THE BIO-ECONOMY STRATEGY

science
& technology

Department:
Science and Technology
REPUBLIC OF SOUTH AFRICA

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FOREWORD BY THE MINISTER OF SCIENCE AND TECHNOLOGY

Science and technology are crucial to South Africa's development. The White Paper on Science and Technology (1996) laid out the route for revising science and technology efforts to address the needs of a newly democratic nation. We subsequently developed the National Biotechnology Strategy (2001) to initiate the development of technologies and associated products and services that would address the science-based innovation needs in the health, industrial and agricultural sectors of the economy.

We have built capacity and infrastructure, developed value chains, gained experience and encouraged a growing interest in the application of biotechnology to a range of areas – new diagnostics, vaccines and therapeutics, improved crops and livestock, cleaner and more efficient industries. This Bio-economy Strategy is designed to complete the cycle, amalgamating our experience, expertise and competitive advantages to create a world-class biotechnological system of innovation. This is a system that operates at a higher level than mere project support; it is more productive, more responsive and more relevant to the needs of South Africans. It makes a positive impact on the South African economy.

A key aspect of this new strategy is coordination. Both industry and government have research, development and innovation needs, which are required to maintain a competitive edge and ensure efficient service delivery. Together with academia, science councils and other institutions, we have the collective expertise to drive innovation for South Africa's benefit. However, this expertise is still largely fragmented – conflicted by competition and not aligned in a common purpose. The Bio-economy Strategy outlines key mechanisms for coordinating innovation efforts, ensuring that role players can contribute – rather than compete – for opportunities, resources and outcomes.

There are also strategic innovation competencies that should be developed and enhanced, and strategic innovation programmes that should be supported in order to develop critical mass and achieve outcomes relevant to our collective needs.

Although the Department of Science and Technology has an important role to play in coordinating the leadership that will implement this strategy, the strategy itself extends far beyond the mandate of the Department. It is essential that the Departments of Trade and Industry, Health, Agriculture, Forestry and Fisheries, and Environmental Affairs, among others, are involved in directing research, development and innovation activities that address their needs. Science councils and universities are called on to respond by developing human capacities and technological capabilities; and industry should participate directly to guide and extract value from developments and to create new, globally competitive products that create jobs and wealth and improve the quality of life of South Africans.

The Bio-economy Strategy is thus not a Department of Science and Technology strategy – it is a South African strategy.

Mr Derek Hanekom

Minister of Science and Technology

FOREWORD BY THE DIRECTOR GENERAL OF THE DEPARTMENT OF SCIENCE AND TECHNOLOGY

Science and technology (S&T) are essential components of the government's strategy for the empowerment of all South Africans as they seek to achieve their social, political, economic and environmental goals. This vision was first articulated in the 1996 White Paper on Science and Technology, which was based on the premise that South Africa would use S&T to be economically competitive on a global scale and to provide essential services, infrastructure and effective health care for all South Africans. Central to this was the National System of Innovation, which facilitated the development of innovative ideas, products, institutional arrangements and processes to address more effectively the needs and aspirations of the country's citizens.

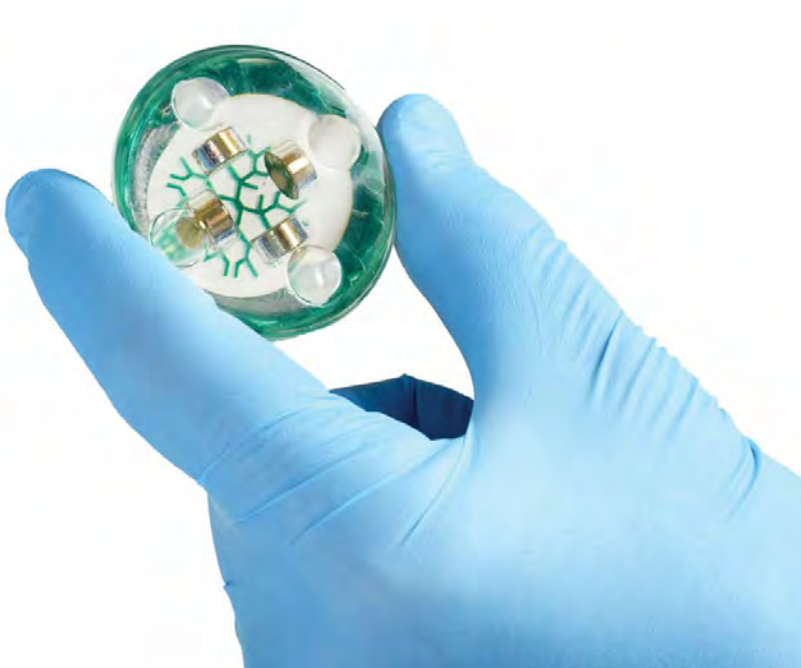
In 2008, the Department of Science and Technology published the Ten-Year Innovation Plan, which further elaborated on this vision. This plan seeks to transform the South African economy into a knowledge-based economy, in which the production and dissemination of knowledge leads to economic benefits and enriches all fields of human endeavour. The "Farmer to Pharma" concept was identified as one of the five Grand Challenges in the plan. It was conceptualised as the interface for integrating South Africa's rich natural biodiversity, indigenous knowledge and applied biotechnologies. The outcomes of "Farmer to Pharma" span the whole spectrum of the bio-economy (health, agriculture and industry), but the focus of the concept is limited.

In view of this shortcoming, the Bio-economy Strategy was conceived, where bio-economy is not restricted to biotechnology, but is inclusive of other disciplines such as information technology, social sciences and engineering. This inclusiveness is critical to developing a holistic solution for the agriculture, health and industry sectors. The strategy builds on achievements, incorporates the lessons learnt and moves forward with initiatives that can address the challenges of the future. It focuses on creating an enabling environment for stakeholders – including government departments, established industry, venture capital and the broader public – and on interacting with life-science role players, academics, researchers and private sector entrepreneurs to create value. It serves to identify areas where public policy can remove barriers, encourage innovation and improve cooperation between stakeholders.

The measure of success for this national strategy will be the level at which S&T drives enhanced productivity, economic growth and socio-economic development in South Africa.

Dr Phil Mjwara

Director General



EXECUTIVE SUMMARY

The term "Bio-economy" encompasses biotechnological activities and processes that translate into economic outputs, particularly those with industrial application. Within the South African context these may include, but are not limited to, technological and non-technological exploitation of natural resources such as animals, plant biodiversity, micro-organisms and minerals to improve human health, address food security and subsequently contribute to economic growth and improved quality of life.

The vision is for South Africa's bio-economy to be a significant contributor to the country's economy by 2030 in terms of the gross domestic product (GDP). This is to be achieved through the creation and growth of novel industries that generate and develop bio-based services, products and innovations. Such endeavours should translate into a corresponding increase in new companies and growth of existing companies that provide and utilise these solutions. On a macro-economic and developmental level, South Africa's thriving bio-economy has the potential to make the country more competitive internationally (especially in the industrial and agricultural sectors); create more sustainable jobs; enhance food security; and create a greener economy as the country shifts towards a low-carbon economy.

South Africa's Bio-economy Strategy provides an economic engine for the new economy that will, in turn, provide a basis for future growth. The strategy builds upon the strong foundation laid by two ground-breaking initiatives of the Department of Science and Technology. The first is the National Biotechnology Strategy of 2001, which was aimed at initiating the development of technologies and associated products and services to address the vital science-based innovation needs of the country in the health, industrial and agricultural sectors of the economy. However, it soon became apparent there were gaps in the strategy framework – it focused on commercialisation of technologies that were close to market, representing a quick return on investment, instead of being formulated to develop an innovation value chain for biotechnology-based products.

The second initiative is the Ten-Year Innovation Plan of 2008, which is aimed at transforming the South African economy into a knowledge-based economy, in which the production and dissemination of knowledge leads to economic benefits and enriches all fields of human endeavour. The plan identified five Grand Challenges, which include the "Farmer to Pharma" concept envisaged to provide the interface for integrating South Africa's rich natural biodiversity, indigenous knowledge and applied biotechnologies. Although the target outcomes of the "Farmer to Pharma" concept span the entire spectrum of the bio-economy (health, agriculture and industry), a more coordinated and integrated South African focus is needed.

The Bio-economy Strategy has been formulated to be more productive, more responsive and more relevant to the needs of South Africans; and to make a marked positive impact on the lives of all South Africans. This new strategy provides a high-level framework to guide biosciences research and innovation investments, as well as decision-making as South Africa adapts to the realities of global transition to a low-carbon economy. Designed to have a technology-push and market-pull approach, the strategy addresses the country's developmental goals and needs, as well as its industrial and agricultural competitiveness.

An important development entrenched in the strategy, is the drive to expand the country's shift in focus from developing biotechnology capabilities – and subsequently the biotechnology sector as a whole – to developing a bio-economy, where the biotechnology sector joins forces with the ICT sector, environmental agencies, the social sciences and other technologies, especially IKS community of practice, to create holistic solutions and industrial applications for agriculture as well as the health and industrial sectors, in order to create a world-class biotechnological system of innovation.

It is vital for the role players within the bio-economy to collaborate effectively if the bio-economy is to succeed. The strategy focuses on creating an enabling environment for a wide range of role players that include government departments, established industry, venture capital and the broader public; and on interacting with life-science role players, academics, researchers and private sector entrepreneurs to create value. It serves to identify areas where public policy can break down barriers to encourage innovation and improve cooperation between stakeholders. A key focus is to develop and enhance strategic innovation competencies and support strategic innovation programmes to develop critical mass and achieve outcomes relevant to our collective needs.

The Department of Science and Technology, in consultation with other relevant stakeholders, has identified three key economic sectors – agriculture, health and industry – as being the most in need of, and likely to benefit from key levers to drive the implementation of the South African Bio-economy Strategy.

Agriculture

Of the three sectors identified as crucial elements of the bio-economy, the agricultural industry currently has the highest economic impact. With relatively little capital infrastructure required, it remains a key opportunity for poverty alleviation, job creation, economic development and household food security in South Africa, on the African continent and abroad.

The Bio-economy Strategy's objective for agriculture is to strengthen agricultural biosciences innovation to ensure food security, enhance nutrition and improve health, as well as enable job creation through the expansion and intensification of sustainable agricultural production and processing. These interventions should be driven by strategic need as well as market demand, and will require strong private-sector involvement.

Biotechnology will play a crucial role in helping to improve the heat-resistance and drought-tolerance of crops and address the challenges of climate change, diminishing water and grazing, and potential loss of biodiversity. The skills and solutions that emerge from biotechnology research need to be effectively transferred to emerging, small-scale and commercial farmers.

Health

Disease burdens South Africa's health system. The way in which South Africa chooses to address global challenges such as communicable diseases plays an important role in determining the country's research agenda. South Africa needs to develop the ability to manufacture drugs, vaccines and other biologics locally, to improve the health sector's bio-economy and to help the country achieve its public health goals.

The Bio-economy Strategy's objective with regard to health is to support and strengthen the country's local research, development and innovation capabilities. By drawing on these capabilities, South Africa will be able to manufacture active pharmaceutical ingredients, vaccines, biopharmaceuticals, diagnostics and medical devices to address the disease burden, while ensuring a secure supply of essential therapeutics and prophylactics. The development of new and improved therapeutics (drugs, vaccines, phytomedicines and biopharmaceuticals), diagnostics and medical devices is a key area of intervention.

The need to strengthen and coordinate the informal herbal medicines market presents an opportunity to grow the African traditional medicines sector, via a value-addition approach through cutting-edge biodiversity-based bioprospecting and product development research.

Industry and the environment

The industrial bio-economy focuses on two areas – industry and sustainable environmental management. The former involves bio-based chemicals, biomaterials and bio-energy. The latter involves water and waste as a means of providing environmental sustainability for the industrial bio-economy.

The chemical industry is the foundation of manufactured goods. It provides inputs for a wide range of products such as pharmaceuticals, food, fuels, plastics and other materials. The emerging industrial bio-economy is expected to bring about improvements in the manufacturing sector's energy intensity, water usage, waste management and greenhouse gas emissions. These enhancements will improve the industry's competitiveness and reduce its environmental footprint.

The Bio-economy Strategy's key objectives with regard to industry and the environment are to prioritise and support research, development and innovation in biological processes for the production of goods and services, while enhancing water and waste-management practices in support of a green economy.

The herbal product manufacturing venture remains a national priority, with potential to contribute significantly to the national GDP. Current global trends indicate an increase in herbal product market value. The developing countries have emerged as the main suppliers of herbal and natural products to the developed world. South Africa possesses a major comparative advantage in biodiversity and climate for sustainable cultivation and processing of herbal products. The Bio-economy Strategy aims to focus on the industrial potential to turn it into a competitive advantage for the Southern African region.

Future prospects

Envisaged outcomes within the next five years, and beyond, are to carve a niche for South Africa in the globally competitive pharmaceutical industry; to fund centres of competence in the top five national health priorities; to increase foreign direct investment in health-related R&D; to strengthen the functional technology platform for agricultural biotechnology; and to strengthen research, development and innovation in the production of human and animal vaccine. Such endeavours are envisaged to yield a robust economic growth and subsequently improve the quality of life.

While there is no single route to attaining a viable bio-economy, it is clear that South Africa needs to significantly increase its gross expenditure on relevant research and development RDI. This funding should be used to capitalise on the country's opportunities and strengths and to adapt lessons learned locally and from other countries. The training of scientists, engineers and technicians at all points through the entire innovation value chain should be intensified, as well as the development of "technopreneurs", who are vital in developing diverse technologies into innovative products and services at the downstream end of the value chain.

The Department of Science and Technology, as the lead agent of this strategy, will continue to engage with line departments to promote cooperation, facilitate the strategy's broad implementation, and ensure synergy, alignment and better coordination of activities. It is crucial to note that the success of the strategy hinges on the coordinated efforts and unanimous will of all stakeholders involved, and will require due conscientiousness, patience and robust investments in order to achieve its goals.

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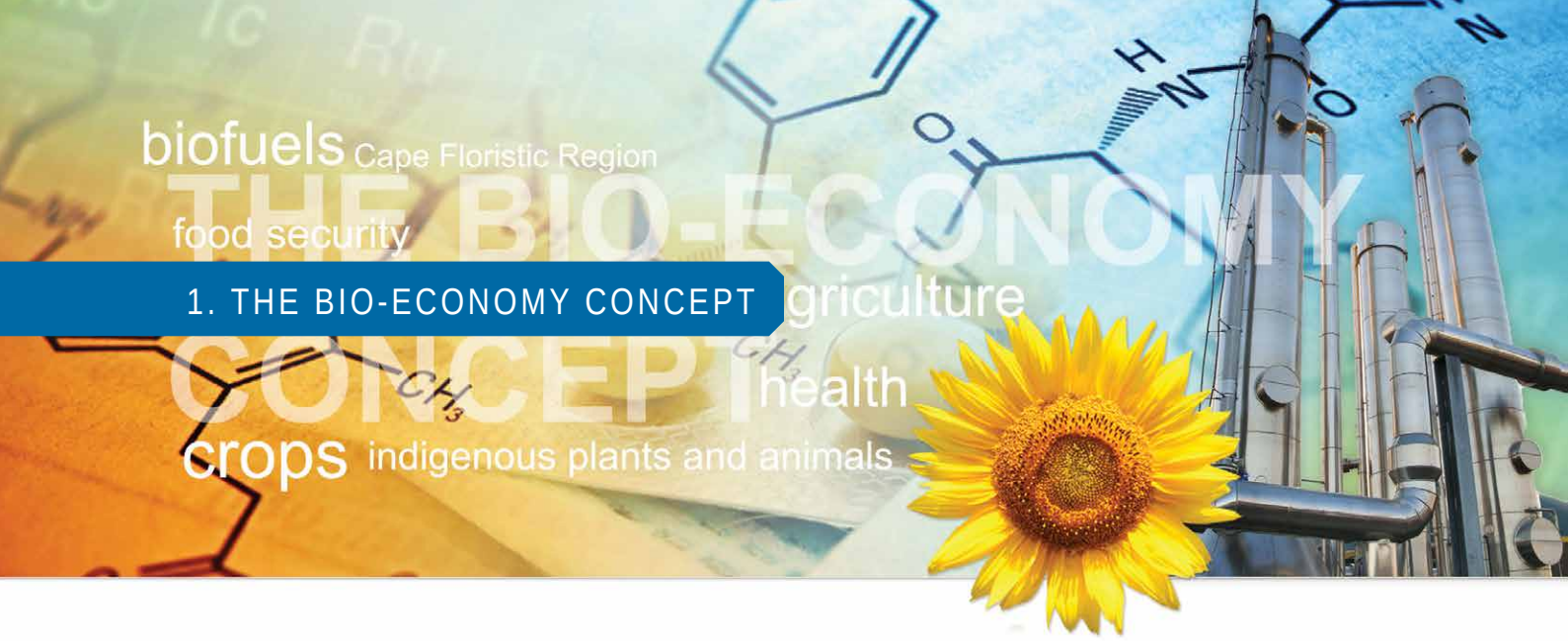


1.1 From a Biotechnology Strategy to a Bio-economy Strategy

The policy framework encapsulated in the Department of Science and Technology's 2001 National Biotechnology Strategy aimed to create incentives to grow the biotechnology sector. The strategy resulted in the establishment of biotechnology innovation centres, the main structures of which were BioPAD, Cape Biotech Trust, LIFElab and PlantBio, as well as two other structures, namely the National Bioinformatics Network and the Public Understanding of Biotechnology Programme.

