

# Status of Biotechnology in Africa: Challenges and Opportunities

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**Abstract:** For the past three decades Africa has been a net importer of food!! In recognition of this situation and the significant role agriculture plays in Africa's development, the continent, under the auspices of New Partnerships for Africa's Development (NEPAD), developed a number of initiatives to enhance agricultural growth, alleviate poverty and improve quality of life. Some of these initiatives are in the African Union (AU)-NEPAD Science and Technology Consolidated Plan of Action in which the flagship programmes on indigenous crops are contained and the NEPAD Comprehensive African Agriculture Development Programme (CAADP).

Agricultural biotechnology alone will not solve the multitude of problems that farmers in Africa face; however, it has the potential to make crop breeding and crop management systems more efficient thereby generating improved crop varieties and higher yields. The challenges facing the continent on biotechnology and biosafety include lack of fund; loss of trained technical expertise; slow development of the biotechnology sector; inadequate Intellectual Property Rights infrastructure; government not taking a more active political role in promoting the technology and the issue of public acceptance brought about by activism. The lag in development of a governance capacity for biotechnology is seen in the current status of the development of national biosafety frameworks (NBFs) in Africa. Out of the 53 countries of the African Union, only 16 countries have laws, regulations, guidelines or policies related to modern biotechnology. Of these, only South Africa, Burkina Faso and Egypt have had experience in the assessment of applications for commercialization of any biotech crops. The combination of inadequate policies and legal frameworks require urgent attention that is led primarily by Africans if it is to achieve credibility in the eyes of African governments, African civil society and African people.

Keywords: Africa, biotechnology, biosafety, NEPAD.

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# Introduction

Africa has a wealth of natural resources with the potential to drive economic growth and social development: land, minerals, biological diversity, wildlife, forests, fisheries and water, although these are unevenly distributed. Africa's economies and people are vulnerable to environmental hazards such as droughts and floods, the frequency and extremity of which is likely to be increased by climate change. In addition, sub-Saharan Africa is experiencing faster degradation of many environmental resources, important to poor people, than any other region. Problems include land degradation, desertification, biodiversity loss, deforestation, loss of arable and grazing land, declining soil productivity, pollution and depletion of freshwater.<sup>1</sup>

One of the central messages emerging from the assessment of Africa's status in the global economy is the need for Africa to emphasize building the capacity to solve its own problems. Every problem enumerated above has one or more solutions in the application of science, technology and innovation. Application of science and technology has contributed significantly to defining an economic divide between rich and poor nations. It follows, therefore, that the rate of scientific and technological development largely determines the pace of socio-economic development. To close the gap between rich and poor nations will require deliberate measures to build scientific and technological capabilities of the poor countries.

# Science and Technology in Africa's Development Agenda

African leadership, through the Africa Union (AU), has committed themselves to the economic and technological development of the continent as their priority. The objectives of the AU include the promotion of sustainable development at the economic, social and cultural levels as well as the integration of African economies and the advancement of the development of the continent by promoting research in all fields, in particular in science and technology.<sup>2</sup> Africa's Science and Technology Consolidated Plan of Action (CPA) was developed in 2006 under the auspices of the New Partnership for Africa's Development (NEPAD). In the field of biotechnology, NEPAD and the AU Commission have established a high level African panel on biotechnology to 'facilitate open and informed regional multi-stakeholder dialogue on, *inter alia*, scientific, technical, economic, health, social, ethical, environmental, trade and intellectual property protection issues associated with or raised by rapid developments in modern biotechnology'.<sup>3</sup> In the NEPAD framework

African leaders recognize that science and technology will play a major role in the economic transformation and sustainable development of the continent. One of NEPAD's overall objectives is to bridge the technological divide between Africa and the rest of the world. It recognizes that such technologies as information and communication technologies are critical in remote sensing, environmental policy-making and planning and agricultural development. These technologies will also enable African countries to establish efficient early warning and monitoring systems for conflict management and natural disaster prevention.

# Africa's Consolidated Plan of Action on Science and Technology

In 2003, the NEPAD Office of Science and Technology carried out surveys of Science and Technology (S&T) institutions on the African continent and the results were compiled into regional reports of S&T capacity status. Following this regional workshops, studies and consultations were held on key issues which led to the adoption of an outline of plan of action for S&T in Johannesburg, South Africa and the subsequent publication of the AU-NEPAD Africa's Science and Technology Consolidated Plan of Action (CPA). The CPA was adopted in 2005 by the African Ministerial Conference on Science and Technology (AMCOST) at its second conference in Dakar, Senegal. The same document was endorsed a year later by the AU Summit in Khartoum, Sudan. The CPA articulates Africa's common objective of socio-economic transformation and full integration into the world economy. It reaffirms the continent's collective action for using S&T for meeting the developmental goals of Africa with key pillars being capacity building, knowledge production and technological innovation. The CPA recognizes that S&T in Africa is plagued by such factors as weak or no links between industry and S&T institutions, a mismatch between R&D activities and national industrial development strategies and goals. The consequence of these weaknesses is that research findings in public institutions, including universities, do not get accessed and used by local industries especially small and medium enterprises.

The CPA comprises of three key areas: research and development programmes; improvement in policy conditions and building innovation mechanisms; and implementation, funding and governance strategies.

# **CPA R&D Programmes and Implementation**

The programmes contained in the CPA are implemented through regional networks of centres of excellence, consisting of hubs and nodes. The

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programmes engage existing institutions into regional networks in order to pool available human and technical resources and strengthen the development of high quality S&T. The objectives of these networks are: to improve quality of and access to infrastructure and facilities; develop further institutional and political regulations; improve the human skill base; obtain political and civil society support; strengthen the capacity of regional institutions; integrate R&D into sectoral programmes; improve the applicability of S&T towards the Millennium Development Goals and Sustainable Development; and to develop innovative funding instruments and build international partnerships.

Research and Development Programmes of the CPA consists of five clusters. Under each cluster there are several programmes. The clusters are: *Cluster1: Biodiversity, Biotechnology and Indigenous Knowledge:* This cluster focuses on the conservation and sustainable use of biodiversity; safe development and application of biotechnology; and securing and using Africa's indigenous knowledge base.

*Cluster 2: Energy, Water and Desertification:* This includes building a sustainable energy base by increasing rural and urban access to environmentally-sound energy sources and technologies; securing and sustaining water to ensure sustainable access to safe and adequate clean water supply and sanitation; combating drought and desertification by improving scientific understanding and sharing of information on the causes of and extent of drought and desertification in Africa.

*Cluster 3: Material Sciences, Manufacturing, Laser Technology and Post-Harvest Technology:* This includes the development of new and improvement of existing infrastructure by building new skills or expertise in material sciences, promoting the sharing of physical infrastructure and exchange of scientific information and the promotion of public sector partnerships in material sciences research and innovation.

*Cluster 4: Information and Communication Technologies; and Space Science and Technologies:* This includes the creation of experts engaged in computer science, information systems as well as informatics; building skills in software research and development. It also includes the establishment of the African Institute of Space Science.

*Cluster 5: Mathematical Sciences:* This includes the establishment of an African Mathematical Institutes aimed at strengthening the African Mathematical Institutes network that was constituted in 2005 with the sole purpose of building a new generation of African scientists and technologists with excellent quantitative problem-solving skills.

# Priorities in Biotechnology for Africa's Regions

Activities of Cluster 1 have been greatly enhanced with the publication of the book *Freedom to Innovate: Biotechnology in Africa's Development'* written by a High Level Panel on Modern Biotechnology with Juma, C and Serageldin (2007) as editors.

In order to address the issue of inadequate resources to develop and safely apply biotechnology (human, infrastructure, and funding) the AU through the NEPAD Office of Science and Technology established the African Biosciences Initiative in 2005. This led to the creation of networks of centres of excellence in strategically placed hubs around the continent, viz, BecANet in Kenya, SANBio in South Africa, WABNet in Senegal, and NABNet in Egypt; with these hubs are a number of nodes. Each of the five AU regions has the following biotechnology missions to carry out (Table 1).

Networks	Nodal Point	Hub National	Centre Focus	Area of Work
NABNet (North African Biosciences Network)	Egypt	Research Centre (NRC)	Bio Pharma- ceuticals	<b>North Africa:</b> to lead the continent in research into bio-pharmaceuticals, drug manufacturing and test kits.
WABNet (WestAfrican Biosciences Network)	Senegal	Senegalese Institute of Agricultural Research (ISRA)	Crop Biotech	West Africa: to carry out research using biotechnology tools to develop cash crops, cereals, grain legumes, fruits/vegetables and root/tuber crops.
SANBio (Southern African Network for Biosciences	South Africa	CSIR, Bioscience Unit	Health Biotech	<b>Southern Africa:</b> to deliver benefits from health biotechnology by researching into the causes and prevention methods of a range of diseases, in particular, TB, malaria and HIV/AIDS.
BecANet (Biosciences East and Central Africa)	Kenya	International Livestock Research Institute (ILRI)	Animal Biotech	East Africa: to focus on research into livestock pests and diseases in order to improve animal health and husbandry.Central Africa: to build and strengthen indigenous capacity by identifying, conserving and sustainably using natural resources and also researching into the impact on biodiversity of events such as climate change and natural disasters.

### Table 1: NEPAD OST Networks of Centres of Excellence in Biosciences

## Status of Biotechnology and Biosafety in Africa

The role that modern biotechnology can play in the economic transformation and sustainable development of Africa has been documented in several publication.<sup>4</sup> It has acquired increased significance as a result of a variety of factors including rapid scientific and technological advances, increasing commercialization of genetically engineered foods, increasing food insecurity, increase in food prices, and the roles of anti-Genetic Engineering and environmental activism.

James (Brief 37, 2007) enumerated the following as the most compelling case for biotechnology and more specifically GE crops in their capability to contribute to:

- Increasing crop productivity, and thus contributing to global food, feed, fiber and fuel security, with benefits for producers, consumers and society at large;
- Conserving biodiversity, as a land-saving technology capable of higher productivity on the current 1.5 billion hectares of arable land, and thereby precluding deforestation and protecting biodiversity in forests and other *in-situ* biodiversity sanctuaries;
- Reducing the environmental footprint of agriculture by contributing to more efficient use of external inputs, thereby contributing to a safer environment and more sustainable agriculture systems;
- Mitigating climate change and reducing greenhouse gases by using biotech applications for 'speeding the breeding' in crop improvement programmes to develop well adapted germplasm for changing climatic conditions and optimize the sequestering of CO<sub>2</sub>;
- Increasing stability of productivity and production to lessen suffering during famines due to biotic and abiotic stresses, particularly drought which is the major constraint to increased productivity on the 1.5 billion hectares of arable land in the world;
- the improvement of economic, health and social benefits, food, feed and fiber security and the alleviation of abject poverty and malnutrition for the rural population dependent on agriculture in developing countries;
- the cost-effective production of renewable resource-based biofuels, which will reduce dependency on fossil fuels, and, therefore, contribute to a cleaner and safer environment with lower levels of greenhouse gases that will mitigate global warming; and
- as a result, provide significant and important multiple and mutual benefits to producers, consumers and global society.

He further suggested that the most promising technological option for increasing global food, feed and fiber production is to combine the best of the old and the best of the new by integrating the best of conventional technology (adapted germplasm) and the best of biotechnology applications (novel traits).

In the recent publication of the AU-NEPAD, *Freedom to Innovate*, one of the key recommendations was that biotechnology and biosafety 'should adopt the "co-evolutionary" approach in which the function of regulation is to promote innovation, while at the same time safeguard human health and the environment'.

Genetic engineering (GE) techniques are employed in few countries in Africa with the commercialization in South Africa, Egypt and Burkina Faso in such crops and traits as insect-resistant cotton and maize, as well as herbicide-resistant soybean and/ or the combination of these traits. These are grown by both the commercial and small-scale farmers. Agricultural biotechnology research in Africa focuses on controlling diseases and pests; improving the storage properties of crops and food; improving weed control, improving yield and quality of foods; protecting natural resources; drought and salt tolerance and biofuel production. The crop of interest especially in Southern and East Africa is maize. Bioscientific researchable areas include insect resistance, virus and bacterial resitsance, drought tolerance and fungal resistance. Other crops of interest include: sorghum, millet, bananas, sweet potatoes, sugar cane, cowpea and cassava. Aside from pest and diseases protection, attempts are being made on nutritional quality improvements, such as biofortification of sorghum, cassava, etc. with vitamins and proteins.

Forty-five member states of the African Union recognized the need for agricultural biosafety by signing or acceding to the Cartagena Biosafety Protocol. They committed to develop national biosafety systems as well as set out "appropriate procedures in the field of safe transfer, handling and use of living modified organisms resulting from biotechnology that may have adverse effect on conservation and sustainable use of biological diversity and taking into account risks to human health". In practice, these commitments translate into the development of functional National Biosafety Frameworks (NBFs) to oversee the development and utilization of GE products. However, as recognized by the AU and NEPAD programme, the safe development and application of biotechnology to address heretofore intractable problems in food production, environmental degradation and human disease face a number of constraints. Seventy seven per cent of AU member states have been making slow progress towards developing the key components of the NBFs that include: (a) a policy on biotechnology; (b) laws and regulations on biosafety constituting a regulatory regime for biotechnology; (c) an administrative system for handling applications and issuance of permits; and (d) a mechanism for public participation on biosafety decision-making.

As of now 11 African countries (South Africa, Egypt, Burkina Faso, Kenya, Togo, Tunisia, Mali, Mauritius, Algeria, Sudan and Zimbabwe) have developed their NBFs with 12 countries (Senegal, Ghana, Nigeria, Cameroon, Uganda, Tanzania, Malawi, Mozambique, Ethiopia, Namibia, Madagascar and Zambia) with interim NBFs and the remaining 30 countries with no NBF or at best at 'work-in-progress' stage. Morris (2008) observed that despite the well-intentioned GEF strategy, the efforts of the UNEP team in assisting AU member states in the development of NBFs and the science-based approach to risk assessment and management advocated in the Cartagena protocol, it appears that individual countries are placing a variety of interpretations on the protocol and taking a variety of paths towards dealing with the issue of GE crops.

In view of the constraint of inadequate policies and legal frameworks urgent attention is needed and this attention has to be led by Africans if it is to achieve credibility in the eyes of African governments, African civil society and African peoples. With this goal in mind the NEPAD African Biosciences Initiative initiated the establishment of the African Biosafety Network of Expertise (ABNE) with the support of Bill and Melinda Gates Foundation and in collaboration with the Michigan State University. ABNE responds to a real need, recognized by the continental community of nations, the AU, to ensure that its societies have the capacity to assess if, and when and how biotechnology products may be judged to pose no safety risk to the environment or human health; the ability to regulate these biotechnology products using the latest science and applying the highest standards of global practice.

The main objective of ABNE is the provision of biosafety resources for African regulators which is to support regulators as they make decisions on safe use, deployment and management of biotech products that are locally developed, imported and adopted in Africa. The main focus of this service network includes:

- Building an African Biosafety resource for regulators with focus on the members of the National Biosafety Committees (NBCs), Institutional Biosafety Committees (IBCs) and staff in the plant quarantine (PQ).
- Long term goal to build functional regulatory systems in Africa

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n NBFs Algeria, Egypt, Sudan, Burkina Faso, Mali, Mauritius, Kenya, Zimbabwe, South Africa, Togo and Tunisia		
Tanzania, Mozambique, Ethiopia, Uganda,		
Botswana, Burundi, DR Congo, Congo, Gabon, Cameroon, Central African Republic, Benin, Ivory Coast, Sierra Leone, Liberia, Guinea Bissau, Mauritania, Niger, Libya, Eritrea, Djibouti, Burundi, Swaziland, Lesotho, Guinea, Gambia, Madagascar and Seychelles		
Angola, Somalia, Equitorial Guinea, Chad, Guinea Bissau, Western Sahara and Morocco		
	Kenya, Zimbabwe, South Africa, Togo and Tunisia Senegal, Ghana, Nigeria, Namibia, Zambia, Tanzania, Mozambique, Ethiopia, Uganda, Madagascar, Rwanda and Malawi Botswana, Burundi, DR Congo, Congo, Gabon, Cameroon, Central African Republic, Benin, Ivory Coast, Sierra Leone, Liberia, Guinea Bissau, Mauritania, Niger, Libya, Eritrea, Djibouti, Burundi, Swaziland, Lesotho, Guinea, Gambia, Madagascar and Seychelles Angola, Somalia, Equitorial Guinea, Chad,	

# Table 2: Status of the Member States with regard to the Developmentof their National Biosafety Frameworks, as of June 2009

### What Do We Need to Develop Biotechnology in Africa?

These include among others: aiming for more coordination between strategic policy making in sustainable agriculture and agricultural research. There should be political will and commitment to use the tools. There is need to have adequate resources, human and infrastructure and capacity building/strengthening. Regulatory frameworks that will work and enforcable should also be established. All stakeholders' should also be involved. There is also need to promote intra-Africa trade through harmonization of biosafety regulation as our borders are quite porous and remove trade barriers among the traditional trading partners. Public understanding and acceptance of the products of the technology should also be enhanced.

### Endnotes

- <sup>1</sup> Commission for Africa (2005).
- <sup>2</sup> African Union (2000).
- <sup>3</sup> African Union (2006).
- <sup>4</sup> Kalibwani, Fred *et al.* (2004).

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# Secrets to Developing a Successful Biotechnology Industry: Lessons from Developing Countries

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*Abstract:* A handful of developing countries have successfully built some of the necessary scientific, technological and industrial capacity to take advantage of the opportunities presented by biotechnology. The early enthusiasm and expectation that biotechnology will address some of the challenges of poor countries has not translated into the successful diffusion and use of the technology to meet the economic and social needs of most countries, especially in Africa.

This paper discusses four strategies or approaches that have been used to develop biotechnology industry in some developing countries. The paper argues that it may be necessary to start with small demonstrative initiatives and build the necessary capacities using inspiring initiatives; encourage partnerships and joint-ventures; narrow the focus of biotechnology programmes in the beginning; and encourage participation and commitment of all the key ministries and the private partners in designing and implementing national biotechnology strategies.

*Keywords:* Africa, alliances best practice, biotechnology, development, strategies.

