United Nations Conference on Trade and Development

The Biotechnology Promise

Capacity-building for Participation of Developing Countries in the Bioeconomy

United Nations

New York and Geneva, 2004

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UNCTAD/ITE/IPC/2004/2

PREFACE

At its fourth regular session held in Geneva from 17 to 22 May 1999 the United Nations Commission on Science and Technology for Development (CSTD) selected as the substantive theme for the inter-sessional period 1999-2001 "National capacity-building in biotechnology". This theme included the following: human resource development through basic science education, research and development, as well as their interdisciplinary aspects; the transfer, commercialization and diffusion of technology; increasing public awareness and participation in science policy-making; and bioethics, biosafety, biodiversity, and the legal and regulatory matters affecting these issues to ensure equitable treatment.

It was recognized that developing countries were deriving only limited benefits from biotechnology due to declining investments in public agricultural research and development. Furthermore, the dominant role of developed countries' private sector in biotechnology makes it difficulty for developing countries' public sector research to benefit from the new innovations.

Agricultural biotechnology offers the potential for increasing and improving food production capacity and promoting sustainability. However, few countries and private firms own most of the agricultural biotechnology innovations. The investment in public agriculture research systems in developing countries has declined. The objective of the meeting was to identify areas of concern and recommend possible strategies that could promote equitable use of resources.

A planning meeting was held in Cambridge, Massachusetts, from 2 to 3 September 1999, in conjunction with the international conference on "biotechnology in the global economy", which was co-organized with Centre for International Development at Harvard University. Thereafter, the CSTD bureau decided that three panels would be organized to address the main aspects of biotechnology, capacity-building, legal and regulatory issues, and public awareness and participation.

The first CSTD panel on "capacity-building in biotechnology" was held in Tehran, Islamic Republic of Iran, from 11 to 13 April 2000. The main objective was to identify key priorities and steps for developing countries and countries with economies in transition to build their capacity to monitor, assess, regulate and manage the impact of biotechnology applications and ensure their safety as well as generation of knowledge for the development of biotechnology by developing human resources through education, training and research.

The second panel addressed legal and regulatory issues in biotechnology and was convened in Geneva, Switzerland, from 3 to 5 July 2000. This panel examined issues related to intellectual property rights (IPR), biosafety, bioethics and other regulatory policies areas relating to the transfer and diffusion of biotechnology in the key sectors of agriculture, health and environment. The objective of the meeting was to identify the key issues and capacity-building needs that were necessary ingredients for building legal and regulatory frameworks for equitable access and protection of innovations as well as safe use of biotechnology products and services.

The primary objective of the third panel, on public awareness and participation in science policy, held in Tunis, Tunisia (14-16 November 2000), was to analyse and devise a process for building public awareness about the opportunities and challenges presented by biotechnology through the development and promotion of dialogue amongst scientists, the biotechnology industry, policy makers and the public. The Commission recognized that the public does not sufficiently trust many national regulatory regimes as providers of balanced and accurate information on complex issues in science and technology. It also noted that the public understanding of biotechnology issues was very low. Therefore, it was important to find alternative communication mechanisms for public participation in policy development.

This report draws on materials from the panel sessions, country case studies and expert background papers addressed by the CSTD in the course of its undertaking to meet the above objectives of the theme of the inter-sessional period 1999-2001. Additional materials cited were generated in the course of compiling the report and from experts and publications. Given the volume of materials and similarities in the content of the national reports and case studies, all documents cited are represented in a summarized form.

This report was prepared for the United Nations Commission on Science and Technology for Development by Victor Konde, in collaboration with Albert Sasson, under the direction of Mongi Hamdi. Overall, guidance was provided by Khalil Hamdani. Comments on the report were received from Professor Richard Braun and Drs. Phillip Aerni, Susan Musembi, Peter Singer and Andy Simpson. Production assistance was provided by Laila Sède. The views expressed in this report do not necessarily represent those of the Commission. Similarly, the selection and/or editing of country reports and reproduction of selected sections of background reports prepared for UNCTAD do not necessarily represent a bias on the part of the Commission.

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ABBREVIATIONS

Bt	*Bacillus thuringiensis*
CBD	Convention on Biological Diversity
CTB	cholera toxin beta-subunit
DNA	deoxyribonucleic acid
ESTs	expressed sequence tags
GEF	Global Environmental Facility
GMO	genetically modified organism
IPR	intellectual property rights
LMO	living modified organism
SNP	single nucleotide polymorphism
TRIPS	trade - related aspects of intellectual property rights
UNEP	United Nations Environmental Programme
CSTD	United Nations Commission on Science and Technology for Development
UNCED	United Nations Conference on Environment and Development
UNCTAD	United Nations Conference on Trade and Development
UNESCO	United Nations Educational Scientific and Cultural Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Overview

Biotechnology has been a subject of great public interest since the late 1980s. By 1992, through Agenda 21 of the United Nations Conference on Environment and Development (UNCED), the international community recognized the important role that biotechnology would play in agriculture, health, industry and environment. A number of national leaders saw biotechnology as a vehicle through which developing countries could leapfrog to achieve national development.

The international community also recognized the need to help developing countries build sufficient human resources, regulatory capacity, research funding and governance institutions to enable their participation in biotechnology. Significant strides have been made in biotechnology development beyond those anticipated in 1992, but developing countries have increasingly remained behind.

Many programmes and initiatives have been developed by different international and regional institutions to help developing countries build national capacity in biotechnology. While the focus of international organizations and industry was on biotechnology opportunities, the public has become increasingly suspicious of some biotechnology products. The greatest resistance was to agricultural biotechnology products, where human, animal and environmental health risks dominated the debate. This debate has diverted the attention of national and international organizations from the wider benefits of biotechnology.

The United Nations Commission on Science and Technology for Development (CSTD) acted in a timely fashion to help developing countries come to terms with biotechnology issues. This report departs from mainstream work done so far in biotechnology as it focuses on successes and steps taken by developing countries and countries with economies in transition to build national biotechnology industries. This report does not focus on biotechnology research but rather on biotechnology industry development.

The report does identify some of the common features of successful biotechnology development models in case analysis. It also points out the important roles, in some case complementary roles, of each biotechnology sector, such as industrial and environmental biotechnology, or the role of plant biotechnology in the growth of industrial and pharmaceutical sectors. The level of financial resources that kick-started the various projects are highlighted where information is available.

Chapter I highlights some of the biotechnology opportunities, challenges and trends globally, and their implications for developing countries. Chapter II addresses priority setting, and assessing national capabilities and options to build biotechnology industries. Chapter III evaluates progress made so far and the way forward to enable resource-poor nations to participate in the new bioeconomy. Chapter IV focuses on international trade and its implications for biotechnology from the perspectives of developing countries. Chapter V addresses global governance of biotechnology, while chapter VI looks at public awareness and participation in policy formulation. Chapter VII develops a generalized concept of biotechnology development models based on cases sighted.

The report is different from previous ones on biotechnology in three major aspects. First, it focuses on opportunities and challenges rather than just benefits and risks that have dominated public debates. It argues that unless the opportunities are taken and challenges addressed, benefits and risks will remain obscured by economic and social considerations rather than just science.

Secondly, the report addresses the wider application of biotechnology and supports this line of thought with country case studies to develop models that may be used by developing countries at different stages of development. It presents different models and suggestions based on successful cases from developing countries.

Thirdly, the report takes the reader through most of the stages of developing a biotechnology industry. It presents both private and public initiatives with pointers on how and why some cases were successful. It admits that a one-size-fits-all model in biotechnology may not work. This makes the report unique.

Chapter I
The Promise of Biotechnology

1.1 Overview of biotechnology development

Biotechnology, a set of revolutionary techniques, has been the subject of public policy aspirations for the last two decades. Agenda 21, the work programme adopted by the 1992 United Nations Conference on Environment and Development, stated that biotechnology "promises to 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, support for sustainable methods of aforestation and reforestation, and detoxification of hazardous wastes".

The biotechnology industry is estimated to have generated at least $34.8 billion in revenues and employed about 190,000 in publicly traded firms worldwide (Ernst and Young, 2002). An estimated 4,200 public and private biotechnology firms were in operation. These are impressive results, given that in 1992 the biotechnology industry was estimated to have contributed about $8.1 billion.

The number of modern biotechnology - based drugs and vaccines approvals have also increased - from about 23 in 1990 to over 130 by 2001. There are about 350 biotechnology-derived drugs and vaccines in clinical trials targeting over 200 diseases. A number of organisms have had their genomes (genetic composition) sequenced or decoded. The human, mosquito and malaria parasite genomes are among those that have been sequenced. These activities are expected to increase the number and pace of drug and vaccine discoveries.

The area of farmland planted with transgenic crops or GMOs has also increased - from about 1.7 hectares in 1996 to about 60 million hectares in 2002. Four countries, the United States (66%), Argentina (23%), Canada (6%) and China (4%) - planted 99% of the global transgenic crop area. China had a 40% increase in its *Bt* cotton area, which occupied more than half (51%) of the national cotton acreage (James, 2003). About 51% of soybeans, 20% of cotton and 9% of maize acreage globally were planted with transgenic varieties in 2002. India commercialized *Bt*-cotton in 2002, while Colombia and Honduras grew pre-commercial acreage of *Bt*-cotton.

The use of biological catalysts or enzymes has entered almost every industry. There are at least 600 different products and more than 75 types of enzymes that are used in industries. The global market for industrial enzymes is about $1.6 billion. The demand for other biotechnology-related products, such as feed additives, has continued to grow, with vitamins and amino acids accounting for about $3 billion and digestive enhancers $1.3 billion (UNCTAD, 2002).

Biotechnology has also been used to reclaim waste land through the use of microorganisms and plants that remove and/or degrade toxic compounds. Some firms have incorporated biotechnology techniques in their production to decrease energy and water consumption, improve productivity and reduce the number of processing steps. All these actions could lead to an improved environment, sustainable use of resources and increased productivity.

Biotechnology-related applications and products have penetrated all sectors of the economy. The technology has begun to overcome the bottlenecks that, in the last century, favoured chemical substitutes against biological ones. As the knowledge base of biotechnology consolidates, the number of platforms that will depend on it will multiply to generate new fields.

Despite these developments, biotechnology does not seem to have taken root in many developing countries and the goals have not been attained. Food insecurity, disease and poverty still ravage a huge section of the human population, mainly in developing countries. Public attitudes and political will towards biotechnology have changed in some regions of the world. Similarly, the wider applications of biotechnology are buried in the debate surrounding genetically engineered crops. It is also possible that biotechnology may be gaining wide use in other fields that are not part of the current debate.

1.2 Industrial and environmental biotechnology opportunities[1]

Industrial and environmental biotechnology is a broad category of technologies that employ enzymes and microbes in a wide range of industrial and pollution control processes. Industrial biotechnology products and processes are likely to become as ubiquitous as those of the chemical industry today. Some analysts compare the current status of biotechnology to that of chemistry in the 1870s when it had a limited range of applications (e.g. dyes). Today, industrial chemistry is found in the food processing, pharmaceutical, fuel production, textile, fertilizer, water and paper industries, among others. Industrial biotechnology is likely to develop the same way (*The Economist*, 2003).

1.2.1 Industrial enzymes

Enzyme technology is going to play a crucial role in industrial biotechnology. This includes native and genetically enhanced enzymes likely to function in environments previously thought to be hostile, as well as the engineering of new metabolic pathways in organisms to empower them to play a new role. For instance, enzymes have been developed for use in detergents and production of biofuels, vitamins, amino acids and fine chemicals. Novozyme has developed enzymes for use in animal feed, food, textiles, leather, oil/fat and meat processing, among others. It has over 700 products and 100 different types of enzymes and microbes, replacing chemical products that pollute the environment. Similarly, Genencor is developing enzymes with improved performance in detergents and vitamin C, biofuel, sugar and biopolymer production (Reverchon, 2002), while Prodigene is manufacturing TrypZen, a recombinant trypsin used in wound care and food processing.

Such innovations will cut the cost of production, the number of processing steps and energy spent. They are also likely to reduce the cost of investment, environmental

pollution and demand for high-grade feedstock. For example, vitamin B2 chemical synthesis is a complex eight-step process. However, BASF AG's new biotechnology process reduces it to a single step. The biotechnology process reduces overall costs by about 40%, carbon dioxide emissions by 30%, resource consumption by 60% and waste by 95%. Similarly, the antibiotic cephalexin synthesis is also involved a multi-step chemical process but is currently reduced to a mild biotransformation. The biotechnological process uses less energy and input chemicals, is water-based and generates less waste (OECD, 2001).
Some of these enzymes come from organisms that live in hostile environments, organisms generally referred to as extremophiles, such as those found in hotsprings, salty waters and polluted surroundings among others. The organisms survive in these environments because they possess unique enzymes that support live-saving pathways, whereas in such environments most organisms would be killed. The enzymes could be harnessed for industrial use, such as detergents used in detergents, textile industry, pharmaceuticals and bioremediation processes. Firms such as Applied Molecular Evolution, Genencor and Maxygen are interested in extremophiles for their peculiar metabolism and evolution.

1.2.2 Bioplastics

There is significant interest in the production of plastics made from renewable resources because they are biodegradable and thus environmentally friendly. Of the 40 billion tons of global production of plastics, bioplastics accounts for only 500 million tons (roughly 1.25%). If their production costs could be halved, the amount of bioplastics produced in 2010 could be trebled (Reverchon, 2002). The main platforms for bioplastic production include the use of microbes, plants and animals to produce desired plastic polymers, and the use of microbes and/or enzymes to convert carbohydrates and/or proteins into desired plastics (*The Economist*, 2003).

For example, Cargill-Dow Chemical Company employs enzymes to produce Ingeo or Nature Works PLA, a polylactic acid (PLA) product made from glucose. It has commissioned a $300-million plant that can manufacture 140,000 tons of Ingeo, for use mainly in packaging. Similarly, DuPont employs a transgenic bacterium containing biochemical pathways from three different micro-organisms to convert (maize) glucose syrup to 1,3-propandiol, used to manufacture a polyester called Sorona, a copolymer, made from 1, 3-propandiol and terephthalate (oil product).

Some bacteria synthesize and accumulated polyhydroxyalkanoate (PHA), used to make bioplastic, up to 80% of their weight. The firm Metabolix is developing plastics from PHA and has genetically engineered plants to produce PHA. Metabolix planned to start commercial production of PHA by the end of 2003 (*The Economist*, 2003). There is increasing interest in bioplastic production as it is biodegradable and comes from renewable sources. However, the cost of the final products remains higher than equivalents made from fossil fuels.

1.2.3 Biofuels

Although ethanol powered the first car of Henry Ford, very few cars today use ethanol (alcohol). Brazil uses fuel blends with up to 20% of ethanol, while in the United States nearly a tenth of all motor vehicle fuel sold is blended with up to 10% ethanol. Ethanol is produced from cane sugar in Brazil and from maize in the United

States. The US ethanol production is expected to reach 75 billion litres a year by 2020 from the current 9 billion.

In January 2003, Iogen, a Canadian firm, opened a pilot plant that converts straw into ethanol using cellulase. Iogen's main partners and investors in the EcoEthanol project are Shell, Petro-Canada and the Government of Canada (see www. Iogen.ca). Canada intends to quadruplicate its ethanol production, up to 1 billion litres, between 2000 and 2005. While the production, transport and consumption of gasoline generate 11.8 kg of carbon dioxide per gallon (3.8 litres), ethanol generates 7 to 10 kg of carbon dioxide if conventionally produced, and only 0.06 kg if one relies on bioprocesses (Reverchon, 2002).

1.2.4 Bioremediation

Bioremediation refers to techniques that employ living organisms, such as microbes and plants, to extract, eliminate and/or bind toxins in forms that are not harmful to the environment. These include biostimulation, biotransformation, biostabilization and biofiltration. For instance, microalgae are used in ponds to eliminate nitrogen and phosphorous, and aquatic plants (e.g. water lentils) are used to extract heavy metals in industrial effluents. These natural processes have been employed for many years to eliminate pollutants.

Modern biotechnology techniques promise to enhance the performance of these natural processes in pollution control. For example, mercury is a highly toxic metal that accumulates in the food chain when released in water, for example in the Minamata accident, where inhabitants of the Japanese island of Kyushu suffered the toxic effects of fish poisoned by mercury-rich industrial effluents. Since naturally thriving mercury-tolerant bacteria are rare and cannot be grown easily in culture, researchers at Cornell University inserted the metallothionein gene into *Escherichia coli*, which grows well in culture. The genetically engineered bacteria are placed inside a bioreactor that efficiently removes mercury from water. The bacteria are later incinerated and the accumulated mercury is recovered (European Commission, 2002). Existing techniques of mercury removal are expensive and inefficient.

Phytoremediation refers to the use of plants to remove pollutants from water and soils. There are about 1.4 million polluted sites in Western Europe alone. Current techniques are costly and destroy soil structure. The use of plants that can store 10 to 500 more pollutants in their leaves and stems is cheaper and stabilizes the soil structure. Above all, the metals can be recovered from ashes and reused.