These biotechnology innovation centres resulted in several platforms[1], spin-off companies and commercial products and services being formed, bringing with them new jobs and increased capacity. They also promoted knowledge of biotechnology, intellectual property management and commercialisation, and improved public understanding and awareness of biotechnology.

Since the implementation of the National Biotechnology Strategy, it has become apparent that there are several gaps and inefficiencies in the innovation value chain. The main gaps in the National Biotechnology Strategy were the result of an implementation model that based its focus on harvesting opportunities that represented a quick return on investment. The strategy was not formulated to develop a value chain for biotechnology-based products, but focused on commercialisation of technologies that were closer to the market.

The biotechnology innovation centres developed the infrastructure, skills and technologies required to stimulate the biotechnology industry. As biotechnology infrastructure and skills have become more established, there is an increasing need to link biotechnology applications to the more classical sectors, where specific needs or applications are identified and from where they can be driven. South Africa now needs to link these biotechnology capacities in the sectors that need them most, such as health, agriculture (including agriprocessing and fisheries) and industry (mining and the environment).

The National Biotechnology Strategy has reached a level of maturity where it has become essential to re-evaluate. Biotechnology can provide solutions for a large number of the health and resource-based problems facing South Africa and the rest of Africa, and it is necessary to utilise these solutions fully. In addition, we know that life sciences cannot be restricted to the biotechnology arena; developments have occurred where non-biological systems can have significant applications on living things. Therefore, the resultant emerging bio-economy needs to be nurtured through its application in the agriculture, health and industry sectors.

(A summary of the National Biotechnology Strategy can be viewed in Annexure 3).

1.2 Bio-economy concept

"Bio-economy" refers to activities that make use of bio-innovations, based on biological sources, materials and processes to generate sustainable economic, social and environmental development. In the bio-economy the entire innovation system/network, ranging from ideas, research, development, productisation[2] and manufacturing to commercialisation, should be used to its full potential in a coordinated manner.

The Bio-economy Strategy provides an economic engine for the new economy that will, in turn, provide a basis for future growth. These science-based "bio-solutions" can, for instance, be used to:

- manufacture high-value protein products such as biopharmaceuticals and vaccines;
- produce biofuels;
- improve and adapt crops;
- remedy industrial and municipal waste;

1 A DEPARTMENT OF SCIENCE AND TECHNOLOGY biotechnology platform is defined as an entity that addresses a strategic need/gap in the innovation value chain by offering world-class technical services and expertise to external stakeholders. In order to maintain quality standards, certain internal or collaborative projects should be undertaken to develop and maintain the platform's expertise at the cutting edge. ACGT. 2012. *Review of Technology Platforms: Role in the South African National System of Innovation*, commissioned by the Department of Science and Technology.

2 Productisation: The act of modifying something, such as a concept or a tool internal to an organisation, to make it suitable as a commercial product. Accessed on 28 January 2013, URL: http://en.wiktionary.org/wiki/productization#English

- reduce production costs;
- reduce environmental impacts;
- improve the quality of products; and
- improve the performance of a range of economic sectors.

The vision is for South Africa's bio-economy to be a significant contributor to the country's economy by 2030, in terms of the gross domestic product (GDP), through the creation and growth of novel industries that generate and develop bio-based services, products and innovations, with a corresponding increase in the new and existing companies that provide and utilise these solutions. On a macro-economic and developmental level, a thriving bio-economy has the potential to:

- make the country more competitive internationally (especially in the industrial and agricultural sectors);
- create more jobs;
- enhance food security; and
- create a greener economy as the country shifts towards a low-carbon economy.

The bio-economy in South Africa should address the country's socio-economic development goals of poverty reduction and improved quality of life, while ensuring continued economic growth. Having a technology-push and market-pull approach, the strategy addresses the country's developmental goals and needs, as well as its industrial and agricultural competitiveness as South Africa adapts to the realities of global transition to a low-carbon economy.

As clearly articulated in the New Growth Path (NGP), job opportunities exist in new economies such as the knowledge economy. The bio-economy is part of this knowledge economy where human capital development, specific skill sets and innovation are required. The bio-economy can provide economic benefits when applied in various labour-absorptive industries in the country. These include i) manufacturing – which requires re-industrialisation in sectors such as pulp, paper, sugar and textiles; ii) green economy relative to waste and energy security; iii) minerals and mining beneficiation; and iv) agriculture innovation. Furthermore, the bio-economy is also aligned within the Industrial Policy Action Plan's key initiatives, such as pharmaceuticals in the production of local active pharmaceutical ingredients (APIs) and manufacturing of vaccines. In the green economy there are considerable recycling, re-use and recovery of industrial waste that can be achieved with biological methods as well as the production of biofuels.

The use of biotechnology solutions is not new to the country. South Africa is ranked ninth among the 14 "mega-biotech" nations[3] on the basis of the number of hectares of genetically modified crops under cultivation. However, biotechnology is not the only element in a healthy bio-economy. Developing the bio-economy will require a range of competencies beyond biotechnology, including information and communications technology (ICT), nanomaterials research and manufacture, bio-entrepreneurship, the social sciences and intellectual property management.

As the world's third most biologically diverse country, South Africa has a major comparative advantage. The country is home to almost 10% of the world's known plant species and 15% of all known coastal marine species. South Africa comprises nine unique vegetation types (biomes), of which three have been declared global biodiversity hotspots, and is also the only country to contain an entire floral kingdom – the Cape Floristic Region. South Africa's natural capital of biological diversity, combined with its wealth of indigenous knowledge[4], forms one of the country's greatest assets. This capital can be used to the advantage of South Africa in the current economy through multiple approaches, including providing raw materials for the natural product sector; bioprospecting for the development of pharmaceutical, cosmeceutical or industrial applications from compounds found in plants, animals and micro-organisms; and use of indigenous plants and animals as food sources.

The Bio-economy Strategy aims to build on the achievements of the National Biotechnology Strategy, incorporate the lessons learnt and move forward with initiatives that can address the challenges and embrace the opportunities of the future. It focuses on creating an enabling environment for stakeholders – including government departments, established industry, venture capital and the broader public – to interact with life-science role players, academics, researchers and private sector entrepreneurs to create value. It identifies areas where public policy can remove barriers, encourage innovation and improve cooperation between stakeholders.

3 International Service for the Acquisition of Agri-biotech Applications, 2011. ISAAA Brief 43-2011: Global status of Commercialized Biotech/GM crops: 2011. Accessed on 19 November 2012, URL: http://www.isaaa.org/resources/publications/briefs/43/executivesummary/default.asp

4 Indigenous knowledge systems refer to a combination of knowledge, skills and technologies that communities of particular geographic regions have developed, and continue to develop, around their conditions and environment. Individuals' knowledge and communities' collective knowledge provide unique opportunities for South Africa.

Case study 1: The Skin-tone Evener Candidate Product development project

The Cosmeceuticals consortium, which comprises partner organisations that represent different expertise to enable the successful development of the candidate product, conducted preclinical research to meet the above-mentioned product standard parameters. The knowledge holder partner is a traditional healer who is the founder and trustee of a community trust called the Mothong African Heritage Trust, a community development organisation that is located in Mamelodi township, east of Pretoria.

The relevant skills development process was conducted via the training workshops that were managed by the Department of Science and Technology at the Agricultural Research Council (ARC) and Council for Scientific and Industrial Research (CSIR) in 2011. Relevant bioprospecting skills were transferred whenever necessary to support the farming and basic food processing farming endeavour to develop an agri-business for the community trust. Further support was provided to supply the project with basic farming infrastructure and in the management of small farming skills transfer. Empowered by the allocation of land by the Tshwane municipality to the community trust, the Cosmeceuticals team developed a business plan that was submitted to the Technology Innovation Agency for funding to erect a pilot plant on site. The first candidate product to be piloted for cultivation and pre-processing is a skin-tone evener product that has met all the efficacy, safety and quality standards. The pilot plant will be in operation by the end of March 2014, and envisaged to be fully operational by the end of 2015. Two patents were registered locally in 2012, one international Patent Cooperation Treaty (PCT) patent on the skin-tone evener was filed in May 2013 and one acne patent was filed in August 2013. The intellectual property royalties will be shared equitably among the consortium members.

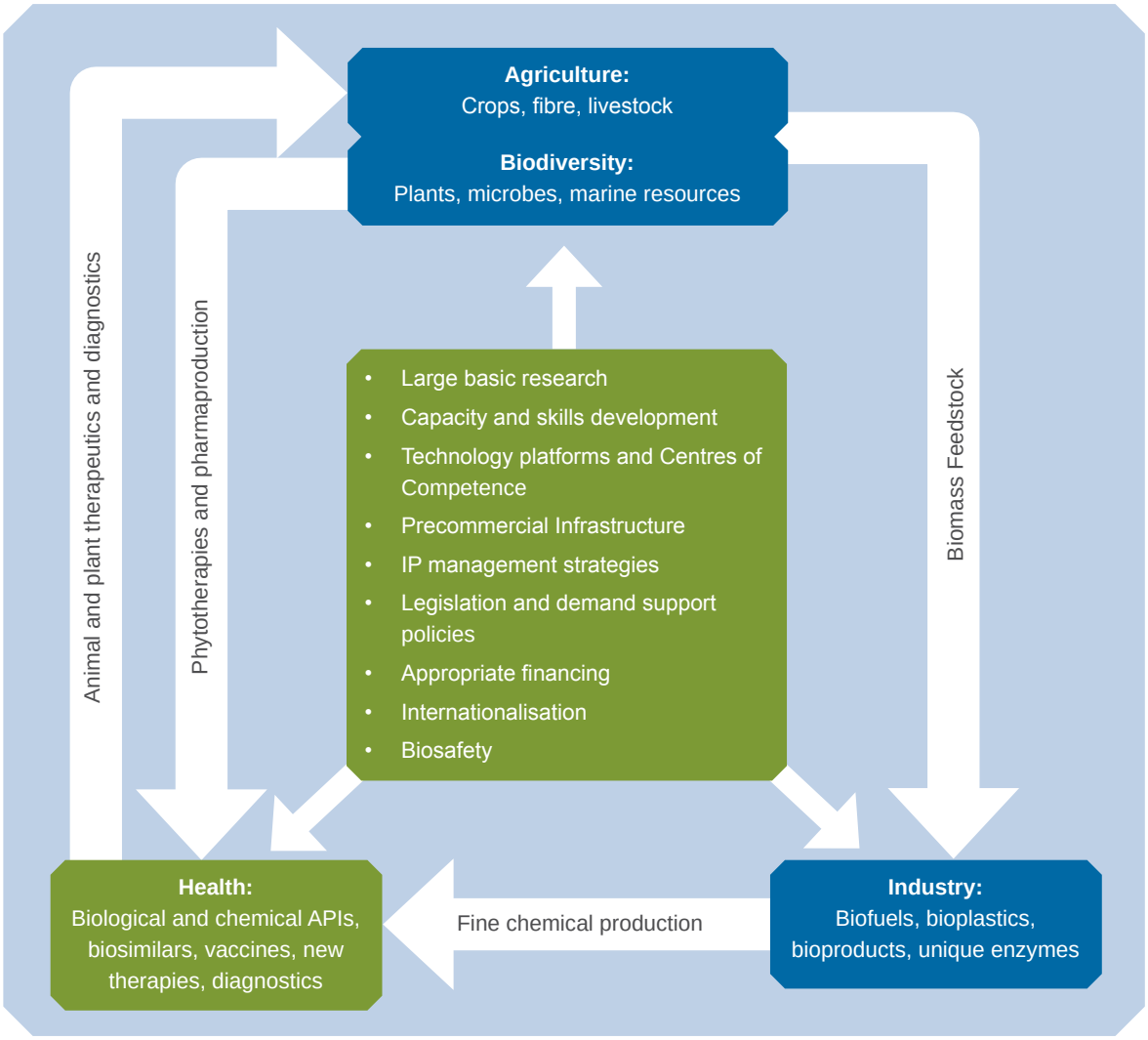


Figure 1: Interconnectedness of the bio-economy

Bioscience solutions primarily have application in the health, agriculture and industrial sectors, where clean processes for the production of biological renewable resources are important. Figure 1 illustrates the interconnectedness of the bio-economy landscape (adapted from the Organisation for Economic Cooperation and Development (OECD) report[5]).

1.3 Role players in the bio-economy

The bio-economy cannot be restricted to biotechnology. The application of non-biological systems on living things can be significant. The Bio-economy Strategy therefore shifts the focus from developing the biotechnology sector to developing a bio-economy, where the biotechnology sector will join forces with the ICT sector, environmental agencies and the social sciences to create holistic solutions for the agriculture, health and industrial sectors.

South Africa's private sector plays a key role in developing a sustainable, knowledge-driven, science-based bio-economy sector that is capable of innovation and commercialisation. It is important that the government remains responsive to this and acts resolutely and pre-emptively to facilitate this development. The role players within the bio-economy will have to collaborate effectively if the bio-economy is to succeed.

These role players include:

- industry;
- academia;
- science councils;
- non-governmental organisations;
- community-based organisations;
- not-for-profit companies; and
- the government.

The proposed roles of the different government departments are indicated in the matrix below.

The Department of Science and Technology, mandated to foster innovation in South Africa, is playing a leading role but the input, activity and policies of the private sector and other government departments are equally important. It is therefore necessary that the government commits to developing a sustainable bio-economy that encompasses all its strategies and plans, especially those that are related to biotechnology, such as the Green Economy Strategy.

While this strategy may be led by the Department of Science and Technology, it will be guided and monitored by interdepartmental stakeholder groups. This interdepartmental structure will function as a subcommittee of the Economic Sectors and Employment Sector Cluster of government. The Department of Science and Technology in consultation with relevant government departments, respective implementing agencies and other relevant stakeholders will develop implementation frameworks, which will guide all associated stakeholders in developing implementation plans with respect to the Bio-economy Strategy. It is envisaged that stakeholders will implement the Bio-economy Strategy on the basis of identifying specific niches which

	Drive innovation	Priority setting	Human capital development	Implementation of innovative strategies	Funding
Science and Technology	✓		✓	✓	✓
Health	✓	✓	✓	✓	✓
Trade and Industry	✓	✓		✓	✓
Agriculture, Forestry and Fisheries	✓	✓	✓	✓	✓
Environmental Affairs	✓	✓		✓	✓
Higher Education and Training			✓		✓
Economic Development	✓	✓		✓	✓
Energy	✓	✓		✓	✓
Mineral Resources	✓			✓	✓
Rural Development and Land Reform	✓	✓	✓	✓	✓
Water Affairs	✓	✓		✓	✓
Social Development	✓	✓	✓	✓	✓
Human Settlements	✓	✓		✓	✓
Traditional Affairs	✓	✓		✓	
National Treasury	✓	✓			✓

Figure 2: Proposed roles of the different government departments

5 OECD. 2009. *The Bio-economy to 2030: Designing a Policy Agenda*, Paris: Organisation for Economic Cooperation and Development (OECD)

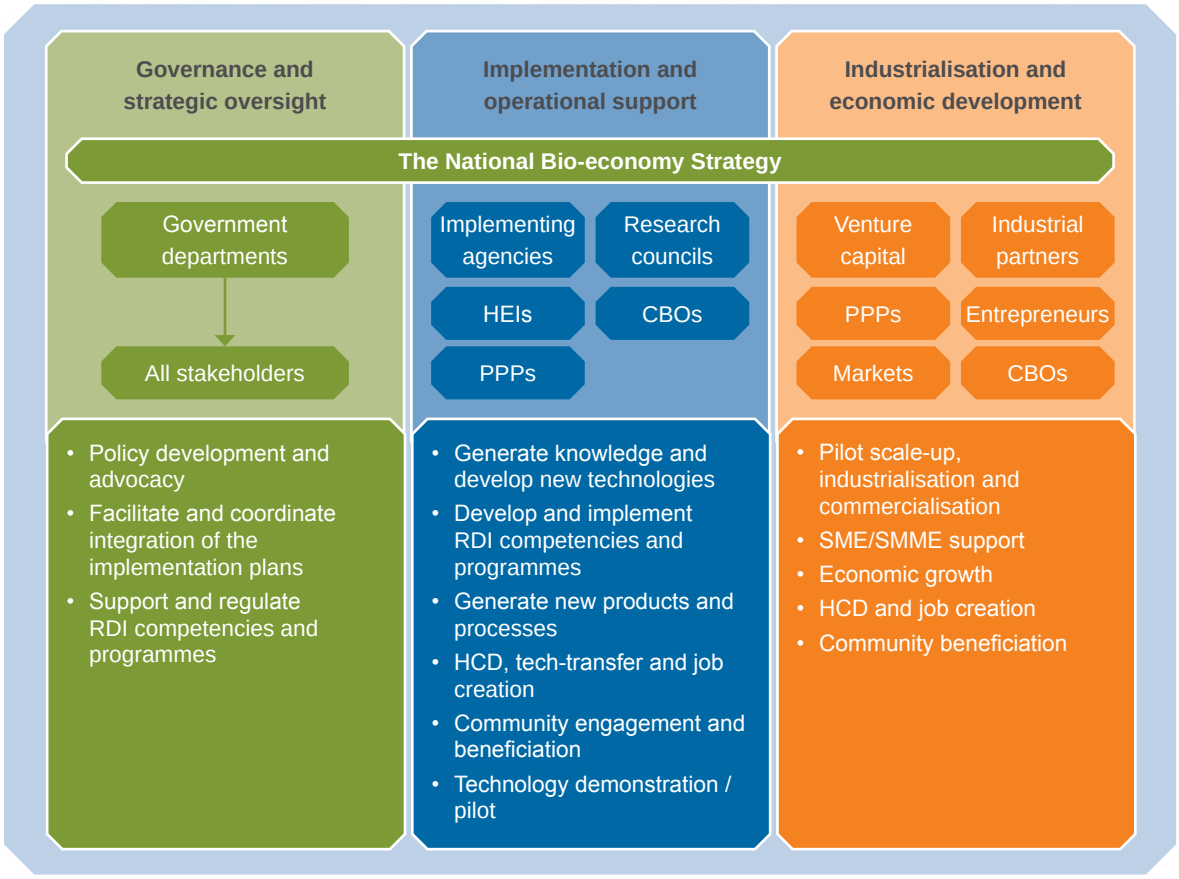


Figure 3: Roles of different stakeholders

fall within the ambit of their mandates. It is acknowledged that the strategy encompasses a number of cross-cutting elements, and these relevant government departments will develop implementation plans with the Department of Science and Technology. Research and development across sectors will be fully integrated into the appropriate line departments, which will improve synergies within the national system of innovation. Figure 3 provides an overview of the roles of the different stakeholders within the Bio-economy Strategy. The effectiveness of this integration will be measured through its outputs. The suggested indicators are listed in Appendix 1. These indicators will be expanded to include sector specific indicators.