# Introduction

Widespread optimism was expressed in the early development of biotechnology that it will contribute immensely to meet some of the global challenges. During the United Nations Conference on Trade and Development in Rio in 1992, biotechnology was seen as a possible tool that could "make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes for transforming raw materials,

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support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes".<sup>1</sup>

Since then, the global biotechnology industry has grown tremendously. For example, it is estimated that over 400 biotechnology health products targeting over 200 diseases<sup>2</sup> were in use. The revenues from products and services in the health sector alone has increased from about US\$8.1 billion in 1992 to about US\$58.5 billion in 2008. It is estimated that publicly trade biotechnology firms in the US alone were worth about \$360 billion as of 2008.

Similarly, about 125 million hectares were planted with genetically modified (GM) crops in 25 countries (three from Africa) by about 13.3 million farmers.<sup>3</sup> This is thought to be the fastest adoption rate of any agricultural technology in history. Most of the GM crops being planted especially in developed countries carry more than a single trait in one variety or hybrid. In terms of benefits, GM cotton is thought to have increased yields, reduced insecticide use and increased income of farmers by up to 50 per cent in China and India.<sup>4</sup>

Industrial and environmental biotechnology has also been growing at a very fast pace over the last decade driven by fuel insecurity, environmental concerns (climate change), rapid technological developments and business opportunities. The surging oil price since 2003 presented a perfect storm that drove policy makers, industrial leaders and scientists to invest in biotechnology platforms, especially in alternatives to petrofuels.

For example, the bioethanol and biodiesel production and consumption have grown rapidly over the last few years. The global bioethanol production nearly doubled between 2000 and 2005 while that of biodiesel nearly quadrupled in the same time. Brazil and the United States account for nearly 90 per cent of the 62 billion litres global production of bioethanol in 2007. The total bioethanol production is expected to reach 127 billion litres in 2017 according to the *OECD-FAO Agricultural Outlook: 2008-2017*. Biodiesel production is expected to reach some 24 billion litres by 2017.<sup>5</sup> In terms of feedstock, Brazil derived all its bioethanol from sugarcane while the United States derived most of bioethanol from corn.

There is a greater policy push for development of domestic biofuel production capacities in developing countries as a way of eliminating excess agricultural produce as well. For example, it is thought that India increased the mandatory blending levels of petroleum with bioethanol from 5 per cent to 10 per cent to get rid of excess sugar which, if dumped on the international market, would have depressed international market prices further.<sup>6</sup> However, both developed and developing countries have been investing heavily in industrial biotechnology with a great focus on second-generation biofuel production technologies using non-food raw materials.

It is, thus, not surprising that the number of industrial biotechnology patents were estimated to have increased from 6,000 in 2000 to 22,000 in 2005. Currently, about seven per cent of the products in the chemical sector, worthy about \$77 billion, are produced using industrial biotechnology platforms (biobased feedstocks, fermentation or enzymatic conversion) in 2007.<sup>7</sup> Sugar is seen as an important feedstock in chemical industry that could be converted into bioethanol and a variety of basic building blocks for various chemicals.

The growth of biotechnology in developing countries has been equally impressive. Countries such as Brazil, China, Cuba, India, Singapore, South Korea and South Africa have committed significant resources and provided policy directions for the development of a domestic biotechnology industry. Countries such as Singapore and Korea have even emerged as global centres for cutting-edge stem cell research. These countries are offering modern facilities and support similar to the strategies they employed during the development of information technology.

Many of trends in the global biotechnology industry could greatly benefit Africa. In many areas, Africa could become an influential player and exploit the technology to meet its own economic and social development. Currently, the continent is largely being bypassed.

In this paper we argue that part of the challenges that continue to prevent Africa from benefiting from biotechnology include the lack of focus and coordinated strategies, and failure to identify clear and realistic opportunities that inspire and induce sustained public support for biotechnology.

The paper is structured as follows: Section 2 presents a broad overview of selected characteristics of the biotechnology industry, section 3 highlights selected national examples that have successfully been used to build some biotechnology capacity while section 4 points out some of the critical elements and lessons learned from the policy strategies implemented by the discussed developing countries (Brazil, Cuba, Korea and South Africa).

## Some Common Features of the Biotech Industry

It is important to remember that biotechnology is both a multidisciplinary and knowledge-intensive field as much as it is a business that requires good regulatory and market structures. Here we look at selected key characteristics of the biotechnology industry by providing an overview of the need to attract the right investment, to seek ways of cutting costs and sharing risks and to design favourable government policies that encourage research and investment.

### Biotechnology: The Science and The Business

Jong (2009) summed up the business of biotechnology simply as "cash plus pipeline equals new company". In a nutshell, many biotechnology start-up companies have no product on the market but promising potential products of interest to investors. Similar sentiments were echoed by Stelio Papadopoulos, Vice Chairman of the SG Cowen – a financier of biotechnology – who was quoted saying "Genentech (the first biotechnology company to go public) showed that people invested on the hope that new technology or ideas could make a big difference".<sup>8</sup>

The continuous generation of new knowledge keeps public or private investors excited about future growth prospects in the biotechnology industry. Biotech companies, in turn, have to keep innovating if they want to ensure increasing returns through new products and attract more investment.

However, most investors do not necessarily invest in the products alone but take the bet on an entrepreneur's management capabilities too. The risks of bringing the product to market involve the navigation of complex regulatory procedures and hurdles that could be expensive. Thus, in addition to exciting opportunities, investors take a bet on a sound *management team* <sup>9</sup> that they can trust to bring the product(s) successfully to market. This is not necessarily unique to biotechnology but is common to most other sectors.

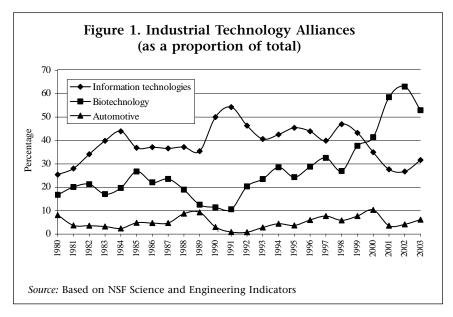
Like other areas of business, the opportunities need to pass at least two basic tests to be of interest to investors: 1) A general trend towards improving or changing the status of the entrepreneur(s) and investors involved 2) Management teams that have the capacity to develop and believe they can successfully realise the venture.<sup>10</sup> Therefore, it is not surprising that biotechnology seems to flourish in regions and countries where resources are available, possess talented and experienced successful entrepreneurs willing to invest in the projects of other community members and continuous reinvention of the industry is encouraged.<sup>11</sup> Many of the biotechnology clusters are among the regions where resources (finance, R&D and management) are mobile and success is celebrated. For example, the biotechnology clusters of California and New England (Boston area) have generated a number of biotechnology firms due to the high concentration of top life research universities. As a consequence, a number of firms founded elsewhere tend to migrate to these centres for several reasons, including access to knowledge and finance. They are homes to some of the key biotechnology investors and are rich in qualified and experienced scientists, managers and service providers that have been involved in the development of biotechnology firms over the last three decades.

In 2007, for instance, Targanta Therapeuticals moved from Montreal to Boston just ahead of its Initial Public Offering (IPO) while Logical Therapeutics moved from Pittsburgh to Boston as well following a \$30 million in venture capital funding. Even though Boston is an expensive place for growing a start-up, it offers the innovation ecosystem that few other places can provide.<sup>12</sup>

# Industrial Technology Alliances

Industrial technology alliances, as defined by the US National Science Foundation (NSF), are "industrial technology linkages with the aim of codeveloping new products or capabilities through R&D collaboration".<sup>13</sup> There are at least four factors that promote the development of industrial alliances in biotechnology: (1) the multidisciplinary nature of R&D activities; (2) the increasing complexity of R&D; (3) the uncertainty of commercial success of R&D products; and (4) the cost of R&D activities.<sup>14</sup>. Firms may seek alliances to spread the cost, risks and uncertainty, especially in fields where there are restrictive and often lengthy regulatory regimes.<sup>15</sup>

Globally, the number of industrial technology alliances developed per year has grown rapidly from about 185 in 1980 to about 695 in 2003. In the last three decades, most of the industrial technology alliances have involved firms in the United States, Europe and Japan. About 50 per cent of the industrial technology alliances in 1980 involved firms in biotechnology, information technology and automotive firms. The share of alliances in these three industries increased to 64 per cent in 1990 and 91 per cent in 2003 (see Figure 1). One study that looked at the number of research alliances signed by the top 22 pharmaceutical firms in the world revealed that their partnership arrangements increased from 27 in the 1982-87 period to about 87 in the 1987-92 period and 112 in the 1993-1997 period.<sup>16</sup> Similar trends are also emerging among developing countries. For instance, Cuban biotechnology firms have increasingly entered



into joint ventures and other collaborative arrangements with other firms in developing countries. However, it seems most of the collaboration in biotechnology are marketing seeking in nature. Small emerging firms with good biotechnology products lack the marketing and financial resources needed to exploit their products in emerging markets abroad.

For instance, Heber Biotech of Cuba has entered into various strategic alliances with Brazilian, Chinese, Indian and South Africa firms. In many cases, Heber contributes a number of its biotechnology products and the production platforms while the partners contribute the financial, institutional and operational resources needed to produce and market the products in agreed markets (For details see page 24).

This is not surprising as most partnering arrangements could, potentially, play a key role in the development of technological capabilities in start-up firms. Such capacity would be specialized and related to specific products and services. Furthermore, such partnering would also be useful in promoting the adoption of good management and industrial production standards especially in new and emerging fields.

### **Biotechnology Clusters and Centres of Excellent**

The importance of clusters in biotechnology cannot be overemphasized. In Europe, Japan and the United States of America, biotechnology programmes to foster national competitiveness seem to have been based on well established and managed national public research institutions in agriculture, environment, mining and human health. Some of these institutions developed biotechnology research centres that accumulated considerable technological capabilities in the field and served as major sources of scientific knowledge in various aspects of biotechnology.

Biotechnology clusters, as already mentioned above, have generally formed in locations with excellent life science and biomedical research universities and centres, sufficient financial support, talented entrepreneurs and other support institutions. These include large and well established technology clusters in New England and California in the United States, the Biovalley (France-German-Swiss border), West Havana scientific biopole in Cuba and the Cape Town biotechnology cluster in South Africa among others. The presence of excellent research centres seems to be a prerequisite but is not sufficient by itself to stimulate the emergence of a vibrant biotechnology industry.

### **Favourable Government Policies**

There are many factors that are driving the growth of the biotechnology industries but none has been as decisive as favourable government policies. Government policies have been instrumental in the growth of the agricultural, industrial, environmental and health biotechnology subsectors. For instance, research in the bioenergy sector has been driven largely by favourable government policies in the European Union, Brazil and the United States. The policy differences in these countries, for instance, have influenced private and public investment.<sup>17</sup>

The successful bioethanol production in Brazil and Zimbabwe and the successful co-generation of electricity from bagasse (and coal) by sugar mills in Mauritius are just among many examples where government interest played a greater role in bio-energy sector.<sup>18</sup> Governments in these countries guaranteed to either buy the excess electricity or pass policies that required blending of petroleum with ethanol by all oil marketing firms and production of motor vehicle that were tailored to use such fuels. Several countries, including Brazil, Columbia, Cuba, India, Thailand, Mexico and the Philippines, provide incentives to their sugar industries to promote co-generation of electricity from bagasses, a technology that was pioneered in Mauritius and Hawaii. Similarly, biorefineries in the US benefit from government support. The Energy Bill passed by the US Senate in December 2007 is an example. The bill seeks to boost production of fuels, power and other products from biomass through an investment of about US \$ 3.6 billion and mandates that 36 billion gallons of biofuel will be consumed by 2022, of which 15 billion gallons may be bioethanol derived from corn.<sup>19</sup> To achieve this target, the Farm Bill passed in 2007 also provides \$1.1 billion to encourage farmers to grow biomass crops and \$1.1 billion in tax credits for biofuels, including from cellulosic materials with a target of 7.5 billion biofuel production by 2012.

Public interests or concerns are also playing an important role in biotechnology policy and its evolution. The increasing consumer concerns over antibiotics used in animal production and consumer interests in natural products are fuelling the growth of the market for bio-based products (e.g. probiotics and nutraceuticals). On the other hand, public concern on the use of GM crops and animals is limiting the adoption of transgenic crops and animals for industrial use.

Perhaps nowhere has government policy been more important to biotechnology development as in agriculture and health where differences in perception of risk have had a major impact. The moratoriums imposed by government on field trials and cultivation of genetically modified crops have hampered investment in biotechnology. The ban by the US administration on use of public funds in stem cells research is thought to have encouraged migration of researchers to Korea and Singapore – propelling the research capabilities of these countries to new levels.

Other areas of governance such as intellectual property rights (IPR) and technology commercialization have also been essential to the development of biotechnology.<sup>20</sup> This is important as industry and public research institutions and universities have worked very closely in the development of biotechnology products and services. In initial stages, most biotechnology start-up seem to emerge from or with some input of research universities and their scientists. Clear technology commercialization regulations and intellectual property ownership rules are key to securing private investment, seeking partnerships and defining equitable sharing of the benefits of such activities.<sup>21</sup>

## Strategic Approaches to Develop the Biotechnology Industry

Many African countries are unlikely to possess the human, institutional

and financial resources needed to apply biotechnology in all sectors of the economy and the level of investment and regulatory procedures required to successfully develop and bring innovative biotechnology products to market. One of the challenges in recommending strategies lies in setting priority areas for biotechnology research, product development and use due to the number of competing urgent needs in agriculture, nutrition, health, industry and environment, to mention but a few. This is made more difficult by the long list of support measures that are needed in order to enable biotechnology deliver, such as human capital, R&D investment, industrial and market regulations, infrastructures and their related policies, among others.

To tackle these challenges, we discuss simple but effective approaches that have successfully been used by a number of developing countries, including some Africa countries. These approaches are not mutually exclusive and they are less complex and within the current institutional set-ups and constraints of many African countries. They do not necessarily involve creation of new centres but rather smart use of incentives that may save resources, create jobs and propel Africa to a new stage of development.

# *The Project Approach: The Cases of Genomics Development in Brazil*

One of the common ways of acquiring technology is through challenging projects. For example, very few will argue with the assertion that the human genome project launched in 1990 "spurred a revolution in biotechnology innovation around the world and played a key role in making the United States the global leader in the new biotechnology sector".<sup>22</sup> It revolutionized methods for genome sequencing and analysis and led to the development of tools for designing and developing biotechnology-based diagnostic, management and treatment of diseases.

In the same vein, the scientific community was stunned when a Brazilian team of scientists announced they had completely sequenced the first plant pathogen genome using a virtual institution - Organization for Nucleotide Sequencing and Analysis (ONSA). *The Economist* wrote "SAMBA, football and...genomics... The list of things for which Brazil is renowned has suddenly got longer".<sup>23</sup> At the time genome sequencing was the preserve of centres of excellence such as The Institute of Genomic Research (TIGR - now Craig Venter Institute) and the Sanger Center, among others.

The project was not triggered by some national consensus or special workshop but a suggestion by one Brazilian scientist to the São Paulo State Research Support Foundation (FAPESP) to consider financing a genome sequencing project. FAPESP is entitled by law to one percent of all the revenue collected in the State of São Paulo, Brazil's richest state, and FAPESP is required not to spend more than 5 per cent of the funds on administration.

The choice of *Xylella fastidiosa*, an organism with a genome size of 2.7 megabases, was based on its economic importance and its relatively small genome size. The organism causes losses of approximately US \$ 100 million to the citrus industry in Sao Paulo. The State of Sao Paulo accounts for about 87 per cent of Brazil's orange production, corresponding to 30 per cent of the world production.

From the outset, FAPESP decided to fund the genome sequencing project to involve as many laboratories and scientists as possible in the acquisition and development of modern biotechnology tools. Therefore, they settled for a virtual institute composed of about 34 independent laboratories and teams belonging to universities and research institutions with some basic knowledge of sequencing. For this reason, the initial \$11.6 million budget helped to set up two central sequencing laboratories and a bioinformatics unit that serve to coordinate the project while all the other selected laboratories received the necessary equipment and training.

The management of the institute was tailored to encourage the generation of high-quality data in the shortest possible time. The selected laboratories agreed to generate a minimum number of high quality sequences in a fixed time. Laboratories that deposited more good quality sequences got more money. Further, the representatives of the participating laboratories, about 200 participants, met once every four to five weeks in person to review progress and make fresh plans. This was important as daily management was performed via the Internet.

ONSA was so successful that the Ludwig Cancer Research Institute invested US \$ 15 million in ONSA for its Human Cancer Genome Project. ONSA deposited over 1 million sequences which made the team one of the main contributors to the Human Cancer Genome Project. Similarly, the United States Department of Agriculture (USDA) contracted ONSA to sequence a strain of *X. fastidiosa* that afflicted vineyard in Californina. The ONSA project also spun-off two companies and exposed more than 200 scientists to cutting-edge genome sequencing tools. The knowledge acquired has enabled many participating laboratories to attract contracts and funding and seek partners. One can argue that carefully selected projects could easily stimulate innovation and technological development and catapult a selected number of centres to a new level of development. In Africa, the African Malaria Network Trust (AMANET) is playing an important role in building capacity in research institutions to undertake malaria vaccine clinical trials by providing training, equipment and developing the trial sites as well as promoting collaborations. A number of these centres are already participating in vaccines clinical trials.<sup>24</sup>

### Strategic Sequencing of Biotechnology Industry Development: The Case of Korea

One of the challenges faced by Africa countries with limited resources in developing a biotechnology industry is deciding which sectors or fields to support. It is for this reason that the Korean biotechnology initiative is a good example of how to harness limited resources to focus on common areas that play a key role in all sectors. Here we place focus on the Korean Biotech 2000 plan to draw some lessons.

In 1993 the government developed the Korea Biotech 2000 plan<sup>25</sup> of action with three main phases and a total investment budget of US \$ 15 billion by 2007. The first phase (1994-1997) aimed at acquiring and adapting bioprocessing technologies and improving performance of R&D investment. A total of US \$ 1.5 billion was earmarked for the first phase: \$ 482 million from the government and \$1 billion from the private sector. The main goal of this phase was to establish the scientific foundation for the development of novel biotechnology products.