There are many hyperaccumulating plants. These plants accumulate lead, zinc, nickel, copper and cobalt, among others, at levels toxic to other plants. For example, *Sebertia acuminata* can contain up to 20% of nickel in its sap (nickel is generally toxic to plants at a concentration of 0.005%). Similarly, the fern *Pteris vittata* accumulates arsenium while conserving a very rapid growth and a high biomass. The firm Edenspace has acquired the commercialization rights of the fern (now called edenfern™) for use in phytoremediation. The potential market for Phytoremediation in the United States alone was estimated at $100 million in 2002 (Tastemain, 2002).

Current research seeks to enhance, through genetic engineering, the ability of plants to accumulate heavy metals. For example, the introduction of two *Escherichia coli*

genes encoding an enzyme involved in transformation of arsenate into arsenite into the genome of *Arabidopsis thaliana* enables the plant to accumulate three to four times more arsenium than the normal plants (Tastemain, 2002). Similarly, tobacco plants with bacterial genes that control the synthesis of an enzyme-detoxifying trinitrotoluene, TNT, have been developed. Such initiatives could improve bioremediation processes through the introduction of genes controlling specific degradation pathways.

1.2.5 Biofertilizers and Biopesticides

Nitrogen supply is a key limiting ingredient in crop production in many African countries. It is often not available and/or beyond the reach of many poor farmers, especially those in rural areas. However, biological nitrogen fixation (BNF), the fixing of atmospheric nitrogen by microbes and making it available to plants, could be harnessed to improve the soil fertility and productivity of crops (Mekonnen et al., 2002). These microorganisms are often referred to as biofertilizers. However, biofertilizers also include microorganisms that solubilize phosphorus to make it available for plants (Garg et al., 2001).

Many microorganisms have the ability to fix nitrogen. These include *Azospirillum, Azotobacter, Rhizobium, Sesbania*, algae and *Mycorrhizae*, while *P. striata*, and *B. megaterium* and *Aspergillus* are among other microorganisms that solubilize phosphorus. In return, the plant provides these organisms with a favourable habitat and a carbon source in a symbiotic relationship. It is this relationship that is critical in seeking to broaden the use of biofertilizers in association with many food crops.

Biofertilizers have been used in Kenya, the United Republic of Tanzania, Zambia and Zimbabwe (Juma and Konde, 2002). They are easily produced locally and the technology needed to produce them is not complex. In some countries, the demand has often outstripped production of the pilot plants. Expansion of these pilot plants could help improve food productivity in Africa.

The use of biopesticides in the control of pests is well established. For example, sterile tsetse flies (the vector of sleeping sickness) were used to control and eliminate the tsetse fly population on the island of Zanzibar. Similarly, the cassava mealybug, *Phenacoccus manihoti*, was effectively controlled using a wasp, *Apoanagyrus lopezi*, from Latin America, and this work was awarded the World Food Prize. The bacteria *Bacillus thuringiensis* (Bt) has been used by farmers to control worms and insects for many years. Nematodes, bacteria, fungi and viruses may be used to control industrial, home and farm pests.

On a large scale, the use of biopesticides has remained small, representing only a small fraction of the global $8 billion pesticide market. *Bacillus thuringiensis (Bt)* alone accounts for 90% of the $160 million biopesticides market (Jarvis, 2000). The biopesticide market is driven by consumer, retail and government demands for reduction in use of chemical fertilizer use. The limiting factors include lack of spectrum (few targets), slow killing rate, batch variations, high sensitivity (to soil types, chemicals, temperature and moisture content) and low stability (short shelf-life and high storage needs).

Biofertilizers and biopesticides present developing countries with an excellent opportunity to enhance their crop yields. Countries such as Bangladesh, Brazil, Kenya, the United Republic of Tanzania, Zimbabwe and Zambia have had successful pilot plants for the production of biofertilizers, and demand has often exceeded production. Biopesticides, too, could help increase crop yield, reduce import bills and increase export earnings. Taken together, they could provide an affordable source of agricultural inputs, especially in rural areas where chemical inputs are unavailable or resource-poor farmers cannot afford them.

1.2.6 Other sectors

Other industries such as mining are already benefiting from biotechnology. Bioleaching is a common technology in developing countries' mines. The small mining sector, often targeting small mineral deposits, could use bioleaching technology to improve the quality of the final products and reduce waste associated with mechanical cracking. In other cases, amethyst, agate, diamond and gold mining still use harmful chemicals. Finding biotechnological solutions will increase the value and earnings from this sector, as well as reduce environmental degradation.

The leather and textiles industries have been among the major environmental polluting industries. The use of enzymes will reduce industrial discharge through recycling of water, cut down the electrical and water bills and improve the quality of the final products. Plants need not be rebuilt, but simple adjustments and replacement of harsh chemicals with biological systems are sufficient. With minor additions, enzymes and microbes could easily be produced locally. With a reduced clean-up bill, increased earnings and turnover, the industry will be set to become competitive.

Paper production plants in some developing countries have either been closed or are uncompetitive. However, biotechnology presents this sector with many advantages that were never available before. The use of microbes and enzymes could replace chemicals, resulting in water and heat savings and improved quality of paper. Genetic engineering may produce designer wood that will grow faster and, when processed, require few steps, resulting in extra savings and improved quality of paper. Many of the paper manufacturing plants that are currently uncompetitive could soon become exporters of paper.

The most promising areas for many developing countries will lie in approaches that add more value to their raw materials. For example, technologies that will convert cassava into export products (e.g. plastics, sweeteners or fibres) will empower many poor farmers who currently do not have an international market for their products. These fibres or polymers will be used to generate bags, plates and other utensils that have a higher value than the raw materials. Biotechnology could present a means by which to indirectly market products that are currently difficult to sell. With a market for tubers, their production could exceed that of cereals in no time, in many developing countries.

Another promising application for developing countries lies in the conversion of waste into useful products. Specifically, food waste may be broken down into amino acids, fuels and fertilizers that would benefit the rural and urban poor. Unlike the pharmaceutical industry, many developing countries could easily enter this market.

The use of microbes and enzymes will be key in this revolution, and developing countries need to seize the opportunities.

Many developing countries aspire to industrialization. The desire to migrate from raw material exports to processed products and increase their share of international trade provides the driving force. The ability to export finished products is partly dependent on technologies used, which may determine the quality of the products. Trade incentives such as the US Africa Growth and Opportunity Act of April 2000 should provide a basis for facilitating the transition towards industrial processing. Asia and Latin America have fast-growing and robust textile industries, partly because there is a ready market for the products.

Biotechnology promised to cut the costs of investments while improving the quality of products. It also promised to provide flexible processing and manufacturing platforms that could easily be modified and adapted. In addition, it was going to reduce industrial stockfeed quality demands, waste production, energy, water and use of hazardous materials in production among others. In addition, the demand to meet market needs should force these countries, some with emerging and others with already growing markets, to seek alternative technologies. Industrial biotechnology is likely to play an important role.

1.3 Agricultural and food biotechnology

1.3.1 Overview of agricultural biotechnology

Plant biotechnology includes microbiology (e.g. biopesticides and biofertilizers), tissue culture (e.g. the clonal multiplication and production of planting material), marker-assisted breeding and disease identification and genetic engineering (e.g. the transfer of genes for one organism to the other, and deactivating or activating gene expression). The *in vitro* (in the flask) growth of plant tissues and/or organs, followed by the clonal multiplication of the relevant plants to supply genetically identical and disease-free planting materials (referred to as tissue culture) to farmers, horticulturists, forest-tree growers and nurseries, is by far the most widely adopted biotechnology in developing countries.

For example, tissue culture has been used in oil-palm in Malaysia, Côte d'Ivoire and Indonesia, banana and plantain in Central Africa and Latin America, tubers and root crops (e.g. cassava in sub-Saharan Africa), tobacco, legumes, fruit trees, and many flower species and varieties in Colombia, and roses in Ecuador and Zambia. Tissue culture could be enhanced by advanced biotechnology techniques.

All the organisms used in agriculture and animal husbandry nowadays are the products of genetic modification for over 10,000 years through domestication, selection and artificial breeding methods aimed at generating plants and animals with improved performance. Tools such as artificial hybridization and forced mutagenesis have led to several crop plant varieties and animal breeds that may not have existed in nature. For example, the current commercial wheat is a product of at least 11 different varieties.

However, exchange of genes between biologically unrelated organisms does not occur in nature. Genetic engineering techniques permit selected genes to be moved

between two or more organisms, even across different kingdoms (e.g. plants and animals), to generate transgenics or genetically engineered organisms. Some examples of genetic engineering organisms are the incorporation of genes for insecticidal proteins of *Bacillus thuringiensis* (*Bt*) into the genomes of several crop species such as tobacco, maize, potato, rice and cotton, among others; genes for the synthesis of beta-carotene from daffodil and a bacterium into rice ('golden rice'; Ye et al., 2000); genes for human haemoglobin into tobacco plants; genes for human milk proteins into rice; and gene for the hepatitis B surface antigen (HbsAg) into a yeast (*Pichia*).

Few developing countries are able to carry out the whole spectrum of research and development activities leading to the commercialization of genetically engineered organisms. Many countries have limited human resources, institutional capacity, and legal and regulatory regimes to actively pursue research in agricultural biotechnology. However, the economies of many developing countries still largely depend on agriculture (for food supply, export and employment) and do not have or have very small subsidies from government. Their farmers are facing the following challenges to:

- Increase their production productivity and competitiveness at national, regional and international levels (within the framework of fair trade regulations);

- Protect environment and biological diversity, while reducing agricultural inputs (water, fertilizers and biocides), improve soil fertility and conservation (e.g. biological nitrogen fixation), and increase nitrogen and phosphorus absorption by crops;

- Diversify agri-food production so as to meet the changing needs of the consumers and food industry.

Advanced agricultural biotechnology can contribute to meeting these challenges. Current genetic modification (engineering) has provided protection against herbicides (for easy management of weeds) and some pests or both herbicides and pests. Work is ongoing to protect plants against devastating insect, viruses, bacterial and fungal diseases as well as drought, cold, and salt levels. In addition, food crops with improved nutritional or health values are being designed. Biotechnology has to help, especially resource poor farmers, to produce more food in a sustainable way.

The use of all technologies available to enhance food production may have a greater impact than one technology that may not suit different societies. Adoption of any of the biotechnology-related products, if successful, could enhance acceptance of other advanced biotechnology products. Unless producers/farmers see the benefits of the new technologies in terms of increased yields, the productivity of crops and animals and profitability adoption will be met with scepticism.

1.4 Health-related biotechnology opportunities

This is a field that has received significant attention from industry, government and international bodies. It is also the area where biotechnology has made significant inroads both in developed and in developing countries. The field, with the exception of animal cloning and stem cell research, is generally less controversial. For these

reasons, this report will not duplicate what is already known but will focus on the benefits of biotechnology for poorer nations.

Developing countries, most of which are in the tropics, have a high disease burden. Some of the major health diseases include malaria and tuberculosis, which spread fast in countries with poor housing and sanitation, as well as HIV/AIDS. The economic development of nations, where millions of able-bodied people spend a significant proportion of their time bedridden while thousands more die from preventable and treatable diseases, is likely to be compromised.

There are few alternative drugs for some of the most devastating diseases (e.g. malaria) in poor countries as the economic cost of producing drugs may exceed the proceeds from their sales. Some of the biotechnology platforms promise to cut down the cost of drug development. Currently, the rate at which disease-causing organisms are developing resistance to the few available drugs threatens to outpace drug development (Newton and White, 1999). Biotechnology tools such as genomics promise to increase the pace of target molecule validation, which will in turn shorten the time required to develop a number of drugs for the same disease.

1.4.1 Antibacterial compounds

There are over 5,000 antibiotic substances known today, with global production in excess of 30,000 tons and a total market value of $24 billion (European Commission, 2002). Bacterial resistance to antibiotics has increased mainly due to increased use/abuse and similarities in antibiotic properties and structure, which lead to cross-resistance. This raises the cost of health care. In the United States alone, antibiotic-resistant bacteria result in about $4.5 billion extra health care expenses. The search for completely different compounds that attack bacteria through new mechanisms such as fluoroquinolones, quinoprisitin, dalfoprisitn, linezolid, ketolides and glycylcyclines is of great interest. A number of compounds have been found in animals, for example anti-microbial peptides such as magnainin, isolated from frogs.

There is also increased interest in the search for specific genes in the sequenced genomes of major pathogenic bacteria to identify gene(s) coding for key but unique metabolic processes in the pathogenic microorganism. An inhibitor molecule can then be engineered to attack such a process. Experts estimate that bacterial genomics have already given about 500 to 1,000 new broad-spectrum antibacterial targets. In addition, bacteriophages are making a comeback and can be of significant help for a few specific applications (European Commission, 2002).

Another promising approach has been the combining of current antibiotics with compounds, "guardian-angel", that neutralize antibiotic-resistant bacteria. Clavulanic acid is one such compound, although it is ineffective in protecting the cephalosporins, frequently used in hospitals. The beta-lactamase inhibitors already developed have not progressed to clinical use because of their high production cost (European Commission, 2002).

1.4.2 Protein engineering

The modification of the activity of proteins is another research area of interest. For instance, Genencor is designing tumour-destroying proteins as well as proteins that

will prorect the immune system against viruses and cancers, just as vaccines do. Similarly, Maxygen has produced effective versions of interferons alpha and gamma, yet to be tested in people, and is developing proteins that would behave as vaccines against bowel cancer and dengue fever. Others include Viracept, a protease inhibitor for HIV (by Agouron) and Relenza™ (by Biota Holdings), an inhibitor of neuraminidase of the influenza virus (The Economist, 2003).

1.4.3 Genome analysis

There is a strong belief that biotechnology tools, such as genomics, will make a significant impact in the near future (Singer and Daar, 2002). With the human and some animal genomes almost sequenced and tools for analysis of sequences developed, the pace of target evaluation and product/service development is likely to increase. It may soon be possible to treat inheritable diseases by correcting genetic defects (manipulation of the genetic information of the cells in the laboratory, with their subsequent sending back into the patient) and develop personalized treatment regimes (Coutelle and Rodeck, 2002).

The developments in genomics hold a lot of value for health. If genes that enhance resistance to environmental stress and diseases are identified, it will be possible to activate them. Similarly, it is possible, in some cases, to predict the likelihood of populations or individuals succumbing to known diseases, such as cancers, using genetic information (Hsing et al., 2001). This could lead to personalized treatment or designing drugs for populations of known genetic make-up.

1.5 Food - and nutrition - related biotechnology

Food and health have always been closely linked – and not only in popular belief. Both foodstuffs and medicines have the power to heal bodily dysfunctions, while an imbalance can disrupt our well-being. At the very foundation of human health and well-being lies the ecosystem of intestinal microorganisms. This complex microflora, comprising a wide range of different bacterial species, plays several roles: supplying the human host with additional value from foodstuffs; protecting against intestinal infections; and contributing to the development of the immune system.

Many health-improving properties of certain foodstuffs are already well known: dairy products may strengthen the immune system; fruits and vegetables contain vitamins that protect humans against infections; meat and fish deliver proteins important for the growth and development of the young body; fibre-rich foodstuffs are important for the intestinal transport of digested food; and plant hormones have a long-term protective function against cardiac diseases and, probably, cancer (European Commission, 2002).

1.5.1 Nutraceutics

Nutraceutics are functional foodstuffs capable of modifying one or more organic functions favourably, in addition to their nutritional effect. In the 1990s, research on functional foods led to products that were found to be "anti-cholesterol" (oil derived from maize) and "anti-oxidant" (a grapevine synthesizing more resveratrol) among others. For example, David Sinclair and his team at Harvard University indicated in

the journal *Nature* that resveratrol could lengthen the life of a yeast (*Sacharomyces*) cell by 80% by activating enzymes that prevent cancer, stave off cell death and boost cellular repair systems. This naturally occurring molecule builds up in undernourished animals and plants attacked by fungi.

The world market for nutraceutics was estimated to be about $14 billion in 1997 and with a growth rate of about 20% per annum, according to Arthur D. Little. Larger firms such as Novartis AG, Danone, Unilever, Nestlé and Campbell, Monsanto Co., Johnson & Johnson and Dupont Co., are all are focusing on this growing market with various products. For example, Nestlé launched a bottle of milk containing fatty acids "omega 3 and 6" as prevention of coronary diseases, Unilever commercialized a "hypocholesterol" margarine, which helps prevent the accumulation of "bad" cholesterol, and others such as Campbell, Kellogg's and Quaker have developed soups, beverages and cereals, which can help digestion, prevent cardio-vascular diseases and hypertension.

Nutraceutics are driven by consumer demand for healthier products. For example, Danone launched Actimel in 1995 as a small bottle corresponding to an individual dose. By 1999, more than 600 million bottles had been sold worldwide. In France, Actimel was dubbed the "morning health gesture". Therefore, food firms are using biotechnology techniques to help them capitalize on emerging demands by consumers concerned about the quality of food and its impact on health. This is important especially in rich countries where many consumers take a lot of vitamin pills and other food additives to correct the deficiencies of an unbalanced diet. Genetic engineering could be useful for producing food ingredients deprived of some undesirable elements or enriched with healthy substances to qualify as nutraceutics.