1.4 Role of the Department of Science and Technology

To ensure the success of the Bio-economy Strategy, the Department of Science and Technology undertakes to:

- coordinate stakeholders and role players;
- develop strategic innovation competencies; and
- develop strategic innovation programmes to address strategic gaps or opportunities for the country.

1.4.1 Coordinate stakeholders and role players

The array of stakeholders and role players that needs to interact meaningfully within a dynamic and complex system demands structural coordination. To this end, the government's "capacity to provide leadership for economic development"[6] should also be increased.

The Department of Science and Technology primarily ensures effective coordination and responsiveness (on behalf of the government) to industry and academia. Such coordination will guide the development of strategic science capabilities and science programmes while helping to identify and address gaps and system failures.

1.4.2 Develop strategic innovation competencies

The development of strategic competencies and infrastructure will underpin the bio-economy's competitiveness. The Department of Science and Technology, working closely with multi-stakeholder coordinating committees, will drive the development of the following competencies and infrastructure in the country. The requirements identified for growth include:

6 National Development Plan. 2012. Accessed April 2013. URL: http://www.info.gov.za/issues/national-development-plan/index.html

- development of the full value chain from concept to product;
- bioinformatics, functional genomics, structural biology, synthetic biology and systems biology;
- technology service platforms;
- pilot-scale infrastructure;
- incubation facilities;
- financing;
- human capital development;
- instruments to address specific knowledge needs;
- knowledge management to develop a bioportal;
- intellectual property management; and
- development of strategic innovation programmes.

1.4.3 Develop strategic innovation programmes to address strategic gaps or opportunities for the country

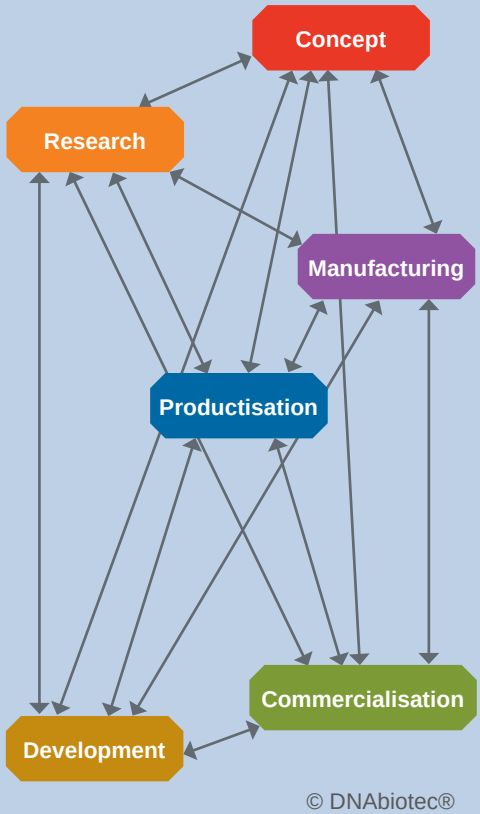
The Department of Science and Technology will take the lead in developing science-based programmes to address strategic gaps or opportunities for the country. During the implementation phase, defining priorities based on national imperatives will be paramount. Furthermore, innovative programmes should help guide strategic high-risk ventures, with the added benefit of developing human capital, improving technological infrastructure, optimising the bio-economy's value chain and improving participation in the innovation system. These programmes should also focus on competitive applications that capitalise on local resources or geographical strengths.

It is imperative that such programmes are coordinated and managed at the highest level, and that key stakeholders are involved from the outset to ensure uptake and alignment. The success of the Bio-economy Strategy is dependent on the collaboration of the different government departments in setting the priorities, providing the necessary funding and developing the required human capital.

The strategic innovation programmes should address all aspects of the innovation pipeline, taking into account the non-linear nature of the pipeline, as well as the links within the pipeline. An example of a non-linear innovation pipeline is depicted in Figure 4, but there are others in existence.

1.5 Conclusion

These three components of the strategy – coordination structures, strategic innovation competencies, and strategic innovation programmes – form the basis of implementation of this strategy. They are expanded in the following sections, firstly on a cross-cutting basis, and then per sectoral and/or thematic area.



Concept/Idea: Ideas are continuously harvested and scanned for in the bio-economy. This node represents the formulation of the idea, starting with prior knowledge. At this node, ideas are evaluated against market needs and eventually mature to a level that is ready for research.

Research: Mature ideas are researched via the scientific process, to generate valid research results.

Development: Research results are developed as proof-of-concept pilots. If necessary, they can be returned for further applied research. Specific aspects of the envisaged product are tested to ensure success of the proof of concept.

Productisation: The technology is packaged in the form of a product that will be accepted by the market (e.g. shape, dimensions, colour, and texture). At the end of productisation, a prototype that can be manufactured is generated.

Manufacturing: The product is manufactured. Aspects such as scaling up of production are key.

Commercialisation: A business activity that takes the manufactured product and launches it into the market via marketing, sales and other commercial tools. Commercialisation success is measured in sales, and ultimately, benefit (social or financial).

Figure 4: Non-linear innovation pipeline

2. STRATEGIC CONTEXT

2.1 Introduction

South Africa remains a country of extreme inequality. People living at one end of the spectrum enjoy some of the highest living standards in the world, while those at the other end lack access to basic amenities, suffer food insecurity and are highly susceptible to major diseases such as HIV and tuberculosis (TB).

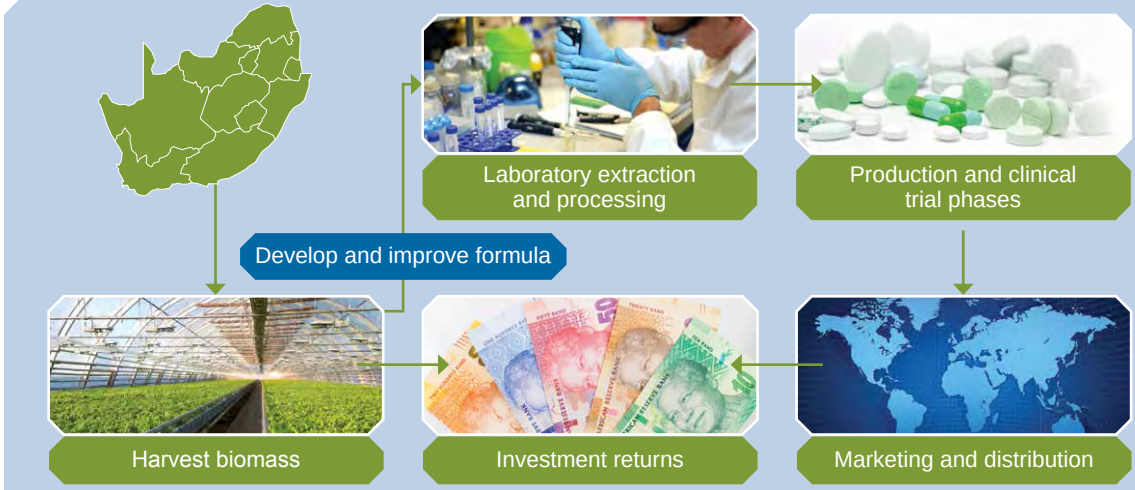
The National Development Plan[7] proposes to reduce poverty and inequality significantly by 2030, by:

- raising employment by promoting economic growth;
- improving the quality of education, skills development and innovation; and
- building the state's capability to play a developmental, transformative role.

A robust bio-economy that involves all South Africa's economic sectors, draws on the strengths of role players from both the public and private sectors, and is underpinned by a sound bio-economy strategy can help grow the economy. The Department of Science and Technology has identified three key economic sectors – agriculture, health and industry – as being the most in need of, and likely to benefit from a comprehensive bio-economy strategy.

2.2 Agriculture

South Africa is a semi-arid country – only 13% of its land area is considered arable. Climate change and population growth are significantly affecting the country's ability to meet its citizens' needs. Many households already face food insecurity and poor nutrition, with 14% of the population considered vulnerable to food insecurity, while about 25%



The business/beneficiation model for the bio-economy is twofold. The model encompasses non-technological "low hanging fruits" and high-end technology-based beneficiation. For example, the non-technological beneficiation may include royalties from uses of IKS, commercial harvesting of raw biomass such as plant material through responsible bio-conservation practices, etc. Both segments will constitute employment creation through low and high-end skill HCD. The beneficiation model encourages strategic public private partnership and promotes social cohesion through socio-economic development.

Figure 5: Beneficiation

7 National Development Plan. 2012. Accessed April 2013. URL: http://www.info.gov.za/issues/national-development-plan/index.html

of children younger than six years are developmentally stunted due to malnutrition.

Agriculture is critical for ensuring food security. It is also a major employer, responsible for 8% of formal employment in the country. As agriculture intensifies, biotechnology will play a crucial role in helping to improve the heat-resistance of crops and address the challenges of climate change, diminishing water and grazing, and potential loss of biodiversity. Crops are important as a food source for both humans and livestock. The livestock sector contributes 49% to agricultural output.[8] Integrating South Africa's bio-economy with those of neighbouring countries in Southern Africa will increase arable land and access to water resources.

Agroprocessing has the potential to provide income-generating opportunities and access to food for the poor, as well as growing the international market. It should therefore be a major player in the growth of the bio-economy. The sustainable use of South Africa's biodiversity should form an integral part of agroprocessing, while the commercial cultivation of indigenous plants should be promoted.

The bio-economy of agriculture is discussed in greater depth in Chapter 4.

2.3 Health

Disease burdens South Africa's health system. Together with food insecurity and malnutrition, these conditions hamper the country's efforts to address its Millennium Development Goals, particularly the goals of eradicating poverty and hunger, and reducing child mortality.[9]

The way in which South Africa chooses to address global challenges such as communicable diseases plays an important role in determining the country's research agenda. One key objective of the Millennium Development Goals, as set out by the United Nations (UN) and signed by 189 countries, including South Africa, is to combat the scourge of HIV, TB, malaria and other diseases. According to the UN Millennium Project, "Science, technology and innovation policy needs to be oriented towards finding vaccines and cures for these diseases, while creating new institutional frameworks from which new research collaborations can spring."[10]

Many locally manufactured drugs, including generics, are made using imported active pharmaceutical ingredients. This has negative implications for the bio-economy. Although the local pharmaceutical industry generates about R30 billion per year, this is greatly offset by the cost of importing the required ingredients. South Africa needs to develop the ability to manufacture drugs, vaccines and other biologics locally, to improve the health sector's bio-economy and to help the country achieve its public health goals.

The bio-economy of the health sector is discussed in greater detail in Chapter 5.

2.4 Industrial and environmental sector

The chemical industry is the foundation of manufactured goods. It provides inputs for a wide range of products such as pharmaceuticals, food, fuels, plastics and other materials. This industry has historically been driven by the exploitation of non-renewable feedstock derived primarily from fossil fuels (petroleum, gas and coal) and industrial minerals. The emerging industrial bio-economy is expected to improve the situation in respect of the manufacturing sector's energy intensity, water usage, waste management and greenhouse gas emissions. These enhancements will improve the industry's competitiveness and reduce its environmental footprint. Furthermore, it will be the

8 Agriculture in SA. Accessed November 2012. URL: http://www.info.gov.za/aboutsa/agriculture.htm

9 Millennium Development Goals: South Africa. Accessed 7 November 2012. URL: http://www.indexmundi.com/ south_africa/millennium-development-goals.html

10 UN Millennium Project. 2005. *Innovation: Applying Knowledge in Development.* UN Millennium Project Task Force on Science, Technology and Innovation. Earthscan. p 25.

focal point towards the development of agricultural and health sector products with industrial application and commercial viability.

The industrial aspects of the bio-economy will be galvanised by legislation that creates demand for green products and puts a price tag on environmental pollution. Given the increasing drive towards a decarbonised economy, it is foreseeable that lower-carbon-emitting, bio-based products will be traded between different countries in future. This could create a market pull to which bio-based products could easily respond.

The contribution of the industrial and environmental components of the bio-economy is discussed in greater detail in Chapter 6.

2.5 The local bio-economy innovation landscape

The National Development Plan's objectives include increasing the size and effectiveness of the innovation system, and ensuring closer alignment with companies that operate in sectors consistent with the country's growth strategy.[11]

To effect this, the local research, development and innovation landscape needs to be better understood.

Biotechnology in South Africa is dominated by research projects, science councils and small biotechnology firms. There are no large, integrated biotechnology firms to speak of that are indigenously South African. Multinational corporations have a presence, albeit mostly through their distribution and marketing partners. Their research and technology development are usually conducted elsewhere.

Since 2002, the government has invested over R1 billion in implementing the National Biotechnology Strategy of 2001. The investments were allocated to research and development projects, establishment and incubating companies and platforms. The overall investments in companies, platforms and projects yielded more than 240 technology-based products and services, supported more than 400 science graduates, created about 1 000 jobs and produced more than 20 patents. The biotechnology innovation centres also used this government funding to leverage 25% additional funding from external sources. Despite these successes, ensuring the sustained performance of biotechnology companies has been a challenge, as is the case internationally.

In early 2010, the biotechnology innovation centres were incorporated into the Technology Innovation Agency, which was established to address the "innovation chasm" and the fragmentation of funding instruments. The agency also incorporated the Innovation Fund.

The Technology Innovation Agency is now operational. Its broad objectives are to:

- provide funding and complementary services to bridge the gap between the formal knowledge base and the real economy;
- stimulate the development of technology-based services and products;
- support the development of technology-based enterprises, both public and private;
- provide an intellectual property support platform; and
- stimulate investment (venture capital and foreign direct investment).

The National Biotechnology Strategy supported a linear model of science, technology and innovation. In this model, universities generate basic knowledge, which science councils then exploit and translate into innovative technologies that can be commercialised by industry. As a result, there is considerable activity in basic research (by universities) and applied research (by science councils).

While this is one model of science innovation – and has been instrumental in identifying gaps and inefficiencies in value chains – mature bio-economy systems have more complex models that include "industry pull", where applied research (whether academic, by a science council or a firm's research division) is guided by an industry's needs. Some models also use "inward technology transfer", where successful technologies are imported and adapted to the local environment and market.

The most successful and mature bio-economies, such as the United States of America and Switzerland, use a model that focuses on creating an enabling environment for biotechnology and related fields by implementing a suite of incentives to stimulate innovation and allow all stakeholders – the government, industry and academics – to interact and extract value from biotechnology.[12] It should be noted that models can coexist and complement each other.

A strong bio-economy is knowledge intensive and requires a high level of research and technical skills, especially in the disciplines of genomics (the study of the genomes of organisms), proteomics (the study of proteins) and bioinformatics (the study of how biological data is stored, retrieved and analysed). "Non-scientific skills", such as business skills, legal and regulatory expertise, and knowledge of financing and patenting, are equally important.

11 South Africa. 2011. *National Development Plan: Vision for 2030.* Government Printer: Pretoria.

12 OECD.1997. *National Systems of Innovation*. OECD: Paris.

The global shortage of skills has been identified as a major constraint to the development of the bio-economy. Not surprisingly, there is strong international competition for skills, which has resulted in high workforce mobility. This indicates a need to integrate human resources development into research, development and innovation policy, and to create an environment conducive to attracting and retaining skilled people.

This strategy is based on the assumption that the issues facing South Africa's bio-economy – including human capital development, knowledge exploitation, market development and governance – cannot be addressed in isolation, but need to be solved in an integrated, holistic fashion to yield coordinated, systemic interventions. To harvest local research and development for commercialisation, the country should build its capabilities from the bottom up (through training, research and development), while accelerating efforts for the development and establishment of support facilities and suppliers (backward integration) and technology localisation.

This strategy focuses on priority issues such as using intellectual property management and foreign direct investment strategies to fast-track market and industrial development. It also aims to leverage partnerships to gain access to useful intellectual property and other resources, and to create sophisticated incentives for industry participation. Globally, knowledge and intellectual property flows indicate that this is the most appropriate method to fast-track industrial development.