The second phase (1998-2002) focused on consolidation of the scientific foundation to develop platform technologies and improve industrial R&D capabilities. A total of US \$ 2.3 billion (\$1.6 billion for the private sector and \$ 720 million from public sector) was earmarked for this phase. The last phase (2003-2007) targeted development of commercialization capabilities to achieve increased global market share of Korean development biotechnology products. The target was to achieve a 5 per cent global market share for Korean novel biotechnology products. An investment of \$10.5 billion (of which US \$ 4.3 billion was to come from the public sector) was envisioned as necessary to achieve the objectives of the third phase.

In order to achieve these goals, a management and operating committee was put in place consisting of the public and private sector. Each of the ministry involved indicated their level of investment and the key technologies to be acquired or developed. For example, during the second phase, the Ministry of Science and Technology focused on screening and development of new drug, genomics and integrating information technology and nanotechnology in life science while the Ministry of Agriculture and Forestry focused on bioprospecting and biodiversity screening and protection, transgenic technologies and plant and animal genome research.<sup>26</sup> In a way, they sought to target technology platforms that could be used for more than just one set of products.

It is now estimated that the biotechnology industry in Korea has an annual turnover of \$4 billion a year and has been growing at approximately 10 per cent per year.<sup>27</sup> It was also recognized that most of the Korean biotechnology firms focused on stem cell, cell therapy and anti-cancer drugs followed by nutraceuticals or functional foods with health enhancing properties.<sup>28</sup> Some of the major products include Hepatitis B vaccine (40 per cent of world the market), amino acids (20 per cent of the world market) and rifamycin (10 per cent of the world market). A number of key technologies developed in Korea have been licensed to some of the top firms such as GlaxoSmithKline and Johnson & Johnson.

The creation of a platform where public research institutions and the private sector interact was one of the key elements for the commercial success of research outcomes. Another key element is central planning where the government ministry responsible for promoting biotechnology in the country does not necessarily control most of the research centres or provide incentives to industry directly. Getting the commitment of other ministries to promote human resource development, technology transfer and development and to support industrial growth in the areas of interest may be important.

Another interesting element is that the Korean biotechnology sector imported most of the enabling technologies such as fermentation, vaccine and drug screening and production capabilities from developed countries to enable it to develop and export drugs, vaccines and diagnostic kits. In addition, the biotechnology strategy has been focused and goal-oriented. They chose where and what they needed to build their industry as well as whom to work with. For instance, Korea had biotechnology innovation partnerships with Denmark (2006), Israel (2008) and United Kingdom (2008) in addition to science and technology research centres in Germany (Korean Institute of Science and Technology, KIST-Europe, 1996) and in Russia (Korea-Russia Scientific and Technological Cooperation Center, 1991).

### Biotechnology as Part of National System: The Case of Cuba

In 1980, a small team of Cuban scientists set out to produce alphainterferon. Within 42 days, the team had accomplished the task. Encouraged by the results the Government funded the establishment of a host of institutions, which included the Center for Biological Research in 1982, which was later replaced by the Center for Genetic Engineering and Biotechnology (CIGB) in 1986. It also established centers that specialized in immunology, biomass conversion, animal production and tropical medicine.

By 2000, there were at least 33 university departments and 210 research institutions employing about 12,000 scientists and 30,000 workers, respectively, involved in biotechnology. The CIGB alone employed more than 1,200 scientists and technicians in eight divisions and 192 laboratories by 1999.<sup>29</sup> CIGB is composed of individual quality research units that together form a 'centre of excellence'.

Cuba's R&D expenditure as percentage of GDP was estimated at 1.2 per cent and the country invested about \$1 billion over the last 20 years in biotechnology. In return Cuba's biotechnology centers have produced at least 160 medical products, 50 enzymes and probes for plant diseases among others.<sup>30</sup> In some cases, Cuba produced unique remedies or products that other nations did not have. For example, the cardiostrep, a product that could be used to dissolve fat clots, was a unique product. By 1998, the biotechnology sector was making up to \$290 million in sales and placed the sector as the fourth main foreign exchange earner after tourism, tobacco and nickel exports. Since then, Cuban biotechnology research institutions have developed commercial arms that are increasing seeking partners abroad to increase their market share and expand the benefits from their R&D investments.

The Cuban biotechnology industry is a closed network or cluster of supportive institutions. It comprises R&D, exports and imports, manufacturing, information and communication, maintenance, advisory and policy, and regulatory institutions. This structure promotes recombination of knowledge and is cost-effective. Although Cuban biotechnology is government-managed and driven, it has all the characteristics of a mature privately managed business cluster.

The Cuban medical and health-care biotechnology industry is part of the national health-care system and targets the country's health problems. Most of its research products are generated largely by native scientists. The industry is a closed circle where spin-off firms remain linked to research and production institutions. It is the result of a national endeavour, with proper human and financial resources.

By making biotechnology part of the health-care system, biotechnology policies and support are discussed from a specific national area of interest rather than in general terms. In a way, a country could include biotechnology in an area where it thinks it can make a major contribution. This also departs widely from the approaches used in Africa where biotechnology and biosafety policies have been developed largely with support from outside. While there is nothing wrong with external funding, many good projects are often abandoned once the donor that supported the initiative leaves for reasons not related to biotechnology.

### Technology Transfer through Joint Ventures and Alliances

As stated earlier, strategic alliances are a common feature in biotechnology but are largely concentrated in developed countries. However, there is increasing evidence that developing countries' biotechnology firms are seeking partners both in developing and developed countries for different reasons. For example, the Cuban biotechnology firm Heber is establishing joint-ventures with other firms in developing countries such as Biocon of India to exploit their technologies and access markets. Furthermore, Cuba's CIMAB SA entered into a joint-venture with Biocon to develop a state-ofthe-art facility to produce CIMAB's monoclonal antibodies for the treatment of headache and neck cancer. The new firm, Biocon Biopharmaceuticals Private Limited (BBPL), will develop and market a range of monoclonal antibodies and cancer vaccines. Under this arrangement, Biocon holds the marketing rights in India, whereas Cuban CIMAB has a licensing tie-up with a US company for marketing of the products in the US, Europe and Japan.<sup>31</sup>

A similar trend is observed in China and South Africa where strategic joint-ventures are being promoted even by government support institutions. For example, South Africa's Public-Private Partnership (PPP)<sup>32</sup> initiative supported the establishment of the Biovac Institute – a joint venture involving British, Cuban, Thai and local interests (jointly called the Biovac Consortium) and the government of South Africa's former State Vaccine Institute. Similarly, government supported biotechnology funds have facilitated the acquisition of technology by local firms. BioPAD secured the transfer of recombinant expression technology (strains of micro-organisms and cell lines) from the Swiss based firm - Solidago AG – to produce Bioclones at a cost of \$ 5.3 million investment. This facilitated

the development of Ribotech Pty as a joint-venture between Bioclones and Solidago AG with government support.<sup>33</sup> BioPAD is a Biotechnology Regional Innovation Centre (BRIC) established by the Department of Science and Technology to promote the development of the biotechnology industry in South Africa in 2006.

These arrangements are seen as crucial in enabling countries lagging behind to quickly gain access to knowledge, learn and run a business without needing to rediscover the "wheel". The risks of developing, producing, distributing and marketing new products is drastically reduced in such joint-ventures because even the least developed country party may easily obtain exclusive access to its market especially where the government has a stake in the firm. Key to these arrangements is the government playing a facilitating role in technology transfer through joint ventures by completing science and technology agreements. For example, South Africa is already coaching Zambia on how to redesign its biotechnology policy. To do this, South Africa insisted in including biotechnology as one of the areas of cooperation between itself and Zambia in the science and technology agreement. A similar push is also seen in the recent science and technology agreements between Brazil, India, Nigeria and South Africa. With rapidly developing economies and growing markets, some developing countries are strategically seeking joint-ventures to position their firms to benefit from these trends. It illustrates the different options for joining the biotechnology revolution by riding on the R&D investments made by others.

## **Reselling the Promise: Common Elements in Success Strategies**

All the strategies given above have succeeded by selling a better future upon which the people and their government could bet on. Just like the private sector, governments are unlikely to put resources in programmes that do not seem to promise returns to their electorates or tax payers. To achieve this, research institutions may have to demonstrate their ability to deliver once they get support for exciting small demonstration projects, or well-planned and coordinated large initiatives. Scientific and technological successes should be duly awarded in order to encourage the private sector to continue to invest and governments to address other national issues through biotechnology.

### Starting Small to Showcase

As discussed earlier, the Brazilian genome sequencing project, ONSA,

demonstrated what could be achieved and how it could be done. ONSA enabled Brazil to join the exclusive club of genome sequencing powerhouses. It is this success that gave birth to the Brazilian National Genome Project Consortium in 2003. As of 2007, a number of the key crops and a host of pathogen genomes had been sequenced by several sequencing teams in Brazil that were designed and managed almost in the same fashion as ONSA.<sup>34</sup> In a way, the success of the small projects was important in encouraging and scaling up of the genome sequencing project.

This is not particularly unique to biotechnology. The successful development and application of tank bioleaching process for gold in South Africa in 1980s and commercial application of solvent extraction electronwining of copper in the 1970s in Zambia led to the wide adoption of both technologies in the mining sector in both developed and developing countries.<sup>35</sup> In countries where government support may not be so strong, demonstration of the application and benefits of biotechnology could be very important.

It is difficult to choose one or two projects to embark on in developing a biotechnology sector in a country. Some of the key lessons from the cases discussed in this paper include the need to: (1) identify an institution around which the project could be anchored (e.g. the three sequencing and bioinformatics laboratories in the ONSA model) and supported (e.g. FAPESP in Brazil), (2) ensure the project is exciting to entice the participation of top scientists, is of economic or social relevance, manageable and likely to stimulate further growth in the field and, finally, (3) build in sufficient and targeted incentives designed to encourage all participating institutions to deliver.

#### Phased and Well Coordinated Development

In the case of Korea, clear goals were set and managed in a coordinated manner with every ministry involved indicating how much investment will be made at each stage of development in close partnership with the private sector. This is particularly important in a multidisciplinary, knowledge-dependent and highly regulated industry to ensure that the national strategy is implemented in a coherent manner. In a way, one can promote both collaboration and competition during the implementation – both of which could speed up the process and efficiency of implementing the program.

In Africa, the Organization of African Unity (OAU), now African Union (AU), launched the Pan African Rinderpest Campaign (PARC)<sup>36</sup> in

1986 to completely eradicate Rinderpest, a viral disease that could wipe out up to 90 per cent of the cattle in an area, on the continent. With about \$200 million investment from the EU and technical support from various institutions PARC developed a vaccination campaign in 22 African countries, four regional emergency vaccine banks, two regional coordination centres and centres for vaccine quality control and disease diagnosis in African countries. With 35 participating countries, PARC was successful because of its communications unit that helped sensitize farmers, veterinary experts, policy makers and donors. By 1999, the disease was confined to a few locations in Africa.

The key components in all these cases include the involvement of key players, the clear identification and communication of the targets and performance, sharing of responsibilities and promoting the projects. In a phased approach, ensuring that all the parties understand their roles and responsibilities is important.

### Narrowing the Focus to a Few Challenges

It is never easy to pick winners or undertake technology forecast. However, with a bit of careful planning, perfect timing and careful search, one can try to focus on a few challenges as was the case in Cuba. Though Cuba already had a larger pool of scientists than most developing countries, it is often thought that the outbreak of meningitis, dengue fever and conjunctivitis accelerated the development of the biotechnology industry in the early 1980s. With no vaccines to many of these diseases anywhere in the world, the Cuban teams spent time studying work in the developed countries to identify where they could make quick progress. However, this process was first facilitated by the Biotechnology Front- a multidisciplinary team of professionals that was exploring the potential of biotechnology in partnership with the government.<sup>37</sup> Since then, the Cuban biotechnology sector has been seen as part of the ministry of health than the ministry of science and technology.

One can argue that part of the success in the development of the biotechnology industry in Cuba is its narrow focus which quickly enabled it to achieve critical mass and concentrate its limited financial and institutional resources. It may prove difficult for many African countries with limited human and financial resources to achieve success if they target all areas where biotechnology can potentially make a contribution. Even where resources are available, it is difficult to imagine how South Africa is going to achieve its "Ten Year Plan" of the Department of Science and Technology to be "among the global top ten nations in the world in terms of the pharmaceutical, nutraceutical, flavour, fragrance and biopesticide industries" in the next 11 years time. Especially when its own audit of the biotechnology sector in South Africa in 2007 revealed that about 58 per cent of the biotechnology products are in agriculture rather than health or pharmaceuticals<sup>38</sup> and South Africa is not exactly among the top 20 producers of pharmaceuticals.

### Selecting a Specific Field: The Case of Biofuels

One area where Africa is likely to be competitive is biofuels derived from sugarcane. Other than Brazil at number one, Zimbabwe (2), Malawi (3), Swaziland (4), Sudan (6), Zambia (8), and South Africa (9) and Tanzania (13) are all in the top 15 lowest cost sugar producing countries out of 77. Therefore, there is great potential for Africa to produce biofuel at production costs that could compete with petroleum at a price of \$30 per barrel. Other reasons for pursuing biofuels in these countries include: enabling more people to gain access to cleaner cooking fuels, reducing dependency on imported petroleum, acquiring technical know-how for producing biofuel, lowering the cost of transportation and creating an alternative market for surplus sugar and, for some of the country, lowering the high transportation costs (especially in landlocked countries).

Africa also has plenty of biomass for biofuel production. Some of which is a nuisance, such as the water hyacinth that is choking river and lakes in Kenya and Zambia. The continent could also grow plenty of different types of energy and oil crops. As enzyme technologies to convert cellulose into glucose continuously improve, the cost of producing biofuels will fall. For example, Genencor, a biotechnology firms specializing in enzyme design and production,<sup>39</sup> has released a host of enzyme cocktails that eliminates pH adjustment, reduces heating and saves enzymes in the production of ethanol even from whole grain and from cellulosic materials.

There is also a great interest by the private sector to invest in biofuels production in Africa. For example, Zambia has seen an increased and renewed interest in the biofuels through new investments by the private sector. A Chinese and Zambia joint-venture seeks to invest about \$3 billion in a 700,000-hectares jatropha plantation and related extraction facilities<sup>40</sup>, Zambia Sugar is expanding its production capacity of sugar by 70 per cent through a \$150 million investment that includes production of bioethanol (about 30,000 tons per year).<sup>41</sup> In this context, Oval Biofuels<sup>42</sup> has already commissioned a refining plant in Lusaka and Biomax limited is planning

to invest over US \$50 million in a palmoil processing facility.<sup>43</sup> There are many other private and international initiatives promoting the use of biofuels to meet various development challenges in a continent whose energy consumption per capita is the lowest.

Despite these interests and opportunities, national biofuel strategies are still emerging and have no clear objectives. It is not clear whether biofuels are being pursued to expand and diversify exports, reduce imports, encourage use of modern energy resources, create jobs, build the necessary knowledge base or divert excess agricultural raw materials to bioenergy production. This is important as the next generations of biofuel processing facilities, or biorefinery, seek to integrate the production of biofuels with that of high-value products. Work is now focusing on generating specialty chemicals for animal feed, functional foods (nutraceuticals), pharmaceuticals and industrial alcohols, among others, from common crops such as maize, cocoa, soyabeen, sorghum, sunflower and wheat, among others.

While Africa may not compete in generating the next technology platforms, clear strategies could help the continent adopt, integrate and use the emerging technologies to generate new products and services for its citizens and export. It is here where research and development work could help shape the future, create markets and technologies opportunities that excite investors and contribute to national development.

## Conclusion

For many African countries, biotechnology remains an undeveloped industry that seems out of reach. The central argument in this paper is that African countries can develop their biotechnology sectors using several strategies that meet their own needs. Central to all the strategies described is the need to narrow the focus to a few feasible challenges for which alternatives solutions may not be competitive. They would inspire scientists and industry to respond to an economic or social challenge and provide learning opportunities or a platform to launch future undertakings.

Coordination is often the main challenge in national and regional initiatives. This stems from the fact that institutional roles and responsibilities are often defined by one agent that wishes to own and coordinate the project. Therefore, it is important that projects are seen as national in character, involve all the key ministries, institutions and private sectors and each assumes roles and responsibilities as well as commitments to deliver. Further, a central coordinating committee with selected focal points may be more useful in ensuring all parties feel involved than a single agent seeking to own and coordinate the initiative.

There is sometimes an obsession with the creation of centres of excellence and national or regional innovation hubs. This stems from the observation that a high concentration of excellent R&D institutions with the necessary intellectual capital has been critical to the emergence and growth of a biotechnology sector in advanced developed countries. However, biotechnology R&D in these countries is concentrated in regions that combine excellent research with a good ability to commercialize research output.<sup>44</sup> It is highly unlikely that many African countries can afford to build such embedded centres of excellence in biotechnology in the initial stages. Secondly, steady investment will be required to ensure the continued success of the centres. This can only be assured if the research outputs are relevant to national needs or exciting to private investors.

African countries often lack the market structures, appropriate and supportive regulation and good partnership arrangements. A survey of African biosafety regulations showed that support for biotechnology products in agriculture remains low. This affects research interests in plants and animals even for non-food purposes, and hinders the building of the necessary capacity that would have benefited other sectors.

The example of bioethanol, given above, highlights a few exceptions where public goals may coincide with private interests. For instance, the locations of some of the biofuel refineries in rural areas of Zambia meet both private interests to cut costs of production by eliminating the cost of transportation for raw materials, and public goals to develop rural areas with few optional income generating ventures. One exciting development is the use of portable biofuel refineries that could be located closer to markets (e.g. new mining sites located far from modern amenities such as electricity) and/or closer to sources of raw materials through manage-and-operate models.<sup>45</sup>

There is evidence that countries can quickly build up capacity by seeking partners with the necessary technologies and products with the aim of learning to innovate and manage biotechnology through jointventures. Friendly governments that wish to promote their relationships with Africa for various reasons such as Brazil, China, Cuba, India, Korea, Malaysia and South Africa could provide both product and process technologies for projects that benefit both parties.