1.5.2 Probiotics and prebiotics

Probiotics are microbial food additives or ingredients that restore a good balance of beneficial microbial flora in the gut. They consist mainly of lactic acid bacteria, bifidobacteria and yeasts. They have health-promoting impacts in the oral cavity, stomach, small and large intestine, and the vagina. Prebiotics, unlike probiotics, are non-digestible carbohydrates such as fructo- and galacto-oligosaccharides that exert health-promoting effects by improving the characteristics of intestinal flora. Prebiotics, like dietary fibres, act as anti-constipation, faecal bulking and pH-reducing ingredients. However, their major mechanism lies in their support of probiotics.

The European Commission's cluster on Proeuhealth research is studying gastro-intestinal-tract functionality and human health. The cluster aims to provide:

- A clearer understanding of the relationship between food and intestinal bacteria, and human health and disease;
- New molecular research tools for studying the composition and activity of intestinal microbiota;
- New therapeutic and prophylactic treatments for intestinal infections, chronic intestinal diseases and for healthy ageing;
- A molecular understanding of immune modulation by probiotic bacteria and examination of probiotics as vaccine-delivery vehicles;
- Process formulation technologies for enhanced probiotic stability and

functionality;
- Commercial opportunities for the food and pharmaceutical industries.

For example, lactobacilli (bacteria) are known to affect immunomodulation and were reported to reduce the risk of STD infections, including HIV, in women. Increased understanding of the molecular factors of these organisms contributing health effects could allow the selection of probiotic strains, with enhanced protective or therapeutic effects. Delivering the health benefits of probiotics and prebiotics to consumers depends essentially on their successful processing, viability, stability and functionality, as well as on storage. European researchers are exploring optimal process and formulation technologies for use in processing probiotics (European Commission, 2002).

1.6 Emerging trends in biotechnology

1.6.1 Biopharming

Biopharming refers to the production of pharmacological products in genetically engineered plants. By 2003, about 300 trials of crops genetically engineered to produce various therapeutic products were initiated. These include modified tobacco plants that produce Interleukin-10 for the treatment of Crohn's disease, GM potatoes that produce antibodies for reducing the risk of rejection in kidney transplants, GM tobacco that produces vaccines against hepatitis B and drugs against HIV/AIDS, and potatoes that produce human insulin. Other GM plant-produced substances include enkephalins, alpha-interferon, serum albumin and glucocerebrosidase. Clinical trials have begun on crop-grown drugs to treat cystic fibrosis, non-Hodgkin's lymphoma and hepatitis B (*The Economist*, 2003).

Various firms and research centres such as SemBioSys Genetics, Inc., Canada, Planet Biotechnology, Inc., United States and ProdiGene, Inc., United States, have demonstrated the effectiveness of plants as bioreactors (Langridge, 2000; Larrick (et al., 2000). For example, mice fed on potatoes expressing the beta-subunit of cholera toxin (CTB) were resistant to the cholera toxin (Langridge, 2000). Given that CTB gives greater protection against cholera to humans than to mice, one expects higher levels of protection in human. Others include transgenic tomatoes containing a gene from *Escherichia coli* that can protect against diarrhoeal diseases (Lemonick, 2003). Several laboratories around the world are working on their own versions of plant-derived vaccines, using tomatoes, bananas and potatoes among other crops.

Biopharming is mainly driven by a cost advantage. For example, medicinal products could be synthesized in plants at less than one tenth of the cost of conventionally manufactured drugs and vaccines. By the end of the current decade, biopharmaceuticals are projected to grow into a $20 billion industry. It could ultimately bring down the cost of treating some diseases (Roosevelt, 2003).

Animals, too, have been engineered to produce materials for pharmaceutical and industrial use. Once manufacturing biopharmaceuticals in animals becomes efficient, the flow of more than a hundred protein-based drugs currently in advanced phases of clinical trials and many more that are in development in the laboratory would increase. For example, GTC Biotherapeutics, United States, has successfully engineered goats to produce 14 varieties of therapeutic protein in their milk. Creating

a flock of transgenic goats costs about $100 million, a third of the cost of building a protein-production facility. In addition, when a drug maker needs to double production, the solution is to breed more animals, instead of spending $300 million on a new factory. This could decrease the cost of purified therapeutic protein from $150 to between $1 and $2 a gram (*The Economist*, 2003).

Chickens have the advantages of multiplying and maturing early while the desired proteins can be recovered from their eggs. In addition, egg white is an ideal storage medium for compounds. In July 2002, TranXenoGen, United States, announced that it had produced two antibodies (one human and one murine) in the albumens of transgenic chickens. TranXenoGen also aims to produce transgenic chickens whose eggs will contain insulin and human serum albumin (*The Economist*, 2003).

1.6.2 Food taste modification

The use of salt and sugar/sweeteners in food is generally intended to mask the poor taste of some foods. For example, grapefruit juice will not be sweet without added sugar and potato chips will not be flavourful without added salt. The search is on for molecules capable of tricking the taste buds on the tongue. For example, the compound adenosine 5'-monophosphate (AMP), which occurs naturally (e.g. in human breast milk), blocks acidic tastes. When AMP is added to certain foodstuffs, such as coffee and citrus juice, it prevents some of the acidic tastes from being felt by the tongue (Day, 2003). Such activities could have applications in medicine manufacturing as well.

Several food firms, such as Coca-Cola Co., Kraft Foods and Solae, are interest in food flavour and have major deals with research firms involved in tricking the receptors on the tongue by accentuating or blocking certain elements in the food (Day, 2003).

This is useful since processed foods, such as canned soups, sauces and snacks, contain large amounts of salt to mask the bitter tastes, and soft drinks are sweetened to tone down the bitter taste of caffeine. Health and nutrition concerns, fuelled by reports on obesity, diabetes, cardio-vascular diseases and hypertension, are driving the current interest in molecules that could trick the taste buds (Day, 2003).

Linguagen Corp. has discovered about 20 compounds that block bitter tastes and has been granted patents to use four of the compounds as bitter blockers. Since humans have more than 30 different bitter taste receptors, finding a universal bitter blocker is nearly impossible. Linguagen Corp. is also trying to discover and market a natural sweetener to replace artificial ones such as aspartame or saccharine, which often leave a bitter aftertaste. The company plans to license bitter blockers in food, beverage and medicine manufacturers in the United States by early 2004 (Day, 2003). Other research firms, such as Senomyx, are also developing molecules that block bitterness and unpleasant smells and increase the salty taste.

1.6.3 Health and national security

The development of "smart plants" (plants that can detect and/or remove toxins and pollutants) is very important, especially in improving environment, enhancing health and promoting national security. In combination with bioremediation uses, "smart

plants" could detect heavy metals, microorganisms and other environmental changes. Such plants could be used in phytoremediation, while at the same time monitoring the changes in quantities or presence of toxins or pollutants.

For example, Aresao Biodetection (www.aresa.dk/), a biotechnology company in Demark, has genetically engineered Thale cress (*Arabidopsis thaliana*) for the detection of landmines and/or explosives. The plant changes colour from green to red when it comes into contact with explosive materials. The company is also developing plants for detection of heavy metals.

Biometrics, the automated methods of recognizing a person on the basis of physical features such as face, fingerprints, hand, iris and voice, is already being deployed to enhance the identification and verification of individuals. For example, Iridian Technologies's 'iris recognition technology' is already being used at some airports and borders for identification and verification of persons. It is more accurate, faster and easy to use than standard methods.

Recently, Harvard University researchers (20 January 2004) announced the production of "Pocket", a portable, battery-operated protein analyzer that may cost only $45 commercially. It could be used in immune assay experiments to detect several diseases, including HIV. Similarly, Lawrence Livermore National Laboratories announce the production of a portable DNA analyzer for detection of infectious agents. Many of such tools are likely to reach the market in the near future and reduce the costs of equipping, maintaining and running diagnostic laboratories in developing countries and improve health.

For example, Integrated Nanotechnologies LLC has developed a DNA analyzer to detect a host of infectious organisms, including anthrax and SARS. The analyzer is self-contained and does not require operator adjustments between tests, thus making it easier to run. A lighter and commercial version is expected for release this year (2004). Although designed for bioterrorism in developed countries, the analyzer is a useful tool for developing countries too as it could cut down reagent needs and overcome current lack of trained personnel.

Scientist at Purdue University announced (12 February 2004) the development of a chip-sized version of a common detector used to identify proteins, DNA and other molecules. This could radically reduce the size of detection equipment, in a fashion similar to that in which the move from separate transistors to integrated circuitry changed to the size and power of computers and similar equipment.[1]

It is expected that in a decade or two, scientists will have invented tools that can analyse a human genome in a day and make it possible to profile entire populations. For example, the Affymetrix GeneChip array may measure the activities of thousands of genes simultaneously. Cloning, especially of animals, may soon become a routine practice of some laboratories. For example, Aegen Bioscience, has developed a cloning chip that could denucleate, one of the first hurdles in cloning, more than a hundred cells at once.

[1] http://news.uns.purdue.edu/html4ever/2004/040212.Sands.detector.html

Many other efforts are already taking place in various research centres. The Massachusetts Institute of Technology (MIT) has produced a 'biorubber' that could be used safely in engineering heart valves, blood vessels, livers and other elastic body tissues. A collaborative team has produced a 'biogel' that may change its characteristics in response to stimulus, a property that makes the biogel a candidate for construction of controlled drug delivery devices and similar tools.

At the Department of Experimental Surgery at Berlin's Charité Hospital, scientists have developed a small bioreactor containing a matrix of hundreds of membranes, within they have coaxed human adult liver stem-cells to grow into complex living tissue remarkably like a healthy liver. When the researchers feed a patient's blood through the bioreactor, the cultured liver cells take over all the normal, healthy functions of the patient's own diseased organ. The bioreactors are being use in clinics in Berlin and Barcelona to save the lives of patients whose own livers have stopped functioning but whose donor organs have not yet arrived. Others are targeting the liver's regenerative capacity in order to make many transplants unnecessary in the future by hooking patients up to the reactor so their own livers can take time off and recuperate. Research is underway at the University of Pittsburgh to use the tissue-culture techniques developed for the bioreactor to induce the body to grow new liver tissue on its own.

The future trends in biotechnology are likely to be influenced by advances in the other technological fields. Some of the technologies that will make great impressions on biotechnology research and development may include information and communication technologies, materials technology, cognitive technology and nanotechnology (see table I.1**).** The convergence of any of these or all of these and other fields with biotechnology is likely to spin off new technologies that will make a huge impact on industrial competitiveness and quality of life.

Table I.1 The possible impact of technology convergence by 2015

		Biotechnology	**Material technology**	**Nano-technology**
Biotechnology	**Genetics** ***Genetically modified foods*** Customized foods/for different climates	Improved nutrition, health and environment	Improved health	Positive energy effects and health needs assessments
	Computational biology Drug testing simulations- ***Biopharma shifts; custom drugs and diagnostics***	Industry Dev., reduced cost, time and custom-designed drugs	Health data on chips	Health
	Biomedical engineering *Minimally invasive surgery; artificial tissues/organs, neural prosthetics* *Health/life expectance/costs*	Lower costs/time, increased life expectancy	Facilitating	Facilitating
	Tissue engineering *Artificial heart tissue,* *Treat heart attacks with generated tissues*	Improved health	Eliminating premature deaths	
	Smart materials Personal ID/database, ***Instant secure ID/Data***	Security (biometrics)	Instant remote purchasing	Facilitating

	Agile manufacturing *Global business enterprise (consumer-direct order-deliver/maintain/track)* ***Power of business NGOs in above***		Consumer power, Government control	
Nanotechnology	**Smart system-on-a-chip** ***Micro-locator tag with communication*** *Enabled persistence surveillance/logistics*			Industrial efficiency, Privacy barriers
	Nano-instrumentation Bio-measurements/genetic ***Timely health information***			Preventive medicine
	Molecular manufacturing Calalytic air nanoscrubber; molecular-scale for removal of CO, CO_2 at source Decrease in environmental effects of fossil fuel use			

Source: Anton, P.S. et al. (2001).

Materials technology and nanotechnology are enabling the development of smarter, smaller, productive, efficient, durable, multi-purpose and user-friendly materials. Such materials will enable the construction of tiny devices that could be embedded in animal or plant tissue for controlled drug delivery, monitoring tissue activity, performance and location of the organism.

Genomics may enable individuals to predict the chances of catching a given disease, physical appearance and, perhaps, levels of intelligence. Similarly, the ability to produce replacement organs and better delivery and diagnostic systems will improve health. Taken together, these technologies will enable production of materials that will interact (identify, communicate, analyse and protect) with the user. Taken together, they will affect many industries (see table I.2 for some examples)

1.7 The implications for developing countries

Developing countries face a daunting, but not impossible, task in becoming real players in the new technology-driven economy. The greatest challenge lies, firstly, in amassing sufficient human capital capable of sustaining scientific enterprise, secondly, the political will and management foresight required to harness the developing technologies and, thirdly, having the ability to seek unique but efficient research, development, production and marketing strategies. Similarly, the legal and regulatory regimes that would promote technology development and safeguard the public interest have to be set up and cultivated.

These technological advances will bring new opportunities, benefits and risks, just like the current technologies. They may help increase the life span and the quality of life. For example, ailing organs that shorten life could be replaced and diagnostic systems could be improved, be accessible and available. It will also be possible to stop some infection by blocking mechanisms by which disease-causing agents enter the body, proliferate and colonize body tissues.

These opportunities are unlikely to be evenly distributed but will have a positive impact on all. For example, vaccines could be administered as a single treatment through the use of drug delivery devices, cutting down the need for two to four visits to clinics to get boosters. Combined with increased information availability,

reduction in cost, complexity and energy needs of diagnostic systems, even village clinics may benefit.

However, it is also important to address the policy issues related to these technologies as they develop. For example, human cloning is one subject where the rights, ownership and integration of clones in human society remain controversial and unresolved. Similarly, the rights, choice, incentives and selection of surrogate mothers that would carry these clones may be controversial too.

As tools get smaller, smarter, more productive and efficient, the mass education of entire populations will assume new proportions. Knowledge will be easy to access, systems easy to configure and produce. Consequently, the responsibility of individuals will increase. Similarly, the chance of abuse of any of these technology platforms will increase proportionately. By the same token the security of individuals will increase as detection tools and protective materials become cheaper. Managing the benefits and risk of technology will be part of the future governance challenges.

Table I.2 Some of the future technologies and their benefits

Technology	**Purpose**	**Firms involved**
Biofuels	To provide alternative fuels and energy from biomass	Cargill-Dow, Iogen (Canada)
Biosensors	To locate and monitor the molecular and human/animal activities/position	Biacore, Digital Angel, Oxford Biosensors, Sensatex
Bionics	Produce devices for neural transmission and stimulation, and functional artificial body parts	Advanced Bionics, Bionic Technologies, Oplobionics Corp
Cognitronics	Develop communication platforms between intelligent being and machine (e.g. robots and computers)	Bionic Technologies, Iguana Robotics, Neural Signals
Combinatory Chemistry	Develop platforms for quick evaluation of drug/vaccine target and possible allergens	Aurora Biosciences, Bioanalytical, Genetech, Symyx
Molecular farming	Provide smart and precise tools for molecular design, production and manipulation	Molecular Nanosystem, Nanowave, Zyvex
Stem cell (cloning)	To clone animals and organs/tissue from the person/patient's own cells	Advanced Cell Technology, Biotransplant, Geron,
Genomic	Profiling individuals based on their genetic materials; its analysis for the development of vaccines, drugs and diagnostic systems; and prediction of developing known conditions; silence or activate genetic information	Celera Genomics Incyte Genomics DeCode Genetics

Box I.1 Empowerment of old technologies by new advances: The case of conventionally bred fruits and vegetables, Syngenta, United States

Syngenta, a major biotechnology company, has produced a variety of fruits and vegetables produced using conventional biotechnology techniques. The company has produced watermelons that are consistently sweet, with a distinct shape and colour. These varieties are seedless, have a thin red layer inside and a thin coat outside, leaving very little inedible parts.

The company has also bred other crops such as tomatoes and cantaloupes that are selected on outstanding shape, colour, taste and size. The company has, in partnership with three other firms, established a marketing network called NewProduce Network to distribute and sell its products. Consumers are paying roughly threefold per kilogram the cost of the large watermelon for Syngenta's new products. The success of the new products may see the release of new fruits and vegetables with fancy attributes.

Syngenta is one of the major crop biotechnology companies formed following the merger of the crop sciences units of AstraZeneca and Norvatis in 2000. The company has sequenced the *japonica* rice variety and is the third largest seed supplier.

Syngenta has used the advances in genomics and other biotechnology tools to improve the quality of its fruits and vegetables. This enables it to avoid the debate over GMOs in the fruit and vegetable lines. In addition, the knowledge from genomics may have also helped the production of herbicides and pesticides to protect maize, rice, vegetables and fruits.

It is reasonable to argue that as new technologies come along, some of the older technologies become more efficient and useful than before. As in this case, conventional breeding has yielded high-value products by employing advanced knowledge. Developing countries may not have the capacity to operate at the frontiers of technology but could empower older technologies using new technologies.

