A NATIONAL BIOTECHNOLOGY STRATEGY

FOR

SOUTH AFRICA

June 2001

Executive summary

South Africa has a solid history of engagement with traditional biotechnology. It has produced one of the largest brewing companies in the world; it makes wines that compare with the best; it has created many new animal breeds and plant varieties, some of which are used commercially all over the world and it has competitive industries in the manufacture of dairy products such as cheese, yoghurt and maas and baker's yeast and other fermentation products.

However, South Africa has failed to extract value from the more recent advances in biotechnology, particularly over the last 25 years with the emergence of genetics and genomic sciences (the so-called 3rd generation). Already many companies and public institutions elsewhere in the world are offering products and services that have arisen from the new biotechnology. In the USA alone, there are 300 public biotechnology companies with a market capitalisation of $353 billion and an annual turnover of $22 billion p.a. Moreover, the growth of biotechnology industries is not restricted to the developed countries. Developing countries such as Cuba, Brazil and China have been quick to identify the potential benefits of the technology and have established measures both to develop such industries and to extract value where possible and relevant.

The strategy outlined in this document is designed to make up for lost ground and to stimulate the growth of similar activities in South Africa. Biotechnology can make an important contribution to our national priorities, particularly in the area of human health (including HIV/AIDS, malaria and TB), food security and environmental sustainability. In the pursuit of these priorities, we are fortunate in that we can be guided by the experiences of other countries. For instance, we know that to achieve success a country requires a government agency to champion biotechnology, to build human resources proactively, and to develop scientific and technological capabilities. In addition, successful commercialisation of public sector-supported research and development (R&D) requires strong linkages between institutions within the National System of Innovation and a vibrant culture of innovation and entrepreneurship, assisted by incubators, supply-side measures and other supporting programmes and institutions.

Some of these components of a successful biotechnology sector are already in place in South Africa. However, a number of gaps are identified in this document and certain interventions are suggested to address these problems. The recommendations are divided into two categories, namely new institutional arrangements and specific actions for Government departments. In the case of the former, the Panel has recommended the establishment of a Biotechnology Advisory Committee (BAC), under the auspices of the Cabinet's Economics Cluster, the responsibilities of which will include the implementation of this strategy, co-ordination of biotechnology R&D and alignment with national priorities.

A key component of the strategy is the creation of several regional innovation centres (RICs) to act as nuclei for the development of biotechnology platforms, from which a range of businesses offering new products and services can be developed. The RICs will be required to work in close collaboration with academia and business in order for the centres to become active nodes for the growth of the biotechnology sector. Using both existing funds and new allocations specifically designated for biotechnology, and employing well-trained scientists, engineers and technologists in a multi-disciplinary environment, the centres will stimulate the creation of new intellectual property (IP). The successful protection and exploitation of this IP will be made possible by a new venture capital fund and an array of new and existing support structures. It is emphasised that the main focus of the RICs will be the creation of economic growth and employment through innovation.

A number of recommendations are made to Government, including support, both financial and at a policy level, for the formation of the BAC, which will be responsible for the implementation of this strategy. The proposed actions will require an annual budget of R182 million, of which R135 million is required for the funding of the RICs and the associated R&D programmes, R20 million for the venture capital fund, R25 million for additional funding to strengthen the link between academia and industry and R2 million to run the BAC, plus a once-off establishment cost of R45 million for the RICs. This document also urges the Government to complete a number of important revisions to the legislative and regulatory environment, including the extension of the activities of the Bioethics Committee and the revision of the Patents Act, in order for the strategy to be successful.

Finally, careful attention must be given to the development of the appropriate human resources and to the public understanding of biotechnology. It is Government's responsibility to ensure that new biotechnology products or services do not threaten the environment or human life, or undermine ethics and human rights. Several actions to meet these responsibilities are proposed in this document.

Foreword

The first century of the new millennium will belong not only to communications, or information technologies, but also to biotechnology, which will bring unprecedented advances in human and animal health, agriculture and food production, manufacturing and sustainable environmental management.

To embrace biotechnology is to further embrace our commitment to the realisation of our national imperatives and specifically:

- To improve access to and affordability of health care.
- To provide sufficient nutrition at low cost.
- To create jobs in manufacturing.
- To protect and cherish our rich environment.

To achieve our objectives, we will be required to assimilate biotechnology skills rapidly in order to commercialise country-specific applications and reduce the economic gap between developed and developing countries.

Without doubt, we will need to exercise caution and judgement in the application of biotechnology.

We will need to ensure that the potential risks to human health and the environment arising from the commercial use of genetically modified organisms in food production are properly managed.

We will need to continuously assess our biotechnology programmes within the framework of the constitution, which ensures our rights to safety, to choice and to information.

We will need to establish suitable regulatory systems in order to participate as exporters and importers in the international trade in biotechnology products.

We will need to increase the level of public awareness and acceptance of these products.

In many respects we are fortunate: new advances in biotechnology promise to make the path of progress a great deal easier and shorter. We stand at the crossroads and our response to this opportunity will shape our future.

Minister of Arts, Culture, Science and Technology, Dr Ben Ngubane
11 June 2001

Dr R Adam, the Director-General of Arts, Culture, Science and Technology wishes to express his gratitude to the drafting team

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Table of contents

List of figures

List of tables

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Chapter 1: Introduction

1.1 The nature of biotechnology

Biotechnology is a body of techniques that use biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use.[1] Biotechnology has developed through three major phases. The first generation largely involves the use of selected biological organisms to produce food and drink (such as cheese, beer, and yeast). The main cluster of techniques in this generation is fermentation, plant and animal breeding and the clonal propagation of plants.

The second generation is the use of pure cell or tissue culture to yield new products. This generation is associated with the production of metabolites such as antibiotics, enzymes and vitamins. Major developments in this generation include the exploitation of a growing body of scientific knowledge relating to the properties and characteristics of microorganisms such as fungi and bacteria. A characteristic of this generation is that mutagenesis and the selection of strains and cultivars are used to improve metabolite and crop yields.

The third generation, modern biotechnology, is associated with recombinant DNA technology. It involves the "application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles".[2] Industrial applications can be found in pharmaceuticals, agriculture, specialty chemicals, bioremediation and cleaner production methods. The earliest applications in pharmaceuticals targeted the production of proteins such as insulin, diagnostics and vaccines for viral and bacterial diseases. In agriculture the application of recombinant DNA technology has focused on the genetic improvement of crops.

It is noted that all biotechnology practitioners use third-generation techniques, regardless of whether their core processes are first, second or third generation. Consequently, an important, but not exclusive, strategic focus in biotechnology is to

[1] UNEP, 1992. *Convention on Biological Diversity*, Article 2. United Nations Environment Programme.

stimulate the development and application of such techniques as a means of providing a source of innovation and competitive advantage for the biotechnology industry as a whole[3].

Biotechnology is characterised by a number of unique conditions. Firstly, it is a *cross-cutting* technology. It is subject to wide application, across sectors and biological boundaries. A technique developed for and applied in human health can be used in agriculture and *vice versa*. Therefore the management of economic production can be organised in such a way as to benefit from this 'cross-fertilisation' feature of biotechnology. Isolated research and development (R&D) activities organised around traditional sectors (agriculture, health, industry and the environment) are likely to deny a country the opportunity to exploit pervasive aspects of the technology.

Secondly, the biotechnology industry is also a *research-intensive* industry. Compared with other major industries, such as the chemicals industry, which has an average research intensity[4] of about 5% of revenue on R&D, or even the pharmaceuticals industry, which has an average research intensity of 13%, biotechnology companies spend between 40% and 50% of revenue on R&D. Historically, it was the interests and enthusiasm of individual scientists and scientific institutions that led to the establishment of the biotechnology industry, sometimes in the absence of market-pull. This close relationship between universities or research institutions and the new biotechnology industry remains today. Diversifying and moving to a competitive edge in the technology are based largely on measures that stimulate the emergence and growth of R&D-intensive companies.

Thirdly, the development and application of biotechnology requires a convergence of skills from a variety of disciplines. It requires appropriate combinations of biochemistry, genetics, information technology, engineering and several other expertises. It is thus a *multi-disciplinary* field.

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[2] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Article 3.
[3] See Appendix 1, The Competitive Needs of Modern Biotechnology.
[4] Research intensity is the ratio of R&D expenditure to revenue.

Finally, the industrial application of biotechnology requires the acquisition of strong scientific and engineering capabilities, and the deployment of new knowledge in production processes. This has necessitated the establishment of links or partnerships between science, engineering and technology institutions (SETIs) and private companies. Biotechnology is thus a *highly-networked* endeavour.

Biotechnology in focus

Biotechnology is not new. It has been used for many centuries in agriculture and manufacturing to produce food, chemicals, beverages and many other products that have been of benefit in many areas including nutrition and health care. Examples of the 'old' technologies include fermentation (such as in the production of rum from molasses or beer from malt) and plant propagation and breeding (to create new hybrids that have improved yields).

However, there is a 'new' biotechnology which has emerged in the last 25 years and which has been built on new knowledge areas such as genomics and proteomics. This knowledge enables a far greater understanding of the role of genes in biological systems. In particular, it has allowed geneticists to move genetic material from one life form to another in a way that was not previously possible and more recently, to change even the function of a single cell in an organism (from, say, a stem cell to a kidney cell).

The ability to transfer genetic material is not in itself new. During traditional plant breeding, genes are mixed randomly between parents that may themselves be of different species. In the case of the more extreme interspecific plant hybridisations these crosses would not be possible in nature, but require sophisticated tissue culture techniques. Plant breeders have for many years also used mutagens to modify the genes in agricultural and crop plants in order to obtain desired traits. However, 'new' biotechnology has multiplied many times the range of biotechnology products and the speed with which it is possible to obtain such products. New biotechnology has also increased our understanding of living systems in a way that was previously inconceivable. We can now identify the genetic basis of many diseases and develop drugs to counteract the action of many pathogens.

The transfer of genetic material has caused concern among members of the public who fear that by breaking the species barrier (referred to as horizontal gene transfer) unknown and potentially harmful genetic changes could occur. Biotechnologists are involved in a number of projects to assess the potential risk of such an event and its implications for our environmental safety. For instance, it is already known that horizontal gene transfer is more efficient between some organisms, and can quickly rearrange their genetic material in totally unpredictable ways. In other cases gene transfer happens very slowly, indeed at a rate that is too small to observe except over hundreds of years.

Already human health has benefited significantly from advances in the new biotechnology. More than 50 drugs have been commercialised in the past decade addressing illnesses such as cancer, arthritis and heart disease. Vaccines and hormones that were initially extracted from animal tissues are now produced in genetically modified bacterial and animal cells (for example, insulin and the Hepatitis B vaccine).

Clearly, the potential of biotechnology to improve the quality of our lives and the quality of our environment is considerable. It could bring huge advances in health, nutrition and remediation of the environment, to name but a few. In the realisation of these benefits we will have to be judicious and selective, avoiding those technologies which challenge our ethical value systems (such as human cloning) and focusing instead on those which can provide significant advances with the minimum risk. In the process, it will be important to continuously engage with and inform public understanding of the work of biotechnologists, in order to avoid misunderstanding and to ensure public support.

Biotechnology poses a number of unique challenges for politicians, scientists, policy makers and members of the public; sustainable progress will be possible only with the active collaboration of all these role players.

1.2 Why a national strategy?

"The most startling innovation will occur at the confluences of these three profound scientific currents (quantum mechanics, information technology and biotechnology). If we want to be a competitive country and indeed a competitive continent, we need to ride these waves and to know as best we can where they are taking us." (Rob Adam, Chair of the National Research and Technology Foresight Board)

The White Paper on Science and Technology considers science and technology to be central to creating wealth and improving the quality of life in contemporary society. Furthermore, the South African Government recognises its responsibility for creating an enabling environment for innovation, specifically as a means of achieving the national imperatives of reducing the impact of HIV/AIDS, job creation, rural development, urban renewal, crime prevention, human resource development and regional integration. It is believed that biotechnology can play a major role in addressing these imperatives.

The National Research and Technology Foresight (NRTF) exercise and the review of SETIs recognised that developments in bioscience are driving an economic revolution that could shape the future of human development. The NRTF findings indicated that there is a decline in the resource-based economic activity such as mining, primary agriculture and traditional manufacturing. The study also indicated that the developments in information technology and biotechnology would be the cornerstone of the knowledge-based economy. The wealth of the biological diversity in South Africa was also identified as a focal point for growth.

The SETI report highlighted the need for the development of biotechnology in all three of the major science councils (MRC, ARC and CSIR) representing the disciplines of health, agriculture, environment and industry. The report considered the development of these institutions necessary for them to retain their competitive edge and remain institutions of global standing.

The major benefits of biotechnology to economic growth and quality of life have to be balanced by considerations of environmental, health and socio-economic impact of the technology. The Departments of Agriculture and Health face the task of introducing the technology and, more specifically, genetically modified organisms (GMOs) in a manner consistent with the theme of economic growth within the context of environmental sustainability. Similarly, the Department of Environmental Affairs and Tourism is challenged to implement the Protocol on Biosafety and the Convention on Biological Diversity.

The Government is therefore faced with the challenge of creating jobs and economic growth without impacting negatively on human health and the environment and it has given an expert group the task of providing a strategy to achieve the twin objectives.

1.3 Methodology and scope

Following a Government request for a biotechnology strategy, an interdepartmental steering committee was established to define and then manage a process for the preparation of such a document. The committee consisted of representatives of the Departments of Arts, Culture, Science and Technology (lead department), Trade and Industry, Agriculture, Health, and Environmental Affairs and Tourism. In the first instance, the committee called for nominations to an expert panel which would be responsible for the detailed compilation of the strategy. The panel was duly appointed by the Director-General of Arts, Culture, Science and Technology.

The expert panel assembled in early May 2001 and over a period of 10 days it prepared the draft document, guided by the terms of reference (see Appendix 2) provided by the steering committee and the following principles:

- Consultation with interested parties.
- Awareness of, and building on, previous similar or related initiatives in the Government or civil society.
- Consensus within the panel.

In terms of its activities, the panel:

- Agreed on the definition of biotechnology (see below) for this document.
- Reviewed all existing legislation and background information provided by the steering committee and other players in the biotechnology arena.
- Conducted more than 30 interviews (see Appendix 3) with key stakeholders, including representatives of universities, science councils, industry, industry associations, consumer bodies and NGOs (the contents of both the background material and the interviews were recorded and used as important source material for this document).
- Considered all funding regimes that promote biotechnology developments, private sector engagements in the field, state and private sector support for biotechnology business ventures, institutional infrastructure for the development of biotechnology capacity, human resources and skills development in biotechnology, and the ethical and social issues arising from biotechnology research.

Biotechnology is a set of technologies including, but not confined to, tissue culture and recombinant DNA techniques, bioinformatics and genomics, proteomics and structural biology, and all other techniques employed for the genetic modification of living organisms, used to exploit and modify living organisms so as to produce new intellectual property, tools, goods, products and services.

1.4 Structure of the report

The report is divided into three main sections, reflecting its primary objective, namely that it should be a strategic document and should clearly indicate the steps or actions to be taken by the Government and other players, for biotechnology to have a positive socio-economic impact.