The High Level Panel on Modern Biotechnology rightly stated that the "report is about the role of biotechnology in the transformation of

African economies"<sup>46</sup> and made excellent recommendations on regional and local innovation hubs. However, these hubs are unlikely to emerge without targeted efforts, coordination and commitment of all the government ministries (not just ministers of science and technology) and incentives for the private sector to participate in a joint initiative to improve the future economic opportunities for the African continent.

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# Status of Biotechnology Policies in South Africa

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*Abstract:* Current progress with regard to the adoption, diffusion and regulation of biotechnology in Africa has mainly been in the area of agricultural biotechnology. Industrial and pharmaceutical sectors are still in their infancy. Most African countries rely on agriculture for economic growth as well as food security. Appropriate policies are necessary for progress in biotechnology and the development of such policies has been a great challenge for most African countries. To date, only a handful of African countries have policies and guidelines in place. In this paper, the policies that South Africa has developed for dealing with the issues related to adoption, diffusion and regulation of agricultural biotechnology are discussed for purposes of comparing the South African position with other African countries that have adopted biotechnology.

*Keywords:* African countries, agricultural biotechnology, biotechnology policies, regulations, South Africa.

# Introduction

The implementation of biosafety regimes that allow the safe harnessing while closely monitoring potential side effects is a priority across Africa. Notable efforts in this regard are currently at an advanced stage particularly in the agricultural sector: "agricultural ministers within the continent's largest trading bloc, the Common Market for Eastern and Southern Africa (COMESA), have endorsed a Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa (RABESA)".<sup>1</sup>

RABESA aims at tackling the issues that genetically modified organisms (GMOs) raise for trade and access to emergency food aid.<sup>2</sup> Most African countries, however, face challenges in their attempts to develop and implement biosafety regimes because of lack of infrastructure, resources or capacity to implement the regimes. The prevailing situation

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in most African countries testifies to the fact that even if regional guidelines are agreed, the cost of regulation and testing of biotechnological products will be relatively high due to the above problems that face African countries.<sup>3</sup> These challenges notwithstanding, framework policy documents have been adopted in the region. The frameworks consist of Africa's Science and Technology Consolidated Plan of Action adopted by the New Partnership for Africa's Development and the African Union; the report of the High-Level African Panel on Modern Biotechnology; the African Position on the Issue of Genetically Modified Organisms and Agriculture, adopted by the Conference of Agricultural Ministers of the African Union; and the draft African strategy on biosafety presented by the African Union's Directorate of Human Resources, Science and Technology. Some of the core policy objectives that emerge from these framework documents are evidently geared towards fostering adoption and regulation of biotechnology.<sup>4</sup> Two relevant objectives that can be mentioned in this regard are: building Africa's capacities to develop and safely apply biotechnology in agriculture and ensuring that policies are science-based. These are some of the objectives that have been agreed on as core guiding principles for policymaking at the regional level.<sup>5</sup>

# Status of and Policies for Biotechnology in South Africa

South Africa has a National Biotechnology Strategy (NBS) in place. This strategy is a policy framework, which is aimed at creating incentive for the biotechnology sector.<sup>6</sup> South Africa was also the first African country to approve transgenic crops for commercial purposes and is the leader in agricultural biotechnology research and development on the continent.<sup>7</sup> The country equally performs a substantial magnitude of Africa's research and development in biotechnology since this area of research is considered a tool for addressing development challenges such as food security and improved health care.<sup>8</sup>

A study of public research pipeline in selected African countries established that there is widespread approval and use of insect-protected cotton. The reason for this trend is that "most regulatory authorities in developing countries have found it easier to approve this crop because they are not required to assess food safety—an area in which few developing country regulatory authorities feel competent".<sup>9</sup> South Africa stands out in this regard as an exception insofar as transgenic crops are already commercialized. The impressive progress can be attributed to South Africa's "rich natural resources, such as diamonds and gold and well developed financial, legal, communications, energy and transport sectors".<sup>10</sup> These sectors provide biotechnology with more developed infrastructure.

## Adoption

A report on the global status of genetically modified crops, which was released in 2008, predicted that the future adoption of such crops in developing countries in the period 2009 to 2015 will depend mainly on two major issues: "first, establishment and effective operation of appropriate, responsible and cost/time-effective regulatory systems; second, strong political will and support for the adoption of biotech crops that can contribute to a more affordable and secure supply of food, feed, and fiber".<sup>11</sup>

Appropriate policies are very important for ensuring public acceptance of biotechnology and political good will is closely related to policies insofar as it influences the acceptance of the technology among the people. South Africa has made strides in agricultural biotechnology. For instance, insect resistant cotton, herbicide tolerant cotton, herbicide tolerant Soya, insect resistant white and yellow maize have been approved for commercial cultivation. This position is in great contrast with other African countries that have only approved insect resistant cotton because, as mentioned in the introduction to this paper, these countries do not feel competent to handle issues of food safety. The problems in most African countries are "lack of advanced scientific expertise regarding biotechnology..." and "the harnessing of this expertise and the implementation of a comprehensive policy regime".<sup>12</sup>

The progress that South Africa has made is commendable in view of the fact that during the apartheid era, agricultural biotechnology was a neglected area "except for some basic studies in plant improvement".<sup>13</sup> During the eighties, however, efforts were made to develop expertise and institutions were established for this purpose.<sup>14</sup> The NBS has facilitated the adoption of biotechnology. The strategy has attempted to guarantee that stringent biosafety regulatory systems, which ensure that the technology is utilized in a manner that causes minimum disruption to the environment while addressing the country's sustainable development goals and imperatives.<sup>15</sup>

The NBS has been useful for closing the gap between research activities and commercialization. It equally addresses the issue of human resource development.<sup>16</sup> With regard to human resource development, which as mentioned above is a problem in most African countries, South Africa recognizes the biotechnology industry's potential to address some of its historical and socio-economic imbalances. In this regard the industry is being used to attract young scholars to the field of science and technology through skilled job creation and international partnering for skills transfer.<sup>17</sup>

The biotechnology sector in South Africa, however, has some weaknesses, which are slowing down the adoption of modern biotechnology. The problems that have been identified by Wolson are: institutional arrangements that are not conducive to promoting sufficiently effective linkages between researchers in different disciplines and/or organizations, limited employment opportunities in the local biotechnology industry for graduates as well as brain drain.<sup>18</sup>

### Diffusion

Effective dissemination of information to the public is essential for the diffusion of agricultural biotechnology. Dissemination of information to the public is not developed in most African countries.<sup>19</sup> Most frameworks and regulations that are being developed or are already in place in a number of African countries "do not articulate explicitly the issue of dissemination of information regarding biotechnology risks and benefits".<sup>20</sup> This position is very surprising because Article 5 of the African Model Law on Modern Biotechnology, which African countries should be following in establishing their regulatory regimes, clearly provides for public participation in decision-making.<sup>21</sup>

South Africa has attempted to address this problem through the regulations that have been made under section 20 of the Genetically Modified Organisms Act, 1997 (GMO Act), which requires applicants to notify the public of a proposed release of GMOs prior to the application for permit for such release. Interestingly, issues have been raised that the Act and the subsequent amendment Bill were passed into law without proper public consultations.<sup>22</sup> The Act equally has other limitations that are discussed in the section under regulation. South Africa has also launched the Public Understanding of Biotechnology Programme "to promote understanding of the potential of biotechnology [and] ensure broad public awareness and engagement in public debate".<sup>23</sup> The effectiveness of the programme certainly depends on how well it is implemented.

### Regulation

The international and regional regulatory frameworks are relevant particularly in a globalized environment. A discussion of such frameworks is beyond the limited scope of this paper but it suffices to mention that the Cartagena Protocol, which is an internationally binding legal instrument, sets out obligations, which "do not fully align with national needs and priorities of many African countries".<sup>24</sup> In this section the effort that South Africa has made in regulating agricultural biotechnology in view of such a challenge is discussed. Current literature that has dealt with the issue of regulations has focused on the policies in place, policy gaps, the legal framework and status of biotechnology regulation.<sup>25</sup>

In assessing the adequacy or otherwise of the regulatory frameworks in place, the following factors should be taken into consideration:

- i. 'Broader public consultation that considers all relevant stakeholders' views.
- ii. Maintaining flexibility without losing credibility.
- iii. Establishment of a concise policy framework on which the legal framework can be based.<sup>26</sup>

These factors are used in this section for assessing the progress that South Africa has made.

As noted earlier, South Africa's NBS offers regulatory and legal support mechanisms insofar as it addresses regulatory and legal issues though there are still concerns in this regard particularly on the need to streamline legislation.<sup>27</sup> One concern is that the NBS has not fulfilled the promise to completely review biotechnology legislation in South Africa.<sup>28</sup> This concern is based on the fact that the legislation in place (GMO Act) does not "constitute an adequate biosafety regime that ensures GMOs are appropriate and do not cause harm to the environment, or to human health".<sup>29</sup> The Act also seems to be limited in scope as it only applies to viable living GMOs and not products of GMOs. Section 1 of the Act appears to absolve developers of GMOs from liability and shifts liability to users of GMOs. Such a provision amounts to overprotection of the biotechnology industry.<sup>30</sup>

Apart from the GMO Act<sup>31</sup>, biotechnology is also regulated through environmental and health related legislation. Because of the growing nature of the biotechnology industry, many policy documents, strategies, road maps and plans have been developed in the country.<sup>32</sup> The NBS, however, acknowledges that some of the legislations require amendment and there are also inconsistencies that need to be addressed.<sup>33</sup> The NBS has thus recommended policy and legislative reform that is aimed at creating an enabling legislative framework for development and commercialization of benefits from biotechnology. The fact that such reforms should not limit the benefits derived from biotechnology is emphasized.

# The South African Situation in Relation to Other African Countries

The points for comparing the South African situation with other African countries are the three factors that were mentioned earlier: Broader public consultation that considers all relevant stakeholders' views, maintaining flexibility without losing credibility and establishment of a concise policy framework on which the legal framework can be based.

Country **Regulations and guidelines** Comments in place Cameroon A Bill has been drafted for Under Article 44, prior informed consent Regulating Safety in Modern or prior informed agreement must be Biotechnology. obtained from the National Biosafety Authority before importation or exportation of genetically modified organisms. Biosafety Regulations and There are no provisions for access to Egypt Guidelines were adopted by the information and public participation in ministerial Decree 136/1995. decision-making. Kenya The Biosafety Act, 2008 was The Act will foster the enforcement of signed into law in regulations and guidelines.34 February 2009. Mauritius National Biosafety Public notification process is provided for in the framework. framework has been drafted for consideration by the legislative authority. Uganda Draft biosafety framework There are no provisions for access to is in place. information and public participation in decision-making. South • The Genetically Modified Public notification process is provided for Africa Organisms Act 15 of in the law. 1997(GMO Act), has been in force since 1999 and was amended in 2007

A summary of Africa countries that have regulations and guidelines in place is given below:

Continued

	<ul> <li>The National</li> </ul>	The chapter on biodiversity provides for
	Environmental Management Act 107 of 1998 (NEMA).	safety aspects, access to genetic resources and benefit sharing.
	• The Environment Conservation Act, No. 73 of 1989	Provides for mandatory requirements for Environmental impact assessment for GMOs.
Zimbabwe	Research (Biosafety) Regulations are in place since 2000.	There are no provisions for access to information and public participation in decision-making.

#### Continued

### **Public Consultation**

The general population in South Africa does not understand "the scientific basis underlying the potential benefits, risks and ethical and environmental issues of biotechnology and [there is] a perception that biotechnology is generally synonymous with genetically modified foods (GMOs)".<sup>35</sup> These are the crucial issues that require public consultation in order to facilitate the adoption and diffusion of agricultural biotechnology in any country. The NBS highlights the fact that scientists do not usually communicate in a language that is accessible to the public and the media reports do not usually convey sufficient details that can inform the public. This is very challenging because the media plays the important role of setting the agenda for public debates and consultations.

The NBS requires that careful attention be paid to fostering public understanding of biotechnology. The strategy has gone a step further in proposing the following action points by the government for purposes of ensuring that the government fulfills this responsibility:<sup>36</sup>

- i. Articulation of a single biotechnology vision for South Africa so that the public is not confronted by differing opinions from government departments on issues of national priorities.
- ii. Campaigns on issues relating to biotechnology in order to give accurate information on the inputs of the various government departments that are charged with supporting or implementing particular initiatives in the field of biotechnology.
- iii. Providing the media with information representing all sides of the debates and encouraging the conveyance of biotechnology issues to the public in a responsible manner.

The Science and Society Directorate of the Department of Arts, Culture, Science and Technology has been entrusted with the task of undertaking the above action points.

# Flexibility

Biotechnology is a growing field and regulations or laws in this area, as has been correctly emphasized, "must change, adapt and evolve as the field changes, adapts and evolves."<sup>37</sup>

South Africa recognizes the need for flexibility. The NBS acknowledges the fact that the existing policies and legislations provide a broad enabling framework for the development of biotechnology but in view of the rapid manner in which the field is growing, "new legislation and regulations need to be formulated and implemented in such a way as not to limit the benefits to be derived from biotechnology."<sup>38</sup> The following relevant action points are suggested in the NBS:<sup>39</sup>

- i. Reviewing the existing legislation with implications for biotechnology and proposing new legislation or amendments.
- ii. Provision of uniform guidelines for Science Councils, universities and technikons on Intellectual Property Rights for inventors.
- iii. Providing institutional capacity to implement any new legislation.

An interesting development is currently underway in relation to action point (ii) above because lack of commercialization of biotechnology products is a major concern in South Africa as "there is little appreciation for the value of intellectual property as an instrument of wealth creation in South Africa.<sup>40</sup>" Legislation is being considered along the lines of the United States of America's Bayh-Dole Act<sup>41</sup> in order to create effective science-industry linkages. The Bayh-Dole Act was enacted in the United States of America to give effect to the policy consideration that promotes the transfer to industry of federally-funded technology developed within universities. Draft legislation has been proposed for a South Africa are quite similar to what prompted the enactment of the Bayh-Dole Act in the United States of America.

South African universities receive government subsidy for research and most of the external funding that the universities receive does not attract full cost recovery.<sup>42</sup> This situation makes it ideal for South Africa to borrow the underlying policy framework in the Bayh-Dole Act, which requires universities and other research institutions to seek protection for their intellectual property in exchange for the right to own and exploit it as well as to accrue revenue from such rights.<sup>43</sup>

# Policy and Legal Frameworks

The points that are discussed under public consultation and flexibility

above may give the impression that South Africa is making an effort to base its legal frameworks on sound policies that are developed after public consultation. It would, however, be rather presumptuous to paint a very colourful picture of South Africa's achievements without drawing attention to some of the issues related to biotechnology that have ended up in litigation. Attention ought to be drawn to such issues for purposes of putting forward helpful lessons for other countries in the region who are still developing policies and regulations for biotechnology.

A case in point is *Trustees, Biowatch Trust v Registrar: Genetic Resources, and Others.*<sup>44</sup> The applicant (Biowatch) was a trust whose primary object was to engage in 'nature conservation activities'. The second respondent (the Executive Council for genetically modified organisms) was established under section 3 of the GMO Act and had the duty of advising the first respondent (the Registrar, genetic resources - hereinafter 'Registrar') on all the aspects of GMOs. Biowatch made an application under the Promotion of Access to Information Act 2 of 2000 (PAIA) seeking the following:

- i. Under which legislation field trial licences had been granted prior to the GMO Act coming into operation;
- ii. An update of all licences that had been granted since the GMO Act came into operation;
- submission for Biowatch to inspect the licences, as well as any other form of authority, granted during the period 1998 to October 2000, as well as permission to inspect the records regarding compliance with public participation provisions under the GMO Act;
- iv. details of all pending applications pertaining to GMOs; and
- v. the exact co-ordinates of field trials and crops that had been approved for commercial release.<sup>45</sup>

The relevant legislations that Biowatch relied on in bringing their application before the high court (Transvaal Provincial Division) are the GMO Act, the National Environmental Management Act 107 of 1998 ('NEMA'), as well as section 32 of the Constitution of the Republic of South Africa Act 108 of 1996. Section 32 of the Constitution provides as follows:

- 1. "Everyone has the right of access to
  - a. any information held by the state; and
  - b. any information that is held by another person and that is required for the exercise or protection of any rights.

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2. National legislation must be enacted to give effect to this right, and may provide for reasonable measures to alleviate the administrative and financial burden on the state".

The Promotion of Access to Information Act 2 of 2000 (PAIA) is the national legislation that gives effect to subsection 2 of the constitution.

Biowatch had previously requested the above information on four different occasions before resorting to litigation but the requests were not granted. The Registrar did not respond to the first, third and fourth requests. There was a partial response to the second request insofar as the Registrar provided Biowatch with a list of all GMO permits but declined to provide details of risk assessment arguing that the Executive Council (second respondent) had not authorized the Registrar to release such information. With regard to the fifth request, the defence was that the Registrar was not legally authorized to release the exact coordinates. It was on the basis of such inadequate response that Biowatch moved to court to seek redress.

During the hearing, all the respondents argued that Biowatch's formulation of the information it sought was unsatisfactory. In particular, they argued that "the information sought was so wide as to make it extremely difficult for the Registrar and the Council to properly respond thereto".<sup>46</sup>

Biowatch was partially successful in its application as it was granted access to some of the information that it sought. The first two respondents were ordered to provide Biowatch with eight of the eleven categories of information sought by it in the fourth request as the other requests had been granted somehow before the case was disposed of.

The case illustrates the fact that access to information and public consultation still need to be made a reality in South Africa. Apart from this case, critics have pointed out that the GMO Act was enacted hastily without adequate public consultation since several multinational companies were already allowed to grow and import GMOs.<sup>47</sup>

### Conclusions

Developing effective policies and regulatory frameworks for biotechnology, particularly focused on agriculture is a real challenge. This fact is evident from the discussion of the South African situation in this paper.