1.7 Conclusion

Greater technology transfer and innovation in biotechnology will be determined by the policies adopted concerning products and services derived from biological processes. For example, the rate of adoption of transgenic maize by exporting countries is affected by national and international policies as well as by market opportunities and public attitudes.[2]

One of the controversies in the biotechnology debate involves access to new technologies. Many countries and institutions are questioning the extent to which biological materials could be protected by international property regimes. There is a growing realism that if the intellectual property regimes are not harmonized, trade in biotechnology products and innovations will be affected. A strict patent regime may hinder research and development while lack of protection will inhibit investments in research and development. Developing countries will have to work with developed

countries to create equitable distribution and access to biological materials and innovations.

Agenda 21, especially chapter 16, recognizes the importance of investment in biotechnology capacity-building. Despite this pledge that world leaders made, very few countries have invested adequately in biotechnology. The levels of manpower, institutional strengths and regulatory regimes in many developing countries are below expectation. Increased efforts on the part of developing countriess and assistance on the part of developed countries are necessary if the promises of biotechnology are to be realized.

The current trade arrangements that are characterized by quota allocations, tariff escalations and phytosanitary and non-phytosanitary conditions discourage developing countries from being more than exporters of raw materials. Biotechnology products may be in the semi-processed or processed category. They may also face similar trade barriers. These and other barriers prevent investments in research and development by Governments, firms and institutions.

The tragic events of 11 September 2001 in the United States bring new challenges that may have been taken for granted. Bioterrorism, if not properly handled, could emerge as another barrier to technology transfer. Countries with advanced technologies may be less willing to provide the knowledge to countries whose capacity to manage and monitor its use is weak. Therefore, countries must take deliberate steps to build in-house capacity to manage and develop biotechnology. There will be nothing more dangerous to world peace than having countries whose backyards could be used, without their knowledge due to lack of monitoring capacity, to manufacture deadly agents.

Biotechnology has to address, alongside other tools, the demands of the 800 million people in developing countries who are chronically malnourished and the 2.5 billion people who lack adequate sanitation. It should help halt the loss of 90,000 km^2 of forest lost annually and industrial waste that is fuelling climate change. When political will is cultivated, institutions strengthened, science foundations established and financial support systems developed, biotechnology could start to deliver on its promises.

The regulatory regimes, the financial resources and management systems favourable to biotechnology may have to be strengthened in developing and developed countries. National policies are likely to influence technology transfer using market controls or imposition of standards that are too high to meet.

The global governance regime will determine the pace of technology advance and turnover. If the private sector is stifled by regulations and policies that are not technology-sensitive, such as withdrawal of public funding to cloning and use of stem cells research, the pace of change will be slow. This is because government funding is needed for research activities at public research institutions and in industry. Secondly, laws that ban the use of given materials will halt advances even in private institutions. Thirdly, private interest will be stifled if commercialization of innovations in a given discipline is not allowed. Similarly, the lack of protection of innovations could reduce private investment in research and development activities.

Therefore, developed countries carry a higher responsibility in ensuring that the global governance regime of biotechnology is responsive to the needs of inventors and flexible to encourage transfer and diffusion in developing countries. This is a role that they do not seem to have played very well so far as evidenced by the number of case studies in this report.

Developed countries are major donors to developing countries. It is in their own self-interest to ensure that the huge markets of developing countries are graduated to the high-end consumers of products from advanced technologies. It is also in their own self-interest to include science and technology in technical cooperation agreements and project funding.

If developed countries could harmonize their policies with respect to advances and regulation of biotechnology products and services, poor nations will find it easier to develop their own regulatory regime. If the current disagreements over transgenic plants spill over to the future biotechnology products, developing countries will lose.[16]

Chapter II
Building capacity for national biotechnology development

2.1 Capacity-building: Determining the needs

The scientific foundation upon which biotechnology industry development flourishes has to be solid. Therefore, assessing and building strong scientific and entrepreneurial bases may be important. Above all, technology is a product of humans, and innovations are driven by many factors such as passion, profits and excellence. The lessons from developing countries and countries with economies in transition that have built significant capacity in biotechnology could help guide other countries to model their industrial development accordingly to meet their unique needs and status.

This chapter seeks to identify factors that could help biotechnology to develop nationally. Unless the basic structures needed to harness this collection of powerful techniques are available, the promise may take long to come to fruition or may be lost altogether.

It may be useful to bear in mind that developing countries constitute a group of countries at different levels of development. However, it is possible that the basic factors that may determine quick growth of biotechnology in countries at different level of developments may be similar.

2.2 Setting research priorities

Biotechnology is a diverse field in its application and multiplicity of procedures in each given area. Therefore, research priority setting is important though difficult in the face of limited resources and manpower, and overwhelming conflicts of interests. Even when a country chooses to focus on one field, such as biopharmaceuticals, the numbers of medical disorders or illnesses that need attention remain very large.

However, research priority setting gives both a focus and benchmarks to be attained. Countries have used this approach to create institutions whose research area is limited to one crop (e.g. three cassava research centres in Zambia), one animal disease (e.g. trypanosomiasis research facility in Kenya) or one objective (e.g. vaccine production institute in Cuba). This approach increases specialization but often suffers from the inability to benefit from expertise/facilities in other areas if the institute is isolated. A change in the research agenda could also make the centre irrelevant.

The process of research priority setting should be seen to be legitimate and fair (Daniels and Sabin, 1997). Unless the authority under which the research priorities are set is recognized and respected even good intentions will not be realized. Similarly, the research priorities may have to be acceptable if they have to gain

support. More importantly, the goals should seem reasonable and justifiable if the projects will have to be funded.

These values are not necessarily the values of good science and do not ensure success. Often, scientists and their institutions conduct research based on assumptions built on current knowledge. New development could often change the objectives. For example, if vaccine development is the main aim and then promising leads for new drugs development are overlooked, the benefits of an effective drug may be lost if a vaccine is not developed in time. Therefore, priority setting should not supersede the need for flexibility to pursue promising leads. At the same time new development should not overshadow the original goal.

Small biotechnology firms in the United States developed transgenic crops to generate resources to finance development of pharmaceutical products that take a long time to bring to market due to stringent regulatory regimes (Schimmelpfennig et al., 2000). Developing countries could adopt a similar strategy by focusing on biotechnology development niches with significant short-term returns to the national economy. Experience acquired may lead to development of more sophisticated tools, products and services.

Technological niches help those lagging behind to catch up with the leaders, employing a unique strategy. One area where technological niches have been exploited is genomics. Brazil's genomic power has was developed in a short period of time by combining the genomic and information technology to develop virtual genomics institutions. In the three-year life of its centre, Brazil has contributed more than a million human expressed sequence tags (ESTs) and three whole organism genomes; this makes it one of the most productive genome sequencing and analysis centres in the world (see chapter III, development of ONSA).

The biotechnology research priorities of many developing countries do not seem to differ very much in ranking because of the breadth of their goals. For example, most national country reports seem to place agriculture, medical and industrial biotechnology among the top three. Only those that have developed a biotechnology base could be said to have clear priorities. For example, Cuba's biotechnology has a great emphasis on medical applications rather than agriculture or industrial applications. This is in line with the country's emphasis on good health standards for its people. Other areas such as agriculture and fisheries have benefited from Cuba's health biotechnology development. For example, the country has produced transgenic fish and plants.

On the other hand, biotechnology development in Africa and Latin America has a strong bias towards agriculture even when health is ranked very highly. Most of the programmes on capacity building and policy aspirations in these countries seem to target agricultural biotechnology. The research institutions that have acquired significant capacity are agricultural centres.

To illustrate these efforts, we will use country reports prepared for the Commission on Science and Technology for Development to demonstrate how countries or regions have set biotechnology research priorities. We will also demonstrate the relevance of research priorities in meeting national aspirations using different biotechnology tools.

2.2.1 The case of industrial and environmental biotechnology in the Islamic Republic of Iran

Industrial and environmental biotechnology was placed above food and medical biotechnology but below agricultural biotechnology. The Islamic Republic of Iran as an oil producer is likely to derive greater benefits from industrial and environmental biotechnology due to the structure of its economy. The Biotechnology Centre of the Iranian Research Organization for Science and Technology (IROST) has five research areas, of which two focus on application of biotechnology in processing and engineering, and on environmental remediation.

The Environmental Biotechnology Centre has been experimenting with 52 microorganism isolates for desulphurization using the Gibb's assay. A strain designated FMF, a *Rhodococcus*, has been found to be useful. It has also been investigating the ability of microorganisms from the Persian Sea to clean up oil spill (biodegradation of oils). Similarly, they have been employing microorganisms (e.g. *Aspergillus niger* and *Bacillus coreas*) to decolorize textile effluent.

The application of biotechnology to industrial processes has received significant attention. The Bioprocess and Bioengineering Unit has developed and installed a distiller that is currently being used at a pilot plant. They also produce bioreactors with 1-20 litres capacity, while a 3000-litres stirred fermentation system has also been developed. Currently, they are developing a mixed vacuum dryer.

The National Research Centre for Genetic Engineering and Biotechnology introduced programmes in plant and industrial biotechnology in 1998. Animal and marine biotechnology programmes were introduced later in 1999. Only medical programmes were introduced earlier (1992).

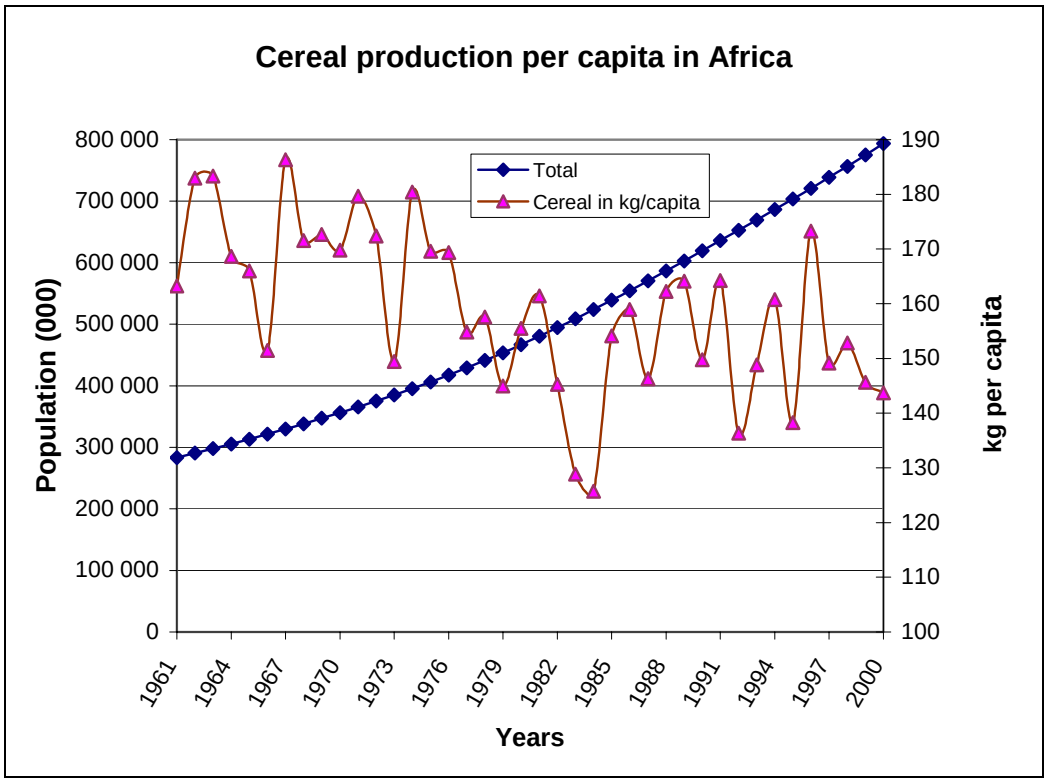
The economy relies heavily on the oil industry, which accounts for more than 85 per cent of its exports. The textile industry has a long history and is probably the second largest contributor to foreign currency (it earned about 2 per cent in 2000). These two industries are also some of the most environmentally unfriendly industries. Therefore, investment in cleaner processing and reclamation of polluted lands is a priority.

In this case, research priorities match national aspirations. The research priorities have been accompanied by a national decision to fund application of biotechnology in these research areas, which has sustained the programmes initiated in different centres and projects run by the Biotechnology Center of IROST. Technologies developed in these areas have been diffused to other sectors as well.

2.2.2 The case of agricultural biotechnology in Eastern and Central Africa

In Africa, agriculture features very high on any development agenda. Almost 50 per cent of the population depends on agriculture for their survival. Unfortunately, the cereal yields are lowest in Africa and arable land is limited. The population of Africa has increased threefold, while cereal production has increased twofold in the last four decades. Consequently, cereal production per capita dropped from 183 kg in 1962 to 143 kg in 2000 (see figure II.1).

Figure II.1. Comparison of cereal production per capita and population growth



Source: FAOSTAT, 2002.

Therefore, African countries have made agricultural biotechnology their top priority. The Eastern and Central African region is composed of Burundi, the Democratic Republic of the Congo, Eritrea, Ethiopia, Kenya, Madagascar, Rwanda, Sudan, the United Republic of Tanzania and Uganda. These countries have formed the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA). ASARECA, in conjunction with the Agricultural Biotechnology Support Project (ABSP) at Michigan State University, commissioned a study that developed a list of agricultural research priorities for the region (Johanson and Ives, 2001) as shown in table II.1.

The country reports seem to point to two factors. Most of the biotechnology research is concentrated in public institutions, and Governments are setting the research agenda. Secondly, most of the biotechnology research efforts have been added to existing institutions except where countries have significant investment resources.

Table II.1. Research priorities in African crops
African crops, current production and research constraints being targeted

Crop	Production (Metric tonnes)	Research priority targets
Maize	18 402 504	Yield, disease, pest, storage, weed

Beans	1 820 271	Disease, pests, N & P deficiency, drought
Sorghum	4 89 409	Weed, genetic base, pest, disease, acid tolerance
Bananas	5 660 575	Pest, diseases, processing, genetic base
Wheat	2 297 345	Yield, disease, soil fertility, weed, drought, tillage
Potatoes	12 080 990	Disease, soil fertility, storage
Coffee, Green	787 378	Soil fertility, disease, pest
Seed Cotton	1 168 853	Disease, pests
Rice, Paddy	3 832 051	Weed, soil fertility, pests, disease
Cassava	45 495 641	Disease, pests

Source: ABSP and FAOSTAT (2002).

The lack of major differences in the research priorities of many countries within given regions gives hope for the development of regional alliances. These have been used successfully in some agricultural, veterinary and medical projects. Therefore, countries with limited financial and human resources could benefit from regional alliances by sharing information, human resources and facilities.

2.3 Health-related biotechnology research priority setting in developing countries

The potential of biotechnology-related tools for improving the health of mankind is high. However, meeting the health needs of the millions of people living in poor nations is a challenge. Many developing countries do not have enough human, financial and institutional resources to compete or meet the investments required in order to participate in biotechnology research. This situation is compounded by the multiplicity of useful biotechnology techniques, the multiplicity of protocols to achieve the same objective and the large number of competing and pressing health problems.

It is important to select the tools that could be used to meet the research priorities. The tools may be selected on the basis of their ability to make a significant difference in improving health, address the most important issues and meet objectives within a realistic time frame (Daar et al., 2002). Technologies may also be selected on the basis of their ability to create new knowledge, economic implications and social acceptability.

In a recent study, scientists ranked different biotechnology techniques on the basis of their ability to meet the needs of the poor in developing countries. Diagnostics, recombinant vaccine and drug/vaccine delivery technologies were ranked among the top three. This presents another method of prioritizing technologies on the basis of immediate and long-term needs and their usefulness. Table II.2 provides a list of the

top 10 biotechnology tools on the basis of their usefulness and likelihood of achieving significant health improvement within 5 to 10 years.

Table II.2. Ranking biotechnologies likely to improve health in developing countries

Rank	Biotechnology technologies	Score
1	Modified molecular diagnostic techniques for infectious diseases	288
2	Technologies for recombinant vaccine development for infectious diseases	262
3	Technologies for drug and vaccine delivery	245
4	Bioremediation to improve environmental quality	193
5	Sequencing pathogen genomes to improve diagnosis/vaccine/drug development	180
6	Women-controlled systems against sexually transmitted diseases	171
7	Bioinformatics for drug target identification	168
8	Nutrient-enriched transgenic plants to counter deficiencies	159
9	Recombinant technology for therapeutic product development	155
10	Combinatory chemistry for drug discovery	129

Source: http://www.utoronto.ca/jcb/

Health-related biotechnology research priorities to be addressed by new developments in genomics were the subject of the Africa Genome Policy Forum (AGPF) held in Nairobi (4-8 March 2002). The forum consists of various representatives of Southern, Western, Eastern and Northern African countries.

The AGPF identified malaria, HIV/AIDS and tuberculosis as the three major research priority diseases to be addressed by genomics. It also identified challenges such capacity-building in research and development, policy development, technology foresight and financial investment. The aim in setting research priority was to help achieve some depth and avoid rediscovery of what is readily available. The recommendations are being pursued through the New African Partnership for Development (NEPAD), the Joint Centre for Bioethics (Toronto University) and African Centre for Technology Studies (ACTS) (ACTS, 2002).