In Chapter 2 an overview of the status of biotechnology in South Africa, as seen in the context of global developments and opportunities for developing countries, is provided. In Chapter 3 a more detailed analysis and identification of key problems and issues is presented. In Chapter 4 these issues are addressed by proposing a number of strategic objectives and interventions. The main recommendations of the report are summarised in Chapter 5.

It is noted that the strategy is aimed primarily at Government and its associated institutions, including all public-sector funding and performing agencies. As a result, the material in each section is divided into those categories that are the primary means by which Government can influence the development of biotechnology. These include the legal framework, the funding mechanisms, the creation of new infrastructure and institutional arrangements and the construction of research capacity through appropriate human resource development. In each of these fields, Government has a number of instruments with which to achieve certain outcomes and this report clearly indicates both the desired outcomes and the interventions by which such outcomes can be achieved.

Chapter 2: The socio-economic and international context for biotechnology in South Africa

2.1 The economic, environmental and socio-political context

Since our first democratic elections South Africa has had to deal simultaneously with a number of challenges and opportunities. We have undertaken the transformation of a divided society and we have opened our economy to global competition. The rapidly unfolding global agenda has provided opportunities for direct foreign investment and technology transfer, but has at the same time, introduced challenges associated with open markets and trade barriers. We also find that our fortunes and development trajectories are fully embedded in the African continent.

In addition to our current transformation, we also have to face a transition from an industrial society to one that is knowledge-based. During the industrial revolution, technological development and industries emerged. The main elements of these developments included energy, chemicals, manufacturing and communications. Now, in the knowledge society, ICT is more prominent. The current impact of ICT on the shaping of economic activity is such that fears have been expressed about comparisons between the "wired" and "non-wired" countries of the world. It is possible that an echelon of highly mobile knowledge workers who share a global work ethic and perhaps even "global" values will overlay large numbers of marginalised peoples. However, technology r, does not stand still and many developing countries may be able to seize opportunities that these technologies present and be able to "leapfrog" into the future.

South Africa has the largest economy on the African continent, accounting for 25% of Africa's GDP. Although the economy is moving towards becoming a service economy and the share of the GDP from agriculture has fallen, this sector still represents some 4 to 5 % of the GDP. Although South Africa is a net importer of technology and is generally successful as a technology adapter and extender, it is important for the economic growth of the country to develop and enhance new competencies. Biotechnology in the fields of agriculture, health care and industry is poised to play such a role in the South African economy.

In addition, South Africa is now an active member of the Organisation of African Unity and often plays a leading role in various science and technology-related agreements. For instance, South Africa is one of the few countries in Africa that has commercial production of GM crops (albeit on a much lower scale than China, the USA, Canada and Australia). It is likely that South Africa's relations with Africa will become more influential in many fields of endeavour. Biotechnology could play an important part in this African globalisation, with South Africa as a leader and the centre for training and innovation. For example, together with UNESCO's Biotechnology Action Council, the ARC has established a Biotechnology Education and Training Centre for Africa at its facility near Pretoria.

2.2 Lessons from the rest of the world

There are a variety of lessons that South Africa can learn from the organisation and management of biotechnology in other countries, particularly developing countries such as Cuba, Brazil, Argentina, Thailand and China, which have made significant strides in the development and commercialisation of biotechnology over the past two decades.

2.2.1 Brazil

Brazil is emerging as one of the developing country leaders in biotechnology because of its deliberate strategy of targeting those areas that are of national economic priority (see box) and organising its R&D activities in such a way as to exploit scientific expertise and technical infrastructure across the institutional landscape. It has also created a national biotechnology focal centre that spearheads R&D.

A significant contribution to the understanding of citrus crop diseases and cancer has resulted from focused funding of genomic sequencing in Brazil. The FAPEPS genome project has been recognised internationally for its contribution to the understanding and development of interventions into cancer and crop pests. Brazil now has a world-class capacity to address local problems, such as the unusually high incidence of head and neck cancer and specific pathogens that are of local interest to farmers.

The *Oswaldo Cruz Foundation (FIOCRUZ)* was a national public agency conducting research and training in medical biotechnology, but has since extended its activities to agricultural biotechnology as well. Its research focuses on the application of molecular biology and the development of vaccines for diseases such as tuberculosis. It has generated a number of recombinant vaccines and diagnostic kits. The Foundation holds at least two patents for diagnostic kits for hepatitis B and rubella.

2.2.2 Nigeria

Nigeria is one of the African countries that has embarked on a determined programme to exploit biotechnology for the benefit of its peoples and to ensure that Nigeria becomes a key participant in the international biotechnology arena within the next decade. The Federal Executive Council (Cabinet) has approved the Biotechnology Policy and Programme of Action (Strategy), which places strong emphasis on the food and agriculture, health and environmental sectors and bioresource development.

Strategy implementation will be achieved with a multilevelled arrangement of institutions, consisting of the following:

- The Minister's Council, responsible for policy formulation and consisting of relevant ministries.
- The Technical Committee, consisting of professionals to be drawn from the ministries, R & D/ academic communities, the organised private sector and other stakeholders.
- The National Biotechnology Development Agency, which is to provide the platform for networking (both local and international), co-ordination, awareness creation, R&D management and biotech entrepreneurship development.

R&D will be done by specific institutions/universities, with the agency ensuring that specific research targets are met. The programme has the following components:

- Biotechnology entrepreneurship.
- Bioresources development.
- Capacity-building in human resources and infrastructure.
- Networking (Nigeria is one of the few African countries that have joined the International Centre for Genetic Engineering and Biotechnology (ICGEB), an organisation that promotes the transfer of technology between countries).

The Federal Government is providing the National Biotechnology Development Agency with US$263 million per annum for three years as a take-off grant to fund the executive programmes in agriculture, health, industry, environment and human resource development.

2.2.3 Cuba

Cuba is a developing country that has made significant strides in biotechnology. With 35 national research institutes dedicated to health-related biotechnology and 25 agricultural centres, the country has generated a variety of biomedical and agricultural products. It now produces the world's only successful anti-meningococcal vaccine, which is patented worldwide. Other successful vaccines include those for hepatitis B and cholera. One of the important factors is that the various components of the Cuban biotechnology industry are inextricably linked. New products are developed at various specialized research centers transferred to other centres for animal testing and clinical trials. Once this has been completed, large-scale production takes place at dedicated facilities established especially for this purpose. An important feature is therefore the close interaction between these centres.

It is estimated that Cuba has invested more than US$1000 million in its biotechnology research centres alone. Cuba did not invest in biotechnology *per se*, but invested in projects to utilise biotechnology to solve the problems of the nation (e.g. meningitis, and hepatitis). Initially knowledge was simply imported or assimilated in order to speed up it's own biotechnology industry, allowing time for the acquisition and development of and new skills and technologies.

2.2.4 USA

We can also learn from developed countries such as the USA that has the largest and most profitable biotechnology industry, consisting of more than 1,300 companies, with combined revenues of over $22 billion and employing 162,000 people. Of the top 15 Nasdaq-listed companies that have produced returns in excess of 3 000% over the last five years, four are biotechnology companies. Over the two years from July 1998 to June 2000 the USA industry raised a total of $2.9 billion in initial public offerings (IPOs), $10.8 billion in re-offerings and a further $3.1 billion in venture stage financing, and over the past ten years brought more than 50 new drugs onto the market.

The extraordinary success and growth rate of the USA biotechnology sector is the result of many factors that are most easily considered within a framework of the production, protection and exploitation of intellectual property.

Production

- Well-funded public sector biotechnology related R&D. In the USApublic sector health and medical R&D amounts to R211 per capita, compared with South Africa's expenditure of R3 per capita. It is very unlikely that world-class biotechnology companies will emerge in the absence of world-class public research.
- A research environment allows high risk, long term projects and in which the consequences of failure are limited.
- An academic domain which is multidisciplinary and well adapted to the rapid absorption of new technologies and knowledge. The tertiary educational institutions are fundamental to the provision of both the skills and the research outputs that form both the capacity and content of those companies that are subsequently formed to develop commercial products or services

Protection

- The passing of legislation whereby the universities retained the intellectual property rights to work financed by public funds and were encouraged to enter into agreements with industry to exploit such rights (the Bayh Dole Act). The benefits to the inventor, as opposed to the universities, are unique to each institution and are covered in agreements between the inventor and the university.
- The decision by the USA Patent Office to allow the patenting of new life forms, so long as these are non-human andnon-naturally occurring, and have a proven utility. This decision encouraged the early development of biotechnology industries in the USA and attracted biotechnology expertise from the EU, where such patents were not initially allowed. In recent years

the EU has moved to align itself with the USA position, and issued a directive to all member countries in this regard.

Exploitation

- A close relationship between the academic domain and the commercial or market-facing domain. In particular, academics must have ready access to business skills and financial and legal support. Such services are typically to be found in the incubators closely associated with biology departments and institutions.
- A sophisticated and extensive venture capital market, investing in the early start-up phase of new biotechnology companies. It is not just good ideas that lead to new and profitable companies; often large amounts of private equity or venture funding are required to take start ups from initial concept development, through proof of concept, and finally to product launch and market development.
- A well-educated cadre of entrepreneurial managers who can form the management team of the new companies and can supply the skills, energy and commitment to drive their companies through adversity to success.
- An environment with strong linkages between institutions and companies providing a range of services. This is especially necessary in the area of drug discovery, since many of the new biopharmaceutical companies are not fully integrated and rely on other players for much of the expertise required to commercialise a potential product.

2.2.5 Australia

Although Australia has a much smaller population than the USA, it has produced on a per capita basis, almost double the number of biotechnology companies (160 public companies, 20 of which are listed). The total biotechnology sector generates annual revenue of roughly R4 billion, 70% of which is generated by listed companies. 40% of the sector's sales is exported.

The Australian Government spends roughly one billion rand a year on biotechnology research. Most of this money is spent through the universities, followed by the CSIRO, the National Health and Medical Research Council (NH&MRC) and the Australian Research Council. In the 1999/2000 Budget, the Government increased its allocation to the NH&MRC, doubling the Council's budget over the next five years. This was in response to the recommendations of the Health and Medical Research Strategic Review (the "Wills Review"), which noted that Australian public funding for Health and Medical R&D was low by international standards (USA R211 per capita; Australia R76 per capita, South Africa R3 per capita).

Finally the lessons from Australia point to the importance of securing a number of sources for the funding of biotechnology companies (see Figure 1), including the growing presence of donors.

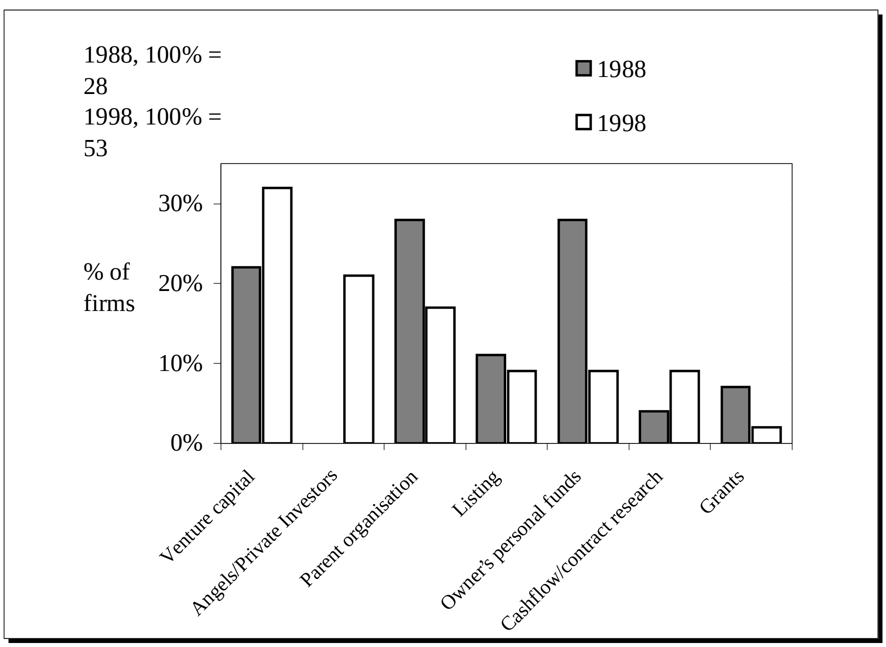

Figure 1. Sources of funding for Australian biotechnology companies

2.2.6 Conclusions

In conclusion, the lessons that South Africa could learn from the management of biotechnology activities in other countries are:

- To achieve coherence and maximise the use of scientific capabilities and to exploit the pervasive features of biotechnology, a country requires a body to champion biotechnology. Those countries that have been able to move up the technology ladder and to draw economic benefits from biotechnology are ones that have established well-funded and staffed agencies dedicated to biotechnology.
- The need to make deliberate efforts to build scientific and technological capabilities (with the emphasis on human resource development). It is important to allocate a large portion of biotechnology R&D to the acquisition of state-of-the-art equipment and related scientific information.
- Investment in biotechnology R&D must be based on an explicit national goal of generating products and processes and commercialising these on domestic and international markets.

2.3 A brief survey of biotechnology in South Africa

Biotechnology in South Africa is poorly represented in the 2nd and 3rd generation areas, but an important contributor to GDP in terms of 1st generation. A list of the major contributing industries, together with their respective turnovers, is given in Table 1.

It is apparent from the table that biotechnology plays an important role in both the manufacturing and agricultural sectors of the economy. Factors that have driven the development of these industries include the presence of large markets (such as food and beverage), investment by Government in applied research to support certain sectors (such as agriculture) and readily available production technologies (dairy products). However, most of the above, including many 2nd generation products, have become commodities of limited profitability and low margins. In general, competitors in such product areas are driven to decrease costs of production through incremental innovation and are looking to 3rd generation technologies as a means of securing a competitive advantage.

Table 1. Production volumes and annual revenues of the major biotechnology sectors

	Production volumes (tons)	Annual value[5] (R mil)
1st Generation		
Barley beer	2 700 000	26 190
Sorghum beer	540 000	1 080
Wine and distilleries		5 546
Ethanol		105
Natural vinegar		38
Maas and buttermilk	70 000	588
Yoghurt	50 000	500
Cheese	45 000	1 260
Yeast	55 000	450
Minerals bioleaching		100
Waste water treatment		4 000
Bioremediation/Environmental		10
Agricultural production[6]		45 000
2nd Generation		
Lysine	11 000	130
Vaccines (animal and human)		120
3rd Generation		
Production of biopharmaceuticals		5

[5] Mostly in the year 2000.
[6] Includes plant tissue multiplication by the ARC and at least 20 SMEs, the production of cultures of nitrogen-fixing bacteria and organic fertilisers, seed production, etc. Agriculture accounts for about 6% of GDP.

Lysine is an interesting case study in this regard (see box). A number of important lessons have been learnt from the establishment of this business, some of which are detailed. In particular, potential sources of competitive advantage for 2nd generation biotechnology producers have been identified, including the development of low-cost carbohydrate, support for expanding the skills base to provide key innovations, low-cost

Case study of a 2nd generation product
The AECI Lysine Project

AECI and its joint venture partner, the IDC, had two reasons for investing in the AECI Bioproducts lysine plant. The first was to establish a South African capability in 2nd generation biotechnology and the second was to use this skill to create a new business in fine chemicals for animal nutrition. Lysine was chosen as the first product to be manufactured, as this was a rapidly growing business with a reasonable local market. Further, the technology challenge was judged to be achievable, but with a significant barrier to entry into the field of 2nd generation biotechnology.