2.6 Comparison with other countries

South Africa has much to learn from high and middle-income countries that have succeeded in developing a sustainable bio-economy. Some of the critical success factors are a strong science foundation, positive institutional collaboration, private-public partnerships and a sturdy skills base produced by world-class organisations. These are supported by an enabling environment that includes a properly coordinated regulatory framework, research and development tax incentives, rational resource allocation for effective public-private partnerships, entrepreneurial development and strategic government interventions.

Table 1 (on page 16) provides the basis for evaluating the contribution of key inputs, such as research and development capacity, financing and government support, into building a more productive bio-economy.

This comparison supports the notion that South Africa should invest in building a strong science and technology workforce, as well as support venture capital funding and incentives for start-up biotechnology companies.

Other developing countries that have benefited from developing their bio-economy used policies to nurture and strengthen the science system. In the globalised environment, many countries have benefited from transnational trade in intellectual property. India's vibrant generic drug industry was built on existing technologies developed elsewhere. They have been able to develop intellectual property legislation and management strategies that balance the rights of multinational drug-development companies with those of a growing generics industry.

In countries with a smaller and less mature bio-economy, such as South Africa, state intervention is imperative to bolster business activities in the absence of large private-sector players and readily available venture capital. To date, the government has played a key role in promoting market success in strategic biosectors through its policy instruments and by enlisting public research institutions. However, there remains much work to be done.

The United States (excluded from the table) focuses on biotechnology patents and has the largest number of dedicated biotechnology firms in the world. The country also boasts the highest number of publicly traded companies that use biological innovation as their core competence. The success of dedicated biotechnology firms in the United States can be attributed to a thriving venture capital market and massive public support for research and development, which accounts for about 80% of total Organisation for Economic Cooperation and Development (OECD) public expenditure in the bio-economy.

In Brazil, more than 60% of the existing biotechnology businesses were incubated within science parks and

13 Brazil Biotech Map. 2011. Accessed 30 November 2012. URL: http://www.clustercollaboration.eu/documents/270120/0/Brazil_Biotec_Map_2011.pdf

* Total number of researchers (FTE figures not available)

14 Countries by population. Accessed April 2013. URL: http://en.wikipedia.org/wiki/List_of_countries_by_population

15 UNESCO 2010. Science Report. Accessed April 2013. URL: http://unesdoc.unesco.org/images/0018/001899/189958e.pdf

16 Brazil to Invest 10 Billion Reais in Biotechnology. Accessed 30 November 2012. URL: http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aOMpCJMWluaY&refer=latin_america

17 Business Financial Assistance for Indian Biotech Entrepreneurs. Accessed 30 November 2012. URL: http://www.indiabiotech.in/Business-Financial-Assistance.htm

18 Beyond borders: Global biotechnology report. 2011. Accessed April 2013. URL: http://www.ey.com/Publication/vwLUAssets/Global_Biotechnology_Report_2011/$FILE/Biotech_BeyondBorders_2011.pdf

19 Brazil Biotech Map. 2011. Accessed 30 November 2012. URL: http://www.clustercollaboration.eu/documents/270120/0/Brazil_Biotec_Map_2011.pdf

20 Investment Opportunity, Biotechnology. Accessed 30 November 2012. URL: http://www.investindia.gov.in/?q=biotechnology-sector

21 BioTechCorp, 2011. *Malaysian Biotechnology Country Report, 2009/2010*. Kuala Lumpur: Malaysian Biotechnology Corporation.

Table 1: Comparison of indicators relevant to a bio-economy

	Country	Australia	Brazil	Cuba	India	Malaysia	Singapore	South Africa
Knowledge and skills	Population[14]	22 823 882	193 946 886	11 247 925	1 210 193 422	29 570 000	5 312 000	51 770 560
	Full-time equivalent (FTE) researchers[15]	73 173	133 266	5 525*	154 827	9 694	27 301	19 320
	FTE researchers per million inhabitants[15]	4 224	694	493*	137	372	6 088	393
	Scientific publications (2008)[15]	28 313	26 482	775	36 261	2 712	6 813	5 248
	Bio-economy-related publications (2008)[15]	17 813	17 792	451	14 674	1 128	2 411	3 306
Financial support	GERD as % of GDP[15]	2,06% (2006)	1,1% (2007)	0,44% (2007)	0,8% (2007)	0,64% (2006)	2,52% (2007)	0,93% (2007)
	Funding	Venture capital with government support. The industry is established, now making Australia the 5th largest biotechnology centre in the world.[17]	Brazil government made R37,6 billion available for biotechnology (2007 – 2017).[16] Access to R800 million venture capital fund.	Government the source of investment and funding. R168 million per annum focused mainly on health biotechnology.[18]	Amounts not available. Several funding departments for biotechnology institutes, NGOs, individuals, students, researchers and professionals. Large number of venture capital companies.[17]	2006-2010: R13,6 billion (57% government funding from various departments).	Government provided R23 billion (2006-2010). Venture capital for pre-commercial phase still difficult.	Government provided ± R0,9 billion (2002-2011).
	Government support[18]	National Biotechnology Strategy (NBS) (2000). Used different instruments to implement, with Biotechnology Australia responsible for NBS activities. NBS terminated in 2008 and replaced by the Industrial Biotechnology Strategy.	Government support since 1970s. Created BrBiotec Brasil initiative in 2010 to foster technical and business cooperation. Strong government intervention.[19] Incubation parks supported.	Founded the Centre for Genetic Engineering and Biotechnology (1986). Invested US$1 billion over 20 years to develop science node.	Biotechnology Regulatory Authority of India Bill, 2011. This authority was set up as an independent body and legal committee to control the production, research, transport, import, and usage of organisms and products of modern biotechnology.[20]	Launched National Biotechnology Plan (NBP) in 2005. Malaysian Biotechnology Corporation responsible for coordinated implementation of NBP.[21]	Established Biomedical Sciences Industry Partnership Office (2010).	National Biotechnology Strategy (12001). Established biotechnology innovation centres and the innovation fund. Bio-economy Strategy.

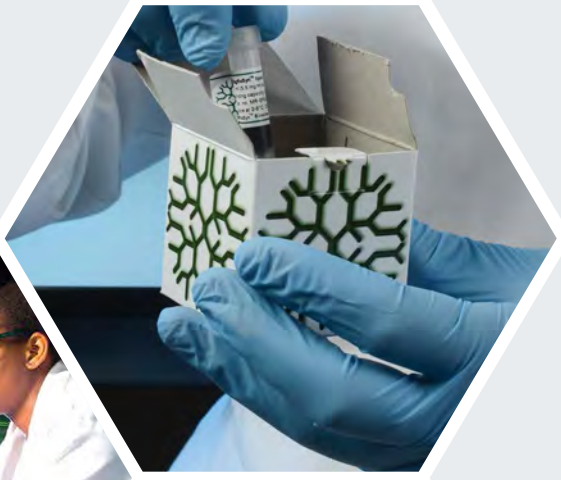
94% of the businesses are linked with universities. This is particularly useful for co-development, infrastructure sharing and use of specialised services.[13]

The Brazilian government launched an "energy self-sufficiency grand challenge" that resulted in a biofuels industry boom that turned the country into a world leader in industrial biotechnology. Cuba, on the other hand, focused on technologies to secure its domestic pharmaceuticals supply, especially in the area of biologics. Today it is a world leader in health biotechnology, exporting fermentation-based technologies to countries like India, Brazil and China.

India and Malaysia used backward integration to develop key biotechnology sectors. A major characteristic of this model is the focus on niche sectors that meet domestic needs first, but have potential to become globally competitive over time. Innovation in these countries was driven by public research institutions and a mixture of supply-and-demand policies.

India did not grow its bio-economy organically by following the traditional route of sequential research, development, innovation and commercialisation. Instead, it leapfrogged into a leadership position by building critical mass, providing an investor-friendly policy framework for multinational research and development companies, and assimilating technologies developed elsewhere by using various intellectual property instruments.

The above analysis suggests that, while there is no single route to attaining a viable bio-economy, it is clear that South Africa needs to increase its gross expenditure significantly on relevant research and development. This funding should be used to capitalise on the country's opportunities and strengths and to adapt lessons learned from other countries.



3. FACTORS ENABLING A BIO-ECONOMY

To achieve a successful, thriving bio-economy, South Africa needs to:

- attract, grow and sustain human capital;
- achieve and maintain world-class research standards;
- ensure access to next-generation technologies;
- close gaps in the innovation pipeline;
- improve incentives for innovation and funding for research, development and innovation;
- improve access to global intellectual property and knowledge pools;
- ensure that research is aligned with mainstream and interface IKS and grass-roots innovation initiatives within the national system of innovation;
- align regulations with needs in the innovation pipeline;
- implement the existing ethical framework to guide biotechnological research;
- engage in effective communication and marketing; and
- institute an effective leadership framework, including all the stakeholders, to guide the strategy's implementation.

These factors, and their accompanying interventions, cut across all sectors and are discussed in this chapter. Sector-specific interventions are elaborated on in Chapters 4 to 6.

3.1 Human capital development

South Africa has a limited number of people with sufficient training to develop the bio-economy and take advantage of existing opportunities. A critical mass of appropriately skilled people is a prerequisite if the country is to compete successfully in the international bio-economy, as countries such as Cuba, Brazil, the United States and India demonstrate. In addition, a healthy bio-economy has to be underpinned by good basic education in mathematics and science.

The training of scientists, engineers and technicians at all points in the value chain should be intensified. There is a particular need to develop "technopreneurs" who can develop diverse technologies into innovative products and services at the downstream end of the value chain. An incentive system that provides the necessary absorptive capacity within the industry should be put into place simultaneously with the development of human capital. It is essential to attract and retain key skills. Unless absorptive capacity is addressed as a key driver of this strategy, South Africa will continue to "export" key skills to other countries and international sectors, remain under-skilled, under-resourced and fail to implement effective technology transfer.

The following specific goals, taken from the Department of Science and Technology's Human Capital Development for Research and Innovation Strategy, inform this strategy:

- Increase research productivity and training capacity of supervisors and researchers.
- Grow the number of students enrolled for, and graduating with, master's and doctoral research degrees.
- Provide opportunities for postdoctoral students, especially in an industry environment.
- Boost the number of technologists and technicians with the skills and training to perform bio-economy-related activities.
- Increase research and development support for strategic science and technology domains to maximise their effect on innovation and economic development.
- Facilitate skills development at community level.
- Grow research and innovation output by improving coordination between, and joint interventions with, various government departments.
- Foster international partnerships that will help expand and improve research and innovation in South Africa.

3.2 Towards research excellence

The performance of some South African universities, based on their international publications, is on par with that of

some of the top European universities[22]. Despite this, the country's scientific productivity – in terms of patents in life sciences and related fields – is generally poor compared to its BRICS peers (Brazil, Russia, India and China) and other countries (such as Australia, Ireland, South Korea and Singapore). Adequate funding for life sciences disciplines and large research infrastructure and platforms is needed to raise the country's production of patents in life sciences to the levels of its BRICS partner countries.

Resources for research need to be increased, with agriculture, health and industry taking priority. It is also necessary to improve research investment into the basic scientific disciplines that underpin biotechnological development, including bioinformatics, systems biology, synthetic biology, structural biology and functional genomics. Non-scientific disciplines such as intellectual property (IP) management and awareness should also benefit from this investment.

Within this context, bioprospecting and biosafety are very important to build on the current strengths of South Africa. The country's rich biodiversity and indigenous knowledge systems provide significant resources for bioprospecting unique offerings with potential socio-economic value. These include micro-organisms, enzymes, agrichemicals, pharmaceuticals (herbal medicines/African traditional medicine), cosmetics which contain extracts or compounds of indigenous biological resources, fragrances and flavourants, as well as livestock. The capacity and capabilities of previously established initiatives such as the metagenomics platform need to be assessed in order to enhance their potential to facilitate and support sustainable bioprospecting activities. Capabilities with the potential to offer a considerable competitive advantage for local manufacturing industries may then be strengthened and relevant bioprospecting initiatives consolidated.

The generic value chain below depicts the lead product development stages that are undertaken to generate value-added products in three IK-based flagships, namely, African traditional medicines, Cosmeceuticals and Nutraceuticals and represents a summary of testing phases during which efficacy, quality and, most importantly, safety are tested and validated. The process begins with an IK-based information sharing process between the knowledge holder/community and research scientists. This initial phase ensures strict compliance to the relevant national regulations, while fostering a national system of science and technology. The lead development process undergoes a rigorous laboratory and animal testing that covers the lead validation and optimisation stage. On condition that the lead meets the quality, safety and efficacy standards, the lead enters a candidate product development phase that covers the clinical/human studies. On passing the product development phase of development, the candidate product finally enters the commercialisation process. The beneficiation aspect for community and IK holders is undertaken in every step of the innovation value chain.

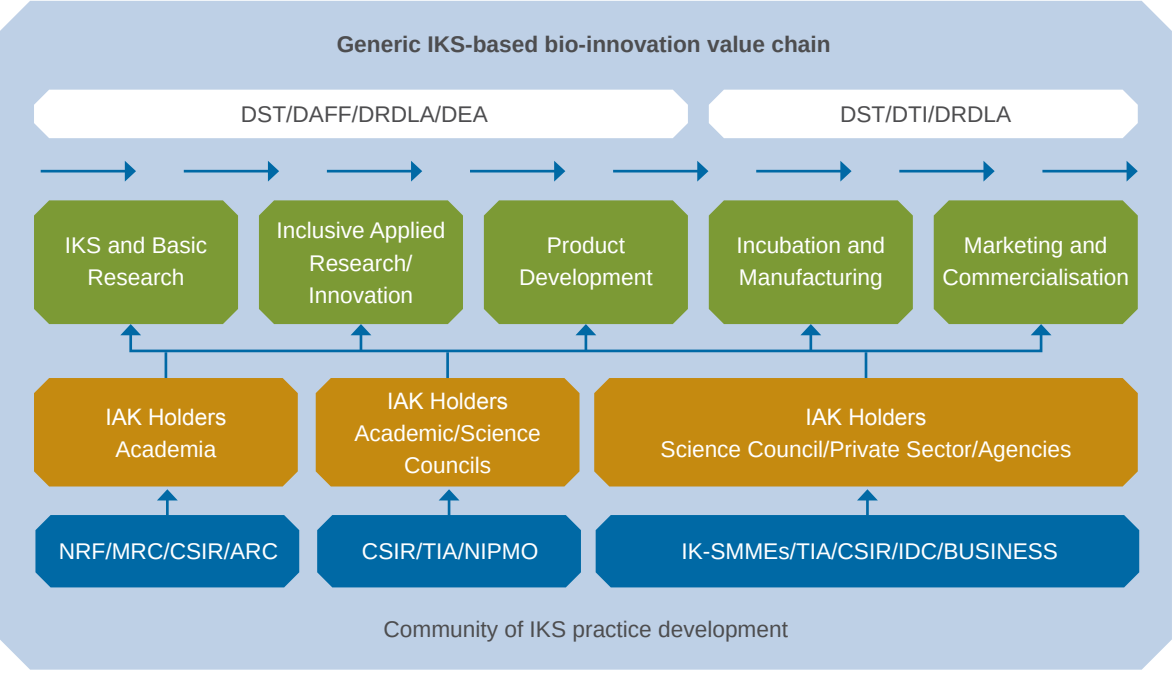


Figure 6: The IKS-based bioprospecting and product development innovation value chain

22 World University Rankings 2012-2013. Accessed 12 March 2013. URL: http://www.timeshighereducation.co.uk/world-university-rankings/2012-13/world-ranking

With regards to Biosafety it is essential to be aware that biotechnology includes some remarkably powerful tools that are used for the creation of new products and services. To ensure sustainability of such products, safety is an essential component, not only for the final approval of the product, but for every stage of the development process, including planning. Biotechnology as a field is developing very rapidly, and biosafety needs to be an initiative that develops apace with the technologies. An overarching Biosafety platform that is accessible to researchers and the industry needs to be strengthened.

3.3 Ensure access to next-generation technologies

Cutting-edge science is becoming increasingly sophisticated, with developments building on each other at a rapid pace. Currently, each university, biotechnology company and government department has to independently source the latest equipment and knowledge at great time and financial expense. Instead, the Bio-economy Strategy will endeavour to make these solutions centrally available to all role players through technology service platforms. This system requires a governance structure to manage the development and service provision of these technology platforms.

3.4 Enhance the innovation system

Enhancing and building the different nodes of the innovation system and the linkages between the nodes (as in Figure 3, page 10) will require increased state investment in life science incubators, science parks and pilot facilities for demonstration purposes. Such investments will, in turn, reduce investment risk and stimulate follow-on funding by the private sector. Successfully closing the gaps within the innovation pipeline will also contribute towards better linkages between researchers and industry, and promote further public support for research.

3.5 Incentives and funding

The R1 billion invested during the eight years of the National Biotechnology Strategy was allocated to health (45%), agriculture (28%), industrial biotechnology (6%) and platforms (17%). More than 60% of these funds were dedicated to research and development activities. The funding allocation for the sectors identified in the Bio-economy Strategy is inadequate. The proposed interventions will require additional resources.

A variety of incentives are available; these include the Department of Higher Education and Training funding for academic institutions, science-based innovation and patent support, as well as the Research and Development Tax Incentives and the manufacturing tax incentives, which are already available to various components in the bio-economy value chain.

