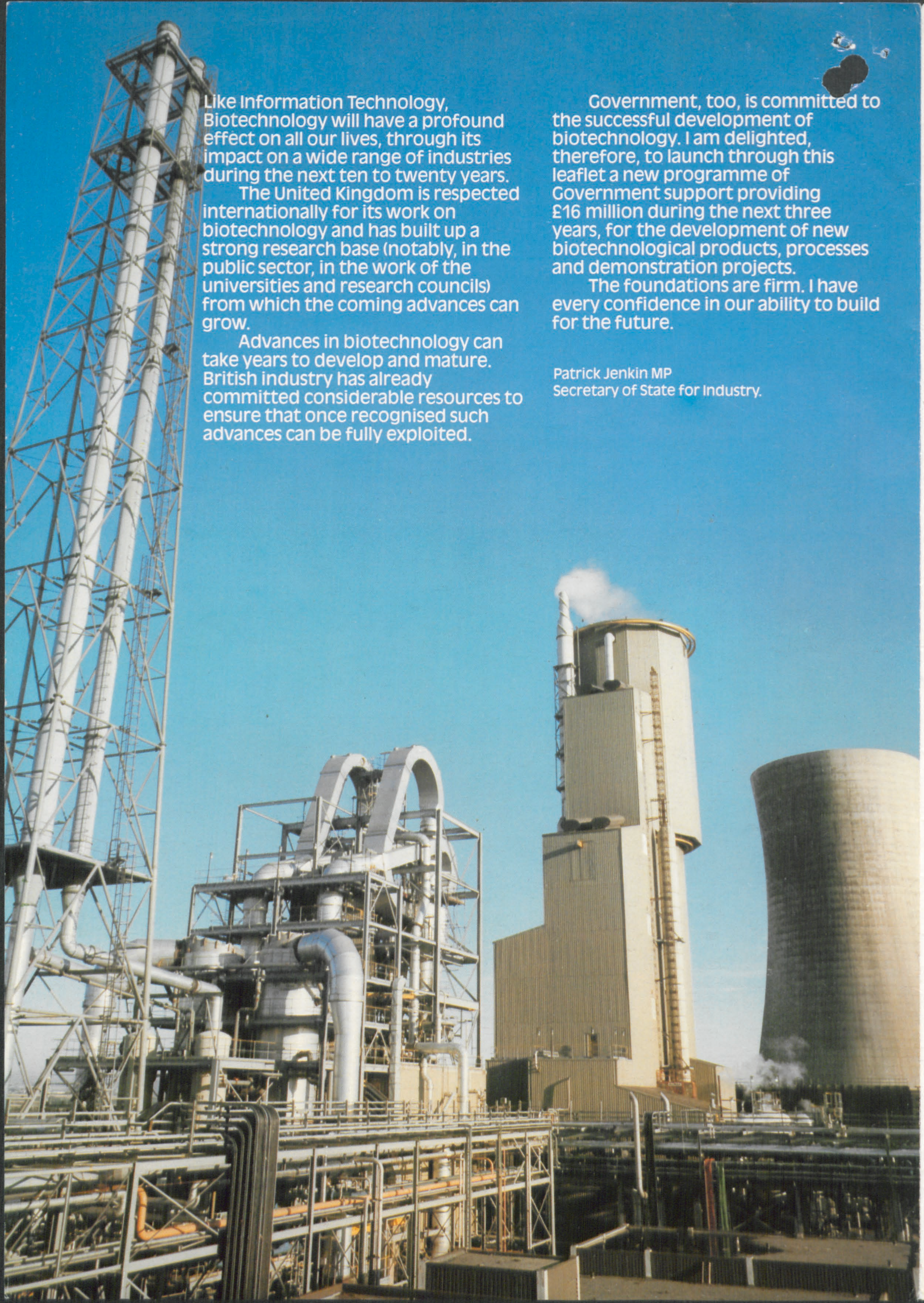
The United Kingdom is respected internationally for its work on biotechnology and has built up a strong research base (notably, in the public sector, in the work of the universities and research councils) from which the coming advances can grow.

Advances in biotechnology can take years to develop and mature. British industry has already committed considerable resources to ensure that once recognised such advances can be fully exploited.

Government, too, is committed to the successful development of biotechnology. I am delighted, therefore, to launch through this leaflet a new programme of Government support providing £16 million during the next three years, for the development of new biotechnological products, processes and demonstration projects.

The foundations are firm. I have every confidence in our ability to build for the future.

Patrick Jenkin MP
Secretary of State for Industry.



The world's first large-scale single cell protein plant at ICI, Billingham UK. Process design and engineering by John Brown in association with ICI.

Biotechnology – the potential

Recent interventions in nature's chemistry will have significant impact upon the future for a range of industries.

In one, health care, commercial success is imminent. In others such as food and agriculture, the potential is good. Pharmaceuticals, chemicals, waste treatment, mining, process plant/control equipment, scientific equipment/reagents – all these and more will be affected.

Government is concerned to ensure that Britain is able fully to exploit biotechnological advances as they occur over the years. The necessary transfer of technology will require long-term investment by industry in biotechnology R&D. There is already growing public sector investment in this field.

To support this research and development in industry and promote the application of biotechnology, the Department of Industry is offering:

- grants of one third (in some cases more) of the costs of selected projects, processes and product developments
- grants for consultancy
- increased support for centres of biotechnological expertise

The industries:
food•agriculture•pharmaceuticals•chemicals•waste-treatment•mining•process plant and control equipment•scientific equipment and reagents•horticulture•oil

The products and processes:
enzymes•peptide hormones•food processing•vaccines•enhanced oil recovery•antibodies•other proteins eg. blood clotting factors, interferons•diagnostic kits•amino-acids•vitamins•other fine chemicals•energy generation eg. methane•metal extraction•new and improved plant varieties•food and food components eg. single cell protein, sweeteners•water and effluent treatment•biodegradation•pesticides•oils•and many others

The techniques:
batch and continuous fermentation•enzyme technology•cell and enzyme immobilization•cell and tissue culture•cell fusion (monoclonal antibodies)•genetic engineering•downstream processing

Support for consultancy

Your company may be ideally placed to take advantage of biotechnology, but may not be aware of the possibilities, or may need an economic or technical feasibility study.

Firms can now apply for a grant to engage a consultant, to carry out studies at three different levels:

Modern antibiotics plant – Beecham Group

- Strategic studies – support can be provided for studies to assess the opportunities and commercial risks that biotechnology presents, and to help in strategic decision-making. Where appropriate, multi-client studies will be supported.
  UP TO 50% FUNDING, TO A PROJECT LIMIT OF £25,000
- Feasibility studies – support is now available for technical and economic studies of specific product developments, process developments and market assessments. One important area is waste treatment and upgrading, where there may be scope for early application and benefits. Other topics will, however, be considered.
  UP TO 75% OF PROJECT COSTS, TO A PROJECT LIMIT OF £10,000
- Problem solving – small and medium-sized companies can obtain advice on manufacturing or technical problems through the Manufacturing Advisory Service or the Small Firms Technical Enquiry Service, which cover the main areas of manufacturing industry.
  100% OF COSTS BETWEEN 5 AND 15 CONSULTANCY MAN-DAYS

Support for the above studies is available on a selective basis; the Department will need to approve your choice of consultant and the terms of reference of your project. Guidelines on the available support plus a list of possible consultants can be obtained by ticking the appropriate box in the coupon at the end of this leaflet.

Support for innovation

Government is looking to support the research and development of innovative projects and processes, and many biotechnology projects, including demonstration projects, are likely to be eligible.

Support will usually take the form of a 25% grant (33⅓% until May 1983).

Higher levels of support may be available for some longer-term projects. Support is selective, and applications cannot be considered if work has already commenced.

Support is also available from the Department jointly with the Science and Engineering Research Council (SERC), through the Teaching Company Scheme, which aims to develop partnerships between academic establishments and companies to help improve manufacturing performance and methods. Under the Scheme graduates are recruited to work in your company, supported by academic staff, and their costs are shared between the Department and the SERC.

Other sources of public support for biotechnology are listed towards

ANNEX III

the end of this leaflet. The Department works closely with these other public bodies, especially the SERC Biotechnology Directorate. In this way Government provides support for biotechnology through basic research to product and process development.

Support for centres of expertise

The Department of Industry has agreed to support R&D in selected areas of technology at the following institutions, as part of its support for the UK's biotechnology effort. Emphasis is being given to joint projects with industry.

PUBLIC HEALTH LABORATORY SERVICE, (At the Centre for Applied Microbiology and Research, Porton Down)
For fermentation technology

WARREN SPRING LABORATORY and ATOMIC ENERGY RESEARCH ESTABLISHMENT, Harwell
For downstream processing and other projects

BIOTECHNOLOGY INSTITUTE AND STUDIES CENTRE TRUST*
For extended work on biocatalysts

PATSCENTRE INTERNATIONAL, Royston
For pilot fermentation and downstream processing plant

The Department is considering support for further major biotechnology facilities, in addition to those already funded notably through research councils, both in their institutes and with the University Grants Committee, in the universities.


Electrophoretic separator developed by AERE Harwell, following early MRC work

Biotechnology in industry – firmer foundations

UK success in biotechnology will grow from:

- an adequate supply of skilled manpower
- basic science
- ready access to technical information
- skilful use of patenting

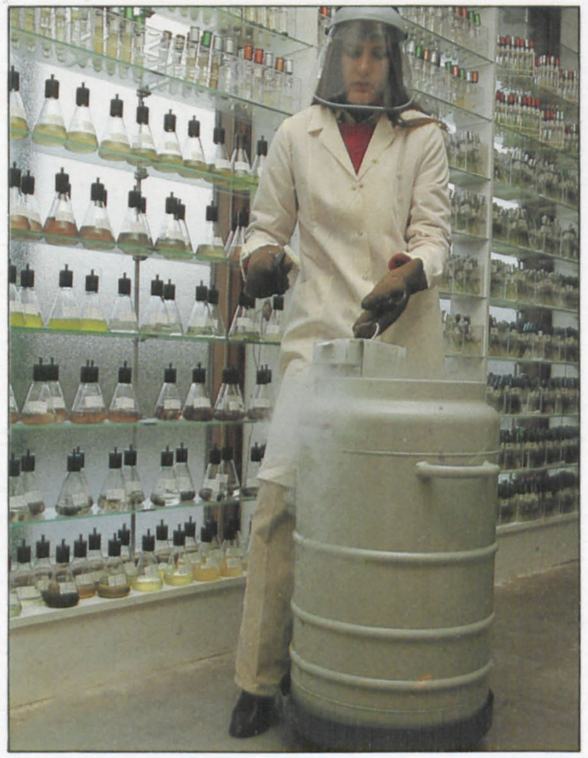
These provisions are a continuing concern of government departments and research councils. Coordination is provided by the Interdepartmental Committee on Biotechnology, which is led by the Department of Industry.

Current objectives of the Department:

Culture collections – to make the unique resource of the National Collections of Micro-organisms more widely useful to industry by

- encouraging stable funding
- developing a central information system
- fostering relevant R&D
- establishing a new collection of animal cells and hybridomas including a depository for use in patenting

Biotechnology information – to improve access to biotechnology information and encourage appropriate information services.


Cryopreservation at the Institute of Terrestrial Ecology Culture Centre for Algae and Protozoa

More information

For more information on the Biotechnology Programme please complete the coupon and send it either to the address given or to any Department of Industry Regional Office, or to the Scottish Economic Planning Department, or to the Welsh Office Industry Department.

Other sources of public support for biotechnology are:

Science and Engineering Research Council
Biotechnology Directorate
Central Office
Polaris House
North Star Avenue
SWINDON SN2 1ET
(Tel: 0793 26222)

Medical Research Council
20 Park Crescent
LONDON W1N 4AL
(Tel: 01-636 5422)

Agricultural Research Council
160 Great Portland St
LONDON W1N 6DT
(Tel: 01-580 6655)

British Technology Group
Kingsgate House
66-74 Victoria St
LONDON SW1E 6SL
(Tel: 01-828 3400)

Scottish Development Agency
120 Bothwell St
GLASGOW G2 7JP
(Tel: 041-248 2700)

Small Firms Technical Enquiry Service and Manufacturing Advisory Service
PERA
Melton Mowbray
Leicestershire LE13 0PB
(Tel: 0664 64133)

Welsh Development Agency
Treforest Industrial Estate
Pontypridd
Mid-Glamorgan CF37 5UT
(Tel: 044-385 2666)

Natural Environment Research Council
Polaris House
North Star Avenue
SWINDON SN2 1EU
(Tel: 0793 40101)

To: Biotechnology Unit
Laboratory of the Government Chemist
Department of Industry
Cornwall House
Stamford Street
LONDON SE1 9NQ
(Tel: 01-928 7900 ext 601/628)

I would like more information about:
(please tick appropriate box(es)).

- grants towards the costs of projects, processes and product developments ☐
- grants for consultancy ☐

Name .... Name of Company ....

Position in Company .... Address ....

*University College London, Polytechnic of Central London, University of Kent.

Science & Tech

DEPARTMENT OF INDUSTRY
ASHDOWN HOUSE
123 VICTORIA STREET
LONDON SW1E 6RB
TELEPHONE DIRECT LINE 01-212 3301
SWITCHBOARD 01-212 7676

JU279

Secretary of State for Industry

30 November 1982

The Rt Hon Sir Keith Joseph Bt MP
Secretary of State for Education & Science
Department of Education & Science
Elizabeth House
York Road
London SE1

2/12.

Dear Keith,

Thank you for your letter of 22 November.

2 As you will see from the attached speech and Press Notice I was able at Wednesday's Press Conference to make some appropriately complimentary remarks about the contribution of the universities and Research Councils in biotechnology.

3 As far as the new biotechnology programme itself is concerned the emphasis is, as you point out, on biotechnology in industry and in particular the need to help firms to pull through developments in the universities and elsewhere to the market. Much of the work to be supported will be carried out by industry itself. But support for centres of expertise in research institutes or the universities is by no means ruled out as long as there is a recognisable industrial focus to the work. Indeed one of the centres of expertise we have already decided to support, together with some companies, is the Biotechnology Institute & Studies Centre Trust (comprising University College, London, the University of Kent and the Polytechnic of Central London). Others will be considered. The new Biotechnology Unit I have set up at the Laboratory of the Government Chemist will work closely with the Research Councils and other Departments and with such a pervasive subject as biotechnology there is clearly scope for jointly supported projects.

4 I look forward to receiving from you the draft text of our response to the Education, Science & Arts Committee Report on Biotechnology and agree that it would be appropriate to issue it over our joint signatures.

5 I am copying this letter to the recipients of yours.

Yours

Patrick

Science & Tech, Jan '80,
Second Report on Biotechnology

2

Prime Minister:

22/11

DEPARTMENT OF EDUCATION AND SCIENCE
ELIZABETH HOUSE, YORK ROAD, LONDON SE1 7PH
TELEPHONE 01-928 9222
FROM THE SECRETARY OF STATE

The Rt Hon Patrick Jenkin MP
Secretary of State
Department of Industry
Ashdown House
123 Victoria Street
London SW1E 6RB

22 November 1982

Dear Patrick.

Thank you for your letter of 25 October about the initiative to stimulate biotechnology in industry which you are launching this week.

It seems that most of the measures within your initiative are understandably aimed at supporting the private sector of industry. I very much hope that, even if only exceptionally, centres of expertise in the universities and Research Councils might be eligible for support from your Department, if their work is seen to be particularly promising but to be constrained by the level of funds available to those centres through their normal sources of funding. Your report to the Prime Minister earlier this year (which covered the report of the Official Committee on Biotechnology) acknowledged the excellent work being done in the universities and Research Councils in this field. Since then the University Grants Committee has announced its own biotechnology initiative and the Research Councils continue to increase their support for biotechnology; but there are nevertheless still pressure points where a small injection of funds by your Department might have a disproportionately good effect.

I would in any case urge you to include in your remarks at the Press Conference on 24 November some laudatory remarks about the contribution by among others universities, polytechnics and Research Councils. I would be reluctant for their contribution to go unrecognised, by default so to speak.

You will, I expect, recall that we are due to respond jointly to the Education, Science and Arts Committee's interim report on Biotechnology which was published in late July. I have recently told Christopher Price, the Committee's Chairman, that we hope to reply in a few weeks' time (our respective officials had earlier agreed that my Department should be in the lead on this response even though your Department retains its lead on biotechnology as an overall subject). My officials are in touch with yours about the terms of the response and I shall of course clear the text with you in due course;

indeed I believe that it might be appropriate for it to issue over our joint signatures. I hope it can appear soon after your announcement; the text will gain from reference to that initiative.

I am copying this letter to the recipients of yours.

Ever

Keith

Science & Tech, Jan '80,
ACARD Report on Biotechnology

010

Sci: Tech 2

DEPARTMENT OF INDUSTRY
ASHDOWN HOUSE
123 VICTORIA STREET
LONDON SW1E 6RB
TELEPHONE DIRECT LINE 01-212 3301
SWITCHBOARD 01-212 7676

JU13
Secretary of State for Industry

25 October 1982

The Rt Hon Sir Keith Joseph BT MP
Secretary of State for
Education & Science
Department of Education & Science
Elizabeth House
York Road
London SE1

Prime Minister

26/10

Dear Keith,

I will be launching in November an initiative to stimulate biotechnology in industry. In view of the interest of your Department and those of other colleagues in this subject, I thought it would be helpful to set out our plans.

2 Over the past few months my Materials and Chemicals Requirements Boards, together with officials and consultants have been assessing industrial requirements for the further development of biotechnology. I now propose to introduce a range of measures aimed at assisting companies to increase the volume of applied research and development in this field. The particular measures and their objectives are:

Measure	Objective
Grants for consultancies and feasibility studies	Greater industrial awareness of threats and opportunities
Increased support for innovation and assistance with demonstration plants	Increase volume of biotechnology R&D in industry
Support for DoI/Industry programmes at CAMR, Porton Harwell, WSL, etc	Strengthen existing centres of expertise in the public sector

Support industrial development of culture collections and improve access to information on biotechnology.	Strengthen biotechnology infrastructure

3 The cost of the programmes outlined is expected to be £16 million over 3 years and will be found from within my Department's existing PES provision. It is not possible to divide the initiative along strict departmental lines but I am sure my officials will consult with yours about any proposals received which are of interest to your or other Departments.

4 To promote and monitor these initiatives I have set up a biotechnology unit based at the Laboratory of the Government Chemist. This unit will in addition identify gaps in existing programmes and commission contractors to carry out the necessary work to fill these. The majority of the staff in the unit will be seconded full time from industry to provide expertise not currently available in my Department. The unit will be able to recommend the levels of funding necessary to ensure the work is carried out. It will work closely with other Departments and the Research Councils, in particular with the Biotechnology Directorate at SERC. The Departmental staff will be found from within existing staff ceilings.

5 I will be launching the initiative at a Press Conference on Wednesday, 24 November. A publicity brochure is being prepared in consultation with officials from your Department and the other main Departments concerned.

6 I am copying this letter to the Prime Minister, Francis Pym, Geoffrey Howe, Jim Prior, Peter Walker, Michael Heseltine, George Younger, Nicholas Edwards, Norman Fowler, Janet Young, Nigel Lawson, Norman Tebbit, Arthur Cockfield and Sir Robert Armstrong.

Yours

Patrick

NBPM

15/7

s/c JV

Sci & Tech

CHANCELLOR OF THE EXCHEQUER

Treasury Chambers, Parliament Street, SW1P 3AG
01-233 3000

PRIME MINISTER

I have seen Patrick Jenkin's minute of 28 May enclosing a copy of the report of the official cabinet committee on biotechnology.

2. I think the broad message of the report is encouraging. The UK seems to be keeping abreast of developments in biotechnology and there is no evidence that Government support is inadequate. What is important now is to ensure that we reap the benefit of commercial exploitation of the technology. This will require some perseverance in the face of the technical and commercial failures that are inevitable in the early years.

3. I have noted Patrick's intention to give biotechnology a higher priority in his Department's expenditure plans. I think it is right that, within the general constraints on expenditure by all Departments, we should do our best to make sufficient resources available to ensure the successful commercial development of the products of this new technology.

4. Copies of this minute go to Patrick Jenkin and the other recipients of his minute.

(G.H.)
15 June 1982

DA

Sci + Tech

10 DOWNING STREET

From the Private Secretary

8 June 1982

Dear Jonathan

Report of the Official Cabinet Committee on Biotechnology

The Prime Minister was grateful for your Secretary of State's minute of 28 May, with which he enclosed the report of the Official Committee on Biotechnology. She accepts his recommendation that the Official Committee should remain in existence for a further one year.

I am sending a copy of this letter to John Kerr (HM Treasury), David Clark (DHSS), Barnaby Shaw (Department of Employment), David Edmonds (Department of the Environment), Julian West (Department of Energy), John Rhodes (Department of Trade), Muir Russell (Scottish Office), Adam Peat (Welsh Office), Stephen Boys-Smith (Northern Ireland Office), Robert Lowson (MAFF) and David Wright (Cabinet Office).

Yours ever

Willie Rickett

Jonathan Spencer, Esq.,
Department of Industry.

One year only
MT.

Prime Minister

Paragraphs 2 to 4 of Mr Jenkin's minute below summarise recent progress in biotechnology in the private sector and government. Para 10 of the paper at A summarises action planned for the future. Dr Nicholson supports Mr Jenkin's conclusion that the Official Committee should continue for a further year to coordinate this work. Agree?

WR
7/6

W.0370

PRIME MINISTER

c: Sir Robert Armstrong

REPORT OF THE OFFICIAL CABINET COMMITTEE ON BIOTECHNOLOGY

I support, and indeed was partly responsible for, the Secretary of State for Industry's proposal to keep this Committee in existence for a further year. My reasons were as follows:-

(a) The expertise in the Department of Industry in biotechnology is thin (because the Department has had little previous interaction with 'biological' industry) and the Department will need support from other Departments like MAFF, Environment and the Research Councils where there is some expertise.

(b) The response to some of the recommendations of the Spinks report are necessarily medium term and cross-Departmental. It will be some time before the effectiveness of the responses can be assessed.

(c) Biotechnology has probably been oversold in terms of timescale and there will be disappointment and disillusionment in the industrial world before there is achievement and profit. The correct Government action during this period will be a matter for fine judgement and the Official Committee is the best forum for preparing advice to Ministers.

RBN.

ROBIN B NICHOLSON
Chief Scientist

Cabinet Office
4 June 1982

cc [illegible]

PRIME MINISTER

REPORT OF THE OFFICIAL CABINET COMMITTEE ON BIOTECHNOLOGY

In March 1981 the Government published a White Paper (Cmnd 8177) as its response to the joint ACARD/ABRC/Royal Society Report on Biotechnology (the Spinks Report). My Department had had the lead in co-ordinating the actions necessary to implement the policy set out in the White Paper. The Chief Engineer and Scientist chaired an Official Cabinet Committee whose report is attached.

2 There has been significant progress in the private sector in the year since the White Paper was published. We estimate that more than 50 companies are using biotechnological processes in the UK and a number of new ventures have been established. Interest has undoubtedly been stimulated by the Spinks Report, the White Paper and the subsequent work that we have been doing. Veterinary vaccines, insulin and medical diagnostic reagents will be the first products brought to the market by the new technology with other pharmaceutical products later in the decade. There will be developments in agriculture and food processing aimed at cheapening the production of human and animal food. Waste management is a more difficult area, of longer term importance. Energy production from biomass offers few prospects in the UK

although there may be export opportunities for process plant. The limited profits during the 1980s which will have to come from products not subject to regulatory delay, will be very important in maintaining investors confidence. Major profits can only be expected to appear in the 1990s and beyond.

3 If the UK is to make further progress and exploit, to the best advantage, its undoubtedly strong position in the basic science, Government backing for engineering and other development is essential. I propose, therefore, to build up the present work to a substantial initiative during the remainder of 1982 under my Department's leadership. Biotechnology will have increased priority in the Department's expenditure plans.

4 All Departments now fully realise the importance of this subject. Actions taken since the publication of the Spinks Report include:-

i authorised current investment of more than £13 million by BTG in biotechnology;

ii increased expenditure by Departments and Research Councils on biotechnology R&D to a current level of £7 million p.a with additional funding of the underlying basic science;

iii a UGC plan to strengthen three university centres at a cost of £300,000 annually for three years and to provide further support for other centres at a later stage;

iv setting up of a biotechnology directorate by SERC with strong links to DoI and other Departments;

v the setting up of a co-ordinating committee for biotechnology by the Heads of the Research Councils

vi continued easing of the regulations bearing on biotechnology.

5 In the course of this work the Official Committee has also reviewed the application of biotechnology to food, to waste treatment, the impact of safety and health legislation, the effects of UK patent law and the needs for education and training in the field. The conclusions of these reviews form the basis of the actions already taken and those planned for the future.

6 Departments are now taking most of the necessary steps but there is a continuing need for the co-ordination of Departmental efforts to maintain momentum. Plans for the future are set out in paragraph 10 of the summary to the report and they include, in addition to the biotechnology initiative, continued support for basic science, collaboration with BTG, SERC and the other Research Councils to ensure exploitation of the science, and further easing of the regulatory environment. In order that this work can be carried out successfully I recommend that the

Official Committee remain in existence for a further year.

7 I am copying this minute and enclosure to the Chancellor of the Exchequer, Secretaries of State for Social Services, Employment, Environment, Energy, Trade, Scotland, Wales, Northern Ireland, the Minister of Agriculture, Fisheries and Food and to Sir Robert Armstrong.

PJ

P J

28 May 1982

Department of Industry
Ashdown House
123 Victoria Street

DRAFT 29th APRIL 1982

REPORT OF THE OFFICIAL COMMITTEE ON BIOTECHNOLOGY

Summary and Recommendations.

1 In the past few years the industrial application of biological processes and organisms - or BIOTECHNOLOGY - has attracted great and world-wide interest as products based on earlier scientific discoveries have started to appear on the market. In the UK particular attention was drawn to the topic by the joint report from ACARD, ABRC and the Royal Society (the Spinks Report) (published in March 1980) and by the White Paper (Cmnd 8177) which the Government issued in response. The Prime Minister agreed that the Official Committee on Biotechnology should continue to coordinate Government action and the Committee now reports on what has been achieved in the past twelve months. It also presents an overview of the topic as a background to the work of the Departments.

2 There will be major markets for biotechnology during the next twenty years in health care, with significant opportunities in food and agriculture and more limited potential in waste treatment, energy production and the provision of basic tonnage chemicals. Both new products (notably in health care) and new routes to products (especially in agriculture and food processing) will be developed.

3 In health care the development of a number of new products such as human insulin, human growth hormone, interferons and some vaccines is already well advanced. Other therapeutic products are likely to be developed. The ease with which these products can be approved for human use varies and depends on how closely they are related to the human-derived material for which they are replacements. In general, however, therapeutic products involve considerable investment of money and time in research, development and testing to ensure safety and suitability for human use and early financial returns cannot be expected. On the other hand diagnostic reagents for laboratory use and some veterinary products do not require such extensive testing and profits may therefore be realised sooner, often making them more attractive propositions for smaller firms.

4 The UK is well placed to exploit the health care applications of biotechnology. Our basic science is good and our pharmaceutical industry is strong. The British Technology Group and the Scottish Development Agency have been active (in collaboration with private investors) in applying appropriate university and Research Council basic science. The need in this area is for the Government to maintain its Research Council and University funding for the basic and applied science. It should continue to minimise regulatory obstacles and, where possible, use public purchasing to establish a sound UK manufacturing capability.

5 Developments in food and agriculture are likely to result from improved plant strains which will have greater disease resistance, give increased yields, and provide products better adapted to their ultimate use in the food processing industry. There should be continued Government support through ARC and MAFF laboratories.

6 Several Departments (DoE, D En, DoI and MAFF) are helping to finance research, trial installations and demonstrations for the treatment of industrial, domestic and agricultural waste. The development of reliable process plant will be expensive. It will require close collaboration between Government and industry and there is scope for some action through public purchasing particularly in the domestic waste treatment area.

7 Naturally grown organic materials (wood, straw, sugar beet) are likely to make only a relatively small contribution to total UK energy needs. Such energy is however valuable to the World economy and this is likely to be reflected in substantial investments in equipment to process feedstock. If biomass becomes an important feedstock for liquid fuels or for the chemical industry, the most important market will be for the export of equipment. This would provide significant opportunities for the UK process plant manufacturers.

8 Overall it will be important to maintain investment confidence since in many areas lead times will be long and profits slow to appear. Some early ventures will not succeed and

those providing the finance must take a long term view. Many biotechnology ventures are internationally mobile. If the UK is to retain an effective share of the world business it must provide a hospitable scientific, industrial and financial climate.

9 Actions taken (or planned) since the publication of the Spinks Report include:-

(i) Authorised current investment of more than £13M by BTG in biotechnology and by the SDA to more than £1.3M.

(ii) An agreement between MRC and BTG that will lead to the commercial exploitation of some MRC know-how by Celltech. BTG is currently establishing an agricultural company to exploit ARC know-how.

(iii) Increased expenditure by Departments and Research Councils on biotechnology R&D to a current level of £6.5M per annum (with additional funding of the underlying basic science). Further increase in funding is planned over the period 1982/4.

(iv) The Secretary of State for Industry plans an initiative later this year to stimulate industrial R&D in biotechnology;

(v) The UGC plan to strengthen 3 university centres at a cost of £300,000 annually for 3 years, and also provide further support for additional centres at a later stage. These provisions, possibly totalling as much as £800,000 per annum, will include some extra posts.

(vi) The Heads of the Research Councils set up an Inter-Research Council Coordinating Committee on Biotechnology to coordinate the work of The Councils. It has just produced its first report.

(vii) SERC has established a Biotechnology Directorate with strong links to DoI and other Departments.

(viii) There has been continued easing of the regulations bearing on biotechnology. GMAG has maintained sensible regulations for research. HSE and GMAG have agreed procedures for dealing with industrial applications.

(ix) The Official Committee has reviewed safety regulations and procedures, patenting and the potential for waste treatment.

(x) An interdepartmental Committee, chaired by the Government Chemist has been established to provide central co-ordination in Government and stimulate development.

10 The Official Committee recommends that:

(i) The Government should continue its present policy for the support of the basic sciences relevant to biotechnology, through the dual support system.

(ii) The DoI, in collaboration with BTG, should build on the initiatives taken with Research Councils to facilitate the exploitation of the basic science.

(iii) The Government should continue to ensure that regulations are not unnecessarily restrictive.

(iv) Consistent with our European Community and other international obligations and the Government's stated policy on public procurement, Departments should use the influence their purchases give them to help the development of a sound UK manufacturing capability particularly for waste treatment and other process plant.

(v) To assist and stimulate technology transfer Departments should ensure that information is available for both producers and users on the potential of biotechnology. This is particularly the case in the health care and agricultural areas. One solution would be to encourage consultancy arrangements.

(vi) Given the high risk and uncertainty of the biotechnology field the Department of Industry should monitor the progress of the smaller companies to ensure that the inevitable bankruptcies do not lead to a major loss of confidence and capability in the UK. Some action through BTG may be necessary.

(vii) The Education Departments in collaboration with other interests should seek to ensure that adequate education and training is provided at all levels from technicians to postgraduates and across all the disciplines involved. The strengthening of a number of university centres, which will result from the UGC's initiative, will go part way to meeting this need. Action is however also required in the schools, in further education and in the public sector institutions of higher education; as to the last, the newly established National Advisory Body for Local Authority Higher Education may assist coordination of initiatives.

11 Government actions are now increasingly organised by individual Departments or handled by separate liaison arrangements but the Official Committee's recommendations call for both new initiatives and a continuation of a number of existing activities. Some will require interdepartmental co-ordination and it is therefore recommended that the Official Committee remain in being for a further year until these actions are underway.

BACKGROUND: PROGRESS IN BIOTECHNOLOGY, 1979-82

12 During the three years that have passed since ACARD began its work on biotechnology, the most noteworthy progress throughout the world has been in the systematic development of the subject as an applied science. Possibilities for the synthesis of complex chemicals, for example polypeptides and antibodies for diagnosis and therapy had previously been clearly demonstrated by pure scientists in universities and publicly funded laboratories. Industrial teams are now working on the particular organisms best suited for their needs, on the stability of products and processes, and on the many other requirements for commercial success. Patenting is prolific. Sufficient material has been produced of some therapeutic chemicals for clinical trial and toxicology to proceed effectively. As yet, there seem to be no major additions to the list of products originally identified as potentially important in the market, but equally there have been no deletions. Insulin, interferon, natural peptide opiates, and hormones have been worked on with great effect. Most of this work has been done in the private sector. New companies, especially in California, have received the greatest publicity, but the large established chemical and drug companies are also increasingly active. Many of them have invested in the new companies and bought research results and patent licenses. This is the current area of growing cash flow; some years may yet have to pass before there is significant business in actual products for health care. New applications of biotechnology are also being developed by the food and some other industries.

13 Meanwhile, governments have been increasing the funding for the basic science and for the areas of applied science where the private sector lacks the mechanisms for pursuing the opportunities. Education and training programmes are being scrutinised. The regulations and codes governing research have been liberalised. Some initial concern about general hazards through the accidental production of dangerous organisms may have been excessive. The regulations for product and process safety have been examined to see whether changes are necessary because of likely advances in biotechnology.

14 Alongside a general attitude of confidence and optimism, there are inevitably some problems and dangers. One is that of a possible mismatch between the payback expectations of some investors and the entrepreneurs themselves due to the time interval needed before major products can be safely and profitably sold. There is complete general confidence in the vital and pervasive role of biotechnology twenty and more years ahead, but less certainty about the lead times for business development during the next two decades. BTG may have a catalytic role to play here. There will inevitably be some failures and bankruptcies in businesses developing in a highly competitive environment. For these reasons the progress of the smaller companies should be monitored by the Department of Industry. If it appears that investment confidence is being seriously undermined consideration should be given to limited, strategic and selective support, possibly through BTG.

15 During the remainder of the decade it will be important to maintain the confidence of investors, entrepreneurs, and the biotechnology community generally, by all possible means. The greatest encouragement will come from any businesses that generate profit. Even if, as is likely, there are no significant profits from major products during this period, quite modest successes may have a disproportionately good effect on confidence and morale. It may therefore be of particular importance for government to stimulate the market for products such as blood components and diagnostic systems which can be brought to the market more quickly than pharmaceutical products.

16 During 1979-82, activity and progress in the UK have been considerable, although clearly less than in the USA. But the position does not compare unfavourably with that in Germany, France, and other members of the European Community. In the UK, government has encouraged both private sector investors and the BTG to build on the good national position in basic science, and form companies mainly with private money. Meanwhile, the Research Councils have been able to increase funding for biotechnology beyond the levels recommended in the Spinks Report. Business developments are often international and companies are looking for the most favourable country in which to establish R&D and production facilities. The UK with its good science base and well defined regulatory framework is well placed to attract inward investment. It is important to ensure that this remains the case.

17 In the rest of this report, we summarise the position, from the UK viewpoint, in each of the major fields of end-use for biotechnology - health care, food, agriculture, waste management, fuels and chemicals. We then survey basic science, education and training, regulation and other general matters, and make recommendations for government action in fulfilment of the undertakings in the 1981 White Paper on Biotechnology (Cmnd 8177).

MARKETS AND APPLICATIONS FOR BIOTECHNOLOGY

Health Care

18 This is the field in which the earliest profits and cash flow may be expected; it could well be the most profitable in the longer term, although just possibly it might be overtaken in economic significance by applications in food and agriculture. Human insulin is likely to be the first success; Eli Lilly are said to be near test marketing in the US and they hope that the current regulatory clearance there for animal derived insulin will be held to apply to new products. The current world market is £140 million pa and this is expected to double by the year 2000 (cf total world pharmaceuticals sales of conventional health care products of £9,000 million). Smaller markets exist for human growth hormone (world market £50 million) and minor products such as ACTH (£3 million).

19 Profits in the mid 1980's could also come from diagnostic systems based on the monoclonal antibody techniques developed in the UK. Celltech (BTG and private investors) have this as their first profit target outside the field of sales of R&D alone. Potential 1990 world markets are £1000 million, but build-up rates are difficult to estimate and marketing skills will be very important.

20 Markets for polypeptide blood components may be developed during the 1980's; total world markets might be £150 million, and growth could be rapid.

21 Beyond these well-defined prospects, genetic manipulation and cell fusion techniques have wide-ranging potential application in diagnosis, preventive medicine, and therapy. The major fields are:

enzymes	diagnostically, to detect cells as in bacteriuria and to estimate tissue levels of specific molecules, eg drugs or trace metals; therapeutically, to correct inborn enzyme deficiencies or to destroy toxic substances or malignant cells;
peptide hormones	to stimulate defective or non-functioning metabolic systems, eg erythropoiesis, reproductive systems;
vaccines	against malaria, the various hepatitis viruses, influenza and tropical diseases;
antibodies as subsidiary tools in treatment	eg to remove leukaemia cells prior to bone marrow transplantation or immunocompetent T-lymphocytes from donor bone marrow;
other proteins	to correct other deficiencies, eg of blood clotting factors; to replace human plasma proteins lost through trauma or surgery; to provide natural analgesics, eg endorphins; interferons.

The human vaccine market could be £1000 million by 2000, but it has to be remembered that many of the applications - eg for malaria - are in countries where social habits and lack of finance can delay medical advance. The prospects for interferon are controversial; on optimistic assumptions, it could have very large sales indeed as the first effective antiviral agent. But its clinical trials are only at an early stage and large scale manufacture is possible before its therapeutic effects have been properly established. There is also scope for products (eg human growth hormone) which have a limited market but are of high social value.

22 Foot-and-mouth disease is an important target for veterinary vaccines. The production technique avoids the cultivation of live virus, and is therefore safer than existing methods. ARC is also working on vaccines for pig and poultry diseases. The market will depend on the economics of livestock rearing unless evidence leads to government requirements for vaccination. Slow growth can be expected; the total ultimate market might be £100 million/year. Active companies include Genentech (USA) and The Wellcome Foundation which works in collaboration with The Animal Virus Research Institute supported by the ARC.

23 Apart from the new enterprises, whose achievements have had much publicity, the international pharmaceutical companies have R&D teams at work, and outside contracts at universities and elsewhere. The cost of taking a drug to the market is often in the region of £50-100 million, so that wherever development is

carried out, it is likely to be the major companies who pay for these "entry fees". Their progress is kept confidential. The entry cost for diagnostic reagents and veterinary vaccines should be lower and within the reach of smaller companies. The next biggest strategic influence in UK is BTG, with interests in nearly forty biotechnology initiatives, mostly small and university based. (Celltech is the largest, now employing 100; others include Speywood (employing 40 scientists)).

24 The government's role in the health care field lies mainly in financing adequate basic science; in support of applied R&D; in regulation to ensure drug safety whilst keeping associated costs and delays as low as possible, and in financially supporting the engineering technology involved in scale-up and production through the DoI, DHSS and Science and Engineering Research Council.

25 The UK has traditionally been strong in basic science for health care and there is substantial Government support through the Medical Research Council (and, for veterinary care, through the ARC). Current expenditure in these two bodies is £4 million p.a. on biotechnology with at least a further £10 million on the underlying science. Another important resource in both basic and applied work is The Public Health Laboratory Service Centre for Applied Microbiology and Research (CAMR) funded indirectly by DHSS at a cost of £5 million p.a.

26 So far, relatively little support has been called for on scale-up and production technology, but small companies may need help in future. The Department of Industry's Materials and Chemicals Requirements Board has a Biotechnology Group which can give assistance through the Department's Product and Process Research and Development Scheme. There is a need for the DoI to work more closely with MRC, CAMR and BTG to ensure successful commercial exploitation of the basic science.

