The United Kingdom

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Introduction

During the last half century biotechnology has undergone radical changes. Historically British scientists and technologists have played a key role in this development.

Table 1. A few dates in the history of UK biotechnology	
1796	Smallpox vaccination, Jenner
1843	World's first agricultural research station founded at Rothamsted
1923	Isolation of insulin, Macleod e al
1928	Discovery of penicillin, Fleming
1946	Large scale penicillin production, Glaxo
1950	Food preservative antibiotic, nisi, NIRD
1950s	Modified penicillins, Beecham
1953	Cephalosporins, Oxford DNA structure, Crick, Wilkins and Watson
1957	Interferon, NIMR, London
1958	Insulin structure, Sanger
1961	Foot and mouth disease vaccine, ARC
1967	Marek's disease vaccine, ARC
1975	Monoclonal antibodies, Milstein
1980	Pruteen, ICI
1980s	Fungal protein for human consumption, RHM
1980s	Cloned oil palm trees, Unilever
1984	Monoclonal antibodies for purification of gamma interferon, Celltech

Government Spearhead

In 1980 the Spinks Report paved the way for accelerated development in both industrial and academic biotechnology. More than 20 recommendations were made, of which most have been implemented. The Department of Trade and Industry, DTI, took over the lead responsibility for biotechnology and in 1982 the Secretary of State launched a campaign to

foster the development of biotechnology in industry with the objectives shown in Table 2.

Table 2. Five key objectives of DTI support
– Raise awareness of opportunities for biotechnology – consultancy support
– Raise level of industrial research & development – innovation support
– Improve biotechnology infrastructure – culture collective, information services
– Identify and tackle strategic weaknesses – expensive agricultural raw materials
– Identify and promote sectors of biotechnology that represent particularly important opportunities for UK

To implement these priorities the Government Chemist established a Biotechnology Unit, BTU, staffed by civil servants and secondees from industry. With eight staff the BTU has been effective in ensuring the proper appraisal of proposals for support from industry. The BTU has also been pro-active in identifying and promoting biotechnology sectors of industrial significance, described in more detail later.

Key Objectives

1. Awareness

The Department's initiative in supporting biotechnology is part of a wider scheme known as Support for Business', which also embraces other key technologies. Various levels of support were available to companies (ranging from large multinational to the novice, one man start-up) to employ a consultant to provide specialist skills that the company did not possess. The BTU had more than 100 candidate consultants which it could call upon. Discontinued now, largely because of its success, the DTI provided almost £0.64 million for consultancy support. Waste treatment proved to be a surprisingly interesting sector. Consultancy support was followed up to assess the impact achieved. A high level of success was achieved as judged by further development within a company, according to the follow-up studies.

Other awareness raising activities include the launch of a pilot scheme to provide fermenters to secondary schools, support to the Open University to produce a series of videos, and the publication in 1984 of the Directory of British Biotechnology. A second edition was produced by a private company at the end of 1986.

2. Research and Development

Support for innovative research encourages companies to spend more on high risk projects that would not have proceeded otherwise. This involves the largest element of spending to date. A grant of up to 25°/0 of eligible costs is payable to a single company, but no single project has received support for more than three years. About half the 200 proposals received have been funded. Company support for the projects outlined is estimated at around £50 million (April 1987 figures) with DTI support at £13.179 million. Additional support for collaborative research exceeded £10.323 million.

Although biotechnology is moving at a fast pace, it is too soon to see any commercial benefits, although some R&D projects are beginning to bear fruit. Two examples of the fruits of R&D support are (i) ICI Agricultural Division – production of polyhydroxybutyrate, PHB, from micro-organisms. (ii) Amersham International – the development of the Amerlite, luminescent immunoassay system.