The experience that can be drawn from South Africa for the benefit of other developing countries is that it facilitates the development of policies and regulations if there is a clear strategic approach in dealing with the challenges that arise from developments related to biotechnology. The NBS is a clear example that other countries can borrow from South Africa. The second example is the fact that the Constitution as the supreme law in the country provides for avenues through which members of the public and pressure groups can gain access to court in order to claim their right to be involved in the decision making process; a right which is equally provided for under the African Model Biosafety Law. The interesting South African case of Biowatch, which is discussed in this paper, clearly illustrates the importance of providing for such rights in the Constitution and having a legislative framework in place. Hopefully, other African countries can draw lessons from the South African experience with regard to both strengths and weaknesses in its policies and regulations.

### Endnotes

- <sup>1</sup> Wafula (2007).
- <sup>2</sup> ibid.
- <sup>3</sup> ibid.
- <sup>4</sup> For a detailed review of these frameworks, see the IISD Biosafety Policy Brief (2007).
- <sup>5</sup> IISD Biosafety Policy Brief (2007), p.1.
- <sup>6</sup> Department of Science and Technology (2001) National Biotechnology Strategy for South Africa, SANBI. Available at http://www.sanbi.ac.za/outputs/publications/ strategy.pdf (hereinafter NBS 2001).
- <sup>7</sup> A Joint Research Report of the Center for International Development (CID), Harvard University, USA and the Southern Africa Labour and Development Research Unit (SALDRU), University of Cape Town, 'Public Attitudes towards Agricultural Biotechnology in South Africa' 5th April 2002. Accessed at http://www.africabio.com/ status/agricb.htm on 2nd March 2009
- <sup>8</sup> Cloete, Nel, Theron (2006).
- <sup>9</sup> Niang-Sithole, Cohen, Zambrano (2004), p 571.
- <sup>10</sup> Louet (2006).
- <sup>11</sup> Clive (2008), p.17.
- <sup>12</sup> Mbote-Kameri (2002), p.69.
- <sup>13</sup> Ofir (1994).
- <sup>14</sup> *ibid*.
- <sup>15</sup> South African Department of Foreign affairs. The Convention on Biological Diversity (CBD). Accessed at http://www.dfa.gov.za/foreign/Multilateral/inter/cbd.htm on 17th February 2009.
- <sup>16</sup> Cloete, ibid. (2006), p. 557.
- <sup>17</sup> *ibid.* (2006), p.557.
- <sup>18</sup> Wolson (2005).
- <sup>19</sup> Mbote-Kameri (2002).
- <sup>20</sup> Mbote-Kameri (2002), p.68.
- <sup>21</sup> African Model Biosafety Law, April 2001.
- <sup>22</sup> Biowatch (2004).
- <sup>23</sup> Wolson (2005), p.153.
- <sup>24</sup> Mbote-Kameri (2002), p.62.
- <sup>25</sup> ICRISAT and the policy environment on biosafety in Africa. Accessed at http:// www.scienceinafrica.co.za/2003/june/icrisat.htm on 17th February 2009.

- <sup>26</sup> Andanda (2006), p.1368.
- <sup>27</sup> Gastrow (2008).
- <sup>28</sup> *ibid*.
- <sup>29</sup> Mayet (2000).
- <sup>30</sup> Andanda (2006).
- <sup>31</sup> The GMO Act was amended by the Genetically Modified Organisms Amendment Act (No. 23 of 2006), which came into effect on 17th April 2007.
- <sup>32</sup> Cloete, Nel, Theron (2006).
- 33 NBS (2001), p.32.
- 34 Njagi (2009).
- <sup>35</sup> NBS (2001).
- 36 NBS (2001), p.59.
- 37 Gale (ed) 1993, p.2
- <sup>38</sup> NBS (2001), p.50.
- <sup>39</sup> NBS (2001), pp.50-52.
- <sup>40</sup> Government of the Republic of South Africa. South Africa's National Research and Development Strategy (2002), Pretoria, p.68.
- <sup>41</sup> The Bayh-Dole University and Small Business Patent Procedures Act of 1980.
- <sup>42</sup> Wolson (2005).
- <sup>43</sup> *ibid*.
- <sup>44</sup> South African Law Reports (2005).
- <sup>45</sup> Paragraph 14.
- <sup>46</sup> Paragraph 42.
- <sup>47</sup> Biowatch 2004.

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# Biotechnology for Agriculture Enhancement in Ghana: The Challenges and Opportunities

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> Abstract: Ghana, a developing country in sub-Saharan Africa, has agriculture as a major contributor to the economy. The system of agriculture is, however, subsistence and needs to be developed as the nation strives to attain a middle income status. For agriculture to develop for enhanced economic growth, biotechnology has been identified as one of the technologies that must be utilized for rapid development. Biotechnology is in its developmental stages in Ghana and the research institutions as well as the universities are using the various tools for research and also to support the farmer. There are several challenges that the development of biotechnology is faced with; these however, present opportunities that can be exploited. This paper outlines agriculture based biotechnology research activities in Ghana using the Council for Scientific and Industrial Research Institutes as a case, and other challenges and opportunities that come along with the technology. Information on advances made in plant biotechnology, the constraints confronting researchers, and how the technology is being tailored to benefit the agriculture industry and the nation are discussed.

Keywords: Agriculture, crops, Ghana, research, technology

### Introduction

Ghana, a developing country in Sub-Saharan Africa, is located in West Africa - the Gulf of Guinea to the south of the country, Cote d'Ivoire to the west, Republic of Togo to the East and Burkina Faso to the north.<sup>1</sup> The climate is tropical with bimodal rainfall distribution from April to July and from September to November in the south. In the north the

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rainy season begins in April and lasts until September. Annual rainfall ranges from about 1,100 mm (about 43 in) in the north to about 2,100 mm (about 83 in) in the southeast. Ghana's agricultural sector can be characterized as low-input, rain fed (a paltry 0.05 per cent is under irrigation), small holder dominated, heavily dependent on women's labour and management, very poorly served by basic infrastructure and support services.<sup>2</sup>

According to the year 2000 population census, there were 18,800,000 people comprising 51 per cent females, and 49 per cent males. The population growth rate is 2.6 per cent with a population density of 78.9 persons per sq. km. The labour force is 4.1 million, with agriculture and fishing comprising 55 per cent, industry - 18.7 per cent, sales and clerical-15.2 per cent (2000 Census). Adult unemployment rate for Ghana is at 8.2 per cent (2000 Census) and the projected population is 36.9 million by the year 2015.<sup>3</sup>

Ghana has twice the per capita output of the poorer countries in West Africa. However, Ghana remains heavily dependent on international financial and technical assistance. Gold, timber, and cocoa production are major sources of foreign exchange. The domestic economy continues to revolve around subsistence agriculture, which accounts for 36 per cent of GDP and employs 55 per cent of the work force.

The economic data of Ghana is as follows: GDP: \$5.9 billion (2002), GDP per capita: \$1,980 (2002), GDP growth rate: 5.2 (2004 cited by government), GNP/capita: \$1,900 (2000 estimate). This is a measure of per capita income that takes into account relative purchasing power across countries. GDP composition by sector is : agriculture: 36 per cent industry: 25 per cent services: 39 per cent (2000 estimates). Per capita income of Ghana in the year 2002 is US\$ 290 while the income per capita growth is 1.3 in 1999-2000. Gross National Income (GNI) is 6.6 billion (ranking102); Budget revenue is \$1.603 billion in 2001, Budget expenditure is \$1.975 billion in 2001 (estimated). Budget deficit: 3.4 per cent of GDP (2004); total debt: US\$5.5bn (2000); \$6.9bn (2001); and \$7.2bn (2002).

As mentioned above, agriculture accounted for almost 40 per cent of GDP<sup>4</sup>, and employs three-fifths of the workforce. However, despite its importance, sectoral growth has lagged behind other sectors of the economy and has been unpredictable, as most farming is reliant upon rainwater. The farming is also done mostly by small scale farmers with very little or no mechanization. The removal of subsidies on fertilizers and other agricultural inputs has adversely affected crop yields. Crop

production in Ghana varies for the various climatic zones; dry savanna to wet forest. Some of the major agricultural crops include cassava, yams, grains, cocoa, oil palms, kola nuts, and timber. Ghana is the second largest producer of cocoa in the world. Large tracts of forest have been cleared for cocoa crop, which thrive in the rich soil of the rain forest. The application and adaptation of modern and improved agriculture practices is slow and the use of biotechnology by the private sector is very minimal. However, the technology is still at the developmental and adaptation stages in schools. Due to the cost involved in equipping laboratories and the need for well trained experts, the knowledge in most educational institutions at the undergraduate level is theoretical. It is only at the postgraduate level that students have some practical exposure, where students have to use the technique for their research work. University agriculture science students are, therefore, encouraged to adopt biotechnology methods to expand the frontiers of agriculture. This is because biotechnology methods could speed the transformation of agriculture to facilitate food security as Ghana seeks to move from low income nation to a middle income level.

Ghana is a member of the United Nations and in 2000 the member states of the United Nations adopted the Millennium Declaration as a renewed commitment to human development. The Declaration includes eight Millennium Development Goals (MDGs) as follows: eradicate extreme poverty and hunger, achieve universal primary education, promote gender equality and empower women, reduce child mortality, improve maternal health, combat human immunodeficiency virus/ acquired immune deficiency syndrome (HIV/AIDS), malaria, and other diseases, ensure environmental sustainability and develop a global partnership for development.

Approximately 70 per cent of the MDGs' target group lives in rural areas, for most of whom agriculture is a critical component in the successful attainment of the MDGs. Agriculture is, therefore, a key sector to be developed and enhanced for the attainment of the millennium goals.

This paper outlines agriculture based biotechnology research activities in Ghana using the Council for Scientific and Industrial Research Institutes as a case, and other challenges and opportunities that come along with the technology. Information on advances made in plant biotechnology, constraints and how the technology is being tailored to benefit the agriculture industry are also outlined here.

# **Biotechnology Applications in Ghana**

The application of biotechnology in Ghana has been for medical research and diagnostics as well as agriculture research. Biotechnology application started a little over two decades ago using mainly tissue culture tools for teaching and research purposes. Other technologies that came along were ELISA for disease diagnostics and isozymes for characterization. Below (Table 1) is list of major bodies employing biotechnology for agricultural research.

Table 1: Institutions carrying out Biotechnology activities in Ghana

Institution	Biotechnology Application
Universities	Teaching and research
Biotechnology and Nuclear Agriculture Research Institute	Teaching and research
Cocoa Research Institute of Ghana (CRIG)	Research, teaching and training
Council for Scientific and Industrial (CSIR)	Research, training and research teaching

The Council for Scientific and Industrial Research (CSIR), which is the governing body overseeing scientific research in Ghana, is leading in the application of biotechnology in agriculture. The council is made up of 13 institutions.

The list of institutions within the CSIR that are using biotechnology in research include: Crops Research Institute, Animal Research Institute, Forestry Research Institute, Food Research Institute, Oil Palm Research Institute, Savanna Agriculture Research Institute, Plant Genetic Resources Research Institute and Science and Technology Policy Research Institute (STEPRI).

# Application of Biotechnology Activities in Some of the Institutions

The Oil Palm Research Institute has the mandate to carry out research on oil palm and coconut. The mission of the institute is to conduct sustainable and demand driven research aimed at providing scientific and technological support for the development of the entire oil palm and coconut which are vital for the cosmetics industries. Presently, molecular diagnostic tools are being used in the institute for the development and production of coconut ecotypes tolerant to the Cape St. Paul Wilt Disease.

The Forestry Research Institute of Ghana is mandated to undertake

forest and forest products research to ensure sustainable management and utilization of Ghana's forest resources and to engage in the commercialization of the research results and services. To enhance their research activities, they are using biotechnology tools for clonal micropropagation and molecular characterization of forestry germplasm.

The Animal Research Institute is also one of the CSIR institutions with mandate to undertake research aimed at providing solutions to problems relevant to the livestock industry in Ghana. The institute is also to advise government through the CSIR on livestock production policy matters, and to help the country to become self-sufficient and achieve food security in animal protein supply. Livestock production in Ghana contributes 7 per cent to the agricultural gross domestic product (GDP) and domestic production of meat supplies only 30 per cent of the national protein requirement. Factors affecting livestock production in Ghana include lack of improved breeding stock, poor nutrition, diseases, and poor marketing systems, non-availability of capital and high interest rates and transaction costs on credit. Biotechnology holds promise for improving the productivity of livestock in the area of animal breeding, nutrition and health. Presently sampling for serological /molecular monitoring of PPR in small ruminants in 3 agro ecological zones in Ghana has commenced. This would allow the epidemiology of the disease in the country to be studied using molecular based (RT-PCR) diagnosis tools. The molecular based diagnosis of PPR will form the basis for early diagnosis and control of the disease in the country.

The Crops Research Institute (CRI) is mandated to carry out research on all the food crops in Ghana. The mandate crops range from legumes (cowpea, soybean, groundnut, bambara groundnut), through cereals (maize and rice), roots and tubers (yam, cocoyam, taro, cassava, frafra potato and sweet potato), to vegetables (pepper, garden eggs, tomato, onion, leafy vegetables), plantain and banana, tropical fruits (citrus, mango, avocado, pineapple, cashew, pawpaw), and industrial crops (rubber and sugar cane). The institute has well established and functional biotechnology laboratories for the enhancement of research activities of breeders, agronomists and related disciplines. The biotechnology laboratories have objectives to provide the basic molecular tools vital for the enhancement of breeding programmes towards crop improvement and release. The laboratory has established collaboration with advanced laboratories and other sister institutes for the application of current state-of-the-art molecular techniques for crop development. The following biotechnology applications can be carried in the facility: *in vitro* rapid multiplication and plantlet production and cleaning planting materials to eliminate pathogens. There is a reliable system for exchange of clean planting materials, cryopreservation, somatic embryogenesis, proteomics (tools for genetic engineering), another cultures (applied in rice improvement), and long term conservation of vegetatively propagated crops.

Presently the tissue culture activities in the CSIR-CRI laboratory include: receiving *in-vitro* materials, rapid multiplication of induced mutation cassava plantlets, rapid multiplication of clonally propagated crops, *in-vitro* conservation of germplasm using slow growth techniques, production of clean planting material, embryo rescue during crosses, somatic embryogenesis toward crop improvement, cryopreservation techniques for the conservation of vegetatively propagated crops, and efficient post-flask management of *in-vitro* plantlets. The tissue culture outfit of the facility has successfully used the technique in cassava, plantains, bananas, sweetpotato, pineapple, cocoyam, yam, mango, frafra potato, jatropha and citrus.

The molecular biology laboratory has the human capacity to apply the following techniques: genotyping/fingerprinting of germplasm, genetic diversity studies, marker-assisted selection as applied in breeding programmes, disease diagnostic studies, gene mapping, gene mining for trait capture, primer design and gene silencing in crop improvement.

The use of these techniques will help reduce breeding time, increase essential nutrients, improve yields, enhance stress tolerance, improve resistance to disease and pests, and lead to development of new products and growing techniques. These are aimed at producing varieties to serve industrial processing and address issues including global warming and its effects on drought in crop production.

Presently at the CSIR-Crops Research Institute, the biotechnology tools have been applied to several crops, including cocoyam (*Xanthosoma* sp.), groundnut, cassava, yam plantains and bananas, sweetpotato, maize and soyabean. Considering cassava as an important staple and industrial crop in Ghana, the Crops Research Institute over the years has released improved cassava varieties to farmers. These varieties are high yielding and tolerant to most diseases and pests. However, these varieties are mainly used for industrial products like starch, gari, and few staples. In that effect the local landraces which are preferred by farmers and consumers because they have good cooking qualities for all the food preparations have been

left unattended to. These landraces are susceptible to cassava green mites and Africa cassava mosaic virus (ACMV) with its attendant low yields. Several research interventions have been put in place to improve the farmer-preferred cassava landraces. These include introgression of ACMV resistance genes into local landraces; induce mutation breeding to improve shelf life of tubers and starch content; and introgression of useful genes into the local landraces to improve the shelf life. The local cassava varieties that are popular with the farmers have short shelf life leading to rotting of fresh tubers when not used immediately after harvest. The research activities, therefore, include the use of biotechnology (Marker Assisted Selection) for pyramiding useful genes from wild relatives of cassava into elite progenitors to develop landraces with prolonged shelf life and pest and disease resistance. Genes for resistance to pest, diseases and delayed post harvest physiological deterioration are, therefore, being mined for in the wild gene pool. Current tissue culture activities include rapid multiplication of induced mutation cassava plantlets and clonally propagated crops, in-vitro conservation of germplasm using slow growth techniques, production of clean planting material, embryo rescue during crosses, somatic embryogenesis for crop improvement, cryopreservation techniques for conservation of root and tuber germplasm, and efficient post-flask management of in vitro plantlets. Crops that are being worked on currently using tissue culture techniques include cassava, plantain, banana, sweetpotato, pineapple, cocoyam, yam, mango, frafra potato, Jatropha, citrus, bambara groundnut. At CRI, biotechnology applications are aimed at reducing maturation time, enhanced nutrients, yield and stress tolerance, improving resistance to disease, pests and herbicides, meeting processing needs for industry, and reducing time for crop development.

