

National Biotechnology Audit 2007

BIOTECHNOLOGY USE AND DEVELOPMENT IN SOUTH AFRICA



science & technology

Department: Science and Technology REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF SCIENCE AND TECHNOLOGY

Vision

 $\bullet \bullet \bullet$

To create a prosperous society that derives enduring and equitable benefits from science and technology.

Mission

To develop, coordinate and manage a national system of innovation that will bring about maximum human capital, sustainable economic growth and improved quality of life.



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Executive Summary

This document presents the results of an effort to identify and survey the biotechnology activities in South Africa. The report aims to provide a quantitative picture of biotechnology activities in the country (according to international standards), to identify needs and constraints and to fulfil the international obligations of the Department of Science and Technology to the Organisation for Economic Cooperation and Development (OECD).

The OECD "list based definition" of biotechnology techniques is used as screening mechanism in order to identify organisations which are involved in the field. With a return rate just above 80%, seventy eight South African companies were identified to fulfil the criteria as being biotechnology active firms and thirty eight companies fulfilled the criteria as being core biotechnology companies.

The majority (70%) of both active and core biotechnology firms were identified to be situated in Gauteng and in Western Cape. Approximately one third of the companies are spin-offs. Thirty six percent of the spin-offs companies are coming from government agencies and 28% from universities. The median age of the biotechnology active companies is eight years.

The biotechnology active firms declared that they were involved with 1542 products – 58% in agriculture. The core companies declared that they are involved with 559 products at different stages of development. Sixty eight percent of the products were related to agriculture and 57% were at R&D stage. A difference between the core and the non-core active companies is that the former have the majority of their products in the R&D stage while the latter have the majority of their products in products in products in market stage.

Sixteen biotechnology active firms (nine core companies) were identified to be involved with living modified organisms.

The total number of employees in the biotechnology active firms exceeded 72800, of those 2051 were involved with biotechnology related activities (up from 1800 during 2004). Previously Disadvantaged Individuals (PDIs) were 59% and females 52%.

The core companies employed 765 people and they exhibit a relevant growth of 22% during the 2004 to 2006 period. The majority of the companies (90%) employ less than 50 people each. Fifty four percent are PDIs and 47% are female.

The biotechnology active companies declared that they had revenues from biotechnology R767.6 million during 2006 (R624.4 million 2004). Their revenue from biotechnology related exports was R211.4 million during 2006 (R229.1 during 2004).

The turnover of the core firms was R520 million (2006) and biotechnology exports were R 86 million.

The core companies are active in collaborative ventures. The main reasons behind the collaboration efforts are "production and manufacturing" and "R&D". Their main collaborating partners are universities and other biotechnology firms.

The core companies declared that they raised R216 million during the 2003 to 2006 period. The majority of the funds came from the BRICs (36%) and the Innovation

Fund (19%). R&D expenditures increased from R48million in 2004 to R76 million in 2006.

Both groups of companies identified that the major constraints they face are related to the "long times for regulatory approvals" and "access to capital and human resources". Similarly they declared that additional support services are required in the fields of "intellectual property management"; "marketing internationally" and "fund raising". The concerns related to filling vacancies are related to lack of staff with experience, qualifications and expertise. The core companies also mentioned the lack of financial resources for attracting appropriate candidates. The identified constraints and needed support services have obvious policy implications.

While this is the second effort of the Department of Science and Technology to monitor the biotechnology scene in South Africa, the two reports are not directly comparable and any attempted comparisons may lead to misleading conclusions. The differences arise mainly because of the evolving definitions of what constitute a biotechnology company and secondarily because of differences in the response rates of the two efforts.

Introduction

Biotechnology is internationally believed to be the next revolutionary scientific endeavour in the history of humanity. Researchers suggest¹ (Freeman et al. 1997) that the same way that steam power and the railway and more recently information and communication technologies have revolutionised society, biotechnology will change the way we live and we think about living organisms and society.

Biotechnology as a research domain opens up the way for new applications in healthcare, agriculture, food production, environmental protection and new scientific discoveries. The new technologies regenerate old industries and create new businesses offering skilled jobs that sustain knowledge-based economies and produce economic growth.

The South African Government supports biotechnology and encourages home grown research. A recent report² identifies that South Africa exerts leadership and provides the example for the adoption and acceptance of biotech crops in the African Continent and globally. South Africa is classified as the only mega-country in the African Continent and one of the 14 biotech mega-countries in the world. Countries are classified as biotech megacountries when they grow 50,000 hectares, or more, of biotech crop. Furthermore, a multi-criteria survey³ identified that an approving climate of opinion prevails towards biotechnology in the country.

Recently, new structures have been established in the country in order to enhance biotechnology research and innovation in accordance with the "National Biotechnology Strategy"⁴. The main instruments are the four Biotechnology Regional Innovation Centres: Cape Biotech, BioPAD, ECoBio, and PlantBio - the National Bioinformatics Network and the Public Understanding of Biotechnology Programme. The four Centres aim to promote and support the national biotechnology innovation system. Their objectives are to establish biotechnology research platforms and to support the establishment of new firms in the field.

- 2 James C. (2007), "Global status of commercialised biotech/GM crops: 2006" International Service for the Acquisition of Agri-Biotech Applications, ISAAA, accessed at URL: http://www.isaaa.org March 2007.
- 3 Pouris, A. (2003), Assessing public support for biotechnology in South Africa, South African Journal of Science 99:513-516.
- 4 DST (2001) A National Biotechnology Strategy for South Africa, Department of Science and Technology, Pretoria



The National Bioinformatics Network has been established to address the country's needs in trained personnel, adequate computing, networking, teaching, training and laboratory facilities for bioinformatics. Research in bioinformatics is also being enabled and conducted throughout the network. Finally the Public Understanding of Biotechnology Programme aims to promote understanding of the potentials of biotechnology and to ensure broad public awareness, dialogue and debate on its current and potential future applications.