Since the commissioning of the plant the business has struggled for a number of reasons, including:

- High technical risk. Biotechnology embraced a new area of technology for AECI. It was initially not well understood and the risks were underestimated. As a result, the technology development took a longer time that was estimated,and cost a great deal more. Although the initial capital cost for the plant was R250 million, the total cost to the shareholders before the plant reached positive cash flow was about R700 million
- Lack of suitable skills. A significant part of the time and cost invested in the project was dedicated to the development of a pool of skills both of a scientific and an engineering nature, but also in the areas of operations, fabrication and maintenance.
- Low technology maturity. In a post-project audit, it was established that the technology was not sufficiently mature when the project was initiated and consequently a number of the key business decisions were flawed and had to be changed during the project. Furthermore, it was clear that a better methodology for ensuring that the science, engineering and business elements of a project were maintained in coherence was required (called Stage-Gate methodology).
- Poor benchmarking. Biotechnology is a particularly rapidlymoving technology and bio-businesses therefore also change very quickly. The experience with the lysine project was that, over the period of the project, lysine changed from being a fine chemical with attractive margins to being a volatile commodity with margins typical of the agro-processing industry. As such only plants of a size several times that of the South African plant could remain competitive. The importance of good benchmarking of the international competition cannot be overemphasised.

power, economies of scale, disposal of liquid effluent, low manpower costs and market access. Some of these factors are already in place, or under development (such as low-cost power). Others remain the subject of future requirements and are addressed in this strategy (such as expertise development).

The future of the plant is still uncertain and there is a possibility that the skills and experience accumulated as a result of this investment could be dissipated. However, the company has recently stated that ‘as a producer of threonine, its future is secured’. It is noted that threonine is a 3rd generation product, which supports the focus of this strategy on 3rd generation technologies and markets. As has been previously stated, it is the advances in this area that hold the key to building sustainable competitive advantage for all biotechnology.

Nevertheless, there are a number of existing markets, including certain niche but highly profitable export markets, which demand non-GM products. This requirement calls for strict separation of GM and non-GM value chains, and is discussed in more detail in Chapter 4. Already 25% of cotton planted in South Africa is GM, and 6% of maize (see Table 2). It is noted that of the three crops that have already been commercialised, all three are products of multi-national seed companies.

These figures are low in comparison with the USA, which already has 22 million hectares under GM soyabeans, 4.5 million hectares under GM cotton and 8.4 million hectares under GM maize.

Table 2. Present area under GM crops and to be commercialised within the next year

Crop	**GM variety**	**Area (ha)**	**Percentage of total (%)**
Maize	Bt Yellow Maize	70,000	6
Cotton	Bt Ready and Roundup Ready Cotton	15,800	28
Maize	Bt White Maize	To be commercialised at the end of 2001	N/A

Chapter 3: Key issues and problems

A 1998 survey indicated that there were more than 500 biotechnology projects, covering the areas of human health, vaccine development, microbial genetics, biomining, plant genetics and biocontrol. Despite the large number of projects, very few products and processes have been commercialised. Two main factors have probably contributed to this low level of commercialisation, namely an unfocused approach to national biotechnology R&D and the small South African market, which is not sufficiently attractive for investment in product development. The survey also found that the funding of biotechnology was approximately R100 million per annum.

3.1 Institutional arrangements

The R&D institutional landscape in South Africa is partly defined by the science and technology system of the apartheid past and partly by the National System of Innovation (NSI), which is set out in the White Paper on Science and Technology Preparing for the 21st Century. The previous system was designed to deliver specific outputs and lacked the flexibility and capacity to adjust to the changing political and technological environments.

The NSI is defined as "a set of functioning institutions, organisations and policies which interact constructively in the pursuit of a common set of social and economic goals and objectives"[7].

This would allow a more dynamic and flexible system to operate in an external environment of constant flux. The NSI has a significant role to play in achieving the goals of promoting competitiveness and job creation and of enhancing the quality of life through the development of human resources and the promotion of an information society. The strategies should be premised on a knowledge base and be environmentally sustainable.

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[7] As defined in the White Paper on Science and Technology.

The review of the SETIs and the National Technology Audit revealed that:

- The system has a well developed, but ageing science, engineering and technology infrastructure.
- The activities within the system are in some cases inappropriate and absorb valuable resources.
- Without an injection of substantial capital (equipment requirements in 1998 were R500 million) the level of innovation and support for economic growth in fields subject to technological change is in danger of becoming sub-optimal
- Despite the introduction of the NSI, the system continues to suffer from poor interaction and networking between institutions and between producers (the performers of research) and users of knowledge (industry and Government).
- Opportunities for exploiting the technological base have been missed.
- In order to promote an effective NSI, improved co-operation and integration between and among disciplines, institutions and sectors are of paramount importance.
- The greater part of the science system is closed and linear models of R&D are prevalent.

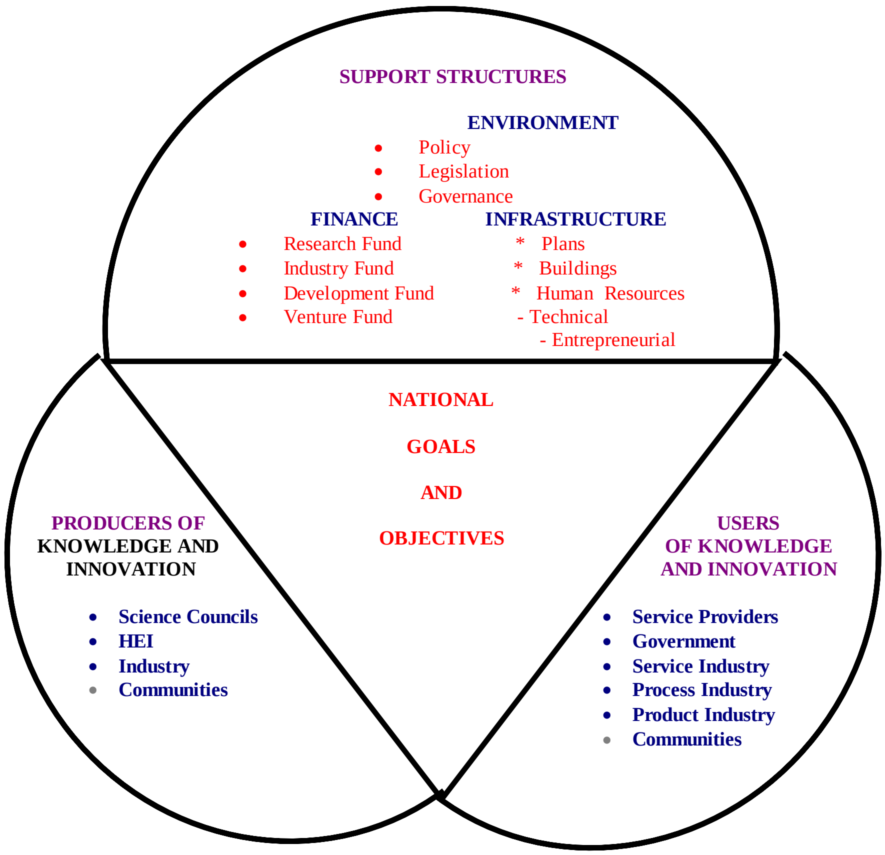

Figure 2. Dynamics of the National System of Innovation

A number of other studies have shown that in South Africa there are many educational and research institutions that have a stake in biotechnology. Research in the area of biotechnology lacks focus and, while many of the centres in South Africa are performing cutting edge research, the ideas that are developed are rarely taken any further. However, these groups have had little impact on the development of a sustainable biotechnology industry owing to the following factors:

- They are very small by international standards and therefore lack critical mass; and
- they lack a sustainable source of financing.

As South Africa re-integrates into global science and technology it has to be aware of important changes in international understanding of the way in which research is undertaken and knowledge is generated. In the industrialised countries it is increasingly acknowledged that:

- Knowledge is to an ever growing extent produced in the context of its applications and there are greater expectations that support for research will lead directly to economic and social benefits for the nation providing the support.
- There is an inescapable trend towards larger and more interdisciplinary teams working in more transdisciplinary research activities.
- There is a growing diversity of participating organisations to be found in today's research teams.
- There is a continuing trend towards greater international linkages in research teams.

As a result of the difference between what exists and what is required, opportunities to learn and innovate are lost. The NSI still has the potential to contribute to the sustainable development of the South African economy and society. There is, however, a danger that if these concerns are not addressed soon, SET in South African will not be in a position to contribute to economic growth.

3.2 Human resources considerations

Despite the existence of several centres of excellence in South Africa, where the research is driven by well-trained and experienced staff, there is generally a lack of adequate expertise and skills. This is a major constraint on the development of biotechnology in South Africa. This situation is not restricted to biotechnology. Statistics from the 1997/8 National R&D Survey indicated that South Africa numbered 7 researchers per 10000 labour force, compared with the USA's figure of 59 per 10 000 and Korea's of 64 per 10 000.

Several factors contribute to the lack of expertise in biotechnology. Although many graduate students are trained, there are limited opportunities for these graduates in either academic or industrial positions. In addition, the general climate is not conducive to the development of biotechnology, which further limits the prospects of even the most innovative individuals. Consequently, South Africa loses many trained personnel.

The very poor remuneration packages for trained and experienced biotechnologists in South Africa contribute to the shortage of skilled people. An average post-doctoral bursary is approximately 40% of the amount a good post-doctoral fellow can earn abroad. We are therefore unable to compete on the international market to attract post-doctoral fellows. Until the situation improves we are unlikely to attract post-doctoral fellows or expatriate biotechnology experts to a career in South Africa.

Graduates entering the job market lack the skills that are required to stimulate a biotechnology industry. There is an obvious need for greater emphasis on entrepreneurial and innovative skills in our training programmes. In addition, students should receive interdisciplinary training in aspects of law and business as these skills are integral to a successful career in biotechnology. Moreover, graduates may receive very narrow specialised training and consequently be poorly equipped to adapt to changes in technology.

3.3 Funding of biotechnology R&D

Funding of biotechnology R&D is derived from the following principal sources (estimated amounts in brackets, where available):

- Parliamentary Grant to Science Councils (R48 million)
- Competitive funds, including THRIP (R13 million), Innovation Fund (R20 million) and SPII (< R1 million)
- Department of Education funding of the higher educational sector (R20 million)
- Private sector, local and international (R20 million)

- International donors[8] and funding agencies[9] (R5 million)

Data available to us for the amount of biotechnology R&D currently being undertaken by the universities, technikons, science councils and other SETIs follow (estimated amounts in brackets):

- ARC (R12 million)
- Mintek (<R1 million)
- CSIR (R25 million)
- Universities and technikons (~R63 million)
- Private sector (R13 million)

Similarly, data for the allocation of this funding between different market sectors are not available at present. A survey conducted in 1998 indicated that the bulk of the funding was focused on the human health area, with plant biotechnology the next most important area (see Figure 3).

[8] Such as the Bill and Melinda Gates Foundation and the Wellcome Trust.
[9] Including the EU Framework Programmes.

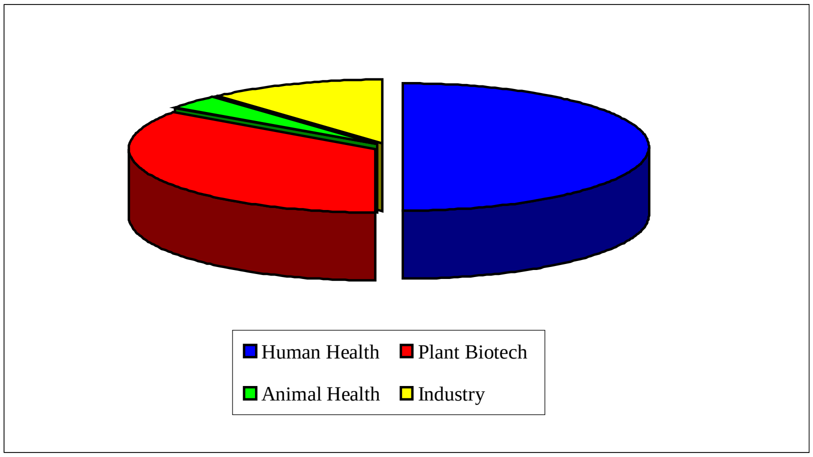

Figure 3. Approximate sectoral allocation of general biotechnology funding (industry includes environmental, chemical, mineral, food and beverages)

A number of studies have indicated inadequate public and private sector funding for research in general, especially in comparison with developed countries and emerging economies. Our analysis of the South African funding for biotechnology R&D has revealed the following key issues:

- There are very few quantitative data available on funding for biotechnology (that can be used to guide policy making).
- funding for public sector biotechnology is generally inadequate, particularly for staff positions at the level of post doctoral and experienced research workers at universities.
- Although the venture capital industry is relatively well developed, consisting of over 64 firms managing total assets of R28 billion, the industry has little interest in either biotechnology or financing start-up companies (see Appendix 2).
- There is very little private sector biotechnology R&D, reflecting the high- risk nature of this type of investment and the absence of any incentives to share the risk (such as tax allowances and Government supply-side measures).
- The allocation of funds available to universities and other performing institutions is not well coordinated and focused and the reward system for university publications favours quantity rather than quality.

3.4 Commercialising biotechnology

In South Africa we have limited support for the commercialisation of biotechnology; hence only a few biotechnology companies exist. A recent survey identified 46 companies engaged in activities broadly related to biotechnology (from 1^{st} to 3^{rd} generation), but only a small proportion of these are involved in 3^{rd} generation biotechnology.

There are a number of reasons for the failure of investment in R&D to generate commercial activity. As noted in Chapter 2, experience of other countries has identified key factors that stimulate biotechnology industry. These factors are summarised in Figure 4.