27 Therapeutic products are controlled by the Medicines Act, and requirements for products of cell cloning or gene manipulation should not be more onerous than those for products made by chemical synthesis. Research will be needed to see how far clearance for one polypeptide is applicable to very closely related compounds. Generally, such problems in the UK are solved by collaboration between firms and DHSS. This pragmatic approach is envied, and is being copied, by other countries.

28 There will be fierce international competition in the marketing of these new pharmaceuticals. It is essential that the aim should be wherever, possible, to help UK firms establish a UK manufacturing and marketing base from which products can be successfully sold overseas.

Food and Agriculture

29 Biotechnology played a large part in food production and farming before the advent of systematic gene transfer and manipulation. Fermentation has been used for many centuries in

the production of alcoholic drinks and some milk and meat products. Plant and animal breeding has sometimes been achieved by slow, painstaking empirical methods.

30 Food ingredients, additives and processing aids have more recently been produced by biological techniques and further advances are to be expected with the advent of newer techniques. In addition to additives which can improve the quality and consistency of food, protein can also be produced by biotechnological processes. Fermentation methods have been devised for the production of human food protein from starch (RHM) and animal feed protein from methanol (ICI) and from hydrocarbons. The development of these processes necessitated considerable engineering and process control advances by the companies concerned. BTG has invested in RHM's process for production of human food protein. It is, however, likely that the most significant applications for biotechnology in the food industry will arise in processing of food. New processes can be introduced by the development of immobilised enzymes or cells, which allows continuous processing with little loss of enzyme. Whole cells or isolated enzymes can be used to make substitutes for familiar products, for example cocoa butter substitutes from vegetable oils.

31 One of the earliest techniques identified for genetic manipulation was that of transferring the capability of nitrogen fixation, present for example in peas and beans, into cereals (which at present require artifical nitrogenous fertilisers for

high crop yields). The ARC Unit of Nitrogen Fixation at the University of Sussex has a leading role in this subject. However, it is a complex problem, unlikely to be solved quickly; further the use of plant carbohydrates to provide the energy needed for nitrogen fixation could lead to some reduction in crop yields.

32 Private and public sector laboratories have made considerable advances in tissue culture, which involves the growth of plant cells in a nutrient medium in laboratory or factory vessels. This technique provides means for greatly accelerating the development of new strains of plant. It has already been used to produce improved and more consistent commercial oil palms, and other plants more tolerant to alkaline/acid soils. It can improve disease resistance. It can be used to develop plants well suited to their end use in food processing.

33 The Government's part in biotechnology for food and agriculture will grow in importance. At present, it pays for a greater proportion of the research than in the health care field, and this is especially so for agriculture. Private investors are likely to provide money for companies to develop and market seeds and other starting materials, and the BTG is already actively seeking to promote this process. To exploit fully these new materials, as also the newer veterinary products noted in paragraph 22, will require improved farm husbandry, and so enhanced advisory services and education. New farm waste

management methods will gradually become important (see below paragraph 36). Agriculture already uses much higher technology than a few decades ago; Government has played a large part. The changes over the next few decades may be just as great and this is recognised by The Agricultural Departments.

34 Food processing will involve major chemical engineering projects and the DOI through its Product and Process Research and Development Scheme and the SERC Directorate will be able to support this development work. As in the case of health care, Government must continue to avoid the creation of unnecessary regulatory obstacles but biotechnology is unlikely to present any totally new problems for the regulatory system.

Waste Management

35 There are two areas for the possible application of biotechnology: economic recycling of useful material, and the removal of nuisance. They can, in principle, be combined, and this always looks attractive. However, there are obstacles. Waste managers tend to give overriding priority to safety and to the avoidance of nuisance, and hence prefer familiar, reliable methods to innovation even if these latter might ultimately be profitable. Waste generation is extremely widespread and diffuse; where it is not (as in factory operation), waste recovery and recycling is much easier. Another reason is that waste is variable in kind and different wastes are mixed at source (eg the domestic dustbin). Furthermore waste managers may have little control over the nature and volume of the waste to be treated. Finally, most waste managers wish to get rid of waste

as quickly as possible because it is unpleasant: consequently investing in means of upgrading it is not popular. Even in industry, waste treatment is not a top priority unless effluent disposal has a significant cost because of a need to prevent nuisance.

36 It is in the area of industrial (including agricultural) waste that there may be most scope for biotechnology. The combination of high energy costs, increased plant scale, and higher value for recycle, makes waste treatment increasingly more attractive. Firms can control the composition of their effluent by altering process conditions. There are cases where firms have jointly designed process conditions and effluent treatment - for example, in Canadian and Swedish paper pulp bleaching. Where farming is intensive (eg pigs and poultry), there can be a steady supply of consistent liquid waste which together with odour can cause a considerable nuisance if dwellings are near. Methane can be a useful by-product from the digestion of animal waste although with the exception of some large piggeries and poultry units the quantities are only sufficient for use on the farm itself. Total quantities will be very small in relation to overall UK gas and oil use and the farmer will only respond if there is a financial incentive to do so or if there is the additional stimulus of regulation (such as Water Authorities are providing by the stringency of their controls over discharges to water courses).

37. In general, biotechnology can only be used when attitudes to waste management are already innovative. It has only a minor part to play in the improvement of conventional methods - for example in the generation of gas from suitable waste tips. Changes in the economic climate are unlikely to be a major stimulus to the application of biotechnology to waste management. Regulation could provide more stimulus, but can rarely if ever be justified solely because of the desirability of introducing a new technique: it rests rather on the need to meet a particular environmental objective or standard irrespective of the method employed.

38. Market forecasts are very uncertain but one estimate suggests that the demand by the public authorities could amount to £500 million over the next 10 years for conventional equipment for waste removal and treatment. There has been limited private sector activity in innovative equipment and methods and this began over a decade ago; progress will continue to be slow.

39. Government has two roles. One, exercised already mainly by D En, DOE and the Agriculture Departments, is to ensure that work is done to make bio-technological approaches available wherever they are commercially attractive or regulation creates opportunities. The other, exercised by DOI, is to encourage the use of biotechnology in industrial and domestic waste management, through grants under the Product and Process Research and Development Scheme.

Fuel and Chemicals

40. Some overseas countries have major programmes to convert biological material (biomass) into fuels such as ethanol and methane. Particularly well known is the programme in Brazil to produce motor fuel fom sugar cane and cassava. An optimistic assessment places the maximum biomass resource in the United Kingdom at about 50 million tons of coal-equivalent per annum (15% of UK fuel use). Two-thirds of this energy resource would come from waste and about one-third from energy crops to be grown mostly as catch crops and trees on marginal agriculture land. Current studies include a mapping of the waste resource and a survey of land availability for energy crops. There are experimental projects on catch cropping, short rotation forestry and the cultivation of natural vegetation.

41 The difficulties in utilising waste by biotechnology have already been described (para 35). The amounts of gas produced would be small (6% of the present North Sea gas supply). Biomass handling would be expensive, reaction times slow (digestion periods of 10 to 20 days) and energy conversion poor.

42 The UK process plant industry has identified export opportunities for equipment for tropical countries, where biofuel prospects are better. For ethanol production, raw materials account for 60 to 70% of the cost. Cellulosic biomass, such as wood and straw, is cheaper than starch or sugar sources such as potatoes and beet but cannot be fermented without prior treatment. The development of organisms capable of rapidly

degrading cellulose is an important target for genetic engineering and ARC is supporting work in this area.

43 Another possible area of application is the use of micro-organisms to enhance the recovery of oil from reservoir rocks by increasing the oil mobility. At present using conventional techniques it is possible to recover only 40-60% of the oil from the reservoir. Several university and industrial laboratories are investigating organisms that might be able to live in the high temperatures and pressures of oil reservoirs. Further research is needed but the rewards from success could be high.

44 Biological processes can produce a wide range of basic tonnage industrial chemicals - ethanol, acetic acid, citric acid and many others. Unlike the chemical routes to these products which operate at high temperature and pressure the new biotechnological processes require only mild conditions. Plant capital costs, however, can still be high because products are formed in large volumes of dilute aqueous solutions. The energy costs of separation are high. Feedstocks, eg carbohydrates, may be more expensive than petroleum feeds. These cost factors are less significant for high-value products such as pharmaceuticals or food components but the economics of biotechnological processes for bulk low-cost chemicals are very uncertain. With the high production costs of biomass in the UK this is unlikely to be an important route for the production of industrial chemicals. If production of ethanol from biomass becomes an economically attractive proposition then the UK is likely to

import the ethanol from tropical regions as a feedstock for industrial chemicals. At this stage it is far from clear that further processing of the ethanol by biotechnological techniques will compete with conventional chemical methods.

45 Microbiological processes already play some role in the extraction of metals like copper from ores by leaching. There is potential to extend the use of such processing to other metals, including uranium and nickel, and to extraction from very low grade ores, using naturally occurring or genetically manipulated organisms. In the longer term microbial leaching may also be used in preference to existing methods to extract some metals from high grade ores, although there will be substantial engineering and biological problems to overcome. Micro-organisms can also be used to recover and concentrate metals from solution, although so far these processes have only been used to purify effluents. Further R&D is required to explore the full potential of these metal recovery processes.

Process Plant Requirements

46 Biotechnology will create new needs for process plant. The growth of living cells require sophisticated reactors and a close control of the processes. ICI have pioneered the development and application of large-scale continuous fermenters and Rank Hovis McDougall have developed computer process monitoring for their pilot plant fermenter used in the manufacture of the food protein Mycoprotein. Allied Lyons have a joint venture with John Brown to market continuous brewing for power alcohol production. The

experience in design and construction gained by these companies will be of great value as large-scale applications of biotechnology develop. In almost all areas for large-scale use of biotechnological techniques, better basic processes are required to ensure commercial viability. Process plant firms must be encouraged by DOI and SERC to work in collaboration with companies developing biotechnology processes before large-scale production is contemplated.

OVERSEAS ACTIVITIES

47 In Germany the Ministry of Research and Technology (BMFT) launched a major national programme in 1972. The strong West German chemical, pharmaceutical and process plant industries are well placed to take advantage of developments. BMFT's biotechnology research budget in 1980 was about £19 million. But much of this money is being spent in a major Government centre for research at Braunschweig Stockheim, with which BMFT are dissatisfied. At present, BMFT believe that they need new initiatives and have asked for UK advice and ideas. Collaboration between Germany and the UK on aspects of biotechnology is being arranged by the Department of Industry, and is initially concentrated on culture collections (see below, para 71) and safety regulation.

48 The French Government has published two reports on biotechnology "Science de la Vie et Société (1980)" and "La Biotechnologie Demain (1981)". The second report was critical of French industry and suggested that it was behind industry not only in America and Japan but also in Germany, the Netherlands and the UK. The French Government is still considering its plans but has now designated biotechnology as a priority area. It has allocated some £20 million for expenditure in 1982 and has appointed a Director for biotechnology. As in the case of Germany, the new Director has come to UK to discuss ideas, and similar collaboration is being arranged.

49 Japan has been a world leader in the limited but significant business of making amino acids and nucleotides for many years. Japanese companies are investing heavily in enzyme technology, genetic engineering and cell immobilising techniques. The Government actively supports the subject in universities and industry at a cost equivalent to £8 million per year. There is Science Council support for about a hundred universities. A number of UK companies are looking for opportunities to break into the Japanese market.

50 The United States scene has been discussed above (paras 12 and 16): it is characterised by the ready availability of private venture capital. Although government action is not obvious, much of the private venture capital invested in firms like Cetus, Genentech and Genex is underwritten by the funds provided by the National Institutes for Health and other Federal agencies and by basic R & D in the universities.

51 There has been considerable Government attention directed to biotechnology in Brazil, Canada and Australia.

52 A limited European Community Research and Training programme in bio-molecular engineering has recently been agreed. The first stage will be a two-year programme costing 8MUA (£4.6 million), concentrating on agriculture and safety. The Commission's draft proposal for a Council Recommendation on recombinant DNA work is unduly restrictive as it stands because it would require advance notification of all genetic manipulation experiments. The UK

has taken the lead so far in opposing these undue restrictions and is seeking the support of like minded States for future Community discussions on these draft recommendations.

3 Overall the UK is investing less in biotechnology than the Americans but our total efforts are comparable with those of Germany, France and Japan. This does not mean that the present position is satisfactory and many initiatives for the Government have been identified in this report. In addition the UK could gain from collaboration with other countries provided the areas for collaboration are selected carefully; the lead on this being taken by DOI.

GOVERNMENT MACHINERY AND ACTIONS

Basic Science

54 The Spinks Report called for the Research Councils to increase substantially their support for biotechnology to at least £3M a year and to set up a Joint Committee to develop a coherent programme. The Government in its White Paper agreed that biotechnology should have a high priority amongst university research activities and, despite the financial constraints, the Research Councils and universities have continued to expand their research in this area. Annual Research Council expenditure is already £5M and is planned to grow to more than £6M over the period 1982/4 with at least another £10 million spent on relevant basic sciences. To share the benefits of fundamental and applied work, the Councils have set up a liaison committee. The SERC and Department of Industry have established a joint Biotechnology Directorate, with an industry-based Chairman of its management committee and full-time official staff. This seeks to link basic researchers with those responsible for development, to help with priority fixing and ensure good support for key areas. These actions meet immediate needs, and the Committee recommends no further co-ordination at this stage.

Development, engineering and exploitation

55 The Spinks Report also called for the development of a coherent programme of industrial research and development costing about £2½M annually to follow up the invention and clearance of new products. The programme would involve industry, Government and the universities. The establishment of an

nterdepartmental steering group was also recommended. The Official Committee was established after the publication of the White Paper as the Government co-ordinating machinery and through it put in hand a review of the adequacy of existing programmes. Alongside the large investments of the private sector and the vigorous activity of large existing firms and small new ones, government has allocated money, through existing schemes, to provide support for projects with long lead times. BTG has been particularly active, and is using catalytic investment to help forty projects covering a wide range of biotechnology products and processes; current commitments total £13M. BTG is planning to commit a further £15M over the next 3 years. They propose to seek out opportunities to invest in down-stream applications of biotechnology particularly in areas of small volume high added value products at the frontiers of technology. There may be opportunities to support appropriate areas of the process plant industry and they will continue to respond actively to University prospects. DoI's Materials and Chemicals Requirements Board has established a Biotechnology Committee and has so far allocated £0.7M, mainly as 25% grants to stimulate longer term private sector projects. The Government Chemist has been given special responsibility for monitoring needs, and has formed an interdepartmental group to study opportunities and the impact of regulatory obstacles (see below).

56 Because of the probable rapid growth in development and engineering of production processes, the Secretary of State for Industry plans a publicised initiative later in 1982, as part of

the innovation package announced in the Budget. £10 million will be allocated, over three years, to cover consultancy for small firms as well as grants for projects. Information and control technology are likely to be important in biotechnological development, because processes will need very precise conditions. Within the initiative, it is also proposed to try to create partnerships between universities and small groups of firms, perhaps also involving banks and financial institutions, to exploit university ideas in commercial terms and to feed back research needs. Firms like ICI have pioneered such arrangements, and we believe that some stimulation by SERC and DoI grants could extend them to a wider range of firms. At a time when private sector R&D is tending to suffer because of difficult trading conditions, such partnerships could help to maintain the level of seedcorn activities.

Education and Training

57 The Spinks Report recommended that urgent consideration should be given to the provision of trained manpower for biotechnology and the White Paper accepted this. The needs for education and training have been examined both by the Education Departments and the Royal Society and they agree that the overall requirements for manpower with specific biotechnological skills are unlikely to be very large and that they can be met by strengthening existing resources. The University Grants Committee has recently decided to earmark £300,000 annually for three years to strengthen 3 university centres of biotechnology, and intends to provide further support to additional centres at a

later stage. The total amount of the earmarked funds could be as much as £800,000 annually. This initiative, together with the universities' plans, will meet the call in the Spinks Report for new university posts, and will strengthen the infrastructure in the universities. There is general agreement, across both university and public sector higher education, that there should be little, if any, development of new undergraduate degrees specialising in biotechnology; rather, specialisation should take place at postgraduate level. the need at undergraduate level is for a basic grounding in the appropriate disciplines, although a number of existing courses might reasonably develop a biotechnological emphasis through the incorporation of specialist options at the later stages of the course. Some moves in this direction are already occurring.

58 All four natural science Research Councils support postgraduate training in biotechnology. The MRC has been running a special programme since 1980 which provides ten extra studentships; the NERC awarded six postgraduate studentships in early 1982 for training and research in environmental aspects of biotechnology; and the SERC plans an increase in its support from present levels of 9 research studentships 12 CASE studentships and 25 advanced course studentships.

59 For technicians, expected growth in demand can be met through the existing course system but action is being taken by the Technician Education Council (which covers England, Wales and Northern Ireland) and by the Scottish Technical Education Council

to investigate the need for curriculum development. The Manpower Services Commission has also re-aligned part of its Training Opportunities Scheme and could contribute towards meeting future demands for technician training by providing new programmes. The Open Tech, supported by the Manpower Services Commission, promises wider access to technician education, which should be of benefit to biotechnology.

60 In schools, the DES are seeking to broaden the scientific education of all pupils up to the age of 16 and wish to see a curriculum that contains more applied work and takes full account of existing and new technology. A handbook "The Use of Micro-organisms in Schools" is for example being brought up to date to help teachers introduce experimental work related to biotechnology. Broadly comparable developments are taking place in Scotland.

61 A problem facing industry is that not all the necessary skills lie in one firm. There will be a growing need to retrain and gather together people from different disciplines to give new combinations of skills. This will call for joint ventures between companies and for access to training programmes to upgrade the skills of existing staff.

Safety and Regulation

62 The UK regulatory regime has been compared with that in other leading industrial countries and has been found to be favourable for the development of biotechnology. Relations between industry and academics on the one hand and the staff of the Inspectorates and officials concerned with product approvals on the other are excellent. The work of the Genetic Manipulation Advisory Group (GMAG) has allowed developments to proceed in a satisfactory way and regulations have been relaxed as confidence has increased. However, there is now concern in industry that the notification procedures for large scale use of genetically engineered organisms are cumbersome and action is needed to ensure that the UK remains an attractive industrial environment. The new procedures referred to in paragraph 9(viii) of the Summary and Recommendations should go a considerable way to meet this concern. Talks between DES and HSE on the future of CMAG are proceeding as a matter of urgency and a report to Ministers and the Health and Safety Commission will be made as soon as possible.

63 The White Paper (Cmnd 8177) recommended that a balance must be struck between the rapid exploitation of the new processes and protection of consumers but there is concern, particularly in the food industry, about the time required to obtain product approvals. The system of external advisory committees is thought, by industry, to be unwieldy. DHSS and MAFF recognise the need to avoid unnecessary delay and have instituted changes, but staffing difficulties are causing problems. DHSS is discussing with other Departments arrangements for a scheme for the monitoring and inspection of laboratories for pharmaceutical product and chemical testing so that test results obtained in the UK can be acceptable overseas.

64 Companies seeking approval overseas for drugs and food and food additives often experience long delay, notably in the USA. DHSS and MAFF, in consultation with the Foreign and Commonwealth Office, will continue to press for easier international approval of new biotechnology products. They will explore the extent to which products approved by the European Community and by its member States could be accepted more quickly into the USA and vice versa.

Patenting

65 There is little evidence that the UK patent system constrains the development of biotechnology. It is common

practice under United Kingdom Patent Law for the inventor to deposit a sample of the micro-organism, at an early stage, in a publicly accessible culture collection. Industry, however, sees risks in this system.

66 It has been advocated that the United Kingdom Patent rules relating to release of micro-organisms should be changed to those of the European Patent Office (EPO). There, at the applicant's request, the availability of deposited micro-organisms is limited to an independent expert only who gives an undertaking not to make samples available to a third party. A change in United Kingdom rules to adopt the EPO system would require legislation. The United Kingdom inventor, of course, has the option of patenting through the EPO.

67 The United Kingdom inventor could rely on a sufficient description since the deposit of a micro-organism is voluntary under United Kingdom law. An argument against this practice has been the difficulty of describing a micro-organism. However should be possible to characterise a genetically-manipulated micro-organism by describing the process by which it can be obtained from the starting organism.

68 Although there are no serious problems in practice with patenting the Department of Industry will continue to monitor the situation and deal with problems on a case-by-case basis.

Culture Collections

69 The UK has a number of well established culture collections covering industrial bacteria, fungi, dairy organisms, yeast cultures etc which provide well characterised micro organisms for development work.

70 There are two problems to be resolved regarding these collections and their expansion and use as a resource. First which collections should be retained and how they should be funded? Second, what long term storage conditions are necessary to ensure the strain stability of genetically engineered micro-organisms? An inter-Research Council committee has been established to consider problems associated with culture collections.

71 Both France and Germany are keen to cooperate with us on the solution of these problems and clearly there would be advantages in having common collections for Europe. The DOI is taking the lead in these negotiations and in the meantime will encourage the existing funding agencies to continue their support while the long-term strategy is developed.

OVERALL POSITION

72 The UK is clearly not so well placed as the USA to benefit from developments in biotechnology but nevertheless our position is comparable with that of other European countries. Some of the large UK firms, particularly pharmaceutical companies, are investing in research organisations in the USA which enables them to cover a wider spread of activities than is available within Europe.

73 We have a sound basis onto which we can build future developments, with good basic science, a strong pharmaceutical industry and major chemical firms investing substantially in R&D on biotechnology.

74 The educational system is now confident that it can meet the needs for education and training from within existing resources and using existing mechanisms.

75 The prime need is to bring through to commercial profit the result of current R&D and all departments are committed to assist in this. The initiative to be launched later this year by the Secretary of State for Industry will be aimed at linking together the research results of the universities with the engineering required for full-scale production. There are however unlikely to be any early profits from the scale of products and it will require sustained activity to ensure commercial success.

76 There is clearly further work for Departments to do and a need for continued inter-departmental collaboration. The Committee therefore proposes that it should continue in existence for a further year. It could provide a clearing house in whitehall for proposals put forward by DES and HSE for a revised future role for GMAG. It could also co-ordinate the work of several Departments in schemes arising from planned biotechnology initiatives.

Cabinet Office
29 April 1982

MBPM.

8/5

Sci & Tech

CHANCELLOR OF THE EXCHEQUER

Treasury Chambers, Parliament Street, SW1P 3AG
01-233 3000

PRIME MINISTER

FUTURE OF THE OFFICIAL COMMITTEE ON BIOTECHNOLOGY

Keith Joseph wrote to you on 21 April reviewing the first year of the Official Committee on biotechnology and recommending that it should be continued for a further year.

2. Biotechnology is an area of enormous potential which cannot be ignored. It is encouraging that Celltech appears to have made a good start, and that other private companies are becoming increasingly aware of the opportunities which biotechnology offers. As the Official Committee has undertaken some useful work in this important area over the past year I have no objection to its continuation in its coordinating role for a further year. It is sensible to assume wind-up after this second year; although this might always be reconsidered if a case for not doing so could be made out.

3. I endorse the proposed programme of work. The Committee should not lose sight of the fact that due to the pressures on Government expenditure as a whole, it may be difficult to accommodate any proposals which require additional Government expenditure. Although applications from industry for R & D assistance towards biotechnology projects may be increasing, this phenomenon is not limited to biotechnology. It is not possible to meet all the pressures on the funds allocated for high technology purposes, and the level of support for biotechnology in the form of R & D assistance or support for joint ventures must depend on priorities within this area as a whole.

4. I am copying this to Keith Joseph, Peter Carrington, Jim Prior, Peter Walker, Michael Heseltine, George Younger, Patrick Jenkin, John Biffen, David Howell and Mark Carlisle and to Robin Ibbs and Sir Robert Armstrong.

(G.H.)

7 May 1981

Science & Technol

JS

cc last para
+ Mr Duguid

10 DOWNING STREET

From the Private Secretary

30 April 1981

Dear Ian

The Prime Minister has seen your Secretary of State's minute of 21 April, about the Official Committee on Biotechnology.

She is content that the Committee should continue to carry out a coordinating function for a further year, with a view to winding up its role at the end of that period.

I am sending copies of this letter to Roderic Lyne (FCO), John Wiggins (HM Treasury), Richard Dykes (Department of Employment), Kate Timms (MAFF), David Edmonds (Department of the Environment), Godfrey Robson (Scottish Office), Don Brereton (DHSS), John Rhodes (Department of Trade), Julian West (Department of Energy), Peter Shaw (Department of Education and Science), Gerry Spence (CPRS) and David Wright (Cabinet Office).

Yours ever

Mike Pattison

Ian Ellison, Esq.,
Department of Industry.

1

PRIME MINISTER

I attach a minute from Keith Joseph, reporting on the first year's work of the Official Committee on Biotechnology.

As you asked when approving its establishment, the Secretary of State has considered whether it needs to continue in existence beyond the initial year. His firm recommendation is that it should continue, although with the remit to seek to wind itself up after a further year's work.

None of the other Ministers involved have commented. We have been in touch with John Ashworth, who firmly endorses the view that the Committee's work should continue - his comments are at flag A.

The Policy Unit (flag B) agree that there is further work to be done in the field. But they ask whether our machinery is adequate, given the recent precedent of information technology. (When Weekend World looked at French industrial strategy several weeks ago, Brian Walden's research in France showed that information technology and biotechnology were both amongst the handful of areas of concentration identified by the French some time ago, with considerable government resources devoted to co-ordination and improvement in these fields.)

Yes mt

Would you like to ask the question whether our existing effort in this field is adequate; or are you content to accept Sir Keith Joseph's advice, and extend the present arrangements for a further year, with a view to winding up the co-ordinating machinery thereafter?

Yes mt

MAP

29 April 1981

28 April 1981

MR PATTISON

cc Mr Hoskyns

BIOTECHNOLOGY

1. You asked for views on the continuation of the Interdepartmental Committee on Biotechnology. From Sir Keith's minute of 24 April it seems quite clear to me that this Committee has useful work to do which needs to be co-ordinated across Departments. I have little doubt that the co-ordinating job is necessary. The right question is whether existing arrangements should be continued or strengthened.

2. In the somewhat analogous case of information technology, it was decided to continue an Interdepartmental Committee, to give a Minister special responsibility for the subject, to set up a new unit at the Cabinet Office, and a new advisory committee. Have the Department considered whether any similar initiatives are necessary to strengthen the arrangements for hastening biotechnological developments? On the face of it, an Interdepartmental Committee chaired by the DoI Chief Scientist may not be sufficient.

3. I am copying this note to John Hoskyns in case he has anything to add.

AD.

ANDREW DUGUID

CONFIDENTIAL

To: MR SANDERS

From: J M ASHWORTH

Future of the Official Committee on Biotechnology

1. You asked me to let you have a note on this topic by close of play today. I attach a draft suitable for the Prime Minister. You will note that I have come down very clearly in favour of retention of the Committee.

2. I have not spelt out the consequences of discontinuing the Committee. At the very least it would put the Government in an awkward position given the commitment in paragraph 14 of Cmnd. 8177. More importantly it would make management of the policy shifts that I mention in my last paragraph more difficult and I suspect that we would be driven to re-establishing the Committee under another guise.

3. For your own information I also attach a copy of a letter I wrote recently to the Official Committee (BT). I just do not know how issues of that kind could be tackled without the BT machinery.

4. I am sending a copy of this minute and the attachments to Sir Robert Armstrong.

24 April 1981

Atts

CONFIDENTIAL

THE FUTURE OF THE OFFICIAL COMMITTEE ON BIOTECHNOLOGY

The Secretary of State for Industry has suggested that the official committee on Biotechnology be kept in being for a further year despite the fact that it has carried out the task (drafting the White Paper on Biotechnology, Cmnd 8177) for which it was created. The Secretary of State presents a number of arguments which have led him to this conclusion - including the fact that the White Paper committed the Government to coordinate the activities of Departments and pressure is growing for making that commitment (para 14 of the White Paper) more explicit. These arguments stem from an acceptance of the view (vigorously expressed by the ABRC/ACARD/ Royal Society Joint Working Party report on Biotechnolgy) that present departmental arrangements are not - to use the report's words - "well suited to the development of a subject like biotechnology which, at the moment, straddles the divisions of responsibility both among Government Departments and among Research Councils and the arbitrarily defined fields of fundamental and applied research".

The White Paper (Cmnd 8177) has been widely criticised for not taking sufficient account of this point. In particular, there is a real danger that without firmer guidance than seems likely at present too many small groups in too many Universities and Polytechnics will try and enter the field at the expense of adequate provision for those, better established groups, who can really keep up with the (fierce) international competition. The recent editorial in the New Scientist (23 April, copy attached) makes the point a little stridently but I believe these views are generally held amongst the scientific community. It would be rash to rely on normal inter-departmental coordination mechanisms to solve issues of this delicacy and complexity.

A separate but related issue that has also arisen since the White Paper was published concerns the predatory recruiting activities of some foreign firms. I attach a news item from the Sunday Times (19 April) which captures the flavour of recent comments. It is difficult to gauge how serious the situation is - the number of those who have actually emigrated (as opposed to those who have spoken wildly about doing so) is probably small. However, at the present stage of development of genetic engineering the emigration of a small number of key people could make all the difference between the success or failure of initiatives such as those of ICI (in developing Pruteen) or CellTech (in developing their second generation of products). Probably more serious is the demoralising effect that a few well publicised emigrations would have on those who remain in the UK.

In this difficult and charged atmosphere I think the case for retaining the official committee on Biotechnology is strong. It is always difficult to manage the switch from a policy which is primarily science and technology orientated to one that is market orientated. In the words, again, of the Working Party report "the United Kingdom has not shown itself particularly adept [in the past] at recognising when there is the need for this kind of switch in policy nor, when the need is seen, for making the necessary adjustments". The continued existence of the official committee will not, of course, guarantee that these desirable adjustments will be made, it will just make it very much more likely.

CABINET OFFICE
Central Policy Review Staff
70 Whitehall, London SW1A 2AS Telephone 01-233 7089

W 02331

22 April 1981

Dear Duncan,

Biotechnology: Possible Brain Drain

I was delighted to see from your letter to Richard Bird that you are "disinclined to do nothing" on this issue. Unfortunately I will be in Paris when this topic is on the agenda at the next meeting (27 April) of BT. I would be grateful, therefore, if the following points could be raised.

1. I still believe that the recommendation in the Spinks report was the right one viz that about 20 new posts should be created. When the total number of University posts is being cut it is even more important to be seen to be encouraging novel, promising activities. After all if 3,000-4,000 University lecturers are to be prematurely retired why not make it 3,000-4,020 and create 20 new posts?

2. When we discussed these issues in BT before the line the DES took was that "centres of excellence" could not be created, they must be allowed to evolve naturally. This view is reflected in the White Paper. We now know, however, that a considerable amount of "restructuring" will have to go on in the Universities and I wonder whether, in these circumstances, there is not a case for a more dirigiste approach? For example, should we not be thinking of designating Mike Fowler and the Wolfson Unit at Sheffield a 'centre of excellence' for plant tissue culture biotechnology and encouraging those others (say the better remnants of the late Professor Street's group at Leicester) to move to Sheffield? Similarly, should we not be actively encouraging the movement of some tenured staff from their present posts to the laboratories of those like Paul Broda (at UMIST) or Bill Brammar (at Leicester) who are well on the way - if they have not already - achieved 'centre of excellence' status. There is no doubt in my mind that underlying some of the resentment that the White Paper occasioned was the feeling that it would encourage too many non-viable groups in too many Universities and Polytechnics to try and catch up with a bandwagon that was already moving too fast for them. I think a clear policy along these lines will do much to stop the draining of a few rather important brains - and is probably desirable on other grounds too.

Dr D Davies

3. I believe that (1) and (2) above, if implemented together, would go a long way to restoring morale and preventing a serious "brain drain". I do not believe that the actions open to us are necessarily as limited as you suggest in your letter.

   The Research Councils would have to be in the lead in designating "centres of excellence" and - more important - "centres of non-excellence" and arranging with the UGC that the appropriate movement of people (and equipment?) occurs.

I hope that on 27 April the BT Committee would be able to recommend a policy along these lines and to set in motion the necessary machinery for its implementation.

I am copying this to the recipients of yours.

Yours sincerely

John

DR J M ASHWORTH

c PS/Secretary
Mr Manzie
Mr Leeming
Sir Geoffrey Allen SRC
Dr Gowans MRC
Dr Reilly ARC
Mr F H Allen CSD
\- Dr Aram

Dr D Davies
Department of Industry
Abell House

c.c. R. Courtney ✓

Science & Technology
Jan 80

RESTRICTED

ADVISORY COUNCIL FOR APPLIED RESEARCH AND DEVELOPMENT
70 Whitehall, London SW1A 2AS Telephone: 01-233

23 April, 1981.

Dear Sir Keith,

After publication of the Government's White Paper on biotechnology (CMND 8177) I reconvened those members of the joint Working Party on biotechnology who were immediately available. We considered the Government's White Paper and wish to make the enclosed comments on it. I obviously support these comments as Chairman of ACARD as well as Chairman of the Working Party.

However, the other two sponsors - The Royal Society and the Advisory Board for the Research Councils - may no doubt wish to comment on other aspects of the White Paper or, possibly, somewhat differently than ACARD and the Working Party. I am therefore copying this letter to the President of the Royal Society and to Sir Alec Merrison, Chairman of ABRC in the hope that they will consider this.

I am not copying the enclosed comments to the Press, though I have, of course, been approached by many reporters since CMND 8177 was published, but have limited myself to extremely brief comment, believing that the detail is best debated between ACARD, or the other sponsors, and departments.

Yours sincerely,

Alfred Spinks

Dr. A. Spinks.

The Rt. Hon. Sir Keith Joseph, MP.,
Department of Industry,
Ashdown House,
123 Victoria Street,
LONDON, SW1E 6RB.

RESTRICTED

WHITE PAPER ON BIOTECHNOLOGY (CMND 8177): STATEMENT BY THE JOINT WORKING PARTY ON BIOTECHNOLOGY

GENERAL

1. The Working Party welcomes publication of a White Paper on biotechnology as indicating Government recognition of the importance of the subject. It is, however, concerned that despite acceptance in the White Paper of the need for urgent action in some areas, the Government's response to the report has been delayed for almost a year and even then shows little sign of positive initiatives or financial commitment. Circumstances have changed considerably since the report was submitted to the Government in February 1980. There have been some encouraging initiatives: e.g. the creation of Celltech; a welcome increase and broadening of NRDC activity, and one or two private sector initiatives. But, on the other hand, the general climate for development of biotechnology has, in many ways, deteriorated and notably so as regards the universities. The scientific community, especially, had therefore hoped for signs of positive action. Their absence and the lack of any sense of urgency, despite evidence of growing activities overseas, has left many biotechnologists profoundly depressed.

2. The Working Party agrees that the main responsibility for turning biotechnological concepts and discoveries into products and services lies with industry itself. But in terms of modern biotechnology the industry is in a barely embryonic state. As pointed out in the Working Party's report (para 4.4) at present "there are neither established university departments to promote it (or to provide the necessary manpower) nor well-developed industries to provide market-pull". There is, therefore, a need for funds to carry projects beyond the point where primary research has been done, but commercial development has not begun (the pre-development gap). In the absence of an established industry some commitment by Government, not least in terms of finance, is crucial and should be at least comparable to that made by our major industrial competitors. As the Working Party argued "The slow growth in its [biotechnology] application by various industries doubtless reflects poor profitability of existing business, the prevailing fiscal and regulatory climate and the cost of development - matters over which the Government should assist industry so that it can be more enterprising". (Summary, para 4). The position has worsened since the report was brought out and there is now greater pressure on both industry and the universities. The Government's support for Celltech, as a joint enterprise of the public and private sector, was a significant and welcome step in the right direction which we hope will lead to further initiatives. We doubt whether the private sector would have been able to take this initiative alone. We regret, however, that the Government has not, in general, announced comparable actions in the White Paper to meet our other major recommendations.

The following more detailed comments relate to specific paragraphs in the White Paper.

Paragraph 2

While it is true that biotechnology is not new to British industry, and some firms are actively involved, the level of current activity is exaggerated in the White Paper when compared with the future opportunities. But these opportunities could easily be lost; there is little sign that British industry has yet recognised them and is taking the required action. As an illustration - in five recent issues of the periodical "Nature", of some 48 advertisements for posts in biotechnologically-related subjects, only 4 were from British firms. Similarly members of the Working Party themselves have had approaches from overseas

Governments and industrial firms on biotechnology, but not from the United Kingdom. The Working Party is concerned that, given the evidence of a relative lack of enterprise by British industry, the Government has not seen fit to stimulate greater effort by constructive intervention.

Paragraphs 10 and 12

The Working Party believe that a much greater effort is urgently needed to marshal the scientific and engineering resources essential for the development of biotechnology. Our report stressed the interdisciplinary nature of biotechnology and the shortage of people with experience in some of the relevant areas. It therefore recommended the expansion of centres of excellence and the provision of 20 additional research and teaching posts within these centres. This modest initiative was required as a first step to focus national talent and resources in centres with early prospects of productivity in research and training, rather than spreading them thinly over a large number of universities and research establishments. Since our report was submitted, this need has become even more urgent. The situation has, for universities, become more difficult and will continue to do so as the proposed expenditure cuts take their full effect. If a contracting university system is to respond adequately to an expanding industrial need then it is imperative to determine priorities and to ensure such concentration of effort, in both teaching and research, as will protect the ability to recruit young staff, and to meet the country's continuing and growing needs. In the absence of such decisions, however difficult, there is a tendency which is all too evident already for each university and each relevant department to assume an equal importance in biotechnology and press for expansion in a band-wagon effect. Moreover disappointment over the absence of adequate resources is beginning to be reflected in a 'brain-drain' of some of the potential leaders in biotechnology to the U.S.A. and continental Europe, where developments in biotechnology are being actively encouraged.

We do not believe that the White Paper does anything to meet this increasingly pressing need. We suggest that the Department of Education and Science, the University Grants Committee and the Heads of Research Councils, acting rapidly in concert, should identify and specify publicly 4 or 5 centres of excellence in biotechnology; make new posts available in these centres and facilitate the transfer of staff to them from other institutions and encourage cooperation from these centres with scientists based elsewhere.

Paragraph 11

The Working Party is pleased to note the commitment of additional resources to biotechnology by the Research Councils and the machinery they have established to co-ordinate their activities. The scientific community has been anxiously looking to the Research Councils and the Government to give a lead and in this context publicity is needed about the terms of reference and constitution of the "simple and informal machinery" and how to make contact with it. We understand that the Department of Industry and the Science Research Council are to appoint a co-ordinator for biotechnology. We welcome this appointment and hope to see the individual's role and activities, which should be publicized widely, extended to embrace fields of biotechnology which are the responsibility of other Research Councils. We assume that the coordinator will assist the Department and its Chemicals and Minerals Requirements Board, to make the best possible use of that part of its R & D budget in which the White Paper indicates biotechnology should stake a claim. Since we reported, there has been some improvement in the level of awareness amongst Research Council staff of the desirability of creating return for their efforts through industrial development. We welcome this trend and urge the co-ordinating machinery of Government Departments and Research Councils to encourage and reward it still farther.

Paragraph 14

The Working Party wishes to know much more about the proposed Government machinery to co-ordinate the activities of Government Departments and to establish contacts with the Research Councils and other bodies. If the machinery is to be effective its membership, remit and modus operandi must be made known and a point of contact publicised. We would also like confirmation that, as we suggested, it will be given technical support. Moreover, it is essential for the machinery to ensure that industrial and scientific viewpoints from outside Government are taken fully into account.