The recently published "Ten Year Plan" of the Department of Science and Technology⁵ (DST 2007) sets the vision that South Africa should be "among the global top ten nations in the world in terms of the pharmaceutical, nutraceutical, flavour, fragrance and biopesticide industries" by 2018.

Following international best practise, the Department of Science and Technology commissioned the eGoliBio⁶ to undertake the first audit of the South African Biotechnology sector during 2004.

This document presents the results of the second effort to identify and survey the biotechnology activities in South Africa with particular emphasis in the "core" biotechnology companies. The report aims to provide a quantitative picture of biotechnology activities in the country (according to international standards), to identify

6 EgoliBio (2004), Audit of South African biotechnology sector, Modderfontein, South Africa.

Freeman, C., and Soete, L. (1997), The Economics of industrial innovation, MIT Press, Cambridge, MA.

⁵ DST. (2007), Innovation towards a knowledge-based economy – Ten year Plan for South Africa 2008-2018, Department of Science and Technology, Pretoria.

needs and constraints as identified by the stakeholders and to fulfil the international obligations of the Department of Science and Technology to the Organisation for Economic Cooperation and Development (OECD).

The next section outlines the definitions used in the survey. The section "target population" discusses the identification of the companies undertaking biotechnology activities and the following section outlines the results of the survey.

Definitions

Biotechnology is the use of biological processes, organisms, or systems to manufacture products intended to improve the quality of human life. As such it has a multiple usage across sectors and industries and organisations utilising biotechnology cannot be classified under one classification code.

In its effort to promote the development of compatible indicators internationally the Organisation for Economic Cooperation and Development OECD⁷ (2006) has developed both a single definition of biotechnology and a list-based definition of different types of biotechnology. The single definition defines biotechnology as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."

The problem associated with the use of such a general definition is that the interpretation of the definition can vary broadly if is left to the respondents. To help with the interpretation of this definition, the list-based approach was developed.

The OECD list-based definition of biotechnology techniques is as follows:

DNA/RNA: Genomics, pharmaco-genomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of anti-sense technology.

Proteins and other molecules: Sequencing/ synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signalling, identification of cell receptors.

7 OECD. (2006), OECD framework for biotechnology statistics, Organization for Economic Cooperation and Development, Paris Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bio-reactors, bio-processing, bio-leaching, bio-pulping, bio-bleaching, biodesulphurisation, bio-remediation, bio-filtration and phyto-remediation.

Gene and RNA vectors: Gene therapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.

Nano-biotechnology: Applies the tools and processes of nano/micro-fabrication to build devices for studying bio-systems and applications in drug delivery, diagnostics etc.

For this survey both definitions have been used. As a matter of fact the respondents were requested to go through the list based definition and if they did not undertake any of the indicated activities to stop completing the questionnaire (appendix 1).

In the level of a firm, a "core" firm is one that is using at least one biotechnology related technique and whose main economic activity is biotechnology. A biotechnology active firm is one that either performs R&D in biotechnology or produces and sells biotechnology products. Core firms are a sub-set of the biotechnology active firms set.

The utilisation of the OECD definitions and approaches facilitates the comparison of the national biotechnology scene with those of other countries. However, the results reported in this report are not comparable with those of the EgoliBio survey.





Target Population

The target population of the biotechnology surveys is all firms that use biotechnology in their production process or in order to develop products or processes.

For the 2007 survey the target population consists of 241 firms. The names and addresses of the relevant firms were received by a number of stakeholders. The stakeholders were: Biotechnology Regional Innovation Centres (BRICs), AfricaBio, Research Councils, incubator facilities, Registrar of GMO's Act and Plant Breeders' Rights Act, organisations providing incentives for research and development and commercialisation (i.e. Innovation fund, support program for industrial innovation, technology and human resources for industry programme); relevant associations (e.g. ACROSA) and the Department of Science and Technology (lists of the previous biotechnology survey).

Exclusions from the surveys include universities and service organisations (e.g. laboratories, legal firms) that provide only services to biotechnology firms. These entities, even though related to biotechnologies do not meet the main criterion of biotechnology surveys, i.e. to provide information on firms that use biotechnology to develop new products and processes. The country's research councils (e.g. CSIR; ARC; MINTEK; MRC) were included in the population as according to the classification scheme of the Frascati manual⁸ (p 55) they belong in the private sector (they charge market related prices, they can spin off companies etc.). Companies that are involved exclusively in marketing and distributing biotechnology products are excluded from the survey as they do not undertake any biotechnology activities.

Frascati Manual (2002), The Measurement of Scientific and Technological Activities: Proposed Standard Practice for Surveys on Research and Experimental Development, Organisation for Economic Cooperation and Development, Paris.

Survey

The survey was initiated with the collection of the names of the target companies. The particulars of the companies were verified and the appropriate persons to respond to the survey were identified through telephone calls. From the target population of 241 companies, five were not possible to be identified and six were identified to have been closed down. The guestionnaires were e-mailed and two e-mail reminders and a telephonic reminder followed up. After the telephonic follow up we had received 186 responses (response rate 80.8%). Of those responses 78 companies were identified to fulfil the criteria as being biotechnology active firms. Thirty eight companies fulfilled the criteria as being core biotechnology companies. The 38 core companies are a sub set of the 78 biotechnology active companies. Twelve companies among those who did not respond were followed up for non-response analysis. All twelve companies were identified as being non-biotechnology active firms.

The respondents of all core companies were approached telephonically in order to confirm particular responses and thank them for their participation. With the respondents of three of the participating companies, biotechnology related issues were discussed in arranged meetings.

Results

Biotechnology Active Companies

This section presents the findings related to the 78 biotechnology active companies.

Figure I shows the geographical distribution of the biotechnology active companies. Forty three percent of the companies are in the Gauteng area and 26% in the Western Cape.

