BIOTECHNOLOGY IN THE UK

A SCENARIO FOR SUCCESS IN 2005

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EXECUTIVE SUMMARY

This report addresses the question**:**

What would 'success' look like in the field of biotechnology, in the UK, by 2005?

Success is defined here as maintaining and improving the commercial strength of UK-based organisations which develop, sell, or apply biotechnology for national and global markets, and therefore enhancing our relative economic progress. It also means the UK improving its attractiveness for companies of all nationalities as a place to site value-adding activities which are based around biotechnology. The purpose of having such a vision of success in biotechnology in 2005 is to set a 'stretch target' for all the stakeholders in this area; and to give those involved in the UK science base a better idea of how successful biotechnology activity would exert a strong 'pull' on the science base.

The report presents the result of a substantial research project, which culminated in a two day workshop in February 2000. At the workshop, which involved 20 individuals from biotechnology-based companies operating in the UK, from government agencies, and from the major public research bodies in the UK, a scenario for biotechnology in 2005 was developed. The scenario is seen as *attractive,* and *more* than just a continuation of current trends, but still *credible,* given prompt action by those concerned. Some key elements of the scenario are:

- A significant proportion of pharmaceutical innovations will be based on genomics and genetics, if not in the drugs themselves, then in the methods used to identify and develop and target them to responsive patients.
- Biotechnology applications in the food industry in the UK continue to be hampered by problems of public confidence but there will be new markets for some higher-value-added products (e.g. 'nutraceuticals' and biosensors).
- There are a number of non-controversial applications of genomics – in public health policy, in environmental remediation and traditional crop breeding.
- The NHS (as a market), NICE and the FSA become champions of biotechnology innovation.
- Active growth of quality dedicated biotechnology firms supported by more venture capital, large healthcare and agrifood firms and a strong science base.
- Harmonisation of the European patent system and a credible, transparent European-wide regulatory framework.

The economic consequences of the scenario are significant:

- The contribution of biotechnology-related impacts to the annual average rate of GDP growth will be approximately 0.2 percentage points per year.
- The UK pharmaceutical trade surplus, currently over £2billion, will double by 2005, with some of this attributable to biotechnology.

These changes imply major consequences for citizens, businesses and government. As scenario statements, they are based on painting a picture which is admittedly optimistic, but is also *realistic*. What remains is for businesses and policy makers to take some of the steps which are implied by the scenario, in order to achieve these targets.

1. INTRODUCTION

The UK is widely perceived to be already relatively successful in the economic performance of its fledgling biotechnology activity. We have significant numbers of specialist biotechnology start-up companies, and our major pharmaceutical companies are leaders in the development and application of the technology. Allied to this, our science base makes a major contribution to the underpinning knowledge base through activities such as the Human Genome Project. So amongst the key ingredients of UK success then, are a pre-existing strong pharmaceuticals sector, effective capital markets, and good universities.

But other countries are also busy assembling these ingredients. Indeed, it could truly be said that the biotechnology sector is the first science-intensive set of industrial activities which has been truly globalised ‘from birth’. The highly networked character of current biotechnology activity, coupled with the growing maturity of the IT systems which can facilitate distributed working, creates a very positive framework for a genuinely global division of labour in biotechnology R&D. This is already evident in the behaviour of firms in the USA and Europe. In the near future, countries with large populations, extensive arable land, constructive regulation, and significant scientifically skilled people may have comparative advantages in participating in this globalised division of labour.

Biotechnology is similar to Information and Communication Technology (ICT) in the sense that it creates many generic *technology platforms* that can change the possibilities for goods and services across a wide range of industries. We have seen this for ICT in telecommunications, entertainment, financial services, retailing and many other sectors. For biotechnology, the obvious targets are pharmaceuticals, diagnostics, agriculture, food, materials technology, environmental technology, sensors and so on. In terms of maturity however, the biotechnology ‘wave’ of structural change in advanced economies is still in its early stages by comparison with ICT. Most of the economic effects are concentrated on the supply side as the core science is unravelled and the key technologies are mastered. But relative investment levels in these activities now will have significant impacts on the relative abilities of countries to exploit the technologies in future decades as the ‘wave’ reaches a crest.

But like all emerging industries, the activities around biotechnology are fragile and susceptible to dramatic accelerations and setbacks as a result of the prevailing social, regulatory, and political climate. Current issues that exercise enormous influence over the prospects of the technology in the UK include:

- Transparent and trustworthy regulatory systems which build public confidence *but also* permit flexible and rapid commercial decision making
- Stable and effective intellectual property rights regimes which give incentives to companies but do not stifle the diffusion of knowledge
- Increased flexibility in the industry-academia interface to allow people and ideas to be moved into new configurations quickly
- A positive climate to favour the controlled application of the technology as well as the development of the science – allowing the development of ‘demand pull’ for biotechnology as well as ‘technology push’

National Governments face many challenges to their policy framework as a result of this evolving situation. How do fiscal, regulatory, industrial and social policies need to adapt to exploit the opportunities that biotechnology presents? This report, and the project from which it arises, is set in the context of all of these policy challenges.

But our particular focus is on the importance of strong systems and institutions in the UK for the creation and diffusion of the scientific and technological knowledge that is at the heart of the biotechnology contribution to the economy. One of the things we understand reasonably well about firms that are competitive in the development and use of biotechnology is that they are heavy users of the outputs of the publicly-funded *science base* in the countries in which they operate. These outputs include first and foremost skilled graduates, but also extend to research collaborations and all manner of industry-university interactions which get grouped together under the rubric of ‘technology transfer’. The UK is a small country that does 4% of the world’s research but produces 8% of the measurable scientific output. It is (in part at least) because of the quality of this science base, and in particular because of its degree of ‘connectedness’ to the international science base, that the UK can be an attractive location for firms to develop biotechnology and its applications. This is crucial in enabling the UK to participate in the wealth creation and quality-of-life benefits which biotechnology-related industries will create.

But as the biotechnology revolution unfolds, the established patterns of interaction between industry and the science base, even in this most science-intensive of sectors, cannot stand still. New fields of scientific and technological research demand new modes of interaction; new skills demand new styles of training and new types of enterprise have to establish collaboration patterns with the science base which may differ from those of ‘old manufacturing’ firms with their traditional corporate R&D laboratories.