Paragraph 17, 18 and 19

Because of the substantial lead times involved in the provision of skilled people, whether specialist graduates or technicians, we believe that more positive action is required by the Government in areas of emerging technology in advance of demand. This is particularly the case with biotechnology where there is, as yet, no existing industry involved with the new biotechnological developments. The position in the universities will be made considerably worse by the current cut-backs and by the (capricious) freezing of voluntarily vacated posts. If such action is necessary it must be done selectively on the basis of established priorities. There are already substantial shortages of trained people, in, for example, genetic engineering and fermentation technology, and the Government must ensure that funds and places are available for short (6 months - 1 year), post-experience courses in such subjects at universities or polytechnics. Schemes to increase collaboration between higher education establishments and industry - such as those listed in paragraph 19 of the White Paper - are suffering largely because of a shortage of people with appropriate inclinations and abilities rather than of money and the Working Party is concerned that the Government has failed in its response to recognize these manpower issues adequately. Moreover, our evidence suggests that, as with so many other fields of engineering, technicians are in short supply. It is by no means too early for action to be taken, nationally, to ensure that biotechnology is not slowed down by such shortages.

Paragraph 20

The Working Party is concerned lest the Government has underestimated the seriousness of the problem of bureaucratic over-regulation and delay affecting the development of new products. We, therefore, reiterate our view - not dealt with in the White Paper - that DHSS should undertake a study of new testing systems for medicines, food additives etc.,with a view to reducing costs and duration of developments.

Paragraph 21

The Government has indicated its determination to remove obstacles to the development of new products. We hope we are right in interpreting this reply to mean that, for known natural products produced by novel techniques, tests of identity, quality and purity would alone be required, and that there would be no need for ab initio toxicological testing.

Paragraph 24

We are pleased to note the Government's positive attitude to international collaboration in biotechnology and to the proposed European Community (EC) programme on biomolecular engineering in particular. We believe that the aim of the European Community programme to broaden biotechnological opportunities in Europe should be encouraged. U.K. involvement should be complementary to, rather than a substitute for, United Kingdom programmes whose value it will enhance. We, therefore, hope the Government will handle sympathetically participation of United Kingdom institutions in an EC programme.

Paragraphs 25 to 31

The Working Party welcomes the Government's recognition that public bodies may have a contribution to make in the development of an efficient and profitable industry in biotechnology. It is convinced that, while the industry lacks form, help by Government is crucial if biotechnology is indeed to become pervasive and develop more rapidly in the U.K. than has hitherto been the case. We, therefore, applaud the Government's courageous initiative with Celltech in stimulating a joint venture between Government and industry; in it lie the seeds for future initiatives. It is encouraging to know that the Board of Celltech intend that the Company's activities will not be restricted to medical diagnostics as is implied in the White Paper. The much wider scope for potential development is recognised.

While commending the ARC's increased emphasis on crop bio-energetics and the application of genetic manipulation in plant-breeding, our report largely excluded consideration of agriculture. Nevertheless we welcome the attention to be given to agricultural production and the relevance of biotechnological developments. While we have not considered these matters in detail we suspect that further consideration may need to be given to the mechanism to demonstrate the potential of crops for non-food uses and even to some advanced crops for food use. Some aspects of this are to be studied by a recently-established ACARD Working Group on food technology.

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3 April 1981

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COMMENT

Can we get anything right?

There have been three major revolutions in industry-oriented research in the past decade—or at least there should have been. First, there was the energy crisis, which was followed by a valiant attempt by the research councils, especially the Science Research Council, to encourage universities to become expert in energy R&D. The government even matched this with money for energy R&D. Unfortunately, the universities did not respond to this encouragement. Then came the microelectronic "chip" revolution, where once again the official response was encouraging. Now comes the biotechnology revolution, where the response leaves much to be desired.

It may not be stretching it too far to say that the biotechnology revolution could be the most important. But while academia wasn't keen to leap aboard the energy bandwagon, and the chip craze is really more suitable for industrial concerns, there are encouraging signs that the universities are, for a change, keen to respond to a national need.

Naturally, the plight of biotechnology was a popular topic at the recent meeting of more than a thousand biotechnologists in Eastbourne. Oddly enough, it isn't really a shortage of money that is the concern. There is a feeling that the British government, with regal disdain, is watching the biotechnology bandwagon roll by. The recent White Paper on biotechnology, drafted in the Department of Industry, was received with almost universal dismay in the biotechnology community. So poor was the response that Duncan Davies, the DoI's chief scientist, and Sir Geoff Allen, chairman of the SRC, went to Eastbourne to try to prove that they aren't such ogres as they have been painted. Confronted by a disgruntled audience, Davies and Allen managed to miss the urgent message voiced by almost every speaker: there is no shortage of venture capital in Britain to pay for biotechnology research; there is a shortage of trained people who can spend the money wisely. In general not enough attention has been paid to training biotechnologists; and in particular the infamous White Paper all but ignored the topic.

Most of Britain's biotechnology units are small, at most 20 people. Such units are not independent, but are usually affiliated to other university departments. Over a year ago the Advisory Council on Applied Research and Development issued a report—known as the Spinks report, after its chairman—recommending, among other things, that 20 new biotechnology posts should be created to attract young postgraduates for further training and research. The White Paper ignored this recommendation, which Davies has called "offensive". He says that other areas of research, including robotics and optoelectronics, could lose out if more money were put into creating new biotechnology posts. This, of course, misses the point that the universities do have other areas of activity that might not be harmed greatly if money were redirected to areas more relevant to national needs.

Meanwhile, biotechnology units spring up like mushrooms in the summer rain. They are doing so in universities with little expertise and poorly equipped laboratories. With money from the SRC and the University Grants Committee (UGC) under pressure, it is easy to predict that established centres, desperately in need of funds for expansion, will be disappointed. Resentment could grow among biotechnology researchers, although perhaps not to the extent of promoting a massive "brain drain" to the United States, where money for biotechnology seems to grow on trees. However, it is not too extreme to say that Britain's push to compete internationally will be blunted by spreading manpower and money too thinly. Celltech, Britain's state-funded biotechnology firm, is already finding it difficult to recruit staff.

Once again, the SRC is doing its bit—as it did for energy R&D and the "chip" and its related areas—but the council has only a minor influence on education in Britain. It does fund postgraduate education, but that depends on having enough people to do the teaching. Geoff Allen claims that the SRC is exerting constant pressure on the UGC to divert more of its funds towards biotechnology. Unfortunately, the threat of hard times ahead seems to have produced a state of near paralysis in the UGC. Scientists say that the Department of Industry should have gently pointed the more conservative Department of Education and Science towards thinking about how to educate biotechnologists. The DoI seems reluctant to do this. But if Britain does nothing, then the little money that has been invested in biotechnology could be wasted. It is no good pointing out that biotechnology could be bigger than the chip if there aren't people around to make this a reality. ☐

PV

cc A. Duguid

PRIME MINISTER

FUTURE OF THE OFFICIAL COMMITTEE ON BIOTECHNOLOGY

Background

1 When you agreed to the publication of the White Paper on "Biotechnology" (Cmnd 8177, 4 March 1981) you asked for a review of the Official Committee on Biotechnology and a submission on whether it should continue. (Mike Pattison's letter of 8 January 1981).

2 The Committee has been in existence for one year. During that time it has prepared the White Paper which incorporated the Government's response to the Spinks Report on Biotechnology. It has also prepared guidelines for overseas posts on inward investment in genetic engineering and is reviewing the impact of patent legislation. All this work needed an inter-departmental committee to co-ordinate views and agree action.

3 The White Paper stressed that the main responsibility for turning opportunities into products must rest with industry; and it pointed to the long established activity by UK firms in biotechnology. The White Paper mentioned (paragraph 2) a number of such firms including some already investing in the newer aspects of biotechnology. The most recent example is Grand Metropolitan's investment in the Swiss company Biogen. This will enable Grand Metropolitan to expand into new areas by a combination of its skill in fermentation technology and Biogen's skill in techniques such as genetic manipulation.

/4 ...

4 The White Paper accepted (paragraph 25) that there might be occasions when public bodies had a contribution to make in exploiting the opportunities for biotechnology. Celltech Limited, set up by four City financial institutions with minority participation by NEB, is now marketing its first product. The number of applications from industry for R & D support by Requirements Boards in the biotechnology field has increased and the Research Councils, NRDC and the Department of Industry's Requirements Boards are all giving higher priority to biotechnology.

Future Work

5 The Official Committee has proposed for itself a programme of work to assist Departments to implement the actions set out in the White Paper. This programme would involve consideration of:

1 Existing R & D programmes and funding mechanisms, emphasising the scope for joint ventures with the private sector.

2 The stock of skilled people in industry and universities and whether future supply would meet the likely demand.

3 The use of public R & D facilities by industry.

4 An examination of the impact of regulations.

5 The work of the NEB, NRDC.

6 The use of public purchasing to promote biotechnology.

7 A proposed European Community Programme.

8 Patenting arrangements for micro-organisms and the maintenance of culture collections.

9 Promotion of awareness of the potential of biotechnology.

/6 ...

6 One typical example of the mix of departmental interests in biotechnology is in the area of regulation. Responsibility here falls to several Departments:-

DHSS	- Responsibility for the testing and licensing of pharmaceutical products.
MAFF	- Testing foods and food additives.
DOE	- Environmental pollution.
HSE/DES (Genetic Manipulation Advisory Group)	- These organisations work together in the formulation of guidelines for the level of containment required for work on genetic manipulation.

The UK has so far been successful in establishing an effective, but not over restrictive, regulatory regime. Companies have, in consequence, found the UK an attractive environment in which to set up biotechnology manufacturing activities. It is important that we continue to strike the right balance between unnecessarily strict regulations, which impede innovation, and an unrestrained regime which risks accidents and setbacks. Cross-departmental advice is needed here. Areas that require particular attention are:-

the problems of scale-up from laboratory to plant operation;

certification of pharmaceutical products made by new techniques;

standards for the measurement and control of dusts arising in new processes.

/7 ...

7 The White Paper committed the Government to co-ordinate the activities of Departments (para 14). There is necessary work to be done and I recommend the Committee's continuation. It should, however, be given the objective of winding itself up in a year's time when Departments should individually take over responsibility for future work and have arranged whatever continuing liaison may be necessary.

8 I am copying this to Peter Carrington, Geoffrey Howe, Jim Prior, Peter Walker, Michael Heseltine, George Younger, Patrick Jenkin, John Biffen, David Howell and Mark Carlisle and to Robin Ibbs and Sir Robert Armstrong.

KJ

KJ
21 April 1981

Department of Industry
123 Victoria Street

Sunday Times 19 iv 81.

x Duncan claims he was "grossly misquoted" in letter of 21 April.

'Poachers' start new brain drain

by Roger Hardman

ONE of Britain's vital new science-based industries is suffering a major "brain drain." Biotechnology experts in conference at Eastbourne last week were deluged with lucrative job offers from abroad, and a top government scientist had to make a special appearance to try to quench the flames of discontent.

Duncan Davies (DoI).

Biotechnologists are the most highly sought after research scientists in the world, and the job "poachers" found the British contingent easy prey. Just last month the government announced in a White Paper that no extra money would be available for research—a slap in the face at a time when Canada has just announced a $400m investment programme, and France, Japan and Germany have all committed themselves to massive state financing plans.

The potential of biotechnology is enormous. Basically it is the science of persuading organisms such as bacteria and plant cells to work for industry, and its ramifications could lead to revolutionary new ways of making plastics and fuels, new methods of mining, and major advances in medicine through such drugs as interferon.

But in Britain scientists depressed at the government's lack of interest are queucing to leave the country. At the Eastbourne conference of the European Congress of Biotechnology poachers from Europe and North America met a warm welcome. No fewer than four separate Canadian organisations were openly touting for talent among the 1,200 scientists.

Probably the man with the most money to spread around was Californian David Gelfand, a director of the high-flying San Francisco company Cetus, which employs 300 researchers. Cetus went public last month and as a result has $108m to spend, most of it on research.

Gelfand waxes lyrical about the joys of surfing in the Pacific, living in the sun and the other advantages of laid-back West Coast life — but the British scientists tempted to join the brain drain will be more enthralled by the hard cash and the sheer scale of the research opportunities.

They will join a distinguised list of emigrants. Among men who have either gone or plan to go are:

- Dr David Harrison, head of fermentation research for the US company Pfizer in Britain. He is leaving to become research director of Biotechnology Australia, a brand new company.
- Dr Bruce Haddock, who was working on the production of hydrogen by micro-organisms at Dundee University. He is now with Biogen in Lausanne, a company in which Grand Metropolitan recently invested £4.4m.
- Drs Alex Graham and R. W. Jones, two of Dr Haddock's team of three scientists. They have gone to universities in the US.

These names are just the tip of the iceberg, according to Professor John Pirt, chairman of the scientific programme committee at Queen Elizabeth College, London University.

"Unless the government does something, the major workers will leave the country," he said. "There are much more exciting possibilities outside Britain.

"The Government is doing absolutely nothing, and I am profoundly pessimistic about its attitude being turned round. The funds are being given for the schemes we have in hand are totally inadequate. X

"If someone offered me adequate resources to pursue my research work overseas I would not hesitate to go."

His attitude is echoed by Dr M. D. Lilly, of University College, London. "I have been demoralised not so much by the lack of money for research but by the lack of money for research staff," he said. "There isn't very much to encourage the good younger researchers to stay in the country at the moment."

Some may even find it hard to get a job in Britain. Mrs Peggy Watts and Dr Angela Stafford, are at Liverpool and Sheffield Universities respectively. Their research sounds esoteric but could be vital. Mrs Watts is researching the growth of celery flavouring from single cells suspended in nutrient, and Dr Stafford is involved with the Madagascan Periwinkle, an inch long white and pink flower that is turning out to be central in the search for a leukemia cure, and where Britain is in competition with Germany and Canada to extract its secrets.

Both are on short term contracts with just over a year to run and fear that by the summer of 1982 they will both be abroad.

Meanwhile, back at the conference hall . . . Dr Duncan Davies, Chief Scientist and Engineer at the Department of Industry, made a flying visit to try and persuade the assembled throng that things were not so black. The scientists seemed unconvinced, and later Dr Davies said: "We will buy them back when we want them. They will come back." The conference noticeboard covered with job offers seemed to say otherwise.

RESTRICTED

H8

cc HMT
CO

Science + Technology

10 DOWNING STREET

From the Private Secretary

22 January 1981

Thank you for your letter of 20 January, with further proposals about the White Paper on the ACARD/ABRC/RS Joint Report on Biotechnology.

As you know, the Prime Minister has already approved the appointments proposal linked to this issue. In the light of that decision, she has reluctantly agreed to revert to the original version of paragraph 4 of the draft White Paper, with the addition of the sentence suggested in paragraph 3 of your letter.

I am sending copies of this letter to Peter Jenkins (H.M. Treasury) and David Wright (Cabinet Office).

M. A. PATTISON

Ian Ellison, Esq.,
Department of Industry.

RESTRICTED

Ac

JU

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Secretary of State for Industry

20 January 1981

Mike Pattison Esq
Private Secretary to the
Prime Minister
10 Downing Street
London SW1

Prime Minister

Sir Keith Joseph wants to revert to an earlier text of one paragraph of this White Paper, but will add a sentence on future intentions re NEB & NRDC. In view of the arrangements you have approved for bringing them together, content to accept KJ's judgment on the tactics of referring to the two bodies in this paper?

MAP 21/1

Dear Mike

WHITE PAPER ON THE ACARD/ABRC/RS JOINT REPORT ON BIOTECHNOLOGY

My Secretary of State has seen your two letters of 8 January recording the Prime Minister's wish that the Government should do nothing to perpetuate the separate identities of the NRDC and the NEB and the amendments she has made, in consequence of this, to paragraph 4 of the draft White Paper.

2 My Secretary of State has minuted to the Prime Minister about a proposal to bring the work of the NRDC and the NEB closer together, with Sir Frederick Wood, currently chairman of the NRDC acting concurrently as chairman of the NEB. He would hope to announce the appointment before the end of the month. This would be not long before the publication of the White Paper on the joint report on biotechnology and he would like the White Paper to be on all fours with his announcement. The appointment of Sir F Wood will have some of the appearance of an NRDC takeover of the NEB (although this is not the intention) and in the circumstances it would seem odd if the White Paper overlooked the work which the NRDC is undertaking to form partnerships in the private sector in high technology activities. Consequently, my Secretary of State would prefer to revert to the original version of paragraph 4 of the draft White Paper which read:

> "(the Government) recognises, however, that some encouragement from the Government is necessary at this stage. It therefore welcomes the work being done by the National Research Development Corporation and the initiatives which have already been taken by the National Enterprise Board to form partnerships with the private sector, in order to help enhance UK competitiveness."

Agreed reluctantly
MT

/3 ...

3 My Secretary of State would be happy to reverse the order of the references to organisations if this helped to meet the Prime Minister's point. If the Prime Minister agrees to my Secretary of State's proposals that there should be a single chairman for both bodies, it would be possible to add an additional sentence on the following lines:

> "The Government intends to bring about better co-ordination between the activities of these two organisations and has recently appointed Sir Frederick Wood, the chairman of the NRDC, to act concurrently as chairman of the National Enterprise Board, to ensure this."

4 Because an appointments question is involved I am sending copies of this letter only to Peter Jenkins (HM Treasury) and David Wright(Cabinet Office).

Yours ever,

Ian Ellison

I K C ELLISON
Private Secretary

Science
+ Tech

10 DOWNING STREET

From the Private Secretary

8 January 1981

The Prime Minister has considered the revised draft White Paper on the ACARD/ABRC/RS Joint Report on Biotechnology, which you forwarded under cover of your letter of 30 December.

She is still unhappy with paragraph 4 of the draft. She would prefer this to read:

> "(The Government) recognises, however, that some encouragement from the Government is necessary at this stage. It therefore welcomes the initiative which has already been taken by the National Enterprise Board to form partnerships with the private sector in order to help enhance UK competitiveness."

Subject to this amendment, she is now content that the response should be published as proposed earlier in this correspondence.

The Prime Minister has asked that the work of the official Committee on Biotechnology should be reviewed at the end of its first year of existence, and that a further submission should be put to her as to whether the Committee should continue. She would like this submission to come forward in April.

I am sending copies of this letter to Peter Jenkins (HM Treasury), Richard Dykes (Department of Employment), Jeff Jacobs (Department of the Environment), Godfrey Robson (Scottish Office), Don Brereton (DHSS), Nicholas McInnes (Department of Trade), Geoff Dart (Department of Energy), Peter Shaw (Department of Education and Science), Kate Timms (MAFF), Gerry Spence (CPRS) and David Wright (Cabinet Office).

MAP

Miss Cecily Morgan,
Department of Industry.

JS

CONFIDENTIAL

Ind B.
Science + Tech.

10 DOWNING STREET

From the Private Secretary

8 January 1981

BF 22.1.81

I spoke to you yesterday about some concerns the Prime Minister has expressed whilst considering the Government's response to the recent biotechnology report.

She has questioned the need for the existence of an NRDC and an NEB. She ~~is~~ was concerned to ensure that the Government's reply to the ACARD/ABRC/RS Report did not say anything that might help to perpetuate their separate identities. She would like your Secretary of State to consider whether the roles of the two organisations might usefully be merged.

I am sending copies of this letter to Peter Jenkins (HM Treasury), Gerry Spence (CPRS) and David Wright (Cabinet Office).

M. A. PATTISON

Mrs Catherine Bell,
Department of Industry.

CONFIDENTIAL

1

PRIME MINISTER

You asked that the Government response to the Biotechnology report should avoid saying anything that will perpetuate the separate identities of NRDC and NEB.

I will take up the question of the separate identity of these bodies direct with the Department of Industry. I think it best not to spell out that question in dealing with this draft report, because there are a very wide range of people involved, and there would almost certainly be unproductive leaks about your wishes.

The report makes reference to both NEB and NRDC, but none of the references commit the Government to maintaining the two as separate bodies. In the present draft, they are mentioned in paragraph 4 (where you have asked for the NRDC to be deleted); paragraph 9 (where the reference to NRDC foreshadows paragraph 26); paragraph 14; paragraph 26; and paragraph 29. The only paragraph which defines distinct roles for the two bodies, side by side, is 26. But this is does not imply that their roles are mutually exclusive, and Government publication of this paragraph would in no way inhibit Government freedom of action to merge their activities. On the covering letter to the most recent draft of the paper (beneath this note), you argued that the cephalosporin research was the single outstanding NRDC success in this field; but DOI have listed other less well publicised ones in that paragraph.

Subject to the specific amendment you have asked for in paragraph 4, could we proceed as follows:

- Publish the report as it stands; Reluctantly agreed

- I will separately instruct that the Official Committee on Biotechnology should be reviewed after a year's work, and that your authority must be obtained for it to continue; Agreed

/ - I will

Agreed MT

- I will take up the issue of NEB and NRDC directly with Keith Joseph's office, initially without involving the many Departments with an interest in the Biotechnology report?

MP

7 January 1981

1

PRIME MINISTER

The Department of Industry has now reconsidered the proposed Government response to the ACARD/ABRC/RS Joint Report on Biotechnology. I attach their letter explaining how the revision has taken account of the points you made on the original draft. Your earlier comments are at Flag A.

You will see that the modifications do limit the implied praise for NED and NRDC, although the Department defend the specific basis for some of the references to the two bodies.

Content that the revised draft should be published?

31 December, 1980

JH

DEPARTMENT OF INDUSTRY
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PS/ Secretary of State for Industry

Mike Pattison Esq
Private Secretary to the
Prime Minister
10 Downing Street
London SW1

30 December 1980

Why do we need an NRDC and an NEB? I do not want anything said in this reply that will perpetuate their separate identities. MT.

Dear Mike,

You wrote to Catherine Bell on 8 December with the Prime Minister's comments on the draft Government response to the ACARD/ABRC/RS Joint Report on Biotechnology.

2 I have already written to you (my letter of 15 December) about the point raised by the Prime Minister on the European Community R&D programme. You told me by telephone that the Prime Minister was content with Lord Trenchard's speech in the House of Lords debate on 17 December. Lord Trenchard made it clear to the House that the UK was now very guarded in its approach to the EC programme but would continue to participate in discussions to see if a worthwhile programme could be formulated. You also told me that the Prime Minister agreed to the reply to ACARD being in the form of a White Paper and Lord Trenchard announced this in the debate.

3 The Prime Minister made a number of other points, first about the Government co-ordinating machinery for biotechnology referred to in paragraph 14 of the draft response. The machinery is the official Committee on Biotechnology set up in March 1980 within the Cabinet Office under DoI chairmanship. The terms of reference of the Committee (attached herewith) are incorporated in paragraph 14 of the draft response.

Please review at end of the 12 mths i.e. March '81.

4 Second, the Prime Minister asked whether the reference in paragraph 4 to the National Enterprise Board, welcoming its involvement, is appropriate when the Board is undergoing major management changes. We feel the reference to the NEB should not be withdrawn at this stage, given that the NEB's investment in Celltech Ltd was approved by the Secretary of State, and is now a matter of fact. However, since it is unlikely the NEB would contemplate further investment in biotechnology, we have reworded the penultimate sentence of paragraph 4 as follows (amendment underlined):

> "(The Government) recognises, however, that some encouragement from the Government is necessary at this stage. It therefore welcomes the work being done by the National Research Development Corporation and the initiative which has already been taken by the National Enterprise Board to form partnerships with the private sector in order to help enhance UK competitiveness."

But the NRDC has not been alive to possibilities in this field

/5 ...

5 The last sentence in paragraph 9 of the draft response said that the NEB (and NRDC) may have a part to play in further developing biotechnology. This reference to the NEB has now been deleted.

6 The Prime Minister's third comment was about allocating roles, in paragraph 9 of the response, to "the institutions which failed over interferon". The picture is not quite as black as that. It is true that early publication of the discovery of interferon in the late 1950s pre-empted the possibility of patent protection in the UK and much of Europe, but patents were obtained in the USA, Canada and West Germany.

7 The interferons, whatever their potential, have not yet proved to be articles of commerce. They are being produced only in the quantities needed for clinical trials and research. NRDC and MRC formed a consortium with ICI, Wellcome and Glaxo around 1960 to further the commercialisation of the original discovery but this consortium was dissolved after some 6 or 7 years, as the technology available at the time did not seem likely to lead to viable business. The institutions currently involved do appreciate the steps needed to secure commercial exploitation of new discoveries.

8 MRC and Celltech Ltd, which will exploit certain discoveries made in MRC laboratories, have signed an agreement which controls the publication rights of the MRC scientists involved, to help in securing adequate protection for industrial property rights.

9 Finally, the Prime Minister was not entirely happy with paragraph 26 and the description of NRDC's role, especially relating to the cephalosporin antibiotics. We have modified paragraph 26, to link NRDC's involvement in securing patent protection and exploitation with those responsible for the scientific discoveries. We also think that we should do greater justice to Professor Abraham and his collaborators at Oxford University. We have, therefore, re-drafted this sentence to read:

> "The outstanding success of the cephalosporin antibiotics, which were discovered by scientists of Oxford University and the Medical Research Council and for which the Corporation secured world-wide patent protection and licensing, is well known."

10 On the Prime Minister's more general comment, we feel that the account of NRDC's role is well balanced. The Corporation has been active in biotechnology for many years, but the really outstanding success of cephalosporin - a health-care product which has benefited numerous people throughout the world and contributed over £100 million to the UK in royalties (mostly from overseas manufacturers) - has tended to overshadow its other substantial successes. These include the BHK21 cell line, which is used to produce much of the world's foot-and-mouth disease vaccine; the high value enzymes produced for diagnostic kits

sigh

/by ...

by Whatman Biochemicals Ltd (which NRDC was intrumental in setting up); RHM's fungal protein in which NRDC invested £0.5 million; and the plant develped by Biomechanics Ltd for producing methane from industrial waste.

... 11 A revised draft of the White Paper is attached.

12 I am copying this letter and enclosures to the recipients of yours.

Yours sincerely,
Cecily Morgan

CECILY MORGAN
Private Secretary

CABINET

OFFICIAL COMMITTEE ON BIOTECHNOLOGY

COMPOSITION AND TERMS OF REFERENCE

Note by the Secretary of the Cabinet

By direction of the Prime Minister a Committee has been constituted with the following composition and terms of reference -

COMPOSITION

Dr D Davies, Department of Industry (Chairman)

Representatives of -

Treasury
Ministry of Agriculture, Fisheries and Food
Department of the Environment
Scottish Office
Department of Health and Social Security
Department of Trade
Department of Energy
Department of Education and Science
Health and Safety Executive
Central Policy Review Staff

Other Departments will receive memoranda and minutes of meetings and will be invited to attend meetings as necessary.

TERMS OF REFERENCE

To keep under review national and international developments in biotechnology and to co-ordinate as necessary related Government policies; and to report to Ministers as appropriate.

SECRETARIAT

The Secretaries are Dr R H Aram, Cabinet Office and Mr R T King, Department of Industry.

DRAFT WHITE PAPER ON BIOTECHNOLOGY

1. Biotechnology - the industrial application of biological organisms, systems or processes - has recently attracted international interest. Its importance to the United Kingdom has been highlighted by a joint report ("Biotechnology", HMSO) of the Advisory Council for Applied Research and Development , the Advisory Board for the Research Councils and the Royal Society, published in April this year. The Government welcomes this report as an important contribution to policy thinking. It agrees that biotechnology will be of key importance to the world economy in the next century, and of rapidly growing importance before then. It recognises the value of production methods for food, medical and other industrial goods that reduce demands for fossil energy, and the possibilities for completely new products and technologies, especially in medicine and agriculture.

2. Biotechnology is not new to UK industry. Some companies have long been aware of the opportunities offered by biotechnology and have readily exploited them. For example, Glaxo has been applying biotechnology to medicine, particularly using fermentation methods, ever since it introduced large scale manufacture of penicillin to the UK in 1946. In 1957, Beecham research laboratories first isolated the most basic form of penicillin from fermentation broths. From this basic form was developed a wide range of so-called semi-synthetic penicillins of great value in medicine. The Wellcome Foundation Ltd has been working since 1974 on manufacturing interferon by a process based on human cells in culture. Wellcome has established a plant which is producing material very much purer than other clinically-used interferons. This is believed to be the first industrial-scale plant of its type in the world. ICI is exploiting the latest recombinant DNA techniques to modify the micro-organism which it produces for animal feed so that the production process is more efficient. Ranks Hovis McDougall have developed a microbiological source of protein for human consumption derived from carbohydrates. Tate and Lyle have long been working on the conversion of carbohydrate feedstocks into chemicals using fermentation and enzyme technology as well as conventional chemical means. Since the last century, UK firms have been in the forefront of engineering developments in the biological processing of sewage and waste, including the isolation of useful products such as methane. The foregoing are only a few out of the many examples of UK industry's involvement in biotechnology.

3. The main responsibility for turning the concepts and discoveries of the underlying science into useful products and services that can be marketed at home and abroad rests with industry. The Government's financial and economic policies are designed to provide an environment in which private initiative and enterprise will be encouraged to take advantage of the opportunities as they emerge. This is the context in which the Government has considered the joint report and developed its policy on biotechnology. An Appendix identifies those paragraphs in this White Paper which respond to specific recommendations in the joint report.

4. The issues raised in the joint report call for early consideration and action because, in many applications of biotechnology, lead times are long, and developments are slow to make an impact. The Government therefore particularly welcomes the increasing recognition by private firms and investors that biotechnology, and other high technology projects, are sufficiently promising to justify investments that will not be rewarded for some years. Venture capital of this kind has been available in the USA on a large scale, but the Government is concerned that Europe is lagging behind. It believes that the private sector route offers the best prospect of building a vigorous, efficient industry in those areas of the technology most appropriate to the United Kingdom. It therefore welcomes the steps being taken whereby financial institutions are beginning to make more long term investments in technological ventures. It recognises, however, that some encouragement from the Government is necessary at this stage. It therefore welcomes the work being done by the National Research Development Corporation and the initiative which has already been taken by the National Enterprise Board to form partnerships with the private sector in order to help enhance UK competitiveness. It also recognises its role in education and training, in some aspects of research and development, and in safety and health. All these matters are dealt with in this White Paper.

Special Features to Biotechnology

5. Biotechnology includes the use of living systems to synthesise useful substances or break down harmful ones. It has certain special features. The chemical reactions involved are highly specific, often use little energy, and usually do not require fossil fuels as feedstock. However, biotechnology also poses special problems when applied to high volume processes. The systems concerned generally work in a water environment and are sensitive to disturbance; the yield of products often depends critically on the precise control of the processes, and plant is frequently costly and complex. Separating the desired product from the growth medium and processing to a suitably finished state are often difficult and expensive production steps, notably for high volume products which require drying. These considerations imply heavy investment outlays and will influence the prospective return on such investment.

6. The joint report suggested that developing subjects such as biotechnology, which are of relevance to a number of different Government Departments and are at the stage requiring strategic applied research, may require research-funding mechanisms beyond those at present available. The machinery for co-ordinating work on biotechnology which the Government is setting up (paragraph 14) will be able to consider this matter.

7. The development of biotechnology will provide the private sector with new scope to exercise its enterprise and initiative. Private sector companies are best able to make the necessary judgements about products for the market and processes for making them and to assess market prospects with imagination and a realistic appreciation of the risks. The markets for biotechnological developments will be international and highly competitive. The Government looks to the private sector to exploit British scientific and technical discovery and build up its competitive position by importing good developments through licences or otherwise as well as from its own R&D; to develop British success as international business, where possible by export of goods and services; and to seek out and take up suitable opportunities for co-operation with foreign companies in the European Community and elsewhere.

8. For some applications of biotechnology heavy investment will be needed and a long time may pass before a significant return can be expected. This is likely to be so, for example, in the case of the production of chemicals such as alcohol or other fuels in large tonnage, and of food and feed-stuffs. In certain medical applications, however, results may be obtained more quickly, although the safety testing of medicines inevitably takes time and costs money. In applications which require neither large-scale engineering nor such critical safety testing, such as medical diagnostic reagents, there will be opportunities for small and new companies as well as large and well-established ones, and success may well be achieved quite quickly.

9. Small firms play a crucial role in industrial innovation. The Government is committed to fostering the growth of the small firms sector. In two successive budgets a number of measures have been introduced designed to encourage their establishment and growth. These measures apply broadly across the whole range of industry and trade and will confer special benefit in developing fields such as biotechnology. The Government is also continuing with the limited arrangements for the direct support of R&D and innovation, for example through Departmental R&D Requirements Boards and schemes for product and process development. As far as public expenditure limits permit, biotechnology will have a claim on the R&D budgets of Government Departments. Research Councils, Universities and the Centre for Applied Microbiology and Research (CAMR) will continue to give high priority to aspects of biotechnology which offer a good prospect of scientific advance. As described later, the National Research Development Corporation may have a part to play.

Research and Development

10. The harnessing of all relevant skills, including engineering, is necessary to strengthen the scientific base of biotechnology. The United Kingdom is fortunate in having a strong scientific and research capability on which biotechnology can build. Much expertise is to be found in both the private and public sectors, in R&D laboratories, CAMR and university departments. There are already well-established biotechnology-based processes being used in the chemical and pharmaceutical industries and others are being developed.

11. The joint report recommended that biotechnology should have a high priority among university research activities; the Government agrees with this view. The universities and the Research Councils already recognise the area as one of particular scientific promise. Within the resources available to them, the universities may be expected to devote increasing attention to expanding the already substantial amount of research, and the Research Councils also intend to do so. In the next few years Research Council expenditure on biotechnology will almost certainly exceed substantially the annual figure of £3 million proposed in the joint report. The Research Councils have set up simple and informal machinery for co-ordinating their activities and this will be linked with the new Government co-ordinating mechanism outlined in paragraph 14.

12 The joint report recommended the expansion of university teaching and research facilities in biotechnology. The Government considers that the established policy of selective support from the Research Councils, combined with resources which the universities themselves devote to research is the most suitable method of supporting university research in biotechnology. Centres of special expertise are best built around brilliant individuals. Only a few such centres can be expected to be supported in those areas of biotechnology which need expensive equipment such as pilot plant. Thereafter, other good research workers are attracted by the good facilities, and the desirable concentration follows naturally.

13. The Government has considered the role of specialised biotechnology institutes which exist overseas and agrees with the joint report that there is no clear need for such a Government Research Establishment in the United Kingdom. Early consideration will, however, aim to identify how best to use existing facilities and expertise in publicly-funded establishments to advance biotechnology for health, industrial and other applications.

14. The Government recognises the need, identified in the joint report, to co-ordinate the activities of Government Departments in relation to biotechnology. The Government is establishing machinery to do this so as to ensure the coherence of Government policies, and to review national and international developments. Close contacts will be established in this area with the Research Councils, the National Research Development Corporation (NRDC), the National Economic Development Council (NEDC) and the National Enterprise Board (NEB). The adequacy of existing programmes, and their co-ordination, will be given early and urgent attention.

15. The Government believes that companies can form profitable partnerships with Government Research Establishments, CAMR and also with universities and Research Councils. The universities will be able to draw on their existing experience in mounting co-operative research proposals with industry, and the Research Councils will continue to take account of the industrial promise of research proposals.

16. The Government agrees with the joint report that it is important to assure the long-term future of culture collections essential for biotechnology. The Research Councils have already established a joint committee to consider, as they arise, problems connected with existing culture collections in their field of concern and the new Government co-ordinating machinery will meet the needs of other bodies.

Education and Training

17. The joint report recommended that urgent consideration should be given to the provision of trained manpower for biotechnology which the Government agrees to be an essential pre-requisite if industry is to take advantage of developments later in the decade. One need is to strengthen skills in the engineering profession; this was emphasised in the report of the recent Committee of Inquiry. The higher and further education system already has arrangements which can take account of the future manpower demands which biotechnology will generate. But it can respond directly only to clear signals from the employment market such as the rewards and opportunities for potential recruits and manpower demands arising from investment by industry. Biotechnology's need for highly qualified manpower is likely to be met for some time through the specialist postgraduate training of graduates with a proper grounding in basic biological science or in engineering.

18. The provision of technicians from a wide variety of backgrounds - from agriculture, biochemistry, applied biology, paramedical studies, etc - will

become increasingly important as biotechnology develops. The Government believes that the likely demands can be met within the existing flexible technician education system. Local colleges in England and Wales can devise courses to meet employers' specific requirements with subsequent validation by the Technician Education Council, and, in Scotland, the Scottish Technical Education Council devises and validates courses in the light of employers' needs. Lead times involved in devising and mounting new or amended programmes necessarily mean that qualified manpower cannot be supplied as quickly as some employers might expect. However no substantial concern has been expressed by employers about technician training in biotechnological areas. If such concern should be voiced, mechanisms for change and reform exist.

19. The Government agrees with the joint report that collaboration between universities, Research Councils and industry in biotechnology should be fostered. Schemes for the interchange of personnel between industry and academic institutions are valuable and many already exist. The Science Research Council and the Royal Society are, for example, developing their schemes to increase the flow and the Government commends these and similar schemes to industry. The relevant trade associations and bodies such as the British Co-ordinating Committee for Biotechnology (BCCB) can also make valuable contributions at the interface between Government, academic institutions and industry. In many cases individual initiatives will be the most effective method of collaboration between academic and industrial research groups.

Safety and Health

20. The Government considers it essential to maintain a balance between the need to foster innovation and the need to safeguard public safety and health and the natural environment. This applies to product safety testing, which must be viewed in the context of the benefits of new products, and to the control of experiments which use such techniques as genetic manipulation.

21. For the toxicological testing of pharmaceutical products, food additives etc, the most onerous and time-consuming tests are those carried out to check for the possible side-effects of new substances, for example, cancer. But biological products such as insulin - an area in which biotechnology is likely to be further developed at a fairly early stage - are not generally subject to this kind of toxicological testing. Tests of quality and purity will, of course, be required. It will be the Government's aim

to ensure that, subject to necessary safety considerations, there are no unnecessary obstacles.

22. In the case of genetic manipulation, the Government accepts the view of the Genetic Manipulation Advisory Group (GMAG) and the Health and Safety Executive (HSE) that procedures for the notification of experiments should, as recommended in the joint report, continue to be relaxed whenever new scientific knowledge shows that it is safe to do so. GMAG and HSE have recently agreed that experiments falling into containment category I and those which can be carried out under normal conditions of good microbiological practice need no longer be notified to the two bodies case by case. Another large group of experiments, falling into category II, are able to go ahead concurrently with submissions to GMAG and HSE. The Government sees a continuing need for prior notification and authorisation for experiments likely to fall into the higher III and IV containment categories.

23. The Government believes that GMAG should continue to maintain close liaison with similar advisory and regulatory bodies abroad, some of whom undertake useful periodic reviews of the ways in which different nations regulate genetic manipulation experiments. The Government agrees with the joint report that supranational regulations which may be formulated, for example, by the European Community (EC), should respect the flexible arrangements which have been found satisfactory in the United Kingdom and permit similar flexibility in the future.

International Collaboration and Competition

24. The Government wishes to encourage international collaboration between industrial firms and between governments and academic institutions. If the European Commission's proposal for research in biomolecular engineering is taken up by the Community, the Government would wish to see the United Kingdom participate and seek the best value from it. This would call for the active participation by research contractors in this country; for the effective dissemination and utilisation of research findings, (subject to adequate safeguards for the protection of inventions), and for adequate co-ordination between national research programmes and the work being carried out at community level. The Government already publicises EC research opportunities and, through established channels, would take steps to bring an EC biomolecular engineering research programme to the attention of industry and universities. International

collaboration is, subject to legitimate commercial considerations, particularly to be welcomed in areas where projects are beyond the financial and technical resources of any single participant, or where a co-operative approach, even on smaller projects, produces results of benefit to all.

Government and Industry: The Way Forward

25. The level of private investment in biotechnology is much higher in the USA than in Europe. Large companies and individuals there have seen the great potential and are backing high technology ventures whose profit prospects are some years ahead. The Government recognises that some companies in the UK are already exploiting the technology and others have projects under consideration. It is however concerned that firms in other countries may be seizing more quickly than UK companies, the opportunities offered by biotechnology. The Government believes that an efficient and profitable UK industry can only be built by the private sector. Nevertheless, there may be occasions when public bodies have a contribution to make. Other measures will be employed where appropriate. For example, the Government intends that, as far as the continuation of its existing programmes permits, the facilities and expertise of CAMR should be readily available to industry for both basic research and development processes to production stages.

