Report of the ABRC biotechnology sub-committee: a report to the Chancellor of the Duchy of Lancaster / from the Advisory Board for the Research Councils.

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Report of the ABRC Biotechnology Sub-Committee

A Report to the Chancellor of the Duchy of Lancaster from the Advisory Board for the Research Councils

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The Rt Hon William Waldegrave MP Chancellor of the Duchy of Lancaster Cabinet Office 70 Whitehall LONDON SW1A 2AS

26 June 1992

REFERENCE COPY 1475/
Wellcome Centre for Medical Science

Dear chancellor,

ABRC BIOTECHNOLOGY REPORT

I am pleased to be able to send you the final report of the ABRC's Biotechnology Sub-committee. The Board hopes you will find the report of interest and that you will agree to its publication.

Biotechnology is an important and pervasive tool, widely employed in modern biology and with increasing application in other disciplines. It is likely also to be of great significance to the UK's future industrial competitiveness so that scientific management in this area is a matter of widespread interest. For these reasons the ABRC established a Biotechnology Sub-committee as part of its work "to promote effective collaboration between the Research Councils" and "between Government Departments and Research Councils". The Committee was chaired by Professor Richard Gardner FRS, an independent (non-executive) member of the Board and Director of the ICRF Developmental Biology Unit at the University of Oxford, and it included the DTI's Chief Engineer and Scientist as a link to other Government Departments.

The Committee carried out a full review of current research in biotechnology, summarised in the Annexes to the Report, and considered the coordinating mechanisms that are now in place. The Committee concluded that no research coordination problems presently arise. The Biotechnology Joint Advisory Board, established in 1990 by SERC and DTI, provides a broad forum in which industrial membership affords an informed overview of wider requirements. The Report's Annexes provide the ABRC with a benchmark against which biotechnology can be kept under review. BJAB's report to ABRC later this year on progress in developing its action plan will provide the first of what we expect to be an annual scrutiny of research coordination across the Councils.

I also draw your attention to recommendation C in the report, that "cross-Council funding and Research Council funding of Government and other laboratories should take place wherever this is appropriate in achieving the best scientific objectives". In considering the Committee's Report, the ABRC was confident in its

support of this recommendation which will help to clarify the position of the Research Councils in relation to the internal market for Government funded R&D and will also be a signal to the wider academic and research community. We expect that the greater part of research activity supported by the Science Budget will continue to be in Higher Education Institutions and in Research Council Institutes; but the scientific criteria of excellence, timeliness and pervasiveness are more important in judging which proposals should be funded than the particular location of the research.

your in uns,

lavid

DAVID PHILLIPS



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Chancellor of the Duchy of Lancaster Minister of Public Service and Science

Sir David Phillips KBE FRS
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ABRC BIOTECHNOLOGY REPORT

Thank you for sending me this Report, which I have read with interest.

I am grateful to Professor Gardner and his colleagues for preparing this useful survey of activity in what has been a rather complex area. I note the Sub-Committee's conclusion that there are no continuing problems of co-ordination in this field which require new mechanisms. I hope that the Biotechnology Joint Advisory Board, now with all five Research Councils in membership, will continue to monitor the situation, make any necessary recommendations in good time, and liaise closely with your own Board.

I have noted the Sub-Committee's other recommendations, in particular recommendation C to which you drew my attention. I strongly support the Board's conclusion. It is entirely consistent with our policy on opening up an internal market for Government funded research and development. I trust that, in the light of this conclusion, the Research Councils will now develop policies to ensure that the laboratories of other Councils and of other Government agencies are eligible to compete for Research Council funds wherever, in the words of the report, this is appropriate in achieving the best scientific objectives.

I believe that the Sub-Committee's report would be of interest and use to the wider scientific community too, so I am happy to agree to your request that it should be published.

WILLIAM WALDEGRAVE

Advisory Board for the Research Councils

Sanctuary Buildings, Great Smith Street, LONDON SW1P 3BT

Report of the ABRC Biotechnology Sub-Committee

Executive Summary

The ABRC's Biotechnology Sub-committee was established in accordance with the Board's prime responsibilities to:

"promote effective collaboration between the Research Councils and the harmonisation of their activities."

Biotechnology is not a scientific discipline, but rather an expanding collection of technologies based on scientific advances which are useful for many of the current and future programmes of the Research Councils. Furthermore, opportunities for collaboration through technology transfer to industry often arise.

The Sub-committee has assessed the scope of biotechnology, it has reviewed the need for coordination of research within the science base, and it makes a series of recommendations to this end. It also recognises that current research provides a flavour of excitement about the scientific and industrial opportunities which biotechnologies now present.

The Sub-committee has not identified any areas where coordination is a problem at present, nor has it received any evidence from Government Departments or other bodies that coordination problems exist between them and the Research Councils. Opportunities for parallel development arising from the overlapping interests of the Research Councils are considered to be valuable and should be encouraged, provided that the overall support for biotechnology is subject to continuing review.

INTRODUCTION

- 1. This is the first report of the Advisory Board for the Research Councils' Subcommittee on Biotechnology, the terms of reference and membership of which were agreed by the Board at its meeting on 30 January 1991 (ANNEX A).
- 2. The committee met three times:
 - a. on 10 July 1991, in London, when the coordination of biotechnology among the Research Councils was discussed;
 - on 17 September, in Oxford, when coordination between the Councils and other bodies was discussed;
 - c. on 17 October, in London, when the content of this report was agreed.

A list of papers considered by the committee is attached (ANNEX B).

BACKGROUND

 The principal motive for the establishment of the Biotechnology Sub-committee was the ABRC's responsibility:

to promote effective collaboration between the Research Councils and the harmonisation of their activities.

4. Concern that close attention should be paid to the coordination of biotechnology research has been expressed frequently during the last two decades. This has been partly because biotechnology is perceived to have great potential for attacking health and environmental problems, and partly because it promises significant economic benefits. Past attempts at coordination have not been consistently successful and, as a consequence, there has been widespread concern that coordination has yet to be tackled effectively. The Sub-committee briefly reviewed previous coordination issues affecting the Research Councils (ANNEX C).

- 5. The Science and Engineering Research Council established a dedicated Biotechnology Directorate (BTD) in 1981. In response to the 1988 Blundell Review of BTD, SERC established the Biotechnology Joint Advisory Board (BJAB) jointly with DTI. Subsequently, AFRC and NERC became members of BJAB, and MRC later accepted observer status and nominated an additional member of the Board. During the following eighteen months, BJAB developed a strategy for biotechnology, reified in a document launched by Peter Lilley MP (the then Secretary of State for Trade and Industry) on 18 September 1991. ESRC and MRC subsequently joined BJAB as members in 1992.
- 6. Because BJAB was originally established without the full membership of all Councils, some observers suggested that it might not be a satisfactory mechanism to enable biotechnology coordination across the science base. It was also felt that there might be a risk that past coordination problems were still present. Because of this perception, the Chairman of the ABRC met with the Research Councils, and with the Chief Engineer and Scientist of the DTI, in July 1990. A paper describing the position at that time, brought to the ABRC on 24 July (ABRC(90)36), led to the proposal to establish the present committee.

THE SCOPE AND BOUNDARY OF BIOTECHNOLOGY

7. The 1979 Spinks Committee, set up by the Advisory Council for Applied Research and Development (ACARD), the ABRC, and the Royal Society, defined biotechnology as:

"the application of biological organisms, systems or processes to manufacturing and service industries."

The committee felt that while such a definition had a useful role the interests of the Research Councils were rather wider, embracing the science underpinning the applied view of biotechnology.

- 8. Members therefore agreed that it is neither possible nor useful to try to define the scope of biotechnology within the science base. It is not a scientific discipline. Rather, it is a set of generic tools: enabling methodologies and technologies with wide actual or potential employment, defined by their operational objectives and their application to an aspect of biology. This may be with an economic purpose, in industry, or for the public good, in health and environmental care. It serves no purpose to set disciplinary boundaries to biotechnology since it cannot be defined in such terms.
- 9. If several Research Councils are involved in the development of novel and basic methodology it is not surprising that their programmes appear to overlap. The different motives for which the programmes were established will be masked by superficial similarities but the distinctions between such programmes are usually more clear if one looks at the projects covered by the programme. These distinctions also become apparent where the final customers of the technology can be anticipated, or as the evolving biotechnology is applied to particular problems. The committee believes that it is the "parallel development" of Council programmes which leads some observers to perceive problems of coordination where none exist. In fact there is value in this development: the techniques are likely to be proven and refined by common application to different problems.