3.5.1 Bio-Innovation Venture Capital Fund

The Bio-Innovation Venture Capital Fund will be established and managed as a public-private partnership, both as a way to attract private capital and to provide an exit mechanism for investors. The Department of Science and Technology will facilitate the establishment of this partnership, which will focus on funding for research, development and innovation in biotechnology.

It is estimated that the fund will require R2 billion, of which the government should supply R300 million to R400 million (15% to 20%) over three years, with investors contributing the remainder. An investment pipeline for the fund will be developed locally through the Bio-economy Strategy, and internationally through inwards technology transfers. In terms of the National Biotechnology Strategy, biotechnology innovation centres were tasked with leveraging funding for biotechnology start-ups from the private sector. It is therefore likely that the Technology Innovation Agency, in partnership with the Industrial Development Corporation, will play a key role in facilitating a venture capital fund by using government funds to attract private capital.

3.5.2 Private-sector funding (national and international) and philanthropic partnerships

Leveraged funding should be used to seed local philanthropic initiatives and social challenges such as HIV and TB. Private-sector funding and in-kind capital (in the form of, for instance, technology platforms and intellectual property) could be sourced through corporate social investment programmes. Examples of successful public-private philanthropic initiatives are the International AIDS Vaccine Initiative, the Medicine for Malaria Venture, and the Foundation for Innovative New Diagnostics.

These philanthropic partnerships should be able to access venture capital funds for further funding once the proof-of-concept stage is reached.

3.6 Access to global intellectual property and knowledge pools

South Africa needs to access global knowledge pools and intellectual property if its bio-economy is to succeed in an increasingly competitive world. South Africa is currently constrained by a generally weak understanding of intellectual property management in the private and public sector. The country needs to implement a strategy to exploit expired, expiring or unenforceable patents to produce bioproducts locally, at a fraction of the cost of importation.

Immediate opportunities that could be exploited include acquiring intellectual property (including patents, technology packages and training) for the manufacture of biosimilars (subsequent versions of approved biopharmaceutical products made by a different sponsor following patent expiry), generics and possibly biofuels and genetically modified organisms (GMOs).

The establishment of the National Intellectual Property Management Office (NIPMO), which has a national network of technology-transfer offices, has laid the foundation for strategic intellectual property management. This needs to be expanded to improve intellectual property brokering and trading nationally and internationally.

3.7 Alignment with national priorities

A large portion of the scientific research conducted in South Africa is not aligned with national priorities. This is, in part, due to limited funding and incentives for local research, which encourages local researchers to enter into better-resourced collaborations with international partners with competing agendas. Internationalisation is generally regarded as a positive trait in academia, but it does reduce research into local priority issues. This is particularly concerning in view of South Africa's relatively small pool of researchers.

A more coordinated and integrated South African focus is needed. It is essential that, in international research, South African needs and priorities are also addressed. To this end, the Bio-economy Strategy has identified three priority areas for research and development – agriculture, health and industry/the environment. Providing funding to national research consortia that operate in these fields should be prioritised. The strategy also proposes strengthening international partnerships to fast-track local research and development capacity-building and the use of inbound intellectual property.

3.8 Alignment of regulations

Regulation is a necessary instrument to protect the public, while stimulating industry and innovation by setting standards. However, novel bioproducts that were locally developed or licensed continue to face regulatory hurdles that are unnecessary in some cases. In addition, bio-entrepreneurs who seek to transact intellectual property with international partners are often not given suitable guidance or support regarding exchange-control policies. These factors have, in the past, motivated local innovators to take their products to other countries, resulting in loss of intellectual property and job-creation opportunities for South Africa.

It is essential that all government departments involved in aspects of the bio-economy be committed to the Bio-economy Strategy. Regulations that are not aligned with the Bio-economy Strategy need to be reviewed. Effective regulations and their implementation are necessary for the bio-economy to succeed. Regulations regarding new bioproducts, and the mechanisms and bodies responsible for the enforcement of these regulations, should be reviewed. Specifically, the regulations related to the following Acts need to be reviewed:

- The Genetically Modified Organisms Act, 1997
- The Medicines and Related Substances Control Act, 1965
- National Environmental Management: Biodiversity Act, 2004
- The National Health Act, 2003
- The Intellectual Property Rights from Publicly Financed Research and Development Act, 2008
- The Currency and Exchanges Act, 1933
- The Consumer Protection Act, 2008

3.9 A stringent ethics framework

Modern biotechnology often raises ethical issues that should be carefully considered because they can affect human well-being, society and the environment. Ethical controversies include issues related to developing, producing and using GMOs, transgenic and cloned animals, and stem cells. Bioprospecting (discovering and commercialising new products based on biological resources) that uses indigenous knowledge, confidentiality of genetic information and the environmental effects of biotechnological advances are also matters to be considered.

For the Bio-economy Strategy to achieve its objectives, the regulatory landscape should address the ethical implications of all innovations, while taking care not to stifle research and innovation. The country should strike a healthy balance between recognising the potential benefits of biotechnology and ensuring that research is ethically conducted. This will require constantly evolving ethical and regulatory frameworks.

The Bio-economy Strategy should be responsive to both the social and economic needs of the South African population. Because public funds will be used to achieve the goals of the strategy, all initiatives need to be viewed

as a social contract between scientists and society. Where data need to be shared, strategies to facilitate this process will be required. Researchers will need to conform to the highest levels of integrity in line with the principles enshrined in the Singapore Statement on Research Integrity. Competent and responsible National Research Ethics Council reviews and clearances will be conducted where necessary. Role players involved in the implementation of this strategy have to ensure that these committees function in line with international standards.

3.10 Effective communication and marketing

As the bio-economy comprises a complex set of technologies that are often explained in terms that are heavy with jargon, the public's understanding of it remains limited, especially with regard to biotechnology.[23] Yet the public already interacts with bio-based products in the form of food, medicines, vaccines and environmental interventions on a daily basis. The Bio-economy Strategy strongly supports initiatives to promote public understanding of the technologies underpinning the bio-economy.

This strategy seeks to enable a vibrant, globally competitive bio-economy, which requires individual life-science products and the system of innovation as a whole to be marketed to local and international markets and stakeholders. Such promotion should include participation in, or hosting of, international conferences and other relevant forums. It should also make use of electronic marketing, by creating and maintaining a South African bioportal that provides information on relevant technology skills, opportunities, products and linkages in the South African bio-economy.

3.11 Institutional arrangements

The local science and technology landscape has developed considerably in recent decades, resulting in different institutions having conflicting and overlapping roles and activities. There is a need to:

- coordinate current institutional arrangements in terms of their mandates, functions and activities in respect of bio-economy-related issues;
- strengthen key institutions; and
- encourage institutional collaboration.

Such refinement has to be geared towards maximising the national system of innovation's performance to assure industrialisation of the bio-economy.

3.12 Government and coordination

An effective bio-economy strategy requires the cooperation of many key stakeholders. Each of the sectors of the bio-economy (described in the next chapter) will be creating a coordinating committee to give effect to this at the implementation level. Government stakeholders include the Department of Trade and Industry, the Economic Development Department, the Department of Health, the Department of Higher Education and Training, the Department of Environmental Affairs, and the Department of Agriculture, Forestry and Fisheries. Public research organisations, the private sector and civil society will also play key roles.

It will therefore be prudent to establish an appropriate leadership mechanism to guide the strategy's implementation. Overseeing the sector coordinating committees will be the responsibility of the Department of Science and Technology.

23 Public Understanding of Biotechnology Survey (2004). Commissioned by the Department of Science and Technology.

4. THE AGRICULTURAL SECTOR AND THE BIO-ECONOMY

4.1 Strategic objective

The Bio-economy Strategy's objective with regard to agriculture is to strengthen agricultural biosciences innovation to ensure food security, enhance nutrition and improve health, as well as enable job creation through the expansion and intensification of sustainable agricultural production and processing.

4.2 Strengths and opportunities

Primary agriculture contributes about 2,5% to South Africa's GDP and about 8% to formal employment. Agriculture has strong links to the broader economy, with the agro-industrial sector comprising about 12% of GDP.[24] The primary production, secondary input and agroprocessing sectors together form the "agro-food" complex, an important economic sector. While the country produces enough food to meet local needs on a national scale, there is widespread household food insecurity.

South Africa has well-established maize, sugar cane, wine and deciduous fruit industries for the local and export markets. These industries depend on research, development and innovation to remain competitive. Historically, the Agricultural Research Council (ARC) and its institutes, as well as universities, provided a strong research and technology development base to support the primary agricultural industry. However, extension work (communicating know-how on new and improved crops/livestock to farmers) is poorly resourced and needs to be strengthened.

Recently, a few small local companies that commercialise biopesticides and innovative new crop-propagation and post-harvest technologies have emerged. However, the ARC remains government's primary instrument for driving agricultural innovation, and significant reinvestment is required to maintain and grow sustainable crop yields.

South Africa has a rich biodiversity that includes indigenous crops and animals that have adapted to harsh local conditions yet still offer superior nutrition. Local knowledge has helped unlock the value of these indigenous resources. However, a growing population and limited water and arable land require new approaches to meeting the country's needs.

Geopolitically, the development and encouragement of agro-innovation across Africa should be viewed as a longer-term outcome of this strategy. Tertiary education of nationals from across Africa remains critical. Where appropriate, influence should be brought to bear on the regional harmonisation of regulations governing the registration and introduction of new varieties of crop/livestock and biocontrol agents to enable sustainable, competitive agriculture across the continent.

Responsible genetic engineering remains a critical technology for agriculture and in South Africa presents a significant competitive opportunity for sector development.

4.3 Strategic interventions

Of the three sectors identified as crucial elements of the bio-economy, the agricultural industry currently has the highest economic impact. Research and development interventions in this field will help ensure food security, improve general nutrition and create jobs both in agriculture and in research. These interventions should be driven by strategic need as well as market demand, and will require strong private-sector involvement.

Unlocking the value of indigenous crops, coupled with consumer demand for "natural" products, presents opportunities for South Africa to capitalise on its biodiversity and capture niche markets. Indigenous products that show promise include monatin (a sweetener), fortified sorghum, rooibos and honeybush.

Short- to medium-term strategic interventions to enhance the sector's competitiveness are outlined below and span the full innovation value chain.

24 South Africa Online. "Agriculture, forestry and land". Accessed 8 November 2012. URL: http://www.southafrica.co.za/about-south-africa/environment/agriculture-forestry-and-land/

4.3.1 Establish a coordinating committee to advise, guide and monitor agricultural innovation

A committee comprising key representatives of government, industry and academia should be established to guide agro-innovation. The committee would prioritise resource allocation, monitor research and development progress, and recommend initiatives to enhance and develop the sector within the scope of the Department of Science and Technology's implementation plan.

4.3.2 Establish a network of agro-innovation hubs that enhance technology transfer and extension

The skills and solutions that emerge from biotechnology research need to be effectively transferred to emerging, small-scale and commercial farmers. Regional agro-innovation hubs can act as catalysts for the collective enhancement of production, agroprocessing and marketing by farmers, scientists and innovators. This further enables extension work, a critical need in the intensification of agricultural development. The role of IKS will be critical in enhancing grassroots innovation for food security and improving quality way of life.

Case study 2: The IKS community technology transfer initiative on Moringa agri-business development

The IKS Policy (2004) explicitly mandated the National IKS Office to lead the technology transfer initiative through a skills transfer and the stimulation of grassroots and community-driven innovations. In 2011, this policy directive was initiated via the research, development and innovation approach using the super-nutritious *Moringa oleifera* tree. This community development drive employs the cultivation research skills of the ARC and the innovation research capacity of the University of the Witwatersrand and the University of KwaZulu-Natal.

Two community-based cooperatives led the farming community development venture, namely, Phedisanang Construction and Projects Primary Cooperative Limited (located in Tooseng, rural Limpopo) and the Sedikong Organic Cooperative (located in Atteridgeville township, Pretoria). The research and product development has added value to eight Moringa products that the two communities produce and commercialise in the informal sector. Innovation research has given rise to new products, namely, the Moringa ice tea and the Moringa vitamin water, with the latter product resulting in a local patent registration in 2012. The intellectual property royalties will be shared equitably among the Moringa team member organisations.

4.3.3 Crop/livestock improvement for biotic and physical stresses associated with climate change (including indigenous crops)

Crop/livestock improvement is a basic programmatic requirement for the agricultural sector. Research and development programmes need to focus on the commercial sector and on indigenous crops/livestock to develop traits appropriate to emerging and subsistence farmers.

4.3.4 Agroprocessing initiatives

Agroprocessing reduces post-harvest losses, extends shelf life and improves the quality and safety of foods. There are significant opportunities for agroprocessing to add value to agricultural produce, and enabling mechanisms should be devised to expand agroprocessing innovations and establish small and medium enterprises that improve the quality of South African agroproduce.

4.3.5 An integrated food nutrition research programme

Food quality is of growing importance, not only for the local market but also for the export market. The government needs to partner with universities, science councils, the private sector and civil society to promote research into the nutritional composition of food and the detection and elimination of contaminants.

4.3.6 Animal vaccine capabilities

Local research and biotechnology institutions have the capability to develop vaccines and diagnostic kits to mitigate the risk of potentially devastating outbreaks of livestock diseases. World-class platforms have been established to support research and development (at Onderstepoort Veterinary Institute) and the manufacture of animal vaccines (at Onderstepoort Biological Products). However, further investment is required to build human capital and critical infrastructure to reinvigorate this sector.

4.3.7 Energy crop initiatives

The emerging biofuels industry will rely heavily on the agricultural sector for low-cost, low-maintenance energy crops (such as sweet-stem sorghum, sugar beet, triticale and some species of grass), cultivated exclusively for biofuel production. The ARC and other relevant stakeholders

need to consolidate and enhance their research and development in this field, as significant developments in science, technology and engineering are still required to enable cost-effective conversion to biofuels. Clear linkages should be maintained with the industrial biotechnology initiatives described in Chapter 6 of this document.

4.3.8 Biocontrol and biofertilisers

The National Biotechnology Strategy supported a number of small, dedicated biotechnology firms that commercialised biocontrol products such as biopesticides, plant-growth regulators and biofertilisers. These products benefit the environment as they reduce the need for traditional chemical pesticides and fertilisers. Such biotechnology firms are essential for a robust, competitive agricultural sector. Programmes to enhance commercialisation of technologies should be developed.

4.3.9 Aquaculture

Aquaculture promises a cost-effective means of providing a sustainable protein source. This emerging sector in South Africa has a strong need for research, development and commercialisation to help establish it as a sustainable and growing component of the broader agricultural sector.

4.3.10 Soil conservation

Soil conservation is critical to the sustainability of agriculture. Investment is required to ensure that soil conservation and optimal practices are researched and implemented by commercial and emerging farmers.

4.3.11 Water resource management

Agriculture uses a significant portion of available water in South Africa. In order to intensify agriculture to address food security and job creation objectives, research into the optimal management practices for irrigation and recycling should be supported.

4.3.12 Build high-value skills and capacities to enable agro-innovation

Although broadly dealt with under the human capital section of Chapter 3, the growing shortage of suitably trained agricultural scientists is considered a special case for urgent intervention. The creation of an incentive system to promote key skills, including plant-breeding, agronomics, plant physiology and biometry in tertiary-level agricultural education is critical.

4.3.13 Co-funding initiatives for innovation

The agricultural sector is well established and values the importance of research and development in order to maintain a competitive edge. Industry-relevant research and capacity development will be supported and stimulated through programmatic co-funding initiatives between industry bodies and government.

4.4 Impact

The agricultural sector is of critical importance to the growth of the South African economy. With relatively little capital infrastructure required, it remains a key opportunity for poverty alleviation, job creation, economic development and household food security in South Africa.

Expanded research and development is essential to maintain this sector's competitiveness, particularly in the light of climate change and population growth, but also to expand the agricultural opportunities available to South Africa.

Developing the ability to formulate and manufacture animal vaccines locally has the potential to save the agriculture industry billions of rands in input costs and lost income, while also ensuring security of supply. Outbreaks of foot-and-mouth disease in cattle and avian flu in ostriches have already cost the local industry hundreds of millions of rands in lost export revenue, posing a significant threat to employment. African horse sickness is a growing problem. Affordable animal vaccines and breeding of more sturdy indigenous animals will substantially benefit the industry.

Indigenous crops need to be developed and commercialised to improve food security and affordability, and create export opportunities for niche products. A vibrant crop-improvement biotechnology industry, together with a world-class nutraceutical and agroprocessing sector is essential to maintain the competitiveness of South African exports.

The development of energy crops and processes to support the country's emerging biofuels industry can help develop rural areas and will support the green economy.

In terms of measuring progress in the agricultural portion of the bio-economy, there are both input and output measures. The input measures include increased fiscal expenditure on research, development and innovation projects, on the provision and establishment of equipment and infrastructure, and on coordinating networks. These will be lead indicators for the outcomes from such investment, which will be measured through the number of patents awarded, the number of bio-innovation firms established, and the number of products available commercially.

In the longer term, as the agricultural sector becomes more competitive, there will be increased job creation through agricultural effort, and there will be more locally developed indigenous and GMO crops. More multinational companies will have invested infrastructure in their South African holdings, and ultimately there will be an expansion of revenues derived from agriculture.