3. Infrastructure

Although the DTI takes the central role in supporting industrial biotechnology, many other Departments are concerned with aspects of health, agriculture, environment, energy etc. Co-ordination is maintained by the Interdepartmental Committee on Biotechnology, ICBT, for which the BTU supplies the secretariat. This co-ordinating activity has resulted in the production of a simple guide to UK regulations and regulatory bodies, a document of particular value for companies new to biotechnology. The BTU also provides the secretariat to the Industrial Consultative Committee on Biotechnology, chaired by a DTI Minister and consisting of senior industrialists. Its terms of reference are to identify and recommend to government, priorities and policies that encourage the exploitation of biotechnology by UK industry.

The BTU underpins certain strategic technologies by major funding of two public sector laboratories, widely regarded as centres of excellence: Harwell and the Centre for Applied Microbiological Research, Porton.

To facilitate access to data from the UK's 9 microbial culture collections, the BTU has instigated the formation of MiCIS, the

Microbiological Information Culture Service. MiCIS went 'on line' in March 1987 and enables subscribers to make cost savings on microbial selection. It is hoped that MiCIS might eventually become part of a pan-European data bank.

A DTI survey on regulation revealed that the UK regime is regarded as sensible, pragmatic and generally preferable to other national regimes. It allows innovation to flourish, while offering adequate safeguards to the worker and consumer. Patenting has produced problems, particularly with regard to the basic patentability of biological innovations. Plants cannot be patented in the UK, although the DTI's view is that the protection offered under the Plant Varieties Act is no longer adequate. The ICBT is of the view that UK law on patents should be harmonised with the European Patent Convention in restricting access to cultures deposited for patent purposes. The DTI feels that UK law must change to harmonise it with the situation in the USA and elsewhere.

With regard to control of genetic manipulation, the DTI is concerned to avoid the imposition of new controls on industry, except where clearly justified. In view of the anticipated large increase in type and frequency of environmental release, it is likely that the existing Advisory Committee for Genetic Manipulation case-by-case review system may need revision. The OECD report of 1986 provides a framework for new controls. The DTI has recommended to the European Commission, EC, that risk assessment should figure largely in new biotechnology programmes.

The DTI is prepared to co-ordinate UK industrial input into the EC risk assessment programme and assist in making links with European and other countries. It is keen to stimulate interest in an awareness campaign about biotechnology aimed at the general public, to dispel any ill-formed public perceptions, especially with reference to planned release.

Most organisations active in biotechnology have representation on appropriate committees. Two bodies stand out at present, the British Co-ordinating Committee for Biotechnology, BCCB, representing professional bodies and the Association for the Advancement of British Biotechnology, AABB, acting for industry and open to companies, non-profit organisations and individuals.

4. Priority Sectors

Because the scope of biotechnology is so broad, the BTU has analysed the technology on a sectoral basis, taking into account the following aspects: market characteristics, UK sectoral characteristics, technology development characteristics, the relevant UK technology base and a suggested strategy for future development. An action plan gives five sectors a priority status:

- Enzymes (biotransformations)
- Diagnostics (biosensors)
- Agriculture
- Food
- Process plant/instrumentation

It is believed that these sectors, taking into account UK strengths and weaknesses, will afford the country major opportunities in future.

Gradually the major biotechnology firms are agreeing with the notion that collaborative research, particularly at the precompetitive stage, is a sensible and viable solution to very costly research, especially when the DTI is prepared to fund up to 50% of programme costs. Successful ventures include the development of biosensors by Amersham International, Thorn EMI and the National Institute of Medical Research and also the development of the novel food, mycoprotein developed in collaboration by Rank Hovis McDougal and ICI. Examples of the larger consortia are listed in Table 3, below. The largest of these, the Plant Gene Tool Kit' is a £3million/3 year programme involving 11 companies, 2 universities and 2 research institutes, which will develop routine methods for the transfer of genes into plant material. Each participant has free access to all research results.