PRESENT AND PROSPECTIVE ACTIVITY SUPPORTED BY RESEARCH COUNCILS

- 10. The principal biotechnological approaches presently used by the Research Councils and by industry, and the range of applications to which they have been addressed, are summarised in Table 1 in Annex D. The set of applications used here deliberately follows the analysis of the BJAB strategy document (on which, see below) with the addition of human health care, which was not addressed by BJAB but for which support falls primarily to MRC and DH.
- 11. The Councils have each provided a report of their current activities to the committee. These reports can only hint at what the committee recognises is a clear flavour of excitement about the scientific and industrial opportunities which biotechnology currently presents. A common framework, addressing the disaggregation in Table 1, has been used in drafting these reports which are attached at ANNEX D(1-4).

<u>The committee recommends</u> that the activity matrix and the associated summaries contained in this Report should continue to be used by the ABRC, updated on a rolling basis by the Research Councils, to inform its consideration of biotechnology support.

- 12. The committee does not consider it either practical or useful to assign lead responsibilities for different areas of biotechnology research. The balance of interest is such that, in most areas, there is no obvious lead Council to whom such responsibility might be assigned. The Research Councils use those technologies which are most appropriate to address the existing and emerging scientific problems which are already defined as part of their responsibilities. Many of the technologies will be appropriate to several Councils.
- 13. There are a number of areas in which biotechnology is likely to enable significant scientific developments, or within which increasing applications are likely to be found. Examples which were discussed included: bioelectronics; biosensors; neurobiology; and process engineering. The committee was also of the view that biotechnology will have growing significance in the environmental sciences. In this area, NERC should make use of the expertise of other Councils in rapidly establishing a proper niche.
- 14. The committee considers, however, that the development of biotechnology is currently so swift that any catalogue of forward opportunities would be patchy, and rapidly become outdated. Furthermore, the potential scope of such a list is unclear. An understanding of biology can underpin other technologies, an example being the way neurosciences have informed the development of fibre optic control networks.
- 15. The committee has reviewed reports from: the National Economic Development Office; and the US National Science Foundation. It also discussed at length the BJAB strategy document, which contained a wealth of useful advice. It noted that there were further recent reports on biotechnology from the EC and the OECD. It concludes that these collectively provide adequate source material for those wishing to identify prospective activity.

COORDINATING MECHANISMS BETWEEN RESEARCH COUNCILS

16. From the evidence which it received, the committee was unable to identify any areas of biotechnology within the Science Base where a problem of coordination appeared to exist at present. Nor was evidence presented by Government Departments or by other bodies that coordination problems existed between them and the Research Councils. Nevertheless, Members recognised that coordination of biotechnology, especially between the Research Councils, has presented problems in the past. The committee therefore reviewed those coordinating mechanisms which are currently in place, and considered the extent to which these might continue to meet future requirements.

17. There is an apparent overlap of activity in many cells in the summary matrix in Table 1. The Research Councils describe (in ANNEX D) those coordinating mechanisms which are currently in place in these areas. In many areas the apparent overlap, as noted above, is not realised because there are differences in focus. In other areas the overlap is real, but bench-level coordination among practitioners ensures that unnecessary duplication of effort is avoided. The committee is persuaded that existing mechanisms work well because they serve the common interests of all parties.

<u>The committee recommends</u> that the Research Councils continue to keep an overview of all coordination at these levels, but that they should not be required to impose formal reporting arrangements simply as a matter of course.

18. There are advantages in a plurality of funding agencies, each with its different angle of approach, and some research is inevitably of interest to more than one agency. The committee has considered whether members of one Council's Institutes should be eligible to compete for funds assigned to another Council's initiatives. It appears to be a widely held belief that SERC cannot fund work at the institutes of other Councils. The SERC charter makes no such prohibition, but that Council cites a Treasury ruling - which it believes to be germane - that Government Departments shall not fund work which is the responsibility of another. Support given by SERC to other Councils could be seen as an inappropriate subsidy and this issue raises the question of boundaries of responsibilities.

19. While there are difficulties in making funds assigned to one Council open to others, the committee agreed that there was merit in a general movement in the direction of the widest possible competition for funds, and noted the successful example of MRC's funding of research at the AFRC Institute of Animal of Physiology and Genetics Research at Babraham. The Councils are increasingly developing joint programmes in areas of common interest. For example, AFRC and NERC work jointly on pollutants and their transport. In these cases it has been possible to agree cross-funding of institutes. Such cooperation has included SERC in supporting work in AFRC Institutes as part of the joint programmes on Plant Biochemistry and Transition Metals in Biology. The committee welcomes such developments, and hopes they will go further.

The committee recommends that, providing that Councils' scientific programmes are clearly focused and that overlaps occur in methodology rather than purpose, cross-Council funding and Research Council funding of Government and other laboratories should take place wherever this is appropriate in achieving the best scientific objectives.

20. Opportunities for coordination at a strategic level within the Research Council system, and the workings of BJAB, are considered below.

THE BIOTECHNOLOGY JOINT ADVISORY BOARD

21. The committee is agreed that BJAB has proved to be a most important and useful forum between the Research Councils, the DTI and industries using biotechnology. BJAB provides a broad forum for the evaluation of scientific developments, placed within an informed overview of the wider requirements for innovation in industry. One of the successful aspects of this forum, from the Research Councils' perspective, is that it has tried neither to set an agenda for future research nor to identify failure to deliver or to exploit research. BJAB does not seek to second-guess priorities for either the Research Councils or industry.

22. The committee recognises the merit in separating the original advisory and executive functions which BJAB had held for SERC and DTI. This separation will strengthen its advisory role, provided that the membership of BJAB changes to reflect the current science, thus ensuring that the people involved are close to emerging ideas and technologies. BJAB can have an important role as a watchdog, delivering advice to the Research Councils, or to the ABRC, to which the Councils' policy making bodies can respond. The future membership of the Board will be an important factor in its success in that role.

The committee recommends that BJAB should report not only to Councils but also directly to the ABRC to inform its discussions of, and advice to Ministers on, coordination and biotechnology issues.

- 23. While BJAB's advice will facilitate coordination and influence attitudes, there will be some issues of harmonisation between Research Councils which will need to be dealt with by meetings of Heads of Research Councils (HORCs) or the ABRC.
- 24. The committee noted that BJAB's overall consideration of biotechnology had been orientated to industrial applications, and certain areas therefore fell outside that remit. It addressed neither environmental issues nor medical research related to health care. This is partly due to its origins in the SERC/DTI link. Additional formal and informal links may be needed: to address MRC's wider concerns; and for DoE, AFRC, NERC and SERC (and perhaps MAFF) to develop a coordinated biotechnology strategy for the environment. These mechanisms need not be as formal as BJAB if that is not seen by the relevant parties to be appropriate. We refer to this issue below.
- 25. The committee recognised that biotechnological research raises significant and growing issues of wider public concern, which extend beyond the boundaries of existing scientific programmes. These issues, and the potential for a pervasive contribution to discussion on broad issues of economic and social concern, made it desirable that ESRC should consider joining BJAB at an early date. To this end, the committee asked its Chairman to convey its views to the Chairman of ESRC and commend membership of BJAB to that Council (ESRC became a member of BJAB early in 1992).

THE BJAB STRATEGY DOCUMENT

- 26. It is too early for the Councils to be able to report in detail on the extent to which the advice contained in the BJAB document will influence their own strategies. But it is agreed that participation in the exercise leading to its production has been of significant value. Research Councils have the opportunity to position their Corporate Plans and activity within the perspective of BJAB's advice and, where appropriate, to develop coordinated programmes.
- 27. The recommendations on priorities which BJAB has gathered are the product of advice collected from a very wide range of industrial and academic experts, as the annex to the report demonstrates. It is an interesting and important document because of that, and the advice will consequently be given great weight. But, as an industrial liaison mechanism, BJAB's success will also depend on continued industrial involvement, as we note below. Industrial responses to the document would enable the Councils to see the priorities of industry and, having identified matching priorities within their own programmes, would allow industry and the science base to tackle common objectives and form a common development strategy. The document's success will depend upon how successful it is seen to be in providing a framework for identifying those common areas.

<u>The committee recommends</u>: that the outcome of discussions within the Councils should be brought back to BJAB; and <u>endorses</u> BJAB's commitment to produce an action plan for future work, which will be informed by these responses and by industrial feedback.

OTHER AREAS FOR COORDINATION

28. The Inter-Departmental Committee for Biotechnology (ICBT) includes Research Council representation. It is chaired by DTI, which has lead responsibility for biotechnology among Government Departments. The Research Councils' experience is that ICBT has not proved to be an important forum for the discussion of biotechnology research priorities, nor for the coordination of programmes. This has, in part, been because the level of Departmental representation has been at too junior a level with insufficient scientific input.