Figure 2 shows the way that the biotechnology active companies are incorporated. Sixty four percent of the companies are Pty (Ltd); 12% close corporations and 9% parastatals.

Twenty five of the 78 companies declared that they were spin-offs from other institutions. Figure 3 shows the origin of the spin-off companies. Thirty six percent of the spinoff companies declared that they were coming out of government agencies and 28% out of universities.

Fifty two companies (66%) declared that they were mainly South African owned and twelve that they were foreign owned. Fourteen companies did not respond in the question.



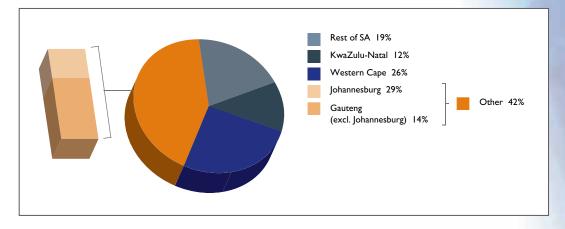


Figure 1: Geographical Distribution of All Biotechnology Active Companies

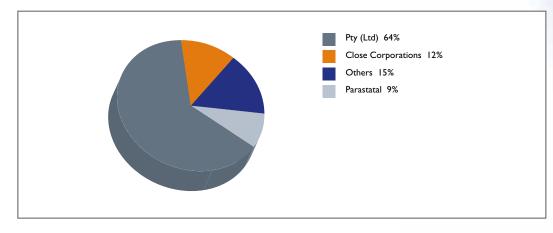


Figure 2: Type of Enterprises/Organisations of all Biotechnology Active companies

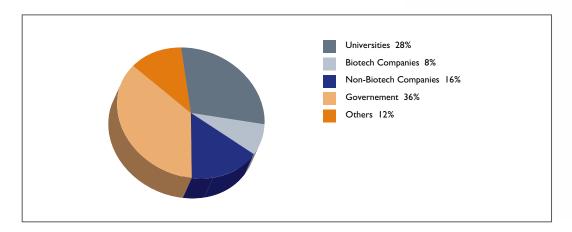


Figure 3: Origin of Spin-Offs of Biotechnology Active Companies

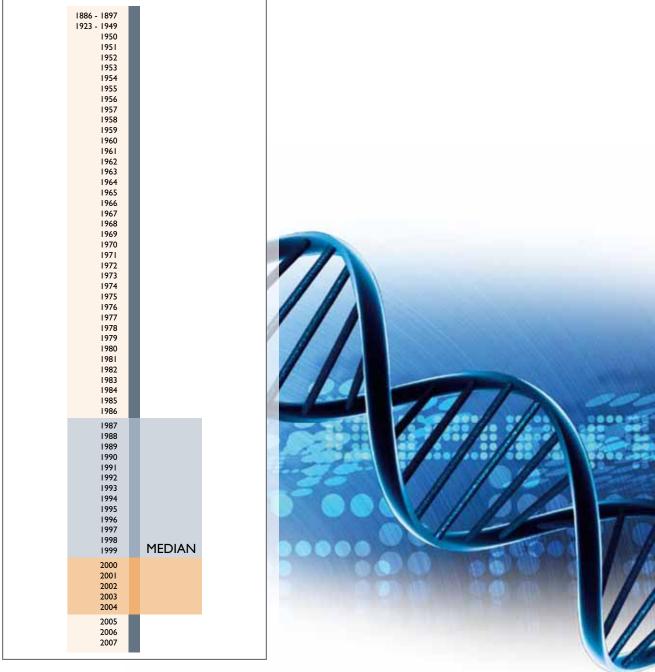


Figure 4: Box and Whiskers of Age Profile of Biotechnology Companies

Figure 4 shows the age profiles of the biotechnology active companies. Fifty percent of the companies were established after 1999 and 25% after 2004. Seventy five percent of all companies have been established since 1986. The relatively "young" profile of the biotechnology companies is undoubtedly the result of the Government's efforts to develop and promote the industry.