### Status of Biosafety Law

As the biotechnology tools are developed and adapted, there are sectors that need critical attention, and these include biosafety issues, and regulatory mechanisms on biotechnology. Biosafety is the safe use, transfer and handling of living organisms modified through modern biotechnology and it reviews the scientific evaluation of the potential of a genetically modified organism (GMO) to effect human and animal health and the environment. Issues concerning biosafety are very sensitive. Human health, environmental and socio-economic issues are the three major concerns of biosafety. The decision-making components of biosafety are: national

policy, stakeholder input, safety issues which comprise environmental and food safety and non-safety issues which comprise socio-economic considerations, international agreements, ethical issues, impact on trade and public opinion. To serve as a guide for issues relating to biosafety and legal, technical, administrative and information management systems, are the Cartagena Protocol on Biosafety (CPB) and National Biosafety Framework (NBF). Some key elements of an NBF are a government policy on biosafety, a regulatory system, an administrative system, a decisionmaking system and mechanisms for public participation and information sharing. Ghana has put in place a comprehensive programme for Biosafety Systems Project (PBS) and an advisory group. The necessary foundation was built through the training of scientists, trial managers and regulators on confined field trials. Policy/legal framework was reviewed and the Ghana biosafety draft law for resubmission to cabinet has been done. Biotechnology communication workshops have been held among scientists, the media, farmer groups, policy makers, NGOs and members of parliament. PBS has offered training on biosafety, food safety and biosafety curriculum development through internships. To circumvent the delay in the passage of the Bill and allow for the practice of good science, a biosafety Legislative Instrument (LI) has been drafted. The LI uses the existing CSIR Act 521 of 1996 as a template since it has provisions for the conduct of research in general and seeks to simply extend this to the conduct of research on GMOs. Arrangements have been made at institutional levels to see to procedures, liability and redress, miscellaneous and schedules. The LI recognizes and empowers the National Biosafety Committee (NBC) as the National Focal Point on Biosafety, authorizes the conduct of confined field trials, provides the regulations for the conduct of confined field trials and does not allow the commercialization or release of products to farmers and consumers. Approval by the NBC for researchers to conduct confined field trials and contained laboratory experiments, will be on a case-by-case basis. Some confined field trials that would be conducted include ACMV resistant cassava, Bt maize, Bt cotton and Bt cowpea. If guidelines are followed, these GM foods are safe, however, legitimate concerns will not be ignored. The vigorous training of scientists, technicians and the provision of functional laboratories is critical.

## **Biotechnology Opportunities and Challenges**

Considering the above biotechnological developments in Ghana, there exist several challenges and opportunities that can be utilized to change

the phase of agriculture in the country and this will affect the sub-region. There is tremendous opportunity to promote effective collaboration between Ghana and countries well advanced in the use of biotechnology. There is plenty of manpower. There is advantage of the labour force which is not expensive and can be fully utilized in collaborative research for manpower training and technology transfer.

One underexploited area in biotechnology in Ghana is the use of *in vitro* methods<sup>5</sup> for the production of clean planting materials which are in high demand. Application of tissue culture techniques in the horticulture industry is barely existent and this opportunity can be taken up to supply clean planting materials. This system needs the assistance of molecular tools to ensure that the clonal materials that is produced maintain their genetic integrity with the application of fingerprinting techniques. The systems available in other countries where planting materials of vegetatively propagated crops are replaced after a number of seasons can be adapted and enforced in Ghana. This will keep the disease pressure down and ensure high production levels. Previous studies using sweetpotato have revealed that when clean tissue culture produced planting materials are used the yield is 30 per cent higher than when regular planting materials are used. This practice must, therefore, be encouraged. The government can enforce laws that will ensure that growers replace their vegetatively propagated crops with certified clean tissue culture produced planting materials. This will also help check the spread of diseases and create jobs. The law too will help keep laboratories producing the planting materials in business and the private sector should be encouraged to take advantage of the opportunity.

There, however, exist the challenges of availability funds for the rapid development and adaptation of biotechnology tools to serve all aspects of agriculture. The establishment of effective collaboration can help identify sources of funding that can be tapped for the biotechnology sector. Policy development, government contribution to science and technology as well as regional collaboration are required to aid and promote biotechnology.

There is also a big gap of knowledge in all sectors of society as to what biotechnology is and what it can offer to the agriculture sector. To date some of the science and agriculture textbooks at the basic education level talk of biotechnology as fermentation only. Knowledge about modern biotechnology is greatly lacking and this poses a big challenge that needs to be tackled from the grassroots. There is need to organize training sessions for the science and agriculture science teachers and seek opportunities to revise the information in the school textbooks to include some current issues on modern biotechnology. Policy makers and journalists also need to be well educated in the field of biotechnology to enable them to draw informed conclusions on related issues. This will help break the communication gap between policy makers and the researcher in the laboratory. This will create the opportunity to carry out studies on how countries which are ahead of Ghana in biotechnology issues manage to educate the various stakeholders and adapt them to improve our system.

The ability to share regional projects, personnel and research findings is also very vital for the advancement of biotechnology for agriculture enhancement in Ghana and the sub-region. Within the African sub-region regional research areas can be identified to share funds and research findings. Regional training can be organized to build capacity. The equipment supply and maintenance system as well as sources for laboratory consumables can be explored and strengthened. Along these lines inter-regional policy development will lead to the promotion of biotechnology.

In this present day of technological advancement one of the big challenges that the faces the laboratories in Ghana as we develop biotechnology, is the reliable supply of electricity and water. Presently, the availability of a borehole that serves the CSIR-Crops Research Institute has helped deal with the water supply problem, and this is a step in the right direction since there exists a lot of good quality cheap underground water that can be tapped. The underground water can also be tapped to irrigate farm lands. That way it can stop the reliance on rain water for crop production. Advantage need to be taken of this great opportunity. Tapping of underground water technology needs to be modernized and the cost also needs to be reduced to encourage several others to use that option. Standby generators are used in the incidence of interruptions in power supply. These are, however, very frustrating and expensive. Therefore, concrete solutions need to be evolved. Alternative sources of energy should be explored in Africa to reduce the over dependence on hydro power and the use of fossil fuel for our energy needs. There is need to tap the solar energy and channel it for use in the laboratories. Wind energy can also be used as an alternative to the energy from the local electricity producers. A pilot project in one of the institutes of the CSIR has demonstrated this. There are, therefore, opportunities for these technologies to be developed to boost the application of biotechnology

in agriculture development because the high cost of electricity and water is a great challenge to the competitiveness of local industries in Ghana.

The availability of reliable and constant supply of laboratory consumables also pose a challenge since these are not produced locally. This provides an opportunity for producers and suppliers to explore this market and supply the needed items. In line with this, local alternatives can, where possible, substitute the imported products. This will also go a long way to provide jobs and create worth.

The field of animal health is another area that can be explored for great opportunities in meat and meat products' production and job creation. Biotechnology is useful in disease diagnosis, insect pest management, recombinant vaccine production and animal nutrition. Biotechnology can be used to produce enzymes that promote digestion of complex food substances in animal feed and for production of high quality feed meeting dietary requirements of essential amino acids and manipulating gut microflora for improved rumen activity. Rapid increase in livestock production is required to help feed the ever-increasing population growth of human population. Modern biotechnology seeks to augment conventional methods of improving livestock for enhanced productivity. Development of necessary infrastructure and capacity for the application of biotechnology to turn the livestock sub-sector into a vibrant industry in Ghana is needed. Development of diagnostic kits for livestock and poultry diseases including foot and mouth disease, Avian influenza, Brucellosis, Gumboro, African Swine Fever, lumpy skin disease, viral diseases affecting guinea pigs and PPR in small ruminants are also very vital.

Ghana, a developing country in West Africa, is a primarily an agricbased nation. It has plans to move from a low-income nation to middleincome. Industrialization has a crucial role to play. A platform for interaction amongst all stakeholders towards the development of new biotechnologies in industry that can have substantial implications for the improvement of life and business is very vital. The development of cuttingedge technologies for adaptation and modification of biological organisms, processes, products and systems in nature for the production of goods and services will enhance the creation of new products for industry. On developing new industrial processes, including recently discovered oil in Ghana, our local manufacturing industry will become more competitive. Industrial biotechnology should be used to aid systems in cleaning the environment and to reduce the impact of manufacturing waste. The development of these technologies will be applied for sustainable production of biochemicals, biomaterials, and biofuel from renewable resources.

A major challenge that biotechnology has to deal with is the acceptance of the technology and its products. Biotechnology applications in Ghana offer a bright future for the enhancement of agriculture in Ghana. Educating tomorrow's generation in biotechnology holds the key to a better Ghana.

### Conclusion

Farmers and agriculture underpin the well-being of the world's population. Agriculture is changing continuously: every year for the last 10,000 years, farmers have improved their weed control and water management. In each decade, farmers have won and lost battles with pests and diseases and adopted new varieties of their crops. Exploitation of biodiversity is important to the livelihood of subsistence farmers and commercial growers. Modern genetics, mutation and molecular methods, and plant breeding can benefit producers, consumers and the environment.

Traditionally in Ghana, biotechnology is being used as a tool to give plants new traits that benefit the agricultural production, environment, and human nutrition and health. For the past couple of decades the plant biotechnology has been applied to produce clean planting material, conserve germplasm and rapidly multiply crops with desirable trails. The application of molecular biology has been used to mine for genes and characterize germplasm with preferred characteristics that are of industrial use such as high starch and for bio-fortification. There are a number of industries using crops as raw material. Desirable traits need to be introduced in the crops to meet the demands of the industry. CSIR-CRI has been selected to be a National Center of Specialization for the sub-region under the West Africa Agriculture Productivity Project (WAAPP) and this puts the institute and the CSIR in the focal point to intensify the development of biotechnology tools. There will also be the need for technical backstopping. Partnerships with advance laboratories need to be in place for routine update of the fast advancing techniques in biotechnology. Government support for providing reliable supply of energy and laboratory supplies is crucial. With the passing of the Legislative Instrument on Biosafety in Ghana, the country is prepared to carry out confined field trials on sweetpotato, cassava, maize, and cowpea. It, however, needs training for staff in handling genetically modified organisms.

### Endnotes

- <sup>1</sup> The country is precisely Latitude: 5 degrees, 36 minutes north and Longitude: 0 degrees, 10 minutes east. Half of the country lies less than 152 meters (500 ft.) above sea level, and the highest point is 883 meters (2,900 ft.). Total land area is 238,540 sq. km of which 57 per cent (13.6 million ha) is agricultural.
- <sup>2</sup> www.ghanaweb
- <sup>3</sup> www.nationalencyclopedia.com
- <sup>4</sup> Alhassan (2003).
- <sup>5</sup> Quain, (2002).

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# Role of Critical Infrastructure and Incentives in the Commercialization of Biotechnology in India

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Abstract: Commercialization is a process by which the new knowledge is converted to products and services of commercial value. The model for commercialization of biotechnology is not a linear assembly like model. Due to emerging status of knowledge and involvement of biological systems legal and ethical challenges also arise and make the commercialization process longer, costlier and risky. Despite these entry barriers, we find many countries have appreciated the potential of biotechnology to produce useful and safer products and services in many areas of human activity and have invested and reaped fruits in terms of successful products in the market. We find from these accounts the results vary with the level of maturity of the industry and priority assigned by the nations and investments made in skills and generation of new knowledge. Among the developing countries, India is one of the early investors in biotechnology. Efforts were started as public initiatives. Skill generation, infrastructure development along with knowledge generation was taken up by the Department of Biotechnology. Multi-pronged efforts established visible capabilities in the public research system. Despite these efforts for one and half decades very little has happened at the commercialization level. This gap in realization of Indian research efforts as commercial successes has been a puzzle. In this paper, the author attempts to investigate the reasons behind slow commercialization. The approach is based on the hypothesis that to achieve successful commercialization in knowledge intensive field with high rates of turn over like biotechnology, the company should have (i) high levels of capabilities in R&D and strong network, to supplement and complement skills and facilities and (ii) an environment which is highly facilitating (high levels of preparedness of the technology delivery system) through favourable policies for regulation, accessing fiscal resources in terms of finances, infrastructure and skills, fiscal incentives, enhancing awareness of the public, etc. The study involved survey of 223 companies having some interest in biotechnology commercialization. The results of the survey show that access to funds, critical technical facilities and skills of desired quality have been the major obstacles .As for as the facilitating environment and critical infrastructure for commercialization is concerned, many companies found it to be not very favourable. The incentives are inadequate and confusion in regulatory policies has discouraging effect.

*Keywords:* Biotechnology, developing country, India, commercialization, incentives, infrastructure.

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# Introduction

Commercialization is a process by which the new knowledge is converted to products and services of commercial value. The model for commercialization of biotechnology is not a linear assembly like model. It requires constant touch with research for the paradigm is not 'expansion of scale' but 'expansion of scope'. Commercialization, in addition to this continued connection with research or knowledge generating units, requires patronage of policy makers to facilitate the process be it protection or regulation and also an environment in which required skills materials, channels of distribution and awareness of ultimate consumer. Due to emerging status of knowledge and involvement of biological systems legal and ethical challenges also arise and make the commercialization process longer, costlier and risky. Hence "patronage of policy makers" is particularly significant in the case of biotechnology though some of the above conditions are valid for any frontier technology.

Despite these entry barriers, we find many countries have appreciated the potential of biotechnology to produce useful and safer products and services in many areas of human activity and have invested and reaped fruits in terms of successful products in the market. We find from these accounts the results vary with the level of maturity of the industry and priority assigned by the nations and investments made in skills and generation of new knowledge. Among the developing countries, India is one of the early investors in biotechnology. Efforts were started as public initiatives. Skill generation, infrastructure development along with knowledge generation was taken up by the Department of Biotechnology. Multi-pronged efforts established visible capabilities in the public research system. Despite these efforts for one and half decades very little has happened at the commercialization level. This gap in realization of Indian research efforts as commercial successes has been a puzzle. In this paper, the author attempts to investigate the reasons behind slow commercialization.

### Commercialization in the Innovation Process

In the innovation process, commercialization is a relatively costly and difficult phase. It is the process of taking new knowledge, process or product beyond R&D phase and actually introducing it into production or in the market place. The location of this process is in the business sector and the R&D results may be self generated or outsourced. There is a widely quoted 'rule of thumb' that for every dollar spent on research 10 dollars are spent

in development and 100 dollars for commercialization. The ratio thus is R:D:C 1:10:100. This magnitude becomes one of the major inhibiting factors to commercialization in developing countries. Though this ratio varies among industries, it is largely true for large process-oriented projects where pilot plants and lot of regulatory compliances are required.

Though commercialization occurs through the companies, many a times the technology to be commercialized is developed outside the company. The major sources are public research system or other companies within or outside the geographical boundaries through different instruments of technology transfer. The nature of impediments vary depending on the nature, characteristics and maturity of the technology or knowhow transferred to the company.

Thus the typical commercialization process can be depicted as:

Tech.Transfer  $\bigcirc$  commercialization  $\bigcirc$  Public Res system  $\bigcirc$   $\bigcirc$  other companies (  $\rightarrow$  Pilot /Up scaling  $\rightarrow$  Production  $\rightarrow$  Market In-house R&D)

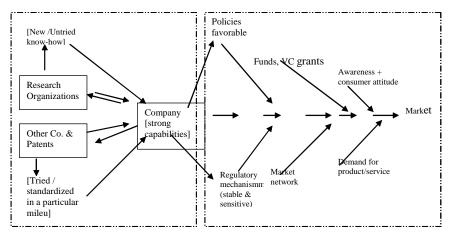
The efficiency with which the knowhow transferred to a company goes through the intervening phases to commercialize different products /services depends primarily on two factors:

- 1. The inherent capacity of the firm to absorb new knowledge and proceed with further steps and
- 2. Factors external to the company like policies, market, network, and supportive infrastructure & financial meshanisms. Thus, it seems to be a combination of strength/competence (technical, managerial and marketing) of the company, which is commercializing the technology and environment congenial for this which leads to successful commercialisation. Thus, the whole process can be schematically depicted (Figure on next page).

The status of knowledge in the field, organization of knowledge generation and transfer processes and implementational strategies adopted by different countries are important factors which influence and lead to different results. In this paper we restrict our study to the status of commercialization of biotechnology in India.

### Theoretical Framework and Methodology

According to Batherham (2000) companies which want to succeed in new



Thus the commercialisation process to succeed requires

- Sound research base
- Technologically Competent companies
- Congenial and encouraging environment

economy need to invest in new skills and technology and align themselves with research institutions that perform basic research. According to an Australian report (Anonymous 2002), success factors in the commercialization path are listed as R&D products and services, IP protection, market analysis, regulatory issues, alliances and collaboration and availability of capital. This partially compares well with our identified factors. Furman *et al.* (2002) observe common innovation infrastructure include: (1) cumulative technological sophistication, (2) human capital resources available for R&D activity and (3) resource commitments and policy choices such as investment in education and training, IP protection, openness to international trade and R&D tax policies. Of Furman *et al.'s* list we consider R&D tax policies as part of incentives.

As mentioned earlier, of the two major factors affecting the process and pace of commercialization we look at the factors external to the company, i.e critical infrastructure and incentives. The other factor relating to the companies' capability has been dealt with in the earlier studies (Visalakshi and G.D.Sandhya 2000, Ramani and Visalakshi 2001, and Visalakshi 2004). The infrastructure critical to BT commercialization, according to us, include skill, funds and supportive institutions and industry, market and required policies in place.

While listing out the various factors we realize some of the factors serve as part of infrastructure as well as new rules/amendments serve as incentives. For example, as strong IP law operative in a country could Role of Critical Infrastructure and Incentives in Commercialization of Biotechnology 67

become part of infrastructure while an amendment which favours inclusion of living modified organism could be an incentive for biotech research and commercialization.

### Incentives

Incentives are measures that are put in place to induce people and organizations to generate positive outcomes. In the case of science and technology, the different types of incentives can be classified in the following categories: fundamental incentives, institutional and infrastructural incentives, financial and fiscal incentives, budgetary incentives, legal and regulatory incentives, government procurement incentives, honorific incentives, and knowledge-base incentives.

The fundamental incentives are those which may stated as initial conditions for socio-economic development, such as those provided by a market economy which includes free competition, private property, openness to the global economy, efficient bureaucracy and a stable democracy.

Institutional and infrastructural incentives could be made more efficient, particularly those for technological innovation (such as science parks), transfer, extension, diffusion, popularization, information, networking (including professional associations) and international cooperation. While institutions and infrastructures for R&D need to be modernized, strengthened and better linked to industry, infrastructures for information and communication technologies are particularly important for any developing countries since these technologies can substantially improve productivity and efficiency in all sectors of the economy and support technology transfer and networking. Hence the need to put into place incentives for their application and diffusion.