- 29. The committee concluded that the ICBT was unlikely to become an important forum for the Research Councils in the future. Cooperation with DTI, which provides a central link to other Departments, has made excellent progress through BJAB and the committee felt that an additional mechanism would serve no useful purpose. However, it will be for the Departments themselves to determine the future of ICBT.
- 30. Health care and DH. The area of health care falls primarily to MRC and DH. During the committee's review, MRC only had observer status on BJAB, and DH is not represented on BJAB. It is expected that DH will fund biotechnology research and set priorities for that funding, but will not itself carry out the research. There are likely to be some biotechnology issues in this area, such as biomedical materials, which are of significance, both for the public good and for economic reasons, which will also be relevant to SERC. However, no coordination problems in this well-defined area are envisaged within the science base, and MRC's acceptance of BJAB membership in February 1992 further marks the success of integration in this area.
- 31. Coordination between the Research Councils and other Government Departments might be addressed through ad hoc working groups focused on key research areas, rather than through ICBT. These groups should have restricted membership with specific interests in activity on that area. We referred to this issue above. For example: DoE, NERC, AFRC and SERC could operate a similar system for environmental biotechnology to that suggested for DH and MRC; and DTI and OST might wish to use such groups for coordinating the UK line on EC biotechnology programmes. The scientific lead on some programmes resides with the Councils, for example with AFRC on Framework III programme development and with MRC on bio-informatics and HUGO. However, ministerial responsibility is found where attribution for these programmes falls, and this gives the lead to DTI on Framework IV but to the Department responsible for the Science Budget (at the time of the review DES, now OST) on basic research. BJAB could fill a useful coordinating role in providing a forum for discussion across the EC spectrum.

The committee recommends that no grand overall committee should be instituted to bring these leads together, but rather that each body should determine how it would best seek advice, disseminate information and coordinate its part of the UK effort.

- 32. Coordination with industry will be promoted effectively by continued support of BJAB. But the committee believes that awareness is a mutual responsibility. The Councils will note the research priorities that have been highlighted in the BJAB sectoral reviews, but there is also a need for industry to make itself aware of the science base's capabilities and needs. The success of BJAB as the key link to industry will depend on significant feedback in refining that strategy; that will depend on the involvement of top managers and directors as well as industrial scientists.
- 33. Notwithstanding the role that the committee foresees for BJAB, there will be circumstances in which individual Councils will wish to organise industrial fora to focus on particular issues relevant to their areas of interest. This is entirely appropriate and, like the ad-hoc groups discussed above, such fora are neither precluded by the existence of the larger body nor should they affect its operation.
- 34. Coordination with the UFC (and successor HEFCs) is likely to be an historical issue, if the HEFCs confirm that they do not intend to renew the UFC special topic funding for biotechnology. While there has been no conscious coordination with Research Councils in this initiative, some of the same scientists have been involved in both UFC and RC committees. The UFC (UGC) initiative has placed in HEIs staff who have applied for Research Council grants and developed an ethos for biotechnology. But the committee has some doubts as to the extent to which these posts retain a relevance to biotechnology in the 1990s.

The committee recommends that, if a decision is made to extend the UFC initiative, then the ABRC should exhort the HEFCs to coordinate more closely with Research Councils: such initiatives will always benefit from discussion between the Funding Councils and the ABRC.

CONTINUING COORDINATION WITHIN THE SCIENCE BASE

- 35. The committee has not identified any continuing problems of coordination. The committee concludes that, given the developing success of BJAB as a common forum with the DTI and industry, there is no need to introduce additional mechanisms to promote the coordination of research programmes in biotechnology. But it recognises that this does not obviate the need for coordination. In fact, the committee believes that adequate "safety net" mechanisms are already in place.
- 36. Specifically, the committee identified three occasions each year when issues of coordination, including those relating to biotechnology, might be recognised and addressed by the ABRC:
 - a. the Forward Look meeting, in March, for the coordination of programmes already planned;
 - b. the meeting with Government Chief Scientists, for coordination with Departments;
 - c. the research opportunities meeting, in the autumn, when emerging science and potential programmes can be discussed and forward coordination needs can be identified.

The committee recommends that a review of coordination should be an annual standing item for the ABRC, and should also appear on the agenda of the meeting of HORCs immediately preceding whichever Board meeting is most appropriate.

It may be desirable that additional parties (such as Departmental Chief Scientists) be invited to that HORCs' meeting for this item, in which case the reservation of some separate part of the meeting for such business would seem to be appropriate. The first occasion on which this item should arise is when Councils report on their responses to the BJAB strategy document later in 1992.

In Conclusion

The committee recommends that it should keep a watching brief on biotechnology, pending an agreement between Councils on the success of BJAB in formulating its action plan. In the interim, it proposes that it should not continue to meet unless requested so to do by the ABRC, or until the Chairman of the committee identifies immediate business falling within the committee's terms of reference.

SUMMARY OF RECOMMENDATIONS

The ABRC Biotechnology Sub-committee recommends that:

- A. the matrix in Table 1, and the associated summaries in Annex D, should be updated on a rolling basis by the Research Councils and used by the ABRC to inform its consideration of biotechnology support;
- B. the Research Councils continue to keep an overview of coordination at all levels, including <u>ad hoc</u> bench level arrangements; but that they should not be required to impose formal reporting arrangements simply as a matter of course;
- C. providing that Councils' scientific programmes are clearly focused and that overlaps occur in methodology rather than purpose, cross-Council funding and Research Council funding of Government and other laboratories should take place wherever this is appropriate in achieving the best scientific objectives;
- D. BJAB should report not only to Councils but also directly to the ABRC; and that, as biotechnology develops, so the membership of BJAB should change to reflect the current science and thus ensure that the people involved are close to emerging ideas and technologies;

- E. the outcome of discussions about the BJAB strategy document within the Councils shouldbe brought back to BJAB, and used with industrial feedback to formulate an action plan;
- F. no grand overall committee is needed to effect coordination between Research Councils and Government Departments, but each body will determine how it should best seek advice, disseminate information and coordinate its part of the UK effort;
- G. if a decision is made to extend the UFC biotechnology initiative, then the ABRC should exhort the HEFCs to coordinate more closely with Research Councils;
- H. a review of coordination should be an annual standing item for the ABRC, and should also appear on the agenda of the meeting of HORCs immediately preceding whichever Board meeting is most appropriate;
- I. it should keep a watching brief on biotechnology, pending an agreement between the Councils on the continuing success of BJAB and the formulation of its action plan.

Terms of reference

- To define the scope of 'biotechnology' within the remit of the Research Councils, and to map the boundary between biotechnology and related areas of biology.
- To describe the present responsibilities of individual Research Councils within the area defined, and to keep these under review.
- To review current and prospective activity by the Research Councils in the field of biotechnology, and to identify a strategy for its coordination and development.
- To review the interaction and interface between Research Council activities and research sponsored by other agencies (including the DTI and UFC) in the field of biotechnology.
- To consider reports from the Biotechnology Joint Advisory Board (BJAB) as an input to remits (3) and
 (4) above.
- To report periodically to the ABRC on the above remits and to make recommendations on any changes
 which appear necessary to achieve more effective development of research and exploitation policies in the
 field of biotechnology and related areas of biology.

Membership

Chairman Professor R L Gardner FRS, ABRC independent member

Members Professor T Blundell FRS, Secretary AFRC

Dr D A Rees FRS, Secretary MRC

Dr E Buttle, Secretary NERC

Sir Mark Richmond ScD FRS, Chairman SERC

Dr B Richards CBE, Chairman BJAB

Dr R Coleman FRSC, Chief Engineer & Scientist DTI

Secretariat Dr J Adams

Dr M Power

^{*} Other Government Departments with biotechnology interests (including DoE, DH and MAFF) receive papers and are invited to comment through the DTI. At the Chairman's discretion, they may also be invited to attend meetings of the committee for particular items of business.

Papers seen by the Sub-committee, in the series ABRC(BT)(91)

- 1. Constitution, and background to the establishment, of the Sub-Committee.
- 2. Objectives and timetable for the work of the Sub-Committee.
- 3. Coordination of biotechnology research: historical review and recent developments.
- The SERC Biotechnology Directorate (BTD) and the Biotechnology Joint Advisory Board (BJAB): paper from the BTD secretariat.
- Coordination of biotechnology research: ABRC discussion, 1990.
- 6. Biotechnology research presently supported by the Research Councils, and its coordination.
- 7. Biotechnology: a plain man's guide to the support and regulations in the UK (ICBT publication).
- 8. Report of the SERC 1988 Biotechnology review panel.
- ACOST report: Developments in Biotechnology.
- UFC Biotechnology Initiative.
- 11. Biotechnology Joint Advisory Board (BJAB): strategy document.
- Biotechnology research and policy interests among Government Departments, and coordination through ICBT: paper from the DTI.
- 13. NEDO Biotechnology Report: New life for Industry.
- 14. Biotechnology in the United States: NSF report on Biotechnology Opportunities.
- 15. Biosensors: ISI analysis of publications.