26. Specifically the joint report suggests that NRDC and NEB can help with the early stages of exploiting biotechnology. NRDC can play an significant part, and has already invested £3½ million in support of development and exploitation of biotechnology, including new products and services in health care, plant breeding, crop protection and industrial biotechnology. The outstanding success of the cephalosporin antibiotics, which were discovered by scientists of Oxford University and the Medical Research Council and for which the Corporation secured world-wide patent protection and licensing, is well known. It proposes to make available further substantial sums to assist applied research, in genetic engineering and other areas of biotechnology, which may lead to discoveries of practical and commercial significance. NRDC will also exploit the results of research arising in universities and public-sector laboratories. In licensing the latter the Corporation will, as usual, give priority to British manufacturers. The Corporation is also willing to share the risks taken by individual companies in funding biotechnology projects, and believes there will be further opportunities for making such investments. NRDC's investments are arranged in forms suited to the needs of the individual project. The NEB and private sector investors have formed a new enterprise, Celltech, in which NEB is a minority partner. The company will, in particular, exploit UK work on hybridomas in various fields, especially

medical diagnostics. The Government intends that a venture started in this way will become fully independent in a few years.

27. The joint report also made several recommendations on the involvement of Government Departments. They are already considering, within the context of their general policies, the opportunities for applying biotechnology to the enterprises in which they are involved and in projects which may be commissioned. The Department of Health and Social Security is discussing with the relevant trade association whether it could help small firms using biotechnology to enter the health care market. While a change of purchasing policy by the National Health Service, as proposed in the joint report, might be helpful and will be considered, other forms of assistance, for example, the central evaluation of new products, might be more appropriate. Within the limits of its resources, CAMR may be able to assist firms by undertaking commissions for them. The application of biotechnology to effluent treatment, waste disposal, materials recovery and related activities will be a matter for the water authorities, local authorities and private industry to pursue. However, the Government accepts that in some areas suitable techniques do not exist at present, and some existing techniques require further development if their commercial potential is to be exploited. The Departments concerned will consider, in consultation with industry and the appropriate authorities, the opportunities for research, preferably on a partnership basis, to fill this gap.

28. The joint report gave particular emphasis to the range of opportunities for biotechnology "indoors" in the factory production of chemicals, pharmaceuticals etc. But there are also potentially important applications "outdoors" in agriculture. The efficiency of agricultural production may be increased, for example, by breeding more efficient plants, by developing nitrogen-fixing organisms, and by developing new biological control agents such as insect viruses. Agriculture will in addition be an important market for industrial products of biotechnology. There may be opportunities to develop alternatives to traditional agricultural products and to use agricultural crops in alternative ways, for example as industrial feed stocks. For example, vegetable and possible microbial proteins are likely to be used increasingly as meat substitutes. Research is already well advanced to produce novel chemicals based on sugar, and such chemicals may eventually be derived from crops specially grown for the purpose. New methods of treating food by-products and agricultural products, in particular wastes such as straw, could provide valuable new sources of industrial raw materials such as ethanol. Processes for using other surplus or waste agricultural products would be welcomed, provided they are soundly

based technically and that they fall within the regulations controlling agricultural products within the European Community. The United Kingdom agricultural departments consider the pattern of agricultural production on a continuing basis and will certainly bear in mind all relevant biotechnological development. The Government will, in the general context of its Community and agricultural policies, take all possible steps to prevent the creation of impediments to the introduction of new processes based on biotechnology.

29. The Government recognises that constraints to biotechnology development exist and that they will need to be reduced as much as possible. Reference has already been made in paragraph 21 to the time taken to prove products and processes safe. Establishing markets will in many cases also take a long time. Bodies such as trade associations, the Confederation of British Industry and the Sector Working Parties of the NEDC, representing sectors of industry with an interest in biotechnology, have a role in identifying constraints to development. Some constraints have already been removed. The European Patent Convention has been revised to alleviate the difficulties - identified in the report - with patents involving the use of micro-organisms. Any remaining difficulties can be examined by the new Government co-ordinating machinery.

30. Some biotechnological development which takes place elsewhere in the world will not be appropriate in the United Kingdom. Crops will be grown specifically for industrial use only when the net return to the farmer is greater than that of a crop for food use. It is doubtful, for example, whether use of crops to produce alcohol fuel will become economic in the United Kingdom but the economics of such processes must be periodically reviewed. However, developments in other countries provide an opportunity for the process plant industry. The Department of Trade and British Diplomatic and Consular posts overseas are constantly seeking and reporting export opportunities in all fields. There are close links with trade associations, and several have important interests in the field of biotechnology. The joint report proposed the establishment of a new trade association for biotechnology. However, the Government considers that it is a matter for firms themselves to determine whether their interests are adequately served by the trade associations which they support, and to act accordingly.

31. Biotechnology is one of a number of technologies that will be important in providing energy, materials, food, communication, and control mechanisms over the coming decades. Knowledge of the biological systems that can be imitated or simulated is itself growing fast, so that the scope for biotechnology is even more difficult to foresee than the future of technologies such as microelectronics.

But it is already clear that it will be pervasive. At this stage, the need is to participate fully enough in fundamental and applied scientific research to understand all the possibilities, and to create the climate in which selective development can be undertaken by those best able to perceive needs and assess the possibilities and risks. This will be the basis for the Government's policies on biotechnology.

RECOMMENDATIONS MADE IN THE ACARD/ABRC/ROYAL SOCIETY REPORT ON "BIOTECHNOLOGY" AND PARAGRAPHS IN THE WHITE PAPER RESPONDING TO THEM.

The responses to the recommendations in the Report which were directed to Government are given in the following paragraphs of this White Paper.

Recommendation	Paragraph in White Paper
1	10, 11, 15
2	6, 13, 14
3	13, 14, 25
4	29
5	30
6	26
7	19
8	12
9	17
10	19
11	26, 29
12	20, 22, 23
13	30
14	28
15	9, 20, 21, 27
16	27
17	24, 28
18	23
19	16
20	11
21	11
22	15
23	24
24	14

HS

Science + Tech

10 DOWNING STREET

From the Private Secretary

17 December 1980

Thank you for your letter of 15 December, about Lord Trenchard's participation in a House of Lords Debate today on biotechnology. I also had a word with John Ingham on the telephone yesterday.

As I told you this morning, the Prime Minister is content with the line which Lord Trenchard intends to adopt - I understand that this will be, if anything, less enthusiastic for the Commission's proposal than is suggested in the draft you sent me. The Prime Minister has, however, commented that she hopes it will be possible to bury the proposal.

Mrs. Thatcher is also content that Lord Trenchard should foreshadow a White Paper response to the ACCARD/ABRC/RS Joint Report.

MAP

Miss Cecily Morgan,
Department of Industry.

1.

PRIME MINISTER

Amongst your doubts about the draft Government response to the ACARD/ABRC/RS Joint Report on Biotechnology, you expressed the hope that the Government were not favouring the European Commission's proposal for research in biomolecular engineering.

On Wednesday Lord Trenchard will be speaking in the Lords in a Debate on this topic. The attached letter from the Department of Industry sets out their present position in relation to the European Commission proposal.

The draft of Lord Trenchard's speech is attached. The sidelined passage at Flag A shows what the Department is disposed to accept, but I understand that Lord Trenchard proposes to be even less enthusiastic.

He would, however, like to take the opportunity to announce that the Government intends to publish a White Paper response to the Joint Report.

Although we have not yet seen a draft revised to your requirements, are you content that he should confirm that there will be a White Paper?

MAP

Yes. but hope we shall be able to bury the proposal.

MT

16 December 1980

JH

DEPARTMENT OF INDUSTRY
ASHDOWN HOUSE
123 VICTORIA STREET
LONDON SW1E 6RB
TELEPHONE DIRECT LINE 01-212 3301
SWITCHBOARD 01-212 7676

PS/ Secretary of State for Industry

15 December 1980

M Pattison Esq
Private Secretary to the
Prime Minister
10 Downing Street
London SW1

Dear Mike,

You wrote to me on 8 December with the Prime Minister's comments on the draft Government response to the ACARD/ABRC/RS Joint Report on Biotechnology. We are dealing with the points made by the Prime Minister and will reply fully to you as soon as possible, but there is one matter which needs urgent attention.

2 In paragraph 6 of your letter, you say that the Prime Minister has expressed the hope "that the Government is not favouring the European Commission's proposal for research in biomolecular engineering". The position that has so far been adopted by the UK in discussions in Brussels is that we were opposed to the original European Community proposal in this area. A revised proposal has been put forward by the Commission but this is also unacceptable since it has insufficient commitment to research and puts undue emphasis on training. Whilst the UK has said that it supports the principle of a programme, in line with the Ministerial remit in the Summer of 1979 to make a more substantive contribution in defining and promoting a common interest in community matters, it will only agree to a European Community programme that Departments see as being useful to them. Nevertheless, we believe that an appropriate programme could bring substantial benefits to UK institutions working in the field. They are recognised to be technically strong and should be successful in obtaining contracts.

3 Lord Trenchard will be speaking in the House of Lords' debate on Wednesday 17 December on the motion "That this House takes note of the report of the European Community's Committee on Biotechnology (66th Report HL 350). A copy of his proposed speech is attached and follows the lines set out above. The paragraph at the bottom of page 3, in particular, sets out the position and the final sentence of the speech says "we will do all we can to ensure that any community activity is appropriate to our needs before giving it our full support".

4 I should be grateful if you could let me know before Wednesday's debate whether the draft speech is in accord with the Prime Minister's views on this matter.

Yours sincerely,
Cecily Morgan

CECILY MORGAN
Private Secretary

My Lords, I am glad of the opportunity to speak in this debate, and I would like to thank the noble Lord Sherfield for moving the motion in terms which have led to what I think all will agree has been an informed and informative debate.

It would be right to claim general recognition for the view that biotechnology is an area of science and technology likely to assume very considerable importance in the coming years. Biotechnology - which has become the accepted term for the industrial application of biological organisms, systems or processes to manufacturing and service industries - may well become of key importance to the world economy in the next century, and will clearly demonstrate its potential in the final decades of this one. It is for this reason that the Government is giving careful consideration to the subject and to the circumstances necessary for the well-being of this emerging industrial technology in the UK. The Government has been considerably helped in this by the report of the broadly-based Working Party which met under the chairmanship of Dr Spinks and our response to that report will be published soon. The recent creation of the new company Celltech Ltd to exploit some of the opportunities afforded by biotechnology is a clear indication of our awareness of these opportunities, and of our intention to pursue them by appropriate means.

Against this general background, the UK was bound to give careful, and indeed sympathetic, consideration to the concept of a European programme and to such advantages as might accrue from work carried out collaboratively with other member states. An increase in the total European effort in biotechnology would be one of the obvious benefits in mind, but in this respect it may be as well for me to put the proposed Biomolecular Engineering Programme into some sort of perspective.

It is estimated that in the six areas of activity described in the proposal, the United Kingdom is currently spending each year about £3½M of public funds and it is likely that the private sector is spending a similar sum. Under the community programme, as originally proposed, the annual expenditure would have been 5.2 million European Units of Account (or about £3M). However, the supplementary explanatory memorandum I submitted on 8 December shows that it is now proposed by the Commission that the Community expenditure should be limited to about 2½-3 million European Units of Account per year (or about £1½M-£1¾M) of which only about half would be spent on research work. Our contribution to Community research in this area would thus come to about 5% of our national research effort.

The discussions that have taken place on a possible Community programme have been long drawn out - particularly if one includes the time spent considering the subject prior to the Commission's proposal to the Council last January. The length of the discussions reflects the difficulties involved in formulating a European programme which does not impinge too closely on known commercial activities on the one hand, and is not too academic on the other. Everyone recognises that European programmes are not well-suited to work which is likely to give rise to proprietary products or processes and so result in frustrating difficulties over patents and licences; neither are they suited to research which is remote from defined economic or social objectives. However, consideration of these points, and of the national interest does indicate a number of possible areas suitable for Community action.

The first is the removal of international obstacles to trade and to operations. A badly thought-out EEC Directive on health and safety could well prove to be an embarassment and a nuisance. All Member States will want to pursue highly responsible policies in relation to safety and health. Communal European work on safety and health is therefore likely to assist in the establishment of European and international standards to which we can all subscribe, thus avoiding the need for a lot of waste and frustration in protracted and separate national negotiations. Secondly, there is advantage in commissioning work which will be accelerated by testing in a large number of countries - for example agricultural programmes which work towards the development of appropriate technology and might lead to crops whose value will be more clearly identified if they can be quickly grown experimentally in a wide range of climatic conditions. Such programmes usually do not lead to products or major proprietary interest, but good new agricultural practice will be encouraged to spread rapidly, to common benefit. Thirdly, there is benefit from the sharing of experience and the development of mutual confidence between scientists in the field of biotechnology. A European programme of reasonable scale could provide an additional stimulus to Community scientists, without adversely affecting existing national activities. Fourthly, there are advantages in cost-sharing of research work where the economies of scale can be seen to be greater than the bureaucratic diseconomies of European procedures.

These considerations caused us to believe that the original proposal was a little over-ambitious - at least as the Community's first venture into this field. We would have preferred a less expensive programme, with a slightly shorter timescale, concentrating on a limited number of the areas described in the Commission's proposal. The present compromise proposal goes some way to satisfying these requirements. I am afraid, however, that it has reduced the research effort by rather more than we would have liked and has introduced training as a feature of the programme to an extent which has not hitherto been contemplated and which we would find it difficult to justify. We do not share the view of at least one other Member State that there is a significant lack of training opportunities, particularly when one considers what is available within the context of the European Molecular Biology organisation or the Community's own Scientific and Technical training programme. If we fail in our bid to have the proposal amended in this respect we will need to consider carefully whether a programme having such reduced resources devoted to research is worthwhile.

[As appropriate] Perhaps, at this point, I might touch on a number of matters raised by my noble Lords, and considerations arising from them. Attention has been drawn to the possible hazards involved in work of the type included in the programme. It is right that the scientific community should be required to ensure an appropriate degree of safety in this work, but it is now generally agreed that the conjectural risks involved are fortunately not as great as we first feared. Work in genetic manipulation is becoming less hemmed-in by restrictions as we are learning and accepting that the kinds of hazards initially foreseen do not, in fact, exist.

The problem of the protection of intellectual property rights could arise, but if the areas of participation are carefully chosen, we should be able to avoid conflicts of interest here.

It has been suggested that biomolecular engineering requires a special kind of engineer. Industrial bioengineering projects generally involve both biologists and chemical engineers. Certainly engineers so employed must be very willing to learn about different subjects and to be more than usually concerned about precise control. Engineers in this field must be exceptionally able, and exceptionally willing to learn.

I would conclude by saying that the Government recognises the importance of biotechnology and hopes that a Community programme will be beneficial both to the Community and to this country. We will do all we can to ensure, however, that any Community activity is appropriate to our needs before giving it our full support.

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Science + Technology

10 DOWNING STREET

From the Private Secretary

8 December 1980

Dear Catherine

The Prime Minister has considered the draft Government response to the ACARD/Advisory Board for the Research Councils/ Royal Society Joint Report on Biotechnology, circulated under cover of your Secretary of State's minute of 28 November.

She is content with the broad approach of the response, which is clearly designed to give support to the recommendations of the Joint Report to the extent that this is possible without commitment of substantial additional resources.

She has, however, asked for clarification on a number of points. First, she would like more information about the new machinery proposed in paragraph 14 of the draft reply.

Secondly, she has asked whether the reference in paragraph 4, welcoming Government finance, is appropriate at a moment when the NEB is undergoing major management changes.

Thirdly, She is dubious about paragraph 9 of the response, which allocates roles in this work to the very institutions which failed over Interferon.

Fourth, the Prime Minister has noted the reference to the European Commission's proposal for research in biomolecular engineering (paragraph 24) and has expressed the hope that the Government is not favouring the Commission proposal.

Finally, the Prime Minister is not entirely happy with paragraph 26. There has been some criticism of NRDC's past performance. The particular success, with cephalosporin antibiotics, noted in the paragraph seems to her to be NRDC's only success in this field. In his minute of 5 December the Secretary of State for Education has pointed out that the present draft offers a somewhat unbalanced view of the NRDC's role in this one.

I should be grateful for comments on the points raised by the Prime Minister.

/ I

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I am sending copies of this letter to Peter Jenkins (HM Treasury), Richard Dykes (Department of Employment), Jeff Jacobs (Department of the Environment), Godfrey Robson (Scottish Office), Don Brereton (DHSS), Nicholas McInnes (Department of Trade), Geoff Dart (Department of Energy), Peter Shaw (Department of Education and Science), Kate Timms (MAFF), Gerry Spence (Central Policy Review Staff) and David Wright (Cabinet Office).

Yours ever
Mike Pattison

Mrs. Catherine Bell,
Department of Industry.

PRIME MINISTER

① What is the new machinery referred to in para 14?

② As the N.E.B. is under new management is it wise to say we welcome Govt. guidance in para 4

I have discussed with John Ashworth the draft White Paper on Biotechnology.

On balance, he feels that the present draft is about right. He points out that the biotechnology report actually indicates a number of areas where greater Government funding would be valuable. In the current economic climate, the drafters of the reply have therefore to find a way of combining a positive stance towards this field with avoidance of financial commitment. If the reply simply had the function of saying either "yes" or "no" to the main proposals in the report, it could be much shorter. In practice, it has to say "yes, but". Its objective must therefore be to avoid deterring the private sector from the work already in mind.

③ Para 9 "guiding part" to play. To make very initiative which failed with interferon

Against this background John believes that the reply as drafted will be received by the scientific community as the best that can be expected from Government at present.

In the light of these comments, agree to publication in existing form?

④ I think we are not favouring the Euro Comm'n proposal

MAP

⑤ Please re-read para 20. I doubt if we need an NRDC in view of its past performance

MT.

5 December, 1980.

PT

NBPM - covered in my letter of 8/xii to Mrs Bell (DOI)

MAP.

SECRETARY OF STATE FOR EDUCATION AND SCIENCE

S+T

PRIME MINISTER

BIOTECHNOLOGY

- with MAP?

I note that, in Keith Joseph's minute to you of 28 November, he refers to some clarificatory changes in the text of the draft White Paper setting out the Government's policy on biotechnology, as compared with the version which he had earlier cleared with me and other colleagues.

2. While I am content with most of these changes, I would like to suggest a small addition to the third sentence of paragraph 26 of the draft. As it stands, this sentence could be taken to imply that the credit for the success of the cephalosporin antibiotics business belongs to NRDC alone. The discovery which led to the marketing of cephalosporin was in fact made by scientists of our Medical Research Council. Whilst I endorse the idea that the cephalosporin success story should be mentioned in the White Paper, I think it is only right that MRC's name should be publicly linked with that of NRDC.

3. I would like to suggest therefore that this sentence be re-drafted on the following lines:

> "The outstanding success of the cephalosporin antibiotics, which were discovered in the laboratories of the Medical Research Council and for which the Corporation secured world-wide patent protection and licensing, is well known."

4. I am copying this minute to the Secretary of State for Industry and to those to whom his minute was copied.

M.C.

MARK CARLISLE
5 December 1980

JH

Prime Minister

This proposed White Paper *is* an attempt to give a boost to biotechnology, although there is no suggestion of additional government resources.

Agree to publication?

MP 28/xi.

1.

PRIME MINISTER

Would you ask Lady [illegible] see if the W.P. It can be reduced by $\frac{2}{3}$.

A Joint Report on biotechnology from the Advisory Council for Applied Research and Development, the Advisory Board for the Research Councils and the Royal Society was published in April this year. A summary of the Report's conclusions and recommendations is attached. The Government's response has been prepared by an Official Committee on Biotechnology set up within the Cabinet Office under Department of Industry chairmanship. A ...

2 The Committee considered that the response, while dealing fully with the Joint Report's recommendations, should be in the form of a more general statement of the Government's policy on biotechnology and it was therefore prepared as a draft White Paper. The attached text was agreed in substance with colleagues although I have since made several changes for greater clarity - these are sidelined for the information of copy recipients of this minute. The form of presentation has also been agreed and I propose, with your approval, to present the White Paper to Parliament. B ...

3 I have several reasons for proposing this kind of presentation of our views. We acknowledge in our response that biotechnology will be important to the UK. Scientific and business circles increasingly look at this as an exciting area of endeavour, and the private sector investments in the NEB company, Celltech,

/reflect ...

reflect this attitude. I feel that we should present our views in a positive manner which will encourage the present growing enthusiasm.

4 Although we do not propose to initiate much additional action oursleves at this stage - beyond the support we have already given to the establishment of Celltech - the form of presentation of our views is an indication of the importance we attach to the subject. A high level presentation would adequately reflect that importance and indicate to ACARD and the other sponsors of the Joint Report that we have taken their advice seriously.

5 I am copying this letter to the Chancellor of the Exchequer, the Secretaries of State for Employment, Environment, Scotland, Social Services, Trade, Energy, Education and Science, to the Minister of Agriculture, Sir Robert Armstrong and to Robin Ibbs.

KJ

K J
28 November 1980

Department of Industry
Ashdown House
123 Victoria Street

Summary of Conclusions and Recommendations
of ACARD/ABRC/RS JOINT REPORT ON BIOTECHNOLOGY.

1 We envisage biotechnology – the application of biological organisms, systems or processes to manufacturing and service industries – as creating wholly novel industries, with low fossil energy demands, which will be of key importance to the world economy in the next century. Over the next two decades, biotechnology will affect a wide range of activities such as food and animal feed production, provision of chemical feedstocks, alternative energy sources, waste recycling, pollution control, and medical and veterinary care. We are convinced that it will shortly be possible to use microbial and other cells to make a wide range of organic chemicals which either cannot at present be made economically on a large scale or, if they can be made, require extensive inputs of land, energy and capital plant for their production from feedstocks, such as oil, which will become more expensive.

2 For the United Kingdom, biotechnology is an area of high technology with large potential growth offering opportunities for the renewal of various existing industries and the creation of new ones. It can be used by both large and small businesses, and although initial capital and development costs are high for some processes, experience in the United States and in Europe suggests that growth can occur in small companies backed with only limited financial resources.

3 British industry must respond faster to the challenge presented and grasp these opportunities to develop new products and processes and to supply equipment and reagents in both home and overseas markets. By comparison with our competitors – West Germany, Japan, the United States – investment is low and opportunities have been missed. We are concerned that the level of awareness shown by overseas firms and the alacrity with which they approach university and other groups in the United Kingdom is not generally matched by that of British firms. With notable exceptions, these seem less able, less willing and less well informed of the need to take advantage of the potential of biotechnology.

4 Constraints delaying the realisation of this commercial potential exist and

competitors. The Government should stimulate and support this new field and ensure that its rapid development is not impeded by an inappropriate or unfounded concern about the maintenance or growth of existing industries or the conjectural hazards apparently presented by some aspects of the new technologies.

7 Against this background, we make recommendations of two kinds: those for early action in support of training, research, development and innovation, and those to ensure that in the longer term the country is to gain the maximum value from such action.

Our principal recommendations (with reference to paragraph numbers) are –

R1 The Research Councils should substantially increase their support for biotechnology. But because the subject cuts across their areas of interest and expertise and will point up gaps between them, the Councils should also, with the Advisory Board for the Research Councils (ABRC), set up a Joint Committee for Biotechnology. With the support of a Director/Co-ordinator to stimulate new projects in universities and elsewhere, this Joint Committee should develop and co-ordinate a coherent programme of biotechnology research. Building on their present and forward commitments for the subject, the Councils should together reach a spend of at least £3 million annually, the minimum we believe is now required. The Research Councils, with the Joint Committee, should consider making a requirement that a proportion of the grant applications from universities should show evidence of industrial interest. (4.6)

R2 The activities of Government Departments in relation to biotechnology should be co-ordinated; and a coherent programme of industrial research and development involving industry, Government research establishments, universities and Research Associations should be pursued at an annual expenditure of about £2.5 million (including existing projects). An inter-departmental Steering Group should be established to meet these objectives. This would be complementary to and, through common membership, well articulated with the proposed Joint Research Council Committee and should work closely with the National Research Development Corporation (NRDC). Technical support for such a Group might be provided by a unit comparable to the Energy Technology Support Unit at Harwell. (4.8)

R3 We do not support the establishment of a new Government research establishment for biotechnology. But the Steering Group should consider how more use could be made of all the existing establishments, eg the Centre for action is needed in the United Kingdom both to remove these and to promote biotechnology. The slow growth in its application by various industries doubtless reflects poor profitability of existing business, the prevailing fiscal and regulatory climate and the cost of development – matters over which the Government should assist industry so that it can be more enterprising. For example, the present structure of public and private support for R and D is not well suited to the development of a subject like biotechnology which, at the moment, straddles the divisions of responsibility both among Government Departments and among Research Councils and the arbitrarily defined fields of fundamental and applied research. Strategic applied research is in general ill-served by our research funding mechanisms, especially in areas where there are neither university departments to promote it, nor well-developed industries to provide market-pull. There is difficulty in identifying a source of funds to carry a project forward from the point where the primary research has been done but the commercial development has not yet begun – the 'pre-development gap'.

5 Biotechnology lacks university centres specifically for it and this results in a shortage of new ideas for industry and of suitably trained manpower. The absence of an established industry clearly identified with new biotechnologies allows Government policy in one industrial sector to have adverse implications for biotechnology in others and diminishes the attraction of the subject to engineers. The result of such interactions is that biotechnology has not grown in the United Kingdom in the coherent fashion which we believe is merited by its potential. What is required at this stage is a policy of 'technology-push' reflected in a firm commitment to strategic applied research. This will progressively produce potentially marketable products and processes and the policy should then be for a more 'market-pull' approach. In the past the United Kingdom has not shown itself particularly adept at recognising when there is the need for this kind of switch in policy nor, when the need is seen, for making the necessary adjustments. We need, as a nation, much better communication between those who are primarily market oriented and those who are primarily science or technology oriented and nowhere is this more true than in biotechnology.

6 We are not convinced that in our mixed economy the tasks posed by the problems we have identified can be met by the private sector alone. We believe that, in the interests of improving industrial competitiveness and paving the way for industrial innovation, a concerted approach is now needed from Government and industry to provide the coherent framework and mechanisms necessary for the successful development of biotechnology and of industries based on it. This should involve a commitment, financial and otherwise, at least comparable to that taken or contemplated by our major industrial

Applied Microbiology and Research (CAMR), AERE Harwell and the Warren Spring Laboratory (WSL), to advance biotechnology. For example, the Department of Industry should co-sponsor CAMR to strengthen the industrial side of the CAMR programme. (4.11)

R4 The Confederation of British Industry, the Association of the British Pharmaceutical Industry, the Chemical Industries Association, the Food and Drink Industries Council and other trade associations, including that proposed in R5, should actively seek to identify opportunities for advances in biotechnology in the fields of potential interest to their members. They should then take effective steps to inform members of neglected opportunities and to inform Government, trades unions and others of any constraints that need to be removed. This last step might be pursued with in the appropriate Sector Working Parties of the National Economic Development Office as recommended in the ACARD report 'Technological Change: Threats and Opportunities for the United Kingdom'. (4.12)

R5 A trade association of suppliers of process plant and equipment should be formed to provide, *inter alia*, for closer contact between suppliers and research scientists. The proposed trade association should give particular attention to the export potential provided by developing countries and the way it is best pursued. (3.14, 4.13)

R6 The National Enterprise Board in conjunction with the NRDC should investigate the possibility of using some public funds to establish a research-oriented biotechnology company of the kind now taking shape in the United States. A sum of £2 million annually for five years should be sufficient to determine its value and establish the scale of further investment. (4.14)

R7 We strongly support the initiative of learned and professional bodies in establishing the British Co-ordinating Committee for Biotechnology (BCCB) and commend it to industry and Government as a valuable forum. It should develop close contact with the process plant industry. Industry should do more to assist the BCCB financially and be more active in its support for university research. (4.13)

R8 The University Grants Committee (UGC) and the Research Councils, with the backing of the universities, should support the expansion of a limited number of centres of excellence in biotechnology from the best existing in universities. A minimum of 20 new teaching and research posts should be created over the next five years with a capital investment of around £2 million to provide adequate laboratory facilities. We ask the Department of Education and Science (DES) to note the need for additional finance. (4.15)

R9 The Committee of Vice-Chancellors and Principals (CVCP), the UGC and the Committee of Directors of Polytechnics should, with the DES and the Department of Employment where appropriate, consider urgently how to provide an adequate, appropriately trained workforce to match the expected growth of biotechnology and how to encourage greater interaction between departments and undergraduate courses in the biological, chemical and engineering sciences. The DES should take account of these likely manpower demands in its forward planning of the provision for higher and further education. Young scientists and engineers should be made aware of the potential benefits and opportunities which biotechnology can provide. (4.17)

R10 Collaboration should be fostered between universities, Research Councils and industry in postgraduate training in biotechnology. The Science Research Council's CASE award scheme provides a suitable example of a pattern for achieving collaboration of this sort. Attention should also be given, by the Councils concerned, to the promotion of collaborative arrangements with industry at post-doctoral level, for example by encouraging the use of industrial funds to support research workers from industry working in Research Council and university laboratories. (3.3, 4.15)

R11 We wish to see the NRDC play a more entrepreneurial role in the support and encouragement of innovation and the provision of funds for development in a field where inventions are often not readily patentable. To this end NRDC should expand its staff resources for biotechnology, re-examine the financial awards and incentives for academic inventors, and be as much concerned with the creation of new companies as with matters of industrial property. NRDC should lead a study with the UGC, CVCP and the Research Councils to review existing and potential ways of encouraging academic inventors in the United Kingdom and to consider practice overseas. (4.18, 4.19). The NRDC should also continue to pursue with the Patent Office the problem of patents as they relate to micro-organisms. (3.11)

R12 If the opportunities offered by genetic manipulation are to be seized, the Government should, as new research defines more precisely the nature of the hazards involved, modify the regulatory regime appropriately, in consultation with others abroad. The Genetic Manipulation Advisory Group (GMAG) and the Health and Safety Executive should continue as rapidly as possible to reduce constraints upon genetic manipulation experiments while maintaining an adequate degree of safety; to introduce procedures to ease industrial application of these techniques; and to keep the controls in the United Kingdom and other countries under review. (4.20)

Our other recommendations and comments that may call for action are –

R13 There should be continued support for the biotechnology programme of the Department of Energy. The Department of Trade, in conjunction with the Department of Energy, should review opportunities for export of process plant in the field of biomass and waste for energy and should help co-ordinate United Kingdom policy in this field in relation to the EEC. (4.23)

R14 The Ministry of Agriculture, Fisheries and Food, with other Departments, should review the pattern of agricultural production in the United Kingdom in the light of the prospects of using some agricultural products for industrial feedstocks and replacing the production of some agricultural commodities by industrial processes. (4.24)

R15 We commend to the Government the recommendations on financial assistance for small firms in the ACARD report 'Industrial Innovation' (3.19). More particularly, the Department of Health and Social Security should consider whether changes in its purchasing policy for the National Health Service would be justified in order to support the entry of small firms using biotechnology into the market. The Department should also undertake a study on possible new testing systems for medicines, food additives, etc with a view to reducing the costs and duration of development. (4.25)

R16 The Department of the Environment in conjunction, as appropriate, with the Department of Industry, the Natural Environment Research Council (NERC) and other Councils should increase support for biotechnology research relating to effluents, waste disposal, materials recovery, etc and work with local authorities, relevant private industry and research establishments such as WSL, AERE Harwell and the Water Research Centre in studying the potential role of biotechnology in these and other public service fields. (4.26)

R17 If the research programme in biomolecular engineering being prepared by the European Commission is taken up by the Community, the United Kingdom should seek the maximum return from it. Separately, the Government should seek fiscal regulations within the EEC which will allow the use of agricultural feedstocks for industrial biotechnology and not impede the introduction of new processes based on biotechnology. (4.27)

R18 We are concerned that, if agreed in its present form, the draft EEC Directive on genetic manipulation would create a slow and inflexible system of controls based on premises now no longer held by a majority of countries within or outside the Community. The need for a directive should be reconsidered in the light of new knowledge of the conjectural hazards involved. (4.21)

R19 We have concluded that machinery is required to ensure the future of culture collections of living micro-organisms through long term financial support. The proposed interdepartmental Steering Group for Biotechnology should study the way in which existing collections can best be maintained and the merit of establishing further national or international collections. (4.10)

R20 We welcome the Science Research Council initiative to establish machinery to stimulate growth in biotechnology research, particularly in the area of strategic applied research. We believe that capital expenditure of £1.5 million and recurrent annual expenditure of £1 million would be wholly justified and should be achieved as soon as practicable, as a component of the programme proposed in R1. (4.7)

R21 We commend the Agricultural Research Council's continued support for the application of new techniques of genetic manipulation in plant breeding. In common with the Medical Research Council, the ARC should vigorously pursue DNA research applications to improve and create biological products. (4.23, 4.22)

R22 The Research Councils should, through the Joint Committee for Biotechnology, review their roles in relation to industrial development based on biological processes so that their staff are aware of the desirability of creating, wherever possible, a national return for their efforts through industrial development. (4.22)

R23 The proposed Joint Research Council Committee and Steering Group should consider how to encourage international collaboration in biotechnology to the benefit of the United Kingdom. (4.28)

R24 Finally, biotechnology is a rapidly developing subject and the Government should commission a further detailed study to review the position in 4 or 5 years' time. (4.9)

DRAFT WHITE PAPER ON BIOTECHNOLOGY

1. Biotechnology - the industrial application of biological organisms, systems or processes - has recently attracted international interest. Its importance to the United Kingdom has been highlighted by a joint report ("Biotechnology", HMSO) of the Advisory Council for Applied Research and Development , the Advisory Board for the Research Councils and the Royal Society, published in April this year. The Government welcomes this report as an important contribution to policy thinking. It agrees that biotechnology will be of key importance to the world economy in the next century, and of rapidly growing importance before then. It recognises the value of production methods for food, medical and other industrial goods that reduce demands for fossil energy, and the possibilities for completely new products and technologies, especially in medicine and agriculture.

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2. Biotechnology is not new to UK industry. Some companies have long been aware of the opportunities offered by biotechnology and have readily exploited them. For example, Glaxo has been applying biotechnology to medicine, particularly using fermentation methods, ever since it introduced large scale manufacture of penicillin to the UK in 1946. In 1957, Beecham research laboratories first isolated the most basic form of penicillin from fermentation broths. From this basic form was developed a wide range of so-called semi-synthetic penicillins of great value in medicine. The Wellcome Foundation Ltd has been working since 1974 on manufacturing interferon by a process based on human cells in culture. Wellcome has established a plant which is producing material very much purer than other clinically-used interferons. This is believed to be the first industrial-scale plant of its type in the world. ICI is exploiting the latest recombinant DNA techniques to modify the micro-organism which it produces for animal feed so that the production process is more efficient. Rank Hovis McDougall have developed a microbiological source of protein for human consumption derived from carbohydrates. Tate and Lyle have long been working on the conversion of carbohydrate feedstocks into chemicals using fermentation and enzyme technology as well as conventional chemical means. Since the last century, UK firms have been in the forefront of engineering developments in the biological processing of sewage and waste, including the isolation of useful products such as methane. The foregoing are only a few out of the many examples of UK industry's involvement in biotechnology.

3. The main responsibility for turning the concepts and discoveries of the underlying science into useful products and services that can be marketed at home and abroad rests with industry. The Government's financial and economic policies are designed to provide an environment in which private initiative and enterprise will be encouraged to take advantage of the opportunities as they emerge. This is the context in which the Government has considered the joint report and developed its policy on biotechnology. An Appendix identifies those paragraphs in this White Paper which respond to specific recommendations in the joint report.

4. The issues raised in the joint report call for early consideration and action because, in many applications of biotechnology, lead times are long, and developments are slow to make an impact. The Government therefore particularly welcomes the increasing recognition by private firms and investors that biotechnology, and other high technology projects, are sufficiently promising to justify investments that will not be rewarded for some years. Venture capital of this kind has been available in the USA on a large scale, but the Government is concerned that Europe? is lagging behind. It believes that the private sector route offers the best prospect of building a vigorous, efficient industry in those areas of the technology most appropriate to the United Kingdom. It therefore welcomes the steps being taken whereby financial institutions are beginning to make more long term investments in technological ventures. It recognises, however, that some encouragement from the Government is necessary? ? at this stage and it therefore welcomes the work being done by the National Research Development Corporation and the National Enterprise Board to form partnerships with the private sector in order to help enhance UK competitiveness. ? It also recognises its role in education and training, in some aspects of research and development, and in safety and health. All these matters are dealt with in this White Paper.

Special Features to Biotechnology

5. Biotechnology includes the use of living systems to synthesise useful substances or break down harmful ones. It has certain special features. The chemical reactions involved are highly specific, often use little energy, and usually do not require fossil fuels as feedstock. However, biotechnology also poses special problems when applied to high volume processes. The systems concerned generally work in a water environment and are sensitive to disturbance; the yield of products often depends critically on the precise control of the processes, and plant is frequently costly and complex. Separating the desired product from the growth medium and processing to a suitably finished state are often difficult and expensive production steps, notably for high volume products which require drying. These considerations imply heavy investment outlays and will influence the prospective return on such investment.

6. The joint report suggested that developing subjects such as biotechnology, which are of relevance to a number of different Government Departments and are at the stage requiring strategic applied research, may require research-funding mechanisms beyond those at present available. The machinery for co-ordinating work on biotechnology which the Government is setting up (paragraph 14) will be able to consider this matter.

7. The development of biotechnology will provide the private sector with new scope to exercise its enterprise and initiative. Private sector companies are best able to make the necessary judgements about products for the market and processes for making them and to assess market prospects with imagination and a realistic appreciation of the risks. The markets for biotechnological developments will be international and highly competitive. The Government looks to the private sector to exploit British scientific and technical discovery and build up its competitive position by importing good developments through licences or otherwise as well as from its own R&D; to develop British success as international business, where possible by export of goods and services; and to seek out and take up suitable opportunities for co-operation with foreign companies in the European Community and elsewhere.

8. For some applications of biotechnology heavy investment will be needed and a long time may pass before a significant return can be expected. This is likely to be so, for example, in the case of the production of chemicals such as alcohol or other fuels in large tonnage, and of food and feed-stuffs. In certain medical applications, however, results may be obtained more quickly, although the safety testing of medicines inevitably takes time and costs money. In applications which require neither large-scale engineering nor such critical safety testing, such as medical diagnostic reagents, there will be opportunities for small and new companies as well as large and well-established ones, and success may well be achieved quite quickly.

9. Small firms play a crucial role in industrial innovation. The Government is committed to fostering the growth of the small firms sector. In two successive budgets a number of measures have been introduced designed to encourage their establishment and growth. These measures apply broadly across the whole range of industry and trade and will confer special benefit in developing fields such as biotechnology. The Government is also continuing with the limited arrangements for the direct support of R&D and innovation, for example through Departmental R&D Requirements Boards and schemes for product and process development. As far as public expenditure limits permit, biotechnology will have a claim on the R&D budgets of Government Departments. Research Councils, Universities and the Centre for Applied Microbiology and Research (CAMR) will continue to give high priority to aspects of biotechnology which offer a good prospect of scientific advance. As described later, the National Enterprise Board and the National Research Development Corporation may have parts to play.

They missed the significance of the process which led to [illegible] as a result of which the U.S. took out a patent!

Research and Development

10. The harnessing of all relevant skills, including engineering, is necessary to strengthen the scientific base of biotechnology. The United Kingdom is fortunate in having a strong scientific and research capability on which biotechnology can build. Much expertise is to be found in both the private and public sectors, in R&D laboratories, CAMR and university departments. There are already well-established biotechnology-based processes being used in the chemical and pharmaceutical industries and others are being developed.