In order for public policy towards research spending, the organisation of public research and the incentives for industry-university collaboration to evolve productively, we need a clearer vision of how the biotechnology components of the ‘new economy’ are taking shape. This report addresses this task by asking the following question:

- **What would ‘success’ look like in the field of Biotechnology, in the UK, by 2005?**

What do we mean by ‘success‘ in this context? The answer to this question was clearly stated at the outset of the work reported here: success is seen as maintaining and improving the commercial strength of UK-based organisations which develop, sell, or apply biotechnology knowledge, skills, or products for national and global markets, and therefore enhance our relative economic progress and the quality of life for UK citizens. It also means the UK improving its attractiveness for companies from all countries as a place to site value-adding activities that are based around biotechnology. This does not mean that we ignore issues of biotechnology and the nature of the social and political fabric of the UK, but simply that we emphasise the narrower economic definition of success.

Why would it be useful to have a vision of the ‘credible’ level of success to which the UK could aspire in 2005?

- Firstly, and most relevant to the OST who commissioned the work, is the fact that such a vision will give us a sense of what sort of *‘pull’* this level of industrial activity around biotechnology would exert on the science base, in terms of requirements for skills and knowledge based collaboration. Consequently this will be a helpful input to the planning and organisation of the science base over the next few years.

- Secondly, a short range vision of the UK’s future in biotechnology will have the benefit of providing a *common framework* for a wider range of players in industry, government, and the research institutions to shape their policies.

This report presents a ‘scenario’ for success in biotechnology in 2005, and the rationale for that scenario. A scenario is not a prediction or a forecast, so it is not simply an extrapolation of current trends, although it is informed by such considerations. A scenario is, rather, a picture of a set of interlocking pieces in a jig saw. Some of the pieces are firms, their technologies, their markets, and their local and global connections. Other pieces are judgements about the policy and regulatory environment, the actions of other countries, the rate of development of markets and so on. The scenario presented here is one which is seen as both *credible* in the sense that the ‘pieces fit together’ and *attractive* in the sense that it represents an *achievable* step forward in the UK’s share of the global wealth creation which is linked in some way to biotechnology.

Before setting out the scenario it is important to briefly outline the process which was used to generate it, and the people who took part.

DEVELOPING THE SCENARIO

During late 1999 and early 2000 a team of researchers at the ESRC-funded CRIC centre in Manchester co-ordinated the project. The main activities were the following.

1. In November 1999, a small but representative group of about 20 individuals was identified from biotechnology-based companies operating in the UK, from relevant government agencies, and from the major public research bodies in the UK. These people were ‘recruited’ to be the core members of a scenario-generating workshop to be held over 2 days in February 2000.
2. As preparation for the scenario generating workshop CRIC co-ordinated the preparation of the following ‘inputs’:

- A 90 page report on the current shape and size of biotechnology-producing and using industries in the UK, the trends in their growth and competitiveness, and their strengths and weaknesses. This was based on public data and on interviews with the people identified in point (1) above.
- Background papers on how biotechnology affects, and is affected by, such issues as: trends in lifestyles, globalisation of markets, policy toward social inclusion and exclusion, the environment, innovation etc.

- Three *sample scenarios* for the workshop which set the scene for debate, and which illustrated some *key relationships* in the economic and social structure of the UK which influence how the development and take-up of biotechnology products and services proceeds. These three scenarios defined to some extent the extremes of the plausible possibilities for 2005
- An analysis by Cambridge Econometrics Ltd. of how the various scenarios could be quantified in terms of their implications for GDP growth rates, employment, and inflation levels.
- An analysis of the particular features of the linkages between companies and the science base that are important in the biotechnology field.

At the scenario workshop, the participants (who had all received the above inputs beforehand) were presented with a short summary of the opening three scenarios[1]. For the remainder of the workshop, they went through a carefully designed process which broke the jig-saw down into its component pieces, and forced them to make choices about the most credible and desirable position for the UK in 2005, for each separate piece. These were then re-assembled into the ‘fourth scenario’ and refined through discussion, and quantified. This output was then further refined by CRIC into the version presented in this report.

The story told here then, is not a prediction, but it is a believable image of what success could be like in 2005. It has been produced by taking the available public information, the collective wisdom of some experienced participants in the industry and some relevant social science, and feeding these inputs into a short but intense process of synthesis. We believe it is a useful picture for orientating public and corporate policy discussions in this field.

[1] The participants are listed in the box on the facing page

WORKSHOP PARTICIPANTS

Mr Adrian Alsop	Deputy Director of Research, ESRC
Professor Ray Baker	Chief Executive, BBSRC
Dr Simon Bright	Manager, Director of Technology Interaction, Zeneca AgroChemicals
Ms Lindsey Colbourne	Projects in Partnership (facilitator)
Professor Rod Coombs	Director of CRIC, Manchester University and UMIST
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Dr Ken Green	Director of CROMTEC, Manchester School of Management, UMIST
Mr Richard Lewney	Managing Director, Cambridge Econometrics
Professor Gordon Marshall	Chief Executive, ESRC
Mr Andrew McMeekin	Research Fellow, CRIC, University of Manchester and UMIST
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Ms Helena Poldervaart	Projects in Partnership, (facilitator)
Mr Adrian Reed	Research Associate, CRIC, University of Manchester and UMIST
Mr John Robinson	Chairman, George Wimpey plc (Former Chairman, Smith & Nephew plc)
Dr John Sime	Chief Executive, BioIndustry Association
Dr John Taylor	Director General of Research Councils; Office of Science and Technology
Mr Philip Wright	Director, Office of Scientific and Education Affairs, Glaxo Wellcome plc
Mr R D Wylie	Wheb Partnership

2. THE 2005 SCENARIO AND ITS RATIONALE

The 'Success in 2005' scenario was developed at the workshop by the participants, working within a framework and background material provided by CRIC. The background material was compiled through reviewing publicly available reports and data, and through interviews with key members of the UK biotechnology system (see Biotechnology Background Report).