5. THE HEALTH SECTOR AND THE BIO-ECONOMY

5.1 Strategic objective

The Bio-economy Strategy's objective with regard to health is to support and strengthen the country's local research, development and innovation capabilities to manufacture active pharmaceutical ingredients, vaccines, biopharmaceuticals, African traditional medicines, diagnostics and medical devices to address the disease burden, while ensuring a secure supply of essential therapeutics and prophylactics. The health research and innovation priorities are set by the national Department of Health. These priorities are in line with the Millennium Development Goals, which include the reduction of child mortality, improvement of maternal health and reducing the burden of HIV, malaria and other diseases. The UN is of the opinion that: "Science, technology, and innovation policy should be oriented towards finding vaccines and cures for these diseases, while creating new institutional frameworks from which new research collaborations can spring."[25]

5.2 Strengths and opportunities

In 2011, the South African pharmaceutical market was worth about R30 billion ($3,8 billion).[26] The market size of this sector and its contribution to a negative balance of trade is the most significant component in the health bio-economy. South African imports of pharmaceutical products (excluding active pharmaceutical ingredients) were just below R16 billion in 2011. Imports of vaccines and other biopharmaceuticals increased to over R2 billion in 2011. The diagnostics industry (the full value chain) is valued at R7 billion per year.

The local health sector has several strengths that could be used to bolster the Bio-economy Strategy. These include:

- the largest market in the world (by volume) for HIV drugs;
- a well-developed generics industry;
- an improving public- and private-sector focus on generics supply chain management, which offers opportunities for local manufacturing;
- flora and unique micro-organisms offer a largely untapped source of new therapeutics and production platforms;
- modern science, local biodiversity and indigenous knowledge systems could be combined to accelerate product development;
- world-class clinical sciences researchers and a regulatory framework provide opportunities for globally competitive clinical development;
- world-class researchers in basic sciences, drug and diagnostics discovery, and therapeutic delivery systems;
- significant historical and current investments in vaccine production; and
- strategic international partnerships with countries and organisations, which could be leveraged to provide a source of innovation and other benefits.

Research, development, innovation and manufacturing interventions will focus on these opportunities. The health sector will work on discovering and developing new drugs, vaccines and biologics, diagnostics and medical devices, as well as exploring opportunities in clinical research and indigenous knowledge systems based on biodiversity. The local manufacture of active pharmaceutical ingredients for drugs and biologics (including vaccines) will be expanded, and new technologies such as stem-cell therapies will also be explored.

5.3 Challenges and gaps

To address challenges relating to the discovery, development and manufacture of new diagnostic, therapeutic and preventive healthcare products, South Africa needs to:

- invest in human capital development;

25 UN Millennium Project. 2005. *Innovation: Applying Knowledge in Development.* UN Millennium Project: Task Force on Science, Technology and Innovation. Earthscan. p 25.

26 GBI Research, 2012. Emerging Pharmaceutical Market in South Africa to 2017 - Proposed Introduction of New Drug Regulatory Agency (SAHPRA) to Accelerate Drug Registration Process. Accessed 29 January 2013. URL: http://www.marketresearch.com/GBI-Research-v3759/Emerging-Pharmaceutical-South-Africa-Proposed-7025791/

- enhance strategic partnerships for the transfer of skills and the strengthening of discovery, development and pre-clinical activities;
- invest in new and accredited research and development infrastructure;
- expand the clinical research industry, building on pockets of excellence in the public and private sectors;
- develop research and technical capacity, as well as critical mass in key research, development and manufacturing areas;
- improve the response rate of regulatory authorities and develop appropriate regulations for complementary and African traditional medicines;
- fund research and development for new and improved drugs, vaccines, diagnostics and medical devices; and
- coordinate and streamline activities across the product development pipeline.

A cost-effective preclinical and clinical framework is essential to convert the outputs of research and development into usable health products.

Preclinical and clinical research plays an important role in demonstrating the safety and efficacy of products, allowing them to gain regulatory approval for market entry. This part of product development can account for up to 70% of costs. The cost of bringing a new therapy to the market has escalated to over US$1 billion per therapeutic agent and can take 12 to 15 years. These costs are largely due to protracted, complex regulatory requirements, localised preclinical development in developed countries and the high cost of clinical research.

Challenges in the commercialisation and manufacturing processes include lack of infrastructure for pre-commercial and commercial development and, in particular, appropriately accredited infrastructure for technology developments. Small-scale drug and biologics production facilities will encourage local industry to participate in new market segments such as biosimilars. These facilities will also be critical platforms for inbound technology transfers, leveraging international expertise and catalysing private-sector investments.

There is an urgent need for a strategic and coordinated research, development and commercialisation programme within a national agenda.

5.4 Strategic interventions

The development of new and improved therapeutics (drugs, vaccines, phytomedicines, African traditional medicines and biopharmaceuticals), diagnostics and medical devices is a key area of intervention. Historically, investment in health innovations has been substantially greater relative to the agricultural and biomanufacturing sectors. However, compared to other countries, these investments have been insufficient given the time and financial cost of therapeutic development. According to the World Health Organisation, the international aim is to spend about 2% of the health budget on research and development.[27]

South Africa's national system of health innovation includes the development of:

- new drugs, vaccines, diagnostics and medical devices;
- new techniques in process engineering and manufacturing; and
- new approaches and policies in health systems and services, including a better understanding of human health behaviour.

South Africa will build its health innovation system using the "quadruple helix" model to integrate existing role players – the government, academia, industry and civil society – into a unified and coordinated system. According to the model, industry operates as the seat of production, government provides the framework for secure contractual relationships, and universities provide new knowledge, innovation and technology, while civil society will provide inputs as users of the innovations, holders of traditional knowledge and co-innovators through consultation.

The Bio-economy Strategy will prioritise strategic areas of health innovation (see Figure 7[28], page 28). National and international networks will be built to ensure world-class discovery and development.

27 World Health Organisation. 2012. *Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination.* A65/24.

28 Draft Health Innovation Strategy of the Department of Science and Technology.

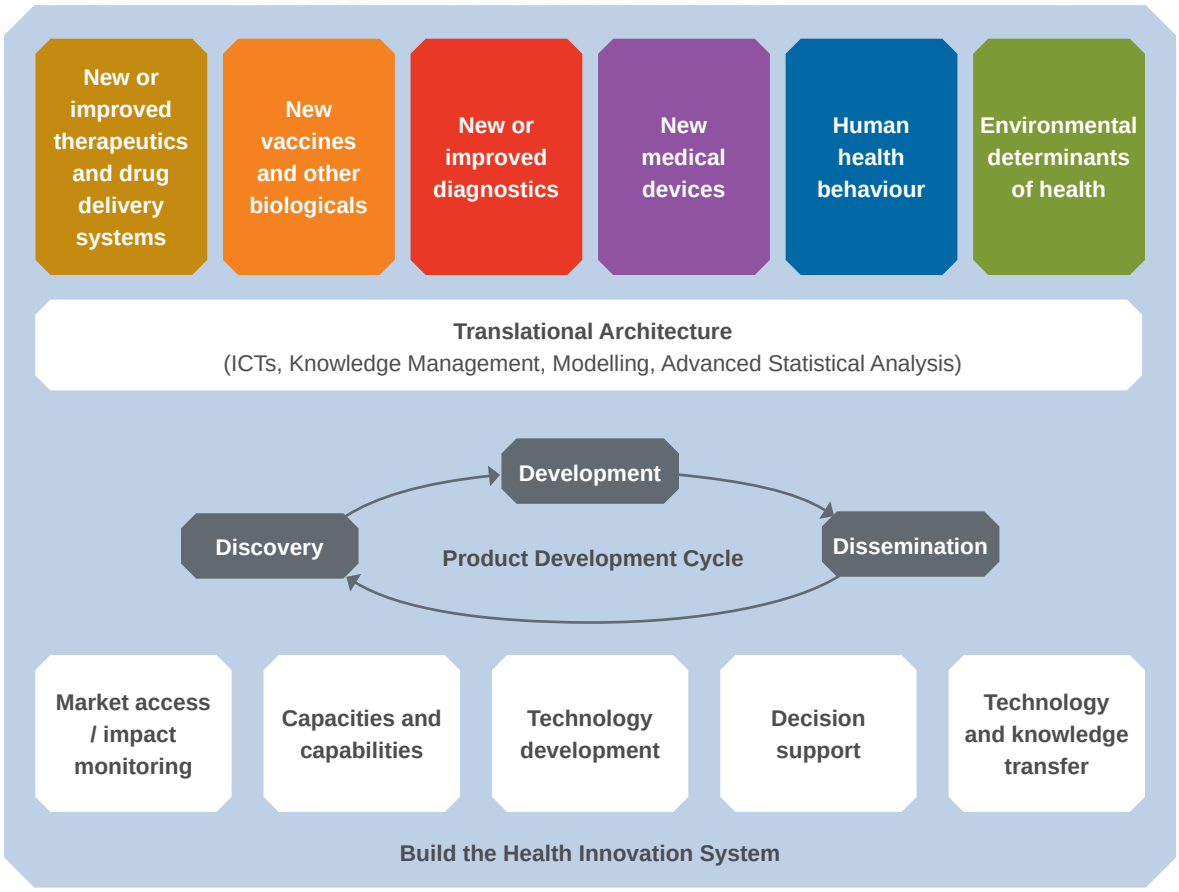


Figure 7: Strategic interventions to build the health innovation system

5.4.1 Develop improved therapeutics and drug delivery systems to address priority diseases

Specific priority diseases will be identified in line with the Department of Health's programme of action and in terms of how these diseases affect the Southern African Development Community region. Virtual networks will be created and strengthened to ensure that the capabilities of institutions are harnessed and expanded. Strategic health innovation partnerships should be established to provide a coordinating function for Medical Research Council networks.

The full value chain for drug design will be addressed, from discovery to new delivery systems (including nanoparticles), while the necessary infrastructure, such as preclinical testing facilities, will be established. It is important that the validation of traditional medicines is included, using the indigenous knowledge system bioprospecting and product development platform. A rigorous validation system for traditional medicine claims should be developed in conjunction with the Department of Health's Registrar of Medicine.

South Africa's untapped rich human genetic resources present a comparative advantage for developing therapies. Clear policy guidelines need to be articulated to guide research and development of new treatments such as gene, stem-cell and tissue therapies. A genomic database and biorepository, together with clear policies on genomic sovereignty, are essential for South Africa to capitalise on this opportunity. Resources for research need to be strategically guided to ensure that South Africa's genomic wealth benefits the country.

5.4.2 Develop new and improved vaccines and biologics

South Africa's vaccine development and biomarker expertise, especially in HIV and TB vaccines, should be strengthened by establishing networks.

Given the increase in chronic diseases and the opportunities for technology transfer and knowledge pools, a private-public partnership to develop therapeutic biologics should be considered. Considerable investments in bioprocessing technology platforms (by local science councils and universities) could be leveraged to attract private-sector investments and anchor a formidable biologics public-private partnership. Investments in the emerging global biosimilars industry will allow South Africa to skip several stages of development.

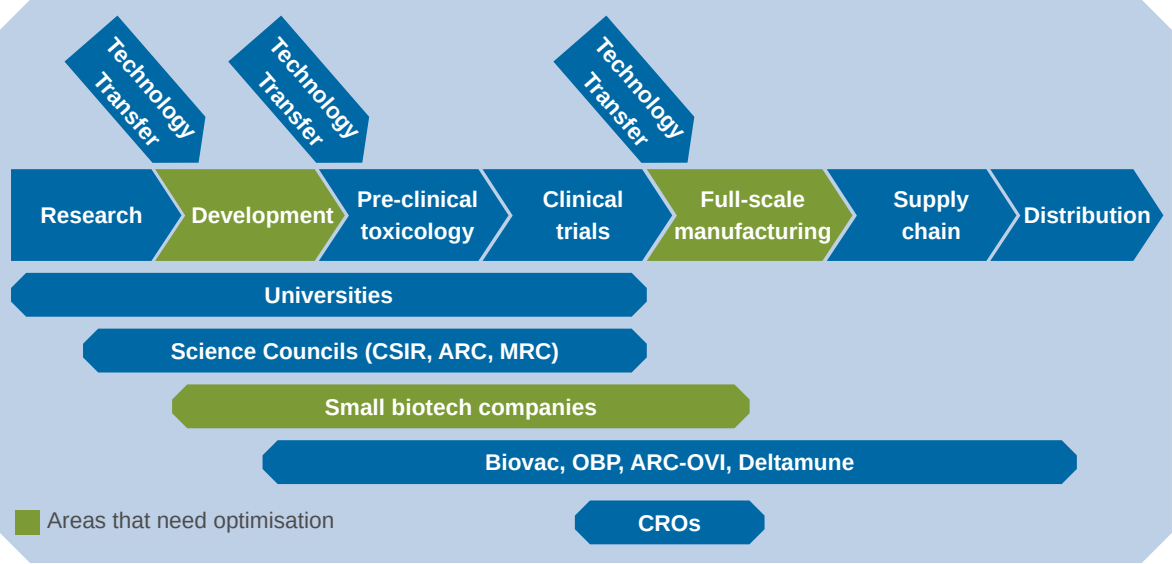


Figure 8: South African Vaccines and Biologicals Value Chain Players

5.4.3 Develop improved diagnostics

Robust, rapid diagnostics are needed particularly in resource-poor areas to enable healthcare providers to diagnose HIV, TB and other high-burden diseases at the point of care. Regular testing of these diseases is essential, and this has created an opportunity to build this industry further.

Government has helped establish a number of companies involved in the manufacturing of diagnostics. In addition, a number of research institutions are developing improved diagnostics. A more concerted and coordinated effort is needed to strengthen capabilities and expertise.

5.4.4 Develop improved medical devices

A large portion of South Africa's medical device innovation occurs in established private firms (bearing in mind that between 80% and 90% of products consumed in South Africa are imported). This innovation generally falls within the existing products and services that the business provides, and addresses a recognised market need. South Africa has a strong history of developing medical devices, such as the CAT scan. Innovations in this field need to be further supported and harnessed.

5.4.5 Strengthen clinical research and development capabilities

Owing to South Africa's high disease burdens, multinational companies and international clinical research organisations conduct local clinical trials using South African candidates. However, they do this without building local capabilities. To develop its therapeutics, the country needs to revitalise its clinical research, curtail high costs and enable commercialisation.

5.4.6 Establish pharmaceutical manufacturing

South Africa needs to grow a pharmaceutical manufacturing sector. This will include the local manufacturing of generic and new drugs, and establishing facilities to encourage the industrial development of biologics and diagnostics. The Department of Science and Technology will create the necessary enabling environment for local manufacturing in partnership with other departments such as Trade and Industry, Economic Development, and Health. Specific technology parks to help achieve this objective will be supported.

5.5 Governance and coordination

To provide an enabling environment for health innovation in South Africa, key stakeholders – including government, industry and academia – should work together in a structure that oversees the implementation and direction of this strategy. Collaboration among South African researchers is essential to build the country's health innovation system. Strategic international partnerships, including multinational companies, also need to be pursued. A specific health innovation structure should not only guide the allocation of resources, but should also monitor progress and recommend new initiatives.

5.6 Impact

Successfully implementing this strategy will fundamentally transform the local industry and create new niche sectors such as biosimilars. The strategy's interventions will also promote clinical development and help emerging technologies become globally competitive.

In 2009, the value of the South African pharmaceutical industry was estimated at R22,6 billion, with R14,4 billion

for direct imports at factory prices. This figure is increasing at 10% per year, outstripping inflation. The strategy aims to replace up to 25% of current imports within a decade of implementation. This translates to R3,6 billion per year (for import replacement) or R6,25 billion (for total industry) at current prices.

Savings on imports and industrial expansion will only occur in the long term but, once achieved, there will be real economic gains for the country. This will help reduce the trade deficit, increase highly technical, sustainable jobs and further investments in innovation, as well as promote the local industry's global competitiveness, earning it export income.

The human vaccine sector is relatively small compared to the pharmaceutical sector. However, it provides a compelling investment case because it ensures security of supply to achieve public health outcomes and is likely to generate economic returns due to import replacement. New investments built on historic capabilities indicate that short-term returns are likely to be positive. An import replacement target of 20% or more (R400 million) represents an attractive investment case.

This strategy aims to renew current infrastructure, thus providing opportunities for new capital formation. More importantly, strengthening local therapeutic manufacturing capabilities will help achieve public health goals and improve the quality of life for all South Africans.

The impact can also be measured through the number of publications and patents, as well as the regulatory approval of health products. As regional and international partnerships and technology transfers are important drivers of the health sector, these will be measured on a regular basis. The actual impact of growth in the health sector will ultimately be measured through the improved quality of life of all South Africans and an increase in life expectancy as a result of a reduction in various mortality rates.

6. THE INDUSTRIAL AND ENVIRONMENTAL SECTOR AND THE BIO-ECONOMY

6.1 Strategic objective

The Bio-economy Strategy's key objectives with regard to industry and the environment are to prioritise and support research, development and innovation in biological processes for the production of goods and services, while enhancing water and waste-management practices to support a green economy.

6.2 Strengths and opportunities

The industrial bio-economy uses micro-organisms and other biologics (such as enzymes) as catalysts in the manufacture of biobased products in the chemicals, food, feed, healthcare, detergents, pulp and paper, textiles and energy sectors. These are also applied in mining and resource extraction, as well as water treatment, waste minimisation and energy production.

The industrial bio-economy focuses on two areas – industry and sustainable environmental management (Figure 9). The former involves bio-based chemicals, biomaterials and bioenergy. The latter involves water and waste as means of providing environmental sustainability for the industrial bio-economy. Enabling technologies were emphasised to demonstrate the significance of this area, as they underpin the activities required for the industrial bio-economy.