Biotechnology coordination: historical review

The Spinks Report.

1. In 1979, the Advisory Council for Applied Research and Development (ACARD), the ABRC, and the Royal Society set up a Joint Working Party (the Spinks committee) to review existing and prospective science and technology relevant to industrial opportunities in biotechnology, and to recommend actions by Government or other bodies to facilitate British industrial development in biotechnology. The Spinks committee, which included both industrialists and academics, recommended first, the setting up of a Joint Research Council Committee and, second, an inter-Departmental Steering Group. The two committees were envisaged as complementary and having some common membership.

Progress following Spinks.

- Following the Spinks report's second recommendation, an Interdepartmental Committee on Biotechnology (ICBT), on which the HORCs were represented, was set up under the Chairmanship of the Government Chemist, "to provide a focus for biotechnology within Government and to stimulate its development".
- 3. The Research Councils followed successful individual initiatives in biotechnology. For example, MRC was instrumental in the setting up of Celltech and established its Collaborative Centre for Industry at Mill Hill. SERC set up its Biotechnology Directorate (BTD) as a strategic vehicle with a strong industrial influence (see ABRC(BT)(91)4).
- 4. It proved more difficult, however, to achieve effective inter-Council co-ordination, as is indicated in the extracts at Annex C(1) from a paper by a SPRU researcher (M. Sharp, 1989). Following the Spinks report's first recommendation, an Inter-Research Council Coordinating Committee for Biotechnology (IRCCCOB) was established but was later dissolved, and succeeded by the Biotechnology Advisory Group (BAG). Nonetheless, difficulties persisted and some were later discussed in the report of the Morris committee in 1989 (ABRC(89)25). A relevant extract from the report, which suggested some possible causes of friction, is at Annex C(2).
- In 1988, a review of SERC's BTD by a panel chaired by Professor Blundell recommended that SERC
 continue active involvement with BAG and with other activities to ensure good coordination with other Councils.
 It also recommended that AFRC and MRC be represented on the BTD Management Committee.
- In 1989 SERC and DTI set up the Biotechnology Joint Advisory Board (BJAB) (see ABRC(BT)(91)4).
 In Spring 1990, AFRC and NERC, who had initially sent observers, joined as full partners and MRC now attends as an observer.

Parliamentary and Government interest

- 7. The House of Lords Select Committee on Science and Technology in its 1st Report (1988-89) commented that coordination between the Research Councils was particularly important in biotechnology, and recommended: that other Research Councils as well as SERC should be involved in the activities of the BTD, and that there should be joint funding of projects.
- ACOST's report "Developments in Biotechnology" (February 1990) recommended (Annex F, page viii, c)
 that inter-Research Council coordination of biotechnology should be strengthened. ACOST's 1990 Priorities
 Advice incorporated the same recommendation.
- 9. At its first meeting on 13 May 1991, the Science and Technology Advisory Group (STAG) (which is a new forum for departmental Chief Scientists and HORCs under Professor Stewart's chairmanship) also discussed biotechnology. The Group noted <u>inter alia</u> the steps being taken by ABRC to promote the coordination of the Research Councils' activities.

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ABRC Biotechnology Sub-committee

Extracts from The Management and Coordination of Biotechnology in the UK, 1980-88, by Margaret Sharp (SPRU), reprinted in Philosophical Transactions of the Royal Society (1989) Vol. 324(B), pp. 509-33.

(i) (p.511)

... the Inter-Research Council Coordinating Committee on Biotechnology (IRCCCOB)... lacked a clear remit, had no industrial members, and no clear linkage with Government Departments. Nor was there any question of appointing a Director or Coordinator to coordinate and stimulate joint activities.

(ii) (p.517)

At this juncture it is necessary to record briefly the demise of IRCCCOB in 1985/6 and its replacement by the higher level Biotechnology Advisory Group (BAG) boasting independent as well as Research Council members and reporting directly to the Heads of the Research Councils (HORCs). IRCCCOB had in fact never been a happy committee, and once the HORCs had turned down its 1983 initiatives for two inter-Research Council programmes in plant biochemistry and microbial physiology, it hardly met and issued only one further report (in 1986) covering the years 1983-85. It was finally wound up when the Reece Review of the SERC Biotechnology Directorate (Reece 1985) revealed the very deep divisions between the Research Councils, particularly the SERC and the MRC, on biotechnology. The hope was that a higher-level group would be able amicably to resolve these differences. So far this has not been the case. BAG has to date proved no better a mechanism than its predecessor for coordinating research council activities, or resolving their disputes.

Extracts from the Review of the Research Councils' Responsibilities for the Biological Sciences (The "Morris Report", April 1989)

CHAPTER 3: OVERLAPPING RESPONSIBILITIES IN THE BIOLOGICAL SCIENCES AND ARRANGEMENTS FOR COORDINATION

Introduction

 In this chapter we describe some research areas which overlap the responsibilities of two or more Research Councils and give our views on the effectiveness of current coordination arrangements. All areas of overlap are too numerous to be described in detail, so we have had to be selective.

Biotechnology

- 2. Since the previous major ABRC review (in 1976), the biological sciences have become increasingly pervasive. This is nowhere better demonstrated than in biotechnology the application of organisms, biological systems, processes or molecules to manufacturing and service industries, and to research itself. It is a generic technology, dependent for its development on advances in basic research, particularly molecular biology.
- 3. The revolution in molecular genetics is the most notable of a number of developments leading to the increased understanding at the molecular level of living systems, whether microbial, plant or animal, and in viruses. Thus, for example, human insulin has been made in bacteria for clinical use and a hepatitis B vaccine has been made in yeast. These products of biotechnology would have been inconceivable fifteen years ago, yet the present achievements will be seen as limited in a few years time.
- 4. The pattern of commercial development is likely to be of accelerating growth as the techniques of manipulation of genetic systems are established in an ever growing range of living systems - for the production of better drugs, disease diagnosis, safer and more selective pesticides, higher yielding and higher quality crops, improvement in animal production and effective treatment of toxic wastes.
- 5. Developments in the products and services to which biotechnology relates are intrinsically based on further advances in basic research and related training. They will loom large in the economy and cover health care, agriculture, processed foods and beverages, waste treatment, some key chemicals and the environment. The total UK sales of the products and services increasingly affected by biotechnology are about £50 billion per annum.
- 6. Because biotechnology may be defined in different ways, estimates of expenditure on biotechnology by each Research Council are difficult to achieve in a consistent way; such expenditures, however, amount to a considerable sum. In the report "The Biotechnology Directorate of the SERC" (Science Policy Research Unit, 1988), the following heavily qualified figures are given (1985/86 financial year): AFRC £10m; MRC £31.0m; NERC £0.8m; SERC £11.7m (Biological Sciences Committee £7.3m., Biotechnology Directorate £4.4m); Total £53.5 million.
- 7. There is extensive overlap between MRC, SERC and also AFRC in areas of research underpinning biotechnology. Such research includes basic molecular biology and genetics, together with aspects of biochemistry, biophysics and cell biology. Interdisciplinary research programmes may have titles such as "molecular recognition", "molecular sciences", "protein engineering" and "biological membranes".
- Attempts were made to coordinate Research Council activity in biotechnology through the Inter-Research Council Coordinating Committee for Biotechnology (IRCCCOB), set up in the wake of the "Spinks Report" (Biotechnology, Report of a Joint Working Party, chaired by Dr A Spinks CBE FRS, 1980). IRCCCOB

was dissolved by the Heads of the Research Councils (HORCS) after a Panel established by SERC and chaired by Dr C H (now Sir Charles) Reece reviewed the work of the Biotechnology Directorate. In its report, the Panel emphasised the as yet unmet need for coordination of SERC's biotechnology programmes with those of other Research Councils, particularly MRC, and also with research supported by the Department of Trade and Industry. In 1985, the HORCS proposed and the ABRC accepted that a Biotechnology Advisory Group (BAG) be set up.