FIGURE 1: UK BIOTECHNOLOGY SYSTEM

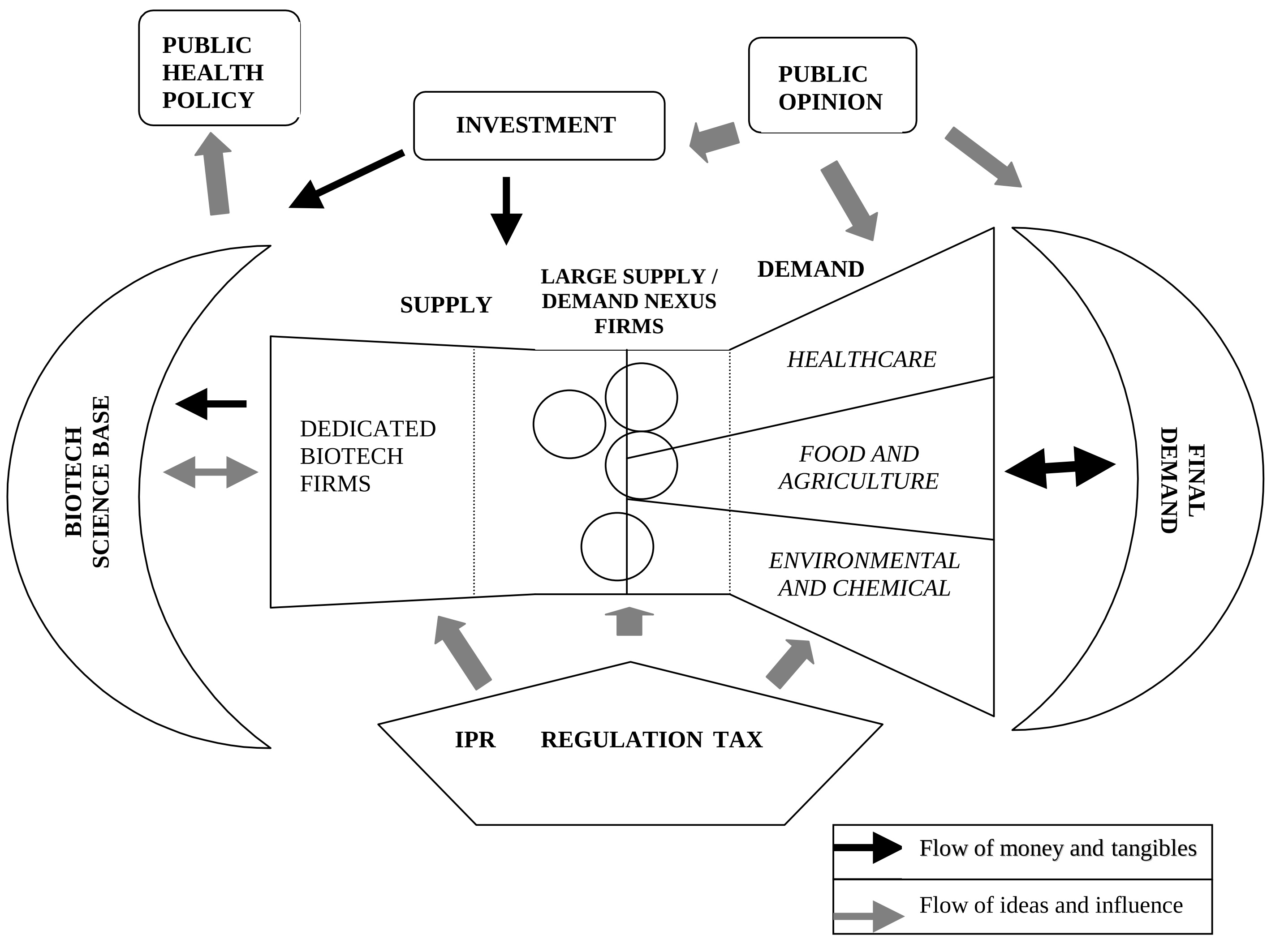


Figure 1 shows the UK biotechnology system, emphasising flows of money and 'tangibles' (goods, people) and flows of ideas and influence. It shows the (two-way) links between the Science Base, Dedicated Biotechnology Firms (DBFs), Large Firms in the Pharmaceutical/Health Care, Agriculture/Food, Chemical and Environmental

Processing industries and Final Demand (e.g. the NHS or final consumers of foods). Investment, in the form of venture capital or corporate venturing, feeds into the science base and into biotechnology firms. Tax regimes, intellectual property laws, and regulations concerned with biotechnology applications affect the whole system. Public Opinion (especially with respect to genetic modification of foods and to some health care technologies) is influential on Final Demand and Investment. The Biotechnology Science Base does not only contribute to the generation of new products and processes, but also provides rationales for new ideas in Public Policy in health and nutrition.

Our scenario is concerned with success in the UK; however, biotechnology has strong global interactions. Some of the institutions - in Investment (into the Public Science Base and into Small Firms) and Dedicated Biotechnology Firms tend to operate mainly at national levels. The Public Science Base, though nationally-funded and organised, exhibit strong international flows of knowledge and skilled people. Large Firms are however strongly globalised and, in its turn, Demand can be seen as operating through national markets satisfied by globally similar products. Regulation, though under national control, shows strong international interconnections with regulations broadly similar across the three regions.

The main elements of the current UK biotechnology system can be presented in two groups of four. (There are obviously overlaps between them and their separation is purely for analytical reasons). These elements (or ‘key choice areas) provided the framework for developing the scenarios. The first four consider the general impact of biotechnology on the primary application areas:

- Healthcare Industries including Pharmaceuticals
- Agriculture and Food
- Environment and Chemicals
- Public Health Policy

The second four are more UK specific, and involve the impact of UK infrastructure on biotechnology development:

- Public Opinion and Final Demand
- Industrial Ecology (the structure of the biotechnology industry, with regard to the numbers of and relationships between small and large firms).
- Investment and Management Skills
- Regulatory Infrastructure

By considering current issues in each of these ‘key choice areas’, it is possible to derive a number of trajectories that might be the drivers of future development. The potential combinations of trajectories are vast, and can be used to generate a large number of different scenarios. CRIC developed three sample scenarios to illustrate how certain combinations of trajectories can be aggregated to create specific ‘visions of the future’. The three scenarios were intentionally divergent, offering limits to the range of possibilities:

Scenario 1:' Things Get Better…Slowly: Pharming but not Farming!'**:** This scenario is an extrapolation of recent trends and is based on the assumption that there will be no major shocks to the UK biotechnology system. The scenario title suggests the continuing steady progress of biotechnology in healthcare industries (pharming), with little or no progress in biotechnology-based agriculture and food (farming).

Scenario 2: 'Stuck in the Pipeline'

This scenario represents a dystopian view of UK biotechnology in 2005, where there has been very little progress in any biotechnology application areas. The scenario title refers to the biotechnology innovation pipeline, suggesting that the science is progressing, but difficulties still persist with exploitation.