2.4 Assessing national biotechnology capabilities

The protocol requires countries to "take necessary and appropriate legal, administrative and other measures to implement its obligations under [the] Protocol" and "ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity" (see www.biodiv.org/biosafety). The assessment of national capabilities in biotechnology is an important step for developing countries. It has also been performed to fulfil the requirement of the Cartagena Protocol on Biosafety.

The assessment of national capabilities should also help policy makers, funding and investors in mapping out biotechnology development plans. A number of countries have used public institutions, private companies, regional and international centres and combinations of the four to foster biotechnology development. The aim has been to accelerate delivery of products and services to the market place.

2.5 Availability of centres of excellence[3]

There is no one definition of a centre of excellence, but it suffices to describe it as one capable of undertaking and producing comprehensive high-quality research and development activities relevant to its mandate efficiently, effectively and with economic impact. These are often centres with sufficient scientific critical mass, infrastructure, steady or broad-based funding portfolio and skilled managers. Often, they are focused on one or few areas of specialization such as a single problem or technology field and are expected to generate useful solutions. It is therefore conceived that centres of excellence in biotechnology consist of those that conduct research, development and production of innovations as well as contribute to biotechnology industrial development (Araoz, 1996).

In Western Europe, Japan and the United States of America, the mid-1980s saw the emergence of biotechnology programmes to foster national competitiveness in the development and application of technology. These programmes were established and managed in national public agencies responsible for research in agriculture, environment, mining and human health. Cross-sectoral committees were formed to ensure that there was coherence and synergy in national biotechnology activities. Austria, Denmark, United States and Italy were among the first countries to form national biotechnology coordinating committees.

Germany developed the first organized government strategy for biotechnology R&D. Its institutional arrangement is composed of a variety of leading science bodies such as the Max Planck Institutes and Frauenhofer Institutes. The institutions are dedicated to biotechnology research programmes, and some have accumulated considerable technological capabilities in the area. They are major sources of scientific knowledge in various aspects of biotechnology.

Some of the leading university actors in the technology include Michigan State University, Washington University, Harvard University, the University of California and the Massachusetts Institute of Technology (MIT) in the United States of America. In Europe, some of the universities that have established strong scientific research orientation in biotechnology include the University of London, Wageningen

Agricultural University in the Netherlands, Glasgow University in Scotland and the University of Bern and the Swiss Institute of Technology Zurich (ETH) in Switzerland. In Africa, leading universities in biotechnology include the University of Cape Town in South Africa, Cairo University in Egypt and University of Zimbabwe in Zimbabwe. There are, however, many other universities in Africa and around the world that now have a considerable base in biotechnology research. National and international public research organizations are also key players in biotechnology R&D.

There are now a number of international public organizations that have become major actors and sources of knowledge in biotechnology. Some are conduits for the transfer of scientific knowledge and information about biotechnology. The United Nations Educational, Scientific and Cultural Organization (UNESCO), the United Nations Environment Programme (UNEP), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Industrial Development Organization (UNIDO), the World Health Organization and the Food and Agricultural Organization of the United Nations have made significant contributions in the facilitation of transfer of knowledge and information on biotechnology. They facilitated international cooperation and development in biotechnology. For example, UNESCO and UNEP established the international network of microbiological resources centres (MICRENS), which were instrumental in training Third World scientists in microbial aspects associated with biotechnology.

In the 1980s, UNIDO spearheaded the creation of the International Center for Genetic Engineering and Biotechnology (ICGEB) with headquarters in Trieste, Italy. The ICGEB is engaged in building national capacity in industrial, agricultural, pharmaceutical, animal and human health biotechnology. It has now more than 30 affiliated centres around the world, some of which have emerged into centres of excellence.

Many of the above centres are located in developed countries and countries with economies in transition. They highlight the importance of local research capabilities in the development of the local industrial base. In assessing national capabilities, the industrial and financial bases have to be included in order to develop a biotechnology industry.

The changes that have occurred in the biotechnology industry provide lessons for developing countries as well. The earlier acquisition of biotechnology start-up firms by large ones in the 1990s has been followed by mergers and spin-offs of specialized units. A complex network of firms and research institutions has developed, each providing a specialized service leading to increased outsourcing. If those with developed financial bases are abandoning the all-in-one model, developing countries need to re-examine their development models to maximize returns on their meagre national investment.

2.6 Building biotechnology capabilities

Countries aspiring to build a biotechnology industry could draw lessons from countries that have developed a mature biotechnology industry. This section will show the importance of focusing human resource development, providing incentives

for research and development and inclusion of the private sector in developing national strategies.

2.6.1 Human resource development

Human resource availability has been identified as one of the key determinants in biotechnology development. The birth of the US biotechnology industry has been associated with presence of individuals endowed with intellectual capital (Zucker et al., 1994). The abundance of scientists with intellectual capital and the flexibility in interaction between academia and industrial clusters accelerated the growth of the biotechnology sector. The strength of basic research capabilities seems to be a determinant in biotechnology or genetic product design and development (Henderson et al., 1999). Many countries have combined local training programmes with international training opportunities. For example, the Department of Biotechnology in India initiated a programme to train at least 500 graduates a year at post-graduate level in biotechnology (Department of Biotechnology, India, at http://dbtindia.nic.in/).

The economies of many developing countries are dependent on a few industries such as mining and agriculture. This makes investments in biotechnology areas less important and very difficult to acquire. Government funding and attention are often directed to the mainstay of the economy and/or foreign currency earners. Therefore, it may be important to look at the priorities of the Government and tailor programmes towards meeting those needs using biotechnology.

2.6.2 Financing biotechnology development

Developing countries lack mature venture capital markets. Where available, investment in biotechnology is viewed as risky and the opportunities it provides seem unclear, as market sizes are often small. Alternative methods are needed to help finance biotechnology development at all levels.

Investments in research and development activities are very difficult to obtain even in developed countries. Government programmes are usually the main sources of finance for research activities (see table II.3). Many of the poor countries have cut budgets to research institutions and universities. Yet these same institutions are the main source biotechnology invention over the last two decades.

Table II.3 shows that, in the United States of America, the Government is the major funding source for federally funded laboratories (100 per cent), universities and colleges (65 per cent) and non-profit institutions (52 per cent). Industry receives about 32 per cent of federal funds. Although industry's share of the national R&D is the highest (68 per cent), most of its funds are spent within industry (98 per cent). Academic institutions received about 6.4 per cent of their total R&D funding from industry.

Table II.3. The sources of R&D funding and performance in the United States (1993-2000)

(in US $billion)

Funding source / *R&D performers*	Federal	Industry	Universities and colleges	Non-profit And non-federal	Total funding
Federal	19.1				19.1
Industry	22.2	177.6			199.8
Universities and colleges	23.3	2.3	5.8	4.4	35.8
Non-profits	5	1.1		3.6	9.7
Total	69.6	181	5.8	8	264.4

Source: National Science Foundation table 1B, National expenditure for R&D from funding sectors to performing sectors.

Biotechnology activities in a number of developing countries have not yet reached the advanced technology end (such genetic engineering and genomics). However, as table II.4 shows, countries such as Brazil and China have contributed to genome sequencing efforts, while scientists in the Republic of Korea and China are working at cell technology level.

The lack of funding for institutional development (infrastructure and personnel development) remains the main hindrance. To overcome this hurdle, some Governments have formed biotechnology venture capital firms (e.g. Chrysalis Biotechnology and Bioventure in South Africa) or provided direct finances to the institutions (e.g. Republic of Korea and India).

The need to reduce cost for biotechnology development is one that concerns many policy makers. It is difficult and expensive to build one state-of-the-art facility to meet all the biotechnology needs. Countries with limited biotechnology capabilities could use universities and other such centres for research purposes and industrial partners for development, production and marketing requirements as long as regulations clearly stipulate the relationships, benefits and privileges of the various players.

Table II.4. Advances in biotechnology and progress made by selected developing countries

Regional leaders	***Genetic engineering***	***Genomics***	***Cell technology***
Africa	Egypt		
	South Africa		
	Zimbabwe		
Asia	India	India*	
	China	China	China
	Thailand		
	Philippines		
	Republic of Korea		Republic of Korea *
Latin America	Argentina	Argentina*	
	Brazil	Brazil	
	Mexico		

Source: country reports.

*Note*s: * Indicates limited capacity or new entrants. Only countries that have significantly contributed to genome sequencing efforts have been entered under genomic. Those with research at the level of advanced cell manipulation and design are entered in cell technology. The list is not complete; rather, it represents some selected countries that serve as regional leaders.

2.6.3 Managing capacity development

Development of entrepreneurs is equally important in biotechnology. In many developed countries, technology transfer offices are now available in most research facilities operated by universities, non-profit and government-funded institutions. They identify inventions, determine the value, define protection of inventions and suggest alternatives to commercialization. These efforts help to elevate the profiles of the institutions, open up new sources of funding and leverage the institutions' bargaining power.

Some developing countries have developed similar mechanisms in their research centres. Most of the poor nations do not have well-established technology transfer,

management and marketing systems. Biotechnology has, most often, been treated as research tool rather than an industry. Therefore, political leaders do not see biotechnology as another tool in their efforts to industrialize.

2.6.4 Regulatory capacity development

It is important to establish regulatory regimes that are strong, flexible and effective. Regulatory policies are still emerging in all countries irrespective of their levels of economic and scientific development. However, basic regulatory procedures are emerging at national, regional and international levels. These encompass biosafety, intellectual property rights and trade in various biotechnology products.

The biosafety and bioethics regulatory capacity in developing countries is still in its infancy. Weak regulatory regimes may lead to indiscriminate distribution of biotechnology products, while a strict regulatory regime may hinder technology transfer, adoption and development. The Convention on Biological Diversity (CBD) emphasizes the need to balance the risk and benefits of modern biotechnology products and services.

The United Nations Environmental Programme (UNEP) and the Global Environmental Facility (GEF) have developed a biosafety project: the UNEP-GEF Project on Development of National Biosafety Frameworks will benefit over a hundred developing countries. The countries are required to build national biosafety regulations into their national legislations. This will also help bring the Biosafety Protocol into force (see chapter 5).

The development of intellectual property regimes has remained contentious. Many countries are in the process of incorporating or extending patents protection to include living forms. There is a growing recognition of the need to balance protection to encourage innovations, public access to advanced technology and protection to conserve traditional knowledge. Protection of traditional knowledge remains largely undefined.

There may be need for harmonization of local regulations to meet the minimum international norms to enhance trade and development of biotechnology products and services. Countries will need to develop strong and trusted regulatory regimes that are transparent enough to dispel suspicions, especially in the wake of bioterrorism and abuse of intellectual property, be it traditional or modern.

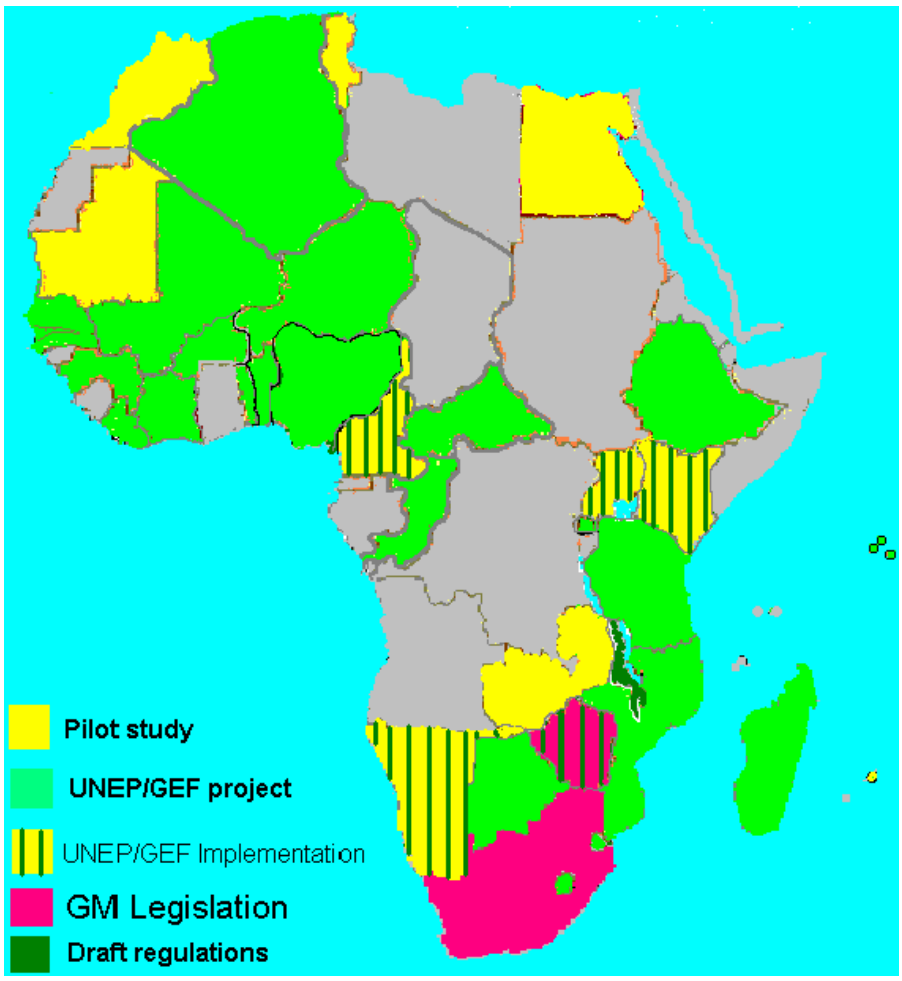
While the IPR regimes may exist both at national and regional levels, biosafety and bioethics have remained at the national level even in developed nations. It is possible for countries to establish a regional biosafety regime to cut the cost of biosafety review processes and development, and concentrate limited human resource and facilities. Such a move may encourage trade in regional biotechnology products and services or those imported into the region.

The safety (or risk) of products and services derived using biotechnology-related techniques has been an issue of great international interest. Biosafety is largely expressed in terms of risk assessment and risk management. The biosafety framework is a set of regulatory instrument(s) designed to promote the safe use, distribution and application of biotechnology methods, products and services aimed

at minimizing the likelihood of causing harm to human, plant, animal and environmental health. At the international level, the biosafety issues are dealt with through the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements of the World Trade Organization (WTO) and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD).

However, for the trade in and use of living transgenic products, the Cartagena Protocol on Biosafety provides general comprehensive guidelines. The Protocol requires member States to establish a biosafety framework or administration. These institutions are charged with the responsibility to monitor the use, generation, movement and release of living transgenic organisms. The review processing body that allows the movement and commercialization of transgenic products needs to be informed, competent, transparent and trustworthy. Figure II.2 gives the biosafety status in Africa.

Figure II.2. Biosafety regulatory status in Africa (2002)



Source: Muffy Koch (2002).

2.7 Development of the biosafety review process in South Africa

The development of a biosafety review body in South Africa provides a good example for other developing countries. South Africa managed a biosafety review process for less than $8,000 per year between 1990 and 1994. The administration did not have a fixed staff or fixed offices but rather voluntary experts contracted by government to review applications. By 1995, the reviewers were paid a fixed fee and a part-time secretariat was established with a budget of $20,000 per annum. Owing to increased applications, a full-time secretariat was established in 1997 with a budget of $40,000 per year. Since 2000, the review process has been carried out through the relevant government departments.

The South African experience showed that if fewer than 50 applications are received per year, a part-time secretariat that opens for business one day per week may suffice. However, if the number exceeds 50, then a full-time secretariat manned by one person is needed. It there are 150 applications per year, three full-time employees are required to run the biosafety review process.

Similarly, the number of individuals in the voluntary scientific committee and voluntary expert team is critical to the proper functioning of the review process. South Africa's part-time secretariat was supported by a 11-member voluntary scientific committee and 56-member voluntary scientific experts to address the different areas of different review processes.

The biosafety review process is a paperwork exercise. The applicant provides all the supporting documents produced by a contractual research unit or by their own laboratories. A stringent and demanding review process can easily bring the cost of the process to almost that of the cost of research and development. Therefore, the biosafety review process has to be fair (without demanding data that current technologies and knowledge may not provide) as it can drastically increase the cost of the final product.

This is very important for developing countries as local research institutions may never afford the high costs needed to generate data required by the review process. It is often forgotten that the products of biotechnology, in addition to meeting the review process, are required to meet the demand of the field within which they fall. For example, transgenic plants will need to meet the Plant Varieties Registration requirement. Secondly, the review process could easily be exploited to lock out the products from poor countries' laboratories where facilities are not developed and budgets limited as well as products from developed countries by requesting evidence of safety beyond that which could be provided by current knowledge. Balancing the need to minimize risks and to enable commercialization of products is central to a successful biosafety review process.

2.8 Technology acquisition and diffusion capacity

Technological development involves three stages. These stages include development of capabilities to operate production efficiently, create new production systems and produce novel products (Dahlman et al., 1985). Technology development also involves application of foreign technologies in production, assimilation of technology by diffusion and adaptation and improvements of the technology by local

experts (Kim, 1980). This suggests that developing countries need to accumulate foreign technology to enhance production and then improve its performance to achieve greater efficiency. Finally, the technology is mastered to enable production of novel technological capabilities.