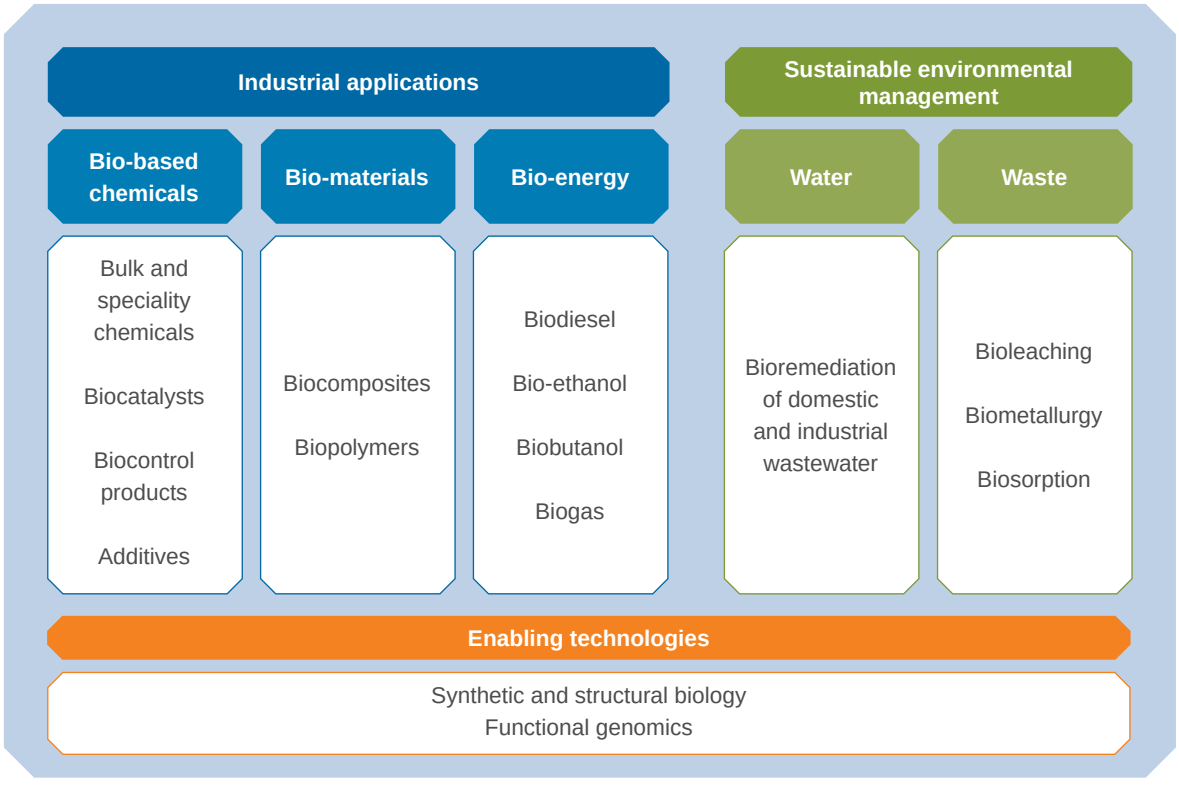


Figure 9: Relevant thematic areas of focus for the industrial bio-economy

Opportunities exist for an industrial bioeconomy in various sectors.

Cross-cutting

The industrial bio-economy is cross-cutting and therefore applicable to various sectors including the chemicals, mining, health, agriculture, food, feed, pulp, paper, textiles and energy sectors.

Chemicals

The chemicals industry is an important part of the industrial bio-economy. Renewable bio-based feedstock is used to produce chemicals. In 2010, this industry contributed between 4% and 5% to South Africa's GDP.[29] Globally, it is estimated that more than 20% of all chemicals will be produced using green technologies by 2020 and 50% by 2050.[30] This trend is driven by the need to reduce costs and create ecologically sustainable industries.

Mature industries

The revitalisation of mature industries (such as sugar cane, pulp, paper and textiles) and resource-dependent industries (such as mining and the petro-chemical sector) need to be explored. These require eco-efficiency and innovation in a low-carbon future.

Sustainable industries

There is increasing demand and preference for sustainable renewable biological resources and bioprocesses as mechanisms for new and revitalised industries. There is opportunity to decouple industrial growth from environmental degradation through more sustainable production methods using industrial-scale biotechnology.

South Africa currently imports all its enzyme requirements. Developing local manufacturing in this area will decrease reliance on imports. Enzymes are a strategic area of interest as they help heavy industries become more environmentally sustainable by reducing water usage, energy consumption, greenhouse gas emissions and other toxic wastes.

The need to respond to global challenges such as climate change, energy and food security in the context of limited water supplies and productive land and the need to reduce carbon emissions should be seen as an opportunity.

Economies of scale in the biofuels industry can drive scarce skills development (particularly in engineering and production), and research and development in fermentation technology and crop improvement.

The Biofuels Industrial Strategy articulated a two per cent penetration level of biofuels in the national supply liquid fuel within five years of its publication. This is equivalent to 400 million litres per annum[31]. South Africa will need to progressively source second-generation biofuels (from non-food lignin and cellulose in woody biomass and sugar bagasse) in place of first-generation biofuels (from simple, edible carbohydrates such as sugar and starch).

6.3 Challenges and gaps

The National Biotechnology Strategy did not invest heavily in the industrial sector. As a result, some of the interventions identified in the Bio-economy Strategy will have no prior infrastructure or dedicated programmes. These interventions will encompass systems, programmes and institutions. There are existing mature industries in South Africa that are linked to the petrochemical, mining, beverages, and waste-water remediation sectors. However, there are sectors that are still in their infancy, including the biofuels and bio-based chemicals and materials sectors. What is required is a clear and coherent role for the industrial aspects of the bio-economy, so that it can contribute to these sectors, demonstrating its value, and ensuring that optimal and effective utilisation takes place.

As more emphasis is placed on environmental sustainability, the waste output from industrial activities cannot be viewed in isolation. There should be a strong focus on the link between environmental sustainability and the industrial bio-economy. South Africa is a water-scarce country, with water availability projected to decrease to less than 1 000 cubic metres per person per year by 2025[32]. This will have a major effect on agriculture in particular. The agricultural sector needs to become more water-efficient and use crops that are more water-wise.

29 Department of Trade and Industry. *Chemicals and Plastics*. Accessed 8 November 2012. URL: http://www.thedti.gov.za/trade_investment/chemicals.jsp

30 *The Bioeconomy to 2030: Designing a Policy Agenda.* Organisation for Economic Cooperation and Development (OECD). 2009.

31 *Biofuels Industrial Strategy.* Department of Minerals and Energy. 2007.

32 National Planning Commission (NPC), (2012), Chapter 7 of the *National Development Plan – Vision for 2030* (Positioning South Africa in the world).

It is expected that the population will continue to grow, which will require an increase in the use of fertilisers to meet demands in food supply. This will negatively affect water quality by loading nitrogen in ecosystems, which poses a threat to ecosystems and biodiversity. Biocontrol products are becoming increasingly important, as biopesticides, plant growth regulators and biofertilisers benefit the environment by reducing the use of traditional chemical pesticides and fertilisers. Research, development and innovation in waste-water treatment and biofertilisers will provide important linkages between the industrial bio-economy and the agricultural sector.

The following challenges and gaps are important to take note of for an industrial bio-economy:

- The industrial bio-economy deals with water security, biodiversity, ecosystem services, waste minimisation, and greening the economy. The challenge is to ensure that biological application has a role to play in providing solutions or alternatives to these underlying areas.
- High fossil-fuel dependency and use results in a negative balance of trade owing to importation and detrimental environmental impacts. A sustainable biofuels industry should avoid agricultural land used for food production, or it may have a negative impact on food security, cause a loss in biodiversity and increase greenhouse gas emissions due to land use and land cover change. The production of biofuels should move away from first-generation technologies to second and third-generation technologies, which industrial biotechnology is well positioned to take advantage of.
- There needs to be alignment with the National Environmental Management Act, 1998, which is supported through various Acts relevant for the bio-economy, including Acts on waste (2008), biodiversity (2004), protected areas (2004) and air quality (2004).[33]
- There needs to be alignment with the Industrial Policy Action Plan and the Advanced Manufacturing Technology Strategy, which aim to create a greener economy. Renewable materials, such as natural fibre-reinforced composites, present an opportunity to create a bio-economy, as these biocomposites can be used in the automobile, aerospace, packaging and building industries.
- The industrial bio-economy will require significant investment as pilot and demonstration-scale units have long lead times and therefore high commercial risks. There is insufficient research and development funding from the private sector.
- There is insufficient human capacity and limited cross-discipline collaboration in the sciences and engineering, which is critical in ensuring scale-up technologies and bridging the gap from scientific application to industrial feasibility.

6.4 Strategic interventions

In a constrained environment, the industrial biotechnology sector will be competing with health and agricultural biotechnology for resources. The drive for research, development and innovation should therefore focus on enhancing existing competencies and filling gaps to create a viable system. The following interventions constitute two strategic thrusts. The first involves interventions of strengthening and preserving activities that had taken place during the implementation plan of the National Biotechnology Strategy. The second focuses on areas where development is required, as well as on unlocking opportunities where no previous interventions have occurred.

6.4.1 Strategic industrial biotechnology programmes

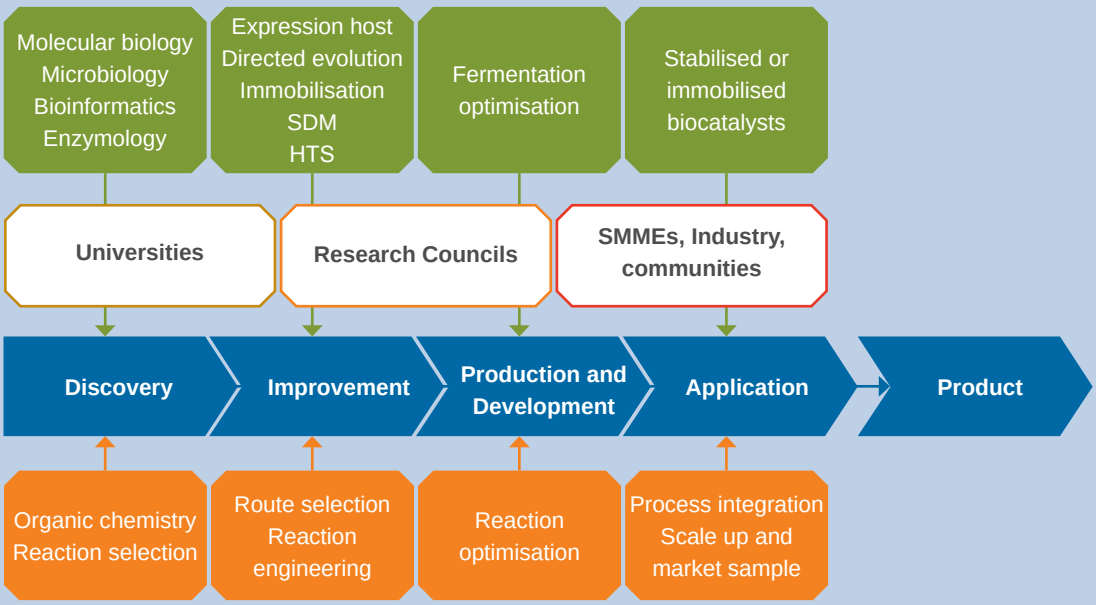
Strategic science programmes should be initiated so that industry-relevant products can be developed to enhance production efficiency, product quality and the industry's competitiveness.These programmes should build on existing initiatives such as biopharming, biocatalysis, biocomposites and mineral leaching.

The key research, development and innovation areas that will stimulate the industrial bio-economy are microbial strain development for important bio-based chemicals, host expression systems for enzyme production, fermentation technologies (solid state and submerged), genetic and metabolic engineering, high throughput biology, bio-informatics and downstream recovery processes. The industrial bio-economy sector will benefit from other national priorities, such as healthcare and food security. The sector should contribute to developments in active pharmaceutical ingredients manufacturing and vaccines, the maturation of which will accelerate demand for upstream inputs. In addition, the industrial bio-economy should work with the agricultural sector to convert agriculture residues, such as lignocellulose feedstock or other energy crops, into biofuels.

6.4.2 Strengthen and develop biomanufacturing capacity and capabilities

As large-scale biomanufacturing activity in South Africa is currently very limited, inward technology transfer from international companies and research groups, as well as supporting development initiatives that adapt such technologies for local use may be necessary. Sustainable

33 Department of Environmental Affairs (DEA), 2012, National Environmental Management Act, available at http://www.environment.co.za/legislation-law/nema-south-africa-national-environmental-management-act-legislation-and-environmental-acts.html. Accessed 23 November 2012.



Why Biocatalysis?

There is an increasing imperative, based on climate change concerns and limits to non-renewable resources, to combine chemical markets with agricultural feedstocks to create a significant bio-economy that will change the way that we make things. Industrial Biotechnology is predicted to be a major contributor to this shift, and Biocatalysis is a key capability.

Biocatalysis provides

i) fewer waste products, ii) lower carbon footprint, iii) less use of toxic solvents, iv) utilisation of renewable feed stocks and v) access to new chemicals not achieved by traditional methods.

What are the products from Biocatalysis?

- Commodity chemicals (e.g. acrylamide as used in mining)
- Pharmaceuticals (e.g. anti-cholesterol drug Lipitor, antibiotics such as ampicillin)
- Food additives (flavours, e.g. menthol)
- Food processing (dough, beer, juice)
- Sugars for food, beverages and medicine (e.g. glucose, fructose syrups)
- Low-calorie sweeteners (aspartame)
- Diagnostics (e.g. glucose monitoring home kits for diabetics)
- Textiles (faded Jeans, fibre processing)
- Leather (depilation)
- Paper (pulping)
- Detergents (many washing powders)
- Cosmetics and fragrances (ambrox)
- Biofuels (biodiesel, bioethanol)
- Renewable chemicals (fermentable sugars)
- Animal feeds (pre-digestion)
- Polymers (polyesters)
- Clean water (bioremediation, e.g. peroxides removal in textile industry)

Figure 10: Biocatalysis

bioprospecting for unique industrial biocatalysts for application in any of a number of bioprocesses may be an area for initial focus. Areas of possible application include the chemical and pharmaceutical industries and biorefineries where biocatalysts can potentially green the processes by replacing synthetic catalysts to give both economic and environmental benefits.

6.4.3 Strengthen local bioprocessing capabilities

The production of biological products has to be scaled up to test economic feasibility. Scaling up bioproduction from small-scale systems to large plants is costly and difficult. Because dedicated biotechnology firms are limited by a lack of capital and engineering expertise for large-scale production and distribution, they should collaborate closely with large industrial firms or use government subsidies to pilot-test biological processes. Pilot-scale infrastructure to support bioprocessing is available at the Council for Scientific and Industrial Research (CSIR) and the Technology Innovation Agency's Umbogintwini bioprocessing platform, but these are underutilised. Access to these platforms will be expanded to allow entrepreneurs to test their production systems.

Research and development initiatives should enable the development of expression systems and extraction processes to increase South Africa's biomanufacturing capability. Bioprocessing capabilities need to be strengthened where there are existing initiatives, but need to go beyond the current platforms. Collaboration and partnerships between industry and academia that can address competence hurdles and knowledge spillovers, and alleviate the risks of transforming knowledge into commercial products, should be encouraged and will be supported.

6.4.4 Develop integrated biorefineries from bio-based feedstocks

In a low-carbon future, biorefineries (comparable to petroleum refineries) will use renewable biomass to produce bioenergy, biomaterials and bio-based chemicals. An industrial bio-economy should develop an integrated biorefinery concept for the co-production of food and non-food (feed, chemicals, materials and energy) to facilitate the transition from fossil resources to renewable bioresources.

An integrated biorefinery will provide cost and energy-efficient ways to make optimal use of biomass for several purposes. Biomass could be used as building blocks for the generation of high-value products such as proteins, fine chemicals, carbohydrates and oils, which create opportunities for a viable industrial bio-economy.

6.4.5 Strengthen wastewater research, development and innovation

As it has a limited water supply, South Africa should improve efficiency in how it uses municipal and industrial wastewater. The country has world-class expertise in wastewater research at universities, research councils and large industrial players.

The Department of Science and Technology will facilitate collaboration to generate knowledge, prevent duplication of work and enhance value addition. Pilot and demonstration-scale wastewater treatment facilities need to be developed to test and market larger-scale treatment facilities. Additionally, innovation in water pollution should focus on bioassays and biomarkers.

6.4.6 Strengthen solid waste research, development and innovation

Economic development has contributed to an increase in industrial, mining and power-generation waste. Electronic waste is also starting to accumulate in landfill sites.

The following biological applications aim to minimise waste generation and create an effective waste-management system:

- closed-loop systems of environmental application using microorganisms;
- harvesting of landfill gas for heating, electricity and as an alternative fuel source;
- beneficiation of biomass waste for energy recovery and generation (waste to energy);
- alternative use of wastewater streams for other products; and
- reuse and recycling of electronic waste, and recovery of its relevant components. Metals from electronic waste can be recovered by combining hydrometallurgical (chemical) processes and bioprocesses (biometallurgy, bioleaching and biosorption).

6.4.7 Synergies with enabling and emerging technologies

The industrial bio-economy should synergise with converging research in order to unlock opportunities (which include areas of synthetic and structural biology, functional genomics and nanotechnology). Furthermore, untapped areas such as marine biotechnology can be beneficially harnessed.