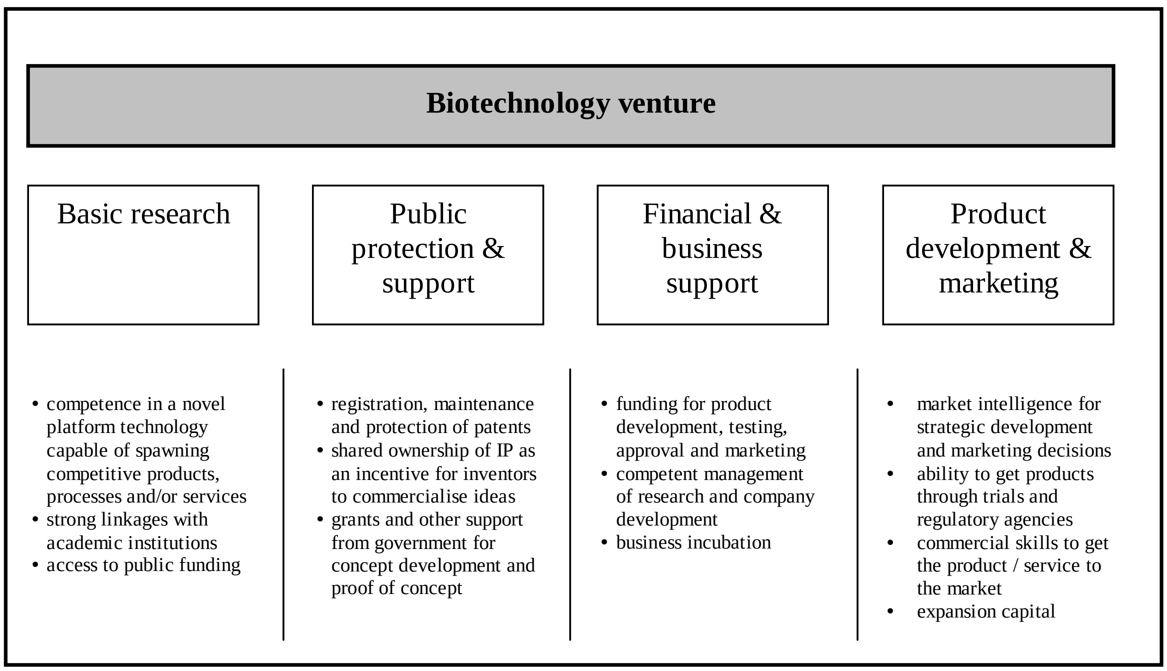

Figure 4. Summary of the basic foundations for the successful commercialisation of biotechnology

Issues such as IP protection, institutional arrangements and financial support are covered in other parts of the report. In this section, we focus exclusively on the status of business support and industrial promotion in South Africa. A number of key issues and constraints have been identified, as follows:

- The manufacturing sector has failed either to attract or to sustain investment in key biotechnology areas, including the manufacture of vaccines, antibiotics, active pharmaceutical ingredients and diagnostics.
- In bioinformatics, the establishment of services and support centres has been inhibited by the high cost (and to some extent low speed) of our communications infrastructure.
- The small size of the local market and the lack of a perceived competitive advantage have prevented the establishment of a local manufacturing industry.
- Traditionally, there has not been a strong culture of commercialisation in the science councils, universities and technikons. Although our scientists have produced excellent inventions, the absence of commercialisation skills and appropriate incentives has prevented the extraction of their commercial value.
- There is significant international outsourcing of R&D by South African industry in the absence of strong links between research institutions and industry.
- A lack of business management skills has inhibited the development of vaccine production in South Africa.
- The negative consumer response to GM foods, principally in the EU, has slowed the adoption of the technology. In some respects, the response of the EU has built alternative markets for non-GM products, which has provided new opportunities for South African exporters. In the implementation of a biotechnology strategy, it will be essential to ensure that these markets are not undermined by the promotion of GM technologies[10].
- The limited participation of social scientists (such as economists) in project teams has prevented the successful commercialisation of new products or services.

[10] This requirement may demand dual streaming of products, whereby GM and non-GM value chains are separated, and kept separate at all stages of the value chain. At the same time, the necessary documentation to support non-GM claims (such as certificates of analysis, Good Agricultural Practice and cGMP documents) will need to be in place.

Despite the above problems, there are many recent developments that are making or will make an important contribution towards the creation of a viable biotechnology industry, including:

- Several studies that have identified key problems and made recommendations to Government and others as to how these can be addressed (such as the Department of Trade and Industry's study on pharmaceuticals, the Foresight studies, the National Genome Initiative, the R&D survey and the Black Empowerment Forum's study on venture capital).
- The Department of Health's initiative to restructure the vaccine industry, which will result in an injection of much-needed capacity and expertise, particularly in vaccine manufacturing technology through strategic equity partners.
- A biotechnology incubator able to supply business support services to start-up companies has been formed and is being funded by Government.
- The development of the South African National Bioinformatics Institute (SANBI).

Standard processes followed by entities engaged in the commercialisation of biotechnology products and services, together with South African examples, are shown in Figure 5.

	Research project	Start-up company	Developing business	Self-sustaining business
Research	• identify novel technology and investigate its action	• scope company's platform technology and focus • proof of concept trials on initial products	• get products through initial clinical / field trials	• identify new formulations / applications / diagnostic derivatives
Public protection and support	• secure research grants • file provisional patents and patent search	• file full local and inter national patents • secure development grants / support	• protect IP and access 3rd party IP where necessary • secure tax concessions / grants	• maintain patent portfolio • secure tax concessions / grants
Financial and business support	• identify potential investors	• secure initial funding • identify milestonesand manage research	• secure further funding through venture capital and other investment sources	• list company on stock exchange
Product development & marketing	• identify competing technologies and potential market size	• identify partners & collaborators	• finalise marketing / development deals with partners / collaborators	• bring product to market with partners
South African examples	• various research projects in universities, science councils, etc. • SAAVI	• Wandile Biopharmaceuticals	• Ribotech • Electric Genetics	• Bioclones (not yet listed)

Figure 5. Standard process followed in the commercialisation of biotechnology products and services

3.5 Policy and legal instruments

South Africa needs to exploit the potential benefits of science, engineering and technology (SET) discoveries to stimulate growth of the economy. National priorities in various sectors were identified in the NRTF reports. Three main focus areas that need special attention were identified: information and communication technologies, material sciences and biotechnology. In this section the existing legal framework for the appropriate utilisation of biotechnologies is reviewed. In addition, South Africa has ratified a number of international property treaties and conventions that have implications for how the country can exploit biotechnology.

3.5.1 International

- Trade Related Aspects of Intellectual Property Rights (TRIPS)[11], in particular Article 27.3(b) which has implications for ownership through intellectual property rights (IPRs)[12].
- Convention on International Trade in Endangered Species (CITES), which regulates the movement of species and, by extrapolation, the movement of genetic material.
- International Undertaking on Genetic Resources of Food and Agriculture (IU – GRFA), which facilitates easy access to organisms, including propagating material for food security purposes under the auspices of the Food and Agriculture Organisation (FAO).
- Convention on Biodiversity (CBD), which has several provisions relating to the development and use of biotechnology in the beneficiation of biodiversity and ensuring the safe application of products. The CBD also addresses aspects such as equity of benefit sharing and technology transfer issues.
- Cartagena Protocol on Biosafety (CPB), which South Africa has not signed. South Africa is at present reviewing the procedure that is followed in the

[11] TRIPS Agreement constitutes Annex 1C to the Marrakesh Agreement establishing the World Trade Organization (the WTO Agreement), which was concluded on 15th April 1994 and came into force on 1 January 1995. The TRIPS Agreement binds all members of the WTO.
[12] Attention is drawn to the fact that TRIPS sets up minimum requirements regarding the protection of IP. Member countries may therefore include the protection of novel plants and animals in their patent acts.

ratification of the protocol with the aim of adopting its objectives. The protocol covers the protection, handling and use of living modified organisms and conservation of sustainable use of biological diversity.

- Protocol to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons, and on their Destruction. This protocol is at present under negotiation in Geneva, with the intention of implementation by the end of 2001. The convention itself was signed in 1975 and has already been implemented. It is possible that the protocol will create lengthy bureaucratic delays for biotechnology companies to ensure compliance.

3.5.2 National

There are many Acts that are relevant to biotechnology in South Africa. Some require amendment and some are inconsistent from one Act to another. For instance, various Acts address only the phenotypic[13] characteristics of organisms and would need to be amended to take into account the genetic characteristics that biotechnology deals with to control the movement of genetic material, intellectual property rights, and the exchange of information. The full spectrum of relevant Acts includes:

- The National Environmental Management Act (NEMA), which is a framework for regulating activities and which may have an impact on the environment. This Act is currently under review.
- The Biodiversity Chapter, which is at present being developed and which aims to make provisions on safety aspects, access to genetic resources and benefit sharing.
- The Genetically Modified Organisms Act (Act 15 of 1997), which, in conjunction with the GMO Regulations, governs biosafety regulatory regimes. The GMO Act comprehensively addresses measures to promote the responsible development, production, use and application of GMOs. Together with NEMA and other Acts, it provides the principles for environmental responsibilities and liabilities. A number of concerns have been raised about the implementation of

[13] Physical and physiological characteristics *vs* genotypic, which refers to genetic composition.

the GMO Act. These relate to capacity within the identified Government departments to implement the various provisions of the Act and the fact that liability is placed squarely on the users (suppliers should share the risk). There is also a public perception that the GMO Act focuses on protecting the environment and not on the implications of foods derived from genetically modified plants.

- Regulations governing the labelling of foodstuffs (under the Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972)) obtained through certain techniques of genetic modification have been published for comment.
- The Human Tissue Act (Act 65 of 1983) regulates the genetic manipulation of gametes or zygotes outside the human body. In terms of this Act, research on embryos is prohibited.
- The Patents Act (Act 57 of 1978), the Trademarks Act and the Copyright Act, which cover patents, trademarks and copyrights, respectively (trade secrets are covered under common law). This legislation determines whether processes and/or products of genetically engineered plants and animals can be patented. There is, however, a lack of clarity on a number of issues that may have implications for the harnessing of both intellectual property and indigenous knowledge in biotechnology. For example, there is -

    - no existing framework for the protection (by its owners) of indigenous knowledge (although this is being developed)
    - no existing equivalent to the plant breeders' rights for animals. (In other words, it is not possible to protect new varieties of animals from use by persons other than licencees or the inventors. As a result, South Africa has lost key unique rights to the commercial exploitation of animals such as Nguni cattle) and
    - no "search and examine" capacity in the patent office and hence there is a lack of sound information on what can be patented (in many cases, private law firms have better searchable records than the Patent Office itself).

- The Animal Improvement Act (Act 62 of 1998)
- The Plant Breeders' Rights Act (Act 15 of 1976)
- The Plant Improvement Act (Act 53 of 1976)
- The Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972)
- The Agricultural Pest Act

It was emphasised in Section 2.2 that one of the key lessons to be learned from the experience of the USA was the right of a university, in conjunction with the inventor, to own all/or part of the intellectual property generated with public funds as a result of R&D in the institution. A similar situation does not exist in South Africa, although a number of institutions apply their own rules. For instance, the MRC may demand all the IP, even on a partially funded project, and some universities give the majority of the rights to the inventors. This issue is discussed further in Chapter 4.

3.6 Ethics

The right of access to health care, food, water and social security is enshrined in the South African Bill of Rights. Chapter 2, subsection 27(2) states that "the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization if each of these rights".

The use of new technologies comes with uncertainties. There are concerns regarding the potential benefits of the application of recombinant DNA technology to society. Arguments against biotechnology include the fact that its use is seen as being unnatural. However, the basis of the objection or the notion of what defines "unnatural" is not always clear as with time certain advances become acceptable.

The benefits of biotechnology include the potential to increase crop production and improve the quality of the crop, thereby contributing to food security. There are, however, several ethical arguments about the use of this technology. These include the ecological effects of releasing genetically modified seeds into the environment and the impact of genetically modified crops on seed markets, the ecosystem and biodiversity.

The final completion of the human genome sequence will still require extensive inputs from the scientific community in order to elucidate the molecular basis of disease. This information will be useful in the development of diagnostic and therapeutic drugs. The information obtained from South Africa's unique population can therefore contribute to this global effort. The ethical issues include the confidentiality of the information how those who donate samples for research benefit from such studies and how to prevent genetic data from being used to discriminate against individuals. In the pursuit of this knowledge, there is a need to ensure respect for human dignity and human rights. In developing countries, the translation of this knowledge (agricultural, economical, environmental and health) is the major ethical issue.

Gene therapy entails the introduction of a normal gene using recombinant DNA technology into cells containing a faulty gene in order to restore normal function. The current limitations of this procedure include the inability to control how many copies of the exogenous gene enter the targeted cells and the inability to target where the exogenous gene inserts itself and to know whether or not it will be expressed once in the cell. The possibility of transferring this foreign gene into the germ line (reproductive) cells and so passing it on to subsequent generations is an ethical issue.

Public perceptions are based on the information conveyed to it. Scientists therefore have a responsibility to convey research findings accurately and in a language understandable to the public. Service providers have an obligation to inform consumers and users adequately and accurately of the potential benefits and risks, both short and long term, of biotechnology.

Each institution has its own ethics review committees. The Department of Health has developed guidelines for clinical trials and has an ethics council to promote and monitor the compliance of South African ethics committees with the relevant legislation and regulations, ethical guidelines and standards.

Ethical issues regarding the application of biotechnology therefore include:

- The disclosure and use of human genetic information.
- Gene therapy and human cloning.
- The potential impact of genetically modified organisms on the environment.
- Horizontal gene transfer from GMOs to other organisms.
- Trans-species gene transfer.
- Participation in research and clinical trials.

3.7 Public understanding

There are a number of issues relating to current public understanding. For instance, there is a lack of understanding of the scientific basis underlying the potential benefits, risks and ethical and environmental issues of biotechnology and a perception that biotechnology is generally synonymous with genetically modified foods (GMOs). Scientists do not communicate biotechnology issues in a language understood by the public and media reports often do not contain sufficient details to inform the public adequately

Some members of the public are concerned about the safety of GMOs and would like to have GMO foods labelled in order to be able to make informed choices on whether to consume genetically modified foods. This also has implications for improving the general literacy levels of the South African population.

It should also be noted that so far South Africa has avoided an extreme reaction from the public and environmental organisations, such as the destruction of commercial GM plantations or experimental fields. Such actions, often violent, have been quite common in Western Europe.

Chapter 4: Strategic objectives and interventions

A number of important issues and priorities in respect of the conversion of biotechnology R&D into viable enterprises have been discussed in Chapter 3. In this Chapter we have sought to translate those key success factors into tangible strategies and actions to be implemented by Government. The constitution and responsibilities of the Biotechnology Advisory Committee are detailed. Similarly, the formation of Regional Innovation Centres (RICs), each having separate technology platforms, and a close relationship with technology incubators, is described. Together, these actions will assist in the creation of biotechnology enterprises and will take biotechnology inventions at least to the prototype stage.

It is emphasised again that the major thrust of this strategy is to develop a viable and sustainable biotechnology industry. In order to achieve this, however, there is a clear need for a very strong research strategy, coupled with a clear development policy, in order to generate marketable products.

4.1 Principles for the proposed biotechnology strategy

A number of principles guided the conception and implementation of this strategy, including to-

- ensure that the strategy meets the national imperatives, including job creation, rural development, crime prevention, human resource development and addressing HIV/AIDS, ultimately leading to economic growth;
- focus on those areas where there is (or is likely to be) a comparative advantage in biotechnology;
- build new programmes that will harness existing national scientific and technological competencies;
- address issues of biosafety; and
- review the strategy constantly in the light of national priorities and international trends in biotechnology development.

The panel has also taken an integrated approach in its analysis and its proposed interventions. This approach allows the identification of each step of the commercialisation process from initial research to a self-sustaining business (see Figure 5). The framework is useful because it highlights both the contents of the pipeline and the support measures or institutions that are required at each step. For example, in meeting the HIV/AIDS imperative, it will be important to build a solid competency in biopharmaceutical and vaccine production, as has been recommended for the focus area of one of the RICs. This is a content requirement. On the other hand, the successful commercialisation of a possible vaccine will require the support of a bio-incubator, or an R&D incentive scheme. This is a supporting requirement. In each case, the necessary interventions are clearly stated and defined.

4.2 Institutional arrangements

Objective: Development of a Co-ordinated Biotechnology Strategy

The development of a strong biotechnology industry in South Africa will initially require a detailed audit of the current situation regarding first, second and third generation biotechnology in order to identify our existing strengths and to build on these wherever possible. We will then have to focus on co-ordination between the various stakeholders, from research institutions to industry. An effective strategy needs to promote development and utilisation of biotechnology at three levels:

- Basic research and technology development.
- The development of ideas into products.
- The commercialisation and marketing of the product nationally and internationally.