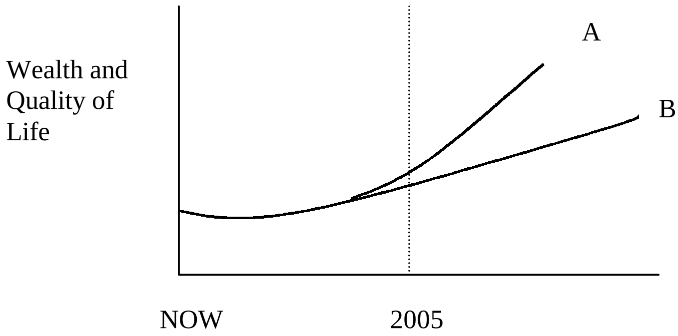
Scenario 3: 'Gene Genie'

This scenario offers a vision of the future where UK biotechnology is beginning to transform several sectors and, with appropriate regulatory structures in place, there is a public confidence in the use of the technologies.

The workshop participants used this material to consider where the UK can realistically aim in the ‘key choice areas’ and thereby construct a new scenario: ‘Genome Genie: Success in 2005’.

SCENARIO 4: 'Success in 2005: The Genome Genie'

This Scenario is the one that the Workshop thought both *credible* (given existing circumstances and appropriate policy actions) and *successful* (for biotechnology's contribution to wealth creation and quality of life). The main assumption is presented in the Figure below, which displays the application of technology (measured, for example, in sales) against time. It presents 2005 as a key 'change point'. A succession of small changes in the institutional arrangements for biotechnology by 2005 will make a big difference to the wealth-creating and quality-of-life increasing potential of biotechnology, lifting it from trajectory B to trajectory A. The difference will be due to the UK's ability to begin to exploit the knowledge of the genomes of plants and animals - especially the *human* genome - that is currently pouring out of the world science base in biotechnology: the Genome Genie would be out of the bottle!



The scenario is presented in two main sections – Industrial / Application *Sectors* within which biotechnology will be exploited and *Influences* on the development, exploitation and demand for biotechnology. Where possible, measurable *indicators* of what success might mean for biotechnology are presented.

The scenario contrasts the situation in 2000 with how it might be described in 2005.

2.1. Healthcare Technologies (Including Pharmaceuticals)

In 2000, the consolidation of global pharmaceutical firms has been continuing through mergers; over the last 10 years, the number of large 'UK-owned' firms has decreased from 5 to 2 (only AstraZeneca and GlaxoSmithkline will remain by the end of the year, and both firms' operational centres are now located overseas). Pharmaceutical firms continue to acquire and form technological alliances with Biopharm Dedicated Biotechnology Firms (DBFs).

Outsourcing of R&D, for example for the identification of new drug molecules and the testing of new drugs for toxicity, has been increasing (currently, approximately 20% of R&D is conducted outside the 'corporate envelope') and this is expected to continue. The development of new drugs is expensive and lengthy – it takes £300-500million over 15 years, on average, to do all the R&D and testing required by law before a new drug can be launched.

Over 200 biopharmaceuticals[2] are currently in development in UK DBFs. Thirteen were approved by the E.M.E.A. (European Agency for the Evaluation of Medicinal Products) in 1998. However, they have yet to make significant market impact globally. In the US however, recent launches of monoclonal antibodies have already exceeded combined sales of $1bn.

The Human Genome Programme is near completion (SNP[3] Consortium established). All firms in the health care sector - including pharma firms and those that make high-technology medical devices - are keen to utilise new pharmacogenetic[4] and genomic knowledge for new products.

In 2005*, there are key areas of exploitation that the UK is expert in, using a variety of biotechnologies, especially genomics. These are: therapeutic proteins, gene therapy, medical devices, monoclonal antibody-based and other diagnostics, and pharmacogenetics. The UK is also strong in the key enabling bioinformatic technologies.*

All pharmaceutical innovations are now in some way based on genomics, if not in the drugs themselves, then in the methods used to identify and develop them. Development time is decreasing, towards an average of 12 years (for leading edge firms, it is even shorter) due to more effective and efficient drug discovery and development through the use of genomics. But regulatory costs in other areas, especially for high-tech medical devices are rising.?

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[2] A Biopharmaceutical is a pharmaceutical product derived from the genetic engineering of micro-organisms (bacteria, yeasts, viruses and fungi), non-mammalian (insect) and mammalian cells or from transgenic plants and animals.

[3] A Single Nucleotide Polymorphism or SNP can be used as a 'landmark' or location marker for the position of a single gene or sequence of genes. In April 1999 a consortium of leading pharmaceutical companies and the Wellcome Trust was established with the intention of creating a public database of these SNP gene markers.

[4] Understanding the responses of individuals to existing medicines, or those already in the pipeline, and targeting medicines through 'medicine response profiles'.

Significant developments have taken place in biopharm markets and in R&D. Bio-pharmaceuticals and other biotechnology-based healthcare products are now 10-20% of total global health care product sales. Biotechnology-based health care R&D (including genomics) is more than 50% of total healthcare R&D that takes place in industry and academia.

There have been significant structural changes in the sector. The UK's strong science base in healthcare-related biotechnology is strongly facilitated by much increased interaction between small firms and large firm. The interaction takes place through mergers and acquisitions, joint ventures, licensing and corporate venturing. The NHS plays a crucial role in offering markets for new biotechnology-based healthcare products; this is stimulating the development of those products

Success has been based on the effective fusion of a number of disciplines (e.g. chemistry, biology, computing, epidemiology, and social science). Success has also depended on the ability of the global healthcare industry to respond effectively to public concerns over the possible problems with commercial exploitation of the human genome and the use of xenotransplantation technologies that raise objections concerning the use of animal species.

2.2 Agriculture And Food (Agrifood)

In 2000, the exploration of how biotechnology can contribute to the agriculture and food industries continues. However, new product launches have slowed down. This is largely due to public opposition in Europe to Genetically-Modified (GM) foods being sold to consumers.

This has led to a major reduction in the planting of GM crops in Europe. Even in the USA, where public opposition is much less, the acreage of GM crops is plateauing. However there is expansion elsewhere, especially in East Asia.

Consolidation amongst large firms that are developing biotechnology-based seeds (the agrifood firms) continues globally (e.g. AstraZeneca and Novartis are merging their agrifood businesses into a new firm, Syngenta). There is a thriving agrifood DBF sector in USA but it is less developed in the UK (and indeed in the wider EU).