- 9. In spite of these attempts at coordination, relationships between SERC, MRC and AFRC regarding biotechnology have been generally unsatisfactory since the establishment of the SERC Biotechnology Directorate. We believe that this has been due in part to the Directorate selecting for attention areas which overlapped the prime responsibilities of other Councils, particularly AFRC and MRC. Difficulties have also been encountered in arranging the financing of collaborative ventures and in reconciling the style of operation of the Directorate with that of other Research Councils, particularly MRC.
- 10. Although the Directorate has invited other Councils to participate in its initiatives, MRC has consistently declined. Differences between the two Research Councils were evident regarding proposed arrangements for funding and for the allocation of intellectual property rights associated with the "Protein Engineering Club" formed in 1985.
- 11. Biotechnology Directorate interests in plant cell culture, whole plant biotechnology, plant molecular biology and biochemistry overlapped those of AFRC. Again, the Directorate's style of operation has been seen by AFRC as an obstacle to collaboration, although the real problem for the AFRC has been lack of funds for collaborative projects.
- 12. AFRC, for instance, could not collaborate in a Directorate initiative (in 1984/85) in plant biology and biochemistry because of a shortage of funds, although the programme was central to AFRC interests. In the event SERC also withdrew from the programme. These withdrawals caused a good deal of ill-will amongst those HEI staff whose expectations of funding had been raised and who then felt let-down.
- 13. In 1987 SERC asked for bids from HEIs for 'Interdisciplinary Research Centres' (IRCs) in a number of research areas, including molecular sciences. It was hoped (and expected) by SERC that other Research Councils (AFRC, MRC, NERC) would become involved. However, there were hardly any initial discussions with the other Councils before bids were sought and these discussions were not effective. In the event, MRC has become involved with the IRC established in Oxford, but this was achieved post hoc and not without difficulties.
- 14. We have dealt at length with attempts to coordinate in biotechnology between Research Councils, which have not generally been successful. Inter-Council relationships are now such that suggestions by one Research Council are regarded with suspicion by others, and BAG is perceived as substantially ineffective. Indeed, the chairman of BAG told us that it was now very difficult and arduous to achieve any momentum in its work.

Concluding remarks

- 37. Each Research Council has properly continued to reorientate itself in response to the rapid developments which have occurred in biology; and the restructuring undertaken by AFRC and NERC in recent years is particularly notable. The Councils have also introduced various arrangements to try and coordinate research in areas of interest to each other. We have commented on certain of these coordination arrangements in the preceding paragraphs. More generally, we wish to acknowledge the significant attempts being made to coordinate the Councils' research and other activities, ranging from regular discussions by HORCs to inter-Council membership of committees concerned with research programmes in particular areas.
- 38. Nevertheless, there can be little doubt that coordination and collaboration between Research Councils is an area of deep concern to researchers in both HEIs and industry, and that improvements are needed. A large number of HEIs staff who wrote to us said that current Research Council responsibilities were

generally not defined clearly enough. Also, inter-Council coordination, mainly achieved by consultation between headquarters' officers and their attendance at relevant meetings of other Research Councils was perceived as inadequate.

- 39. It is important that those employed in administering Research Council supported science should perceive themselves as members of one entity or community, and that they are not to any extent subject to protectionist tendencies. However, there is a widespread impression held by academic members of Research Council committees that assessors are principally intent upon defending the interests of their own Councils.
- 40. Individual Research Councils can react quickly to research problems: for instance, AFRC's response to the environmental problem of straw burning, NERC's response on other issues involving environmental pollution, MRC's response on AIDS, and SERC's development of molecular electronics. SERC's speed of reaction and flexibility reflects its emphasis on HEI support and the lack of a continuing commitment to research institutes. Other Research Councils, of course, also develop interdisciplinary initiatives, but these are often extensively based within their own institutes and thus less visible to the academic community at large.
- 41. However, a coordinated reaction by two or more Research Councils to a research problem is usually much slower in development and generally less satisfactory than when only one is involved. There are exceptions, and collaboration between AFRC and MRC in neuropathogenesis is an example where two Research Councils have produced arrangements as effective as if only one had been involved.
- 42. In our view, coordination between Research Councils regarding biotechnology has been unsatisfactory, and collaboration between AFRC and NERC on 'agriculture and the environment' was cumbersome in its initiation and proceeded only slowly. Also, recent consideration by ABRC of joint Research Council proposals for Interdisciplinary Research Centres has shown that Councils often need to make greater efforts to collaborate in relevant areas.
- 43. However, it is notable that the mission-orientated Research Councils (AFRC, NERC, MRC) were often able to collaborate more effectively with each other than with SERC. Conflict has sometimes arisen from attempts to coordinate basic and strategic research activities promoted from the different perspectives of the mission-orientated Councils and of the SERC. This is evident in biotechnology, where initiatives of the Biotechnology Directorate have been repeatedly in conflict with MRC's view of its mission, particularly in areas of molecular biology and cell biology.
- 44. These conflicts reflect the lack of agreement on the extent to which SERC underpins the work of the mission-orientated Research Councils, an apparent lack of awareness by SERC of the basic research supported by the other Councils, and problems arising from different methods of working. In general, SERC operates with shorter time horizons than the other Councils, which are concerned to develop long-term research programmes working both with HEI staff and their own institutes.
- 45. We certainly do not wish to give the impression that all coordination difficulties concern SERC, nor that that Council has created stumbling blocks. Indeed, we received much comment from research workers in industry complimenting SERC on its successful development of links with industry, particularly in relation to biotechnology, and on its provision for the integration of the biological and physical sciences. Also, it is undoubtedly the case that some excellent SERC innovations for instance, CASE studentships which are held in high regard by both HEI and industry staff -have not been quickly enough adopted by other Councils.
- 46. We were told on several occasions and from a variety of sources that MRC and SERC had not been able to cooperate over some allocations of CASE studentships. This lack of agreement has caused confusion and some resentment amongst HEI staff and their colleagues in industry, and serves as a very visible example of poor Research Council cooperation. This problem should be resolved by MRC's introduction of a CASE-type studentship scheme this year. However, this was not the only example of difficulties concerning research training. For instance, we could not detect much evidence of SERC-AFRC

- collaboration over the deployment of research studentships in agriculture, transferred as they were from AFRC (then ARC) to SERC (then SRC) in the 1960s.
- 47. On several occasions our attention was drawn to "Biological Sciences Themes", published in 1986 by SERC on behalf of its Biological Sciences Committee. This publication is the outcome of an analysis begun in 1982 of all research funded by that Committee. Although a large number of scientists active in the SERC Committee structure were involved in the preparation of "Themes", there was minimal consultation with other Research Councils even though SERC's declared strategy is to underpin the objectives of AFRC, MRC and NERC. This showed a serious degree of complacency regarding consultation, which we believe to be an unintended spin-off from SERC management philosophy. However, "Themes" constitutes published evidence of poor inter-Council consultation and collaboration. Substantial parts of its text could have featured within similar publications from other Research Councils, though that fact seems to have been little appreciated by its authors.
- 48. Management philosophy in mission-orientated Councils is to have on their permanent staff senior scientists who have executive responsibility and are accountable for the success or failure of strategic and longer-term research programmes. These Councils also tend to deploy headquarters' staff to work within their own scientific specialisms. However, in SERC, accountability for longer term programmes is vested in committees, mostly of HEI staff with some from industry, who serve only 3 year or at most 6 year terms. Also, SERC favours the generalist administrator approach, with its scientifically qualified headquarters' staff only infrequently employed in areas related to their specialist training.
- 49. It is thus difficult for SERC to develop a consistent long-term approach to scientific research in the biological sciences, and this difficulty has been compounded by a lack of contact with the strategic thinking of the mission-orientated Councils whose scientifically qualified staff have a long-term planning horizon.

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	Genome Sequencing	Control of Gene Expression (+ Anti-sense)	Genetic Transfer and Transgenesis	Protein Engineering	Control of Metabolism	Acellular Processing (En-, Abzymes)	Post- translational Modification	Animal Cell Culture	Plant Cell Culture	Process Development and Control

ABRC Biotechnology Sub-committee

Research Council support of Biotechnology (November 1991)

Table 1

The principal biotechnology approaches presently used by the Research Councils and the range of applications to which they have been addressed: this disaggregation follows the analysis of the strategy document produced by the Biotechnology Joint Advisory Board, with the addition of human health care.

Abbreviations used in Table:

A = AFRC (major) a = AFRC (minor) M = MRC N = NERC S = SERC I = Industry

Reports on current activity and coordination mechanisms

- D(1) Agricultural and Food Research Council
- D(2) Medical Research Council
- D(3) Natural Environment Research Council
- D(4) Science and Engineering Research Council

AGRICULTURAL AND FOOD RESEARCH COUNCIL

An indication is given below of the biotechnology programmes currently supported by AFRC, grouped according to the 'Applications' identified by the Sub-committee. Much of the work described is funded from the AFRC Science Budget allocation, but there is related research commissioned with the Council by MAFF and by outside bodies. Where appropriate, reference is made to the underpinning science involved, and to coordination arrangements with the other Research Councils.

Approximately £10M of the AFRC Science Budget funds for 1990/91 was allocated to biotechnology with a further £30M to closely related underpinning science.