6.4.8 Establish an advisory committee for industrial bio-economy

A stakeholder advisory committee will be established to guide and monitor the industrial/environmental aspect of the Bio-economy Strategy.

6.5 Impact

Owing to the scale of investments needed to establish manufacturing facilities, large sugar and chemical companies are likely to dominate the future industrial bio-economy landscape. A few mid-tier companies in enzyme production, biocontrol and niche bioproducts are expected to emerge from the consolidation of current dedicated biotechnology firms. Other big industrial players such as food processors, mining companies and water utilities will become important clients for bioproducts. Private-sector players will be an important source of research and development funding.

The following are significant impact areas for the industrial bio-economy:

- enhanced global and local competitiveness of industries;
- ecologically efficient utilisation of renewable materials;
- minimised dependency on fossil fuels;
- reduced production of greenhouse gases and positive contribution to a green economy;
- expanded agricultural production for feedstock on underutilised arable land will provide jobs in rural areas and improve spatial economic development patterns as industrial infrastructure – such as bioprocessing plants and logistics platforms – is located closer to sources of production; and
- a thriving biofuels industry will support the development of the non-fuel industrial bio-economy.

The impact will be measured via the revenues/sales of products, processes and services, as well as the number of new bio-innovation industries created. The role of technology transfer, collaborations and partnerships will also provide an indication of growth within the industrial component of the bio-economy.

7. THE WAY FORWARD AND CONCLUSIONS

The development of the South African economy has historically been driven by exporting natural resources, with minimal beneficiation. This is gradually changing. Other developing economies have been successfully transformed from resource-based to knowledge-based economies, and South Africa seeks to join this community. It is broadly recognised that such a transformation needs to be underpinned by the development of a highly skilled labour force, investment in technology infrastructure and the growth of high-technology industries.[34]

This document has therefore outlined the approach for implementing a knowledge-based bio-economy in South Africa. The 2001 National Biotechnology Strategy helped set the agenda for biotechnology development in South Africa. The Bio-economy Strategy aims to build on the achievements of the former strategy, incorporating the lessons learnt and developing initiatives to address future challenges.

This new strategy provides a high-level framework to guide biosciences research and innovation investments, as well as decision-making. All the relevant sectors need to support and commit to the strategy due to the multi-sectoral and long-term nature of bio-based developments. Although the Department of Science and Technology is a key stakeholder, the Bio-economy Strategy recognises that bio-economy outcomes are far beyond the mandate of the Department alone. Science and technology, as applied to agriculture, human health and manufacturing, among others, requires guidance and support from the relevant departments and industry sectors. This highlights the need to formulate a single, coherent vision for the bio-economy in South Africa, which should drive policy development. Indicators – presented in Annexure 1 – will allow progress towards the objective to be measured, and a comprehensive evaluation will be conducted after five years to guide this highly dynamic field of enterprise.

The Department of Science and Technology, as the lead agent of this strategy, will continue to engage with line departments to promote cooperation, facilitate the strategy's broad implementation, and ensure synergy, alignment and better coordination of activities. The Department will drive a consultative process to define the roles and responsibilities of various government departments, agencies and instruments in implementing the strategy.

Ultimately, this strategy will be carried out through the development and application of a detailed implementation framework for each of the three identified thematic areas. Such plans should embody the principles established in this strategic document, and form a convincing, detailed vision for the continuing development of South Africa's bio-economy.

34 Blankley W and Booyens I. 2010. *Building a Knowledge Economy in South Africa. in South African Journal of Science.* 106, pp 1–6.

Annexure 1: Indicators

The main indicators relevant for a knowledge-based bio-economy include the following:

- foreign direct investment (as a percentage of GDP);
- gross fixed capital formation (as a percentage of GDP);
- manufacturing trade balance (as a percentage of total trade);
- trade balance of high-technology manufacturing goods (in R millions); and
- technology balance of payments.

The table below highlights quantitative output indicators that will be used to track and monitor the Bio-economy Strategy.[35] Detailed implementation plans and value propositions for specific sectors and initiatives will help refine targets in the short, medium and long term.

To achieve the outputs outlined in the table, policy instruments in different state organs related to education, industrial development, demand-side, fiscal and regulation policies need to be well coordinated.

Indicators of critical factors

Critical factors of the strategy		Output indicators
Knowledge base and human resources	• Strengthen basic research excellence. • Promote industry-oriented research programmes. • Facilitate knowledge flow between disciplines. • Develop next-generation technologies. • Develop human capital for the bio-economy.	• Number of publications and citations in high-impact journals per capita. • Size of bio-innovation workforce as percentage of science and technology workforce. • Number of research chairs, centres of excellence, technology platforms and multidisciplinary research and development programmes supported. • Bio-economy research and development as a percentage of GERD.
Knowledge transmission and application	• Technology development infrastructure to facilitate the translation of research and development outputs into products and services. • Strategic development and innovation programmes. • Assimilation and adoption of bio-innovations for new industry applications.	• Number of patents granted. • Number of collaborative product development partnerships. • Availability of technology development and assimilation infrastructure. • Number of technology-transfer transactions. • Availability of incubation facilities of bio-innovation firms.
Market	• Strengthen economic sectors (manufacturing, agriculture, health and environmental) exploiting bio-innovations. • Through enabling legislation, facilitate introduction of new bioproducts.	• Number of regulatory approvals for health products. • Revenues/sales of life science products, processes and services. • Number of field trials with GMO crops.
Industry	• Enable creation of bio-innovation firms. • Strengthen local manufacturing capability of bioproducts. • Attract foreign direct investment in bio-economy sectors. • Alignment of fiscal policy instruments to encourage innovation. • Encourage investment in research and development. • Improve competitiveness of industry. • Exploit regional potentials.	• Number of bio-innovation firms, including dedicated bio-innovation firms by sector. • Venture capital invested in bio-innovation firms. • Technology balance of payment of bio-innovation outputs. • Number of joint ventures and strategic alliances between local bio-innovation firms and international partners. • Multinational corporations in bio-economy sectors locating research and development facilities locally. • Types of biotechnology used by firms.

35 OECD Data: Indicators for Benchmarking Biotechnology Innovation Policies. Accessed April 2013. URL: http://www.oecd.org/sti/innovationinsciencetechnologyandindustry/37450279.pdf

Annexure 2: List of Selected Current Initiatives and Platforms

South African Malaria Initiative, 2006 – An integrated research and development programme to develop new tools to improve malaria prevention and control.

Biodesign Initiative – Integrates synthetic biology, structural biology, systems biology and functional genomics. Develops human capital and strengthens basic research.

South African HIV and Aids Research Programme (South African Aids Vaccine Initiative, 1999), **2009** – Focuses on basic research to develop tools for the prevention, diagnosis and treatment of HIV/Aids.

Public Understanding of Biotechnology, 2003 – Creates awareness and educates the public about biotechnology.

Nuclear Technologies in Medicine and the Biosciences Initiative, 2009 – Research and development on nuclear technologies in medicines and biosciences.

Bioinformatics and Functional Genomics Programme (National Bioinformatics Network, 2003), **2009** – Provides bursaries and grants to support human capital development and knowledge generation.

Biopharming Programme, 2010 – Technology optimisation of the plant expression system to produce biologics (vaccines). Technology transfer, infrastructure development and human capital development.

Biosafety Platform, 2008 – Provides regulatory guidance and support for product development in third-generation plant and animal biotechnologies.

IKS Bioprospecting and Product Development Platform, 2011 – Uses biodiversity, indigenous knowledge systems and modern science tools to develop African traditional medicines, nutraceuticals and cosmeceuticals.

Preclinical Drug Development Platform – Upgrades infrastructure to provide accredited (current good manufacturing and laboratory practices) facilities for preclinical development of therapeutics.

Centre for Proteomics and Genomics Research, 2007 – Facilitates access to state-of-the-art capital-intense genomics and proteomics equipment. It has a hybrid mandate to offer public benefits as well as commercial services.

Metabolomics Platform, 2006 – Studies metabolites and enables screening for toxicity, monitoring and treatment of patients. Could facilitate development of diagnostic tools and therapeutics.

National Genomics Platform, 2007 – Provides a high-throughput genomics research facility to both South Africa and international clients, and facilitates generation of knowledge that will lead to new ventures and companies.

Metagenomics Platform, 2007 – Screens extremophiles and their metagenomes (believed to have evolved specialist functions to cope with survival under extreme conditions) to commercialise enzymes.

Novel Vaccine Platform, 2007 – Develops general-purpose vaccine delivery technology, based on displaying antigenic peptides on the surface of African horse sickness core proteins to address the shortcomings of current animal vaccines.

Process and Product Incubator (Bioprocessing Platform), 2005 – Addresses the needs (and shortage) of bio-entrepreneurs and bioprocess development specialists by providing the infrastructure and a wide range of expertise needed to develop innovative products.

CSIR Protein Expression System, 2009 – Facilitates human capital development and advances cutting-edge technologies and products (protein expression and purification, fermentation and process development, and glycan profiling and analysis).

Drug Discovery and Development (H-3D), 2010 – Addresses the lack of critical modern pharmaceutical industry skills in the field of drug discovery. It mimics a drug discovery centre that bridges the gap between basic research and clinical studies.

Drug Delivery Platform, 2009 – Incubates the development of several patented and patent-pending drug delivery technologies (includes devices) with commercial value in the biopharmaceutical industry.

Institute of Diagnostic Research, 2005 – Researches and optimises affordable, rapid diagnostic tests for infectious diseases.

Annexure 3: National Biotechnology Strategy Review

Proposed objectives and interventions	Comment on status quo	Challenges and threats
Develop a coordinated biotechnology strategy. Establish a biotechnology advisory council. Establish biotechnology innovation centres.	Created the National Biotechnology Advisory Council. Created three biotechnology innovation centres, one national innovation centre in plant biotechnology and a bio-informatics network. These were merged into the Technology Innovation Agency.	Research institutions work in silos. Too much competition and too little collaboration. Lack of alignment and coordination of national system of innovation instruments.
Develop and retain appropriate human resources for biotechnology. Establish career opportunities. Fast-track resource needs of biotechnology innovation centres. Improve postdoctoral fellowship system. Promote curriculum development.	Currently improving postdoctoral fellowships through various government instruments, mainly the National Research Foundation. Created dedicated biotechnology firms, mostly from reorganised university/ research council-based projects. As a result, not many new jobs were created. Biotechnology innovation centres, together with the Innovation Fund, developed critical skills in commercialisation and intellectual property management. Not much progress has been made in influencing curriculum review, except for instances where individual biotechnology innovation centres designed and delivered specific content with local and international partners.	Inappropriately skilled and inadequate science and technology workforce. Shortage of entrepreneurial skills and technology transfer skills and mechanisms. Poor capacity to absorb science and technology graduates. High level of brain drain. Absence of national institutes dedicated to biosciences. Unemployment among life science postgraduates.
Encourage links between large companies and biotechnology innovation centres. Department of Trade and Industry to encourage large company investments in biotechnology innovation centres.	This has largely failed because of the innovation chasm and because there was very little in the research and development pipeline to attract interest from large companies. The Biovac Institute, a public-private partnership, has close relationships with biotechnology innovation centres. Multinational corporations became involved in training postgraduate students.	Lack of research and development and local manufacturing capabilities to attract investment from large companies. Pseudo-dedicated biotechnology firms and technology platforms unable to generate revenue.

Proposed objectives and interventions	Comment on status quo	Challenges and threats
Create biotechnology industry in sectors that are aligned with national imperatives, market demand and regional expertise. Address the most pressing human health issues in South Africa. Improve food security and nutrition. Improve plant production in a changing environment and reduce the impact of agriculture on the environment. Improve animal health and productivity. Support sustainable industrial development using biotechnology.	Very little evidence of new therapeutics developed or health technology assimilated for local innovation and production. Food security issues are being addressed due to the ARC's historical strengths. Limited investments in animal breeding (Nguni cattle) were quite successful, but the number and variety of animals too small. There has not been significant investment in industrial biotechnology. In fact, the country lost some important industrial capacity.	Limited commercialisation of products and services from defined biotechnology firms and/or platforms. Insufficient uptake of technology solutions. Lack of appropriate and accredited technology infrastructure to scale up. Marketing and communication strategies to promote South African innovation for foreign direct investment.
Create an enabling legislative framework to develop and commercialise biotechnology. Review existing legislation with implications for biotechnology and propose new legislation or amendments where necessary. Update the Plant Breeders' Rights Act, 1976, to include DNA fingerprinting. Consider developing legislation to protect the rights of animal breeders. Introduce and implement a "search and examine" capacity in South African Patent and Trademark Office as soon as possible. Introduce and implement the equivalent of the Roche-Bolar provision (which allows research on pharmaceutical drugs under protection) as soon as possible. Provide uniform guidelines for science councils, universities and universities of technology on intellectual property rights for inventors. Provide institutional capacity to implement legislation.	The GMO Executive Council, the Bioprospecting Expert Committee and the Department of Science and Technology continue to support legislative reform. Chapter 8 of the National Health Act needs to be amended to address issues around genetic research. The cost implications associated with patent examinations impede intellectual property examination at the Companies and Intellectual Property Commission. The Department of Science and Technology continues to support capacity-development patent examination. Provisions that allow research on pharmaceutical drugs under protection (Roche-Bolar) are not in place in the country's intellectual property law. Benefit-sharing provisions in the Intellectual Property Rights from Publicly Financed Research and Development Act delineate intellectual property rights for inventors. Mandatory offices of technology transfer provide capacity to implement the Intellectual Property Rights from Publicly Financed Research and Development Act.	Legislation and regulations for GMO are not harmonised. High regulatory barriers for product approval. Technology develops ahead of policy, leading to delays in novel product approval. Global markets are inaccessible due to weak networks and policy instruments. Unable to use knowledge pools effectively. Strategic intellectual property management is still a challenge. Lack of Roche-Bolar equivalent has impeded South Africa's ability to take advantage of expiring patents to generate generic drugs. Lack of clear regulations for the approval of biosimilars.

Proposed objectives and interventions	Comment on status quo	Challenges and threats
Create an enabling bilateral and multilateral framework for the development and commercialisation of biotechnology. The government should ensure that full consultation takes place with relevant departments before signing international, multinational and bilateral agreements.	The Department of International Relations and Cooperation has established strategic relationships with several countries and institutions, but South Africa lacks a national strategic template to ensure maximum value is leveraged and extracted from these relationships. Engagements tend to be limited to institutions.	Incentives to attract multinational corporations to establish research, technology development and manufacturing capabilities in South Africa have not yielded desired outcomes.
Employ international expertise and technologies to address priority issues. Engage strategic partners for the platforms. Programme partners. Bilateral agreements. Millennium Africa Programme.	Prioritised government-to-government bilateral agreement. Supported institutional collaborations in life-science innovation. South African Research Chair Initiative programmes promote import of expertise. Department of Home Affairs facilitating expertise import. Sandwich MSc and PhD programmes in place. Modalities to facilitate mobility of experts in place.	Technology transfer and assimilation has been slow and limited by lack of appropriate competence and infrastructure. Uptake of mobility funds for experts and students has been slow, probably due to marketing and communication challenges.
Provide sustainable funding for the Biotechnology Strategy. Provide government venture capital. Create liquidity in venture capital markets and the valuation of intellectual property. Implement supply-side measures to support private-sector research and development.	Government-backed venture capital has not materialised, possibly because there were not enough opportunities to create a viable portfolio and the skills base was low. The biotechnology innovation centres evolved to play this role through their funding instruments. Venture capital liquidity remains limited. There is no discernible activity in intellectual property trade, partly owing to the misconception that it will deprive the country of intellectual property and research and development excellence, and partly owing to local researchers protecting their funding interests. Research and development tax incentives were developed, but were not appropriately structured for the biotechnology sector and local dedicated biotechnology firms. They did not generate revenue. Other supply-side measures have not made much progress.	Insufficient public and private funding for research commercialisation. Lack of funding for capital-intensive technology infrastructure. Delays in developing local manufacturing capabilities. Inability to increase absorptive capacity of the system and create new jobs. South Africa remains a technology importer with a large negative technology balance of payments. Mismatch in the risk and return of capital budget investment.

Proposed objectives and interventions	Comment on status quo	Challenges and threats
Address ethical considerations relating to biotechnology. Develop a national strategy to address ethical issues associated with biotechnology.	Legislative reforms relating to genetic sovereignty and material transfer are under discussion. The Department of Science and Technology chairs the working group. Published an ethical and legal guidelines manual in 2006, with the endorsement of the Department of Science and Technology. The Department of Science and Technology is a member of the National Research Ethics Council and Animal Research Ethics working group. Established a biosafety platform to coordinate research in ethics and biosafety. The GMO directorate of the Department of Agriculture, Forestry and Fisheries and Medicines Control Council are the custodians of ethical issues.	Illegal bioprospecting and biopiracy of South African genetic resources. Protecting the public. Promoting ethics.
Promote a clear understanding of the potential of biotechnology. Articulate a single vision of biotechnology. Provide public biotechnology education.	Established Public Understanding of Biotechnology programme, managed by the South African Agency for Science and Technology Advancement. The programme has promoted understanding and empowered scholars, journalists and the public to make informed choices on biotechnology issues.	Largely targeted at scholars and insufficiently focused on consumers. Media do not always report correctly on biotechnology issues.

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