A strong biotechnology industry therefore requires not only co-ordination between people and institutions, but also a multidisciplinary approach involving scientists, engineers, economists and business managers.

There are regions in South Africa that have a number of universities, technikons and research institutes in close proximity. Most of these do not collaborate significantly with each other. All require similar infrastructure and equipment, but experience difficulty in acquiring them. Between them there is often a significant skills base in basic and applied biotechnology. Specialist RICs need to be identified and funded in order to promote collaboration.

The temporal gap between biotechnology commercialisation and cutting-edge research is extremely narrow. In the USA on average one publication is cited for every 10 engineering patents. In contrast, each biotechnology patent references on average 17 publications. This makes it essential that the development of a biotechnology industry be strongly linked to research institutions where ideas are primarily generated.

Biotechnology companies are more likely to succeed if they have emerged from an incubator-like environment. Such companies internationally have a 70 to 80% success rate, as opposed to the 20% overall success rate of biotechnology companies. There is currently only one Biotechnology incubator in South Africa. The strategy needs to ensure that there is closer linkage between academia and industry.

Intervention: Creation of a Biotechnology Advisory Committee (BAC)

If South Africa is to make a concerted effort towards the establishment of a strong biotechnology industry, we will need a champion to drive this process. It is recommended that a national Biotechnology Advisory Committee (BAC) be established to ensure that this strategy focuses on national priorities and promotes coordination between the different components of the system. The BAC will have representatives from a diverse group of stakeholders (civil society, the research community, the business sector and Government), be supported by a permanent secretariat and chairperson and could be housed in one of the existing statutory councils. The committee will-

- be an advisory body appointed by the Minister of Arts, Culture, Science and Technology (in consultation with other relevant ministries) under the auspices of the Economic Cluster in Government and reporting to DACST;
- implement this national strategy
- identify national biotechnology priorities, in addition to those mentioned in this strategy
- issue requests for proposals (RFPs) for the establishment of the RICs within established guidelines for the promotion of synergy in the biotechnology community;
- recommend to the NACI and other Government funding agencies, the appropriate programmes and expenditure on biotechnology in South Africa, with the funds being channelled through existing structures such as statutory bodiesmonitor the impact of biotechnology expenditure
- promote the investment of venture capital in biotechnology and the search for industrial partners (other countries have made excellent use of bio-industry portals in this regard[14]); and
- investigate resource mobilisation into biotechnology (skills, funds and facilities).

Intervention: Creation of a number of RICs

The RICs will be established to provide technology platforms in response to the identification of biotechnology focus areas. Each RIC will establish three or four programmes, according to regional expertise and markets. The technology platforms are envisaged as acting as common areas where capital equipment and specialised expertise will be shared by the biotechnology programmes and industry. Two major components of the platforms have been identified as being crucial for the success of the biotechnology strategy:

- Biological Resource Centres (BRC) are an essential component of the infrastructure underpinning biotechnology R&D. They are responsible for

[14] For example, http://www.france-biotech.org/uksite/welcome.htm [France] and http://www.biomedoz.com.au/ [Australia]).

preserving and distributing biological materials and information. They are crucial to the exploitation and maintenance of our diverse natural heritage.

- Bioinformatics networks. Bioinformatics has become an indispensable part of the infrastructure required for biotechnology research. Furthermore, human resource capacity in bioinformatics has become increasingly important across the spectrum in biotechnology, including biopharmaceuticals and plant biotechnology. The enhancement of our competency in bioinformatics has the potential to place South Africa at the forefront of this field.

Apart from bioinformatics and biological resource centres, which are considered to be essential facilities or technologies for all the RICs, it is recommended that each RIC specialise in a one of a number of more specific areas of technology, which are in turn well aligned with the national imperatives, local expertise and market opportunities. More details on the recommended focus areas are given in Section 4.4 under ‘Creating Industrial Opportunities’.

It is essential that each centre also accommodate a biotechnology incubator, which in turn willbe linked to a number of spin-off companies (see Figure 6), thereby ensuring that the outcomes of the R&D in the programmes have the necessary infrastructure to support their commercialisation.

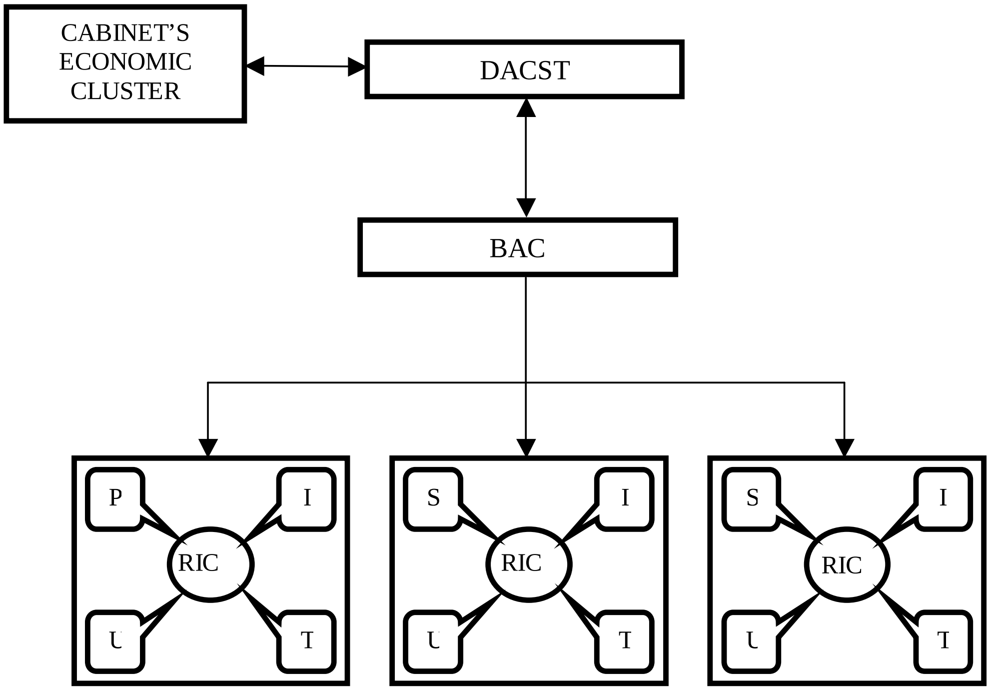

Figure 6. Proposed institutional arrangement (BAC, the Biotechnology Advisory Committee; RIC; Regional Innovation Centre; I, anchor investors; U, incubator; T, technology platform; P, research programme)

In terms of staffing, it is proposed that each RIC should be managed by a Director and the appropriate number of support staff. The management of the RIC should be independent and should facilitate the co-ordination and use of the centre by the biotechnologists in the region and elsewhere. It is not intended that the centre will have a large permanent staff, but rather that the money be allocated to research programmes which will be driven by university, science council and industry consortia. The programmes will employ on a fellowship basis, contract or temporary staff, who will undertake R&D in the RIC.

The incubators are an important component of the RICs in assisting with the commercialisation of inventions arising from a project. As noted in Chapter 2, incubation is necessary to ensure that the appropriate framework is in place for the support of entrepreneurs in transferring technology from the laboratory to the market.

A further component of the RIC's network is the close association with regional anchor investors. These are large companies which will be attracted to the region, as a result of the development of the RICs in overlapping areas of expertise. For instance, a manufacturer of vaccines could be attracted to an RIC that has a strong programme in vaccine development.

4.3 Human resource development

Objectives: Development and retention of appropriate human resources for biotechnology

Apart from a good knowledge of basic molecular biology, a biotechnologist also requires multiple skills, including bioinformatics, information technology, engineering, statistics, genetic epidemiology, business management, product development and legal issues skills. As no one person is likely to be able to be an expert in all these skills, specialists in the above fields will also be required.

It is important that sufficient jobs with competitive remuneration packages be established in South Africa so that top people can be attracted and retained. In addition, the training of scientists in entrepreneurial and innovative skills will be required.

Intervention: Establishment of career opportunities

The establishment of RICs employing both principal investigators and support staff will contribute significantly towards creating career opportunities for experienced and well-trained individuals. The staffing of RICs would include a Director and a core group of specialists to maintain the infrastructure. Associated with the RICs will be number of programme leaders and 30 to 40 professional staff (including post-doctoral fellows) and technical staff, who will be on contract appointment and assigned to the projects. In addition, support for start-up funding would lead to an expansion of the biotechnology industry and thereby to a better absorption of young scientists into career paths in biotechnology.

Intervention: Fast-tracking the human resources needs of the RICs

The establishment of the RICs may be constrained by a lack of suitably qualified senior personnel. An active international recruitment programme, aimed first at South Africans living abroad, might be necessary to supply the RICs' human resources needs and to transfer the appropriate technologies to South Africa.

Intervention: Improve the current post-doctoral fellowship system

We need to establish a number of post-doctoral bursaries competitive with those on the international market. The implementation of this strategy will also increase and stimulate the opportunities for post-doctoral fellows and offer the opportunity for them to enter the job market.

Intervention: Promotion of curriculum development

There is a need to focus on mathematics and science education at high school level in order to generate a pool of students who can enter the field of biotechnology. Educational institutions need to incorporate entrepreneurial and business skills into their curricula. In addition, broader scientific training is required to create the adaptability required in a biotechnology industry.

4.4 Creating industrial opportunities

As mentioned in Chapter 1, the entire biotechnology community, irrespective of whether they are involved in 1st, 2nd or 3rd generation activities, are users of 3rd generation products and services. For instance, DNA fingerprinting techniques are used to characterise micro-organisms, plants or animals and threonine is produced using GM bacterial strains. It is the exploitation of 3rd generation biotechnology (primarily, but not exclusively) that will lead to sustainable competitive advantage. Consequently a number of initiatives in this strategy are focused on this area.

Objective: To encourage linkages between large companies and RICs

The attraction of large anchor investors has been shown to stimulate industrial activity by supporting a number of smaller companies and supply industries. This is one of the features of cluster methodology.

This approach could be followed by attracting major R&D investment from national and international companies in the areas of:

- Plant biotechnology
- Animal health
- Vaccine production
- Fine chemicals industry
- Pharmacogenomics

Intervention: DTI to encourage large company investments in RICs

Objective: To create biotechnology industry in sectors that are well aligned with national imperatives, market demand and regional expertise

A primary recommendation of this strategy is the creation of a number of RICs in order both to build the technology platforms required to support a biotechnology industry and to populate the new product (or service) development pipeline, which could result in new self-sustaining companies serving national and international markets. Selecting the most appropriate focus areas of each RIC will be essential to the success of this strategy. In the following interventions a number of focus areas are proposed.

Intervention: Address the most pressing human health issue issues in South Africa

The most urgent priority in the health sector is the creation of an effective and safe HIV vaccine. To a large extent this is being tackled by the South African Aids Vaccine

Initiative (SAAVI). Nevertheless, it remains an urgent issue, and whatever can be done to speed up the development of such a vaccine must be attempted, including the allocation of additional resources into SAAVI.

Other recommended focus areas are:

- The development of cheap, easy to use, low-cost diagnostics for the public health sector, particularly the rural clinics and hospitals, to support the detection and management of infectious diseases.
- Ongoing development of affordable and safe vaccines (part of the vaccine industry restructuring initiative being undertaken through the Department of Health), including vaccines for TB, cholera, malaria, human papilloma virus and others.
- The development of specific South African-developed drugs against local conditions such as hypertension, cancer, malaria, TB, etc.
- The gene profile of the South Africa population (from both ancient DNA and from immigrant populations) provides a unique opportunity for building on the work done in the mapping of the human genome. This includes the mapping and identification of genes underlying disease structure, elucidation of the molecular basis of diseases common to South Africa and the development of technology to develop medicines and diagnostic tests.
- The creation of a resource database that will identify all the components required for the commercialisation of biopharmaceuticals. This database could be managed and accessed through the bio-industry portal discussed in Section 4.2.
- The establishment of a State- supported facility for the scaling up and contract manufacture of generic biopharmaceuticals.

Intervention: Improve food security and nutrition

Agricultural biotechnology has the potential to improve the nutritional value of the food we consume through the introduction of plants containing key vitamins and amino acids that are low in the diet of many South African households. For instance, new strains of indigenous crops could be produced with an improved amino acid profile or better resistance to disease. This is a particularly important area for South Africa, given the large number of people who live in poverty and are undernourished.

It is important to note that there are already a number of initiatives under way in our research institutions to tackle the problem of food security. These initiatives should be supported and encouraged if we are to overcome past inequalities and create rural economies that are sustainable and productive.

Intervention: Improve plant production in a changing environment and reduce the impact of agriculture on the environment (plant biotechnology)

Due to the harsh environmental conditions in South Africa crop yields are exceedingly low. In addition, climate changes will affect and probably marginalise competitive production using current species in many areas. By their nature large-scale crop production systems are environmentally unfriendly due to chemical pollution, acidification of soils and demand on water supplies. The long distance between South Africa and many of its exports markets places a heavy demand on the keeping properties of many agricultural commodities.

It is widely accepted that traditional breeding alone would be too slow, and often unable, to solve many of these challenges due to limitations in the normal germplasm. Unique opportunities therefore exist to use biotechnology to meet these challenges.

Specific areas that should be focused on include:

- DNAmarker-based selection systems.
- Diagnostic tools for early and accurate pathogen and pest detection.
- Insect- and pathogen-resistant plants to reduce the chemical impact on the environment and improve yields.
- Drought and salt-tolerant crops.

Objective: Improve animal health and productivity

South Africa faces unique challenges in the area of animal health and disease. These include both domesticated animals and our rich natural fauna. The latter often acts as a reservoir for diseases of livestock.

Specific issues that should receive attention are:

- Vaccine development for important diseases.
- Pedigree determination based on DNA fingerprinting.
- Disease detection using molecular markers (particularly the development of portable, but highly sensitive diagnostic kits for the early detection of highly infectious diseases, such as foot and mouth, etc.).

Objective: Support sustainable industrial development using biotechnology (environmental biotechnology)

Despite our diversity of natural resources, we have limited industrial activities that can either add value to or protect these resources. Specific areas in which biotechnology can be used in this regard and which should be targeted include:

- The development of competitive bioprocessing techniques to utilise plant, animal and bacterial sources for the production of chemical products.
- The processing of agricultural products in order to improve one of a number of characteristics, including higher nutritional content and reduced toxicity.
- The development of processes and equipment to support sustainable industrial development and, in particular,to minimise any possible negative environmental impact that may result from industrial development.
- The development of new methods for the bioremediation of existing sites already heavily contaminated and for the reduction of energy consumption and carbon dioxide emissions.
- Further development of the necessary biosafety protocols and legislation.

A summary of the support services available at present to South African biotechnology entrepreneurs and those suggested by this strategy (in italics) is given in Figure 7.