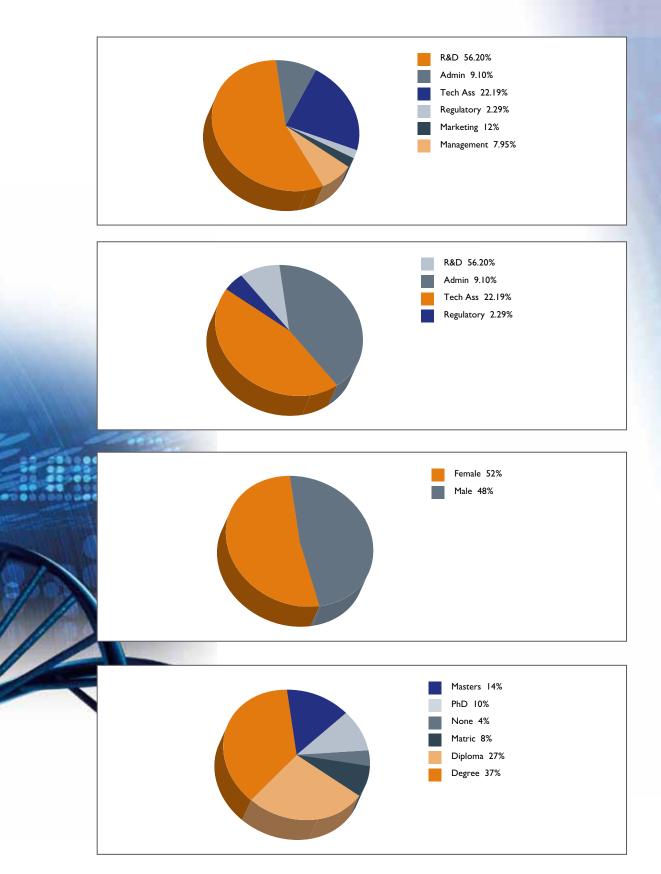
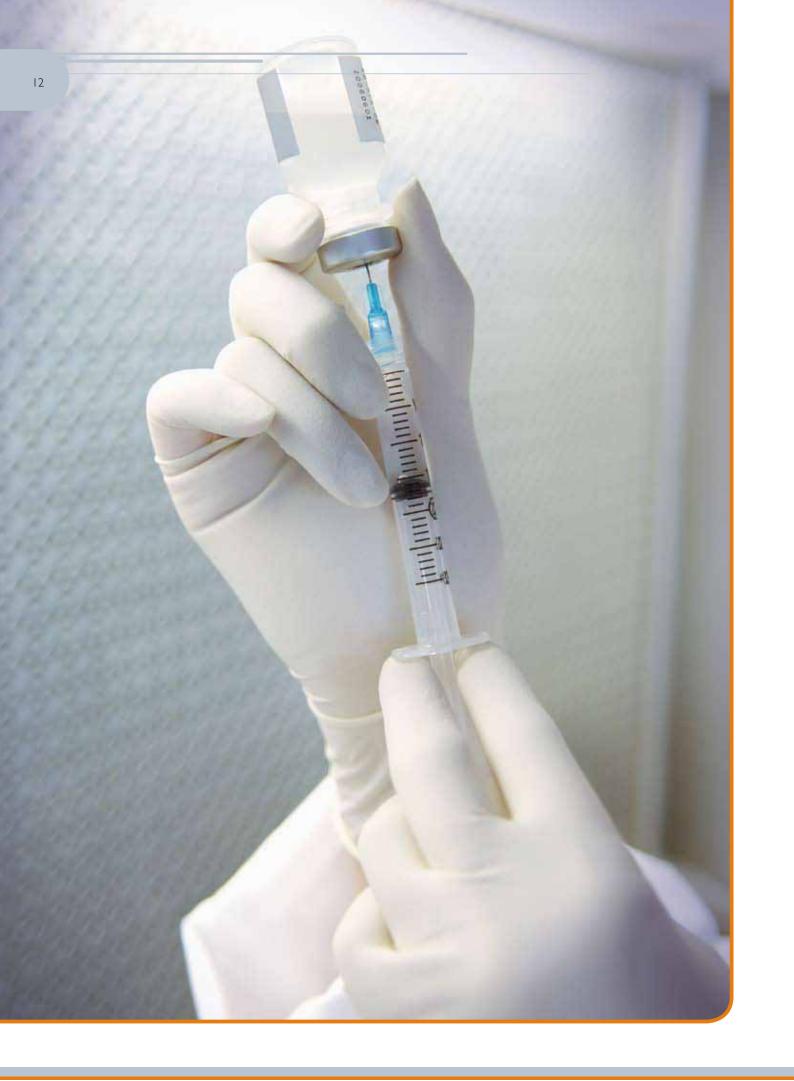


Figure 5: Distribution of 2006 bio-employees in all companies, according to duties, demographics and qualification



The biotechnology active companies declared that they employ 72,844 employees. Of those employees 2051 were involved directly with biotechnology duties. The later figure was up from 1801 during 2004. Figure 5 shows the distribution of the biotechnology related employees according to duties; demographics; gender and qualifications. The majority of employees are employed at R&D duties (56.20%); 41% are white; 48% are male and 61% have degrees. Twenty one companies had more that 50 employees overall during 2006. The most important factors affecting filling biotechnology related vacancies are: Lack of experience (rating 3.67); lack of qualified candidates (rating 3.64); lack of expertise (rating 3.55) and capital resources insufficient to attract candidates (rating 3.33). The rating ranges from 1 for low importance to 5 for high importance.

Figure 6 shows the distribution of the products handled by the non-core companies to sectors and stage of development. Fifty eight percent (58.1%) of the products are related to animal health and 39.9% are related to human health. Just below eighty seven percent of the products (86.9%) were at the stage characterised as "approved/on market/in production"; 11.1% of the products were at the stage of research and development. Comparison between core and non- core companies shows that the core biotechnology companies are focused more on research and development while the non-core companies are focused on existing/approved products

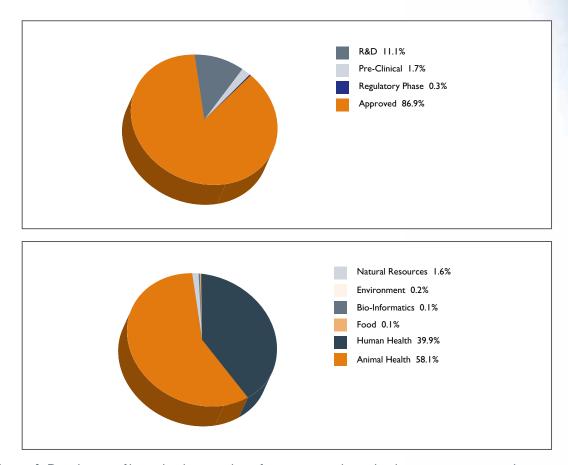


Figure 6: Distribution of biotechnology products from non-core biotechnology companies according to sector and stage of development

Figure 7 shows the distribution of the biotechnology active companies according to the purpose they use biotechnologies. Fifty six percent of the companies declared that they use biotechnologies for product/ process development; 24% for current production purposes and 19.8% for environmental reasons.

Table I, shows that DNA/RNA and cell and tissue technologies are the two technologies used by 41% and 37% of the companies respectively. Process biotechnologies are used by 36% of the companies.