In a survey (OECD, 2001) firms that had relatively sufficient prior experience or partners with experience in bioprocessing considered a biotechnology route. However, other factors such as product quality, cost effectiveness, number of processing steps, environmental concerns, worker-friendliness and availability of raw materials were often weighed before a decision was made to adopt a biotechnology option. Table II.5 shows some of these aspects.

Table II.5 Summary of main forces for adoption of a biotechnology process by three firms

Company	Hoffmann La-Roche, Germany	DSM, Netherlands	Mitsubishi, Japan
Product	Riboflavin (vitamin B2)	Cephalexin (antibiotic)	Acrylamide
Economic	Increased productivity; 50 per cent reduction in cost	Efficiency and improved quality	Low investment in equipment
Environmental	Reduced emissions	Reduced waste and toxicity	Low energy consumption
Process	1 step instead of 6	4 steps against 10	Simple
Length R&D	7 years	5 years	9 years
Determinant	Science push	Competition	Economic factors

Source: OECD (2001).

Unless industries in developing countries can foresee the benefits associated with the technology and have a solid scientific foundation backing, it is not likely that they will take a biotechnology route. Legal and financial incentives may have to be used to encourage firms to acquire new technologies.

Unlike machines, the purchase of transgenic seeds or recombinant vaccines does not constitute technology transfer per se. It is the acquisition of biotechnological capabilities, such as fermentation technologies, that constitutes technology transfer. These technologies are often proprietary knowledge and constitute competitive advantage. This is the knowledge that firms in developing and developed countries are interested in acquiring.

The ability of nations to build on any of these technologies, if acquired, depends on political will, strength of the scientific foundation and the industrial base. Countries

such as India that already had a relatively strong pharmaceutical manufacturing base could easily reconfigure it to meet the needs of biotechnology production processes. They only need to broaden or streamline their operation, such as production, engineering and marketing structures. For countries without prior experience, new networks will have to be established to reduce uncertainty.

It is evident that building capacity to absorb, diffuse and establish new technologies is complex and expensive. However, there are alternatives to the traditional technology transfer models. The use of public institutions such as universities and research centres to acquire, adapt and diffuse new technologies through the use of interactive teams has played a very important role in development of the biotechnology industry in developed countries. Indeed, the spread of the Internet in poor countries was achieved, to a large extent, using universities (Konde, 2002).

Many universities and research institutions in developed and some developing countries have built incubator facilities and technology transfer offices. Incubator facilities nurture inventions into innovations that could be marketed. Many industries in developing countries do not carry out research and development activities. Such industries are unlikely to acquire new inventions or innovations. Incubator facilities could help bridge this knowledge gap by bringing industry, government and research centres to forge a common front.

The models assume that Governments, industries and research institutions see the benefits of working together. While competition may help innovations by stretching the creativity and imagination of individuals to the limit it could also disrupt alliances, thus increasing the cost of accessing, adapting and diffusing technology. Government may have to create incentives that bring competing members of the innovation system together. These could include tax incentives for industries willing to invest in university research and increased funding for research teams working with the private sector. Such incentives will increase access to technology and promote technology commercialization.

While it is gratifying to note that most of the biotechnology research in developing countries is taking place in universities, it is important to bring the private sector and the government programmes to these research facilities. New approaches to overcome barriers to technology transfer and diffusion could include economic incentives to encourage local private sector participation in biotechnology development and seeking out opportunities for partnerships between the public sector and private sector (both at home and overseas) and ways of utilizing knowledge and skills of nationals based in other countries. India is one country that already uses the above initiative.

Governments could also trade technology for resources and market access in a win-win situation. Agreements with firms exploiting some of the local resources should include local capacity-building local. The technologies in such agreements should be acceptable to both parties. Such agreements do not necessarily need to be within the same field of biotechnology.

2.8.1 International alliances for capacity building

One of the most significant developments in the structure of the global biotechnology industry is the development of networks involving partnering activities (Mytelka, 1999). These networks are products of complex interlinkages between a wide range of enterprises, links which are designed to reduce the risks associated with the development of new products, as well as to facilitate information exchange. More specifically, these partnering arrangements help to provide sources of financing through licensing and upfront fees for R&D expenses, reimbursement of expenses for partnered products and services, royalties, profits and other "success fees" associated with the achievement of certain milestones. Such arrangements are particularly important in areas with limited access to other forms of financing, such as venture capital. Even where venture capital is available, these arrangements still serve an important risk-reducing function.

Partnering activities are naturally more concentrated in the industrialized countries, but these arrangements are being extended to developing countries, especially in agricultural biotechnology. In addition to the risk-reducing benefits outlined above, partnering arrangements could also play a key role in the development of technological capabilities in the firms and institutions in developing countries. 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 as industrial production standards in developing countries.

Developing countries have used different forms of partnerships in trade. Most of the exports and imports, especially in mining, involve a complex of networks of trusted transporters, marketing and sales agents. In biotechnology, especially pharmaceuticals, partnerships in research and development, production, distribution and marketing are emerging in some developing countries.

2.9 Some national efforts to build biotechnology capacity[5]

2.9.1 Biotechnology development in the Republic of Korea

The Republic of Korea's biotechnology initiative dates back to 1982, when the Korea Biotechnology Research Association (KOBRA) was formed by a consortium of private firms. The Government enacted the Korea Biotechnology Promotion Law and created the Korea Research Institute of Bioscience and Biotechnology (KRIBB) in 1983 and 1985, respectively.

The Government of the Republic of Korea has made a steady investment in biotechnology. It increased funding for it, encouraged universities to open biotechnology-related departments and established research institutions. The Government is estimated to have invested $500 million, while the private sector invested an additional $1 billion in the first four years. Recently, the Minister of Science and Technology unveiled a plan to invest about $270 million to support genome research, protein chemistry and bioinformatics (*MOST*, 2001).

The Republic of Korea has established official links and offshore centres with China and the United Kingdom for R&D. The offshore centres are set up to foster collaborative research between institutions and individual scientists. These links also

keep local R&D centres abreast of new developments in biotechnology. Recently, the Republic of Korea has been eyeing the San Diego area to create the "Korea Biovalley". While the first two alliances are for manpower training and scientific advancement, the Korea Biovalley concept is meant to foster technology transfer and marketing opportunities for Korean biotechnology products and services.

The number of biotechnology-related firms stood at 84 with an additional 94 biotechnology ventures in incubator facilities in 1999. The Government has set aside about $380 million to help establish another 600 biotechnology-related ventures by the end of 2003. It intends to invest up to $1.8 billion by 2010 in the biotechnology sector (*M. Webb*, 2002).

The biotechnology sector employs about 8, 485 scientists mainly in universities (50 per cent), government research institutions and private firms. The country adopts focused programmes on manpower training locally and abroad. For example, the Republic of Korea plans to train 13, 000 nanotechnology specialists by 2010 at home and abroad, a field that is likely to benefit biotechnology as well as information and communication technology.

The country envisaged biotechnology as another area of economic competitiveness and growth. The goals of the Government were clearly spelt out in the Korea Biotech 2000 plan of action, which has three main phases and requires a total investment of $15 billion by 2007. The first phase (1994-1997) aimed at acquiring and adapting bioprocessing and improving performance of R&D investment. The second phase (1998-2002) focuses on consolidation of the scientific foundation for development of novel products. The last phase (2003-2007) will target biotechnology market expansion locally and internationally.

Some of the major products include hepatitis B vaccine, which captured (40 per cent of the market), amino acids (20 per cent of the market) and rifamycin (10 per cent of the market). Additionally, the country exports medical diagnostic kits, equipment and drugs. As an added incentive, researchers in government-aided institutions are allowed to establish firms to facilitate smooth transfer of technology or innovations with high tacit knowledge levels.

The Republic of Korea developed a complete biotechnology industry strategy addressing all the core sectors such as human resource, research facilities, financial needs, marketing and management capabilities. It employs national and international resources to catch up. It involves the public and private sector partnerships and helps its local capabilities to access international centres to stay abreast of new developments.

The biotechnology sector imported most of the enabling technologies such as fermentation, vaccine and drug production capabilities and exported 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 who to work with. The plan started with building R&D capacity followed by commercialization and marketing capabilities.

2.9.2 Cuban biotechnology sector

In 1980, a small team of Cuban scientists set out to produce alpha-interferon. 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 centres that specialized in immunology, biomass conversion, animal production and tropical medicine.

There were at least 33 university departments and 210 research institutions employing about 12,000 scientists and 30,000 workers by 2000, respectively, involved in biotechnology. The CIGB alone employed more than 1,200 scientists and technicians in eight divisions and 192 laboratories by 1999 (Schulz, 1999). CIGB is composed of individual quality research units that together form a "centre of excellence".

Cuba's R&D expenditure as a 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 centres have produced at least 160 medical products, 50 enzymes and probes for plant diseases among others (Elderhorst, 1994). 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 rather as the fourth main foreign exchange earner after tourism, tobacco and nickel exports.

Cuba developed a manpower base in medical sciences through training programmes at home and abroad. Since the early 1960s, Cuban students have been learning biochemistry and biomedical sciences at the Centro Nacional de Investigaciones Cientificas (National Center for Scientific Research) at home and at centres in France, Mexico, Japan, Switzerland and the United States. This manpower formed the backbone of the biotechnology industry. Furthermore, the highly educated Cubans, though lowly paid compared to similar people in developed countries, are also highly motivated. The Governments accords them free education and health services, and subsidized food and housing.

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 the Cuban biotechnology is government-managed and driven, it has all the characteristics of a mature privately managed business cluster.

In addition, the Cuban strategy in medical and health-care biotechnology has the following characteristics:

- It is part of the national health-care system;
- It targets the country's health problems;
- It is the result of a national endeavour, with proper human and funding resources;
- It is not funded from outside.

2.9.3 Biotechnology in the People's Republic of China

China has invested in modern biotechnology through the National Natural Science Foundation and the Chinese Foundation for Agricultural Scientific Research. Biotechnology benefited from funding opportunities of the National Programme on High Technology Development and the National Programme on Development of Basic Sciences. Through these efforts, skilled manpower was trained and research facilities were equipped.

It is estimated that about 20,000 research and development staff are working in biotechnology. There are over 300 bioengineering research institutes and 200 modern biomedicine enterprises. There are also over 50 biotechnology research and development companies. About 40 biomedical companies are listed on stock exchanges in the country. The biotechnology sector has been estimated to be growing at over 15 per cent annually.

China is one of the only two developing countries that have contributed to human genome sequencing efforts in a more visible way. The Chinese Human Genome Project located north of Beijing is credited with having contributed 1 per cent of the total human genome by 2000. The Leqing City Government in Zhejiang Province provided 8 million yuan ($1 million) in loans to the centre to aid their Human Genome Project research.[4]

In addition, the Beijing Genomics Institute led the sequencing of the *indica* rice whose draft genome map was published in 2002 (Wade, 2002). The Chinese team identified 92% of the rice genes at 10% of the cost of the international project. China is also part of the International Rice Genome Sequencing Project (IRGSP), an international consortium (China, Japan, Taiwan, Province of Republic of Korea, Thailand, France, Brazil, United Kingdom and United States) led by Japan, which has also been working on the rice genome since 1997 to provide a complete and gap-free rice genome map of *indica* rice. India joined the ten-country international consortium in 2000.

The country has produced cloned goats and at least 47 transgenic plants. Chinese scientists have also successfully cloned genes into pigs, sheep, rabbits and cows. The research and development capacity to use biotechnology to improve resistance, productivity and other performance traits in plants and animals has reached the high end.

The demand for meat products in the country is expected to grow. The country has the largest populations of goats, pigs and sheep in the world. It accounts for 157 million of the global 738 million heads of goats, 133 million of the global 1,056 million heads of sheep and 454 million of the global 923 million heads of pigs.[6] With rising incomes, the demand for meat may outstrip production if farming technologies do not improve. The country has taken the lead in using biotechnology to meet the country's agricultural constraints.

Chinese scientists have been exposed to research and training centres and/or funding opportunities in developed countries through programmes such as the Rockefeller Foundation, the McKnight Foundation and the European Union-China collaboration.

Their participation in global projects such as the Human Genome Project has undoubtedly contributed to their developmental efforts in biotechnology.

The European Union-China collaboration has provided unique training opportunities, while the Australia-China tie has been useful in the development of technology for transgenic animals production. For example, Dong Wu BioTeck Farm and Melbourne University agreed to jointly develop genetic techniques such as cell engineering, stem cell cloning and genetic transfer to generate cloned livestock for commercial purposes.

About 242 research institutions were privatized between 1998 and 99 and a number of non-profit research institutions have been reorganized since 2000 with the aim of redefining the research and development strategy. Sub-contracting of research activity has since been developed. The National Academy of Science remains the highest research organization, accommodating about 110 research institutes, 68,000 researchers and 17,000 graduate students, with an annual budget of $600 million.

Therefore, it is important to note the emphasis placed on human resource development, the existence of a critical mass of researchers and the support given by the Government. Currently, developments in nanotechnology have attracted interest from at least 50 universities, 30 institutes and 300 enterprises. These efforts are receiving support from the Ministry of Science and Technology, the National Committee for Development and Technology, the Ministry of Education and the Chinese Academy of Science.

The major government ministries involved in biotechnology promotion include the Ministry of Science and Technology, the Ministry of Agriculture and the Ministry of Health among others. The Chinese Academies of Sciences, the National Committee for Development and Technology and national research institutions play an important role in the development of biotechnology.

2.9.4 Pakistan's biotechnology development strategy

The Government of Pakistan has steadily supported modern biotechnology since 1981 when the Nuclear Institute for Agriculture and Biotechnology held the first course in recombinant DNA technology. The course led to the creation of the Centre of Excellence in Molecular Biology. Since then many other biotechnology institutes have been established and post-graduate courses initiated.

Despite resource constraints, the Government encourages cutting-edge research in biotechnology and provides adequate funding to a number of biotechnology institutes to undertake major projects, particularly with regard to transgenic plants, microbial fermentation, conversion of biomass for production of fuel, diagnostic and drug/vaccine development. By 2000, Pakistan scientists had developed transgenic cotton, rice and chickpeas varieties that are resistant to pests and viruses, and tolerant of high salt concentrations.

To encourage further research and development, the Government through the Ministry of Science and Technology has approved a Rs. 38 million ($643,000) grant for biotechnology research. The project will consider programmes that focus on enhancing biotechnology development and commercialization of biotechnology

products. It will target agriculture, health, industry and environment-related technologies. It also seeks to bring industry, research centres and government together.

International funding sources have also played a major role in the development of biotechnology in Pakistan. It is estimated that countries of the Organisation for Economic Co-operation and Development (OECD) have contributed at least $260 million since 1985 toward biotechnology-related projects. It is estimated that $140 million has been spent on crop improvement research.

2.9.5 Biotechnology in Romania

Modern biotechnology became part of the Romania scientific and technological processes in 1989. The Ministry of Research and Technology promoted and supported the development of biotechnology programmes in universities and research centres. In 1998, the Ministry was replaced by the National Agency for Science, Technology and Innovation (ANSTI) as the central agency for the promotion and development of research activities.

To create a critical mass required to undertake research and development activities, universities created biotechnology-related programmes and departments. Similarly, the national institutes affiliated to the Romanian Academy of Science, the Romanian Academy of Medical Sciences and the Academy of Agricultural and Forestry incorporated biotechnology in their research and development programme.

Romania is also a founding member of the International Centre for Genetic Engineering and Biotechnology (ICGEB). The country has benefited from research and training offered by ICGEB-related laboratories. Furthermore, in September 1999, the Romanian Government developed a regulatory project and directives on research, development, testing, utilization and commercialization of transgenic organisms. The project also offers a legal framework for scientific activities, ensures safety and encourages the use of biotechnology products in conformity with the decision of the Administrative Council of the United Nations Environment Programme.

2.9.6 Biotechnology development in Sri Lanka

The country has built significant biotechnology capacity in the areas of fermentation technology and tissue culture. However, human resources and research capacity in molecular biology in universities and research institutes are limited. The Asian Development Bank (ADB) has recently provided funding (soft loan) for capacity-building targeting education in biotechnology. These funds are being used to build infrastructure in universities and for overseas training of teaching staff for local universities.

The country has also benefited from the International Science Programme (ISP) of Uppsala University to train some of its biotechnologists. The programme supports students who spend part of their research time at home and part at Uppsala University in Sweden. The country has no legislation on biosafety and no legal control over the import of genetically modified materials or the introduction of biotechnology in agriculture.

The national universities have established excellent facilities for post-graduate research programmes. Most of these activities focus on development of molecular genetic-based diagnostic systems for various diseases. There are also facilities for crop research, mainly in national crop research institutes and university departments. However, the country still faces financial limitations to meet the demand of biotechnology development.

2.9.7 United Republic of Tanzania's biotechnology initiative

The United Republic of Tanzania is an agricultural country. Sisal accounted for 27 per cent of export earning in 1958, 29 per cent in 1961 and dropped 12 per cent by 1975. However, agricultural products have always accounted for more than 60 per cent of total export earnings. Currently, about 78 per cent of the 36 million people depend on agriculture. Therefore, the agricultural sector plays an important role in the development and welfare of Tanzanians.