The financing of technological change is of paramount importance for developing countries which lack a full-fledged financial system and which attract little foreign direct investment and commercial credit. The strengthening, privatization and diversification of the financial system should be a high priority in order to increase the availability of venture capital and small credit to farmers and the informal sector. Financial incentives in general and incentives for foreign direct investment in particular need to be reinforced in view of the globalisation of the economy, by removing or reducing constraints in respect of percentage of local equity, local inputs and repatriation of dividends. A more positive approach to multinational corporations is needed if they are to contribute to endogenous technological capacity building. The use of fiscal incentives, such as tax exemptions, rebates, reliefs, holidays, and accelerated depreciations, can be used to promote R&D, linkages with industry, application of technology, training, return of national expatriates, use of foreign consultants, strategic technology import, etc. Many countries have established or are in the process of setting up Export Processing Zones, essentially with tax incentives and facilities for the transfer of technologies, such as more freedom to hire expatriate experts.

Budgetary incentives, except scholarships, are more and more regulated by the new WTO agreements, particularly investment allowances, modernization grants, industrial subsidies and export compensations. This should be to the advantage of countries which cannot compete with the industrialized countries in subsidizing industry.

Legal and regulatory incentives are essential to protect intellectual properties and technologies, to enforce minimum technological standards, to facilitate the hiring of essential foreign experts (residence and work permits, tax holidays) and to discriminate technology imports. In Africa this type of incentives has also been used to enhance the status of researchers. Legal and regularity incentives need to be reviewed from time to time to adjust to changing circumstances. For instance, technology flows are more and more regulated by the market than by bureaucratic regulations although some regulations are needed.

Government procurement can provide important incentives to local industries to upgrade their technological capacity. India is currently not bound by the WTO disciplines on government procurement policies, and can, therefore, use such policies for the benefit of indigenous enterprises. Honorific incentives, such as prizes and awards, are public recognition of excellence and have proved to be particularly cost-effective in promoting innovation and technological improvement.

Incentives to strengthen the knowledge base, such as basic education, encouragement to take science disciplines, technical training, apprenticeship, sabbatical leaves, study tours, participation in international seminars, etc. are extremely important for any socio-economic development. Incentives are the tools which can be used to manage technological change and are vital for socio-economic development.

Incentives can be non-fiscal which may include infrastructure development for industry use like incubators and technology parks, or expanding access to skills through academia-industry interaction, supportive policies for regulation, intellectual property protection, Role of Critical Infrastructure and Incentives in Commercialization of Biotechnology 69

licensing and product approvals, establishment of testing facilities and standards and creation of awareness of public about biotechnology.

## Indian Efforts in Biotechnology

Among the developing countries, India is one of the early investors in biotechnology. Efforts were started as public initiatives. Skill generation and infrastructure development along with knowledge generation were taken up by the Department of Biotechnology (DBT). Multi-pronged efforts established visible capabilities in the public research system. Despite these efforts for one and half decades very little has happened at the commercialization level. With its existing strengths of research capabilities and infrastructure there is a growing expectation from Indian industry to commercialize biotechnology products. There are around 200 firms working in different sectors like healthcare, agriculture, etc. Though there are about dozen products marketed in the country, only a few products are commercialized based entirely on indigenous efforts. This gap in realization of Indian research efforts as commercial successes has been a puzzle and to fill this gap DBT has been making various efforts in the form of policies, schemes and support for the past decade with very little success. Outputs of Indian biotech research have been predominantly published in journals and presented in conferences. Though around 40 technologies have been claimed to be transferred with the efforts of DBT, hardly any product has come out of these transfers. Human resource generation in India was initiated and continues to be under DBTs functions. Though the number of training institutions has increased, there is a severe shortage of manpower perceived by the BT industry in terms of both quality as well as quantity.

Even though India has invested in BT for about two decades (amounting to over 10 billion rupees) and has created over 300 research groups and more than 40 institutions training around 1000 post graduates and post doctoral fellows, the outcome has been only few products. Currently around 200 companies are involved in BT related activities, most of which are small in size. Of these, around 50 companies are involved in modern biotechnology (which includes recombinant DNA and cell fusion, like hybridoma technology techniques). All this portends to some grave problems that are encountered in commercializing BT in India. In this article, the author looks at the role of critical infrastructure and incentives in the context of commercialization of BT and Indian experience on this. In order to find out the factors, which may not hit the casual observer or could be inferred from the large data available at different sources on Indian biotechnology, but that come in the way of commercializing biotechnologies in India, a detailed and in-depth study was necessary. This paper presents the results of the study undertaken during 2003-2004.

Studies by Visalakshi *et al* (1993) which analyses four cases and Ghosh (1996) (analysed 17 cases) throw light on the effort of commercialization in BT in the late 1980s and 1990s. Obstacles to commercial success identified by these studies are the following:

- 1) Institutions involved in R&D did not go beyond basic and applied research and had no funds or skills to do development, up-scaling, etc.
- 2) Joint development of products by research institutions and industry were very rare or non-existent, for reasons of confidentiality etc.
- 3) Reward system which was in place does not encourage post R&D phase activities by the investigating or technology managers to get involved.
- 4) Industry lacs the skills to absorb the technology developed by R&D institutions and to set up production facilities.
- 5) Lack of sufficiently strong patent protection discourages investment by industry in serious basic research.

While some of the problems identified by the above studies have been addressed, others continue to play a part in influencing commercialization of R&D results. The changing patent laws, evolving regulatory framework, and coming into being of new business efforts in the post-genomic era, etc. have created a need to have a look into the status of Indian biotechnology and its commercialization and draw sufficient insights for further action.

# Sample Selection and Description

The sample was derived from various lists like the one by Biotechnology Consortium of India Ltd (BCIL) and added to the list companies from other sources. We had a list of about 350 companies involved in BT and BT related activities in the country. Of these 52 companies did not have valid contact information. Some of them we learnt later as not existing any more and some are still in the initial stage of formation.

Of the remaining companies, about 222 in number, the project team could visit 162 companies located in Ahmedabad, Aurangabad, Bangalore,

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Chennai, Delhi, Hyderabad, Jalna, Mumbai, Pune, Surat and Vadodhara. We collected the required information for the remaining 60 companies from secondary sources.

The sample had a mix of small, medium and large companies. The ownership of the companies in the sample covered all types like public, private, MNCs and joint venture companies. The nature of activity was from research alone to research, production and marketing. The nature of technology used varied from modern biotechnology, traditional biotechnology and marginal biotechnology. The areas of operation spread to agriculture, health, industrial biotechnology, instrumentation etc. Product segments in which the selected companies were active are given below:

### 1. Agriculture

- (a) Aquafeed
- (b) Animalfeed
- (c) Biofertilizer
- (d) Biopesticide
- (e) Seeds (Hybrid)
- (f) Seeds (Transgenic)

(g) Plant nutrients and others

### 2. Healthcare

- (a) Biotherapeutics
- (b) Diagnostics
- (c) Drugs/therap.
- (d) Probiotics
- (e) Vaccines
- 3. Industrial BT
  - a) Enzymes

# 4. Services

- (a) Instruments
- (b) Res. Biology & reagents
- (c) CRO
- (d) CLRO
- (e) Bioinformatics/ genomics

The information sought pertains to

- Earlier efforts at commercialization of BT
- Problems faced
- Experience based opinion on incentives/facilitators of commercialization.

A questionnaire was devised which had basically three sections. An elaborate section was on the capabilities in terms of technologies transferred from various sources to the company and the types of problems faced in adapting and commercializing the same. The last section was on incentives they required to overcome problems/impediments. A suggestive list based on other country experiences was annexed. The data collection was done by both mail and by personal interviews using semi-structured questionnaire.

# Analysis

## Problems Faced by Companies during Commercialization

Based on the responses given by the companies visited and involved in biotechnology we have been able to find constraints to successful commercialization of biotechnology in the Indian context. We observed that they can be grouped under following categories: policy, fund/finance, skill, infrastructure, linkage, market/consumer and external influence like activities by countries outside the India.

List of factors which affect commercilaization are of two types. One set of factors were recognized as common to many companies irrespective of their size, type of products they deal with, nature of their activities, nature of technology used and level of biotechnology involved. The other set includes factors which are specific to companies based on products or size, etc. As the techniques used is linked to the product, many a times we did the analysis as per product groups, e.g. biopesticides, vaccines, etc.

Table 1 gives the constraints identified by companies across the board under different categories.

Category	Actual constraints
Funds	<ul> <li>a) VC funds by state are stringent and difficult to get.</li> <li>b) Private VC companies are risk aversive.</li> <li>c) Current funding pattern is not meeting entrepreneurs' needs.</li> <li>d) VC's are insensitive to specific features of BT.</li> <li>e) There is lack of awareness of banks about requirements of BT.</li> <li>f) Financial crunch stops collaborative projects as public R&amp;D charges exorbitantly for facilities the services.</li> </ul>

# Table 1: Constraints Identified as AffectingCommercialisation of Biotechnology

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Table 1 continued	
Fiscal	<ul><li>a) Tax holidays for BT are not there.</li><li>b) Insensitive duty structurec, Non-existent sales tax concessions, exemptions etc.</li></ul>
Skill	a) Public R&D outcomes are not amenable to commercialization.
	<ul><li>b) Academics lack entrepreneurial capability.</li><li>c) There is mismatch between manpower generated by public system and industry's needs.</li></ul>
	<ul><li>d) The manpower generated is more of technicians (good at repeating work) than being creative/ innovative.</li></ul>
Policy	<ul> <li>a) Non clarity about status of new business propositions – CROs, CLRo's, diagnostics, etc.</li> <li>b) Complicated and long licensing procedures.</li> <li>c) Non exclusive licensing discourages technology transfer.</li> </ul>
External factors	Dumping of cheap products by certain countries discourage new ventures.
Market	Prohibitive cost of creating and developing market in India and abroad.
Infrastructure	<ul><li>a) Lack of incubators.</li><li>b) Lack of concessions for power usage.</li><li>c) Lack of consultancy support for establishing new ventures.</li></ul>
Linkage	a) Procedural problems discourage interaction with public research. Institutions.
	b) Lack of confidence, common language and transparency in interaction with academic partners.
	c) Lack of awareness of research institutions about requirements of industry and product development.
Organisational	a) Lack of appreciation of applied research work and efforts to attitudes transfer technology.
	b) Lack of entrepreneurial capability among public institute scientists.
	<ul><li>c) No encouragement for industry public R&amp;D interaction.</li><li>d) Lack of rewards to scientists (patents in the name of organization and not inventor).</li></ul>

Table 1 continued

From the above table, one can make out that funds and skills are major problems. Lack of understanding specificities of BT and its products appear to be coming in the way of devising facilitating policies which would encourage commercialization of biotechnology.

When the list of constraints was analysed to see any relationship with size of the company, we find finance related problems are more for small companies and policy related problems are faced mainly by large companies. Companies with well established R&D facilities in their own companies have found accessing skill from public research system as a problem, while companies with less developed or no R&D of their own find lack of structures facilitating linkages with public R&D as a major obstacle.

It is observed that companies involved in marginal biotechnology had no problems of regulatory policies. Some of the companies involved in traditional biotechnology faced policy related problems like duty structure, definition/categorization of products, etc. Policies related to regulation and IP protection were felt as not clear and arbitrary which affected their activities and strategies for the companies engaged in modern biotechnology (MBT). These companies also felt the problems related to consumer awareness and market development.

The nature of the problem faced by companies attempting commercialization of vary with different product segments

Diagnostics have predominantly policy and policy derived market problems. Similar is the case with the production of new seeds including transgenics and biopharmaceuticals

Finding finance and developing market seems a major problem of support/service companies like instruments and reagent companies.

Probiotics, micronutrients, tissue culture, biopesticides and biofetilizers companies have common problems related to market in terms of awareness of competition and spurious products leading to loss of confidence. They all also have infrastructure problems in terms of QC, standards, testing facilities, etc.

Vaccines, enzymes and biopharmaceutical companies find problems in terms of in low level academia-industry interaction.

# **Unique Problems**

Enzymes companies are unique in that the non stringent environmental regulation is a road block in creation of markets. Bio informatics companies want more stringent IPR laws in place that are implemented vigorously.

Biopharma companies are constrained greatly by lack of USFDA compliant infrastructure for clinical and pre-clinical trials.

Companies dealing in instruments find lack of recognition for their linkage with biotechnology and absence of special treatment as problems faced by them.

Biopesticide and biofertilizer companies feel pressure of chemical

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companies lobby working against their good. They also find the registration process lengthy and cumbersome.

Diagnostics companies find lack of sera panel availability and rules for public procurement requiring companies to be in market for 2 years coming in the way.

Thus, there are many factors identified which are creating problems for commercialization of BT. The problems common to all are few and related to procedures and weak infrastructure, while those specific to various type of products are many. One could see some dependence of problems to size, viz. small companies have more finance related problem than large ones, which have can muster, enough resources.

Based on the opinions of companies, incentives which could facilitate the process of commercialization have been drawn. We found they could be grouped under the heads - fiscal, infrastructural, policy/procedures and skill.

List of incentives felt as required by the companies attempting commercialization basically fell into four categories: (1) fiscal (2) infrastructure related, (3) policy-related and (4) skill-related.

# Fiscal

- 1. Incentives like tax benefits for export (as IT companies get) and reinstatement benefit which has been withdrawn for manufacturing companies who export.
- 2. Tax benefits/ holidays.
- 3. Favourable exchange rate for export.
- 4. 50% subsidy for capital expenditure in BT.
- 5. Duty free import of machinery.
- 6. Sales tax to be reduced in case of over competition (reducing greatly profit margin).

# Infrastructural

- 1. Encouragement to collaborate with research institutes.
- 2. BT instruments, reagent manufacturers/suppliers need special treatment.
- 3. Testing, standards institutions to be created for recombinant therapeutics, regulatory data generation for transgenic, standard animal houses for preclinical, clinical facilities or at least identification and authorization of such facilities outside the country for compliance data generations.

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- 4. Increasing awareness of VCs and financial institutions about BT business.
- 5. Establishment of quality standards and testing/ certifying facilities.
- 6. Land allocation on priority basis and at concessional rates (China gives it free of cost.)
- 7. Awareness creation (support) for BT products among consumers, bureaucrats, policy makers and implementing agencies.

### Policy-related

- 1) Ban on import of BT products (diagnostics, vaccines drugs, etc.) when domestic capacity to produce exists.
- 2) VCs to be equipped with technical people for approval of proposals in BT.
- 3) VCs should have more freedom from CAG to take decisions in BT (despite high risk and long gestation).
- 4) Industrial R&D should be supported by public funds without strings of collaboration with public research organizations which charge exorbitantly.
- 5) Matching grant for people who want to put up incubators, or establish incubators for small and entrepreunial ventures.
- 6) Harmonized system of classification of BT products which form the basis of tax structures for excise, import, etc.
- 7) Single window regulatory/licence clearance.

### Skill-related

- 1) Facilities for field demonstration new agri BT products to be enhanced.
- 2) Industry academic interaction to be encouraged.
- 3) Skill generation through cooperation and consultation with industry.
- 4) Consultancy/guidance for starting new ventures in BT.
- 5) Facilitation of technology scouting.

From the above list, we can observe that they are corollary of the constraints faced. The incentives accordingly fall under fiscal, skill, infrastructure, awareness creation, easing procedure licensing, trade and regulation. Similarly there are incentives related to size product made technology used, etc.

Smaller companies look for more grants, loans and infrastructural support while companies which are big and established look for tax related incentives and laxed regulatory but stringent IP laws. Across size, Role of Critical Infrastructure and Incentives in Commercialization of Biotechnology 77

companies feel a need for an incentive in awareness creation for consumers, establishment of testing facilities and standards, clarity among bureaucrats and policy makers about biotechnology.

### **Discussion and Conclusion**

From the above analysis it comes out clearly that having a robust infrastructure and creation and existence of vibrant incentive structures can make a difference to outcomes of developing countries efforts to commercialize new knowledge. These become still more critical in knowledge intensive areas like biotechnology. In the case of developing countries, the companies in which commercialization occurs usually lacks capabilities at optimal level and hence depends on the technology delivery system (TDS) (Porter et al 1980) for its better performance. It is also observed that preparedness of TDS complements sub optimal capabilities in the companies (Visalakshi and Sandhya, 2000) in the case of Indian biotechnology. Our study brought out in an indirect way that problems and insufficiencies in these two factors become an impediment to successful commercialization. The major problems relate to skills and funds. The findings coincide with those of a study done in Australia (Anonymous 2002.) It is felt more by smaller companies as they are at start up stage and have no assets to prove their credibility or no revenue coming their way to plough back. This insufficiency also affects hiring people with suitable skills. This to an extent is taken care of by linkages with local public sector research institutions or universities. Some of the small companies have been promoted by technical persons who have contacts with these institutions and use facilities available with them for their work till their infrastructure gets set up and established.

For large companies while funds are not the major problem, there are problems in matching the skills with their requirements. They find the policies that delay the expected rate of return on their investments to be an impediment.

Incentives as they exist are less attractive and awareness of these also is very low and in many cases these schemes are under-utilized. Because of an overall precautionary approach lots of strings are attached to these grantsin-aid and soft loans types of funding of innovation in new areas. These conditions prohibit some of the companies to make use of them. For example, to be eligible for the grants/loans a company needs to tie up with a public research institution which always does the projects on time over run. The other factor which discourages tie up with public and academic institutions is the exorbitant costs for services and facility usage. Policies relating to IPR and regulation are still in the process of evolving.

Thus, the whole situation has a great negative effect on the pace of commercialization. Public research system and companies in India have for historical reasons remained isolated from each other. Now there is realization of mutual dependence due to new policies and global aspirations. Still there is certain level of hesitation from either side in working together in a collaborative mode.

It is expected that factors like efforts of the government, enthusiasm by the industry, robust infrastructure, incentives, and improved capabilities of the companies will result in large scale commercialization of many products at a faster pace.