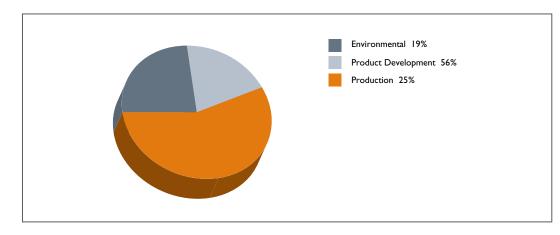




Table 1: Percentage of companies involved in various technologies		
DNA/RNA	41%	
Protein	24%	
Cell & Tissue	37%	
Process	36%	
Sub-cellular	10%	
Bio-informatics	23%	
Nano-biotechnology	8%	
Environmental	18%	
Other	6%	

The biotechnology active companies declared that they had the following revenues from biotechnology: R767.6 million during 2006 (R624.4 million during 2004). Their revenue from biotechnology related exports was R211.4 million during 2006 (R229.1 during 2004).

Table 2 shows the problems identified by the biotechnology active companies as impending commercialisation in the country. "Time required for regulatory approval" is identified as the most important constraint with a rating of 4.01. Access to human resources and cost of regulatory approval follow with a rating of 3.45.



Table 2: Problems for biotechnologycommercialisation in South Africa

Inputs	Rating
Access to Capital	3.90
Access to technology/information	3.07
Access to human resources	3.45
Markets	
Size of Domestic market	3.44
Access to International markets	3.31
Information about markets	3.04
Distribution & marketing channels	3.28
Constraints	
Public perception/acceptance	2.78
Cost of regulatory approval	3.45
Time required for regulatory approval	4.01
Limited international harmonisation	3.20
Patent rights held by others	2.52
Lack of protection for intellectual property	2.64

Table 3 shows the benefits from biotechnology as they are perceived by the biotechnology active firms. While all factors (with the exception of energy costs) received above average ratings, the highest rating 3.89 was received by the statement "market position improved".

Table 3: Benefits of biotechnology to the firm		
Increased productivity	Rating	
Labour costs	3.47	
Capital costs	3.51	
Energy costs	2.63	
Improved products		
New products or processes introduced	3.83	
Product range increased	3.81	
Product quality increased	3.57	
Knowledge based		
Developing new areas for R&D	3.73	
Increase efficiency for R&D	3.85	
Improved Market performance		
Market position improved	3.89	
New market niche developed	3.86	
Sales increased	3.74	

Table 4 shows the importance of attached to various support activities and the percentage of respondents that suggested that the particular activity need further expansion in the country. The activities which received the highest rankings as requiring expansion are IP management; international marketing and fundraising.

Table 4: Support Activities			
Activities	Rating Importance	Requires expansion %	
IP management	4.09	41	
Legal	3.81	22	
International Marketing	4.02	38	
Local Marketing	3.96	33	
Fundraising	3.78	38	
Financial Management	3.62	16	
Project management	3.81	16	
Business planning	4.07	29	
Bio-analytical services	3.21	26	
Process development	3.46	29	
Contract manufacturing facilities	2.91	29	

Overall the biotechnology active companies declared that they own 140 SA patents; 10 patents from USPTO; 14 patents from EPO and 123 patents for other sources. The pending patent figures are as follows: SAPTO 45 patents; USPTO 29 patents; EPO patents 27 and other 66 patents.

Table 5 summarises a number of characteristics for the core and active biotechnology companies. Certain information (e.g. capital raised, R&D expenditure etc) is not available for the active biotechnology companies as they declared that they could not separate their biotechnology related activities from their other business. It is interesting to note that the companies in both groups identified the same constraints and identified the same support services that are needed in the country. The identified constraints identified to be "time to regulatory approval" and "access to capital". The companies identified that the most important services that are required are: support for intellectual property management, support for marketing internationally and support for fund raising. The identification of these constraints and of the required support services has obvious policy implications.

Table 5: Core and Biotechnology Active Companies in South Africa		
Characteristics	Core Biotechnology Companies	Active Biotechnology Companies
Number of companies	38	78
Location	Gauteng 43% Western Cape 30%	Gauteng 42% Western Cape 26%
Incorporation	PTY (LTD) 67%	PTY (LTD) 62%
Spin-offs	Companies 16 From universities 44% From government 31%	Companies 25 From universities 28% From government 36%
Foreign Owned	Companies 5	Companies 12
Median year of establishment	2001	1999
No of employees (2006)	765	72844 In bio 2051
Employment growth (2004-06)	22%	n/a
Employment 50 or more	4	21
Employees' Characteristics	PhD 11% R&D35% Non-white 54% Female 47%	PhD 10% R&D 56% Non-white 59% Female 52%
Products	559	1542
Products - Emphasis	Agriculture 68% R&D Stage 57%	Agriculture* 58% In Market* 87%
Types of biotechnologies	Process Bio 53% DNA/RNA 50%	DNA/RNA 41% Process Bio 36%
Turnover 2006	R 520 million	Bio-Rev R 767.6m
Turnover growth (2004-06)	1.5%	23%
Exports 2006	R 86 millions	Bio R 211.4m
Growth (2004-06)	-45%	-7.7%

R&D expenditure	R76 million	n/a
R&D growth (2004-06)	58%	n/a
Top Constraints	I. Access to capital Time to reg. approval	I.Time to reg approval 2. Access to human resources
Support Services Required	I. IP Management 2. International Marketing 3. Fund raising	I . IP Management 2. International Marketing 3. Fund raising
Funds Raised (2003-06)	R 216 million	n/a
Major Funding Sources	BRICs 36% IF 19%	n/a n/a
Existing Patents From SA	45 23	287 140

Core Companies

Figure 8 shows the geographical distribution of the core biotechnology companies. Forty three percent of companies are situated in Gauteng with the majority of them in Johannesburg. Thirty percent are situated in Western Cape and 19% at KwaZulu-Natal.

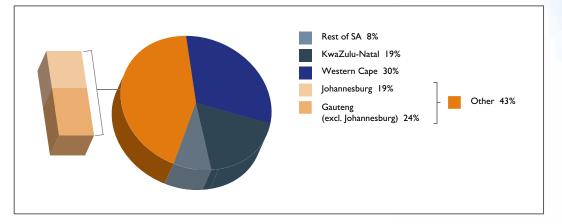


Figure 8: Geographical Distribution of Core Companies

Figure 9 shows the way that the core companies are incorporated. Sixty seven percent of the companies declared that they were Pty. (Ltd) companies and 19% that were closed corporations.