Drug Therapies

AFRC's animal health and welfare programme includes extensive work on development of new and more efficient vaccines against diseases of farm animals. A current example is the involvement of Pitman-Moore in the production and marketing of a vaccine against coccidiosis in poultry, derived from research at the Institute for Animal Health. Future developments will include vaccines developed using DNA technology and non-immune approaches to disease control.

Transgenic animals and plants are providing opportunities for production of medically important pharmaceuticals, for example blood coagulation factors in the milk of sheep and human antibodies produced by hybridomas derived from transgenic mice. Pharmaceutical Proteins Ltd has been established in Edinburgh to commercialise aspects of this research, utilising the work of the Institute of Animal Physiology and Genetics Research. Possibilities for new antibiotics are being generated from studies of metabolic pathways in Streptomyces.

These developments draw on extensive underpinning science, for example in immunology and transgenesis. Formal links are maintained with MRC to ensure complementarity between agricultural and medical advances.

The LINK Protein Engineering Programme, of which AFRC, MRC and SERC are sponsors, is exploiting advances in molecular biology and genetic engineering to design proteins with enhanced or new properties; production of improved drugs is one element of the Programme.

Diagnostics

Many aspects of the Council's programme are concerned with detection of animal, plant and food pathogens; pesticide, food contaminants and other residues; and physiological changes such as the onset of oestrus and pregnancy in farm animals. Developments in diagnostic techniques include the use of monoclonal antibodies, RNA and DNA probes, PCR technology and new approaches to immunoassays.

Biosensors are being developed. The LINK Molecular Sensors Programme, of which AFRC and SERC are sponsors, is developing new molecular sensing mechanisms.

Agriculture

The rapid developments in biological sciences offer substantial opportunity for increasing agricultural productivity and efficiency; for new patterns of farming; and for meeting environment and welfare concerns.

In the animal sector, AFRC research is aimed at accelerating livestock improvement by introducing specific genetic variation; improvements in animal health; and in securing more efficient nutrition, growth, lactation and reproduction. Most UK farm animals are being studied and some new species are being considered. There is an increasing emphasis on the study of fish, where biotechnology shows particular promise of viable commercial development.

The scientific programme underpinning these developments is wide ranging, from molecular to environmental studies:

Genome analysis covers work on chicken, pig and cow genomes, with AFRC institutes playing a major role in coordination of European effort. Close links are maintained with the MRC work on the human genome; joint programmes are currently being planned.

AFRC supported groups are world leaders in the development of transgenic technology for application to farm animals, for example, for controlling growth, nutrition and disease resistance. The AFRC Centre for Genome Research was set up in Edinburgh to develop this potential; MRC are closely associated.

AFRC is a sponsor, with SERC and MRC, of the Eukaryotic Genetic Engineering LINK programme, which includes research on molecular genetics of animals.

A current AFRC priority is on embryonic and somatic stem cell biology. The initial programme is largely centred on animal stem cells, in association with MRC, but an extension to plant studies will start shortly.

There are major programmes at AFRC institutes and HEI supported groups on physiology of growth, lactation, reproduction, neurobiology and behaviour. Embryo manipulation techniques developed at the Institute of Animal Physiology and Genetics Research are being exploited by Animal Biotechnology Cambridge.

An increasing element of the AFRC's research is dealing with studies of whole organisms and their relationship with the environment. The Joint Agriculture and Environment Programme, with ESRC and NERC, is studying herbivore/plant interactions of importance to new farming practice. Maintenance and regulation of biodiversity is a major future concern.

As in the animals sector, the AFRC <u>plant</u> science programme is providing considerable new opportunities for agriculture. Research is aimed at more consistent, sustainable and efficient yields; reduction of the adverse affects of pests and disease; better quality and storage characteristics; and properties which meet new processing requirements. There is also increasing emphasis on non-food plant products including wood, oils and pharmaceuticals.

The science and technologies involved are extensive:

AFRC is significantly involved in the international effort to sequence the genome of <u>Arabidopsis thaliana</u>, which is also being used as a model system to develop technologies for genetically modifying crop plants. The AFRC programme was the first nationally coordinated <u>Arabidopsis</u> project.

There is considerable research on genome mapping, for example in cereals, peas and brassicas, and on mapping quantitative trait loci.

The Council's Plant Molecular Biology programme is studying gene expression, chromosome structure, regulation of development, reproduction, signal perception and transduction. An extension of this programme is currently being planned, targeted more specifically at agriculturally important crops. The Eukaryotic Genetic Engineering LINK programme includes molecular genetics of plants and fungi.

Studies on the control of metabolic pathways include a joint programme with SERC on the biochemistry of metabolic regulation in plants.

There are extensive research programmes at AFRC institutes and HEI supported groups on plant breeding, crop performance, disease resistance and plant quality, underpinning agricultural efficiency.

AFRC's programme on nitrogen fixation extends from the chemistry of nitrogenase through molecular interactions between plants and symbiotic nitrogen fixing bacteria to the ecology of the plant/bacterium interaction and the potential of rhizobia to nodulate non-legumes.

Increasing importance is being placed on the opportunities for use of crops for providing non-food products. Molecular biology and biochemistry programmes at the Institute of Plant Science Research are aimed at production of specialist oils, starches and proteins. Genetically modified crops might be used for production of pharmaceuticals. Wood, fibre, and feed stocks for the chemical industry can be produced. Agricultural waste-products, such as straw, can be utilised.

The Council places considerable importance on the technology transfer aspects of these advances. For example: the Agricultural Genetics Company, which was established in 1983, has a first option to commercialise discoveries in aspects of plant biotechnology at AFRC institutes.

Food sciences

Biotechnology has traditionally played an important part in food production, for example: in fermentation processes. Current developments in the biological sciences are being used to create foods with improved nutritional safety, quality and processing characteristics, to provide new raw materials and new food products, and to explore new options for biopreservation.

The AFRC biotechnology programme in sciences underpinning the food industry and exploring consumer attitudes includes:

Protein engineering to understand structure/function relationships leading to design of novel proteins and enzymes with improved characteristics with respect to processing, food safety and storage.

Genetic manipulation to develop novel or modified micro-organisms for the food fermentation industry and to exploit natural antimicrobials, such as nisin and lysins to control food pathogens.

Fungal genetics to create new and improved strains and applications for yeast and filamentous fungi.

The analysis of metabolic pathways in plants and yeasts for processing, nutritional and health benefits and to provide food flavours, fine chemicals and pharmaceuticals.

Enzymology to understand the principles of biocatalysis in non-conventional environments and molecular recognition to exploit biotransformation and bioseparation for food applications.

Exploring consumer perceptions of biotechnological applications in the agri-food sector.

Environmental Monitoring, Improvements & Pollution Abatement

In recent years, AFRC has extended its research on the relationship between agriculture and the natural environment. Examples where biological sciences are being applied to environmental concerns are:

Use of molecular biology, and other approaches, to study ecosystems and organism populations. 'Molecular ecology' is a current AFRC priority area and a major new programme is planned, in collaboration with NERC. With DTI and industry, the Council is supporting the PROSAMO project, which is studying the behaviour of genetically engineered plants and microbes released into the environment.

Genetic engineering is being used to produce plants with enhanced pest and disease resistance and more efficient up-take of nutrients, thereby reducing chemical emissions into the environment.

Biological pest control covers studies of the population dynamics of insect pests and their natural enemies, and the use of semiochemicals, to modify insect behaviour. Specific biocontrol agents, including nematodes, insects, bacteria viruses and fungi, are being developed as pest controls. Bacteria are being used for bioremediation, for example on degradation of pesticides in soils.

A range of science is being used to understand the effects on biological systems of the predicted changes in the global environment. Application of this research could have a major impact on future agricultural practice. Close links are maintained with NERC and other Councils.

The AFRC/SERC Clean Technology programme includes the application of biotechnology to waste treatment and studies of bioremediation. Biological processes such as photosynthesis are being utilised to reduce energy inputs.

AFRC occasionally funds projects aimed at improving the public perception of biotechnology; a recent example was the schools competition run with the National Centre for Biotechnology Education at Reading.

Chemical Production

The main interest of AFRC is in possible use of plants and animals to produce chemicals, as indicated above.

MEDICAL RESEARCH COUNCIL

Human Health

This area of application excludes work related to 'drug therapies' or 'diagnostics' which appears under those headings. This heading includes:

identification of genes involved in genetic disease (Human Genome Mapping Project)

development of DNA probes for the detection of such genes population genetics

development of technologies for gene therapy (stem cell biology and homologous recombination)

development of technologies for pre-implantation diagnosis of genetic defects

biochemical function of gene products

development of transgenic animals as models of human genetic disease

development of methods of high level gene expression in animal and yeast cell culture systems.