11. The joint report recommended that biotechnology should have a high priority among university research activities; the Government agrees with this view. The universities and the Research Councils already recognise the area as one of particular scientific promise. Within the resources available to them, the universities may be expected to devote increasing attention to expanding the already substantial amount of research, and the Research Councils also intend to do so. In the next few years Research Council expenditure on biotechnology will almost certainly exceed substantially the annual figure of £3 million proposed in the joint report. The Research Councils have set up simple and informal machinery for co-ordinating their activities and this will be linked with the new Government co-ordinating mechanism outlined in paragraph 14.

12 The joint report recommended the expansion of university teaching and research facilities in biotechnology. The Government considers that the established policy of selective support from the Research Councils, combined with resources which the universities themselves devote to research is the most suitable method of supporting university research in biotechnology. Centres of special expertise are best built around brilliant individuals. Only a few such centres can be expected to be supported in those areas of biotechnology which need expensive equipment such as pilot plant. Thereafter, other good research workers are attracted by the good facilities, and the desirable concentration follows naturally.

13. The Government has considered the role of specialised biotechnology institutes which exist overseas and agrees with the joint report that there is no clear need for such a Government Research Establishment in the United Kingdom. Early consideration will, however, aim to identify how best to use existing facilities and expertise in publicly-funded establishments to advance biotechnology for health, industrial and other applications.

14. The Government recognises the need, identified in the joint report, NP to co-ordinate the activities of Government Departments in relation to ?? biotechnology. The Government is establishing machinery to do this so as to ensure the coherence of Government policies, and to review national ?? and international developments. ?? Close contacts will be established in this area with the Research Councils, the National Research Development Corporation (NRDC), the National Economic Development Council (NEDC) and the National Enterprise Board (NEB). The adequacy of existing programmes, and their co-ordination, will be given early and urgent attention. ??

15. The Government believes that companies can form profitable partnerships with Government Research Establishments, CAMR and also with universities and Research Councils. The universities will be able to draw on their existing experience in mounting co-operative research proposals with industry, and the Research Councils will continue to take account of the industrial promise of research proposals.

16. The Government agrees with the joint report that it is important to assure the long-term future of culture collections essential for biotechnology. The Research Councils have already established a joint committee to consider, as they arise, problems connected with existing culture collections in their field of concern and the new Government co-ordinating machinery will meet the needs of other bodies.

Education and Training

17. The joint report recommended that urgent consideration should be given to the provision of trained manpower for biotechnology which the Government agrees to be an essential pre-requisite if industry is to take advantage of developments later in the decade. One need is to strengthen skills in the engineering profession; this was emphasised in the report of the recent Committee of Inquiry. The higher and further education system already has arrangements which can take account of the future manpower demands which biotechnology will generate. But it can respond directly only to clear signals from the employment market such as the rewards and opportunities for potential recruits and manpower demands arising from investment by industry. Biotechnology's need for highly qualified manpower is likely to be met for some time through the specialist postgraduate training of graduates with a proper grounding in basic biological science or in engineering.

18. The provision of technicians from a wide variety of backgrounds - from agriculture, biochemistry, applied biology, paramedical studies, etc - will

become increasingly important as biotechnology develops. The Government believes that the likely demands can be met within the existing flexible technician education system. Local colleges in England and Wales can devise courses to meet employers' specific requirements with subsequent validation by the Technician Education Council, and, in Scotland, the Scottish Technical Education Council devises and validates courses in the light of employers' needs. Lead times involved in devising and mounting new or amended programmes necessarily mean that qualified manpower cannot be supplied as quickly as some employers might expect. However no substantial concern has been expressed by employers about technician training in biotechnological areas. If such concern should be voiced, mechanisms for change and reform exist.

19. The Government agrees with the joint report that collaboration between universities, Research Councils and industry in biotechnology should be fostered. Schemes for the interchange of personnel between industry and academic institutions are valuable and many already exist. The Science Research Council and the Royal Society are, for example, developing their schemes to increase the flow and the Government commends these and similar schemes to industry. The relevant trade associations and bodies such as the British Co-ordinating Committee for Biotechnology (BCCB) can also make valuable contributions at the interface between Government, academic institutions and industry. In many cases individual initiatives will be the most effective method of collaboration between academic and industrial research groups.

Safety and Health

20. The Government considers it essential to maintain a balance between the need to foster innovation and the need to safeguard public safety and health and the natural environment. This applies to product safety testing, which must be viewed in the context of the benefits of new products, and to the control of experiments which use such techniques as genetic manipulation.

21. For the toxicological testing of pharmaceutical products, food additives etc, the most onerous and time-consuming tests are those carried out to check for the possible side-effects of new substances, for example, cancer. But biological products such as insulin - an area in which biotechnology is likely to be further developed at a fairly early stage - are not generally subject to this kind of toxicological testing. Tests of quality and purity will, of course, be required. It will be the Government's aim

to ensure that, subject to necessary safety considerations, there are no unnecessary obstacles.

22. In the case of genetic manipulation, the Government accepts the view of the Genetic Manipulation Advisory Group (GMAG) and the Health and Safety Executive (HSE) that procedures for the notification of experiments should, as recommended in the joint report, continue to be relaxed whenever new scientific knowledge shows that it is safe to do so. GMAG and HSE have recently agreed that experiments falling into containment category I and those which can be carried out under normal conditions of good microbiological practice need no longer be notified to the two bodies case by case. Another large group of experiments, falling into category II, are able to go ahead concurrently with submissions to GMAG and HSE. The Government sees a continuing need for prior notification and authorisation for experiments likely to fall into the higher III and IV containment categories.

23. The Government believes that GMAG should continue to maintain close liaison with similar advisory and regulatory bodies abroad, some of whom undertake useful periodic reviews of the ways in which different nations regulate genetic manipulation experiments. The Government agrees with the joint report that supranational regulations which may be formulated, for example, by the European Community (EC), should respect the flexible arrangements which have been found satisfactory in the United Kingdom and permit similar flexibility in the future.

International Collaboration and Competition

24. The Government wishes to encourage international collaboration between industrial firms and between governments and academic institutions. If the ?? European Commission's proposal for research in biomolecular engineering is taken up by the Community, the Government would wish to see the United Kingdom participate and seek the best value from it. This would call for the active participation by research contractors in this country; for the effective dissemination and utilisation of research findings, (subject to adequate safeguards for the protection of inventions), and for adequate co-ordination between ? national research programmes and the work being carried out at community level. The Government already publicises EC research opportunities and, through established channels, would take steps to bring an EC biomolecular engineering research programme to the attention of industry and universities. International

collaboration is, subject to legitimate commercial considerations, particularly to be welcomed in areas where projects are beyond the financial and technical resources of any single participant, or where a co-operative approach, even on smaller projects, produces results of benefit to all.

Government and Industry: The Way Forward

25. The level of private investment in biotechnology is much higher in the USA than in Europe. Large companies and individuals there have seen the great potential and are backing high technology ventures whose profit prospects are some years ahead. The Government recognises that some companies in the UK are already exploiting the technology and others have projects under consideration. It is however concerned that firms in other countries may be seizing more quickly than UK companies, the opportunities offered by biotechnology. The Government believes that an efficient and profitable UK industry can only be built by the private sector. Nevertheless, there may be occasions when public bodies have a contribution to make. Other measures will be employed where appropriate. For example, the Government intends that, as far as the continuation of its existing programmes permits, the facilities and expertise of CAMR should be readily available to industry for both basic research and development processes to production stages.

26. Specifically the joint report suggests that NRDC and NEB can help with the early stages of exploiting biotechnology. NRDC can play an significant part, and has already invested £3½ million in support of development and exploitation of biotechnology, including new products and services in health care, plant breeding, crop protection and industrial biotechnology. The outstanding success of the cephalosporin antibiotics, for which the Corporation secured world-wide patent protection and licensing, is well known. It proposes to make available further? substantial sums to assist applied research, in genetic engineering and other areas of biotechnology, which may lead to discoveries of practical and commercial significance. NRDC will also exploit the results of research arising in universities and public-sector laboratories. In licensing the latter the Corporation will, as usual, give priority to British manufacturers. The Corporation is also willing to share the risks taken by individual companies in funding biotechnology projects, and believes there will be further opportunities for making such investments. NRDC's investments are arranged in forms suited to the needs of the individual project. The NEB and private sector investors have formed a new enterprise, Celltech, in which NEB is a minority partner. The company will, in particular, exploit UK work on hybridomas in various fields, especially

Its only success

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It would not.

medical diagnostics. The Government intends that a venture started in this way will become fully independent in a few years.

27. The joint report also made several recommendations on the involvement of Government Departments. They are already considering, within the context of their general policies, the opportunities for applying biotechnology to the enterprises in which they are involved and in projects which may be commissioned. The Department of Health and Social Security is discussing with the relevant ? trade association whether it could help small firms using biotechnology to enter the health care market. While a change of purchasing policy by the National Health Service, as proposed in the joint report, might be helpful and will be considered, other forms of assistance, for example, the central evaluation of new products, might be more appropriate. Within the limits of its resources, CAMR may be able to assist firms by undertaking commissions for them. The application of biotechnology to effluent treatment, waste disposal, materials recovery and related activities will be a matter for the water authorities local authorities and private industry to pursue. However, the Government accepts that in some areas suitable techniques do not exist at present, and some existing techniques require further development if their commercial potential is to be exploited. The Departments concerned will consider, in consultation with industry and the appropriate authorities, the opportunities for research, preferably on a partnership basis, to fill this gap.

28. The joint report gave particular emphasis to the range of opportunities for biotechnology "indoors" in the factory production of chemicals, pharmaceuticals etc. But there are also potentially important applications "outdoors" in agriculture. The efficiency of agricultural production may be increased, for example, by breeding more efficient plants, by developing nitrogen-fixing organisms, and by developing new biological control agents such as insect viruses. Agriculture will in addition be an important market for industrial products of biotechnology. There may be opportunities to develop alternatives to traditional agricultural products and to use agricultural crops in alternative ways, for example as industrial feed stocks. For example, vegetable and possible microbial proteins are likely to be used increasingly as meat substitutes. Research is already well advanced to produce novel chemicals based on sugar, and such chemicals may eventually be derived from crops specially grown for the purpose. New methods of treating food by-products and agricultural products, in particular wastes such as straw, could provide valuable new sources of industrial raw materials such as ethanol. Processes for using other surplus or waste agricultural products would be welcomed, provided they are soundly

based technically and that they fall within the regulations controlling agricultural products within the European Community. The United Kingdom agricultural departments consider the pattern of agricultural production on a continuing basis and will certainly bear in mind all relevant biotechnological development. The Government will, in the general context of its Community and agricultural policies, take all possible steps to prevent the creation of impediments to the introduction of new processes based on biotechnology.

29. The Government recognises that constraints to biotechnology development exist and that they will need to be reduced as much as possible. Reference has already been made in paragraph 21 to the time taken to prove products and processes safe. Establishing markets will in many cases also take a long time. Bodies such as trade associations, the Confederation of British Industry and the Sector Working Parties of the NEDC, representing sectors of industry with an interest in biotechnology, have a role in identifying constraints to development. Some constraints have already been removed. The European Patent Convention has been revised to alleviate the difficulties - identified in the report - with patents involving the use of micro-organisms. Any remaining difficulties can be examined by the new Government co-ordinating machinery.

30. Some biotechnological development which takes place elsewhere in the world will not be appropriate in the United Kingdom. Crops will be grown specifically for industrial use only when the net return to the farmer is greater than that of a crop for food use. It is doubtful, for example, whether use of crops to produce alcohol fuel will become economic in the United Kingdom but the economics of such processes must be periodically reviewed. However, developments in other countries provide an opportunity for the process plant industry. The Department of Trade and British Diplomatic and Consular posts overseas are constantly seeking and reporting export opportunities in all fields. There are close links with trade associations, and several have important interests in the field of biotechnology. The joint report proposed the establishment of a new trade association for biotechnology. However, the Government considers that it is a matter for firms themselves to determine whether their interests are adequately served by the trade associations which they support, and to act accordingly.

31. Biotechnology is one of a number of technologies that will be important in providing energy, materials, food, communication, and control mechanisms over the coming decades. Knowledge of the biological systems that can be imitated or simulated is itself growing fast, so that the scope for biotechnology is even more difficult to foresee than the future of technologies such as microelectronics.

But it is already clear that it will be pervasive. At this stage, the need is to participate fully enough in fundamental and applied scientific research to understand all the possibilities, and to create the climate in which selective development can be undertaken by those best able to perceive needs and assess the possibilities and risks. This will be the basis for the Government's policies on biotechnology.

RECOMMENDATIONS MADE IN THE ACARD/ABRC/ROYAL SOCIETY REPORT ON "BIOTECHNOLOGY" AND PARAGRAPHS IN THE WHITE PAPER RESPONDING TO THEM.

The responses to the recommendations in the Report which were directed to Government are given in the following paragraphs of this White Paper.

Recommendation	Paragraph in White Paper
1	10, 11, 15
2	6, 13, 14
3	13, 14, 25
4	29
5	30
6	26
7	19
8	12
9	17
10	19
11	26, 29
12	20, 22, 23
13	30
14	28
15	9, 20, 21, 27
16	27
17	24, 28
18	23
19	16
20	11
21	11
22	15
23	24
24	14

Science & Technology

W 02129

MAP

Mr M A PATTISON
10 Downing Street

WHITE PAPER ON BIOTECHNOLOGY

You will shortly be getting from Sir Keith Joseph a draft White paper which is, inter alia, the Government's response to the recent ACARD/ABRC/Royal Society report on Biotechnology. The Prime Minister might well feel that, considered as such a response, the paper has many of the failings of the previous one (to the Computer Aided Design and Manufacture Report) that she saw.

I write to say that whilst I think I would have such an initial reaction I hope that the Prime Minister will nevertheless agree to publication. There are two main arguments:

1. the really important things are those that are beginning to happen in the private sector. This momentum needs to be kept up and there is already some surprise that the White paper has been so long in preparation. The present text will be seen as supportive and a beginning that can be built on - and it is for this reason that this response should be in the form of a White paper.

2. the bits of the White paper that are very feeble (as opposed to just feeble) are those provided by the DES. Asking the DoI to go back and be nasty to the DES is a pretty cumbersome way of achieving the desired end, viz getting the DES to take a fresh look at the mechanisms for support of what the Biotechnology Report calls 'strategic applied research' and postgraduate training and education. These issues will come to a head in 1981 since two working parties set up by the Advisory Board for the Research Councils will be reporting on the dual support system for University research and support for postgraduate education respectively. Both are showing alarming (to DES officials) signs of producing innovatory recommendations which address the issues raised by Biotechnology but in a wider context. No harm will therefore be done in letting the present feeble text through.

DR J M ASHWORTH

Cabinet Office

12 November 1980

CABINET OFFICE
Central Policy Review Staff
70 Whitehall, London SW1A 2AS Telephone 01-233 7089

① ✓ cc Press Office
② PA
MJS

W 01851 25 March 1980

Dear Mike,

BIOTECHNOLOGY REPORT

1. Your minute of 20 February to David Wright gave the Prime Minister's consent for the ACARD/ABRC/Royal Society Report 'Biotechnology' to be published. Subsequently your minute of 29 February to David Wright gave the Prime Minister's agreement that the Government's response to the Report should be prepared by a Cabinet Committee under Department of Industry chairmanship.

2. I now attach a copy of the printed Report to be published on Wednesday, 2 April.

3. I am copying this letter and the Report to the Private Secretaries to the Secretaries of State for Industry, Employment, Environment, Scotland, Wales, Northern Ireland, Social Services, Trade, Energy, and Education and Science, the Foreign Secretary, the Chancellor of the Exchequer and the Minister of Agriculture, Fisheries and Food, and to David Wright.

Yours sincerely,

John

DR J M ASHWORTH

Mr M A Pattison
Private Secretary
10 Downing Street
SW1

File

Science + Tech

jfh

MR WRIGHT

The Prime Minister has seen Sir Robert Armstrong's minute (A01540) about the ACARD Report on Biotechnology.

She is content with the timetable proposed by Sir Robert for a Government response and agrees that this should be prepared by a Cabinet Committee under Department of Industry chairmanship. I have therefore written to Ian Ellison as proposed in the draft attached to Sir Robert's minute.

M A PATTISON

29 February 1980

ACARD Biotechnology Report

In his minute of 6 February to the Prime Minister, your Secretary of State suggested that the Department of Industry should take the lead in preparing the Government's response to the ACARD Report on Biotechnology.

After discussion with Permanent Secretaries of interested Departments Sir Robert Armstrong has now minuted the Prime Minister on the question of the Government's response to the Report. He thinks that an immediate Government statement on the Report is unnecessary, and recommends that the Government's substantive response should be made, as with previous ACARD reports, some three months after publication. He has proposed the establishment of a Cabinet Committee at official level to prepare this response; the Committee should given particular consideration to the Government's role in dealing with the policy implications of biotechnology and in providing the necessary co-ordination of effort. It is proposed that this Committee should be chaired by an official from your Department.

The Prime Minister has seen and agreed Sir Robert Armstrong's proposal, including the suggestion that the Chairman of the Cabinet Committee should be provided by your Department.

I am sending a copy of this letter to David Wright (Cabinet Office).

M A PATTISON

24-2-80 ?

Ian Ellison, Esq.,
Department of Industry.

1

PRIME MINISTER

Further advice from Sir Robert Armstrong about the ACARD Report on Biotechnology.

He concludes that, despite the advance leak of the Report, the Government does not need to expedite the normal time-table for response.

Sir Robert would like the Government response to be prepared with the Cabinet Office rather than an individual Department in the lead. Content that the response should be prepared on this basis?

MAP

mt.

28 February 1980

Ref. A01540

PRIME MINISTER

ACARD Report on Biotechnology

In my minute of 12th February I undertook to advise you on the handling of the ACARD Report on Biotechnology which you have agreed should be published. I have now had a chance to discuss this with Permanent Secretaries in Departments with an interest in this subject.

2. In the past, the Government has responded to ACARD reports several months after publication. One aspect of the present Report - the central role played by genetic manipulation in biotechnology and possible safety fears - could arouse public concern, and I have therefore considered carefully whether there is a case for a Government statement on publication on this aspect of the Report. It is true that genetic manipulation stimulated much alarm in the early 1970s because of the possible hazards to human health. Since then, however, scientists have taken a more considered look at the risks involved and, in the light of further research, have concluded that the dangers are very much less than was at first feared. Moreover, regulation in the United Kingdom through the Genetic Manipulation Advisory Group is now well established. As a result public and media concern about the safety aspect is much less acute than it was. The Report itself is generally reassuring, and the leak to the magazine <u>Nature</u> failed to arouse any interest in safety aspects. An immediate Government statement on safety aspects does not seem to be needed, and might indeed draw unnecessary attention to safety aspects. I therefore advise against this.

3. I suggest that, as with some previous ACARD reports, a Government response should be made some three months after publication. The Secretary of State for Industry has said (his minute of 6th February) that he would be willing for his Department to take the lead in preparing the Government's response. It will be important for the response to the Report to be in the wider context of how biotechnology generally should be handled. The Report argues that biotechnology promises to provide the basis for important new industries in the coming decades.

My discussions with Permanent Secretaries support this view. The attached brief outline of biotechnology prepared by the CPRS identifies industrial growth points. Britain has the capability to benefit from the developments in biotechnology, but there is a danger, expressed in the Report, that we may react too slowly and inadequately to the new opportunities compared to our competitors.

4. Clearly many of the initiatives will need to be taken by industry itself. But biotechnology will have applications in many areas - industry, agriculture, medicine, pollution control - which cut across a number of Departmental responsibilities. While the interests of the Department of Industry predominate, there is no single Departmental focus. From my discussions with Permanent Secretaries I have concluded that improved Whitehall machinery to advise Ministers is required to focus attention on biotechnology and to make sure that changes in policy in this area are sensibly phased. I therefore propose, subject to your approval, to set up a Cabinet Committee of officials under Department of Industry chairmanship, and with representatives from relevant Departments, to consider Government's as opposed to industry's role in this area, and to provide the necessary co-ordination of effort. A first task of this Committee would be to prepare a response to the Biotechnology Report.

5. If you agree with this approach, I suggest that your Private Secretary might wish to reply to Sir Keith Joseph's minute along the lines of the attached draft.

RTA

ROBERT ARMSTRONG

27th February, 1980

DRAFT LETTER FROM THE PRIME MINISTER'S PRIVATE SECRETARY TO THE PRIVATE SECRETARY TO THE SECRETARY OF STATE FOR INDUSTRY

ACARD Biotechnology Report

In his minute of 6th February to the Prime Minister, your Secretary of State suggested that the Department of Industry should take the lead in preparing the Government's response to the ACARD Report on Biotechnology.

After discussion with Permanent Secretaries of interested Departments Sir Robert Armstrong has now minuted the Prime Minister on the question of the Government's response to the Report. He thinks that an immediate Government statement on the Report is unnecessary, and recommends that the Government's substantive response should be made, as with previous ACARD reports, some three months after publication. He has proposed the establishment of a Cabinet Committee at official level to prepare this response; the Committee should give particular consideration to the Government's role in dealing with the policy implications of biotechnology and in providing the necessary co-ordination of effort. It is proposed that this Committee should be chaired by an official from your Department.

The Prime Minister has seen and agreed Sir Robert Armstrong's proposal, including the suggestion that the Chairman of the Cabinet Committee should be provided by your Department.

I am sending a copy of this letter to David Wright in the Cabinet Office.

/

A BRIEF OUTLINE OF BIOTECHNOLOGY

Introduction

1. Modern industrial societies use chemicals for a variety of different purposes:-

(A) fuels either in their own right (e.g. petrol) or for generating other fuels, especially electricity

(B) feedstocks for industrial plants which produce the bulk chemicals needed for the plastics, textile, toiletry etc. industries

(C) agrochemicals for enhancing agricultural yields either by stimulating plant growth (e.g. fertilisers), protecting plant products from consumption by other organisms (e.g. pesticides) or from competition by other plants (e.g. herbicides)

(D) feedstuffs both for animal and human (e.g. flavourings and preservatives) use

(E) medicinal and veterinarian use.

2. Broadly thee uses can be divided into:

high volume, low value products (A, B, some C, D)

and low volume, high value products (E, some C, D).

At present the chemical industries which produce these products depend overwhelmingly on non-renewable resources (predominantly oil and, to a lesser extent, coal). At some time in the future these industries will have to develop technologies which will enable them to utilise renewable resources - which means products produced by agriculture and forestry. The time scale over which this conversion must take place will be determined by the rate at which the price of oil changes in real terms. The basic scientific knowledge on which these technologies will depend has been acquired very rapidly in the past three decades and it is now possible to to see, in outline, what these technologies will be - for convenience and following convention, we refer to them all as "biotechnology".

Essentially biotechnology is the application of biological organisms, systems or processes to the manufacturing or service industries.

3. There are two major industries which at present can be regarded as exploiting biotechnology:-

(i) the fermentation industry (e.g. antibiotics, brewing)
and (ii) agriculture.

Both produce large volume, low value products but some products of the fermentation industry are of the low volume, high value class. Neither of these industries has experienced a major <u>conceptual</u> advance in technology since pre-historic times when all the organisms (including the yeasts needed for brewing) were first domesticated. Of course there have been major changes in both industries but these have either been of the incremental type (e.g. replacing organic fertilisers by industrially produced chemicals or by using more systematic breeding programmes to improve wild stocks) or have involved extending the natural range of domesticated organisms (e.g. the introduction of the potato and tomato into Europe, the sheep into Australia, the horse into America etc.). The reason for this lack of a quantum change is that, until very recently, we have not understood the nature of the Natural laws to which all living organisms must confirm. All sciences progress at some time from an analytical stage to a predictive or manipulative stage. Physics made this transition in the early 19th century; Chemistry in the early 20th century; Biology is in the process of doing it now (for some other sciences, such as the Earth sciences, the transition is not yet in prospect).

4. There have been two major advances in our conceptual understanding of biological processes and it is on this new knowledge that biotechnology will be based. The two advances have involved (i) Recombinant DNA research and (ii) Enzymes and enzyme systems.

5. Recombinant DNA research

Recombinant DNA research (sometimes popularly known as genetic manipulation or genetic engineering) is a term for a variety of novel biochemical and genetical techniques which facilitate the transfer of genetic material (DNA) from one organism to another and give the recipient some of the genetic properties of the donor. These techniques circumvent the normal inter-specific barriers which prevent such transfers occurring naturally. The importance of the technique is that it allows organism to be designed in order to produce specific products or to grow under particular process conditions. For example, micro organisms can be synthesised (or engineered) which make a hormone such as human insulin or bulk chemicals such as ethanol or to grow on an hitherto unsuitable substrate for them such as methane. Once a bacterium has been genetically engineered to produce the desired product it can, in principle, be grown on an industrial scale and the specific product for which the genetic engineering has been performed, extracted and marketed. Although most current excitement stems from the success of transferring DNA from higher organisms to micro-organisms such as bacteria or yeasts, in the longer term it is likely that the most significant effects of genetic engineering will arise from transferring DNA from one higher organism to another.

Enzyme and enzyme systems

6. A catalyst is an agent which helps forward a chemical reaction without itself suffering any chemical change. Enzymes are organic substances produced by living cells which act as catalysts in chemical change, i.e. biological catalysts. The development and application of new industrial enzymes constitutes a major growth point in biotechnology. Traditionally their use has predominantly been in the food processing industry, and these

enzymes have been obtained from natural sources (e.g. rennin from calf stomachs used in the dairy industry). More recently the capacity of some micro organisms to secrete large quantities of potentially useful enzyme has led to the replacement of some of these traditional sources. More recently still the screening and selection of micro organisms with novel enzymes has produced new products that compete effectively with major industries. For example, a well proved process for producing sweet syrups from starch using fungal cells containing a new industrial enzyme (glucose isomerase) could compete with sugar produced by conventional agricultural methods. Genetic engineering promises to accelerate progress in this already expanding field. Techniques are available to produce enzymes that are either rare or normally present only in organisms which are difficult to grow by using bacteria which can be grown on an industrial scale. In principle, most microbial enzymes could become available at a cost not far from that of the cheapest current industrial enzyme.

7. Another related technological development is the use of so-called immobilised enzymes or cells. The enzymes or cells are immobilised by attaching them to a support such as glass beads so that they can be used in continuous reactors. The enzymes can thus be retained for re-use in a further process run when the product or effluent are removed from the reactor.

Industrial Applications in Prospect

8. Two very different kinds of market are developing for the possible use of the products of biotechnology. The first is in the low volume, high value chemicals area and involves the production, by micro-organisms and/or their enzymes, of compounds such as insulin (see 4 above), interferon, mono-clonal antibodies, perfumes, flavourings, opiates. The other is in the high volume, low value chemicals area where biologically produced chemicals such as ethanol and methane may substitute for petroleum products. These two kinds of market are at present quite separate and respond to different

economic pressures. Biotechnology is bringing them together and the cash-flow generated by the successful initial applications will accelerate this convergence and justify the research and development effort needed to establish yet further processes and bring other products to the market.

9. A third market, closely related to both of those already discussed, utilises the ability of living organisms in general and micro-organisms in particular, to detoxify waste products. We are so familiar with the way in which the water and sewage industries depend on the "sewage farm" that we forget that this system could be extended to handle any waste product if only the appropriate organisms were available. Now there is no conceptual reason why they should not be engineered. In this connection it is also significant that micro-organisms can be surprisingly robust - they have been discovered, for example, living at the centre of the reactor cores of nuclear power stations (where they are at present an unmitigated nuisance) - and it would be surprising if this attribute were not found useful in some waste-treatment processes.

10. It is important to stress that there is now no conceptual difficulty about transferring the ability to fix atmospheric nitrogen to crop plants (thus obviating the need for nitrogen fertilisers); to transfer the ability to make silk from silk worms to bacteria (thus making a new textile industry); to utilise the light organ of a glow-worm to "engineer" a novel form of lighting or to use the electric organ of the electric eel to form a novel kind of battery. There are, of course, real and major technological obstacles still remaining but experience has shown that given a strong enough economic incentive such obstacles rarely last for more than a decade.

Other aspects

11. Because the new industries in prospect do not rely on non-renewable resources they are of particular interest to those areas of the world which

are at present deficient in natural resources (such as Japan) or where climatic conditions favour plant growth. It is no accident that Brazil has at present the largest programme for the industrial production of alcohol (from sugar cane) in the world. It could be that the best technology which the rich "North" can give the poor "South" would be biotechnology. At present countries such as Brazil and Japan provide the best markets for the novel fermentation plants being assembled for the production of chemicals in the high volume, low value category.

Safety aspects

12. The development of new genetic engineering techniques in the early 1970s, which greatly increased the ease with which genetic material could be transferred to another organism, stimulated much alarm because of the possible hazard to human health. The most serious concern was caused by the use in this research of the bacterium Escherichia coli, strains of which reside in the intestine of man and animals. Thus new DNA combinations inserted into E. coli might become widely disseminated in the bacterial, animal and human populations. This concern was linked to the fact that research would include work with the genetic determinants for antibiotic resistance, tumour formation and disease production quite apart from the insertion of genetic material from higher organisms into bacterial cells, the results of which were unpredictable. Thus it was feared that the special properties of these genes might be expressed in bacterial cells giving rise to strains with the potential to release harmful products or to cause novel diseases. In response to this situation, the Genetic Manipulation Advisory Group (GMAG) was established in 1976 and since then all such experiments, to ensure safety, have been carried out under specified conditions of containment which some scientists contend are unnecessarily rigorous.

13. As a result of work done since 1976, we now know that the assumptions underlying such conjectures were incorrect and the probability of such hazards occurring when DNA molecules from higher organisms (animal, plant or fungi) are inserted into bacterial cells was overestimated. In particular, it has been discovered that the genes of higher organisms are organised in a fundamentally different way from those of bacteria. There are further barriers to accidental expression of genes in transfers between different classes of bacteria, since the expression signals of one species

are frequently not recognised by the translation machinery of another. Indeed this species specificity can extend to the level of the genetic code itself, since we now know that there are minor differences between the code used by mitochondria and some viruses and that hitherto supposed to be universal.

14. In addition to these very rapid advances in our understanding of the fundamental differences between higher organisms and bacteria, there have also been a number of other changes which have made scientists less alarmed than they were in the early 1970s by the hazards that might be posed by the use of these techniques. First, we know that laboratory strains of intestinal bacteria that are most frequently used in such experiments fail to establish themselves in animals in competition with the natural flora, and enfeebled ("disabled") strains have been developed that survive only in the closely controlled conditions of the experiment carried out in the research laboratory. Use of such strains, in conjunction with the appropriate physical systems of containement, has meant that the chances of a genetically engineered bacterial cell "escaping" from the laboratory and colonising the environment are very much diminished. Secondly, procedures have been developed that allow the conjectured risks associated with recombinant DNA research to be estimated and expressed in terms comparable with those associated with other hazards. Such procedures of risk-analysis are the result in part of a growing body of experience and evidence stemming from work on the conjectured risks associated with nuclear power stations and petrochemical plants, and in part to the activities of bodies such as GMAG in the United Kingdom and the National Institute of Health in the United States which have stimulated, or deliberately sponsored (NIH), experiments to determine the numerical likelihood of specified risks. Thus as a result of research work carried out in the last four years we can

be confident that the degree of hazard believed in the early 1970s to be associated with recombinant DNA research was exaggerated. Further, we are much more confident now of our capacity to estimate such hazards as do exist and the advisory bodies have developed systems for their estimation and control.

Impact of European Economic Community (EEC) Policies

15. New technology has contributed greatly to the economic health of the EEC, and is in theory welcomed by all Member States. But in practice, strong lobbies of established industry or agriculture tend to exert a disproportionate weight in resisting the cheaper and better products of new technology, particularly where these threaten to perturb patterns of agriculture. There is substantial potential in Europe for conversion of effluents and cheap feedstocks to useful products but costly development will not be undertaken without a degree of assurance that the process will not invite penal levies or have to compete against subsidies as a consequence of European Economic Community policies. This appears to be the present case.

16. For example, development in the United Kingdom of an efficient immobilised enzyme process for converting maize starch into a sweet syrup (isoglucose) that competes effectively with sugar for many food processes was prevented. Although this process promises new markets for maize farmers in the European Economic Community, levies on the new product designed to protect sugar beet farmers have resulted in one firm in the United Kingdom going out of this business, and the development and use of an alternative sweetener and preservative being inhibited. The business remains profitable in the United States where the technology will doubtless be further developed.

17. If European Economic Community policies continue to obstruct developments our ability in Europe to replace petrochemicals by producing basic chemicals from carbohydrates will be hamstrung. The use of biotechnology in transforming agricultural surpluses needs to be recognised by the Community and Common Agricultural Policy legislation that threatens this end should be amended.

Entrepreneurial Biotechnology Based Firms

18. A feature of the utilisation for industrial purposes of modern biotechnology has been the rapid growth of small contract-research firms in California and elsewhere in the U.S.A. These firms have either been founded by faculty members of American universities or have grown up in close association with American university campuses. This phenomenon is reminiscent of the establishment of "Silicon Valley" by Stanford University in the 1960s or the proliferation of "software houses" in the United Kingdom. It is probable that some of these biotechnology based entrepreneurial businesses will grow into major production companies in their own right (following the pattern of Fairchild, Motorola and Hewlett-Packard in micro-electronics) whilst others will remain as contract-research organisations servicing existing production companies. Despite not yet having produced a single marketable product or widely used process the four best-known of these companies have between them an issued capital of $225M.

In conclusion

19. The growth of biotechnology, like other new technologies will result in changes to established industries and will require a positive response from Government, industry, the universities and the trade unions if the

potential benefits are to be maximised. Conventional patterns of agriculture will need to change as industrial methods of production for some products are developed. There is great scope for the use of agricultural surpluses and the waste materials of industry. New employment opportunities will arise as new and expanded industrial processes are developed. These sorts of issues will need to be faced squarely soon if we are to benefit from the opportunities biotechnology offers.

File

DES
Science Tech

BF 5/3/80

MR. WRIGHT

CABINET OFFICE

The Prime Minister has seen Sir Robert Armstrong's minute (A01388) about the ACARD/ABRC/Royal Society Biotechnology Report. I confirm that she is content for the report to be published. She awaits Sir Robert's further advice on the handling of the Government's response.

M. A. PATTISON

20 February 1980

GB

PRIME MINISTER 1. 2

1. Agree publication of report?

Yes MT

2. Advice on lead Dept for reply will reach us later in the week

MAP 18/2

Ref. A01388

PRIME MINISTER

ACARD/ABRC/Royal Society Biotechnology Report

[A] I sent you a copy of the penultimate version of this report (my minute of 28th January) following the leak to Nature. ACARD, the ABRC and the Royal Society have now agreed the report and ACARD is now seeking permission to publish. There have been a number of changes of detail, but the recommendations are substantially the same as the leaked version.

2. The Secretary of State for Education and Science, who has responsibility for the ABRC, has already seen the report and indicated that he is content for it to be published. Following the leak there is a strong case for publishing the report as soon as possible, and I advise that this should be put in hand.

3. Generally with ACARD reports, you have asked the Department most concerned to prepare a response. The Secretary of State for Industry has [B] minuted you (6th February) saying that he would be willing for his Department to take the lead in preparing the Government's reply. The Department of Industry is certainly prominent in the recommendations, but the report also cuts across a number of other Departments' responsibilities. I am therefore consulting with Permanent Secretaries on the way the Government's response should be handled, and I will advise you further on this.

RTA

ROBERT ARMSTRONG

12th February, 1980

Original in Questions filing

File

Science & Technology

Ref: A01362

MR. SANDERS

Supplementary on Biotechnology

Mr. Ian Lloyd MP may ask the Prime Minister what action she intends to take on the recommendations in the ACARD/ABRC/Royal Society Report on Biotechnology. The report has not yet been submitted to the Prime Minister - although she has seen a final draft following a leak of the draft report to Nature.

2. Mr. Lloyd has put down 13 Questions (attached) to a number of Government Departments asking what action Ministers would take on the recommendations in the report. The Prime Minister gave a Written Answer to a priority Written Question from Mrs. Renee Short MP on biotechnology on 6 February (copy attached). This answer proposed that the Prime Minister should say that she expected to receive the report shortly, and hoped to be able to publish it in full.

3. If therefore Mr. Lloyd asks about this the Prime Minister may wish to say that she expects to receive the report of the Joint Working Party shortly and would then consider the report's recommendations.

(D.J. Wright)

7th February 1980

01362

~~PRIME MINISTER'S QUESTIONS 7.2.80~~

Mr ~~Whitmore~~ SANDERS

SUPPLEMENTARY ~~QUESTION~~S ON BIOTECHNOLOGY

1. Mr Ian Lloyd MP may ask the Prime Minister what action she intends to take on the recommendations in the ACARD/ABRC/Royal Society Report on Biotechnology.

The report has not yet been submitted to the Prime Minister - although she has seen a final draft following a leak of the draft report to Nature.

2. If therefore Mr. Lloyd asks may about this the ~~The~~ Prime Minister ~~would therefore~~ wish to say that ~~say that:~~ "she expects to receive the report of the Joint Working Party shortly and would then consider the report's recommendations."

~~reply to any question by saying that~~

~~[illegible]~~

3. Mr Lloyd has put down 13 questions to (attached) to a number government Departments ~~(DI, MAFF, DHSS, DOE, FCO)~~ asking what action Ministers ~~need to~~ would take on the recommendations in the report ~~(attached)~~. ~~Departments have been advised to respond on the above line~~.

~~3.~~ The Prime Minister gave a Written Answer to a priority Written Question from Mrs Renée Short MP on biotechnology on 6 February (copy attached). This answer ~~took the line~~ proposed was that the Prime Minister should say that she expected to receive the report shortly, and hoped to be able to publish it in full.

R. Arm

9/2/80

S

Science & Technology ✓MAP.

DEPARTMENT OF EDUCATION AND SCIENCE
ELIZABETH HOUSE, YORK ROAD, LONDON SE1 7PH
TELEPHONE 01-928 9222
FROM THE SECRETARY OF STATE

M A Pattison Esq
Private Secretary
10 Downing Street
Whitehall
London SW1

6 February 1980

Dear Mike,

ACARD - BIOTECHNOLOGY REPORT

My Secretary of State has seen a copy of Sir Robert Armstrong's minute of 28 January to the Prime Minister which enclosed a copy of the final draft of the Report of the ACARD/ABRC/Royal Society Joint Working Party on Biotechnology. It is understood that this has now been approved by the ACARD Steering Group with no amendments of consequence. The text already takes account of comments from the ABRC, and it may be useful for the Prime Minister to know that Mr Carlisle has no objection to publication, on the assumption that this would be without commitment to the recommendations, which would then fall to be considered by Departments and other bodies concerned.

Yours ever,

Robert Green

R J GREEN
Private Secretary

JU

Science & Technology

PRIME MINISTER

ACARD BIOTECHNOLOGY REPORT

I have seen a copy of Sir Robert Armstrong's minute of 20 January to you, on the prematurely-disclosed ACARD report. Biotechnology is an important subject requiring action in a number of areas, especially by industrial firms, but also by Government. My initial reaction is that a number of the recommendations are likely to be acceptable to Government, although colleagues will have their own views on matters which directly concern them. In approaching the subject we must bear in mind the objective of reducing public expenditure, though I note that for the most part the time-scales for development are longer than for microelectronics and associated technologies.

If the report is to be published, it may be necessary to consider which Department should take the lead in preparing the Government's reply. In this event, and since the Department of Industry features prominently in the recommendations, I would be willing for this Department to take the lead, if that is your wish.

I am sending a copy of this minute to the Secretaries of State for Education and Science, Health and Social Services, Environment and Employment, to the Minister for Agriculture, Fisheries and Food and to Sir Robert Armstrong and Sir Kenneth Berrill.