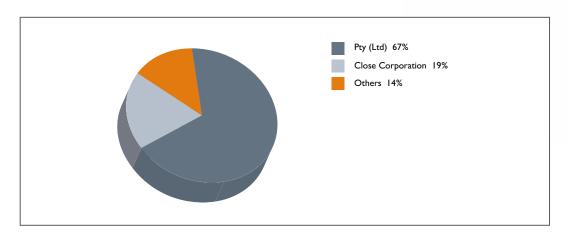


Figure 9: Type of Incorporation Core biotechnology Organisations/Enterprises



Sixteen out of the thirty eight companies declared that they were spin-offs from other organisations/institutions. Figure 10 shows the origin of the spin off companies. Forty four percent of the spin-offs came from universities; 31% from government institutions; 19% from nonbiotechnology companies and 6% from biotechnology companies. Thirty companies declared that they were mainly South African companies; five that they were foreign and three did not declare ownership. Ten companies (thirty three percent of the local companies) declared that they were owned, to a certain extent, by previous disadvantaged individuals

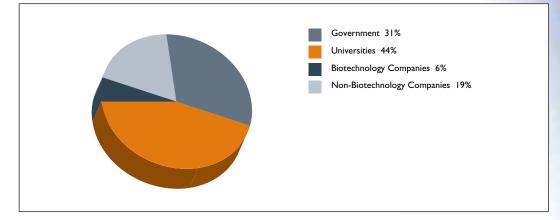


Figure 10: Origin of Spin-off Companies

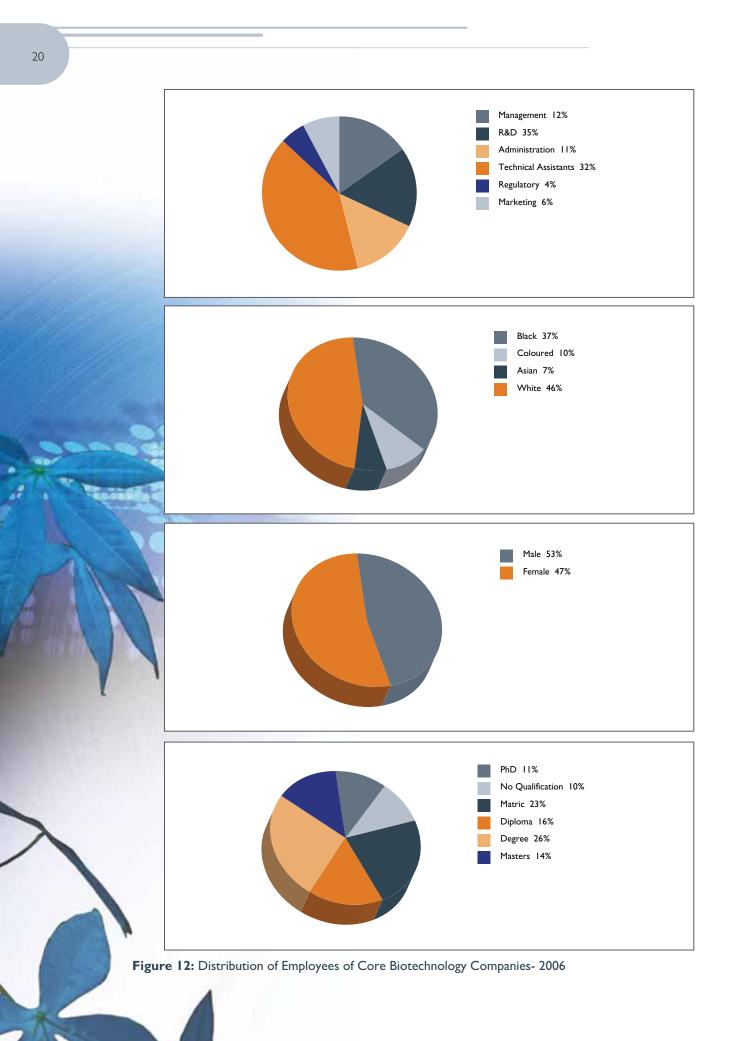
Figure 11 shows the age profiles of the core biotechnology companies. Fifty percent of the companies were established after 2001 and 25% after 2004. The oldest quartile of the companies declared that they had been established before 1996.

Twenty nine out of the thirty eight companies (76,3%) declared that they were employing 20 or fewer employees during 2006. Only four companies (10.5%) they were employing 50 or more employees during 2006. In total, core biotechnology companies were employing 765 employees during 2006, 22% up since 2004 when 627 employees were employed by those companies. During 2006 387 employees out of the 765 (50.5%) were engaged in biotechnology related activities. The relevant percentage for 2004 was 49.2%.

Figure 12 shows the duties, demographics, race and qualifications of employees in the core biotechnology companies during 2006. The majority of the employees in the core companies are employed either in research and development (35%) or as technical assistants (32%). Forty six percent of the employees are Whites, 37% Blacks; 10% Coloureds and 7% Asians.

Fifty three percent are male and 47% female. Only 11% of the employees have PhDs; 14% Masters degrees and 26% degrees.

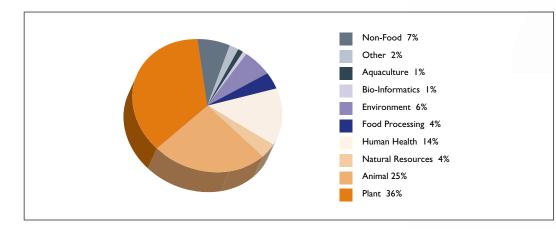
Figure 11: Box and Whiskers of Age Profile of Core Biotechnology Companies



The companies were asked to identify impediments in filling biotechnology related vacancies. The factors identifies in terms of importance are as follows: capital recourses insufficient to attract candidates 3.61; lack of experience 3.53; lack of expertise 3.47; lack of qualified candidates 3.38; competition of qualified candidates 2.69; compensation requirement too high 2.59 and candidates unwilling to relocate 2.06.