Coordination

There are links with AFRC and SERC in many of the areas of basic underpinning science, but none in relation to applications.

The potential applications are of major interest to industry because of their relevance to the development of novel drugs and other therapeutic agents, diagnostic kits. Industry already funds a number of projects.

Drug Therapies

Includes vaccines, drugs and therapeutic reagents.

(a) Vaccines

substantial,underpinning work in immunology, microbial genetics, protein structure in relation to function potential vaccine vectors, including polio, BCG, vaccinia and salmonella adjuvants

isolation of candidate vaccine antigens of many pathogenic organisms including HIV epitope mapping

development of contraceptive vaccines

development of anti-tumour vaccines

animal vaccine development (on commission, at the Collaborative Centre).

(b) Drugs and therapeutic reagents

development of therapeutic reagents for infectious diseases

new drugs for use in cancer treatment

protein engineering related to the design of novel drugs and therapeutic agents

antiviral agents, including HIV

selective drug delivery and targeting (LINK Programme)

Coordination

AFRC, SERC and industry are significantly involved in these areas. All have substantial programmes in the underpinning science, though there are differences of scale, quality and content; there are fewer overlaps in the areas of application.

AFRC's interests relate to animals and plants, though many of the technologies used are common with MRC's. Expertise is shared at scientist-to-scientist level.

SERC's activities are mainly in the underpinning basic science and in the technology of plant and animal cell culture and process development and control. Formal coordination mechanisms are not needed. SERC co-fund the Protein Engineering IRC at Cambridge.

MRC has, and actively seeks, extensive links with industry and other organisations, particularly WHO. MRC participates in the LINK Programme on Selective Drug Delivery and Targeting. MRC is represented on BJAB and has regular meetings with ABPI.

Diagnostics

development of immunodiagnostic reagents, eg for HIV antibody

use of PCR technology to extend work on DNA probes for diagnosing infectious diseases

development of improved methods for detecting genetic disease

extensive underpinning research in cell and molecular genetics, antibody engineering, gene mapping and genome sequencing

Coordination

With AFRC there is extensive overlap in the use of research methods though their programmes are directed towards animal disease. There is sharing of expertise, and some active collaboration, at scientist-to-scientist level.

SERC are mainly concerned with protein engineering - where there are several joint programmes - and with the development and control of systems for the large scale culture of animal and plant cells where there is little overlap if any.

Industry has wide interests in this area. MRC has established numerous one-to-one interactions at the more applied end of the spectrum. Links with industry are the responsibility of the MRC's Technology Transfer Group. The Collaborative Centre provides a base for programmes funded by industry.

Agriculture - Plants

The area is a major element of AFRC's mission. MRC's activities relate to underpinning science which is relevant to both Councils' missions. These include:

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genome sequencing
gene transfer
protein engineering
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molecular genetics of viruses (gene vectors for plants)

Coordination

There is no overlap between Research Councils in terms of mission; there is extensive but justified investment by AFRC, SERC and MRC in particular areas of the underpinning science. Informal contacts ensure that relevant results are notified.

Agriculture - Animals

Animals in the sense of agriculture are the responsibility of AFRC. However, much of the MRC's work on genome sequencing, etc. is as relevant to animals as it is to humans. Relevance is due to common technological approaches and to inter-species applicability of results due to the extensive genetic homology between humans and, for example, the pig.

The relevant areas of the MRC's activity are:

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gene and genome sequencing and mapping
control of gene expression
gene transfer
protein engineering
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Coordination

SERC co-fund the Protein Engineering IRC; no more developed coordination mechanisms are needed in that or in other areas.

There are regular strategy discussions at officer level with AFRC. A joint programme in transgenesis is under way. Effective and extensive scientist-to-scientist interactions.

MRC's interests do not necessitate coordination with industry; this is primarily an area for AFRC.

NATURAL ENVIRONMENT RESEARCH COUNCIL

Definition or definitions of biotechnology, and the disciplines which are recognised within that field whether or not they are currently supported

NERC does not work to a single definition of biotechnology, and sees no need so to do. The Council recognises biotechnology as a broad term to describe the exploitation of biological processes to produce innovative products or processes. It is one of the main thrusts which permeates much of its research in the life sciences. It also recognises that this work is linked with essential underpinning research.

Again, there is no formal recognition of disciplines within biotechnology but, within NERC's ambit, biotechnology research covers a wide range of scientific disciplines including: ecology; molecular biology; microbiology; genetics; and chemistry.

Current work boundaries

NERC does not have programmes or initiatives labelled as biotechnology (there is one exception which is referred to below) so it is difficult to define relevant boundaries within the Council. Boundaries with other Research Councils are essentially the same in biotechnology as in other areas. Those boundaries are defined by NERC's mission: to advance understanding of the natural environment and the processes of environmental change, and to predict future change. In addition, where NERC has particular expertise and facilities (such as at the Institute of Virology and Environmental Microbiology (IVEM)) these may be used for priority research of interest to other Councils.

3. Current stock of activities supported in different disciplines within biotechnology, and the funding mechanisms which enable that support

There are several funding mechanisms for NERC support of biotechnology research. "Responsive mode" research grants and training awards are allocated through the Aquatic Life Sciences (ALS) and Terrestrial Life Sciences (TLS) Grants Committees. Other support is in the "directed mode" through the Marine and Atmospheric Sciences (MASD) and Terrestrial and Freshwater Sciences (TFSD) Directorates. The directed mode research includes Community Programmes and Special Topic Programmes (both, of these at both HEIs and Institutes), and other research within Institutes, Units, etc., funded both by the Science Budget and by customers.

A major application of biotechnology is in research, itself, and molecular biology techniques are now used widely and routinely throughout ecology and other life sciences supported by NERC, at HEIs and at Institutes. This general area is not included in the remaining description of NERC's current stock of activities.

The Culture Collection of Algae and Protozoa (CCAP), based at IFE and Dunstaffnage Marine Laboratory (DML), is a potentially valuable national resource for biotechnology research. NERC also supports the European Collection of Animal Cell Cultures at Porton.

Drug Therapies

NERC neither undertakes nor funds research on drug therapies.

Diagnostics

Research on diagnostics is undertaken at IVEM, largely on contracts, using the expertise on baculovirus expression vectors.

Agriculture - Animals

Most of this work is contract funded at IVEM and consists largely of research on animal viruses aimed at the production of vaccines. Again, particular use is made of IVEM's expertise with baculovirus expression vectors. This is also research supported at HEIs on genetic modification of trout.

Agriculture - Plants

Research in this category is mainly at IVEM and the Institute of Terrestrial Ecology (ITE) and concentrates on tree crops. It includes the use of mycorrhizal technology for improved tree establishment and production, and the development of resistance to viruses and insect pests in tree crops. NERC runs the Tree Biotechnology Liaison Group which brings together UK researchers in HEIs, Research Councils and the private sector.

Environmental Monitoring Improvements

A major aspect of NERC's biotechnology research is the risk assessment of the release to the environment of genetically modified organisms. This is undertaken at IVEM, ITE, The Institute of Freshwater Ecology (IFE) and at HEIs. Research in this area was stimulated by a recently completed Special Topic Programme on Biotechnology.

The risk assessment work clearly demonstrates the importance of underpinning research. Risk assessment of the release of genetically modified microorganisms depends on an understanding of the behaviour of existing microorganisms in the soil, phytosphere etc. Our knowledge of microbial ecology is poor and research in this area is a priority. A second example is the use of proxy organisms to mimic the spread of genetically modified organisms. NERC is studying the natural spread of introduced animals, plants and microorganisms (or their genetic material) as part of risk assessment studies.

Pollution Abatement

IVEM has pioneered research on the development of viral insecticides which make a significant contribution to the reduction in use of polluting chemical pesticides. This work has focused on insect baculoviruses.

There are also examples of research in areas of 'traditional' biotechnology, including the use of reed beds to remove nutrients from sewage effluent, and the use of organic waste to provide a stable, dynamic system to reduce the acidity of highly acid lakes.

Chemical Production

NERC neither undertakes nor funds research on chemical production.

Health care

NERC neither undertakes nor funds research in health care.

4. Analysis of prospective developments among existing and novel activities

This has been addressed in the recently published report of the Biotechnology Joint Advisory Board. The review, inter alia, has taken a wide-ranging look at the environmental impacts and benefits of biotechnology.

In brief, NERC considers that biotechnology gives considerable promise of improvement in environmental quality, for example in the development of biological pesticides and in clean technology processes. However, the use of many forms of biotechnology, in particular the use of genetically modified organisms, is dependent upon risk assessment of release to the environment. The Council sees this as an extremely important area to be developed.