KJ

K J
6 February 1980

Department of Industry

Science & Tech

File

~~B/F 7-2-80~~

MR WRIGHT
CABINET OFFICE

The Prime Minister has seen Sir Robert Armstrong's minute (A01247) about the ACARD Biotechnology Report. She has taken note of the position on this.

I take it that Sir Robert will be minuting further on the question of publication and Government response, if any, after Departments concerned have had an opportunity to consider the text.

MAP.

31 January 1980

TCR

2

Ref: A01247

PRIME MINISTER

The two pages at Flag A contain "Nature's" forecast of the ACARD recommendations

MAP 29/1

RESTRICTED

PRIME MINISTER

MT.

ACARD - Biotechnology Report

The issue of Nature for 24th January contains an accurate account of the contents of the penultimate draft of the report of the Biotechnology Working Party set up jointly by the Advisory Council for Applied Research and Development (ACARD), the Advisory Board for the Research Councils (ABRC), and the Royal Society. I attach a photocopy.

2. Publication of ACARD Reports (including this one) is, of course, at the discretion of Ministers, and in normal circumstances I would have sent the completed report to you after the Steering Group of ACARD had formally approved the text at the beginning of February. In view of the Nature article, however, I am sending you the final draft of the report. We consider that it is most unlikely that the Steering Group of ACARD (or any of the other joint sponsors of the report) will wish to change this text although they may wish to alter parts of the technical Annex.

3. It is true that Ministers have not yet seen the report - and I would advise that answers to any questions should take that line - but it is also true that the Nature report is an accurate summary of the recommendations. I think therefore that the Ministers most concerned in the recommendations should have available a final text as soon as possible, and I am sending copies of it, with copies of this minute to the Secretaries of State for Industry, Education* and Science, Health and Social Services, Environment and Employment, and to the Minister of Agriculture, Fisheries and Food. I am sending a copy of this minute, without the attachments, to Sir Kenneth Berrill.

Robert Armstrong

28th January 1980

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*Who is responsible for the ABRC and whose Department will already have received a copy of the report

nature

24 January 1980

Curing Europe's biological death-wish

LAST WEEK an apparently European firm, Biogen, incorporated in Luxembourg and with a laboratory in Geneva, announced that it has successfully engineered *Escherichia coli* to produce interferon — currently touted both as an anti-viral and as an anti-cancer agent, after some small trials have shown remissions; larger trials are on the way. So does Europe rejoice at its technological breakthrough?

Unfortunately not, for Biogen stockholdings are held almost exclusively in North America. The major exceptions are the seven European scientists involved; with two Americans, the scientists hold one third of the stock. The largest individual stockholder is International Nickel, a Canadian-based mineral company, with the drug firm Schering-Plough — which has bought the international licence to exploit the Biogen creation — in second place. A handful of other bodies have holdings of under 10%. Hence the remark of Charles Weissman, who co-engineered the interferon-producing bug, quoted in this issue (page 323), that it was a shame that European industry had not taken greater interest in Biogen. Apparently those who were forming the company approached a number of firms in Europe, particulary in Switzerland and West Germany — but none was interested in a share in the business.

The fault, then, was doubly Europe's: first, it was a fault not to attempt to draw on its own potential bioengineers through its own 'Biogen' — noone was adventurous enough to set it up, though many had the idea; and second, it was a fault to ignore a ready-made opportunity — Biogen itself — when it was offered.

Furthermore in the UK a number of scientists have been attempting for three years to interest venture capital and the government in a British contract research organisation, akin to Biogen, to no avail. Some who were active in that attempt are now members of Biogen. The National Research Development Corporation, which might be expected to take a lead in such matters, seems content merely to exploit. Whereas four of six major revenue-earners are biotechnical, its past and present biological development projects are outnumbered by the non-biological 10:1.

Neither do European politicians have much to praise each other about. When it began to be possible to make high fructose syrup economically from maizestarch using immobilised enzymes, the Council of Ministers of the European Community — the highest and most political authority — slapped a punitive levy on the process, killing its development (which was already underway in Britain), in the name of protecting beet growers.

No wonder that a draft version of the forthcoming Royal Society report on biotechnology recommends that Europe puts its house in order. Biotechnology must not invite penal levies, says the draft, merely because Community policy is in the grip of interests which 'resist the cheaper and better products of this new technology, particularly where these threaten to perturb existing patterns of agriculture''. Common Agricultural Policy legislation which threatens biotechnology must be revised; and arrangements reached whereby agricultural surpluses can be turned to good use as biotechnical feedstocks.

In this and other ways the report is a strong blast of good sense which the British government — and the Community — would do well to respect. Recession, when individual firms are without the funds to invest, is exactly the moment when governments can move in legitimately to pick up the bill for long-term, strategic research. This also happens to be exactly the moment when technology is finding a new lease of life, through microcircuits and now biotechnology. The nations which will dominate the economics of the 21st century will be the ones that have invested in the new ideas — the ones that have the new processes underway and the new talent in their industries. Engineered bugs and microchips will be the coalfields of the next century: and they are not to be found, but created.

Two great opportunities are shortly to be forthcoming in biotechnology: the £16 million research programme proposed for the EEC which the European Commission should not foolhardily reject; and the recommendations of what will, we hope, be a not too diluted version of the draft report we describe this week (page 324). Europe and the UK must embrace both of them. □

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Biotechnology report urges £10 million programme "to match competitors"

A MAJOR report on biotechnology in Britain — not yet published but made available to *Nature* — calls for a rapid increase in investment to build a competitive industry. It says the "customer-contractor" principle should be scrapped for biotechnology, where the border-lines between basic and applied research are grey. The report is a first draft — though unlikely to be substantially altered — from a seven-man working party set up early last year under Dr Alfred Spinks, a former research director of Imperial Chemical Industries. **Robert Walgate** reviews its hard-hitting and interventionist recommendations.

THE working party was drawn from the Royal Society, the Advisory Board for the Research Councils and the Advisory Committee for Applied Research and Development. It was set up under the previous Labour administration; during its deliberations a Conservative government, committed to non-interference in industrial affairs, has taken office, but this has not restrained its far-reaching proposals.

It says the whole foundation of biotechnological research in Britain should be changed:

"Since 1972, the UK has unlike other countries adopted a very rigorous customer-contractor principle for all its applied R&D funded by government. This approach is well-adapted to short-term or tactical applied work with clear objectives which can be defined by a single customer.

But biotechnology epitomises a field in which scientific knowledge and technical expertise are evolving rapidly, where definite customers have yet to develop in any number; where the research of government departments is divided; where the research will be of interest to a wide range of private industry, public services, etc.; and where the principle need for growth is in strategic applied research much of which will not yield results of immediate commercial benefit for perhaps a decade.

"For such a field the customer-contractor principle has serious shortcomings, and may exacerbate the situation by emphasising an arbitrary and unreal division between fundamental and applied research." Nevertheless the ultimate objective should be to make British industry competitive with the best of its foreign rivals.

Among its recommendations are:

- That the research councils and the ABRC should set up a Joint Committee for Biotechnology to develop a coherent programme of biotechnology research and to coordinate spending of not less than £3million annually (including existing research council initiatives). The Joint Committee would aim to set up new projects in universities and elsewhere, and "should encourage collaboration between experimenters of different disciplines, in different departments and institutions". Applied biologists currently working in medical or agricultural studies should be encouraged to take up biotechnology. A condition might be applied to applicants for grants that they should show evidence of industrial interest in their project.

- That an Interdepartmental Steering Group should be sent up to coordinate the actions of ministries and develop a programme of industrial R&D. The Department of Industry might take a lead in this, setting up cooperative programmes with industry (funded 50:50), research associations, government research establishments, universities, and inventors amounting to £2.5million annually (including existing projects).

- The Steering Group should consider setting up a Support Unit, like the Department of Energy's Energy Technology Support Unit, to do desk studies and build up a list of potential projects for which applications would be sought.

- The Joint Committee and Steering Group should have overlapping membership to avoid a division between basic and applied work, and in any case should review the position in 4-5 years' time.

- There should be no new establishments specifically to pursue research in biotechnology; these can stagnate and exacerbate interdisciplinary divisions. But the Department of Industry should co-sponsor the Centre for Applied Microbiological Research at Porton Down (it is presently sponsored by the Public Health Laboratory Service); CAMR expertise could be well-applied to biotechnology.

- The University Grants Committee and the Committee of Vice-Chancellors and Principals should support the expansion of a limited number of centres of excellence in biotechnology from the best existing in universities. A minimum of 20 new teaching and research post should be established over the next five years with a capital investment of around £2million to provide additional laboratory facilities.

- Urgent provision must be made for training a work-force to match the expected growth of biotechnology; greater interaction should be encouraged between departments and undergraduate courses in the biological, chemical and engineering sciences.

- The Science Research Council's Cooperative Awards In Science and Engineering, which funds research students in joint projects between university and industry, should be extended to the Agricultural and Medical Research Councils; and there should be analogous post-doctoral awards.

> "Government should not impede the rapid development of biotechnology by inappropriate or unfounded concern for existing industries or the conjectural hazards apparently presented by some aspects of the new technology."

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Dr Spinks: he chaired the working party.

- The National Research Development Corporation, one of whose roles is to patent and license appropriate inventions made in universities, "should play a more entrepreneurial role in this area, where inventions are often not readily patentable. The NRDC should expand its staff in biotechnology and review existing financial incentive for academic inventors. The NRDC should be at least as concerned with the development of new business as with obtaining and licensing industrial property.

- The NRDC should continue to pursue with the Patents Office the patenting of microorganisms and press for arrangements, as in the US, which do not require the microorganism to be made available until the patent is granted.

- As new research defines the hazards of genetic manipulation, the UK in consultation with others from abroad should modify regulations appropriately. The Genetic Manipulation Advisory Group and the Health and Safety Executive should continue to reduce constraints while maintaining an adequate level of safety and introduce procedures to ease industrial application.

- The National Enterprise Board and the NRDC should investigate the use of public funds to set up a research oriented biotechnology company (akin to the American Biogen and Cetus). £2million a year for five years should be sufficient to establish if it could be profitable, the report suggests.

- The Ministry of Agriculture, Fisheries and Food and the Department of Industry should jointly investigate the use of agricultural products as feedstocks for biotechnology.

- The Department of Health and Social Security should adjust its purchasing policy to encourage small biotechnological firms.

- The Department of the Environment together with the Department of Industry and the Natural Environment Research Council should consider the use of biotechnology for waste disposal and materials recovery.

- If the European Economic Community decides to pursue its research programme in biotechnology, the UK should seek maximum return from it.

- Government should seek fiscal regulation within the EEC which will allow the use of agricultural feedstocks for industrial biotechnology "and not impede the introduction of new processes based on biotechnology". The report here criticises "the strong lobbies of established industry and agriculture which tend to exert a disproportionate weight in resisting the cheaper and better products of new technology, particularly where these threaten to perturb existing patterns of agriculture". There should be assurances that processes "will not invite penal levies . . . We are concerned that this appears to be the present case."

- Addressing itself to the European Community, the report recommends that "all member states should consider the value of biotechnology in transforming agricultural surpluses, and should seek to amend the Common Agricultural Policy legislation that threatens this end". Further, the EEC directive on the control of genetic manipulation is outdated and should be "reconsidered".

- The report "supports" the SRC in a £1.5million capital, £1million annual expenditure on biotechnology; commends the ARC's initiatives in genetic manipulation, and makes a mild and indirect criticism of the MRC: "The MRC and research councils should review their roles in relation to industrial development based on biological processes so that their staff are aware of the desirability of creating, where possible, a national return for their efforts through industrial development."

Despite the case of cephalosporins (antibiotics emerging from MRC research which are now the NRDC's single greatest revenue earner) "the take-up of discoveries by UK industry is not encouraging". Extra facilities might be provided to researchers for applied work in their own laboratories, or a special development unit might be established. However, the MRC was not set up with industrial development as an objective, and any moves along these lines would require extra resources.

National Collection of Yeast Cultures threatened

THE UK National Collection of Yeast Cultures, one of the most used in Europe, faces closure at the end of this year — unless the Agricultural Research Council can find a meagre £20,000 per annum to support it. "I don't see how biotechnology can carry on without a repository of cultures from which one can select strains" said a yeast microbiologist last week.

The collection has been looking for a home since early 1979, when one of its present co-sponsors, the Brewing Research Foundation, announced that it would withdraw its one-third contribution to the costs of the collection from January 1981. The major sponsor, the Ministry of Agriculture, Fisheries and Food, also decided to withdraw at the same date. The collection must also move from its present location at the BRF, in Nutfield, Surrey.

All would be well, say microbiologists, if there was some firm promise of new funds and a new place for the collection. But despite detailed recommendations to the Agricultural Research Council — who it is widely believed should support the collection — from the UK Federation for Culture Collections, no decision has been reached on either location or funding.

"Individual collections are not sufficient" said one microbiologist. "We keep our own small collections but we do not have time, competence or staff to do routine testing or distribute samples. It would be very serious if we sent the wrong organism".

The UKFCC has recommended that the collection and its four staff be established at the ARC Food Research Institute in Norwich, on a site where the John Innes Institute and the University of East Anglia are already established.

MAFF has placed the problem firmly with the Advisory Board for the Research Council's, which in turn has passed the problem to the ARC. But it would appear that the ARC is not prepared to fund the collection unless it receives extra finance.

Barbara Kirsop, the curator of the collection, told *Nature* that the collection has been in financial difficulty for four years. A number of agencies picked up the bill for short periods in the past, including the ARC which paid 50% of the bill for one year in 1976. "The BRF" said Kirsop "no longer wishes to support the collection because its emphasis has changed over the past ten years. People are using yeasts a lot more and we have constructed a very physiological collection which means we have a great number of yeasts with many interesting and useful properties". The collection holds 10-15 patented strains among a collection of 2000 varieties. "We need to start moving the collection in June, if we are to be out by December," says Kirsop. □

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ADVISORY COUNCIL FOR APPLIED RESEARCH AND DEVELOPMENT
ADVISORY BOARD FOR THE RESEARCH COUNCILS
THE ROYAL SOCIETY

REPORT OF THE JOINT WORKING PARTY ON BIOTECHNOLOGY

January 1980

FOREWORD

In early 1979 the Advisory Council for Applied Research and Development (ACARD) decided in conjunction with the Royal Society and the Advisory Board for the Research Councils (ABRC) to set up a Joint Working Party to study the industrial applications of biological knowledge, ie biotechnology. The terms of reference were:

> "To review existing and prospective science and technology relevant to industrial opportunities in biotechnology;
>
> To recommend action by Government or other bodies to facilitate British industrial development in biotechnology;
>
> To make an interim report to ACARD, the ABRC and the Royal Society in the autumn of 1979 recommending what further detailed study is desirable, noting that actions thought urgent may be recommended earlier."

The members of the Working Party were:

Dr A Spinks, CBE, FRS (Chairman)	Formerly Director of Research, Imperial Chemical Industries, Second Deputy Chairman of ACARD and member of the ABRC
Sir William Henderson, FRS (Deputy Chairman)	Chairman of the Genetic Manipulation Advisory Group and formerly Secretary to the Agricultural Research Council
Dr J M Ashworth	Chief Scientist, Central Policy Review Staff
Sir Austin Bide	Chairman, Glaxo Holdings Ltd, and Chairman of the Confederation of British Industry (CBI) Research and Technology Committee
Sir Arnold Burgen, FRS	Director, National Institute for Medical Research

Professor J F Davidson, FRS	Shell Professor of Chemical Engineering, University of Cambridge
Professor B S Hartley, FRS	Professor of Biochemistry, Imperial College of Science and Technology, London
Professor A W Johnson, FRS	Professor of Chemistry, University of Sussex and Board Member of the National Research Development Corporation (NRDC)

The Report of the Working Party was endorsed by the three sponsoring bodies at the turn of the year. It has been submitted to the Government for their consideration and is now being published in order to draw the attention of industry and others to the potential of biotechnology and to stimulate its development and application by industry.

The Report is not intended to be a comprehensive review of the current state of biotechnology but attempts to identify those aspects of the subject which merit attention and action now. However, some of the topics discussed and their potential significance will be unfamiliar to those outside the subject; an annex is therefore provided to assist understanding and appreciation of the subject.

The three sponsoring bodies are grateful to Dr Spinks and his colleagues for preparing the report. The Working Party wish to acknowledge the support provided by the staff of the Royal Society, the ABRC secretariat in the Department of Education and Science and the ACARD secretariat in the Cabinet Office.

CONTENTS

SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS

1 We envisage biotechnology - the application of biological organisms, systems or processes to manufacturing and service industries - as creating wholly novel industries, with low fossil energy demands, which will be of key importance to the world economy in the next century. Over the next two decades, biotechnology will affect a wide range of activities such as food and animal feed production, provision of chemical feedstocks, alternative energy sources, waste recycling, pollution control, and medical and veterinary care. We are convinced that it will shortly be possible to use microbial and other cells to make a wide range of organic chemicals which either cannot at present be made economically on a large scale or, if they can be made, reqiire extensive inputs of land, energy and capital plant for their production from feedstocks, such as oil, which will become more expensive.

2. For the United Kingdom, biotechnology is an area of high technology with large potential growth offering opportunities for the renewal of various existing industries and the creation of new ones. It can be used by both large and small businesses, and although initial capital and development costs are high for some processes, experience in the United States and in Europe suggests that growth can occur in small companies backed with only limited financial resources.

3. British industry must respond faster to the challenge presented and grasp these opportunities to develop new products and processes and to supply equipment and reagents in both home and overseas markets. By comparison with our competitors - West Germany, Japan, the United States - investment is low and opportunities have been missed. We are concerned that the level of awareness shown by overseas firms and the alacrity with which they approach university and other groups in the United Kingdom is not generally matched by that of British firms. With notable exceptions, these seem less able, less willing and less well informed of the need to take advantage of the potential of biotechnology.

4. Constraints delaying the realisation of this commercial potential exist and action is needed in the United Kingdom both to remove these and to promote biotechnology. The slow growth in its application by various industries doubtless reflects poor profitability of existing business, the prevailing fiscal and regulatory climate and the cost of development - matters over which the Government should assist industry so that it can be more enterprising. For example, the present structure of public and private support for R and D is not well suited to the development of a subject like biotechnology which, at the moment, straddles the division of responsibility both among Government Departments and Research Councils and the arbitrarily defined fields of fundamental and applied research. Strategic

applied research is in general ill-served by our research funding mechanisms, especially in areas where there are neither university departments to promote it, nor well-developed industries to provide market-pull. There is difficulty in identifying a source of funds to carry a project forward from the point where the primary research has been done but the commercial development has not yet begun - the "pre-development gap".

5. Biotechnology lacks university centres specifically for it and this results in a shortage of new ideas for industry and of suitably trained manpower. The absence of an established industry clearly identified with new biotechnologies allows Government policy in one industrial sector to have adverse implications for biotechnology in others and diminishes the attraction of the subject to engineers. The result of such interactions is that biotechnology has not grown in the United Kingdom in the coherent fashion which we believe is merited by its potential. What is required at this stage is a policy of "technology-push" reflected in a firm commitment to strategic applied research. This will progressively produce potentially marketable products and processes and the policy will then be for a more "market-pull" approach. In the past the United Kingdom has not shown itself particularly adept at recognising when there is the need for this kind of switch in policy nor, when the need is seen, for making the necessary adjustments. We need, as a nation, much better communication between those who are primarily market orientated and those who are primarily science or technology orientated and nowhere is this more true than in biotechnology.

6. We are not convinced that in our mixed economy the tasks posed by the problems we have identified can be met by the private sector alone. We believe that in the interests of improving industrial competitiveness and paving the way for industrial innovation a concerted approach is now needed from Government and industry to provide the coherent framework and mechanisms necessary for the successful development of biotechnology and of industries based on it. This should involve a commitment, financial and otherwise, at least comparable to that taken or contemplated by our major industrial competitors. The Government should stimulate and support this new field and ensure that its rapid development is not impeded by an inappropriate or unfounded concern about the maintenance or growth of existing industries or the conjectural hazards apparently presented by some aspects of the new technologies.

7. Against this background, we make recommendations of two kinds: those for early action in support of training, research, development and innovation, and those to ensure that in the longer term the country is to gain the maximum value from such action.

[illegible]r principal recommendations (with reference to paragraph numbers) are -

R1 The Research Councils should substantially increase their support for biotechnology. But because the subject cuts across their areas of interest and expertise and will point up gaps between them, the Councils should also, with the Advisory Board for the Research Councils (ABRC), set up a Joint Committee for Biotechnology. With the support of a Director/Co-ordinator to stimulate new projects in universities and elsewhere, this Joint Committee should develop and co-ordinate a coherent programme of biotechnology research. Building on their present and forward commitments for the subject, the Councils should together reach a spend of at least £3 million annually, the minimum we believe is now required. The Research Councils, with the Joint Committee, should consider making a requirement that a proportion of the grant applications from universities should show evidence of industrial interest. (4.6)

R2 The activities of Government Departments in relation to biotechnology should be co-ordinated; and a coherent programme of industrial research and development involving industry. Government research establishments, universities and Research Associations should be pursued at an annual expenditure of about £2.5 million (including existing projects). An inter-Departmental Steering Group should be established as a means towards meeting these objectives. This would be complementary to and, through common membership, well articulated, with the proposed Joint Research Council Committee and should work closely with the National Research Development Corporation (NRDC). Technical support for such Group might be provided by a unit comparable to the Energy Technology Support Unit at Harwell. (4.8)

R3 We do not support the establishment of a new Government research establishment for biotechnology. But the Steering Group should consider how more use could be made of all the existing establishments, eg the Centre for Applied Microbiology and Research (CAMR), AERE Harwell and the Warren Spring Laboratory (WSL), to advance biotechnology. For example, the Department of Industry should co-sponsor CAMR to strengthen the industrial side of the CAMR programme. (4.11)

R4 The Confederation of British Industry, the Association of the British Pharmaceutical Industry, the Chemical Industries Association, the Food and Drink Industries Council and other trade associations, including that proposed in R5, should actively seek to identify opportunities for advances in biotechnology in the fields of potential interest to their members. They should then take effective steps to inform members of neglected opportunities and to inform Government, trades unions and others of any constraints that need to be removed. This last step might be pursued within the appropriate Sector Working Parties of the National Economic Development Organisation as recommended in the ACARD report "Technological Change - threats and opportunities for the United Kingdom". (4.12)

R5 A trade association of suppliers of process plant and equipment should be formed to provide for closer contact between suppliers and research scientists. The proposed trade association should give particular attention to the export potential provided by developing countries and the way it is best pursued. (4.13)

R6 The National Enterprise Board in conjunction with the NRDC should investigate the possibility of using some public funds to establish a research oriented biotechnology company of the kind established with apparent success in the United States. A sum of £2 million annually for five years should be sufficient to determine its value and establish the scale of further investment. (4.14)

R7 We strongly support the initiative of learned and professional bodies in establishing the British Co-ordinating Committee for Biotechnology (BCCB) and commend it to industry and Government as a valuable forum. It should develop close contact with the process plant industry. Industry should do more to assist the BCCB financially and be more active in its support for university research. (4.13)

R8 The University Grants Committee (UGC) and the Research Councils, with the backing of the universities, should support the expansion of a limited number of centres of excellence in biotechnology from the best existing in universities. A minimum of 20 new teaching and research posts should be created over the next five years with a capital investment of around £2 million to provide adequate laboratory facilities. We ask the Department of Education and Science (DES) to note the need for additional finance. (4.15)

9 The Committee of Vice-Chancellors and Principals (CVCP), the UGC and the Committee of Directors and Polytechnics should, with the DES and the Department of Employment where appropriate, consider urgently how to provide an adequate, appropriately trained workforce to match the expected growth of biotechnology and how to encourage greater interaction between departments and undergraduate courses in the biological, chemical and engineering sciences. The DES should take account of these likely manpower demands in its forward planning of the provision for higher and further education. Young scientists and engineers should be made aware of the potential benefits and opportunities which biotechnology can provide. (4.17)

R 10 Collaboration should be fostered between universities, Research Councils and industry in postgraduate training in biotechnology. The Science Research Council's CASE award scheme provides a suitable example of a pattern for achieving collaboration of this sort. Attention should also be given, by the Councils concerned, to the promotion of collaborative arrangements with industry at post-doctoral level, for example by encouraging the use of industrial funds to support research workers from industry working in Research Council and university laboratories. (3.3, 4.15)

R 11 We wish to see the NRDC play a more entrepreneurial role in the support and encouragement of innovation and the provision of funds for development in a field where inventions are often not readily patentable. To this end NRDC should expand its staff resources for biotechnology, re-examine the financial awards and incentives for academic inventors, and be as much concerned with the creation of new companies as with matters of industrial property. NRDC should lead a study with the UGC, CVCP and the Research Councils to review existing and potential ways of encouraging academic inventors in the United Kingdom and to consider practice overseas. (4.18, 4.19). The NRDC should also continue to pursue with the Patent Office the problem of patents as they relate to micro-organisms. (3.11)

R 12 If the opportunities offered by genetic manipulation are to be seized, the Government should, as new research defines more precisely the nature of the hazards involved, modify the regulatory regime appropriately, in consultation with others abroad. The Genetic Manipulation Advisory Group (GMAG) and the Health and Safety Executive should continue as rapidly as possible to reduce constraints upon genetic manipulation experiments while maintaining an adequate degree of safety; to introduce procedures to ease industrial application of these techniques; and to keep the controls in the United Kingdom and other countries under review. (4.20)

Our other recommendations and comments that may call for action are -

R 13 There should be continued support for the biotechnology programme of the Department of Energy. The Department of Trade, in conjunction with the Department of Energy, should review opportunities for export of process plant in the field of biomass and waste for energy and should help co-ordinate United Kingdom policy in this field in relation to the EEC. (4.23)

R 14 The Ministry of Agriculture, Fisheries and Food, with other Departments, should review the pattern of agricultural production in the United Kingdom in the light of the prospects of using some agricultural products for industrial feedstocks and replacing the production of some agricultural commodities by industrial processes. (4.24)

R 15 We commend to the Government the recommendations on financial assistance for small firms in the ACARD report 'Industrial Innovation' (3.19). More particularly, the Department of Health and Social Security should consider whether changes in its purchasing policy for the National Health Service would be justified in order to support the entry of small firms using biotechnology into the market. The Department should also undertake a study on possible new testing systems for medicines, food additives, etc with a view to reducing the costs and duration of development. (4.25)

R 16 The Department of the Environment in conjunction with the Department of Industry and the Natural Environment Research Council (NERC) as appropriate, should increase support for biotechnology research relating to effluents, waste disposal, materials recovery, etc and work with local authorities, relevant private industry and research establishments such as WSL, AERE Harwell and the Water Research Centre in studying the potential role of biotechnology in these and other public service fields. (4.26)

R 17 If the research programme in biomolecular engineering being prepared by the European Commission is taken up by the Community, the United Kingdom should seek the maximum return from it. Separately, the Government should seek fiscal regulations within the EEC which will allow the use of agricultural feedstocks for industrial biotechnology and not impede the introduction of new processes based on biotechnology. (4.27)

R 18 We are concerned that, if agreed in its present form, the draft EEC Directive on genetic manipulation would create a slow and inflexible system of controls based on premises now no longer held by a majority of countries within or outside the Community. The need for a directive should be reconsidered in the light of new knowledge of the conjectural hazards involved. (4.21)

R 19 We have concluded that machinery is required to ensure the future of culture collections of living micro-organisms through long term financial support. The proposed interdepartmental Steering Group for Biotechnology should study the way in which existing collections can best be maintained and the merit of establishing further national or international collections. (4.10)

R 20 We welcome the Science Research Council initiative to establish machinery to stimulate growth in biotechnology research, particularly in the area of strategic applied research. We believe that capital expenditure of £1.5 million and recurrent annual expenditure of £1 million would be wholly justified and should be achieved as soon as practicable, as a component of the programme proposed in R1. (4.7)

R 21 We commend the Agricultural Research Council's continued support for the application of new techniques of genetic manipulation in plant breeding. In common with the Medical Research Council, the ARC should vigorously pursue DNA research applications to improve and create biological products. (4.23, 4.22)

R 22 The Research Councils should, through the Joint Committee for Biotechnology, review their roles in relation to industrial development based on biological processes so that their staff are aware of the desirability of creating, wherever possible, a national return for their efforts through industrial development. (4.22)

R 23 The proposed Joint Research Council Committee and Steering Group should consider how to encourage international collaboration in biotechnology to the benefit of the United Kingdom. (4.28)

R 24 Finally, biotechnology is a rapidly developing subject and the Government should commission a further detailed study to review the position in 4 or 5 years' time. (4.9)

1. INTRODUCTION

1.1 For the purpose of this study, we have defined biotechnology as the application of biological organisms, systems or processes to manufacturing industry. Bacteria, yeasts, fungi, algae, the cells and tissues of higher plants and animals, or enzymes isolated from such organisms, provide starting points for new industries and for the replacement of existing industrial processes with new or improved biological ones. We have focussed mainly on existing opportunities or those likely to develop over the next 5-10 years and have sought to highlight topics which appear to have the greatest potential for commercial exploitation, and to identify constraints to their development. We have concentrated particularly on the use of genetic manipulation, enzyme technology and fermentation as these have seemed to us to provide the greatest prospects for large-scale utilisation - for example in the manufacture of medical and veterinary products, chemicals, food and energy and for pollution control and waste treatment.

1.2 The conjectural hazards of genetic manipulation (also referred to as genetic engineering or recombinant DNA research) have attracted a great deal of publicity in the last few years. We believe that for the reasons set out in the annex, the initial concerns about these hazards were exaggerated and that the steps already taken in the United Kingdom and some other countries will maintain an adequate degree of safety. The important step now is to ensure that the present regulations are appropriately modified in the light of new knowledge, so that potential industrial benefits are not missed because of too stringent control.

1.3 If our studies have focussed primarily on existing opportunities or those likely to develop over the next 5-10 years (see annex), it is because we are convinced that there are now immediate industrial opportunities and that immediate measures would facilitate them. But the insights gained from development and innovation are likely to feed back rapidly and will increase the scope of biotechnology by an order of magnitude in 10-20 years. Hence the measures we propose will become even more important in the 1990s and will require Government Departments and the Research Councils to monitor closely future developments in this rapidly expanding field.

1.4 Our study is not the first in this field. In particular, Dr E N Emery prepared a valuable report "Biochemical Engineering" for the Institution of Chemical Engineers and the Science Research Council (SRC) in 1976 which focussed however on the biochemical aspects of chemical engineering. But the rapid development of molecular biology (and in particular of recombinant DNA techniques) justifies a new report. More recently the Commission of the European Communities has published three studies on genetic manipulation, biological catalysts and biohazards.

1.5 The Working Party approached a number of major industrial firms using biotechnology in the United Kingdom, Government Departments, Research Councils, trade and research associations and professional bodies, and individuals in universities and elsewhere, and received their views on opportunities, priorities, constraints and remedies in the development of biotechnology in the United Kingdom. Information from other countries was provided by our Embassies and British Council Offices.

1.6 In the next chapter, and in the annex, we consider the current activity in, and opportunities and priorities for, biotechnology in the United Kingdom, and draw comparisons with programmes in other countries.

2. BIOTECHNOLOGY IN THE UNITED KINGDOM AND OVERSEAS

2.1 Biological processes have, of course, been used in industry for many centuries, and there have been substantial advances in such traditional activities as brewing and fermenting during this century. However, biotechnology as a separate discipline is now emerging faster than many expected. Rapid advances in both cell and molecular biology have allowed more confident prediction that a given product can be produced by a biological process or organism at a reasonable cost. Genetic manipulation, involving the transfer of genetic material from one organism to another and giving the recipient some desired characteristic of the donor, has become a practical and quite general proposition. As a result, a rational rather than empirical approach to biotechnology is now feasible, with organisms tailored to specific needs and process conditions. This advance in our view now confers on biotechnology an importance comparable to that of atomic physics, electronics, and most recently microelectronics. It has been said that biology will "launch an industry as characteristic of the twenty-first century as those based on physics and chemistry have been of the twentieth century" (Economist, 2 December 1978). It will, moreover, be an industry based in large part on renewable and recyclable materials and thus adapted to the needs of a society in which energy is expensive and scarce. It will be relevant to a wide range of industries - including agriculture, food and feedstuffs, chemical, pharmaceutical, energy and water industries - and to such diverse products and services as bulk chemicals, antibiotics, vaccines, methane gas, metals, food additives, single cell protein, effluent treatment and waste recycling. As such, it is a growth area in technology and will require new processes, equipment and services, entrepreneurs, venture capital and the wide communication of ideas and know-how. We return to these points later. Moreover, although only some of the potential applications will prove commercially sound for British industry, many others are already being, or will be, put in hand elsewhere in the world. Hence the potential market for British process plant and equipment, reagents and process and systems engineering is expanding rapidly. But the opportunities will be lost if they are not grasped quickly.

2.2 Use of the term 'biotechnology' might be taken to imply a marked degree of coherence in the subject and its application, but this has not yet been achieved. Biotechnology, in practice, embraces a set of desperate but often inter-relating technologies relevant to a broad spectrum of industries and requiring a wide range of science and engineering expertise, often for a single development. Inputs from microbiology, biochemistry, cell biology, molecular biology, chemistry and chemical and biochemical process and control engineering will almost always be required. In many of these fields there have recently been important advances (see annex) relevant to biotechnology. This diversity of inputs and the poor facilities which exist for ready interaction between these disciplines, at least outside industrial firms, highlights the importance of collaborative strategies at company, university, Research Council and Government levels, so that biotechnology can begin to develop more rapidly in the United Kingdom.

2.3 However, the stimulus to biotechnology is not only from rapidly advancing techniques. There has also been a dramatic change in its economic potential. The increase in oil prices since 1973, the associated heightened awareness of the finite nature of resources, and the rapid industrialisation and improved living standards of some Third World countries, have all led to growing economic and trade pressures for cheaper and more secure supplies of energy and chemical feedstocks, for more efficient production, storage and distribution of food and feedstuffs, for more efficient conversion of feedstuffs into animal products and for improved agrochemicals and veterinary products. At the same time, social pressures have increased for improved environmental control and waste management and for more, better and cheaper drugs, vaccines, hormones, antibiotics, etc.

2.4 We would not wish to underestimate the costs and problems of translating new developments into commercially exploitable processes, nor the differing timescales for their impact on society. Moreover, within the diversity of business possibilities in biotechnology, there are substantial differences of emphasis, for example, between the central issues for the low volume, high value-added field of fine chemicals and the wholly different bulk chemicals industry. In some cases the entry cost for biotechnological processes will be as high as or higher than for petrochemical processes and beyond present British supplies of venture capital. Extensive safety testing of products for biological hazards will also demand long term research support. Nevertheless, we believe that industries based on this new discipline are poised on the threshold of a rapid expansion. If exploited successfully, biotechnology could be both a significant contributer to our balance of payments in the 1980s - through import saving and exports - and a new field of employment. Hence it deserves a careful appraisal of relevant Government policies.

Support for biotechnology in the United Kingdom

2.5 It is difficult to quantify existing activity in the United Kingdom as no official research and development statistics relate specifically to this subject. We have, however, received considerable evidence from universities, Government Departments and industry about their activities and have been able to compare this with the effort in some other countries. We are convinced that, relative both to the immediate opportunities and the efforts of our foreign competitors, too little is being done in too unco-ordinated a fashion, and that potential strengths in the United Kingdom are either unexploited or ill-supported.

2.6 One measure of the scale of existing activity is that funded by central Government. Few Government establishments have a significant effort in biotechnology. Until recently, the former Microbiological Research Establishment at Porton was a noteworthy exception, but a recent reorganisation that placed responsibility for this establishment (now the Centre for Applied Microbiology and Research, CAMR) with the Public Health Laboratory Service appears to us to have put its contribution at risk. Some of the projects at AERE Harwell and the Warren Spring Laboratory also fall within our definition of biotechnology. By some definitions, the majority of work funded by the Agricultural and Medical Research Councils might be biotechnology, but with our narrower definition only a small fraction of their budget can be included. For example, although the MRC is supporting a great deal of research which may lead to industrial production, it is not at present supporting any work directly relating to the development of a process on an industrial scale. Modest Science Research Council support through the Engineering Board is attributable but the proportion of their support for biology assignable to biotechnology is unclear. Within these considerable limitations, we believe overall support by the Government and the Research Councils to be no more than £4-5 million annually.

Overseas comparisons

2.7 We have not surveyed overseas activity exhaustively but some of our competitors - notably West Germany, the United States, France and Japan - provide substantial assistance to biotechnology.

2.8 In West Germany, the Federal Ministry of Research and Technology (BMFT) launched a major national programme of biotechnology in 1972 following an extensive investigation by the German Chemical Apparatur Association (DECHEMA). This study recommended the support and promotion of biotechnology on four grounds - it was highly relevant to areas of public interest: environment, food and pharmaceutical supplies; it would improve the competitiveness of West German industry; it would apply knowledge gained from basic biological research; and it would provide training directed towards the application of novel processes. The 1980 research budget of BMFT contains a separate entry for research and development in biotechnology equivalent to nearly £10 million. In addition to this research directly orientated towards industrial objectives, the DFG (Deutsche Forschungsgemeinschaft) supports fundamental research in the biosciences equivalent to some £60 million annually, a proportion of which will be on biotechnology. The main centre for biotechnology research is the GBF (Gesellschaft für Biotechnologische Forschung mbH) at Braunschweig-Stockheim. This was founded through the Volkswagenwerk Foundation in 1968 and taken over by the Government in 1975. The GBF is the only major research institute in the EEC devoted entirely to biotechnology and is a multi-disciplinary institute which carries out both fundamental research and investigations on an industrial scale. It thus aims to fulfil an intermediary role between the public institutions, particularly the universities, and industry. The GBF employs a total of staff of 248 of whom 110 are scientists (60 in permanent positions), and has a budget of £5 million annually of which 90 per cent comes from the BMFT and the remainder from the state of Lower Saxony. Limited additional income comes from industry. Priorities in the GBF programme are appraised by a supervisory board, chaired by a representative of the BMFT.

2.9 We are impressed not only by the scale, but the wide range of biotechnology-related activities supported by the BMFT in industry, universities, notably technical universities, and independent research institutions. These extend from fundamental research to innovation and the provision of services to industry. As a result, many universities and biotechnology groups in West Germany receive research grants from both the BMFT and the DFG as well as their basic salaries from the local State and, in some cases, funds from industry or foundations as well. We understand that the BMFT and the DFG adopt a liberal approach to the use of their grants provided the research objectives are met. The West German entrepreneurial research leader is relatively unconstrained in his use of research staff, however supported, and can pursue, within a single research programme, long-term fundamental research, medium term strategic and short term tactical applied work of direct commercial value.

2.10 By contrast, government funding for biotechnology in the United States, is relatively less important except in the energy field and to a lesser extent in enzyme technology. There is, however, substantial activity in parts of the pharmaceutical and petrochemical industries, and the United States' business community is confident that the exploitation of biotechnology will lead to large profits; this has led to ample private venture capital. Government financial support is thus not needed and industry is wary of government involvement since it feels it might lead to over-restrictive regulation. The major area of government funding is the alcohol fuel programme. In 1980, the United States Department of Agriculture is spending £2 million on new crop varieties for use as ethanol feedstocks and on new methods to convert such materials to ethanol. In addition, it will spend £1 million on the design of small-scale technologies for alcohol and methane production on farms and will commit a further £20 million in loan guarantees for pilot industrial projects for the production of ethanol for use as fuel from agricultural and forest products. The United States Department of Energy has also substantially increased its planned support for alcohol fuels for 1980 to some £10 million. In enzyme technology, the Research Applied to National Needs programme of the National Science Foundation is spending about £½-1 million annually.