The core biotechnology companies declared that they were involved with 559 products at different levels of development. Figure 13 and Figure 14 show the distribution of products to different sectors and to different stages of development respectively. The majority of the products (68%) are in agriculture. Human health products are second in the graph with 14% and environment related products are 6% of the total. Figure 14 shows that 57% of the products are at the research and development stage and 30% are in the category approved/on market /in production. Seven percent of the products are in pre-clinical trials and 6% in the regulatory phase.







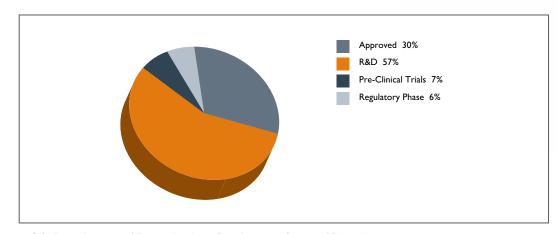


Figure 14: Distribution of Biotechnology Products to Stage of Development

Table 6: Percentage of companies involved in various technologies		
DNA/RNA	50%	
Protein & molecules	29%	
Cell & Tissue	42%	
Process Bio	53%	
Sub-cellular organisms	8%	
Bio-informatics	18%	
Nano-biotechnology	11%	
Environmental Bio	21%	

Table 6 shows the percentage of companies which declared that they were involved with the various technologies indicated in the definition. Fifty three percent of the companies declared that they were involved with process biotechnology (e.g. bio-reactors; bio-processing etc) and 50% declared that they were involved with DNA/RNA (genomics, genetic engineering etc.). Only 8% of the companies declared that they were involved with sub-cellular organisms and 11% with nanobiotechnology.

Figure 15 shows the distribution of the companies according to the time they declared that they need in order to bring their principal product from the initial development phase/proof of concept to the market. Thirty two percent of the companies declared that they need up to 3 years; 21% of the companies declared that they need 6 years or longer.

The majority of the core companies declared that they had collaborative agreements. Only 13 companies declared that they did not collaborate with other companies. Figure 16 shows the number of collaborative agreements of the core biotechnology companies according to purpose of collaboration and the type of the collaborative organisation. The objective of most of the collaborative agreements is "production/manufacturing" and most of the engagements within this objective are with academic institutions and other biotechnology companies. The second active objective for collaboration is R&D. Again the most often collaborative organisations mentioned are academic institutions and biotechnology firms. Non-biotechnology firms appear prominent when the objectives are access to markets and access to IP.



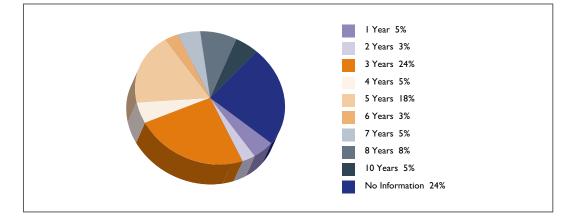


Figure 15: Distribution of Core Biotechnology Companies According to Time they Declared they Need to Bring Principal Biotechnology Products to Market

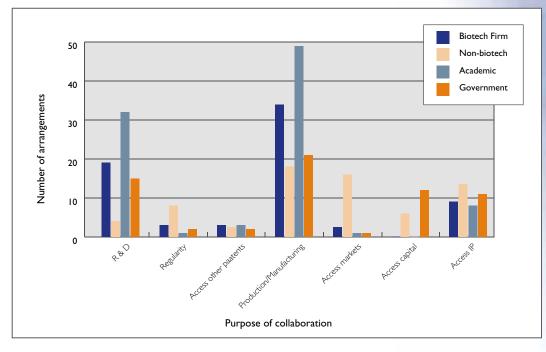


Figure 16: Collaboration of Core Biotechnology Companies

During 2006 the core biotechnology companies had a turnover of R520 millions. This figure was up from R512 million during 2004. This relatively static picture is the result of the decline in sales of a small number of relatively big companies in the field. Seventy nine percent of the companies (30 out of 38) declared an increase in the turnover during the 2004 to 2006 period. It should be mentioned that while the average turnover is R13.7 million, twenty percent (eight companies) of the core companies produce 78% of the total turnover. Exports during 2006 were R86.6 million (down from R157.9 million during 2004). Revenues from biotechnology were R335.2 million in 2006 (R374.3 during 2004) and biotechnology exports were R50 million during 2006 (R95.1 million during 2004)

The core biotechnology companies declared that they spent R76 million for research and development during 2006. This figure was 58% up from 2004 when the companies had spent R48 millions. Seventy three percent (R55.8 millions) of the research expenditure was for biotechnology related research during 2006. Twenty out of the thirty eight companies (52%) declared that they spent less than one million Rands for biotechnology related R&D.

Table 7 shows the rating of the constraints faced by the core biotechnology companies. Companies were asked to rank the various constraints from low importance (weight 1) to high importance (weight 5). "Access to capital" and "time required for regulatory approval" are

identified as the major constraints. As least constraints were identified "patent rights held by others", "lack of protection for intellectual property" and "public perception/acceptance".