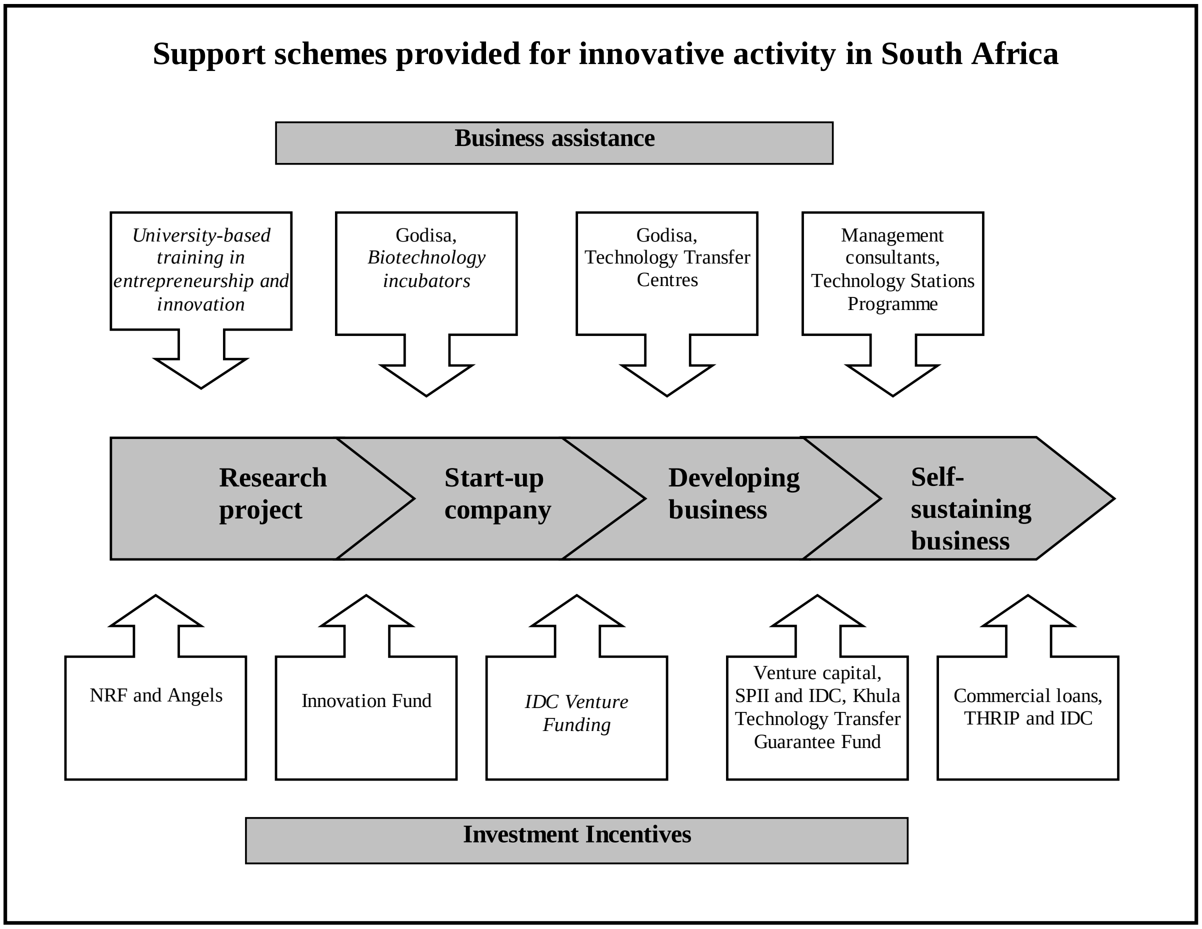

Figure 7. Support schemes, both proposed (in italics) and existing, for biotechnology innovative activity in South Africa[15]

[15] An Angel is a funding agency which provides early-stage seed money, often with no reward or potential for reward Examples are the Bill and Melinda Gates Foundation and the Wellcome Trust.

4.5 Policy and legislative reforms

Objective: Create an enabling legislative framework for the development and commercialisation of biotechnology

Current legislation provides a broad enabling framework for the development of biotechnology. This is a rapidly developing area and new legislation and regulations should therefore be formulated and implemented in such a way as not to limit the benefits to be derived from biotechnology.

Intervention: Review existing legislation with implications for biotechnology and propose new legislation or amendments.

This intervention must include the identification of gaps and the consolidation or amendment of existing legislation to remove duplication or areas of conflict. It is noted that the panel was not able to address fully the impact of the present regulatory environment on the development of biotechnology in South Africa and that this analysis should be undertaken in future, co-ordinated by the BAC. However, it was stated to the panel that there are already several Acts on the statute book provide conflicting legislation with respect to biotechnology, such as the GMO Act and the Agricultural Pests Act (both of which cover cross-border movement of genetic material), and which are also likely to conflict with proposed new legislation, such as the National Environmental Management Act, and legislation on indigenous knowledge, technology transfer and biodiversity.

Intervention: Update the Plant Breeders' Rights Act to include DNA fingerprinting

The present Plant Breeders' Rights Act does not cover the use of DNA fingerprinting to distinguish between different genotypes. In many cases GM plant varieties are not distinguishable from parent genotypes through visual inspection and protection can be provided only on the basis of characterisation using a unique DNA fingerprint.

Intervention: Consider the development of legislation to protect the rights of animal breeders (the equivalent of the Plant Breeders' Rights Act)

South Africa has an excellent history of developing new animal breeds of commercial value, including breeds of ostrich, Angora goats, cattle and sheep (such breeds as the fat-tailed sheep). However, these breeds have in some cases been 'lost' to other parts of the world due to inadequate means of protection. Although the Convention on Biodiversity is expected to provide some protection, it will be important to extend this into a legislative framework.

Intervention: Introduce and implement as soon as possible a "search and examine" capacity in the South African Patent and Trademark Office (SAPTO)

SAPTO is currently only a registration office. Under proposed new legislation the function of SAPTO will be extended to include a 'search[16] and examine' capability. It may not be necessary to provide this function in-house, but rather under contract to a larger patent office (such as the European Patent Office).

It is also recommended that the SAPTO improve its database system and infrastructure in order to provide a reliable and comprehensive service for the legal community. In some cases, the panel was informed that the office's records are incomplete and that better records are available from private law firms.

Intervention: Government should introduce and implement the equivalent of the Roche-Bolar provision as soon as possible

This provision will allow for the development of generic products prior to the expiry of the patent on the ethical product or service. For example, it allows generics companies, in conjunction with their research partners, to develop a process route for the manufacture of a patented drug and file a New Drug Application prior to the expiry

[16] In this context, search refers to an ability to determine whether a patent application is in conflict with, or a duplication of, an existing patentand goes beyond a mere ability to find a previously filed patent by searchable index fields.

of the patent. This provision is fully TRIPS compliant, although it does not allow a company to stockpile the product or begin marketing prior to the expiry of the patent.

Intervention: Provide uniform guidelines for Science Councils, universities and technikons on IP rights for inventors

The granting of rights to intellectual property generated as a result of R&D by a science council, university or technikon with public funds has been shown to be a major incentive for scientists to commercialise their inventions. The present situation in South Africa is inconsistent from one institution to another and prevents both collaboration and innovation within the NSI. It is recommended that a set of guidelines be established by DACST as soon as possible in order to clarify the situation and ensure that inventors and their institutions are well rewarded for their efforts.

Intervention: Institutional capacity to implement any new legislation should be provided

New legislation is often hampered by the lack of capacity for its implementation. It is emphasised that this aspect should not be overlooked in the introduction of new legislation relating to biotechnology.

Objective: Create an enabling bilateral and multilateral framework for the development and commercialisation of biotechnology.

As outlined in Section 3.5.1, the Government has already signed, and may sign in the future a number of conventions to protect the citizens and environment of South Africa. It is important that these conventions should not prevent the country from achieving its objectives in respect of this strategy.

Intervention: The Government should ensure that full consultation takes place with relevant departments prior to signature of international multilateral and bilateral agreements

4.6 Enhancing international co-operation for technology procurement

Objective: To employ international expertise and technologies to address priority issues

South Africa currently produces an acceptable proportion of international knowledge (0.5%), but much of this happens with limited international collaboration. By strengthening our international networks we could considerably improve the efficiency of knowledge generation and technology acquisition. This will leverage our existing investments and improve the efficiency of our system.

Intervention: Strategic partners for the platforms

A key component of the success of the RICs proposed in Chapter 4 will be the creation of strong international linkages with equivalent institutions that are at the leading edge of their field. It is envisaged that the BAC will be responsible for the performance of the RICs through ongoing evaluation according to a number of measures. At least one of these measures will relate to the success with which the relevant centre has established international linkages.

Intervention: Programme partners

Biotechnology R&D is often characterised by a major initial capital investment in equipment. One of the objectives of the RICs is to provide access for its network of users to such equipment. A priority for Government is to ensure participation by industry at the programme level within each centre. It is therefore proposed that the programme develop joint projects with equipment suppliers whereby the suppliers either donate or share a portion of the costs in exchange for beta testing[17] of new prototypes.

Intervention: Bilateral agreements

[17] Beta testing refers to the testing of new prototypes or versions of products prior to market launch. The product is normally provided at no cost to the user in exchange for feedback on its performance.

Since 1994 South Africa has entered into a large number of bilateral agreements, some of which specifically cover science and technology cooperation. It is recommended that strong linkages be formed between programmes in this biotechnology strategy and leading biotechnology institutions in countries with which South Africa has bilateral agreements. In addition, information on existing agreements should be disseminated through the BAC's internet portal for the biotechnology industry.

Intervention: Millenium Africa Programme

The Millenium African Programme has been designed to revitalise Africa as an economic force in the global economy. Biotechnology should be a cornerstone of this programme, the details of which need to be negotiated with our African partners.

4.7 New and innovative financing of biotechnology

Objective: Provide sustainable funding for the Biotechnology Strategy

A number of strategic interventions to improve the benefits that can be derived from biotechnology have already been identified, namely:

- To provide funding for the BAC, principally to cover salaries for the chairperson and secretariat, and to fund policy studies (R2 million p.a.).
- It is estimated that each RIC will require an establishment investment of R15 million[18].
- In the event of a funding constraint, it is not advisable to set up three RICs at a lower level of funding. It is preferable to fund at least one RIC at the full R60 million, with further expansion as funding becomes available.

[18] A 1997 audit by the DACST indicated that South Africa will require R500 million just to keep the current equipment up to date.

- Programme funding at R15 million per programme (each RIC will have at least three programmes with each programme in turn consisting of three or four projects). This funding will be required for salaries and for equipment that will be shared by different groups in the RIC. The Innovation Fund currently funds projects of this nature at R5 million each, while a programme such as SAAVI costs at least R20 million.
- Consider either the supplementation of existing supply-side measures (THRIP, SPII, Innovation Fund, etc.) at R25 million p.a. to strengthen the interaction between industry and academia, or the creation of tax incentives to encourage private sector biotechnology companies to invest in biotechnology (at 120%)
- Establish a venture capital fund to assist in the transfer of technology from research laboratories to start-up companies (R20 million p.a., built up to R80 million). It is not intended that Government administer this fund directly, but rather that it use an organisation such as the IDC to establish the fund and decide on the investments. As noted in Chapter 3 and Figure 9, Appendix 4, there is a market failure in the area of start-up funding and it is one that will not readily be filled by the private sector due to its high risk status. Furthermore, as shown in Figure 10, Appendix 4, it is not unusual for governments to enter venture capital markets.
- Phase in expenditure of about R3 million p.a. per incubator (this requirement is expected to arise only in year 3 after the implementation of the RICs).

In addition, we make recommendations on the following:

- A request that all performing and funding agencies report on an annual basis their expenditure on biotechnology.
- Constant monitoring of the impact of biotechnology expenditure, including the establishment of new companies, the creation of employment, the improvement of quality of life, etc.

Intervention: Government venture capital

In Chapter 3 we identified a number of deficiencies in the financing of biotechnology R&D and its commercialisation. In particular, we noted the reluctance of existing venture capital (VC) companies to finance start-up or early-phase biotechnology companies, and the fact that this is a relatively common phenomenon in most countries other than the USA. The absence of funding and the need for such funds to undertake ‘proof of concept’ studies have led many governments to intervene more significantly in the VC market (see Figure 10, Appendix 4).

It is therefore proposed that the South African Government should consider either the establishment of a new VC fund or to extend its existing funding so that it includes a mandatory allocation to biotechnology. We understand that there is at present only one operational government sponsored fund, which was launched in the year 2000 by Khula and managed by an independent venture capital management firm. The same fund could be used as a means of providing financial support for deserving biotechnology enterprises, thereby removing the need for establishing an additional infrastructure. Alternatively, the money could be directed through the Industrial Development Corporation, which has the necessary expertise and infrastructure to evaluate the merits of applications for funding and disburse the funds.

Intervention: Supply side measures to support private sector R&D

The provision of incentives to encourage private sector R&D has been raised in a number of policy initiatives led by the Department of Arts, Culture, Science and Technology. As a result, a number of new supply-side measures have been implemented, including the extension of the Support Programme for Industrial Innovation (SPII) and THRIP, and the establishment of PI, the Innovation Fund and the Competitiveness Fund. These measures have gone some way towards the introduction of a stronger R&D culture in South Africa and hence an increased focus on innovation.

Nevertheless a significant gap remains between investment by the private sector in R&D and similar investments in other ‘economies in transition’. Tax allowances, which have been applied in countries such as Australia and Canada, have been mentioned as a suitable instrument for achieving the objective of increased R&D expenditure. Such allowances have been discussed previously with the National Treasury, and have been largely refused, on the basis that it would be yet another means of undermining tax collection, and that the appropriate skills for the administration of such an allowance are not available in the South African Revenue Services.

Clearly the need for such allowances still exists and it is the recommendation of the panel that implementation thereof should be reinvestigated by Government at an appropriate time in the future. In the meantime, the allocation of funds from the existing supply-side measures should be focused to allow at least a 10% assignment to biotechnology, thereby adding a further R25 million to the pool of available funds. Furthermore, this allocation should be focused on the sector-specific recommendations made in Section 4.4.

Intervention: Creation of liquidity in venture capital markets and the valuation of intellectual property

Investment in the biotechnology industry is generally characterised in three ways:

- It is long term, with shareholders expecting positive cash flows after a period of at least 5 years and in the case of biopharmaceuticals, at least 10 years.
- The average research expenditure to earnings ratio is very high (about 30 to 40%) i.e. it is a research-intensive industry requiring high initial R&D investment before product (or service launch).
- It is provided largely by VC companies that require liquidity (ability to sell their investment portfolio) of their investments at all points

These characteristics create the need for two innovative mechanisms for financing of biotechnology, which are of particular importance in South Africa, but which could also provide a competitive advantage for our national R&D efforts, thereby attracting additional investment. The two components are the creation of a market place for R&D

projects and a valuation service for SMMEs, particularly as regards their intellectual property portfolios. Both services could be delivered via a web-based portal.

It is proposed that such a portal be established by the secretariat of the Biotechnology Advisory Committee, or be outsourced to a regional centre. The site would contain information of general interest to the biotechnology corps (a good example of a similar site in another country is www.biomedoz.com.au serving the Australian Biotechnology Association), information to attract foreign investors, links to South African biotechnology companies and biotechnology statistics, including R&D and the IP market-place/valuation service. Inventors of IP, and owners of equity in biotechnology companies would be able to use the site as an on-line broker, both offering private equity/IP to potential buyers, and trading (a good example of a general site for IP trading is www.yet2.com.). The valuation service would be useful to a number of constituencies including academics who wish to sell incipient or incomplete IP and business people who lack valuation expertise.