In 2005*, biotechnology applications in the food industry in the UK continue to be hampered by problems of public confidence (especially in GMOs) but there is still potential for new markets for some higher-value-added products. Markets for foods which have some extra benefit are expanding, offering so-called 'nutraceutical' products which have an added health feature, such as those genetically modified to be rich in lycopenes or folic acid. World-wide, nutraceutical markets are valued at £3bn. Markets are also expanding for analytical instruments and systems, such as biosensors that detect the presence of proteins and biological contaminants in the food chain, from 'plough to plate'; the market is valued at about £300m. UK agrifood companies are in the forefront of the development and launch of these new products.*

There has been increased patent activity by UK firms in new agricultural crops for industrial feedstocks; this is an indicator of the early stages of exploitation, and suggests that the UK may benefit from a first mover advantage within the next 5 years. Fifty new Dedicated Biotechnology Firms have been established in Agrifood over the last 5 years, reflecting renewed venture capital investment due in part to the slow shift of public opinion.

Greater knowledge of plant (and animal) genomes has led to the development of new fertilizers and pesticides, targeted to particular plants and pests. In addition, genomics improved traditional methods of selective breeding, which are less subject to public objection than genetic modification.

Success has depended on improvements in global regulatory frameworks, with the main technology producer countries agreeing on ground rules for such things as labelling of foods and the ownership for Intellectual Property. In particular, developing country concerns over the appropriation of their genome resources has begun to be resolved.

2.3. Environment and Chemicals

In 2000, the use of 'old' (i.e. non-GM) biotech in environmental and chemical processing is already well established. It is estimated that 15-20% of global environmental market is biotech-based (about $250-300bn).

There has been a slower uptake of new biotech (mainly since GM applications are not necessarily cost-effective). The cost of bioremediation still higher than incineration and landfill in UK – but more competitive elsewhere.

Possibilities for the use of enzymes in industrial processing are emerging, but their impact so far has been low.

In 2005*, Biotechnology is much used in the chemical processing industry and for environmental remediation of waste streams.*

In chemicals, there is more investment interest in firms making, selling and using biotechnology-based products (especially enhanced enzyme systems) for chemical processing and for energy production.

In environmental waste treatment, biotechnology-based methods are essential to help meet EU targets for reductions in pollutants. The existing regulations on environmental pollution are being more rigorously enforced and more stringent accreditation standards are in place. This is stimulating sales of biotechnology-based environmental processing methods.

UK firms' share of global exports and market shares are rising above trend, due partly to large-scale EU aid for environmental clean-up in Eastern Europe. Sales of biosensors for environmental monitoring are up 10 fold.

Success has been due in part to more effective technology transfer between the public science base and industry.

2.4. Public Health Policy

In 2000, a 'rough draft' of the Human Genome is completed. The MRC initiates new epidemiological databases, which includes new genomic / genetic knowledge. Such explorations have marginal impact at present but their potential for improving health and nutrition policies is great. However, these initiatives will require informed consent from donors and participants, and public concern over the ethical issues of genetic screening is increasing.

In 2005*, advances in biotechnology have led to significant changes in spending patterns in health care provision and research. A mix of public and private funding has increased spending on medicines in the UK to £3-4bn. The health products industry's contribution to science base funding is now 15% and rising.*

The NHS is in the forefront in offering innovative treatments, which encourages the retention in the UK of large pharma and healthcare device firms. There is strong government leadership in diffusing best practice and in educating GPs about new biotechnology-based diagnostics and therapies. The National Institute for Clinical Excellence takes the lead as champion of innovative medicine.

Biotechnology developments offer new directions for public health policy. Four developments are increasingly important:

- *Pharmacogenetics – medicine response profiles to target medicines to those patients who will benefit.*

- *the use of self-diagnostics and screening has doubled and is part of the growing culture of early healthcare intervention.*

- *The greater use of internet-based health information is increasing public knowledge and awareness of health and health products.*

- *Genetic / Genomic-based knowledge, combined with social sciences, is offering new public policies on health promotion, nutrition and environmental sustainability to improve the health of the population and give economic benefit from reduced social gradients in ill health.*

2.5. Public Opinion and Final Demand

In 2000, a significant anti-GM food lobby has stopped sales of GM foods in the UK and slowed down the commercial growing of GM crops. The use of biotechnology in pharmaceuticals is relatively uncontroversial, but there are some public concerns over uses of animals and humans for sources of pharma products and other therapies. There are also some public concerns over the use of 'gene screening' by insurance companies and employers.

***In 2005**, growth of biotechnology markets continues worldwide in all biotechnology-based sectors, with UK firms increasing their global market share. Demand for such products in the UK domestic market has also been expanding*

The shift in final demand has been developing in tune with changing public perceptions of the positive benefits of biotechnology. Specifically:

- *New transparent UK/EU regulatory frameworks have been put in place and have increased public trust; debate in the UK over biotechnology (especially in agriculture and food) is taking more note of the balance that has to be struck between risks and benefits for all technologies.*

- *Public recognition of the benefits of biotechnology for developing countries has grown.*

- *Industry has been showing that biotechnology can have customer benefits by focusing on the products' benefits, rather than on the processes or the underlying technology platforms*

- *Nutritionally-enhanced foods are being positively marketed by leading supermarkets*

Success has been dependent on current UK concerns over biotechnology in agriculture and food not spreading to the uses of biotechnology in health care and environmental/chemical applications. This, in turn, has been due to the healthcare industry learning the lessons of the controversies surrounding GM foods; pro-biotechnology groups, especially those who have experienced its benefits (e.g. patients' groups), have been gaining a larger audience.

2.6. Industrial Ecology

In 2000, there are at least 270 'Dedicated Biotechnology Firms' in UK. The largest has a market capitalisation of £1.3bn. The top five UK DBFs would rank in top twenty US DBFs by market capitalisation. The majority of DBFs are small: seven-eighths have less than 100 employees. There is a bias in the UK towards pharmaceuticals, with more than twice as many Pharma DBFs as agrifood DBFs.

There has already been considerable consolidation amongst UK DBFs, the merging of Celltech, Chiroscience and Medeva being a highly visible example as it enters the FTSE100.

Large UK pharmaceutical and agrifood firms are merging and re-grouping.

***In 2005**, large firms exploiting the benefits of biotechnology are very active in the UK and UK-based large pharmaceutical companies have maintained their UK R&D*

operations. In addition, non-UK pharmaceutical companies are locating more of their R&D to the UK to access UK technology developments.