The United Republic of Tanzania established the Sokoine University of Agriculture in 1984 to produce skilled manpower, conduct research, and provide extension services and commercially useful solutions to the agricultural sector. The University started with three related faculties; Agriculture, Forestry and Veterinary Medicine and two Institutes: the Institute of Continuing Education and the Institute for Development Studies.

The United Republic of Tanzania was one of the countries that were interested in biofertilizers. The Food and Agriculture Organization of the United Nations (FAO) supported a project to identify better strains of *Rhizobia* and established a small fermenter for inoculant production at the University of Dar es Salaam. The University of Nijmegen in the Netherlands helped to train manpower needed for the production of biofertilizers.

Sokoine University of Agriculture developed a commercial biofertilizer production unit for inoculation of soya beans with *Rhizobium strains*. The production of biofertilizers was below the demand for inoculated soybeans planting materials. Although the Government provided some funding ($5,000), it was well below the requirements of distribution and marketing. This hampered extension services, which are vital for the researchers to help farmers use the new technologies and increase awareness of the project.

The country is also part of the Bioearn Project (www.bio-earn.org; an East African Regional Network in collaboration with Sweden that is providing training in molecular genetic tools and other biotechnology related fields). Through this project, the Mikocheni Agricultural Research Institute and the University of Dar-es Salaam are collaborating with the Swedish University of Agricultural Sciences, the Royal Institute of Technology and Lund University on agricultural, industrial and environmental biotechnology as well as biosafety. Most of these collaborations are providing technical and training at post-graduate level.

Sokoine University of Agriculture collaborates with the International Livestock Research Institute (ILRI), a member of the Consultative Group of International Agricultural Research (CGIAR), to develop genetic markers for various livestock

conditions. These include disease diagnostic tools, parasite identification methods and disease-resistant markers.

Despite the introduction of biotechnology-related fields in universities, there is no real government commitment to biotechnology or a specific government programme that seeks to promote biotechnology. Other than institutional initiatives, there is no national funding or programme directed towards the development of a biotechnology industry.

2.10 Conclusion

The lessons revealed by the case studies provide a good basis for countries to formulate national programmes that fit different needs. The Republic of Korea formulates benchmarks by which success is measured. The Government and industry work together in perfect harmony to meet the aspirations of the country.

The Cuban biotechnology strategy is planned and funded by the public sector. Despite the low wages and a relatively small economy, Cuba has developed a vibrant biotechnology industry targeting the health sector. Other sectors have benefited from the success, progress and lessons of the Cuban health-related biotechnology research institutions. After two decades, the benefits of this narrow focus have expanded to agriculture, veterinary and fisheries among others.

The developments that have made the State of Säo Paulo a centre for genomics research present an interesting model that developing countries may find useful. The idea of a network of laboratories working together on different aspects of the same project is not new. However, the incentives that enabled all the laboratories to work efficiently, effectively and productively ensured the success of the project. Without these innovative management systems, the project may have proved expensive and taken a longtime to complete.

Regions that are smaller than Brazil could co-develop such an initiative to complement their limited human, infrastructure and financial resources. The developments in information and communication technologies can enable the formation of a regional biotechnology virtual firm, especially in health-related ventures.

In the United States, the presence of highly trained professionals and good science universities played an important role in the location of the early biotechnology clusters (Zucker et al., 1994). Similarly, some of the successful biotechnology products are associated with good universities. Thus, the strength of basic research capabilities seems to be a determinant in biotechnology product design and development (Henderson et al., 1999). The government has also directly and indirectly funded basic research.

Developing countries such as Brazil, Cuba and India, though using different mechanisms, share many of the aspects of the United States biotechnology development model. They have directly and indirectly funded biotechnology. They have established centres to train manpower and conduct R&D activities. They have built excellent research facilities and established joint ventures with international firms at research and development, manufacturing and marketing levels.

Chapter III
Emerging biotechnology industry

3.1 Biotechnology industries in developing countries

The ability of developing countries to benefit from advances in biotechnology remains controversial. Some believe that biotechnology will not benefit developing countries in any way (Altieri and Rosset, 1999), while others argue that biotechnology will contribute significantly to the development of poor nations (McGloughlin, 1999).

There is evidence that biotechnology capabilities are concentrated in a few countries and that biotechnology remains a research-intensive field. Therefore, developing countries that lack intensive research capabilities are unlikely to be part of this technological revolution. Furthermore, most of the products currently on the market and those in the pipeline are targeting the markets in developed countries and those with economies in transition.

It is also evident that a few developing countries are becoming active participants in the new bioeconomy. These developing countries present beacons of hope from which other countries could tailor their programmes to become participants in the new bioeconomy. At the same time, products that target markets in developed countries may be useful for development just as the mobile phone technology has been widely accepted in poor countries. The extent to which developing countries become participants may depend on their ability to adapt, innovate and use biotechnology products and services safely. It may also be influenced by international regulatory regimes governing biotechnology and the usefulness and applicability of the innovations.

This chapter explores the penetration of biotechnology products in developing countries, other than those of medical and food processing, and emerging biotechnology industries. It also explores the market shares, where possible, of developing countries. Given the extensive studies undertaken in agricultural biotechnology, this chapter addresses mainly industrial biotechnology developments that have largely remained unattended. However, an overview of agricultural biotechnology adaptation in developing countries, due to the central role it is likely to play in future, is also provided. To achieve some of these objectives, this chapter highlights three case studies.

3.2 Technological innovation trends[8]

The last century saw the replacement of plant-derived products with petroleum derivatives for energy and chemical product generation. These remarkable transformations helped humanity to overcome some of the natural limitations of relying on natural processes. The change was largely a result of advances in chemistry and allied fields. This century promises to open new avenues for increasing the use of renewable resources in the global economy. These trends will open up new opportunities for the participation of developing countries in the new bioeconomy. But as in previous technological revolutions, the promise and reality

are different. In the case of agricultural biotechnology, for example, only a handful of developing countries have so far managed to become players in the global economy. The rest have little hope of playing significant roles in the near future. As in other technological fields, participation in the new bioeconomy will be uneven and limited to those countries that make the necessary investments in technological development.

So far, much of the research on policy aspects of biotechnology has focused on agricultural and pharmaceutical biotechnology. The field of industrial and environmental biotechnology remains understudied. Industrial biotechnology covers two distinct areas. The first area is the use of renewable raw materials (biomass) to replace raw material derived from fossil fuels. The second is the use of biological systems such as cells or enzymes (used as reagents or catalysts) to replace conventional, non-biological methods.

Industrial application of biotechnology is emerging as a spin-off from developments in other fields such as the pharmaceutical sector. This emergence is largely because industrial biotechnology has not received the same level of public policy attention, as has biotechnology in other sectors. There are other structural factors that influence the diffusion of industrial biotechnology. These include the dominance of physical and chemical technology as a source of concepts for the design of industrial plants that are important in introducing biological processes.

One of the main advantages of industrial biotechnology is the prospect for the controlled production of biological catalysts. These biocatalysts are more specific and selective than their non-biological counterparts. As a result, they offer greater potential for cleaner industrial production. In other words, biocatalysts generate fewer by-products and can start with relatively less purified feedstock. And because they are self-propagating, they can be used in applications such as waste treatment (OECD, 1998) But despite these advantages, biocatalysts are generally fragile (requiring large amounts of water) and have low volumetric productivity. Over the years, however, incremental technological innovations and new bioreactor designs have helped to improve the industrial performance of biocatalysts. With incremental improvements in biocatalysts and the emergence of new design concepts, biotechnology's capacity to diffuse in the industrial sector will be enhanced. This prospect is enhanced by the growth in the biological sciences, as well as complementary fields such as chemistry and informatics.

The use of biomass for energy and industrial uses has been on the agenda of many Governments for nearly two decades. Much of the interest was triggered by the oil crises of the 1970s. Although interest in the field waned with the decline in energy prices, advances in the biological sciences have continued to enhance the prospects for technological improvement and wider application. In addition to energy, living plants can be used to produce chemicals such as citric acid, lysine and lactic acid. Genetic modification offers new possibilities for using plants as a source of raw materials for chemicals or even finished products. Monsanto, for example, has experimented with a genetically modified crest plant to produce a biodegradable plastic using a gene from a bacterium, *Ralstonia eutropha*. Similar experiments are underway in other chemical firms around the world. One of the most advanced efforts is an initiative by Cargill Dow Polymers (CCDP) to construct a plant to

produce 140,000 tons a year of polylactide (a biodegradable plastic) using lactic acid fermented from corn.

As enzyme technology improves, attention is shifting to other areas of bioprocessing by tapping the potential in the world's wealth of microbial life. Much of this world remains untapped largely because microorganisms have so far been poorly studied and documented. With the advent of DNA sequencing, microorganisms will become an important addition to industrial activities through scientists' discovery of new biocatalysts. The field of genomics is therefore likely to extend its influence from medicine and agriculture to industrial production. Methods such as forced evolution and rational design will increasingly be used to discover new enzymes for industrial use. In addition, methods such as gene shuffling are helping firms to optimize their bioprocessing activities.

It is expected that the genomes of major industrial microorganisms will be sequenced in the coming years, and this will add significantly to the library of industrial biotechnology. Prospecting for biological organisms of industrial value will increase as bioprocessing gains acceptance. The network of agreements between bioprospecting firms, such as Diversa, and biotechnology-related firms such as Dow, Aventis, Glaxo, and Syngenta, illustrates the growing interest in this field. These technological developments will result in new generations of chemicals and polymers that will compete directly with bulk petro-chemical products.

These developments are improvements over a long history of efforts to use bioprocessing in industry. The mining sector, for example, has been using bioprocessing for a long time. Bioleaching is a natural process that helps in weathering of sulphide ores. Organisms have been harnessed successfully in zinc, copper, nickel and gold mining among others. Bioleaching is environmentally friendly, less costly to build and cheaper to run than traditional leaching methods.[7] The use of *Thiobacillus ferrooxidans* to oxidize sulphide metal ores dates back several centuries. But it was not until 1986 that the world's first commercial bioleaching tank for gold-bearing sulphide was commissioned in South Africa by Gencor. The procedure now employs both mesophilic and thermophilic microorganisms.

Developing countries have been the centre of origin for some of the bioleaching technologies. For example, the Biox process owned and developed in South Africa is now used in many other countries, while the success of the largest experimental solvent extraction electro-wining (SXEW) in Zambia has been used in 40 other mines in developed countries. Current efforts are focusing on identifying new organisms that are stable, multiply efficiently and are reliable. Other initiatives focus on identifying organisms for different processes such as reduction of iron and sulphates, as well as those that can be used to dissolve toxic metals in mine waste discharge. Technology is also being developed to inhibit organisms that are involved in mine acid generation. Biofilters for sulphides represent an effective and inexpensive alternative to traditional filters.

The textile and leather industry is another sector that has used biotechnology for decades, especially through the use of enzymes. Firms such as Maps (India), Novozyme (Denmark) and Genencor (United States) are marketing many enzymatic products (amylases, lipases, cellulases, isomerases and extremophiles). Genetic

probes have been developed that could detect adulteration of the merchandise and deterioration of fibre. There is now a movement towards preparation of high-quality fibre from microorganisms, plants and animals, using genetic engineering technology.

The demand for high-quality leather and fibres is likely to increase. Developing countries could add value to their raw materials and meet demands by adopting the new technologies in their processes. The leather and textile industry is faltering or dying in some countries, owing to the poor quality of products and increased costs of production. Biotechnology, if used appropriately, could lower the cost of production and improve the quality of leather and textile products.

The paper industry is another old technology that relies heavily on wood, energy, water and chemicals. New technologies have emerged that are changing the face of this industry. The pulp and paper industry was estimated in 2000 to be the fastest growing market for industrial enzymes. Enzymes are quickly replacing traditional chemicals in pulping, in paper production and in de-inking recycled paper. Biopulping (using fungi) results in a nearly 30 per cent saving of electricity, while treatment with cellulase and hemicellulase reduces wood-drying time considerably. Bioleaching of pulp reduces chemical requirements by 50 per cent. The use of enzymes and fungi increases the physical properties of the fibres and the quality of paper. Many developing countries have lagged behind in technological developments in paper manufacturing and have become importers of paper, even when they have the potential to be exporters.

In addition to industrial applications, modern biotechnology also is likely to make major inroads into the field of environmental management. Using microorganisms or their products, environmental biotechnology involves processes that detoxify industrial waste, clean up industrial contaminants and enhance control of environmentally unfriendly practices. Environmental management is indeed a growing industry that will benefit from further advances in biotechnology. The use of sensors to detect acidity, electricity, ionic strength, heat, light and smoke, among others, has been the basis of many analytical and home instruments. The selectivity of enzymes, other proteins, nucleic acids and carbohydrates has become the focus of research to identify noxious gases in mines and organisms in the environment.

3.3 Participation of developing countries in the bioeconomy

There is no single characterization of the biotechnology industry in developing countries. What is evident, though, is the growing importance of international partnerships and alliances in biotechnology's evolution in developing countries. Such alliances are likely to increase with time. These alliances also serve a larger function: they provide a basis for the kinds of partnerships that are essential for a market inclusion model to function.

The absence of open markets for technology makes technology acquisition difficult. For example, vaccine and drug discovery technologies may not be easy to acquire, as there is not one such technology on the market. However, those that have built significant technological capability (human and facilities) may be seen as denying those that do not have similar capacity the benefits of new advances and could easily become a source of resistance.

Thus, formation of partnerships between those that have the capacity and those that do not may be essential for the effective commercialization of biotechnology products (Juma and Konde, 2002). A winner-take-all scenario that was tried in the field of agricultural biotechnology is slowly giving way to opportunities that explore new models of international cooperation. So far, much of the public debate on this issue has tended to focus on the importance of partnerships between the private and public sectors. While these linkages are important, they are not a substitute for international alliances, under which the private sector plays a critical role in the commercialization of new products.

3.4 Biotechnology commercialization in developing countries

Biotechnology in developing countries has been promoted through government programmes. However, biotechnology research and development are mainly in the hands of private firms in developed countries. Unless developing countries are able to induce private sector participation in biotechnology, alliances between private firms from developed countries and public or private institutions in the developing countries will be viewed with suspicion.

Table III.1 shows that private sector biotechnology development in some developing countries is picking up in all the regions, although it remains small. The table compares the concentration of research centres, where applicable, with the number of companies. It is important to note that there are a significant number of biotechnology companies that conduct applied research and/or have an in-house research unit and also that the table does not, in any way, indicate collaboration between private and public institutions as such data are not available.

Table III.1. The number of biotechnology companies, research institutions and industrial associations in selected regions and countries

Region/country	Companies	Research institutions	Industrial associations
Africa	43	41	1
Argentina	50	20	1
Australia	190	35	1
Brazil	35	>35	1
Canada	361	30	10
China	20	2	1
India	500	90	1
European Union	1500	>1000	19
Japan	400		1
Mexico	90	30	1
United States of America	1457	NA	37

Source: Biotechnology Industrial Organization and Ernst and Young, 2002.

Developing countries are slowly but steadily adopting transgenic products. The number of countries growing transgenic crops has grown from 3 in 1996 to 8 in 2001. Similarly, the area planted with transgenic crops in developing countries has grown from 1.3 million hectares to 14 million hectares over the last 6 years.

Argentina accounts for about 80 per cent of the acreage in developing countries and the People's Republic of China has recorded significant threefold growth in acreage in 2001. Table III.2 summarizes the adoption of genetically modified crops by developing countries.

Table III.2 Commercialization of transgenic crops in developing countries

The growth in area (in millions of hectares) planted with transgenic crops in developing countries between 1996 and 2001 is shown below.

Country	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**
Argentina	0.1	1.4	4.3	6.7	10.0	11.8
Bulgaria					<0.1	<0.1
China	1.1	1.8		0.3	0.5	1.5
Indonesia						<0.1
Mexico	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Romania				<0.1	<0.1	<0.1
South Africa			<0.1	0.1	0.2	0.2
Uruguay					<0.1	<0.1
Total	***1.3***	***3.3***	***4.5***	***7.3***	***11.1***	***14***

Source: International Service for the Acquisition of Agri-biotech Applications (ISAAA), global reviews from 1996 to 2001.

Plants are at the centre stage of the modern biotechnology revolution for production of pharmaceuticals, fine chemicals, industrial enzymes and other products that are not necessarily food or feed (Doran, 2000). Unfortunately, the role of plant biotechnology as a source of renewable fuels, degradable plastics, rubbers, adhesives and other products derived from fossil fuels, in addition to industrial and food products, is buried in the debate over the safety of genetically modified organisms for human health and the environment.

Table III.3 The role of plants in the biotechnology revolution

Industry	**Purpose**
Food	Plants with disease tolerance, stress tolerance, enhanced nutritional quality, improved processing and storage properties e.g. bt-corn, vitamin A enriched rice and flavr savr tomato.