4.8 Ethical issues

Objective: Address ethical considerations relating to biotechnology

Intervention: Develop a national strategy to address ethical issues associated with biotechnology

The BAC should address ethical issues in biotechnology and oversee the inappropriate implementation of codes of conduct that occurs in various institutions and Government departments. Where necessary, the BAC should identify gaps in ethical procedures and make recommendations for these to be addressed. The areas include:

- The disclosure and use of genetic information.
- Gene therapy and human cloning.
- The potential impact of GMOs on the environment.
- Horizontal gene transfer from GMOs to other organisms.

- Trans-species gene transfer.
- Participation in research and clinical trials.

The Department of Health has developed guidelines for clinical trials and the Ethics Council is to promote and monitor the compliance of South African ethics committees with the relevant legislation and regulations, ethical guidelines and standards. The National Bioethics Committee should be empowered to make recommendations to, and monitor the activities of the various ethics committees to ensure the safe application of biotechnology. This Council should have access to all existing institutional ethical guidelines and make amendments as the need arises.

4.9 Public understanding of biotechnology

Objective: To promote a clear understanding of the potential of biotechnology

The lack of public understanding of biotechnology and the issues surrounding it has resulted in a negative backlash in many regions of the world. This has also resulted in selective trade barriers. This situation can be solved only through improved communication and better understanding of the scientific principles that underlie biotechnology. In this way the benefits of biotechnology can be appreciated by the entire country and not just by specialists in the field.

Intervention 1: The Government should articulate a single vision of biotechnology

There needs to be a single biotechnology vision for South Africa. The public should not be confronted by differing opinions from Government departments on issues of national priorities.

Intervention 2: Public education about biotechnology

Campaigns on issues relating to biotechnology should give accurate information containing the inputs of the various Government departments that are charged with supporting or implementing a particular initiative (e.g. NDA, DOH, DEAT and DTI for the GMO Act).

Biotechnology issues should be included in the school curriculum. Encouraging discussion and debate on the potential benefits, risks and ethical and environmental issues regarding biotechnology issues at high school level will help create public awareness because often these discussions will not be confined to the school.

The media must be provided with information representing all sides of the debates and encouraged to convey biotechnology issues to the public in a responsible manner. At present topical issues that will require detailed communication to people at all levels, from the grassroots to top decision makers, include stem cell research, xenotransplantation, GM foods and gene therapy.

It is proposed that the Science and Society Directorate of the DACST should undertake all of the above activities.

Chapter 5: Recommendations

A number of key interventions have been proposed in this document, some of which refer to individual sectors, and the remainder to cross-cutting components of the biotechnology industry, such as the legal and regulatory framework, the development of biotechnology capacity through relevant human resources development and institutions, and support for the commercialisation of biotechnology.

Three major recommendations have been made in this document, namely:

- The Government should articulate a single policy position on biotechnology.
- The establishment of the BAC.
- The formation of the RICs.

In most cases, these recommendations are directed at the Government of South Africa and its associated public sector institutions such as science councils and universities. It is recognised that the Government on its own cannot bring about a fundamental change in the positive impact of biotechnology; it will require the support of the private sector, civil society and others. The ongoing task of creating alignment between the objectives of the Government and the activities of other players is therefore implicit throughout the document.

5.1 New institutional arrangements

5.1.1 Biotechnology Advisory Committee (BAC)

The creation is recommended of a Biotechnology Advisory Committee with representatives from several of its stakeholders, and with the following functions:

- To be an advisory body appointed by the Minister of Arts, Culture, Science and Technology (in consultation with other relevant ministries) under the auspices of the Economic Cluster in Government and reporting to the DACST.
- To implement this national strategy.
- To identify national biotechnology priorities, in addition to those mentioned in this strategy.
- To issue requests for proposals (RFPs) for the establishment of RICs within established guidelines for the promotion of synergy in the biotechnology community.
- To recommend to the NACI and other Government funding agencies the appropriate programmes for and expenditure on biotechnology in South Africa. The funds will be channelled through existing structures such as statutory bodies.
- To monitor the impact of biotechnology expenditure.
- To promote the investment of venture capital in biotechnology and the search for industrial partners.
- To investigate resource mobilisation into biotechnology (skills, funds and facilities).

5.1.2 Regional Innovation Centres

The RICs will be responsible for:

- The establishment and maintenance of technology platforms to be available internally and for satellite groups.
- The establishment of associated biotechnology incubators to facilitate spin-off companies and technology transfer from laboratory to commercial entities
- The appointment of a core of permanent staff and a larger contract staff to undertake the programme work.

5.2 Responsibilities of Government departments

There are a number of general responsibilities that are shared by all departments, as follows:

- To consult with other departments in areas of common interest, and specifically concerning the introduction of new legislation or conventions.
- To prevent conflict between new legislation and/or conventions and this strategy.
- To ensure the safe use of biotechnology.

In addition, it is recommended that each department assume the following specific responsibilities:

5.2.1 Department of Arts, Culture, Science and Technology

In the implementation of the recommendations of this strategy, the DACST will have the following responsibilities:

- The appointment and management of the Biotechnology Advisory Committee (through an existing statutory council such as the NRF).
- General promotion of the biotechnology strategy and the monitoring of its implementation.
- Motivation for funding for the strategy from National Treasury.
- Allocation of funding to the RICs.
- Initiation of a widespread public awareness campaign on biotechnology using the existing infrastructure and capacity in the Science and Society Directorate
- Support for the biotechnology incubators in the RICs.

5.2.2 Department of Trade and Industry

The Department of Trade and Industry is required to implement the:

- Modification of the Patents Act to include the equivalent of the USA Bolar Provisions, allowing for early registration of (and R&D work, including on clinical trials) generic copies of patented medicines.
- Modification of the Patents Act (and hence the Patents Office) to include a 'search and examine' capability.
- Establishment of a biotechnology venture capital fund (through the IDC) to assist start-up biotechnology companies.
- Further promotion of South Africa as an important destination for foreign investment, particularly in the area of biotechnology R&D and product manufacture.
- Drive economic development around the RICs through the attraction of large 'anchor' investors.

5.2.3 National Treasury

The National Treasury is required to consider additional allocations of funding as follows:

- R2 million p.a. for the activities of the BAC.
- R20 million p.a. for a VC fund.
- R25 million p.a. for focused biotechnology R&D in the private sector through existing government supply side measures.
- R135 million p.a. for the running of the RICs and programmes.
- R45 million for the initial establishment cost of the RICs.

In addition, it is recommended that Customs and Excise develop the necessary skills (or outsource this expertise where it cannot be developed) to allow the effective implementation of the biosafety regulations for trans-boundary movement of GMOs (as described under the GMO Act).

5.2.4 Department of Health

The Department of Health can influence the development of biotechnology products and services in a number of ways, including:

- The leveraging of its buying power as a major consumer of health products to stimulate investment (such as the creation of a public/private sector partnership in vaccine manufacture).
- The ethical application of biotechnology through the regulation of clinical trials, fertility clinics, human genetic testing, stem cell research, etc.
- The development of clear legislation for the labelling of foodstuffs.

It is therefore recommended that the Department:

- Use its buying power to stimulate the biotechnology industry in South Africa (for example, in the establishment of a viable human vaccine industry)
- Extend the functions of the National Bioethics Committee to include all ethical issues related to biotechnology.
- Ensure the development of legislation for the labelling of foodstuffs obtained from organisms developed by certain techniques of genetic modification.

5.2.5 Department of Agriculture

The Department of Agriculture plays a key role in many areas of relevance to biotechnology, including the implementation of the GMO Act and the Plant Breeders' Act, and the alignment of the agricultural institutions with national priorities. As a minimum, it is recommended that:

- The administration of applications for trials on GM crops be improved in order to improve turnaround times.
- Training in biosafety be provided for the Advisory Committee, the Executive Council and reviewers.
- The Department develop mechanisms for the stimulation of R&D on biosafety.

- The Department consider ways of protecting the rights of animal breeders, in addition to plant breeders.
- The Department introduce amendments to the Plant Breeders' Act to include DNA fingerprinting as a means of distinguishing genotypes.
- The Department, in conjunction with the ARC and the BAC, identify opportunities for community-based industries arising from the RIC programmes.
- The Minister and the Board members continue to develop the animal vaccine industry through Onderstepoort Biological Products in order to meet national requirements and develop an internationally competitive company.

5.2.6 Department of Education

It is important that the Department of Education should support the development of biotechnology in the following ways:

- Promoting curriculum development at secondary level, particularly in the areas of mathematics, science and life skills.
- Encouraging the tertiary educational institutions to include entrepreneurial and business skills in curricula for biotechnology students at all levels.
- Extending biotechnology training and education in all teaching institutions
- Evaluating its formula for the research component of its financial support of universities.

5.2.7 Department of Environmental Affairs and Tourism

The Department of Environmental Affairs and Tourism will play an important role in the following areas:

- The conclusion of the processes to develop both a legal framework for the protection of indigenous knowledge (this involves participation in the process being co-ordinated by the DACST) and the regulation of the exploitation of our biodiversity (under the CBD).

- Ongoing monitoring and servicing of impending and existing legislation and conventions (to be signed or ratified) to ensure the safe use of biotechnology.
- The facilitation of technology transfer into or out of South Africa regarding biotechnology (in cases of value addition to biodiversity).
- The establishment of a regulatory framework for providing equitable access to biological resources and benefit sharing.

Abbreviations

ARC	Agricultural Research Council
BRC	Biological Resource Centre
CBD	Convention on Biodiversity
CPB	Cartagena Protocol on Biodiversity
CSIR	Council for Scientific and Industrial Research
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CITES	Convention on International Trade in Endangered Species
DACST	Department of Arts, Culture, Science and Technology
DEAT	Department of Environment Affairs and Tourism
DNA	Deoxyribonucleic Acid
DoH	Department of Health
DTI	Department of Trade and Industry
FIOCRUZ	Oswaldo Cruz Foundation
FAO	Food and Agricultural Organisation
GDP	Gross Domestic Product
GMO	Genetically Modified Organism
Godisa	Range of programmes jointly funded by the EU and the DACST to facilitate technology transfer and incubation in SMMEs
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICT	Information and Communication Technology
IDC	Industrial Development Coroporation
IPR	Intellectual Property Rights
IPO	Initial Public Offerings
MAP	Millennium Africa Programme
Mintek	Council for Mineral Technology
MRC	Medical Research Council
NACI	National Advisory Council on Innovation
NBI	National Botanical Institute
NDA	National Department of Agriculture
NEMA	National Environmental Management Act
NH	National Health

NRF	National Research Foundation
NRTF	National Research and Technology Foresight
NSI	National System of Innovation
R&D	Research and Development
RFP	Requests for Proposals
RIC	Research Innovation Centre
SAAVI	South African Aids Vaccine Initiative
SANBI	South African National Bioinformatics Institute
SAPTO	South African Patent and Trademarks Office
SET	Science, Engineering and Technology
SETI	Science, Engineering and Technology Institute
SMME	Small, Medium and Micro-Enterprises
SPII	Support Programme for Industrial Innovation
TRIPS	Trade-related Aspects of Intellectual Property Rights
THRIP	Technology for Human Resources in Industry Programme
VC	Venture Capital

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Legislation

1. Plant Improvement Act, No. 53 of 1976
2. Genetically Modified Organisms Act, No. 15 of 1997
3. Regulations under the GMO Act, No. 15 of 1997, of 26 November 1999
4. Animal Improvement Act, No. 62 of 1998
5. Livestock Improvement Act, No. 25 of 1977
6. Plant Improvement Act, No. 53 of 1976
7. Regulations under the Animal Improvement Act, No. 62 of 1998, of 30 July 1999
8. Meat Safety Act, No. 40 of 2000
9. Animal Diseases Act, No. 35 of 1984
10. Livestock Brands Act, No. 87 of 1962
11. Plant Breeders' Rights Act, No. 15 of 1976
12. Human Tissue Act, No. 65 of 1983
13. Patents Act, No. 57 of 1978
14. Foodstuffs, Cosmetics and Disinfectants Act, No. 54 of 1972

Appendices

Appendix 1. The competitive needs of modern biotechnology

As has been stated in Chapter 1, biotechnology, broadly defined, refers to a set of technologies that use biological systems, living organisms, or derivatives thereof, to make or modify products or processes. This definition encompasses what is termed 1st, 2nd and 3rd generation technologies, where these categories have become an accepted means of distinguishing between three levels of the technology, based primarily on the chronology and maturity of the underlying techniques, but also on fundamental differences in the way in which technologists exploited biological systems to manufacture products.

These differences are most easily understood by way of example. In the 1st generation, either the 'wild type' (naturally occurring) organism was used, or one which had adapted to the industrial environment. For example, beer is produced using a particular strain of yeast called *Saccharomyces cerevisiae*, which over the centuries has been selected on the basis of its ability to grow successfully in the production medium and produce a product of the desired flavour profile.

In the development of our examples, we now need to define two additional terms used by biotechnologists, namely 'vector' and 'genetic composition'. In the case of beer brewing, the vector is the yeast and the genetic composition is the genome, or collection of DNA that contains all the genetic information required by the yeast for it to grow and reproduce. In 2nd generation biotechnology, use is made of a further set of techniques that can change the genetic composition of the organism without introducing new DNA from outside the species barrier. For example, yeasts can be subjected to chemical mutagenesis, and then cultured in selection media, in order to identify mutants that will, for instance, survive only in the presence of a key amino acid, or which 'over produce' a certain metabolite. 2nd generation biotechnology therefore introduced a set of techniques that could change the genetic composition in a random way.

Finally, 3rd generation biotechnology is characterised by the emergence of techniques that were able to move DNA across species barriers, change DNA in a predetermined way, and thereby confer on vectors the ability to produce new products (on the basis of a modified genetic composition). Using DNA from bacteria, for instance, yeasts are now able to produce enzymes and other proteins that previously were not present at all, or perhaps only at very low levels. The three generations therefore differ in their ability to modify DNA: in the case of 1^{st} generation, not at all, in 2^{nd} generation by mutagenesis or cultivar selection within a species barrier, and in 3^{rd} generation with the addition of exotic DNA (or the removal of unwanted DNA).

Industrial biotechnology has emerged as a sector that relies on all three generations. In the traditional food processing industries, no use is made of either 2^{nd} or 3^{rd} generation techniques (as applied to the production vector). On the other hand, all biopharmaceuticals, including insulin and erythropoetin, require 3^{rd} generation vectors. Indeed, many new therapies would not have been possible without such techniques. However, all components of industrial biotechnology share a common platform, which is a set of techniques that apply to the management of biological systems. Furthermore, the competitiveness of all players will depend on their ability to absorb 3^{rd} generation techniques. In some cases consumer resistance, and biosafety considerations, will prevent the application of such techniques to the production vector. Nevertheless process and product improvements in such industries will draw upon knowledge from field such as bioinformatics and proteomics to refine production methods.

The need for 3^{rd} generation biotechnology, even in 1^{st} and 2^{nd} generation industries, is illustrated by means of an example. Lysine is produced using the bacteria *Corynebacteria glutamicum*,which has been subjected to chemical mutagenesis, but is not a GMO. The next step change in the technology will be the introduction of a GMO that will radically improve the efficiency of the process and hence lower the cost. This will be the result of 3^{rd} generation techniques, to yield an organism which could not otherwise have been obtained.