UK-based large Agrifood companies have maintained their R&D operations, growing their science activity, anticipating future product launches when regulatory issues have been fully resolved

Smaller firms are crucial to UK biotechnology developments and there are approximately 400 DBFs in total. Around 50% of the 270 DBFs that existed in 2000 have survived and are financially viable. Some DBFs have grown fast due to consolidation: there are now four in the FTSE 100. DBF employment has grown to 20,000 from 14,000 in the year 2000.[5]

The potential for cross-fertilisation across different scientific disciplines and industry sectors has led to increased interaction between firms in many sectors. Notably:

- *Big pharmaceutical companies have continued to establish strategic partnerships and licences with DBFs for new technological capabilities and commercialisation.*
- *The productive use of genomic knowledge is being facilitated by new bio-informatic DBFs (these are linked to new ICT developments).*
- *There is some intersectoral interaction, as firms span the health, food and agriculture boundaries; geographical clustering of new firms promotes these interactions.*

2.7. Investment and Management Skills

In 2000, DBFs have been facing difficulties attracting Venture Capital, due to lack of notable successes and competition from e-commerce start-ups. Venture Capital to the value of c£75 million was invested in DBFs, the majority of it in amounts of less than £2million. There are currently only 23 biopharmaceutical DBFs. Few DBFs are publicly quoted. There is an increase in overseas sites for investment (especially into Germany)

In 2005*, improved marketing and other management skills in biotechnology companies have ensured money is available for investment. Investor confidence has been fuelled by some big successes with biotechnology markets.*

There has been a move towards the US model in relation to risk taking and its culture of entrepreneurship and acceptance of failure. More favourable tax regimes in the UK, such as reductions in capital gains tax for owned businesses, have increased investment. This has brought about:

[5] These figures represent a compromise between those in the Workshop who thought that the number of DBFs would reach 500, and others who thought the number would remain below 300 but with a high turnover.

- *A threefold increase in Business Angel funding*

- *A doubling of investment by DBFs into the Science Base, concentrating in a few UK 'ivy league' research institutes*

- *A threefold increase in business experiments from academic research, with at least one in five succeeding into the growth phase due to the widespread use of best-practice 'technology transfer' mechanisms, such as incubators.*

DBFs are thriving so that there is a 50% survival rate (an indicator of innovation), employment has increased by over 50%, sales are up threefold and the tax take is up twofold.

2.8. Regulatory Infrastructure

In 2000, there are persistent concerns about the efficiency of regulatory frameworks, the protection offered to innovators by IPR and the impact of taxes.

The regulatory framework is slow for approving biotechnology-based agrifood products. And uncertainty surrounds two new regulatory agencies - NICE and FSA – who have yet to demonstrate their influence. The extent that the precautionary principle is applied in the E.U. might lead to a more risk averse culture than the US.

There are concerns that the current IPR system lacks clarity and consistency and that this might act as a disincentive to industrial innovation. There are, however, attempts to establish a European harmonisation in patent practice through a recent European Directive.

There are also concerns over tax disincentives for venture capital investment and differential national tax rates have an influence on location and investment of R&D and manufacturing.

In 2005, *There is a credible, transparent European-wide regulatory framework in place for AgriFood and for Pharmaceuticals; this is rebuilding public confidence in biotechnology, especially for AgriFood.*

All regulatory agencies have become more speedy and flexible in adapting to challenges from new technology; NICE and the Food Standards Agency are champions of innovation, not "4th hurdles". All regulatory requirements are clear from the outset of R&D.

There is a harmonised European patent system in place. Universities jointly manage IPR with partners within a flexible reward structure; this encourages exploitation of new biotechnology knowledge to the benefit of universities and new small firms.

The general business climate is more friendly to business, with lower taxes (e.g. lower Capital Gains and Corporation taxes, share options policy) especially for high-tech small firms.

3. THE ECONOMIC DIMENSIONS OF THE SCENARIO

(The analysis in this section was provided by Richard Lewney of Cambridge Econometrics Ltd)

In this 'target' scenario for Biotechnology in the UK in 2005, we have defined success in economic and commercial terms. So how successful is 'success'? What does it mean in terms of economic growth, jobs, balance of trade, prices and so on? In this final section of the report, we give some answers to these questions. The answers are based on taking recent trends, but not simply extrapolating them blindly. Instead, we have made the extrapolation taking into account the qualitative features of the 'success' scenario. This shows us what there is 'to play for' in the UK between now and 2005.

3.1 The distinction between production and diffusion

Public debate over whether or not the UK is 'succeeding' with regard to biotechnology covers such questions as:

- is the UK an attractive environment for the dynamic growth of dedicated biotechnology firms (DBFs) that can develop products and techniques to apply the advances in understanding of genetics and genomics?
- is the UK an attractive environment for the location of the R&D sites of the world's major pharmaceuticals firms, whose products will increasingly be based on biotechnology knowledge?
- how does the record of UK firms compare with that of other developed countries in the securing of international patents in the technology?
- are UK firms in other industries adapting rapidly to take advantage of the opportunities made possible by the development of products based on biotechnology knowledge?
- what kinds of products bringing what kinds of benefits might be enjoyed by the general population, notably in the area of improved health care?

The first three questions relate to success with regard to the *production* of goods and services that embody the new technology. In principle, the economic benefits that would follow from success in these areas could accrue regardless of the size of the UK market for them. Indeed, the UK market is typically only a modest contributor to the world market. The second two are questions that relate to success with regard to the *diffusion* of the products that embody the technology. In principle, the economic benefits that would follow from success in these areas could accrue regardless of whether or not the products are produced in the UK or entirely imported.

In analysing the economic impact of the technology, it is therefore important to be clear whether any particular effect is primarily concerned with production or diffusion. If UK success is to be measured by capturing a reasonable share of the world market for a fast-growing, technologically-advanced product, we are concerned with *production*. If UK success is to be measured by securing the benefits of lower production costs, increased productivity or taking advantage of the opportunities offered by a new product to underpin improved competitiveness in other activities, we are concerned with *diffusion*.

In practice, the application of biotechnology is still at such an early stage that attention is mainly focused on success in production. Those industries that stand to benefit most from its application are scarcely distinct from the biotechnology sector itself, and the 'using' industries still require very considerable biotechnology expertise to exploit the opportunities. This contrasts with older technologies where standardisation and specialisation have produced a greater distinction between producers and users and where the economic benefits that come from diffusion are typically larger than those in production.

3.2 How the contribution of biotechnology production to the overall economy is measured

The conventional measures for the direct contribution of production of any industry or group of industries to the economy are:

- value added
- employment
- exports, the trade balance and other balance of payments flows.

Value added measures the incomes generated in the UK from the production activities. These mainly comprise profits and wages and may accrue to UK residents or to residents abroad (i.e. profits may be repatriated in the case of plant owned by an inward investor). *Employment* measures the jobs supported in the UK by the production activities, the wages for which are paid out of value added. Together, value added divided by employment is a common measure of productivity, and high-productivity jobs are often also high-wage, high-skill jobs.