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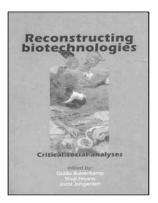
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### **Book Review**

# Reconstructing Biotechnologies: Critical Social Analyses

Guido Ruivenkamp, Shuji Hisano and Joost Jongerden 2008, 368 pages, hardback ISBN: 978-90-8686-062-3 Price: Euro 58./\$ 87

The debate on biotechnology in developing countries has been more or less a polarized debate with supporters and opponents discussing the usefulness and relevance or the problems with biotechnology respectively. Biotechnology is either seen as a boon or as a bane and often it is



assumed that technology is a major determinant with society having little role in shaping it or directing its development. Over the last two decades different approaches and theoretical frameworks have been developed in sociology of science, Science and Technology Studies (STS), anthropology of science and technology and in sociology of development to study the nexus between technology and society and of these, Social Construction of Technology (SCOT) framework and Actor-Network-Theory (ANT) are well known. These theories and frameworks reject technological determinism and grand narratives about technology, development and progress. They posit that technology and society influence each other and there are technological alternatives and paths that are not chosen, not because of technical factors alone. Although the influence of postmodernism is evident, they cannot be reduced to a sub-stream of postmodernist thought. Feminist perspectives on science and technology, including feminist critiques of science and technology, have also contributed to this debate. But in most debates on biotechnology and society, these perspectives are invisible or do not get the importance they deserve. This results in not only a polarized debate but also in a poorer understanding of the issues. This volume rectifies this absence to a great extent. But the articles in the volume are informed by different perspectives and the sub-title critical social analysis is an apt one.

The volume is divided into six parts, preceded by a lengthy introduction. The editors introduce the four core issues addressed by the volume and the need for developing a multi-perpsctival critical social theory. Guido Ruivenkamp's article puts forth a critical-theoretical approach and discusses the possibility and potential for re-appropriation and democratization of life-sciences technologies. He underscores the need for a situational politics to understand and (re)shape the biotechnologies. His theoretically rich analysis should be developed further. But any proposal for alternative technology trajectory should also include the question of value preferences and technological choices. Considering technology as a force for emancipation is an enchanting idea but in the globalized science and technology the scope for oppositional forces getting co-opted is high. In one sense his analysis in too heavily influenced by dialectic, historical-materialist and critical approaches to take into account critical perspectives from other disciplines like bio-ethics and environmental ethics.

Rachel Schurman and William Munro, in their article question some of the assumptions of Guido on technology and the role played by those who oppose technology. They examine how the anti-GM movement politicized agricultural biotechnology and challenged the assumptions made by the state and Multinational Corporations (MNCs) on acceptance of technology. They argue that this resistance has had a profound impact and the resistance was not confined to Europe. This protest, they contend, also led to search for non-GM alternatives. Although the two articles differ considerably in their perspectives on biotechnology and the scope of the intervention, both when read together indicate the need for critical perspectives on technologies. In my view resistance to biotechnology may be necessary but not sufficient to develop a critical perspective on all aspects or applications of biotechnology. For example, the resistance or opposition to agricultural biotechnology in Europe did not result in a similar opposition to medical biotechnology or health sector biotechnology. Thus, the resistance was not to biotechnology per se but applications in a specific sector. The other issue which both articles ignore is the evolution of regulatory responses to technologies and how they affect the acceptance or resistance to a specific technology.

Franz Seifert analyses the opposition to GMOs in two countries, i.e. France and Austria and describes how different the opposition was. In France the attitude of the opposition was against biotechnology anywhere, not just France while, in Austria it was NIMBY(Not In My Back Yard). In Austria the issue of contamination is raised to protect organic farmers and organic farming and organic farmers are not in the forefront of opposition to GMOs. In France the major group that was in the forefront of the opposition placed the opposition in a larger context and in ideological terms.

Les Levidow, whose writings on biotechnology regulation in Europe, particularly in UK are well known, examines the state sponsored exercises in Technology Assessment (TA) and in enhancing public participation on debates on biotechnology. The state is not a neutral player and its policies are in favour of agro-biotechnology. Participatory TA under the auspices of TA becomes an exercise in enhancing the legitimacy and acceptance of agro-biotechnology than a TA on technological choices, and, soociety's needs. In other words, the framing of the issues more or less decides the outcome of the participation by public. Democratizing technological choices is not an easy task and participatory TA can be used creatively but TA is not a process of technological development. But unless the larger question of technological choices and democratic decision making is addressed, there can be no satisfactory solution to this issue. Since democracy is also a question of numbers and as the choice(s) of the majority count more than that of the minority the bigger question is whether the current models of democracy provide enough space for alternative technological choices to compete equally and be assessed.

Joost Jongerden provides a sweeping overview of the peasant question and modernity. According to him the destruction of peasant production system was a goal of the modernity and it was an outcome of the modernity project. A reconstructionist approach would ultimately question the nature of the modernity and its objectives. But peasants seem to have survived the modernity project and not all observers are as skeptical as Joost is. Perhaps the reconstructed modernity will allow peasant system to survive and flourish as an alternative technological system of food production or may co-opt it and contain the resistance and opposition to the modernity project.

Wietse Vroom's article examines the attempts to develop appropriate biotechnologies for potato farmers by International Potato Centre in Peru. She contends that alternative and empowering technological trajectories are feasible. Shuj Hisano's article cautions against the 'add ethics and stir' approach to incorporating ethical concerns and stress the need to politicize the ethics of biotechnology. Les Levidow compares and contrasts the Knowledge Based Bio-Economy (KBBE) and the Alternative Agri-Food Networks (AAFNs) approaches to agriculture and society in Europe. AAFNs challenge the quality agriculture discourse of KBBE and project an alternative framework on bio-economy. In this GM-Free is not just an expression of a technological choice for consumption but also a preference for alternative mode(l) of agricultural production and consumption.

The next three articles discuss the new food networks, regional initiatives for production and distribution of high quality food products and the symbolic and communicative aspects of food and its embodiment in a socio-cultural matrix. These articles indicate the emerging perspectives on food and agriculture and how alternative discourses challenge both the assumptions on modernization of agriculture and food and the role technology plays in it. The local and regional networks and experiments in alternative models of food production and consumption in Europe in one sense can be understood as the return of the repressed. But these models may end up as just models without brining in major changes in technological and social organization of food production and consumption. Only sustained efforts and innovative approaches of alternative technology development that value some choices over mere productivity will take them forward. I wish that there was an article on similar experiments in USA and Canada on organic food production and community supported agriculture.

William Munro's article on the experience of small holders with GM cotton in South Africa indicates how biotechnology could become a contested terrain. In the process new spaces are created and the growers do not always consider themselves as mere consumers of technology. George Essgbey discusses the biotechnology in six countries in Africa and points out the need for developing appropriate biotechnologies in these countries. Msuya analyses GM cotton in Tanzania and argues that existing technologies are unlikely to be of much benefit to resource poor farmers and what is needed is the biotechnology that is reconstructed and appropriate.

Thus the articles in the five parts question the normally held assumptions about agricultural biotechnologies and their relevance. While some call for development of appropriate technology and stress the need for reconstructing biotechnology to suit needs of various types of farmers in developing countries, some question the very logic of applying biotechnology as a solution and discuss the alternative frameworks. The contrast in these is evident. The question is how to reconcile these views and still argue that biotechnology deserves to be reconstructed as an appropriate technology. If the criticisms of those who support quality agriculture based on local/regional production and consumption is valid, then the issue is more of finding non-biotechnology alternatives than that of reconstructing biotechnologies. But the analyses based on the experiences in developing countries call for reconstructing biotechnologies than for switching over to regional/local food production and consumption. Does it indicate that some parts of hyper-(post)modern Europe are more suitable for returning and reinventing local/regional food production and consumption arrangements than other parts of the world? The tension between calls for rejection of agri-biotechnology and calls for re-constructing biotechnology deserves an extensive analysis and critical social analysis can help us in this.

The articles in the next section discuss common property, commons and the appropriate rights regime. Eric Deibel draws on the theoretical frameworks developed Marx, Foucault and advocates an open source approach. Kate Milberry examines the various examples of technology activism including free software, Indymedia, and the Wiki revolution. She concludes with the observation that whether these could result in radical transformation of technical sphere or not, they do indicate that another world is (still) possible. Niels Louwaars argues for developing tailoring rights in such a way that hyperownership does not erode the policy space or the rights of farmers and breeders.

Thus the volume covers a whole range of issues from different perspectives and this makes it a very interesting volume. The task of de/re constructing biotechnologies as envisaged by various contributors to this volume is not an easy one. While some authors have discussed theoretical frameworks, many others have examined the situation in the ground and the need to reorient and reconstruct biotechnologies. In sum this volume calls for a rethink of the traditional approach to biotechnology and development issues. It provides food for thought and tools for analysis. The publishers should bring out a paperback version at affordable price as early as possible so as it increase its availability and accessibility.

One would recommend it to any one interested in biotechnology and development issues.

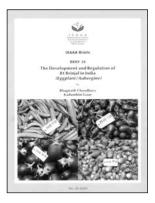
— Krishna Ravi Srinivas Associate Fellow, RIS ravisrinivas@ris.org.in

## **Book Review**

### The Development and Regulation of Bt Brinjal in India (Eggplant/Aubergine),

Bhagirath Choudhary and Kadambini Gaur; ISAAA Brief No. 38, Ithaca, NY, USA.2009. pp.102.

The first decade (1996-2005) of commercialization of biotech crops was clearly the decades of Americas, where over 90 per cent of the global biotech hectarage was grown. On the other hand, ISAAA has projected that the second decade (2006-2015) of commercialization of biotech crops would witness stronger growth



in Asia, especially in China and India. Millions of farmers in both these countries have already benefited enormously from the deployment of a biotech fibre crop, Bt Cotton. In fact, cultivation of Bt cotton was an important contribution to the alleviation of poverty in some of the developing countries.

Given the significant social welfare and economic benefits and environmental benefits of Bt cotton, the present book provides a comprehensive overview of the development and regulation of biotech brinjal in India. It also throws light on the concerted efforts put in to develop insect-pest resistant Bt brinjal the Fruit and Shoot Borer (FSB).

The book *The Development and Regulation of Bt Brinjal in India* is the outcome of the research work of the authors based at ISAAA office in New Delhi. It states that the Bt brinjal technology has been developed and donated by M/s Maharashtra Hybrid Seeds Company (MAHYCO) to public institutes in India, Bangladesh and the Philippines for use in open-pollinated varieties of brinjal in order to meet the specific needs of poor farmers. The book is broadly divided into four parts and consists of eleven comprehensive chapters followed by a detailed list of references.

Part I of the book *Biology, Production and Significance of Brinjal in India* starts with the first introductory chapter which highlights that the three significant developments in improved seeds and crop technologies have changed the face of Indian crop production and contributed to food

security and the alleviation of hunger and poverty. Three major developments were the Green Revolution in the 1960s and 1970s, introduction of hybrid seeds and application of biotechnology which led to the development of first Bt gene in hybrid cotton. It also states that success of Bt cotton and the support and willingness of farmers for the adoption of new technology has led to a widespread support to emulate the success of Bt cotton in other food crops also.

The Origin and Genetic Diversity of Brinjal has been presented in chapter two. It is stated that India possesses rich diversity and varieties in cultivated and closely related wild species of brinjal. Brinjal or *Baingan*, the poor man's vegetable is planted on about 550,000 ha in different parts of India and is a significant source of income of small and poor farmers.

The second chapter refers to the centre of origin and rich genetic diversity of brinjal, followed by biology of brinjal in third chapter. The economic importance of brinjal has been documented in the next chapter as along with the tomato and onion, it is the second most important vegetable after potato in India. India produces 26 per cent of the total 32 million tons of world brinjal production, where as China lead with 56 per cent. (Table 5, pg.15). However, the chapter reveals that farmers often lose a significant share of production due to insects-pests and among them FSB is the most destructive pest of brinjal which accounts for the 60-70 per cent of yield losses. In this chapter, for the benefit of the readers as well as consumers, a comprehensive list of biotech fruits and vegetables, which are at various stages of regulatory development, either at laboratory or in field trials is also given in Table 9.

The second part entitled *Biotech Crops: A Paradigm Shift in Crop Development* deals with the application of genetic engineering to develop biotech crops as insect and virus resistant, herbicide tolerant and to have better quality products. Gradually, there has been significant increase in the cultivated area under biotech crops which reached to 114.3 m ha in 2007 from 1.7 million ha in 1996. The number of countries growing biotech crops also increased from 6 in 1996 to 23 in 2007. With the adoption of new technology, the stage is all set that this trend will continue in the second decade of commercialization, i.e 2006-2015. The chapter also highlights the remarkable success story of Bt cotton which until now was the only biotech crop commercialized in India, with its area increasing from 50.000 ha in 2002 to 6.2 million ha in 2007 – an impressive 125 fold increase in six years occupying 65 per cent of the 9.55 m ha under cotton in India in 2007. With the large scale adoption of Bt cotton, which protects

against damage by bollworms, the total national cotton production significantly increased from 13.6 million bales in 2002 to 31.5 million bales in 2007. As a result, India emerged as the world's second largest cotton producer in 2006-07 and became a major exporter of cotton.

Part III of the book presents Development of Bt Brinjal in India. Bt brinjal which is a state-of-the-art-technology and is considered to be one of the safest, convenient and viable options to control the FSB. The chapter very clearly explains the process how the FSB infests and damages shoots and fruits of brinjal plant. The small larvae of FSB bore into tender shoots, as a result the infected shoots get paralyzed, which seriously affects the 95 per cent of plant growth and flowers. Apart from this simple process, there are other several sources of FSB infestation reported in the chapter. To overcome the great economic losses, there was a genuine need for Bt brinjal, with an inbuilt FSB protection system along with the good farming practices that can help the farmers to protect the crop and get good yields. MAHYCO has developed the FSB-resistant Bt brinjal by using genetic engineering and transformation process similar to the one deployed in Bt cotton. The development of the Bt brinjal involves introduction of cry1AC gene originally sourced from the soil bacterium called Bacillus thuringgiensis (Bt). The insecticidal protein produced by this gene is specific to lepidopteron insects like FSB and is environment friendly. When FSB larvae feed on Bt brinjal plants, they ingest Bt protein which gets activated by gut proteases generating a toxic fragment. The activated insecticidal protein then binds to two different receptors in a sequential manner. The first contact of the insecticidal protein is with the cadherin receptor, triggering the formation of oligomer structure. The oligomer then has increased affinity to a second receptor, amino-peptidaese (APN). The APN facilitates insertion of the oligomer into membrane causing ion pores. These sequential events disrupt the digestive processes that in turn cause the death of fruit and shoot borer.

It is a great honour for MAHYCO which had developed indigenously the first biotech food crop – Bt brinjal – and is ready for its commercialization in the near future. Above all, the company has generously donated the same technology to Tamil Nadu Agricultural University (TNAU), Coimbatore and the University of Agricultural Sciences, Dharwad. At present both these universities are conducting field trials and are hopeful that very soon these varieties are likely to be made available to farmers. Further, based on their special request, MAHYCO has already transferred FSB resistant Bt brinjal technology to Bangladesh and the Philippines. The Concluding Part IV *Bt Brinjal :The Regulatory Framework in India* deals with the prevailing regulatory framework for GM crops in India which has been developed by the efforts of the Ministry of Environment and Forest (MoEF) and the Department of Biotechnology (DBT). The relevant authorities under the Rules 1989 have framed guidelines, protocols and procedures for evaluating biosafety, toxicity, allergenicity, food and feed safety.

Complying with the prevailing regulatory system, MAHYCO obtained permits and submitted all the relevant results of various experimental works on Bt brinjal to the competent authorities. After thorough review, the Committee confirmed that Bt brinjal is safe and equivalent to its non-Bt counterpart. The safety of Bt brinjal was further tested by the results of studies on pollen flow, impact on soil microflora and invertebrates. Given the importance of some beneficial insects in brinjal crop, the concerned authorities directed MAHYCO to conduct studies on the effect of Bt protein on non-target organisms and also proactive methods recommended for insect resistance management. A large number of field trials were conducted by MAHYCO during the period between 2004-08 to ascertain the economic benefits of Bt brinjal hybrids vis-à-vis non-Bt counterparts in different agro-climatic zones. The field trials conducted during 2007-08 generated very positive results of Bt brinjal hybrids in controlling the FSB and increasing marketable yields. The mean marketable yield of 7 Bt brinjal yields was 32.93 tons per hectare compared to 26.28 tons per hectare of non-Bt counterparts. The agronomic performance studies indicated that on average, the amount of insecticides used to control FSB was reduced by 80 per cent which translated to 42 per cent reduction in total insecticides sprayed on Bt brinjal. It is also expected that farmers are going to benefit enormously in terms of reduction in cost of production by saving on cost of insecticides and lower labour cost as a result of reduced spraying. As a result of decrease in insecticide usage, it would indirectly reduce its residues in fruit and environment as well as farmer's direct exposure to insecticides would lead to lesser health risks.

As discussed in earlier chapters, India has experienced remarkable success with Bt cotton because of the consistent and significant multiple benefits that the Bt technology offers. In this context, the development of Bt brinjal which has completed all the biosafety studies prescribed by the Indian regulatory authorities is almost ready to become the second GM crop. It is a remarkable achievement of the scientists at MAHYCO that they have successfully extended the proven significant benefits of Bt from a fibre crop to a food crop that is the lifeline of the millions of farmers as well as consumers in the developing countries.

On the whole the book gives an indepth account of technical and scientific clarifications regarding the biosafety and benefits of the Bt brinjal. The volume is loaded with comprehensive analysis of the wide range of multi-location large scale field trials and agricultural techniques applied on Bt brinjal and its impact on human beings and environment. The book contains as many as 28 tables and 23 figures pertaining to interesting development of Bt brinjal in India. It is a great source of information for the scientists, researchers, civil societies, students and the stakeholders about the implications and prospects of Bt brinjal. It has been aptly stated that the adoption of Bt brinjal by farmers in India would be a very rich experience from which India and the world can benefit enormously by better facilitating the harnessing of the immense power that biotechnology offers to ensure an adequate supply of safe, nutritious and affordable food and contribute to become an important tool to alleviate poverty and hunger in India and other developing countries as well.

This book should serve as an important source as it provides a wealth of information about existing rigorous scientific regulatory approval process in India. To be on safer side, studies on food safety, including toxicity and allergenicity tests have been conducted on rats, rabbits, fish, chickens, goats and cows which have confirmed that Bt brinjal is as safe as its non-Bt counterpart. However, it would have been more useful if the authors had given some practical and concrete reasons to create awarenesss regarding the objective of selecting brinjal as compared to other popular vegetables in India and strengthen their viewpoint to convince Indian farmers for their betterment in society at large.

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