The proposed focus on ‘new biotechnology’ will create opportunities for all biotechnology players. These advances in technology have opened the doors to new diagnostic, analytical and production techniques that will benefit all generations to a greater or lesser extent. As has already been stated, the ability of 2^{nd} generation entities to remain in their present markets will depend on their ability to absorb 3^{rd} generation technologies. The strategic interventions proposed in the National Biotechnology Strategy will increase the availability of skilled human resources, stimulate the development of technologies for new products, attract additional investments in biotechnology, stimulate the related and supporting industries (suppliers, financiers, etc.), and strengthen the biotechnology platform.

Nevertheless, the question remains whether this is all that is required. It is noted that many of the 2nd generation products have become commodities and that the usual rules of commodity chemical production apply, namely economies of scale, low-cost raw materials especially energy, carbohydrate and protein raw materials, low labour cost and low capital cost. Many of these inputs are already in place in our economy. For example, we have an agreement with the sugar industry to provide sugar for downstream value adding industries at export parity less transport cost, we have one of the lowest power costs, and our construction sector is competitive.

However, it will not be easy to identify opportunities for new 2nd generation manufacturers in South Africa. The Indians and Chinese, whose production costs are a fraction of those of the USA and EU, and considerably less than those of South Africa, are offering many of these products. Existing producers in the EU and USA are struggling to compete, and these economies have lost fermentation capacity in the last ten years.

It is likely that there will be niche products in the case of which we can establish a competitive position, including specialised enzymes, chemical production using biotransformation, and amino acids. For some projects, certain incentives will be required, which could be met with existing schemes and programmes, for example through the Department of Trade and Industry, the Industrial Development Corporation, the Spatial Development Initiatives, etc. Each development will need to be considered on a case-by-case basis. It is our opinion that further generic interventions, as contained in the remainder of the strategy document, are neither possible nor desirable.

Appendix 2. The development of a biotechnology strategy paper
Terms of reference for the expert panel

1. Background

Biotechnology is one of the technologies that can be widely applied in various fields such as health, agriculture and agroprocessing, minerals and their processing, criminal justice and defence and environmental management. Most important is that the developments in biosciences are driving an economic revolution that could shape the future of human endeavour. The new revolution brings with it a number of friction points as well as the development opportunities that provide challenges worldwide and to South Africa in particular. These challenges relate to environmental and health regulations, ethics, biological resources and intellectual property right regimes. On the development side, examples include areas such as food security, competitive strength in processing technologies and improved health benefits through drug development.

The Government is therefore challenged to provide an enabling environment for the promotion of such technologies and to facilitate their entry into the global arena in such a manner as will address national needs, in particular the pressing socio-economic needs.

It is because of this that the Cabinet found it necessary for a national strategy on biotechnology to be developed. The Department of Arts, Culture, Science and Technology (DACST) was tasked as the lead agency for the development of such a strategy. An interdepartmental steering committee has been established to develop such a strategy document.

2. Objective

The objectives of the strategy document is to inform Government, industry and the research community about the steps that need to be taken for biotechnology to have a positive socio-economic impact.

3. Scope of the work

The scope of the work would cover a general review of:

- All biotechnology-related legislation in South Africa.[19]
- The funding regimes which promote biotechnology developments through research effort in the private sector, research councils, academic institutions and/or any other donor agencies.
- The levels and types of private sector engagement in this field.
- State and private sector support for the establishment of business ventures in biotechnology, e.g. infrastructure and capital investment.
- Institutional infrastructure for the development of biotechnology capacity.
- The human resources and skills development in biotechnology.

In the review experts would note areas of uncertainty, knowledge gaps and varying perspectives about the effects, benefits and value of biotechnology. Taking the review into account, the expert panel would need to develop a comprehensive definition of biotechnology and devise a strategy for the further development of biotechnology to advance the following:

- Economic growth: optimum utilisation and exploitation of biotechnology by existing industries.
- Unexplored biotechnology areas and industries with growth potential.
- Research and development
- Human resource development.

4. Methodology

- A national strategic plan will be prepared by a group of experts to be appointed by the Director-General of Arts, Culture, Science and Technology. An interdepartmental steering committee composed of representatives of the DACST, NDA, DEAT, DTI and DoH will oversee the work of the expert group and the

Agricultural Research Council (ARC) will be responsible for providing administrative support for the project.

- The experts will be expected to review all the necessary background documents and submissions from various players in the biotechnology arena and to interview relevant Ministers, Directors-General, industry players, tertiary education and science council representatives and policy specialists. A 10-day working session to draft the biotechnology strategy paper will be held in early May at a venue in Pretoria. The issues that need to be addressed range from requirements for amendments to legislation, regulations, policy positions, research support, institutional infrastructure, human resource development, programme interventions, such as the Innovation Fund as well as options on new interventions and incentives.
- The final report must be submitted to the steering committee for submission to the Director-General of the DACST during the second week of June 2001, for submission to the Cabinet on 27 June 2001.

5. Time frame

Item.	Subject Description	Due Date
1.	Interviews and drafting of paper (2 – 11 May)	15 May 2001
2.	Review of report by steering committee	25 May 2001
3.	Finalisation of report by expert group	8 June 2001
4.	Final submission to the Cabinet	27 June 2001

[19] Apart from some sector specific Acts, policies, regulations and guidelines, there is no 'biotechnology legislation' in South Africa at the moment. A comprehensive account of what is addressed in the various sector legislation and what is still outstanding needs to be provided.

Appendix 3. Names and organisational affiliation of interviewees

Name	Company
Ahmed Essop	DoE
Alan Aderem	USA
Andre Kudlinski	DTI
Andrew Simpson	Brazilian Genome Project
Ayanda Ntsaluba	DoH
Bongi Njobe	NDA
Elizabeth Goyvaerts	University of the North
Errol Tyobeka	Wits Technikon
Gert Willemse	DEAT
Heather Sherwin	GenSec Investments
Himla Soodyall	University of the Witwatersrand
Ina Wilken	Consumer Union
Jane Morris	CSIR
Johan Brink	AfricaBio
Johan van Zyl	University of Pretoria
Karen Kallmann	Safe-Age
Kevin Mxolise	Wandile Pharmaceuticals
Khotso Mokhele	NRF
Khungeka Njobe	DEAT
Liezette van Rensburg	University of Pretoria
Liz Harris	ARC
Marjorie Pyoos	DACST
Mel Christiansen	University of the Witwatersrand
Monde Ntwasa	University of the Witwatersrand
Nick Opperman	Agri-SA
Nick Tselentsis	Grocery Manufacturers Association
Rocky Skeef	NRF
Rosemary Wolson	University of Cape Town
Ross Norton	AECI Bioproducts
Sean Klinkradt	Johan and Kernick
Shadrack Moephuli	NDA
Sibusiso Sibisi	University of Cape Town / NACI
Tania Broeveak	Electric Genetics
Tony Pinches	Mintek
Valerie Mizrahi	SAIMR
Vincent Volkhart	Syngenta
Wally Green	Monsanto
William Makgoba	MRC
Willie Maree	Monsanto
Wilna Janse van Rijssen	DoH
Wolf Katz	State Vaccine Institute
Wynand van der Walt	SANSOR

Appendix 4. Summary of the South African Venture Capital Industry[20]

The South African venture capital industry (including private equity funds) consists of about 64 firms and the funds they have under their management are in the region of R28 billion. The size of the industry is comparable to developed countries, excluding the USA, and as a percentage of GDP exceeds that of the Netherlands, Austria and Sweden (see Figure XX).

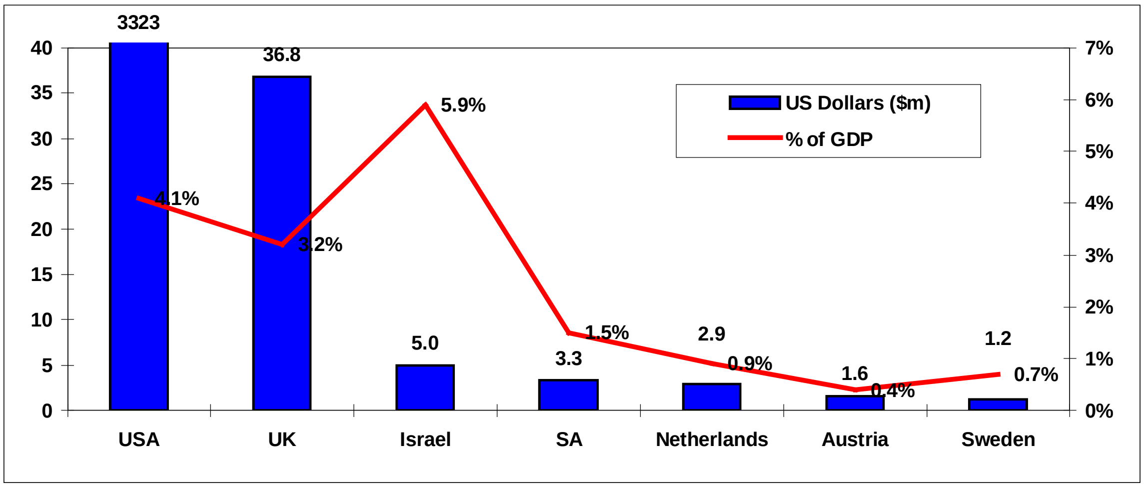

Figure 8. A comparison of the VC industry in South Africa with that in OECD nations

Venture capital has become an increasingly important and fashionable source of funding for small and medium non-listed enterprises. Many enterprises have learnt the harsh reality, however, that it is difficult to obtain finance from venture capital funds, and the venture capital sector has to date not contributed significantly to the development of the emerging entrepreneur. High transaction costs force venture capital and private equity funds to favour large investments over small ones and established enterprises over start-ups. The average investment size is in the region of from R10 million to R15 million. More often than not, though, SMEs seek capital injections in the early stages of their development and they require funds that are small (say R2 million) by industry standards (see Figure 9).

[20] Obtained from the Black Empowerment Forum's report on Venture Capital and Empowerment.

Primarily as a result of its risk-averse approach, the South African venture capital industry has experienced high levels of profitability. A large proportion of its investments have proved successful. In the US the industry norm is expressed by the following ratio: 2 : 6 : 2, that is, out of ten investments two are failures, six show an indifferent performance and two have profitability sufficiently high to compensate for the failures and indifferent performance of the other investments. In South Africa the proportion of very profitable investments is probably slightly higher, and the proportions of failures slightly lower, than the US norm. The reason for the high performance in South Africa is the high proportion of investments into late-stage enterprises, such as for management buy-outs. There are suggestions that management buy-out deals are, on average, yielding higher returns than the other investments. This is supported by data from Europe, where buy-out funds achieved realised rates of return since inception of 19.6%, whereas the combined returns for the other stages of investment were 12.4%. Overall rates of return since inception in the European industry amount to 14.5%. In South Africa the comparable in information is not available, but existing data indicate that the figure is about 30%.

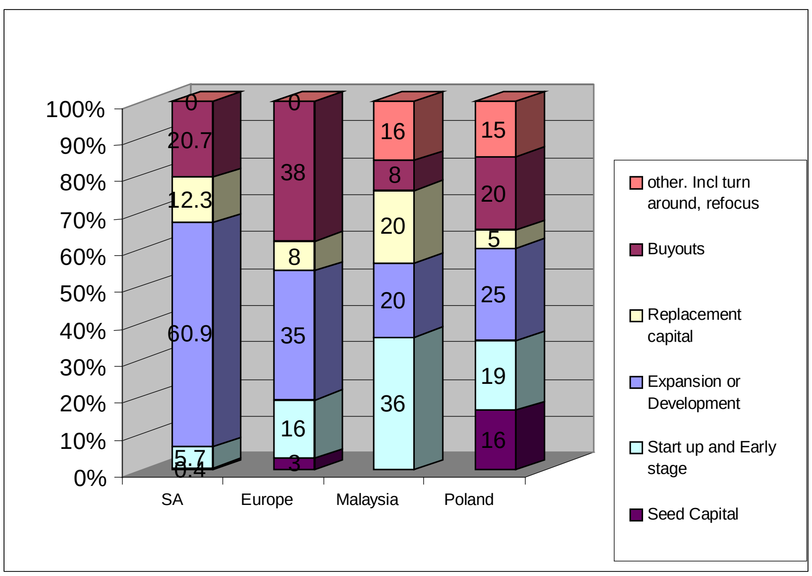

Figure 9. Analysis of investments by stage compared with that in other countries

Furthermore, the Government is a relatively small participant in the VC industry, compared with other developing countries (see Figure 10). At present there is only one fully-operational Government-sponsored fund, which was launched in 2000 by Khula and managed by an independent venture capital management firm. Government's earliest involvement was via the Small Business Development Corporation (SBDC), which at times took up a limited equity stake in its clients. The SBDC has since been restructured into Business Partners, in which Government holds only 20% stake.

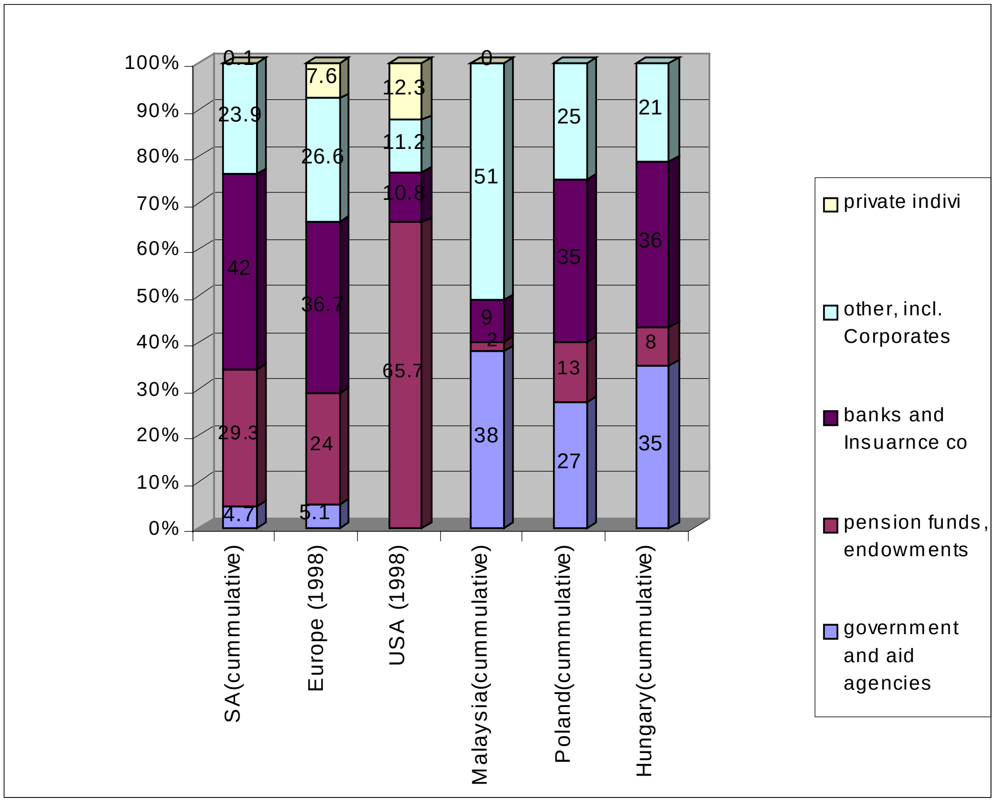

Figure 10. Government is a relatively small participant in the VC industry, compared with other developing countries