5. Relationship between work supported in biotechnology and work supported in other areas

NERC does not have separate mechanisms for supporting research in biotechnology and in other areas. There is a close relationship between its biotechnology research and other research both in the life sciences and in the physical sciences.

6. Coordination

Coordination between research undertaken or funded by NERC and by other bodies is ensured through a number of mechanisms. First there are the regular exchanges between the research scientists in the different organisations and also between the officials. NERC consults other Research Councils during the formulation of new Programmes. Relevant advisory boards and review groups often have representatives or nominees of other Research Councils. Relevant Departments provide assessors on NERC's Science Committees. The Tree Biotechnology Liaison Group is an example of a particular liaison mechanism in one area.

SCIENCE AND ENGINEERING RESEARCH COUNCIL

The SERC supports research directly related to biotechnology through its Biotechnology Directorate, and associated underpinning work or research using biotechnology techniques through the Biological Sciences Committee, Chemistry Committee and Process Engineering Committee. Work supported through other bodies notably the Materials Commission and Information Technology Directorate - is also relevant to biotechnology in so far as it generates basic sciences and technologies which can be applied in new biotechnologies.

The techniques of biotechnology, such as molecular genetics and protein engineering are increasingly gaining widespread use in other disciplines and no attempt has been made in this paper to describe all these applications. Instead, this paper concentrates on research which is directly relevant to the generation of new techniques in biotechnology with a primary focus of improving the range and scope of use of biological systems in industry. Such work is largely supported through SERC's Biotechnology Directorate.

The Directorate's programme focuses largely on generation of the knowledge and skills base in biotechnology of particular relevance to the Pharmaceuticals and Chemicals Industries, and to pollution abatement. The future programme will largely exclude work specifically relevant to agriculture and food (although some generic technologies may be applicable in these areas). Work of relevance to the Pharmaceuticals and Chemicals industries primarily focuses on improving the catalytic, synthetic or transformation potential of biological system, coupled with improving process yield and recovery. Through this, the programme will generate new biotechnologies relevant to design, development and production of new therapeutic agents and speciality chemicals; the programme does <u>not</u> include work on aetiology, pathology or pathogenesis of disease states, development of therapeutic strategies, or on understanding of effects of therapeutic agents on, for example, human physiology and metabolism or disease pathogenesis. The generic technologies developed through the programme may however be applicable in these areas.

Within this broad framework, SERC interests can be classified as follows.

Therapies

Control of gene expression primarily in microbial and animal cell systems; including understanding and development of new methods of control to facilitate pathway engineering, over- or under-production strategies, switching-on pathways of secondary metabolism, etc. Aimed at production of new bioactive compounds, or improved production of known bioactive compounds

Gene transfer and transgenics: development of new host-vector systems, and fundamental understanding of gene transfer methods

Protein engineering: understanding of principles of protein structure and function; engineering proteins for new therapeutic uses; improving properties of proteins including thermostability, PH tolerance, selective binding, etc, for use both as therapeutic agents and for catalysis; improving protein engineering tools eg databases

Control of metabolism/pathway engineering: primarily microbial and animal cell systems, including improved understanding of microbial and animal cell physiology and metabolism and application of control systems to pathway manipulation;

Acellular processing: developing use of enzymes-based routes for novel production of therapeutic agents; extending the potential for biotransformation including new catalysts incorporating catalytic antibodies, non-peptide based synthetic catalysts etc

Post translational modification of proteins; including glycosylation, protein folding and assembly, post-

translational processing including cellular trafficking, and protein secretion. Aimed at improving fidelity of protein production, and understanding role of carbohydrates in protein function;

Animal cell culture: improved methods of growing animal cells in culture for production of therapeutic proteins; including understanding physiology and metabolism of cells in culture, limits to growth, control of cell cycle, control of gene expression

Plant cell culture: improving methodologies of plant cell culture (including fungi) as for animal cells; extending use of plant cells for production of therapeutic agents;

Process development and control: basic engineering theory underpinning design of complete processes; process scale up and integration; process intensification at all stages in process (fermentation, separation etc); separations technology and enhanced recovery; enzyme and cell presentation technologies and culture systems, including cell enzyme/surface interactions; new high performance reactors for non-microbial systems; containment; process modelling, and control. All these areas build on and incorporate work on better understanding of all aspects of the bioprocess including organism/environment interactions, reaction pathways etc.

Diagnostics

Protein engineering: basic understanding of protein function; improved properties of proteins (including antibodies) etc, enabling wider scope for development of detection systems primarily for biosensor applications

Acellular processing: development of novel biotransformation for use in sensor applications; novel production methods for reagents for use in diagnostics

Animal cell culture: development of novel production methods for reagents for use in diagnostics

Process development and control: basic sciences and technologies as for drug therapies; aimed at improved production of diagnostic reagents (no work recently supported)

Agriculture - Plants

Control of gene expression: current areas of scientific/ technological interest as for drug therapies: primarily aimed at producing novel characteristics and products of plants

Control of metabolism/pathway manipulation including improved understanding of physiology and metabolism and application of novel control systems in pathway manipulation. Aimed at novel plant products or characteristics

Work primarily aimed at improving characteristics of crop plants will not be supported in the future, although work using biotechnological techniques for understanding of plant structure and function will be supported primarily through the Biological Sciences Committee.

Food Technology

Process development and control: basic sciences/technologies as for drug therapies. Initiative planed involving SERC and AFRC

Environmental Monitoring/Improvement

Protein engineering: areas as for diagnostics; aimed at improving range of biosensor applications in environmental monitoring

Acellular processing: areas as for diagnostics: again aimed at improving range of biosensor applications

Pollution Abatement

Control of gene expression: basic areas of science/technology interest as for drug therapies; including identification and control of cryptic genes, underpinning development of improved microbial systems for waste elimination or treatment

Gene transfer and transgenics: host-vector systems for microbial systems for waste elimination or treatment

Control of metabolism/pathway manipulation: basic science/technologies as for drug therapies; developing potential of microbial systems in waste elimination or treatment. Understanding of mixed culture systems/microbial ecology

Acellular processing: exploring potential of biotransformation to replace more harmful chemical synthetic routes for clean-up technologies

Process development and control: basic sciences/technologies as for drug therapies, aimed at reducing or eliminating harmful waste products

Chemical Production

Control of gene expression: basic sciences/technologies as for drug therapies

Gene transfer and transgenics: basic sciences/technologies as for drug therapies

Protein engineering: basic sciences/technologies as for therapies

Control of metabolism/pathway engineering: basic sciences/technologies as for drug therapies

Acellular processing: extending range and scope of biotransformation for replacement of existing chemical syntheses, or development of new synthetic routes. Basic science/technologies as for drug therapies

Post translational modification of proteins; underpinning development of enzymes with new functions for biotransformation

Plant cell culture: novel routes for flavours, fragrances and other speciality chemicals (no work currently supported)

Process development and control: basic sciences/technologies as for drug therapies

Work will also be supported on exploring the uses of carbohydrates as chemical feedstocks including underpinning work on carbohydrate structure and function

Coordination

The SERC coordinates its activities with those of other Research Councils through a variety of mechanisms including:

(a) General Mechanisms

presentation of strategy and Forward Look for biotechnology to BJAB, seeking comments from Research Councils and DTI on overall remit and planned activities;

individual discussions of proposed new topics with relevant Research Council officials, and where appropriate in joint meetings involving bench level scientists;

establishment of joint programmes and programme peer review panels in appropriate areas

other Research Council assessors on relevant SERC Committees/Boards and, vice versa, SERC assessors on other Research Council Committees/Boards

seeking other Research Councils' views on borderline grant applications.

(b) Specific Mechanisms

Specific mechanisms exist in the following areas:

protein engineering (joint LINK programme management committee, involving AFRC, DTI, MoD, MRC and SERC)

eukaryotic genetic engineering (joint management committee involving AFRC, DTI and SERC)

molecular sensors (joint LINK programme management committee involving AFRC, DH, DTI and SERC)

selective drug delivery and targeting (joint LINK programme management committee involving DTI, MRC and SERC)

crops for industrial use (joint LINK programme management committee involving AFRC, DTI and SERC)

clean technology (joint initiative and management committee involving AFRC and SERC)

plant metabolism (coordinated initiative involving AFRC and SERC)

biomedical materials (MRC assessor)

(c) ad hoc Discussion Groups

Ad-hoc meetings have been held or are planned in the near future to explore interests in:

food processing (AFRC and SERC)

molecular and biosensors

insect cell expression systems (NERC, SERC)

developmental biology (AFRC, MRC, SERC)

carbohydrates (AFRC, MRC, SERC)

environmental biotechnology (AFRC, DoE, DTI, NERC, SERC)