2.11 In France the programme co-ordinated by the Commissariat a l'Energie Solaire aims at an increase in energy production from crops, agricultural and other organic waste materials (biomass) from present output equivalent to 2 million tons of oil to the equivalent of 10 million tons by the year 2000. In 1979 research and development budget for biomass energy was about £2 million covering direct combustion, breakdown by heat (pyrolysis) and fermentation of wood and agriculture wastes. There are also many research establishments working on wine, beer, pharmaceuticals, sewage and industrial waste treatment. There is no central biotechnology institute similar to that in West Germany, but a number of government research establishments have recently formed a genetic engineering group. A recen[illegible] report commissioned by the President - "Sciences de la Vie et Societe" - has made substantial recommendations on the implications and development of biotechnology which are currently being considered by the French government.

2.12 Japan is a world leader in the production of amino acids, nucleotides, micorbial enzymes and antibiotics by fermentation. Sales from the exploitation of micro-organisms in Japan may reach £5 billion annually. Several continuous processes for a variety of amino acids using immobilized enzymes and cells[1] have been established by Japanese pharmaceutical companies during the last decade. The Japanese Government actively and coherently supports biotechnology in universities, government institutes and industry at a cost equivalent to about £8 million a year. The institutes include the Fermentation Research Institute of the Ministry of Industry and the Institute of Brewing of the Ministry of Finance as well as others in other Ministries covering protein research, polymer chemistry, applied microbiology and biochemistry. There is, in addition, Science Council support in this field for about 100 universities. We understand, further, that a major new national research institute is likely to be established covering the main subjects discussed in this report. The Government is currently studying the whole question of biotechnology through a number of committees looking at production of alcohol fuels, biogenetic technology and alternative methods for producing synthetic materials. In industry, Government institutes and the universities, emphasis is placed on the development of end products for practical use in industry and basic research is seen very much as being in support of these aims. However, despite this outstanding position in traditional industrial biotechnology, there is some concern in Japan about the threat posed to these processes by recombinant DNA technology, in which the USA and Europe are believed to have a lead.

2.13 There are substantial opportunities being created by biotechnology based activities in other countries. Brazil, for example, plans to produce 50 per cent of its petrol requirements from crops such as sugar cane and cassara by 1985. Research in support of this programme totalling more than £13 million over the last two years is concerned with the inproved production of crops, alcohol fermentation processes, the use of alcohol as fuel, and waste treatment. It is estimated that a further £20 million was spent

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[1] Cells or enzymes attached irreversibly to insoluble chemical supports, or irreversibly aggregated, so that they may be used repeatedly as industrial catalysts.

by the Government in private research institutes and by industry. Japan and West Germany already have joint agreements with Brazil for the training and exchange of specialists and for joint research on enzyme production and utilization and methane and alcohol production from organic produce. An Austrian firm has also exported know-how for the setting up of 40 Brazilian plants to produce alcohol fuel.

2.14 By comparison, Government support for biotechnology in the United Kingdom is meagre; there is no focus for biotechnological research and the sense of urgency apparent in some other countries is lacking except among small groups of enthusiasts. Also, since 1972, the United Kingdom has, unlike other countries, adopted a very rigorous customer-contractor principle for all its applied R & D funded by Government. This aproach is well adapted to short term or tactical applied work with clear objectives which can be defined by a single customer on behalf of established industry in a particular sector of the economy - agriculture, oil shipping, chemicals etc. But biotechnology epitomises a field in which scientific knowledge and technological expertise are evolving rapidly; where defined customers have yet to develop in any number; where responsibility amongst Government Departments is divided; where research results will be of interest to a wide range of private industries, public services, etc; and where the principal need is for growth in strategic applied research, much of which will not yield results of immediate commercial benefit for perhaps a decade. In such a field, the customer/contractor principle has serious shortcomings, and may indeed exacerbate the situation by emphasising an arbitary and unreal divide between fundamental and applied research.

Opportunities and Priorities in the United Kingdom

2.15 In view of the wide range and scope of biotechnology we have not sought to provide a comprehensive review of opportunities but have selected certain key areas which we consider to have particular potential, or to present outstanding opportunities, and which we believe, therefore, should receive priority attention. These are -

Genetic manipulation
Enzymes and enzyme systems
Monoclonal antibodies and immunoglobulins

Waste treatment (detoxification, by-product utilization)
Plant cell culture and single cell protein
Production of fuels (ethanol and methane) from biomass.

These together with a number of other smaller but nevertheless important fields, are defined and discussed in the annex. We consider in the following chapter the major constraints to the development and application of biotechnology, and some remedies.

3. CONSTRAINTS AND REMEDIES

Communication

3.1 Good communications and rapid transfer of knowledge and expertise between research workers in industry, universities and government laboratories are acknowledged as vital to industrial success. This is particularly true, however, with new and multidisciplinary technologies such as biotechnology where the professional training of many of the research workers has not prepared them for the problems that they will meet in dealing with those outside their discipline. Co-operation between British universities and industry seems particularly poor in the biological sciences and traditional attitudes of indifference or distrust are prevalent on both sides. Even where the commercial potential of a new scientific discovery is recognised and there is a desire to establish contacts, there is much uncertainty about how to improve the situation. There is an urgent need for scientists in universities and the Research Councils to become more aware of the potential industrial applications of their work so that commercial opportunities are not missed. The difficulties arise largely because the objectives and incentives of industrialists and academics differ. The reputation and career of the academic scientist are directly related to publication of his work in the scientific literature and more especially to being first in the field. Unfortunately, this aim can be incompatible with patenting - which is often impossible after prior publication. As a result, British inventions not protected by patents will be exploited in other parts of the world without financial benefit to the inventor or to the country. By contrast, industrialists seek patent protection to safeguard investment but often fail to appreciate that the academic inventor has little incentive to undertake the additional work needed to bring forward a patent as opposed to quick publication to establish priority of discovery. Occasionally, the time required to achieve secure patenting may exceed the period of a postgraduate grant. Moreover, adequate training of postgraduate students often demands time-consuming fundamental studies that hence compete with the industrial need to patent and exploit discoveries as rapidly as possible.

3.2 The ignorance of most academic scientists about the complexities of patenting, industrial markets, profitability and cash-flow problems limits their immediate usefulness to industry. Many would, however, be happy to devote part of their time to applied problems, but they seldom know what these are. British industry lags behind that of most other countries in the extent to which it uses academic consultants. Such consultancies are an essential part of both academic and industrial education and we were sorry to receive evidence that overseas firms seem more ready than their counterparts here to seek the advice of United Kingdom scientists, to place contracts and to provide them with incentives. Our scientists have played a prominent and at times dominant role in the establishment of modern biology, particularly molecular biology; British industry must not allow the industrial advantage of that position to be frittered away.

3.3 Many submissions to us have referred to the role of SRC Co-operative Awards in Science and Engineering (CASE) in promoting university-industry understanding and collaboration and almost all showed enthusiasm for them. We commend the CASE scheme to other Councils as exemplifying a pattern for achieving both university and Research Council collaboration with industry. We also invite them to give attention to the promotion of such collaboration at post-doctoral level. Successful co-operation will generally result from the initiatives of individuals. Nevertheless more schemes, for example to foster two-way secondments, should be established for promoting closer links between industry, universities, Government research establishments and Research Council institutes. We have been pleased to learn of the initiative by the Royal Society and the SRC jointly to establish an industrial fellowship scheme. We would like to see more financial support for universities by industry, for example by funding temporary appointments. The universities and the Research Councils for their part should consider how to improve the incentives and rewards to researchers engaged in collaborative research and making inventions. We have noted with particular interest the basis of research funding in biotechnology by the West German BMFT; successful applicants receive 100 per cent of the cost of a university project but proof is required of a collaborative link with industry. Moreover, continuation of a first stage grant, or the award of one for a second stage, has to be justified to the BMFT by both partners each year.

Trained manpower

3.4 If the United Kingdom is to benefit from biotechnology, it must train a suitable workforce. Although there is no immediate shortage of good graduates in some of the disciplines making up biotechnology, there is an increasing shortage of adequately trained biochemical engineers. Few university departments specialise in producing chemical engineers with any experience of the handling of biological processes and materials. Industry has largely to train its own people and the lack of staff may delay exploitation of new processes. There is also a shortage of individuals skilled in microbial genetics and some aspects of molecular biology. These shortages will become acute if the level of industrial application of genetic manipulation increases in accordance with the more enthusiastic forecasts. We are also concerned that growth of biotechnology elsewhere in Europe, the United States and Japan will result in a renewed brain drain. Although numbers might not be large they could represent a very high proportion of a limited resource. Already a number of foreign competitors are successfully recruiting young British biotechnologists. This would make an already difficult situation worse. The restriction in university growth in the 1970s has meant that most academics teaching biotechnology are in the 45-50 age group, with very few young lecturers - a highly unsatisfactory situation in a rapidly expanding field.

3.5 We conclude that expertise must be built up in universities, and that this will best be done by expanding the research and teaching capability in a limited number of existing centres of excellence and ensuring their close interaction with industry. We found, however, a substantial division of opinion on whether such centres should concentrate on undergraduate or postgraduate courses. Many argue that biotechnology, as opposed to biochemical engineering, cannot be taught as such at undergraduate level; but some argue that there is no need for more postgraduate courses. The newer scientific disciplines such as biochemistry, geophysics and, more recently, molecular biology evolved over several decades from multidisciplinary research specialities to undergraduate disciplines. It is clearly unwise to establish university courses on a sudden wave of enthusiasm, but we doubt if we can afford to wait for such a slow evolution for biotechnology. There are good arguments for developing courses in centres where biotechnology is developing naturally in departments of biology, biochemistry, microbiology or chemical engineering. Degrees in engineering must satisfy the examination requirements of a professional institution, and biology can be introduced only at the expense of an engineering component. But this problem has been met in the past and surmounted by chemical engineers and the introduction of some four-year undergraduate courses in engineering offers opportunities for innovation. A good grounding in the physical sciences and in mathematics has been recognised as necessary for the professional engineer. Biology will become a necessary component, at least for some engineers, as biotechnology develops and becomes recognised as a subject in its own right. We conclude that it is not too early to envisage undergraduate courses in biotechnology.

3.6 Some of the commercial prospects for biotechnology can be perceived now, but many of the opportunities for financial return and expanded employment will only start to arise some ten years hence. These opportunities will need to be grasped then by many who are today's school pupils. If there is to be a substantial national gain from biotechnology, local authorities, teachers, parents and pupils must be informed of its significance. It will, moreover, be important to bear this in mind in considering the availability and scope of school curricular provision in science and technology and for teachers and pupils to be aware of the benefits of genetic manipulation and other biological processes and techniques whose main publicity has hitherto focussed on the conjectural hazards involved.

The role of the National Research Development Corporation (NRDC)

3.7 The NRDC has a central role to play in the development and application of biotechnology. It has already received substantial royalties from biology and chemistry, eg for the cephalosporin antibiotics and, more recently, synthetic pyrethroid insecticides. Its manpower resources are, however, relatively modest. Of a total of about 50 officers, only 7 are engaged in the biosciences and these are required to cover not only biotechnology but animal husbandry, agricultural chemicals and chemotherapy. NRDC is the automatic recipient of inventions from work funded by most Government research laboratories and the Research Councils, and can assist other inventors if approached by them. The expertise of NRDC lies in the practical problems of transferring the results of academic research into industry and commercial gain: by identifying, and protecting through patents, potentially commercially useful ideas; subsequently licensing the patent property, in the first instance to British industry; and where necessary providing funds to help an inventor establish the potential of an idea or to generate a package of industrial property. In meeting these objectives, NRDC has identified to us two main problems: the need to identify or create an industrial "package" of commercial interest, and obtaining companies as partners or licensees.

3.8 We have received both praise and criticism of NRDC from individuals in universities, Research Councils and industry. The criticism expresses itself, first as a preference by some industrial representatives for more exclusivity and for direct links with research scientists in pursuing new inventions; secondly as a preference by some Research Council employees for direct industrial collaboration in developing and marketing a new product; and thirdly in an apparent reluctance on the part of university scientists to become involved with NRDC.

3.9 We cannot readily judge the rights and wrongs but we believe that inspection of individual cases would generally show the issues to be much less clear than at first sight. But the fact that such criticisms are widely voiced, and that there is a widespread belief, although perhaps unfounded, that the financial incentives provided by NRDC compare unfavourably with those arising from direct contracts with particular companies, are themselves constraints on the effectiveness of NRDC as a vehicle for exploiting academic inventiveness. There appears to be a lack of awareness in practice of the obligations on recipients of government money and of the rights of NRDC. This must be remedied. We are concerned that a lack of appreciation of NRDC, particularly by young scientists, may continue to result in situations such as that which occurred over monoclonal antibodies[1] where patent protection was not sought early enough and British advantage was reduced.

3.10 If British industry is to be regenerated through high technology, it will need to be much easier for academic researchers to become involved in business. There will be a continuing need for this to be encouraged by an agency such as NRDC or through units in universities, research institutes or public laboratories specially set up for the purpose; we doubt whether the majority of researchers would themselves wish to face the cost, complexity, time and effort involved in establishing effective patent protection.

3.11 A specific problem affecting biotechnology is the patenting of micro-organisms. Under the European Patent Convention and the patent laws of most Member States, the applicant for a patent for an invention using a micro-organism of a type not readily available is required to deposit a sample of the organism in a culture collection. This sample must be openly available when the invention's specification is published and, although the Convention

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[1] Antibodies of a single, unique composition (see annex, paragraph 18)

provides certain safeguards over access by third parties before the grant of the patent, these are not considered sufficiently restrictive. As a result, firms are either deterred from pursuing new inventions using micro-organisms or prefer to retain complete secrecy over new micro-organisms and their uses. For reasons considered inadequate by industry, the United Kingdom Patent Office is resisting current attempts to amend the Convention. We are concerned that if companies interested in exploiting the techniques of, for example, genetic engineering cannot protect their industrial property rights, and if useful organisms become public property as soon as they are put into use, they will never be developed. There is every incentive at present for industry to develop only those organisms retainable within a patentable industrial process and to be highly secretive about such developments. This will not benefit the growth of biotechnology and hence is not in the longer term national interest. We recommend that NRDC vigorously pursues with the Patent Office the problems specifically associated with the patenting of micro-organisms.

Process Plant Industry

3.12 We enquired closely into the constraints imposed upon biotechnology by the availability of plant and heard much adverse criticism of the **British** process plant industry both from academic workers and from its customers among the process industries. On the other hand, the process industries themselves may be at fault; the Process Plant Association report that, in developing new technology, foreign companies were more ready to use unproven plant and locally-made equipment than were companies in the United Kingdom. Some of the criticisms may be exaggerated; the fact that the process plant industry is specialised and international means that all countries import plant. But is seems clear that in some ways - particularly in the provision of small equipment requiring elaborate instrumentation and in the development of new equipment - British suppliers have often failed through poor design, quality, price or delivery.

3.13 The development of more refined biotechnological processes will increase the need for specialised equipment such as can already be seen, for example, in advanced sewage works. We are concerned that British industry may be failing to recognise the substantial opportunities offered by the many new and developing fields of biotechnology, at home and overseas. Many argue that there have already been conspicuous failures in

The manufacture of fermentation equipment (at laboratory and pilot plant scale particularly), and in the provision of sophisticated instrumentation and control systems. Britain is thus in danger of losing potentially large overseas markets for such plant and processes. A recent CBI report on "Innovation and Competitveness" suggested that "the intiative for the manufacture of new equipment seems to have passed abroad completely".

3.14 We believe three separate initiatives are required. First, both universities and industry need to provide an infrastructure for biotechnology which is process, rather than solely product, oriented. Secondly, there is a need for much improved communication between the fabricators and suppliers of plant, those in universities, Research Councils, Government research establishments of industry who are active in biotechnology research, and the product manufacturers and service industries utilising biotechnology. In particular, the pharmaceutical, energy and chemical industries should keep their plant suppliers informed of opportunities in home and overseas markets. There is a strong case of the establishment of a new Trade Association to meet this need, particularly for the many small companies. As pointed out in the ACARD report "Technological change - threats and opportunities for the United Kingdom", there is also a role here for the appropriate Sector Working Parties of the National Economic Development Office (NEDO). Thirdly, and a matter which should be the immediate concern of the proposed Trade Association, there is the problem of investment and cash flow. In the development of new equipment, a plant manufacturer would normally join forces with a biochemical manufacture and would then aim to sell the new product to other biochemcial manufacturers. During development there is a negative cash flow which the biochemical manufacturer is reluctant to provide, because the new equipment will eventually be sold to his competitors. At the same time, the equipment manufacturer may not be able to provide development funds over a period of years, particularly if his order book is thin. But in spite of these difficulties such joint developments are badly needed in biotechnology. All the parties involved, including Government, should consider how these problems might be overcome.

Laboratory equipment and reagents

3.15 There appears to be a particular shortage of suitable British equipment for biochemical laboratories; most of this is purchased overseas. The problems of the instrumentation industry are compounded by recent cuts in research support in universities and research institutes. As usual, capital expenditure for the replacement of equipment is the first to suffer.

Suppliers lose a stable home market and are forced out of business. Then the tide turns and a rush of foreign imports results. The Research Councils have tried to promote a 'Buy British' policy, but their support for equipment replacement is too limited to be wholly effective. Better communication and stable long-term support for scientific research would certainly help.

3.16 Similar factors may explain the shortage of United Kingdom based suppliers for biochemical reagents and enzymes, although many would argue that a sizeable British market exists. There is, for example, considerable potential for synthetic neuro-peptides; yet no British suppliers exist, even though Britain leads the world in such research. Specialised chemicals for research can be a profitable venture (as the Radiochemical Centre at Amersham has shown) and private entrepreneurs should be encouraged in this field. A similar situation pertains over the supply of the so-called restriction enzymes used in DNA research. It is unfortunate that, coincidentally with its transfer to the Public Health Laboratory Service, the CAMR should have ceased its provision of such enzymes to the universities. We understand that many research workers have to make their own, a task involving many months' work. We recognise that for commercial organisations there may be a problem of market size in the United Kingdom alone, but there are examples of successful European firms which produce such biochemical reagents and in practice the whole European market is available. There are clearly both new and missed opportunities, a reflection again, we believe, of the inadequate contact between producers of such products and the British academic community.

3.17 There are also problems associated with culture collections of the living micro-organisms that are essential to biotechnology. There are a large number of such collections in a number of separate centres in the United Kingdom where their maintenance is in the hands of those expert in the particular group of organisms. However, the collections are valuable to many outside the centres and collective outside interest may be greater than that of the host organisation. In these circumstances, the funding of a centre by a single agency may be inappropriate. We conclude that machinery is required to ensure the future of such collections through long-term financial support.

Finance

3.18 Among the main reasons for the slow development of biotechnology by various industries are doubtless:

- poor profitability of existing business
- the prevailing fiscal and regulatory climate, and
- the cost of development.

In biotechnology, no less than in other growth points in technology, small to medium sized companies play a critical part in new developments, and the social and financial climate is still not sufficiently in their favour. In particular, smaller companies need to recover any financial outlay within a few years and are unable to support extended research and development programmes. Industry in the United Kingdom, even where it is aware of the value of biotechnology, is at present unwilling or unable to support projects until evidence of a reasonable chance of success can be provided. Other sources of capital - banks, entrepreneurs, etc - seem equally reluctant. As a result, too little risk capital is available for backing ideas through the prototype and early development stages to the point where industrial/commercial interest is attracted. There is thus a significant "pre-development gap" at the stage of speculative research oriented toward industrial applications, a stage at which so much potential biotechnology now lies.

3.19 Many of the financial constraints to which we have referred apply equally to the development and application by industry of other new technologies. The lack of sufficient venture capital to support innovation in the United Kingdom, compared with the more favourable position in the United States or Japan, was identified as a general problem in the ACARD report 'Industrial Innovation' and we commend to Government the recommendations in that report on financial assistance for small firms. We have been impressed by the way private venture capital has supported the establishment in Europe and the United States of companies such as Genentech, Cetus and Biogen and are disturbed to find that there are no similar intiatives in the United Kingdom. We would like to see the National Enterprise Board regard biotechnology as a "high technology area" within the terms of its remit, and in conjunction with the NRDC to establish in the United Kingdom, and with some public funds, a research oriented company of the kind established with such apparent success elsewhere.

Safety legislation and other regulations

3.20 The application of any new technology and of new products which result must inevitably face hard competition from existing products and be pursued within a legal and fiscal framework developed in response to past manufacturing experience and which includes consumer protection, public health and safe[illegible] matters. We are concerned about three areas of constraint bearing heavily upon biotechnology: safety legislation for work in genetic engineering, the associated cost of putting any new drug or food additive on the market and restrictive trade regulations and tariffs.

Safety legislation

3.21 We have received a substantial number of comments on the effects of existing legislation in the United Kingdom on the practice and application of the technique of genetic manipulation. There is concern about the contrast between current regulations in the United Kingdom and those in the United States where there has been substantial relaxation in the guidelines provided by the National Institutes of Health (NIH). It has been claimed that the requirement of the United Kingdom's Genetic Manipulation Advisory Group (GMAG) to have research proposals disclosed to it jeopardises future patents and thus the competiteve position of commercial organisations, and will render this country unattractive for research investment in this area. Another potential constraint mentioned to us was the limited number of places where research can be carried out because of the expensive physical containment facilities currently considered necessary. This exacerbates the problem of training workers in this field, which we have identified as a major need (para 3.4). Moreover, the containment measures are said to limit the productivity of the few trained workers. The GMAG request to be informed on the scale-up of the use of micro-organisms is claimed to have the same result, and could effectively block practical implementation of many potentially useful processes. All of these measures were accepted and often welcomed by the scientists involved at a time when the degree of hazard was conjectural. There is now, however, impressive evidence that many of these conjectures were unfounded (see annex) and there is an increasing appreciation of the potential benefits. At a scientific conference in April, 1979, organised by the Royal Society and the Committee on Genetic Engineering (COGENE) of the International Council of Scientific Unions, there was no dissent from the view that the initial concerns about the possible biohazards of recombinant DNA research, first publicly stated in the United States in 1973 and 1974, were exaggerated. It is, however, doubtful whether this change has yet been appreciated by the media, or the wider public.

3.22 We consider that the responses in the United Kingdom to the conjectural hazards of recombinant DNA research were logical and acceptable in view of the understanding of the subject at the time each step was taken. These steps were [illegible]e study of the possible benefits and risks by the Ashby Working Party set up by the ABRC, the draft of a Code of Practice by the Williams Working Party, and the establishment by the Department of Education and Science (DES) of the Genetic Manipulation Advisory Group to advise the Health and Safety Executive (HSE), among other bodies. Initially, the procedures drawn up by the GMAG were in danger of becoming too restrictive and a considerable discrepancy was produced in late 1978 in the relative ease with which experiments could be performed in other countries when the NIH advised a general lowering of levels of containment. GMAG was, however, already studying alternative methods for the categorisation of genetic manipulation experiments in the United Kingdom. More recent assessments by GMAG have been of the possible immunological hazards, of bacteriological hazards and of the potential of biological containment, as well as assessing the validity of the claims made for various safe host/vector systems[1] and encouraging their development.

3.23 This flexibility of the GMAG approach is resulting in a relaxing of controls in the United Kingdom, but not yet to an extent commensurate with that in the USA as far as most current research is concerned, although we note that the United Kingdom attitude is less restrictive in certain areas, namely, by not prohibiting experiments using specified dangerous pathogens and by less restriction on large-scale use.

3.24 With this appraisal of the situation -

- We encourage GMAG and the HSE to continue as rapidly as possible to reduce the constraints on genetic manipulation experiments consistent with maintaining an adequate degree of safety.

- We support the special attention that is being given to introducing procedures to encourage industrial application of the technology of recombinant DNA and the use of its products on a large scale, noting that the necessary controls must be practicable, within feasible costs, and must preserve commercial confidentiality.

- We support the continuing study by GMAG of biological containment with the objective of adding to the list of approved disabled or otherwise safe host/vector systems as a means of reducing the requirements for physical containment.

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[1] See annex, paragraphs 1-5, for an explanation of the methods and issues involved.

- We recommend that GMAG considers urgently the possible prejudicial consequences ot British industry if controls on genetic manipulation in the United Kingdom are more sever and restrictive than in other countries. We endorse, however, the GMAG policy of not relaxing or abandoning controls without a thorough assessment of risk and benefit which becomes less conjectural with the continuing growth of knowledge in this area.

3.25 Finally, in this context, we must express considerable concern at the draft European Economic Community Directive on genetic manipulation. If agreed in its present form, it will create a slow and inflexible system of controls of experiments in genetic manipulation based upon premises now no longer held by the majority of countries either within or outside the Community. The Commission and the Member States should undertake a complete reappraisal of the need for the proposed Directive. This is especially urgent with regard to the use of products of genetic manipulation. The draft Directive includes 'use' within the proposed control of the experimental or recombination phase of the technique. We prefer to support the GMAG approach, namely that the safety of large-scale production must be assessed on the characteristics of the biological system, the physical plant, the management competence and the training of the personnel and not on an attempt to assign the process to stereotyped categories of risk.

Testing of pharmaceutical and biological products

3.26 Over the last decade, drug discovery and development have benefited considerably from biotechnology. The speed and sensitivity now possible in the accumulation of scientific and technical data have not, however, shortened the development period for new pharmaceutical products, because of increasingly demanding safety legislation. This legislation has dramatically increased the costs of development, reduced the chance of achieving a commercially successful plant and hence adversely affected the introduction of new products.

3.27 Adequate safety testing is of the greatest importance but there has been relatively little investigation of the funadmental bases of the required toxicity testing, the cost of which is now one of the main reasons why the range of commercially viable therapeutic objectives is steadily narrowing. A new initiative in testing procedures would seem overdue. Concern for certain aspects of public safety during recent years has emphasized conjectural rather than demonstrated risks and failed adequately to reflect a balance between suffering caused by the absence of a new drug and the risks from its introduction. We believe that a study should be made of the constraints imposed by present legislation on the launching of new pharmaceutical and biological products to ascertain if these are justified or whether the current costs and time demanded could be reduced.

Impact of European Economic Community (EEC) Policies

3.28 New technology has contributed greatly to the economic health of the EEC, and is in theory welcomed by all Member States. But in practice, strong lobbies of established industry or agriculture tend to exert a disproportionate weight in resisting the cheaper and better products of new technology, particularly where these threaten to perturb patterns of agriculture. There is substantial potential in Europe for conversion of effluents and cheap feedstocks to useful products but costly development will not be undertaken without a degree of assurance that the process will not invite penal levies or have to compete against subsidies as a consequence of European Economic Community policies. We are concerned that this appears to be the present case.

3.29 As an example, we would cite the development in the United Kingdom of an efficient immobilised enzyme process for converting maize starch into a sweet syrup (isoglucose) that competes effectively with sugar for many food processes. Although this process promises new markets for maize farmers in the European Economic Community, levies on the new product designed to protect sugar beet farmers have resulted in one firm in the United Kingdom going out of this business, and the development and use of an alternative sweetener and preservative being inhibited. The business remains profitable in the United States where the technology will doubtless be further developed.

3.30 If European Economic Community policies continue to obstruct developments such as isoglucose, our ability in Europe to replace petrochemicals by producing basic chemicals from carbohydrates will be hamstrung. We are therefore concerned that all Member States in the European Economic Community, and the Commission, should consider the value of biotechnology in transforming agricultural surpluses, and should seek to amend Common Agricultural Policy legislation that threatens this end.

CONCLUSIONS AND RECOMMENDATIONS

4.1 For the reasons set out in this report, we conclude that biotechnology will become increasingly important to industry both here and overseas in the next few years. It offers the United Kingdom major opportunities for a renewal of existing industries and for the development of new ones at a time when there is a growing concern at the decline of some of our traditional industries and the employment they provide. New technical possibilities such as genetic engineering will have an increasing impact on a wide range of industrial and service activities and we underline the view reflected in the ACARD report on "Technical Change - threats and opportunities for the United Kingdom" that the opportunities afforded by these new advances must be actively embraced by industry and Government.

4.2 Some of our competitors - West Germany, Japan, the United States - are already investing substantially more than this country in the development of biotechnology. By comparison, British industry so far seems unable, unwilling or unaware of the need to take advantage of the potential of biotechnology; investment is low and opportunities to create and supply products and services at home and overseas have been missed. Industry must respond faster to the challenge presented, and must reverse the present situation in which foreign companies seem readier than our own to use the expertise in our universities and research laboratories.

4.3 Our study has identified some reasons for this lack of response and a number of constraints on the growth of biotechnology in the United Kingdom. We propose some remedies, in the firm belief that positive action is needed by industry and Government not only to remove these constraints but also to encourage actively the more rapid development of the subject. The problem is not that any one constraint is insurmountable but that cumulatively, and in the absence of co-ordination, the constraints pose a substantial barrier to growth; problems in one aspect of biotechnology can readily become rate-limiting in another. For example, industrial growth depends on an adequate supply of trained manpower and new ideas; biological process development needs the input of research results from a wide range of disciplines. In addition, the versatility, wide application and sheer range of activities encompassed by biotechnology carry with them the penalties of relatively thinly spread resources and the probability that many individuals and organisations are insufficiently aware of its importance.

4.4 Furthermore, a subject like biotechnology which, at this stage, straddles the divisions of responsibility both among Government Departments and among Research Councils and the arbitrarily defined fields of fundamental and applied research, is handicapped by the present structure of public and private support for research and development (R and D) in the United Kingdom. Strategic applied research is, in general, ill-served by our research funding mechanisms and the way they are being applied, especially in areas where there are neither established university departments to promote it, nor well-developed industries ~~to~~ provide market-pull. The problem lies in identifying a source of funds to carry a project forward from the point where the primary research has been done but the commercial development has not yet begun - the "pre-development gap".

4.5 We are not convinced that in our mixed economy the task posed by these various problems can be met by the private sector alone, bearing in mind such important reasons for the present slow development of biotechnology as the poor profitability of existing business, the prevailing fiscal and regulatory climate and the cost of development. We believe that in the interests of improving industrial competitiveness and paving the way for industrial innovation, a concerted approach is now needed from Government, industry and NEDO to provide the coherent framework and mechanisms necessary for the successful development of biotechnology and of industries based on it. This should involve a commitment, financial and otherwise, at least comparable to that taken or contemplated by our major industrial competitors.

4.6 We believe the Research Councils should substantially increase their support for biotechnology. But biotechnology cuts across the areas of interest and expertise of the SRC, ARC, MRC and the NERC. As a consequence, balanced development of the subject will suffer if responsibility is perceived as resting with any one Council; equally it may suffer if it is seen as a peripheral activity of each or highlights apparent gaps between them. Against this background, our first main recommendation is that the Research Councils should set up a Joint Committee for Biotechnology with senior representation from each Council. The Chief Scientists of appropriate government Departments and industrialists with experience in biotechnology should be members. A Director/Co-ordinator should be appointed by the Research Councils to support the Committee and to stimulate the development of new projects in universities and elsewhere on their behalf. The Research Councils, with the Joint Committee, should consider requiring grant applications from universities to show evidence of industrial interest and should encourage collaboration between experts in different disciplines and in different departments and institutes. At the same time we would like to see some applied biologists currently oriented towards medicine or agriculture encouraged to focus on biotechnology. The Joint Committee should develop and co-ordinate a coherent programme of biotechnology research. Building on their present and forward commitments for the subject, the Research Councils should together reach a spend of at least £3 million annually, the minimum that we believe is now required.

4.7 We welcome the initiative by the SRC for an increase in support for biotechnology. Evidence suggests that even existing university groups could present SRC with worthy applications for an initial capital expenditure of around £1.5 million and recurrent grants of £1 million annually. We recommend that this initiative should be pursued urgently as a component of the programme proposed above, and we hope that in doing so the SRC will assess applications in terms both of scientific excellence and industrial potential.

4.8 In parallel with the proposed Joint Committee we believe that Government action is needed in support of industrial R and D, not least because our major industrial competitors are directly and significantly supporting their industry and thereby creating a commercial advantage against which British industry must compete. We have some sympathy with the view held for example, in West Germany, that R and D support cannot be left to economic forces alone and that government intervention is appropriate for making industrial innovation feasible. Such support is called for because biotechnology is a new and growing technology as yet without the range of industry to pursue fully the potentially commercial ideas. Applications of the technology span a whole range of industries including the manufacturing and service sectors and agriculture. It is a field in which small firms have a key role to play. Our second main recommendation therefore, is that an interdepartmental Steering Group for Biotechnology, complementary to the Joint Committee proposed to co-ordinate Research Council research, should be established to co-ordinate the activities of Government Departments and to develop a programme of industrial research and development.

4.9 The Department of Industry (DOI) might take the lead in establishing the Steering Group with, in particular, the Department of Health and Social Security (DHSS), Ministry of Agriculture, Fisheries and Food (MAFF), Department of Energy (DEn), Department of the Environment (DOE), Department of Trade (DT) and the Department of Education and Science (DES). We envisage the Group's objectives as -

> To review the interaction of policies relating to biotechnology and the conflicts of interest arising, including those caused by EEC policies.
>
> To consider publicly-funded research and development in or relating to biotechnology.
>
> To provide, when necessary, any co-ordination of effort not otherwise being achieved.

The second objective might be met by funding machinery analogous to either a DOI Research Requirements Board or to the present arrangements for energy conservation research. It would be for consideration whether this should have its own funds, or whether the existing research requirements machinery in Departments is adequate to meet the needs. Either way, we believe that, in addition to the support by Research Councils, expenditure of about £2.5 million annually (including existing projects) is required now and that it should be spread widely among industry, universities, Research Associations and government research establishments. In the case of industry, we think that project grants should be provided on a 50:50 basis. As well as eliciting proposals for research or the support of industrial development, the Steering Group should initiate desk studies and build up a list of projects for which grant applications would be sought. The Steering Group should consider setting up a unit comparable to the Energy Technology Support Unit to carry out such studies and to provide the group with technical support, and to assist Departments in their sponsorship of industry through the provision of seminars and other means of disseminating information about biotechnology. Close articulation, and a measure of common membership, between the Steering Group and the Joint Committee will be essential to alleviate problems presented by the "pre-development gap" phenomenon and the administrative distinction drawn between fundamental and applied research work. The Steering Group should also work closely with the National Research Development Corporation. We have commented that biotechnology will change rapidly over the next few years. We recommend, therefore, that the Government should commission a further detailed study to review the position in 4 or 5 years' time.

4.10 Urgent actions for the Steering Group under the third objective should be to review existing culture collections of living micro-organisms, to study the ways in which they can best be maintained and to investigate the merit of national or international collections being established, in particular as a source of micro-organisms able to clear up specific pollution problems.

4.11 Although impressed by the scale and the argument in favour of the GBF in West Germany, we are not convinced that it provides the model for the United Kingdom. Large centres can become very conservative, may not focus adequately on commercial value and, far from encouraging multi-disciplinary work, may become rigid in their internal disciplinary boundaries. We believe that more use should be made of all the existing research establishments, for example the CAMR at Porton Down and AERE Harwell, whose programmes in biotechnology would collectively be reviewed by the Steering Group. But these establishments must ensure strong links with industry by making full use of extra-mural contracts. More particularly, we recommend that the DOI co-sponsors the CAMR. We believe that the expertise and facilities now there, notably in growth techniques and product extraction, should be put to substantial industrial use, for example, by testing new fermenters. CAMR could provide valuable practical training in process development for academic researchers and should co-operate closely with university and other centres of excellence in aspects of development work.

4.12 We have drawn attention to the need, generally, for much improved communication between all who are, or might be, involved in the growth of biotechnology. We recommend that the Confederation of British Industry, the Association of the British Pharmaceutical Industry, the Chemical Industries Association, the Food and Drink Industries Council and other trade associations, including that proposed below (paragraph 4.13), should actively seek to identify opportunities for advances in biotechnology in the fields of potential interest to their members. They should then take effective steps to inform members of neglected opportunities and to inform Government, trades unions and others of any constraints that need to be removed. In addition, the Sector Working Parties of NEDO should, as recommended in the ACARD report "Technological Change - threats and opportunities for the United Kingdom", pay particular attention to the interfaces between industrial sectors and potential or actual industrial concerns in biotechnology.

4.13 More particularly, we believe that there is a need for much closer contact between research scientists and the suppliers of process plant and equipment; we were informed that it is often difficult for those abroad to locate British suppliers of such equipment. We recommend that a trade association of suppliers should be formed. The proposed trade association should give particular attention to the export potential provided by developing countries and the way it is best pursued. In some areas an effective answer to foreign competition may well be consortia. We strongly support the initiative of learned and professional bodies in creating the British Co-ordinating Committee for Biotechnology (BCCB) which provides a general forum for the exchange of information in biotechnology. In consultation with the BCCB, the trade association might also provide a valuable source of information to developing countries on industrial training in biotechnologies. We also hope that through such fora industry will be encouraged to promote improved relations with universities, for example through the loan of equipment or the provision of access to facilities to further relevant university research, as happens in West Germany.

4.14 We have commented on the shortage of venture capital and other sources of financial support for innovation in the United Kingdom compared with some of our export competitors and on the absence of new biotechnology based companies. There seems little prospect of similar companies being set up in the United Kingdom at the present time by wholly private finance. This is an area of high technology in which the National Enterprise Board (NEB), with NRDC, should make a contribution by catalysing a partnership of private and public finance. We therefore recommend that the NEB, in conjunction with NRDC, should investigate the possibility of establishing in the United Kingdom, and with some public funds, a research oriented biotechnology company of the kind established so successfully elsewhere. The sum of £2 million annually for five years should be sufficient to determine its value and establish the scale of further investment, whether from the private or public sector.

4.15 If the United Kingdom is to benefit from biotechnology, we must train a suitable workforce and have adequate research facilities. We believe it is essential that a limited number of centres of excellence in biotechnology should be built up in universities from the best existing in the field. We recommend that the University Grants Committee (UGC), the Research Councils and the universities should consider this as a matter of urgency. Such centres of excellence should be well spread geographically, not least in terms of their relation with local industry; should between them cover the full range of biotechnology; and should carry out research both for industry and on grants from the Research Councils. They would provide a focus for post-graduate studentships, CASE and other industrial academic links (paragraph 3.3). For example, the Teaching Company Scheme of SRC might be applied in the biotechnology field. We believe that a minimum of 20 new posts will need to be established over the next 5 years to provide an adequate level of teaching and research within these centres which need to be of a certain minimum size (say 6 or 7 post-doctoral and higher level workers) and to have a substantial proportion of long term assured funding. The UGC should provide capital of at least £2 million to ensure adequate laboratory facilities. We ask the Department of Education and Science to note the need for additional finance.

4.16 At the same time, universities and polytechnics, with the UGC and the Committee of Vice-Chancellors and Principals (CVCP), should consider how to provide greater integration between chemical engineering and biology departments and between courses at undergraduate level. The teaching of biochemistry, microbiology and molecular biology should include their potential applications to industry. Equally, the importance of biological processes and systems should be stressed in chemical and other engineering courses. The proposed centres of excellence at universities would clearly be involved in some undergraduate teaching of the kind suggested. They should also be a focus for the development and teaching of short courses in biochemistry and biology for practising engineers and the provision of some engineering and design experience for professional biologists and biochemists wishing to move into biotechnology.

4.17 The UGC and CVCP should together consider how best to alleviate the growing shortages of those skilled in genetic manipulation and in process and design engineering. The polytechnics also have an important part to play and we urge Directors of Polytechnics to pursue with local authorities the complementary role that their institutions can play in the provision of trained manpower. Technical Colleges and other institutes of further education have an important role in provision of technicians; there are particular shortages in microbiology and the process plant industry. DES in its forward planning of the provision for higher and further education should take account of the likely manpower demands of biotechnology. The Department of Employment should also take note of these likely demands.