Another way in which production contributes to economic well-being is by earning foreign exchange which allows the UK to purchase imports. This contribution can be measured by *exports* of goods and services, but since globalisation is leading both exports and imports to rise in many industries it is usually sensible also to examine the *trade balance*, i.e. the difference between exports and imports. Finally, in R&D-intensive firms, where revenue is earned primarily not from current production but from royalty or licence payments for the use of technology that the firm has developed for use by others, the contribution to the balance of payments will appear as the export of a service. This is identified as 'royalties, licence fees etc', but the industry that originated the patented product is not distinguished in the official data.

Other, indirect ways in which biotechnology production might be regarded as contributing to the UK economy are through the demand which it creates for inputs produced by other industries ('backward-linkage effects') and the demand generated when biotechnology workers spend their wages. Such effects are typically examined in the case of a local economy in which a major plant opens or closes. However, for a reasonably large, open economy such as that of the UK it is in our view inappropriate to record such effects as attributable to the biotechnology industry, particularly because of the risk of double counting. In any case, the scale of biotechnology compared with the rest of the economy is still so small that such effects can be ignored.

3.3 Estimates of the contribution made to the economy by biotechnology production

Value added and employment

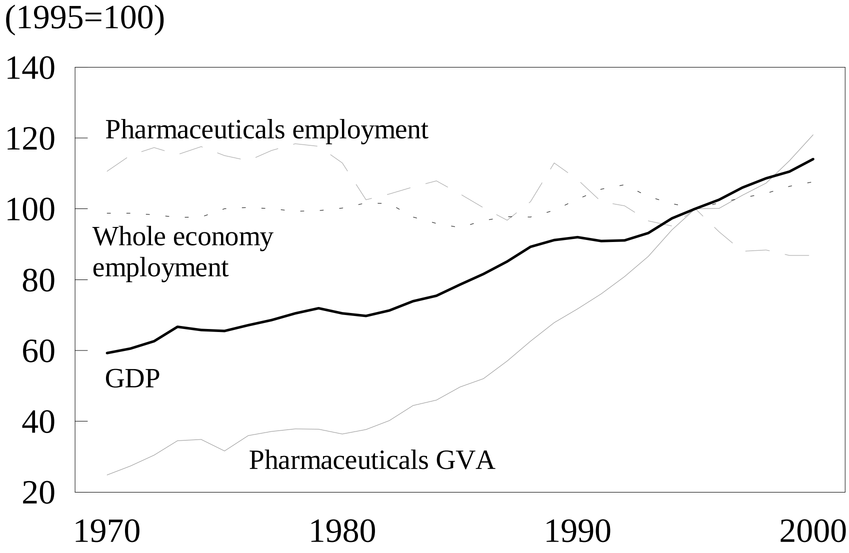
The biotechnology sector proper is not distinguished as a distinct industry in the Standard Industrial Classification. The background paper prepared by CRIC for the workshop estimated employment in the UK's DBFs at about 14,000, and suggested that there may be another 10,000 biotechnology workers outside of these firms. Together, this would amount to a little under 0.1% of the UK workforce. There are no data on value added, but, as a share of the UK total, the proportion will be higher than that for employment because the sector is characterised by high skill and high value added per worker. As a rough guide, value added per worker in the pharmaceuticals industry is about 3.5 times the level in the economy as a whole, and so biotechnology value added can be estimated at 0.3-0.5% of the UK total.

In the 2005 scenario, it is suggested that the DBF sector might double in size over 2000-05. This implies an annual rate of growth of about 15% and this, weighted by the sector's estimated share in UK GDP[6], would contribute about 0.06 percentage points to the overall annual GDP growth rate.

We could choose to include the whole of the pharmaceuticals sector within the ambit of biotechnology, on the grounds that biotechnology is now pervasive within the drug discovery process in pharmaceuticals, either directly or indirectly (even if drugs currently on or coming to the market have been much less affected). Following the same calculation, pharmaceuticals currently accounts for about 0.7% of GDP. Its annual average growth rate in the past two decades has generally been in the range 5-7% pa, and at the lower end of that range recently. If growth at the upper end of that range were achieved over 2000-05 this would contribute about 0.05 percentage points to the overall annual GDP growth rate.

[6] Strictly, gross value added at basic prices, which is the appropriate concept when comparing an industry's value added with the total for the economy as a whole.

OUTPUT AND EMPLOYMENT IN PHARMACEUTICALS



With regard to employment, pharmaceuticals accounts for about 0.2% of employment in the whole economy. Although the industry has seen strong growth in value added over the past two decades, this has been accompanied by strong growth in productivity, so employment has fallen, as the chart shows. Hence, even with quite strong growth in value added projected in the 2005 scenario, the sector is not likely to make much of a positive contribution to employment growth. On the other hand, employment is unlikely to fall as rapidly as in many other manufacturing industries, and the jobs provided are of a relatively high quality.

Trade and the balance of payments

Biotechnology is at such an early stage of development that its contribution to the export earnings and the balance of payments is still very small and, even by 2005, it is likely still to be small.

Pharmaceuticals is one of the UK's sectoral strengths, and this is reflected in its contribution to trade. Exports of pharmaceutical products currently amount to about £7bn, or just over 4% of the UK's total exports of goods in 1999, whereas the pharmaceuticals industry accounts for about 3.5% of manufacturing value added. More striking still, the industry achieves a trade surplus of over £2bn and this has been rising steadily.

In the 2005 scenario, we expect both exports and imports of pharmaceuticals to grow rapidly, reflecting the effects of specialisation and globalisation. A reasonable target for a successful outcome for the UK would be for the trade balance to double by 2005. However, not much of this could be attributed unambiguously to biotechnology because of the comparatively recent nature of the acceleration in the development of biotechnology knowledge and the long lead times involved in drugs development. But the continued long-term strength of the contribution of pharmaceuticals to the UK's trade balance clearly depends upon biotechnology knowledge.

3.4 How the contribution of biotechnology diffusion to the overall economy is measured

The contribution of biotechnology *diffusion* to improved economic well-being and performance is much more difficult to measure but takes essentially two forms:

- a boost to the performance of UK industries (including the public sector) for which the application of biotechnology knowledge could result in improved products
- a boost to the performance of UK industries (including the public sector) for which biotechnology-based products form a key input
- higher-quality goods and services for UK households

Improvements to industry performance resulting from improved products are likely to take a variety of forms, but should be evident in indicators of profitability and trade performance as leading-edge products are developed and brought to market. Improvements resulting from the availability of improved inputs could take the same form, or may take the form of cost reductions. In some cases, these reductions are measured relative to the costs of the next best alternative that would have to be used over the next five years, rather than relative to the present level of costs. This issue is taken up below.