***Table 3*. DTI Sponsored consortia**

Consortium	Objective	Members
rDNA and antibiotics	To improve understanding and control of antibiotic production	4 firms + SERC at 6 universities
Institute of Biotechnological Studies	To extend useful life of immobilised biocatalysts in bioreactors	7 firms at 3 universities
Leicester Biocentre	To improve expression of foreign proteins in yeast	5 firms at 1 university
Plant gene tool kit	To develop gene manipulation techniques for crop plants	11 firms at 2 universities and 2 institutes
Enzyme supplementation of animal feeds	Make low grade animal feeds suitable for non-rumants	7 firms at 2 research organisations
Rapid microbiology using ATP bioluminescence	Development rapid detection and enumeration systems for bacteria in industrial situations	5 research organisations and many firms

Even when 5 or 6 firms collaborate, large research programmes are expensive. This expense can be reduced if a university or research organisation is used as the focus for the establishment of a club with a specific research activity. This situation allows members to tackle problems of general interest, producing state of the art reports for the benefit of members. It is expected that membership fees cover at least 50% of the costs so that viability is ultimately linked to industrial interest. The BIOSEP club focusing on downstream processing and separation technology involves over 50 companies, some foreign. The DTI supports a number of clubs and could consider the support of others.

The organisations that can be supported are listed in Table 4.

Training

The universities and Research Councils undertake most of the basic research and provide the kernel of trained manpower for industrial biotechnology. The quality of basic research in the UK is high and arguably

second only to the USA, with its huge resources. Generally the UK provides the right blend of talent for its industrial needs, although there may be shortfalls in specific areas such as immunology. The education system in the UK is flexible enough to be able to respond rapidly and redress any adverse trends. Education is thus in a state of dynamic equilibrium, carefully pivoted to cope with the increasing demands of industry.

***Table 4*. Who Does the DTI Support?**	
Single companies directly	
Companies	Other companies
	Consultants
	Research organisations
	Educational establishment
	Hospitals
Consortia of companies (and other organisations)	
Clubs	
Centres of Excellence	
Certain public bodies	
Certain foreign companies wishing to research and manufacture in the UK	

Clearly to achieve the right blend of academic and industrial talent requires large resources and a co-ordinated approach from government. To this end the BTU, along with a strong DTI Regional office network, works closely with the four relevant Department of Education and Science (DES) Research Councils. Significant liaison is maintained with the Biotechnology Directorate of the Science and Engineering Research Council, SERC, set up in 1981 with separate resources for funding research. The emphasis of the Directorate's support is for high quality science and technology in the university sector, which, while addressing basic problems, will also provide information from which industry would benefit in the short or long term. Its priority sectors listed below, Table 5, sensibly complement those of the BTU. Much of SERC supported research is also through the medium of club or collaborative activities.

To ensure that the UK does not miss out on some of the exciting work conducted at the AFRC and MRC research institutes, each research council has spawned a company, backed by city investment, which has exclusive

rights to certain areas of work conducted in their respective institutes. Celltech, which exploits much of the MRC monoclonal antibody developments is now the world leader in bulk monoclonal production. Agricultural Genetics Company, AGC, unlike Celltech, does not have its own laboratories, but acts in a venture capital role to ensure exploitation with industry of high calibre research in certain AFRC institutes.

***Table 5*. SERC biotechnology directorate, priority sectors.**
Process engineering
Bioconversions
Animal cell biotechnology
Plant cell culture
Whole plant biotechnology
Host-vector systems
Biosensors and bioelectronics
Protein engineering

Public Sector Funding of Biotechnology

Since the definition of biotechnology, as used by different funding bodies is variable, it is difficult to estimate precisely how funds have been allocated.

***Table 6*. Government R&D funding of biotechnology in the UK**	
Source	*Commitment £million*
Medical Research Council, MRC	27
Agricultural and Food Research Council, AFRC	21
Natural Environmental Research Council, NERC	1
Science and Engineering Research Council,, SERC	3
University Grants Committee, UGC	3*
Ministry of Agriculture, Fisheries and Foods, MAFF	4
Department of Trade and Industry, DTI	6
Other government departments	2
Total	67*
*UGC specifically allocated £3M for new biotechnology projects. A much larger level of funding benefits general funding of biotechnology as part of university R&D.	

The MRC distinguishes between work with a clear intent to produce something of commercial value and basic research, but classes it all as biotechnology. In contrast, SERC spending by the Biotechnology Directorate is included above, but the support to relevant bioscience research is far greater.