4.18 We have discussed the NRDC in some detail and the reasons why it is not as effective as it might be as a vehicle for exploiting academic inventiveness in biotechnology. We conclude that the NRDC has an important role in the support of innovation in this area and that its role should be strengthened. At the same time, we would like to see the NRDC play a more entrepreneurial role in the support and encouragement of innovation in this area and in the flexible provision of funds for the development of projects beyond the first phase of basic research in a field where inventions are often not readily patentable. <u>We recommend</u>, therefore, that the NRDC should expand its staff resources for biotechnology and be as concerned with the establishment of new businesses as with obtaining and licensing industrial property.

4.19 We have commented on the strength of feeling with which some we questioned reacted to the mention of the NRDC. We recommend the NRDC for its attempts to advertise itself more widely amongst the scientific community and would recommend that a statement be issued by the Government making clear and explicit, on the one hand the obligations of those who receive Government or Research Council support for their activities and on the other, the responsibilities of the NRDC towards those who are so supported. We would also like to see improved awards for academic inventors to stimulate industrial innovation. Possible means of encouragement include assigning individuals or the institutions employing them some rights to industrial property they generate, as in the USA; giving inventors a share of the equity of any company set up to develop their discoveries;

and allocating academic inventors some time to interact with industry. We recommend that the NRDC should lead a study with the UGC, CVCP and the Research Councils to review existing and potential ways of encouraging academic inventors in the United Kingdom and to consider practice overseas.

4.20 We are concerned that controls on recombinant DNA research in the United Kingdom should not be more severe or demanding than in other countries. As new research defines more precisely the nature of the hazards, we recommend that the Government, in consultation with others abroad, should modify the regulatory regime appropriately. We recommend that GMAG and the HSE should continue as rapidly as possible to reduce constraints upon genetic manipulation experiments while maintaining an adequate degree of safety. We support the special attention that is being given to procedures to encourage industrial application of the technology of recombinant DNA and the use of its products on a large scale. We also support the continuing study by GMAG of biological containment with the objective of reducing the requirements for physical containment. We recommend also that GMAG attends even more urgently than hitherto to the possible prejudicial consequences to British industry if constraints in the United Kingdom on genetic manipulation are excessive compared with those in other countries.

4.21 We are concerned that the draft EEC Directive on genetic manipulation, if agreed in its present form, would create, on the basis of premises now known to be mistaken, a slow and inflexible system of controls both for experiments and the use of products of genetic manipulation. We recommend that the Government urge the Commission to reconsider the need for a Directive, in the light of new knowledge of the hazards involved.

4.22 Fundamental work relevant to biotechnology supported by the MRC enjoys a very high international reputation and has led to a number of important inventions. However, despite the fact that the successfully patented discovery of the cephalosporin antibiotics has provided the largest single source of income to NRDC the uptake of discoveries in general by British industry has not been encouraging. We discussed the reasons for this in Chapter 2. Whilst there is now active encouragement of MRC workers to obtain protection on innovative ideas, there remain substantial obstacles.

The most serious is that further development work frequently needs secure patent protection and this may conflict with the natural development of scientific ideas or their rapid introduction into clinical practice. Motivation and means are needed for industrial development to proceed without detriment to the science; this will need the provision of extra facilities at the researcher's own laboratory or it could be achieved by collaboration with a special development unit, perhaps at CAMR. The MRC was not set up with industrial development as an objective and to provide for a development unit would require extra resources. Similar problems apply with varying degrees to the other Councils and we recommend, therefore, that the Research Councils should, through the Joint Committee for Biotechnology, review their roles in relation to industrial development based on biological processes so that their staff are aware of the desirability of creating, wherever possible, a national return for their efforts through industrial development. To this end they should consider ways of increasing contacts between scientists in Research Council institutes and industry.

4.23 There have been a number of recent initiatives in this area in addition to that of the SRC discussed earlier. We fully support the ARC programmes to pursue more vigorously the field of crop bioenergetics, genetic manipulation of crop plants and the biochemistry of animal behaviour. We hope that the ARC will stimulate research on the improvement of veterinary vaccines through DNA recombination. We similarly commend the activities of the Department of Energy and the ETSU in assessing the economic potential of alternative energy sources and, in particular, the production of energy from biomass. The experimental programme will identify problems of both development and fundamental science of the biochemical technologies involved. It should, therefore, be of assistance to others such as the Research Councils in assessing priorities. The biomass feedstock for energy production may come from a variety of sources including agriculture, forestry or domestic wastes and there is a need, therefore, for close co-operation by the Department of Energy with other departmental interests through the Steering Group.

4.24 Agricultural policy already needs to take account of the required scale of food production, pollution, preservation of soils, etc together with the wider social implications of policy changes for the rural community.

But increasingly it should also reflect actual or potential use of new agricultural products, or their by-products, as feedstock for industrial processes and for energy production and, for example, the possible harvesting of non-agricultural plants (eg bracken and gorse), bearing in mind any environmental implications. While biomass production specifically as an energy source may not be economic in the United Kingdom, or in much of Europe, there is scope for greater use of by-products. Moreover, within future farm economic frameworks, it may become economic to produce biomass for chemical feedstock, as with the use of wheat for Gasohol production in the USA. Thus Europe should collectively be looking to develop a pattern of agricultural production that makes sense in terms of food, animal feed and chemical or energy feedstocks. We recommend that the Ministry of Agriculture, Fisheries and Food, with other Departments, should review the pattern of agricultural production in the United Kingdom and in the EEC in the light of the prospects for using agricultural products for industrial feedstocks and for replacing the production of some agricultural commodities by industrial processes.

4.25 Much biotechnology relates to services, such as health care or sewage and waste treatment, rather than to products. Funds for such services come primarily from the public purse, through local or central government, and both, therefore, have a responsibility for the development of cheaper processes and should encourage innovation through their purchasing policies. In this respect we recommend that DHSS should consider whether changes in its purchasing policy for the National Health Service, for example for diagnostic reagents, hormones, vaccines etc, would be justified in order to provide a home market for small firms based on biotechnology. If arrangements were also made centrally for the evaluation of diagnostic tests through, NHS Clinical Laboratories or the Public Health Laboratory Service, such firms might be able to sell on a world market on the basis of a stable United Kingdom market and a critically appraised product. We understand that some 95 per cent of the clinical enzymes used in the United Kingdom are imported; we believe this situation should be changed through revised purchasing policies. On the question of safety testing and legislation we also recommend that DHSS should study alternative testing systems for medicines, food additives, etc with a view to reducing costs and the duration of development.

4.26 In the same context, we recommend that DOE, in conjunction with the DOI and the NERC, as appropriate, should increase support for biotechnology research relating to effluents, waste disposal, materials recovery etc; and should work with local authorities, relevant private industry and research establishments such as WSL, AERE Harwell and the Water Research Centre in studying the potential role of biotechnology in these and other public service fields. DOE should also ensure that the United Kingdom gains the maximum advantage from the EEC research programme in secondary raw materials. We have noted that in its recent report on agricultural production the Royal Commission on Environmental Pollution identified the removal of metals from sewage sludge, the degradation of pesticides and other chemicals, problems of anaerobic digestion and the use of straw as matters deserving more study. Biotechnology is relevant to all these. Of course, as with any other major industrial development, biotechnology itself may create new and different environmental impacts and possibly novel pollutants, and these are issues to which DOE and NERC should give attention.

4.27 The Commission of the European Communities has been preparing a proposal for an indirect action programme of research and development in biomolecular engineering with an estimated total cost of about £31 million over 5 years, of which about £17 million would be the maximum contribution from the Community budget - itself ultimately funded by payments from the Member States. The programme would be directed towards enzyme technology - in particular the development of second generation enzyme converters (bioreactors) for the synthesis of new products important to European industries - and to the improvement, through genetic manipulation, of the productivity of micro-organisms for European industries and of plant varieties. Although presented by the Commission in an applied research context, the programme is one containing substantial elements of fundamental research and we are aware that some member states, including the United Kingdom, have questioned the right of the Commission to sponsor such work. While recognising the principle underlying this view, we trust that discussion of the value of a programme in support of biotechnology in Europe will not become overly confused with theoretical arguments about the distinction between fundamental and applied research which, as we have pointed out, is not always helpful in the context of biotechnology. If a formal proposal were accepted by the Council of Ministers, it would be open to United Kingdom research groups and universities, Research Councils or industry to submit proposals for participation on a shared cost basis. We recommend that the United Kingdom should, in those circumstances, seek the maximum return from the programme. United Kingdom policy in this context will need careful co-ordination with the help of the Steering Group.

4.28 The very substantial support for biotechnology in some other countries, compared with the United Kingdom, leads us to conclude that the United Kingdom stands to gain from increased international collaboration through international organisations and bilaterally between Governments, industry, universities, Research Councils or individuals. Such contacts should be encouraged by, for example, the establishment of travelling fellowships or the greater use of existing schemes such as the Royal Society European Exchange Programme, and by support for the BCCB. We therefore recommend that the proposed Joint Research Council Committee and Steering Group should consider how to encourage international collaboration in biotechnology to the benefit of the United Kingdom.

4.29 We have made a number of recommendations for action by Government and others which we believe are necessary if the United Kingdom is to grasp the opportunities presented by biotechnology. Many of our recommendations are largely a matter of co-ordinating relevant policies on finance, safety regulations, trained manpower etc in order to remove constraints to development. But a clear indication is needed of the Government's conviction of the value of biotechnology and some additional expenditure will be needed. The academic research workers in our universities and Research Councils have played a prominent and distinguished part in establishing the sciences on which biotechnology is based. What is needed now is for industry and Government to seize the opportunity to develop biotechnology in a United Kingdom context and to build on it a set of new and secure industries.

OPPORTUNITIES IN BIOTECHNOLOGY

Recombinant DNA - genetic engineering

1. Recombinant DNA research (popularly called 'genetic engineering') is the item for new biochemical techniques that allow fragments of DNA isolated from cells of a plant, animal or micro-organism (donor) to be inserted into another piece of DNA ("vector"), and then transferred to a "host" micro-organism. The latter thereby acquires novel genetic properties through which there is a product or the use of a substrate not attainable nor utilisable by the conventional means of selective breeding or mutation. Examples are to secure the ability of a micro-organism to synthesise an animal protein such as insulin, or bulk chemicals such as ethanol, or to adapt a micro-organism to utilize a hitherto unsuitable substrate such as methane.

2. Before discussing the opportunities presented by this technique, we think it helpful to outline the reasons for our confidence in recommending modification of the regulatory regime affecting genetic engineering. In the early 1970s, new transfer techniques greatly increased the ease with which DNA molecules of unrelated origins could be recombined. This stimulated much alarm because of the possible hazards to human health. The most serious concern was caused by the use in this research of the bacterium Escherichia coli, strains of which reside in the intestinal tract of man and animals. Thus new DNA combinations inserted into E.coli might become widely disseminated in the bacterial, animal and human populations. This concern was linked to the fact that research would include work with the genetic determinants for antibiotic resistance, tumour formation and disease production quite apart from the insertion of genetic material from higher organisms into bacterial cells, the results of which were unpredictable. Thus it was feared that the special properties of these genes might be expressed in bacterial cells giving rise to strains with the potential to release harmful products or to cause novel diseases. In response to this situation, the Genetic Manipulation Advisory Group (GMAG) was established in 1976 and since then all such experiments, to ensure safety, have been carried out under specified conditions of containment which some scientists contend are unnecessarily rigorous.

3. As a result of work done since 1976, we now know that the assumptions underlying such conjectures were incorrect and the probability of such hazards occurring when DNA molecules from higher organisms (animal, plant or fungi) are inserted into bacterial cells was overestimated. In particular, it has been discovered that the genes of higher organisms are organised in a fundamentally different way from those of bacteria. They appear to be in a different type of control unit, and within the linear DNA sequence of genes themselves there are inserts of non-coding DNA that must be "processed" before the genes can be expressed. Bacteria lack this "processing" mechanism, and so there is little chance that a gene from a higher organism could be accidentally expressed in a "shotgun" type of experiment (in which genes from animals or plants are randomly integrated into the host micro-organism). There are further barriers to accidental expression of genes in transfers between different classes of bacteria, since the expression signals of one species are frequently not recognised by the translation machinery of another. Indeed this species specificity can extend to the level of the genetic code itself, since we now know that there are minor differences between the code used by mitochondria and some viruses and that hitherto supposed to be universal.

4. In addition to these very rapid advances in our understanding of the fundamental differences between higher organisms and bacteria, there have also been a number of other changes which have made scientists less alarmed than they were in the early 1970s by the hazards that might be posed by the use of these techniques. First, we know that laboratory strains of intestinal bacteria that are most frequently used in such experiments fail to establish themselves in animals in competition with the natural flora, and enfeebled ("disabled") strains have been developed that survive only in the closely controlled conditions of the experiment carried out in the research laboratory. Use of such strains, in conjunction with the appropriate physical systems of containment, has meant that the chances of a genetically engineered bacterial cell "escaping" from the laboratory and colonising the environment are very much diminished.

Secondly, procedures have been developed that allow the conjectured risks associated with recombinant DNA research to be estimated and expressed in terms comparable with those associated with other hazards. Such procedures of risk-analysis are the result in part of a growing body of experience and evidence stemming from work on the conjectured risks associated with nuclear power stations and petrochemical plants, and in part to the activities of bodies such as GMAG in the UK and the National Institute of Health in the United States which have stimulated, or deliberately sponsored (NIH), experiments to determine the numerical likelihood of specified risks. Thus as a result of research work carried out in the last four years we can be confident that the degree of hazard believed in the early 1970s to be associated with recombinant DNA research was exaggerated. Further, we are much more confident now of our capacity to estimate such hazards as do exist and the advisory bodies have developed systems for their estimation and control.

5. The benefit of genetic manipulation to industrial biotechnology can be achieved only by the use of the bacterium to which a specific capability has been transferred. The DNA recombination procedure has by then been completed. The "use" of that work is the large-scale growth of the bacterium and the extraction of the specific product for which the DNA recombination was performed. If the organism has been selected rigorously for safety as well as for its new property, the new industrial risk could well be much less than that of an existing process. Such an advantage is one of the attractions of the technique for the production of vaccines against the most virulent viruses (see paragraph 9).

6. Genetic engineering has the potential to extend the scope and power of every branch of biotechnology, no doubt beyond limits currently conceived. The Confederation of British Industry (CBI) said, in a memorandum to the former Parliamentary Select Committee on Science and

Technology [1], "this (genetic manipulation) is likely to give rise to many opportunities for medical, agricultural and industrial developments highly beneficial to mankind", and "The United Kingdom, through the skills and achievements of its academic and industrial biological scientists, enjoys a leading international position in molecular biology which could be exploited to establish a dominant commercial position in many areas of applications of these new techniques". In a similar memorandum, the Association of the British Pharmaceutical Industry (ABPI) said, "Because of the skills of its biological scientists - both pure and applied - the United Kingdom is ideally placed to achieve a dominant and leading role in the industrial application of this new technique which will be important in the food, pharmaceutical and chemical industries, agriculture and livestock farming".

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1. Recombinant DNA Research - Interim Report. Second report from the Select Committee on Science and Technology, Session 1978-79. London H.M.S.O.

[illegible] An early impact of genetic manipulation will be in improving existing microbial processes by increasing yields of a desired fermentation product, eliminating unwanted side-products, increasing temperature stability, allowing growth on cheaper media, etc. However within 5-10 years we envisage new types of industrial micro-organisms constructed by recombinant DNA technology which combine the unusual metabolic properties of one organism - such as the ability to produce a solvent for example - with the favourable characteristics of another, such as resistance to damage by heat, lack of toxicity, high growth rate, etc. Fermentations based on such advances could become competitive with petrochemicals or fine chemical precursors for the production not only of natural products but ultimately of chemical feedstocks as well.

8. At present, recombinant DNA technology is mainly directed towards the transfer of specific genes, often from a higher organism, into a particular bacterium (usually Escherichia coli) whose genetics and metabolism are well known. It is still difficult to persuade this organism to express a foreign gene but solutions to this problem are imminent. It should then become possible, in principle, to obtain by cheap fermentation large quantities of proteins and peptides of diagnostic, therapeutic or prophylactic value in both human and veterinary medicine. Interferon (paragraph 38) is a particularly promising prospect, because of its potential as an antiviral agent and as the prototype of a class of nature growth-regulating substances. Therapeutic tools such as human hormones, specific antibodies, blood factors or scarce enzymes are certain to arrive by this route.

9. An immediate and valuable prospect from recombinant DNA research is the production of new cheap, safe vaccines for viral diseases of Man and animals including some, such as hepatitis, not yet challenged effectively. Even when a vaccine is already in production, the existing methods of antigen[1] preparation are likely to be rapidly superseded because the bacterial process will be much simpler and cheaper and the products will be purer and less hazardous. Already considerable progress has been made by such means in an Edinburgh laboratory towards a vaccine for hepatitis B. Moreover, cheap vaccines of high potency offer the prospect of successful international efforts to eradicate costly viral diseases of animals, such as foot and mouth disease. For some of the diseases for which a satisfactory vaccine has yet to be developed,

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[1] A substance (generally protein or carbohydrate) which is foreign to the tissues of an animal and which, on gaining access to them, stimulates the production of one or more specific antibodies (proteins which combine chemically and make harmless that and no other antigen).

there is so far no complete alternative in research and testing to using appropriate primates. Some of these are endangered species. The work of the few groups in this country which have established breeding colonies with concomitant research on the reproductive physiology of these animals justifies strong support and encouragement.

10. Microbiological processes are already a major feature of the food industry. Nevertheless, changes will soon arise in food processing: improved enzymes for the breakdown of starch by hydrolysis or for the utilization of dairy wastes, for example. Improved bacterial or fungal strains of defined character will have an eventual impact even on such traditional processes as brewing, baking and cheese-making by ensuring greater control and reproducibility of flavour and texture.

11. Similar considerations apply to another major, fermentation industry, antibiotics production. Very efficient processes exist already for a few major antibiotics, but genetic engineering will provide improved processes for others and a new generation of intermediates for chemical or enzymic modification.

Enzymes and enzyme systems

12. We consider that the development and application of new industrial enzymes constitutes a major growth point in biotechnology. Traditionally, their use has predominantly been in the food processing industry (eg dairy products) and these enzymes have been obtained from natural sources (eg rennin from calf stomachs). More recently the capacity of some micro-organisms to secrete large quantities of potentially useful enzymes has led to effective replacement of some of these traditional sources. More recently still, the screening and selection of micro-organisms with novel enzymes has produced new products that compete effectively with major industries. For example, a well proved process for producing sweet syrups from starch utilizes immobilized cells containing a new industrial enzyme - glucose isomerase. (But see paragraph 3.29).

13. Genetic engineering promises to accelerate progress in this already expanding field. Techniques are available to superproduce enzymes in E.coli that are either rare or present only in micro-organisms with exacting growth requirements. Moreover, studies are in progress to achieve similar results with more acceptable industrial mciro-organisms (eg yeasts or Bacillus subtilis),

and to achieve high levels of secretion of such enzymes into the surrounding medium to minimise expensive purification steps. In principle, most microbial enzymes could become available at a cost not far from that of the cheapest current industrial enzyme.

14. The use of immobilised enzymes or immobilised cells in continuous reactors is a field that is already showing great potential, limited often only by present competitive cost and the stability of the catalyst under the conditions of optimum use. The variety of new enzymes that are likely to become cheaply available offers great encouragement for such processes. New uses for enzymes can be envisaged for carrying out specific conversions in the chemical and pharmaceutical industries, eg specific hydrations of double bonds, specific degradative conversions (through Hydrolysis) of esters or amides.

15. Oxidation-reduction reactions are difficult to achieve with isolated enzymes, since the biological processes generally utilize other organic compounds essential to the reactions (the so called coenzymes) that are more expensive than the enzymes themselves. There is, however, great prospect that coupled oxidation/reduction processes could be carried out specifically, by immobilised cells genetically engineered to contain large amounts of the enzymes and coenzymes within their membranes (such as specific reduction utilizing ethanol or lactate as the reductant).

16. Other major opportunities for new, cheaper enzymes lie in clinical diagnostic kits, water analysis, flavour and perfume analysis, continuous monitoring of chemical processes (perhaps, via enzyme electrodes), development of semi-synthetic antibiotics, and in waste treatment. The prospects for microbial enzymes in medicine include their use in: the treatment of chronic/physiological disorders and in-born errors of metabolism; improving therapeutic proteins; oral treatment for detoxification; and the use of immobilised enzymes in the construction of blood-dialysis machines. However, the major opportunity for new enzymes may be the development of biotechnology itself, since processing of sugar cane, grain, cellulosic wastes etc for new fermentation processes will demand improved and expanded enzyme technology.

Monoclonal antibodies and immunoglobulins

17. Antibody immunoglobulins have a very wide range of uses as very precise and sensitive analytical reagents for hormones, peptides, proteins, drugs and many other chemicals. They are also important diagnostic tools for blood grouping, hormone assay (insulin, growth hormone etc), tissue typing (eg in transplantation) and the identification of viruses and bacteria, as well as for therapeutic purposes.

18. Immunoglobulins prepared by conventional methods are usually mixtures and hence of less than optimal specificity; they may be of low potency or very scarce. The discovery by Dr C Milstein of the Laboratory of Molecular Biology of the Medical Research Council of a general method of preparing monospecific antibodies of high potency by a cell fusion technique has potentially revolutionized the field, although the method needs further development work. Very briefly, the technique of producing monoclonal antibodies is as follows: antibody producing cells, e.g. spleen cells, from an immunised donor are fused with appropriately selected malignant myeloma cells to produce a rapidly growing hybrid which makes very large quantities of antibody. By cloning, single hybrid cells can be selected from which populations can be obtained which produce a single, highly specific, completely pure antibody. The technique can also be used to produce antigens. Initially, the interest was in the production of highly specific immunological diagnostic tools but clearly the same techniques can in principle be used to produce vaccines, hormones, and interferon. This will require the development of hybrid human cells, at least for certain applications, and work is going on in various places with this end in view. In addition to greatly improving medical applications, monoclonal antibodies, because of their specificity to particular molecules, are of potential value in monitoring industrial processes and effluents and in quality control.

Waste treatment

19. Biotechnology presents substantial opportunities in the treatment of wastes.

(a) detoxification of toxic chemical wastes

The chemical residues from, for example, herbicides and pesticides present potential hazards both to man and the environment and many chemicals used in industry would also be hazardous if allowed to remain in industrial effluents. Most of these materials (ultimately all, perhaps) can be rendered innocuous by microbial action, and methods of producing new and much more effective strains are being actively studied. British scientists have developed strains that detoxify the herbicide Dalapon and German scientists have produced a strain of micro-organism which will grow on 3, 5-dichlorobenzoic acid. There ought to be potential for such species in clearing up after disasters like Seveso and a likely future need will be for national (or international) collections of organisms for such eventualities.

(b) by-product and waste utilization

The agricultural, forestry and food industries produce annually large quantities of organic waste (e.g. cellulosic) which at present create problems of disposal, but which could be converted by biological methods to a range of useful products such as fertilizers, animal feed, fuels and sugars. For example, the energy content of US municipal, farm and forest waste each year has been calculated as equivalent to about 10 per cent of the total US annual energy consumption. Sophisticated use of cellulose, in particular, needs much further work. In some cases (e.g. sulphite waste liquor from paper making), the wastes are reasonably suitable for use in fermentation but in others (e.g. straw, paper), preliminary chemical treatment is essential to break down the cellulose prior to enzyme treatment. There are already processes for the conversion of waste lactose from cheese manufacture to ethanol or animal feed stuffs. Such processes would help reduce the huge EEC subsidy on dried lactose.

(c) sewage

Evidence received indicates that the UK maintains a leading position of expertise in well-engineered effluent and sewage treatment systems and in the biological treatment of waste water; and that the development of new processes and new equipment (for example to deal with difficult effluents) could yield further benefits.

Plant cell culture - single cell protein

20. Techniques for the culture of plant and animal cells, on a relatively small scale, have been developed over the last twenty years, but only more recently has significant potential been identified in their large-scale culture. Materials of interest to the food and pharmaceutical industries such as the mass culture of cell suspension of Dioscorea for steroid[1] precursors will be produced in this way. The Japanese and West Germans have been particularly active in this field, and recently workers in the USA have become interested, and a number of patents have been granted. In the United Kingdom, however, research activity has been limited. Further work is needed before the commercial viability of systems can be demonstrated.

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[1] Steroids are a group of chemically similar, but biologically diverse hydrocarbons, including many important hormones and drugs.

21. Claims have also been made for the production of biomass (as an energy source, or for chemical feedstock) from the culture of photosynthetic green algae selected or genetically engineered for high photosynthetic efficiency. However, the feasibility of the process on a commercially large scale has yet to be demonstrated.

22. The potential for production of cheap protein from microbial (single cell protein) or fungal culture has been recognised for some time, and various major companies have become involved - not all successfully. BP have not pursued their earlier developments although ICI's major new plant for the production of protein (trade name Pruteen) from bacteria using methanol as feedstock is going on-stream. Hoechst (West Germany) and Mitsubishi (Japan) are working on similar processes. Others involved are Rank Hovis MacDougall (using fungi for protein production) and Tate and Lyle. There must be eventual potential in this field although the technical and financial problems are probably greater than was first thought.

23. Development of these microbial processes has itself generated many priority problems for chemical engineering research: the study of bubble columns, fluid mechanics of liquid circulation, gas-liquid mass transfer, behaviour of froths and foams, development of centrifuges, mechanisms of flocculation and sterile engineering. The results of this work will be relevant to a wide range of other fields of chemical and process engineering.

Production of (cheap) liquid and gaseous fuels

24. Some opinion holds that this may be the most important area for biotechnology in the next 10-15 years, and that biotechnology itself will move most rapidly from its existing uses through developments related to the production of fuels. Certainly a wide range of methods for producing liquid (ethanol) or gaseous (methane) fuel already exist and there is a huge market for the products given the right price.

25. Early assessments by the Department of Energy suggest that United Kingdom wastes and crops might, with full exploitation, provide raw materials of energy equivalent to 60 million tons of coal per annum. However, considerable amounts of energy would be used in growth, collection and conversion and the net gain could be much less. The assessments also suggest that some of the technologies could be advanced towards commercial viability. The Advisory Council on Research and Development for Fuel and Power (ACORD) has approved a Department of Energy programme costing £1.5 million to the end of 1980-81. Combustion of solid fuels

from biological material is likely to be the technology of most immediate practical importance, but some emphasis will be given to breakdown by heat (pyrolysis) and biochemical processes, with their potential to produce secondary, more refined, fuels. Much of this work will be carried out through jointly funded contracts with industry. Assessments suggest that digestion to biogas (methane and carbon dioxide) is closer to cost-effectiveness than is fermentation to ethanol.

26. As mentioned under waste treatment (paragraph 19), a range of organic waste materials are potential biological substrates for cheap fuel production. These include milk solids (of which 1 per cent are now lost as effluent), surplus starches, sugars and cellulose from food processing, agriculture etc. Genetic manipulation allows organisms to be developed specifically for use on particular substrates or which are capable of generating different, and perhaps more advanced, chemical fuels. Thus organisms generating propane might be valuable to the dairy industry by disposing of waste and by generating a valuable chemical feedstock. Hydrogen, as a fuel or feedstock, might also be produced through the use of hydrogenase enzyme which could be super-produced through recombinant DNA technology. Another, perhaps more remote, possibility is <u>in situ</u> microbial conversion of coal. Yet another possibility is the replacement of oil or coal as a basic chemical feedstock by polysaccharides[1] or by photosynthetic ethanol.

27. Finally, although in the United Kingdom the main focus is the utilisation of waste for energy in other parts of the world cultivation of crops specifically for energy production is already a reality. Sugar cane is the fastest growing traditional crop, and Brazil has a huge investment programme for fuel ethanol from cane juice and cassava. Although the programme is not immediately economic there are forceful arguments in favour of it. First, it promotes agriculture in an underdeveloped area. Second, the rate of increase in oil prices and the problems of a secure supply of oil from overseas are likely to increase, although sugar prices are themselves unstable and this has made strict economic evaluation difficult. Third, new technology promises greater efficiency of conversion and new profitable uses for side products such as bagasse and hemicelluloses are appearing. In fact, Brazil promises to be the first country in which a major fuel industry based on biotechnology emerges.

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[1] Carbohydrates, such as starch or cellulose, produced by combination of many molecules of sugars.

28. We have already pointed out that process engineers and biotechnologists from other countries are treating the Brazilian experiment very seriously. Other tropical and sub-tropical countries (India, Guatemala) may start similar developments. The USA has launched similar programmes based on grain and forestry. There are great opportunities for United Kingdom process engineers and contractors in developing the plants that will undoubtedly be built in the Third World and elsewhere.

Chemicals and solvents

29. Throughout the petrochemical era, some traditional fermentation processes have remained viable despite the relatively high cost of the starting material. In some cases, eg beers, wines, vinegar, considerations of flavour or food safety have protected processes from cheaper petrochemical alternatives. In others, however, the biological process remains the best. There is a considerable market for citric acid from grain or molasses. Industrial ethanol, acetic acid, acetone and butanol are still produced profitably in some countries, particularly those short of oil. The increasing cost of oil relative to fermentation substrates, and the prospect of yet cheaper fermentations based on industrial wastes, augur well for these industries.

30. Moreover, new fermentation processes have grown up. Japan has pioneered a large industry for production of amino acids and nucleotides by fermentation and holds a virtual but challengeable world monopoly in this profitable and expanding market. Microbial polysaccharides have proved to be another flourishing product with a variety of unexpected uses.

31. Furthermore, traditional processes must benefit from much improved micro-organisms and by application of continuous culture, new enzyme techniques and new techniques of product extraction. New products such as organic acids, animo acids and polysaccharides are also open to competition from new processes. For example, fermentations based on methane or methanol

have particular attractions for production of extracellular chemicals since purification of the desired product from the detritus of the fermentation medium is often a major process cost; clean media like methane or methanol could cut this dramatically. Conversely, cheap but dirty media, such as industrial wastes, could cut costs of products such as ethanol, acetone or butanol that are readily extracted.

32. A vast range of potential new products can be envisaged as microbial genetic engineering develops. Specific mutations allow the steering of microbial metabolism to overproduce a great variety of intermediary products, and recombinant DNA techniques allow introduction of foreign enzymes that could further modify these. Hence the prospects are limited less by the available technology than by the ingenuity of the chemical industry in establishing cheap processes and finding new uses for a new generation of bulk chemicals.

33. In this context, there are substantial opportunities for enzyme technology. Specific modifications to either fermentation chemicals or petrochemicals can be carried out before or after extraction - indeed such modification may greatly assist purification processes. New polymers could be created of precise but complex composition by deployment of a battery of modifying and polymerising enzymes. Novel synthetic routes for fine chemicals, such as drugs and antibiotics can be envisaged.

34. The ACARD report 'Joining and Assembly' drew our attention to the potential of biological adhesive materials. Work is underway in universities in the United Kingdom on the mechanism and strength of adhesive bonds between organisms such as barnacles and their substrates. But this is at present mainly directed towards finding means of reducing fouling of ships and marine structures. Bioadhesives may often not be particularly strong - that of the barnacle is more of a sealant than an adhesive - but they have properties such as resistance to biodegradation which may be of interest. Opportunities for the development of new adhesives may arise through such research, but this seems unlikely to be in the short term.

Pharmaceuticals, pesticides and agrochemicals

35. Antibiotic production is currently the most profitable process of the pharmaceutical industry, and improvements over several decades have yielded very efficient processes. To achieve this efficiency it has not proved

necessary to know much about the genetics of the producing micro-organisms, but genetic manipulation could cut considerably the cost and time to develop new strains, and could in future be essential to commercial success. Moreover, genetic blocks in biosynthetic pathways could yield valuable antibiotic intermediates for further chemical or enzymic modification. Hence prospects for new biotechnology in this already major industry look promising.

36. Biotechnology has not historically made a major contribution to the development of new synthetic drugs. The growing interest in the biological activity of peptides and proteins may change this. There is little chance of such materials being synthesised economically by standard chemistry and it is logical to expect that they will be derived, wholly or through the provision of major synthetic fragments, by genetic engineering techniques.

37. Plants have natural mechanisms for protecting themselves against insect pests and viral diseases. Much fundamental work is still needed here, but the ability to grow plant cells in large-scale tissue culture, combined with new techniques to manipulate their genes and induce differentiation, must offer encouragement to biotechnologists seeking new pesticides, plant hormones, antiviral agents, plant pigments, flavouring agents and perfumes.

Interferons

38. Interferons are naturally occurring antiviral glycoproteins produced by animal cells in response to virus infection. Clinical trials have shown human interferon to be effective as an antiviral agent and interferons also affect the growth of many cell lines. The effectiveness of human interferons in the treatment of cancer remains to be established, but the preliminary results obtained, particularly in the treatment of osteogenic sarcoma, are sufficiently promising to demand further investigation. Interferon therapy requires only a few days of initial hospital treatment. Thereafter, it can be administered by the patient in his home environment. Continuous treatment for over two years seems to have been safe. The major difficulty in carrying out further trials and subsequent widespread use is the limited supply and cost of production of human interferon. All current sources involve large scale cell culture and are very expensive.

Nitrogen-fixation

39. The importance of nitrogen as a rate-limiting factor in agriculture and the cost of fertilizer production from petrochemical resources make the conversion of atmospheric nitrogen into inorganic or organic nitrogen compounds (nitrogen-fixation) by biological means an attractive possibility even though the inescapable energy demand tends to reduce conventional crop yield expressed in calories. Several possibilities are open and being actively explored: the greater use of unfamiliar nitrogen-fixing plants; the use of less well known, natural nitrogen-fixing systems by breeding them into present crops; the genetic manipulation of existing systems greatly to increase their efficiency; and methods of introducing the gene complex that controls the formation of the enzymes for nitrogen-fixation into other species in such a way that it is expressed.

Process engineering

40. Clearly, the novel processes envisaged above will create new problems for engineers. High-volume, low added value fermentations for bulk chemicals, biomass or energy production will demand the ultimate in engineering expertise if they are to compete with alternative processes. Not only will entirely new types of fermenter be required, but essential components in the profitability will be the capital costs and energy efficiency of harvesting, crushing, pre-treatment and filtration; the distillation of a volatile product such as ethanol; the recovery and possible recycling of the micro-organism; the recycling of water and the problems of efficient disposal. Moreover, conversion of side products such as cane fibre (bagasse) and cane pith will be important economic factors. All of these problems must be solved not only in industrial centres but in underdeveloped, non-industrialised countries. A consortium of process, contracting and control engineers is clearly desirable; fortunately the United Kingdom engineering industry has resources that could rise to this.

41. However, it is essential that the process engineers collaborate with the microbiologists and the enzyme technologists at the earliest possible stage. The micro-organism can be adapted to grow under conditions favoured by the process engineer, but conversely the process engineer can solve problems that are intractable for the microbiologist. Hence our emphasis that biotechnology is multidisciplinary *ab initio*.

ABBREVIATIONS

ABPI - Association of the British Pharmaceutical Industry
ACARD - Advisory Council for Applied Research and Development
ACORD - Advisory Council on Research and Development for Fuel and Power
ABRC - Advisory Board for the Research Councils
AERE - Atomic Energy Research Establishment
ARC - Agricultural Research Council

BCCB - British Coordinating Committee for Biotechnology
BMFT - Federal Ministry of Research and Technology (West Germany)
CAMR - Centre for Applied Microbiology and Research
CASE - Cooperative Awards in Science and Engineering
CBI - Confederation of British Industry
COGENE - Committee on Genetic Engineering of the International Council of Scientific Unions
CVCP - Committee of Vice-Chancellors and Principals
DECHEMA German Chemical Apparatus Association
DEn - Department of Energy
DES - Department of Education and Science
DFG - Deutsche Forchungsgemeinschaft (German Research Society)
DHSS - Department of Health and Social Security
DNA - Desoxyribose nucleic acid
DOE - Department of the Environment
DOI - Department of Industry
DT - Department of Trade
EEC - European Economic Community
ETSU - Energy Technology Support Unit
GBF - Gesellschaft fur Biotechnolische Forschung mbH (West German Biotechnology Research Centre)

GMAG - Genetic Manipulation Advisory Group
HSE - Health and Safety Executive
MAFF - Ministry of Agriculture, Fisheries and Food
MRC - Medical Research Council

NEB - National Enterprise Board

NEDO - National Economic Development Office

NERC - Natural Environment Research Council

NHS - National Health Service

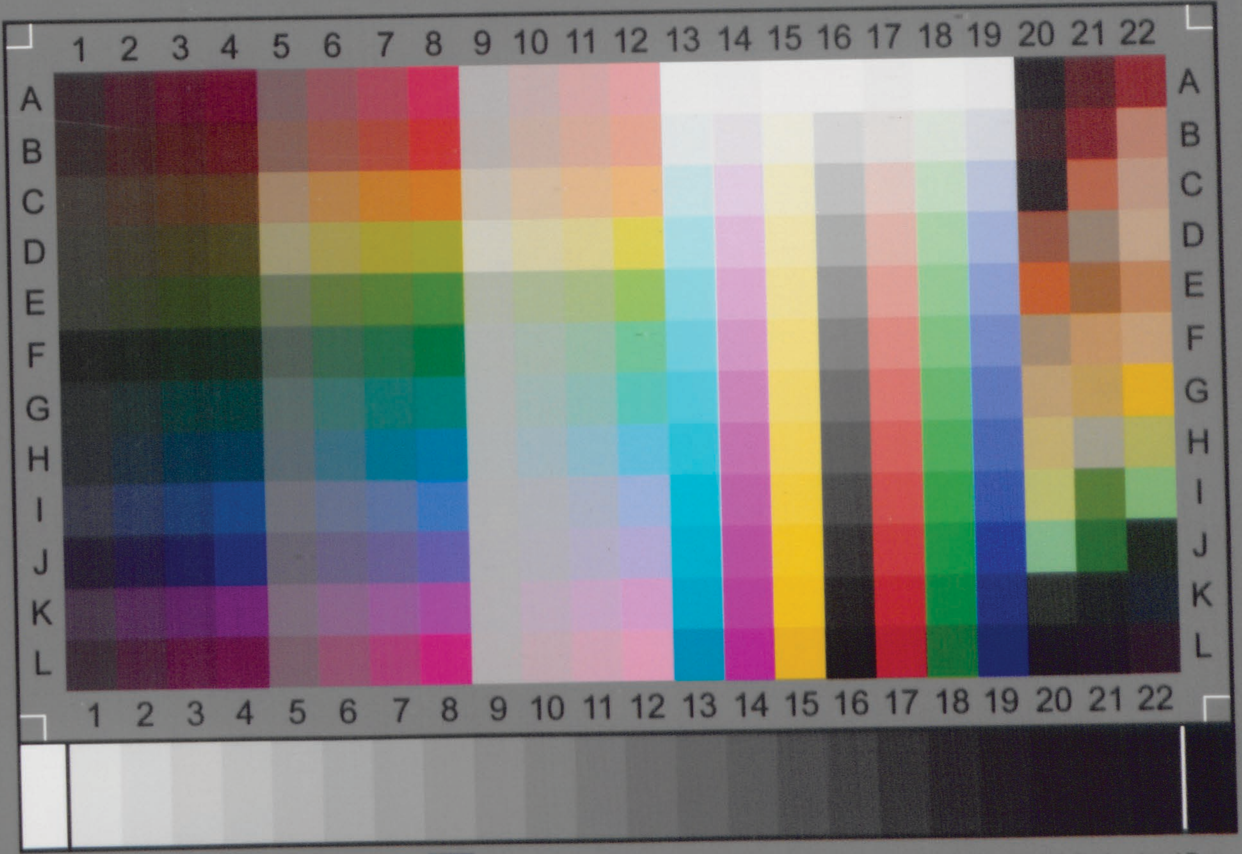
NIH - National Institutes of Health (United States)

NRDC - National Research Development Corporation

SRC - Science Research Council

UGC - University Grants Committee

WSL - Warren Spring Laboratory (of DOI)



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