The benefits to UK households are most apparent in the form of superior quality, for example in the quality of care available from the health sector, and the quality of food and drink products (nutraceuticals) that have been designed to have health-supporting properties. It seems likely that these will be higher-cost, higher quality products.

3.5 Estimates of the contribution made to the economy by biotechnology diffusion

Improvements to industry performance resulting from improved products

The following table identifies the industries that are most likely to benefit from the application of biotechnology knowledge to develop improved products up to 2005. The table excludes pharmaceuticals, whose contribution to GDP growth has been considered above.

Industries expected to benefit from application of biotechnology knowledge to improve products (excluding pharmaceuticals)	**Share of UK GDP[1] in 1999**
Agriculture	1.7
Food & drink	2.5
Fertilisers, insecticides, herbicides	0.2
Bioremediation	<0.1
Other health care products	<0.1
Health services[2]	6.9
Total	c 11.4
Total excluding health services	c 4.5

Note(s): 1 Shares of UK gross value added at basic prices.
2 The value added used to calculate the share includes social work.

On the assumption that GM crops will not be implemented on any significant scale by 2005, the impact on *agriculture* is assumed to be modest, taking the form of the application of biotechnology knowledge and techniques to improve conventional methods of selective breeding.

The main application in the *food & drink* industry (especially food) is expected to take the form of the development of a range of health-supporting products. While there would be some substitution of demand away from other food & drink products, the net effect is likely to be a higher level of (real) expenditure and output. However, plausible estimates of the maximum scale of such an increase (e.g. 10-15% spread over 5 years) imply an addition to the annual rate of overall GDP growth of no more than 0.05 percentage points.

In assessing the contribution of biotechnology to improved *health care* services, we include here the important contribution from improved drugs, although strictly these could be regarded as an improved input to health. We seek also to take account of the contribution of biotechnology knowledge to medical procedures, whether these be to improve diagnosis or to treat specific conditions (notably those that are associated with the patient's genetic profile). How this would, in practice, actually be represented in the economic data requires careful consideration. If a superior service is being provided, this ought in principle to be represented as a higher level of output. In practice, the improvement in quality of health services is unlikely to be well captured in the data and instead output measures will be driven mainly by expenditure, in this case government expenditure on the NHS. New or improved treatments for major conditions tend, eventually, to be made available under the NHS, but whether governments will allow the overall scale of health spending to be driven by technology is a matter of judgement. Our present assessment is that, over 2000-05, while health expenditure will rise quite rapidly, the part of this that should be attributed to the pressure arising from new applications of biotechnology knowledge will be small. If current government spending on health were to rise by, say, 3% pa over 2000-05, resulting in a similar rate of increase in the output of the health industry, the contribution to the annual rate of overall GDP growth would be 0.2 percentage points. When we take account of the fact that some new treatments will displace others currently in place, it seems unlikely that the contribution of biotechnology-driven expenditure would account for as much as a quarter of this.

The other industries may well see striking developments in specific applications, but given the small size of the industries relative to the overall economy it seems unlikely that the impact will register at the first decimal place for annual GDP growth over 2000-05. One specific area is the environmental clean-up market, in which costs are likely to rise over 2000-05 as higher standards are imposed, particularly if new technology increases the technical and economic feasibility of achieving such standards. But while this may represent an important market opportunity, the scale of this activity relative to the size of the overall economy again appears to be too small to have a significant effect on the average annual GDP growth rate.

Improvements to industry performance resulting from improved inputs

The following table identifies the industries that are most likely to benefit from the application of inputs made available by the application of biotechnology knowledge in the coming five years.

Industries expected to benefit from use of biotechnology-improved inputs	**Share of UK GDP[1] in 1999**
Agriculture	1.7
Energy-intensive, pollution-intensive industries[2]	2.2
Water and waste treatment	0.9

Note(s): 1 Shares of UK gross value added at basic prices.
2 Value added comprises paper and chemicals (excl pharmaceuticals)

Agriculture will benefit from improved inputs of fertilisers, insecticides and herbicides. These inputs account for about 13% (in 1995) of the total purchases of the agriculture sector and about 7.5% of the total value of agricultural output. Hence, even a dramatic improvement in the effectiveness of these inputs is unlikely to change greatly the growth prospects for agriculture as a whole. When this effect is weighted by agriculture's share in overall GDP, it is unlikely to be significant in terms of the average annual GDP growth rate.

Similar arguments apply with regard to the other two sectors noted in the table. Although biotechnology-based products may result in significant cost savings for particular processes, the scale of such inputs relative to the industry's other costs is small enough that their impact on the industries' overall growth is unlikely to be large.

Higher-cost, higher-quality goods and services for UK households

New products developed using biotechnology knowledge, or using key inputs that have been developed using biotechnology knowledge, are likely to improve the quality of goods available to UK households. To the extent that this is reflected in increased household expenditure on these products, the economic impact has already been counted in the earlier estimates of increased output of the producing industries.

However, it is worth noting here that some improvements to the *quality of life* of households are unlikely to be well captured in the economic data. This applies particularly to improvements associated with better health care. Attempts to place a value on these kind of quality-of-life improvements so as to compare the benefits with the delivery costs are controversial and we do not pursue this here. It would in any case be a major exercise even to identify the kind of improvements that might occur over the next five years. *However, the fact that they are difficult to measure does not mean that they can be ignored in any calculation of the economic impact of biotechnology.*

Conclusions

The conclusions from the quantitative analysis are that the contribution of biotechnology-related impacts to the annual average rate of GDP growth over the period 2000-05 seems unlikely to exceed 0.2 percentage points. This modest figure should not be interpreted as meaning that biotechnology is unimportant. Rather it reflects the present scale of production of biotechnology-related products: even quite rapid growth from such a small base has only a small impact on the whole economy. Nevertheless, since current UK GDP growth rate is 3%, the biotechnology contribution is considerable.

It seems likely that the importance of biotechnology will be greater in the longer term, after 2005, as the producing sectors grow in importance and as the technology becomes more pervasive. As globalisation of trade forces UK firms to specialise in knowledge-based products, biotechnology currently appears likely to be a key basis for such products. But the main impact is likely to be after 2005.