International Collaboration

The DTI is keen to encourage international collaboration in certain areas of biotechnology. The UK plays an active part in the EC Biotechnology Action Programme and would like to see this further developed, providing it involves industrial collaboration. Things should be better in the EC Framework Programme as there are agreed priority sectors, clear objectives for evaluation and a relationship between Framework and Eureka. Eureka's philosophy involves the exploitation of advanced technologies with a global sales potential best achieved collaboratively within Europe, where companies lead in identifying and conducting projects. Biotechnology has had until now a rather low profile in Eureka for a number of reasons. Within certain sectors such as pharmaceuticals, the notion of near market collaboration is countercultural, as the companies have a long tradition of self sufficiency. However DTI has come dose to stimulating collaboration in vaccine development. There could well be more potential for Eureka in the diagnostics area, where technology is changing at a prodigious pace and all European companies are threatened by US majors. A particularly important, but hidden, aspect of Eureka, relates to its value as a lever for regulatory change.

There is also scope for bilateral collaboration between companies in different countries. Examples include Celltech and the Japanese companies, Sumimoto Corporation and Sankyo, as well as Delta Biotechnology and the US company Stroh.

I have outlined UK collaborative programmes covering a wide range of biotechnological interests. The UK would be willing to internationalise these if other countries would make equal contributions. The areas identified as contenders for international involvement include protein engineering, the genetic manipulation of plants as well as the industrial use of agricultural surpluses. Equally we would be happy to consider other countries' suggestions and help to identify possible industrial participants for such collaboration, especially under Eureka.

Inward Investment

Many overseas companies are becoming interested in the UK as a centre for investment and R&D in biotechnology, not least because of its record of a commonsense approach to product regulation, and effective and predictable approval processes. US biotechnology companies have already

invested in manufacturing facilities for healthcare, biochemicals, biosensors and micropropagation. They have been attracted by the same combination of excellent manufacturing sites, strength in life science R&D, and high quality clinical trials that have made the UK the predominant European country for US pharmaceutical investment for many years. Examples are Welcome and Schering Plough who both recently obtained UK Government approval for the sale of α-interferon, a major event in the development of therapeutics through biotechnology.

The BTU works closely with the Invest in Britain Bureau to attract further investment. Seminars have been held in the USA, Japan and other Far Eastern countries to persuade companies in those countries that the UK is the natural focus for investment to meet the needs of the European market.

Conclusion

It is the belief in the UK that the prime motivator of biotechnology is industry, although this is complemented by a fair fiscal and regulatory regime. The country has a lively and successful biotechnology industry, with tariff free access to the European Market of over 400 million people. It is a centre for growth in which products can be developed and marketed quickly. It has a strong academic base and a large pool of highly trained manpower. With its regional investment grants and its highly developed private financial sector, the UK is one of the preferred locations for biotechnology.

There are numerous opportunities for improved international collaboration and the UK is ready to do its part in seeking parties for projects appropriate for collaborative research.

Postscript

Since January 1988 a change in DTI policy has transformed the focus of industrial support for technology, including biotechnology.

The emphasis is away from providing support to individual companies and now concentrates on exploitation of technology through collaboration. There are several ways in which the DTI, with other government Departments in some cases, will encourage and finance collaborative research:

LINK encourages companies to undertake joint, pre-competitive but industrially relevant research with the academic base. Biotechnology programmes have been agreed in eukaryotic genetic engineering (£4.7M/4 years), biotransformations (£4.0M/4 years), selective drug delivery and targeting (£3.0M/5 years) and food processing sciences (£14.0M/5 years), whilst a further programme of protein engineering is in the pipeline.

National collaborative/ general industrial reasearch programmes encourage collaboration between companies in precompetitive research outside the specific focus of LINK, and may or may not involve academics.

EUREKA encourages industrially led projects with EC or other European partners. These should both strengthen European technological capability in world markets and contribute to the completion of the Single European Market (1992)

Up to 50% government funding is available for all of these schemes.