Table 7: Problems for Biotechnology Commercialisation in South Africa		
Inputs	Rating	
Access to Capital	4.26	
Access to technology/information	3.11	
Access to human resources	3.38	
Markets		
Size of Domestic market	3.47	
Access to International markets	3.54	
Information about markets	3.11	
Distribution & marketing channels	3.35	
Constraints		
Public perception/acceptance	2.79	
Cost of regulatory approval	3.63	
Time required for regulatory approval	4.27	
Limited international harmonisation	3.37	
Patent rights held by others	2.33	
Lack of protection for intellectual property	2.69	

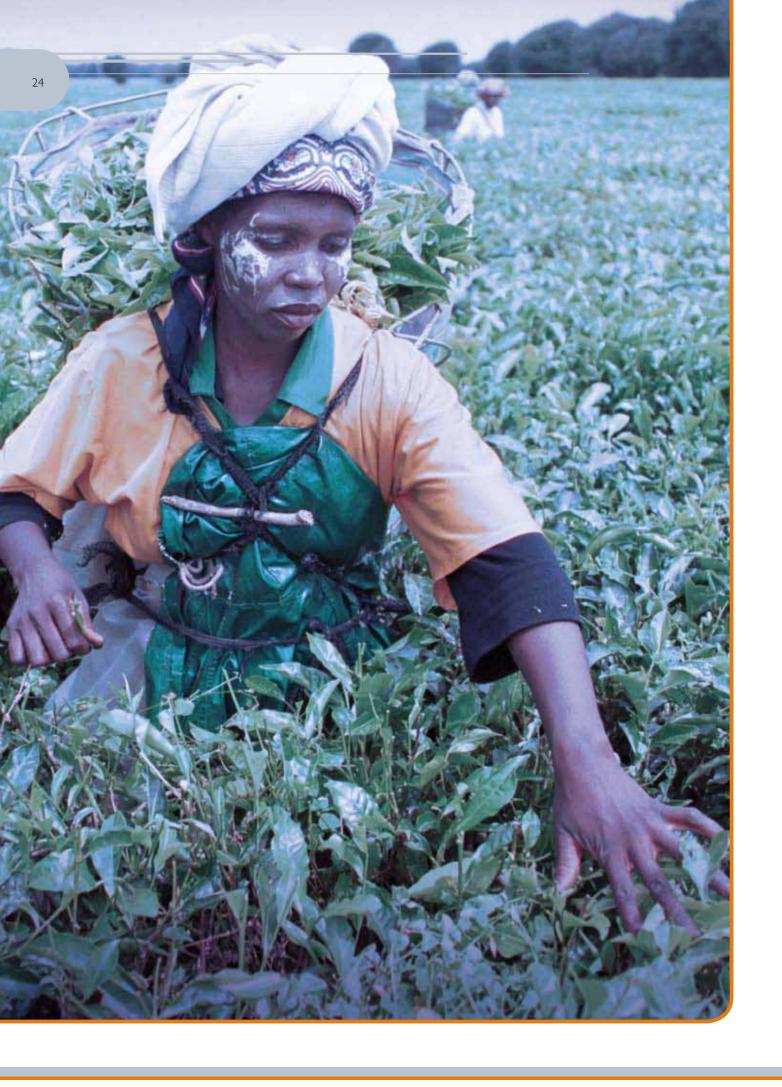


Table 8 shows the ratings of the benefits of biotechnology to the firms as perceived by the core companies. The issues related to "improved market performance" have attracted the highest marks with "market position improved" having the highest mark 4.24. The lowest marks were received by the issues related to "increased productivity".

Table 8: Benefits of Biotechnology to the Firm		
Increased productivity	Rating	
Labour costs	3.08	
Capital costs	3.78	
Energy costs	2.69	
Improved products		
New products or processes introduced	4.01	
Product range increased	4.06	
Product quality increased	3.71	
Knowledge based		
Developing new areas for R&D	3.78	
Increase efficiency for R&D	3.96	
Improved Market performance		
Market position improved	4.24	
New market niche developed	4.12	
Sales increased	4.13	

Table 9 shows the importance that the core companies attach to various support activities and the percentage of respondents who recommended expansion of the particular support activity. "International marketing" and "local marketing" are identified as the most important support activities with ratings 4.20 and 4.18 respectively.

"IP management" and "business planning" follow with ratings 4.15 and 4.05 respectively. The activities which were voted as needing further expansion were IP management (48.6% of respondents); international marketing (42.8% of respondents); fundraising (40%) and contract manufacturing facilities (34.3%).



Table 9: Support Activities		
Activities	Rating Importance	Requires Expansion %
IP management	4.15	48.6
Legal	3.87	28.6
International Marketing	4.20	42.8
Local Marketing	4.18	34.2
Fundraising	4.05	40.0
Financial Management	3.80	20.0
Project management	3.88	17.1
Business planning	4.00	25.2
Bio-analytical services	3.41	28.5
Process development	3.60	31.4
Contract manufacturing facilities	3.15	34.3

The majority of the companies (94%) declared that they had raised funds from different sources during the 2003-2006 period. The total amount declared that it was raised by core biotechnology companies was R 216 million. The majority of the funds come from the BRICs (36%), the Innovation Fund (19%), and THRIP (4%). SA Venture capital contributed 7% and foreign venture capital 2%. Banks and angels contributed 6% each, government other 2% and other was 18%. Thirty eight percent of the companies declared that they raised the funds for commercialisation purposes; 34% to develop production/ manufacturing capability; 14% for clinical/regulatory expenses; 9% in order to repay investors and 5% declared other.

Four out of the 38 companies declared that they had granted biotechnology related IP to other firms. Ten

declared that they had obtained biotechnology IP from other firms and I2 companies declared that they had biotechnology related patents or pending patents. The companies declared that they had 45 existing patents – 23 from the SA Patent Office, 2 from the USPTO, 4 from the EPO and I6 from others. Pending patents were 8 from SAPTO; 6 from USPTO; 5 from EPO and 7 from others.

Nine companies declared that they were involved with living modified organisms and they were involved with 39 organisms. Five companies declared that they were involved with bacteria, three with plants and two with fungi. Thirty of the organisms handled were at R&D stage, three at clinical/regulatory stage and nine at market stage.





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