Drugs/vaccines	Plants that could produce human antibodies, antigens and other vaccines/or drugs to lower production, storage and/or distribution costs, minimize transmission of animal diseases and reduce the risk associated with needles. Still at development stages by Agracetus, Prodigene Inc and Croptech Inc. among many others.
Fibers	Plants that could produce fibres with special qualities (e.g. wrinkle-free) and biodegradable plastics (e.g. polyhydroxyalkanoate [PHA] and biopol by Metabolix).
Fuels	Genetically enhanced plants to increase fuels' material yields and improve upstream conversion into biofuel. Studies on *Arabidopsis* population (switchgrass) are on going in various laboratories.
Biosensors	Plants engineered to be sensitive to contaminants, explosives and microorganisms as well as use of cells to detect concentration and texture of substances. Under development are plants to detect landmines, water quantity, petroleum and heavy metals at various laboratories in the US and the EU.
Industrial catalysts and chemicals	Plants that could produce enzymes for industrial processes to lower costs or inbuilt enzymes for upstream processing or elimination of the need to add enzyme(s) (e.g. ongoing research at Pacific Northwest National Laboratory and Prodigene Inc).

Source: Pew (2001) and BIO. (2002).

Some drugs, such as aspirin and menthol, that are currently in use were derived from plants but are synthesized chemically to meet economic and quality considerations. Biotechnology may offer alternative production systems of plant products by either boosting levels of the desired ingredient(s) in the plant or improving the efficient recovery and quality of final product.

This field is still developing and poor countries with excellent growing conditions for tobacco, potatoes and corn, among others may become the future home for biofarming centres. Countries with the capacity to purify, produce and package these products may have an added advantage. The national regulatory regimes and international governance policies of transgenic crops engineered to produce drugs are still developing. The ability of these regulations to enable participation of poor nations will depend upon their flexibility, responsiveness and inclusiveness.

3.5 Examples of biotechnology commercialization efforts in developing countries

3.5.1 Development of Biocon India, India

The importance of international alliances is illustrated by the evolution of Biocon India. The company was established in 1978 in Bangalore as a joint venture between Biocon Biochemicals of Ireland and local interests. The company started with the production of simple fermentation products and later embarked on its own R&D programme that saw it become a major player in the fields of modern biotechnology. The R&D efforts were inspired by the need to diversify the company's product portfolio. One of the first efforts was to develop a local alternative to Konji—a carefully fermented mass of cooked soybean meal and roasted wheat—imported from Japan. This is a good source of amylases and proteases, enzymes crucial in the hydrolysis of carbohydrates and enzymes.

The process was complicated and largely unknown outside Japan. But after three years, Biocon India successfully mastered the techniques, leading to new fermentation platforms and enzymes that matched those from Japan. These successes were also encouraged by Biocon Ireland, which bought products from the company. Biocon India became an owner of new fermentation technologies, and two manufacturing plants were commissioned to meet demand. Following these successes, Biocon India became a supplier of food enzymes to United States and European markets. In addition to enzyme production, the company also invested in the development of new production systems that incorporated the advantages of solid state and submerged fermentation. After five years of effort, the team developed Plafractor, a solid phase fermentation platform with automated and programmable controls, allowing reliability, repeatability and reproducibility. It is also a closed system that protects the operator and the environment from any toxic agents produced during fermentation. Further, it allows the quick and convenient recovery of fermentation products and saves space and labour. The patented bioreactor recently won the 2001 Biotechnology Product and Process Development Award from the Indian Department of Biotechnology in the Ministry of Science and Technology.

The success story of Biocon India is an example of the importance of international partnerships. While Biocon India carried out innovations and production, Biocon Ireland provided the market for its products, enabling the newly formed firm to have a steady flow of income as well as eliminating marketing costs of products. In 1989, Unilever acquired Biocon Ireland and its 30 per cent share in Biocon India. Unilever's financial muscle and global standing gave Biocon new linkages and access to funds. Biocon learned Unilever's global operations, standards and financial methods.

Biocon India has expanded its operations and ventured into fields such as pharmaceutical research. It established Syngene, which in turn spun off Clinigene International as a wholly owned subsidiary. Syngene has close collaborations with AsraZeneca, Glaxo and BMS, which contribute to its research efforts. Clinigene specializes in genomics and clinical studies to support the pharmaceutical section of the Biocon Group. Biocon has thus developed rapidly through strategic partnerships

with end users of its products. Research, to a great extent, has been driven by the demand of its customers, resulting in accumulation of proprietary technology and development of products and processes. This flow of information between producer and end user was an important input in R&D activities.

Biocon India went through a steep learning curve in global management, standards and negotiations. It exploited the chances that were presented to it, through association with global companies, to expand its markets and product range. All these lessons helped the company to consolidate its position, identify funding opportunities and take advantage of market availability. The creation of different units into individual companies spurred their expansion, depth of research and product development. The autonomy enjoyed by the different units soon led to innovations that became the basis of new companies and new associations with other companies outside the group. Biocon India represents one model of biotechnology commercialization that depends largely on international partnerships and alliances. It carries with it the attributes of inclusion that should be encouraged in the development of industrial and environmental biotechnology.

3.5.2 The development of Herber Biotech, Cuba

The case of market inclusion through international alliances is also illustrated by Cuban experiences in biotechnology commercialization. The Center for Genetic Engineering and Biotechnology (CIGB) has about 192 laboratories in total, equipped with the best instruments from countries such as Japan, Germany and Sweden. These facilities produce vaccines for meningitis B and hepatitis B. Vaccines for HIV, haemophilia and cholera are under development. In diagnostics, CIGB has produced analytical systems capable of detecting HIV, hepatitis B, herpes simplex, Chagas, leprosy and other diseases. It has also produced probes for plant diseases, about 50 enzymes (some of which are produced only in Cuba), and 160 medical and pharmaceutical products.

Cuba moved into the commercialization of biotechnology products through the creation of a semi-private enterprise, Herber Biotech. By 1998, Herber Biotech was recording about $290 million in sales of hepatitis B vaccines and its pharmaceuticals in 34 countries. The company also had representatives in about 50 countries. Nationally, biotechnology was placed just behind tourism, nickel production and tobacco in terms of export earnings. The company is extending its partnerships with other developing countries. For example, in 2001, it established a joint venture with Kee Pharmaceuticals of India, in Haryana. This marketing venture is aimed at getting access to the Indian market through special pricing and technology transfer. Some of the company's main products, such as a recombinant of *streptokinas*e called *cardiostrep*, is used for the hydrolysis of coronary clots or prevention of heart attacks and has a potential market value of about $11 million per year. The market value is expected to grow by 30 per cent annually. Other products involved included *interferon* and *human transfer factor*, also owned by Herber Biotech.

Cuba recognizes that participating in the global market involves forging alliances with a wide range of enterprises, especially those that have extensive marketing networks. For this reason, Pfizer, a US-based multinational firm, is marketing some of Herber Biotech's biotechnology products, such as the meningitis B vaccine. Cuba's biotechnology industry is an example of the importance of political

leadership on technological matters, domestic funding for research activities, creation of appropriate research institutions, and international alliances for product commercialization. The future of the Cuban biotechnology programme will depend on the degree to which these elements are maintained, especially in the face of worsening economic conditions that might divert allocation of resources and political commitment to other sectors.

Cuba's success in biotechnology is attributed to the existence of a critical mass of scientists in natural and applied sciences as well as a political commitment to technological innovations. If the United States market opens up to Cuban products and foreign investment in Cuba picks up, then Cuba will reap more benefits than it currently does from its investments in biotechnology over the last two decades. If this happens, cooperation between Cuban scientists and their American counterparts is likely to increase.

3.5.3 Establishment of Electric Genetics, South Africa

The field of genomics also offers opportunities for developing countries to commercialize specialized bioinformatics services. The data derived from genome sequencing activities need to be analysed to determine the functions, activity and regulation of genes and facilitate product development. Traditional methods of test tube analysis of each molecule's chemical, physical and biological properties are laborious and insufficient when faced with thousands of different molecules from various organisms. As a result, firms devoted to bioinformatics are starting to emerge in developing countries. For example, in 1996 Electric Genetics was established in South Africa to commercialize innovations from the South African National Bioinformatics Institute (SANBI). Electric Genetics is housed at SANBI at the Western Cape University and is funded through a national innovation fund aimed at encouraging science, engineering and technology.

The company and its partners, SANBI and Silicon Graphics, have developed two software packages for clustering, alignment and recombination of sequence data. The first programme is a management system for expression variation analysis and transcript reconstruction, while the second is a sequence tag alignment and consensus knowledge database. Leading genomics institutions such as Celera, the Institute for Genomics Research (TIGR), Paracel, Paradigm Genetics and the German Cancer Research Center have used the programmes. In 2000, Electric Genetics won the prestigious Technology Top 100 Award in its category from the South African Ministry of Trade and Industry. The award was a recognition of the company's excellence in development and research, as well as of its ability to commercialize its products internationally. International partnerships have played a key role in the development of the company.

Electric Genetics may be said to be the marketing arm of SANBI. SANBI is part of the Western Cape University. This association with a local university has given it a unique position. SANBI offers post-graduate courses in bioinformatics and has conducted training for medical representatives in Southern and Eastern Africa in conjunction with Tropical Diseases Research (TDR) arm of the World Health Organization (WHO). Electric Genetics may be said to be a spin-off of a university.

3.5.4 Development of the Organization for Nucleotide Sequencing and Analysis, Brazil

Genome sequencing is a highly specialized biotechnology field that has been largely covered by large organizations such as the Institute of Genomic Research (TIGR) and the Sanger Center. Genome sequencing requires a high level of sophistication and organization in the preparation and tracking of samples and analysis of the voluminous genetic data developed.

However, the Organization for Nucleotide Sequencing and Analysis (ONSA) captured the headlines when it announced that it had successfully completed the sequencing of *Xylella fastidiosa,* an organism with a genome size of 2.7 megabases that infects oranges and causes Citrus Variegated Chlorosis, 2 months ahead of time and $2 million within budget. They had, within the same period, built a genomics institution from scratch that was unique: a virtual institute involving some 34 laboratories located in geographically distant places and belonging to different institutions.

When the São Paulo State Research Support Foundation (FAPESP) decided to fund the genome sequencing project, it also wished to expose as many laboratories as possible to the modern biotechnology tools. Plans to create a single centre were rejected. They settled for a virtual institute that was web (Internet) managed. It was also cheaper than building one large concrete block institute. For these reasons, the project is estimated to have trained at least 200 young geneticists.

FAPESP is entitled, by law, to 1 per cent of tax collected by the State of Säo Paulo. Similarly, FAPESP is not allowed to spend more than 5 per cent of its budget on administrative duties. Given the success and independence it has enjoyed over the years, the genome project has provided another opportunity to score a world's first in a unique fashion. Indeed, Brazil became the first country to sequence completely a plant pathogen.

From its budget of $250 million in 1998, FAPESP is estimated to have spent about $45 million since 1997 on the ONSA project. The initial $11.6 million budget helped established two central sequencing laboratories and a bioinformatics unit, while all the other selected laboratories received the necessary equipment. Rather than appoint, the project requested interested laboratories to send in bids upon which selection was based.

The project developed rapidly. The idea of bacterial genome sequencing was put forward in May 1997. By the mid-November, 1997 the project had been announced, the project structure defined, the steering committee formed, the organism chosen and the participating laboratories selected. The first sequence was deposited in March 1998 and the sequence completed in February 2000. The initial success of the project attracted some of the nationals based abroad to return to Brazil.

The choice of the organism was based on its economic importance, industrial interest and size of the genome. The organism causes losses of approximately $100 million to the citrus industry in Säo Paulo. The State of Säo Paulo accounts for about 87 per cent of Brazil's orange production, corresponding to 30 per cent of the world

production. The size of the genome was reasonable and attainable with the limited resources.

The laboratories involved were largely from institutions of higher learning, principally universities and research institutions. Teams within the institutions organized themselves and submitted bids to the project managers. The project managers selected the teams on the basis of the information provided by the bidding laboratories. The project did not involve any significant international collaboration. Above all, it was limited to laboratories within Säo Paulo as FAPESP is a Säo Paulo State initiative and not a Federal Government body.

ONSA and its partners have contributed three genomes to the public genetic databases: *Xanthomonas axonpodis*, *Xanthomonas campestris* and *Xylella fastidiosa*. The level of genome sequencing that the Brazilian team has achieved is unparalleled among developing countries. It has attracted the attention of the United States Department of Agriculture (USDA), which contracted the Brazilian team to sequence a train of *X. fastidiosa*, which afflicts California's grapevines.

The team had a steering committee consisting of three experts from Europe and two from Brazil that also served as an advisory body. The rest of the organizational structure includes a DNA coordinator who was responsible for the distribution of DNA samples (clones) to the sequencing laboratories and two heads for the central sequencing laboratories. The Bioinformatics Centre coordinated the flow, management and analysis of the data. More significantly, the sequencing laboratories were paid on the basis of the quality of sequences generated (ONSA, 2002).

The management of the institute was tailored to encourage 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 period of time. Laboratories that deposited more good-quality sequences got more money. Further, the representatives of the participating laboratories - 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.

The DNA coordinator, the two heads of the central sequencing laboratories and the heads of the bioinformatics centre formed a working executive committee. This team managed the daily activities of the project. The steering committee visited the team once every six months, prepared a report to the funding agency and made relevant recommendations. These measures partly enabled the project to be completed within time and within budget.

In the process they developed their own genome sequencing and analysis methods. For example, they developed a number of bioinformatics tools and a polymerase chain reaction method targeting the amplification of the central portion of expressed genetic material (mRNA) called ORESTES. These tools are now being used in the generation of about one million expressed sequence tags in human genomes cancer research.

Given the success of ONSA, the Ludwig Institute for Cancer Research, an international organization focusing on cancer, chose Brazil as the location for the express identification of genes relevant to cancer. About $15 million was invested in

this project. The project produced over a million human genes sequences which contributed to the overall human genome sequencing effort. The project also generated a unique method that primarily amplified the expressed regions of genes.

The ONSA project spun off two companies called Alellynx Applied Genomics and Scylla Bioinformatics. Alellyx Applied Genomics was founded by molecular biologists and bioinformatics experts that spearheaded the establishment and success of ONSA. It employs sophisticated computational software to analyse and identify important genetic information from genome sequence data. These data are then used to isolate the genes and reinsert them in plants to produce recombinant variants with the desired traits.

The company maintains close ties with other advanced institutions involved in genome sequencing, annotation and analysis. It has access to significant genome databases currently available and will generate extra genomic information where the need arises.

The initial target of the company is to use advanced computational and biological platforms to analyse and alter the genetic material of soybeans, oranges, grapes, eucalyptus and sugarcane. With a focused staff establishment of 40 scientists with years of experience in genome analysis and plant molecular biology, the company has strategically placed itself to be a comprehensive, efficient and productive service provider of genetic material for the agricultural sector. Alellyx has strategic alliances with Sun Microsystems and Applied Biosystems.

Scylla Bioinformatics was a dream that became a reality only after the birth of ONSA. The funding of ONSA enabled the initial interests to be tested in a real and highly demanding environment. Having successfully managed the Bioinformatics needs of ONSA, the Sugarcane and the Human Cancer EST projects, the team of professor and students began considering the formation of a private bioinformatics company.

Scylla Bioinformatics aims to provide high-performance software to research centres, industry and other organizations that employ genetic data. The software developed by Scylla was the soul of the distributed network of ONSA. The company aims to provide tools to both the scientific community and private companies that would like to establish virtual networks similar to ONSA. Scylla also provides bioinformatics integrated software that could be used for reception, clustering, annotation, gene prediction and assembly, as well as tailor-made client specific software for different genomics project needs. The company has formed strategic alliances with Hewlett Packard.

Both companies received venture funding from Votorantim Ventures. Votorantim Ventures is a multi-sector venture fund ($300 million) that specifically invests in information and communication technologies (ICTs) and life sciences.

The success of the ONSA project has not been limited to the State of Säo Paulo alone. In 2000, The Federal Government decided to extend the benefits of genomics research to the rest of Brazil. Approximately 25 laboratories distributed across Brazil were selected to sequence *Chromobacterium violaceum* with a genome size of roughly 4.7 Mb. The organism is abundant in the waters of the Amazon; though

opportunistic, it causes a fatal disease. The organism also produces violacein, a purple colored pigment, with trypanocidal and antibiotic properties as well as molecules that resemble propylene and polyethylene.

This project created the Virtual Institute of Genomic Research and involves selected laboratories across Brazil (with an estimated area of about 8.2 million square kilometres). Similarly, the genome size is larger, almost twofold, than that of *Xylella fastidiosa*. Therefore, it is important to note that there have been increased genome-related research activities in Brazil since the initiation of the ONSA projects beyond the State of Säo Paulo. For example, the Virtual Institute of Genome Research has sequenced *Mycoplasma synoviae,* an organism that infects chicken. In combination with other organisms, it causes fatal respiratory diseases in poultry. Brazil is the second largest producer of poultry, with export earnings of roughly $1.3 billion.

ONSA could be considered to be a centre of excellence with units that are distributed throughout the State. They planned together, and shared human, financial and material resources and management via the web, just like a single institution. More importantly, they shared work rather than just ideas. This case demonstrates a unique model that could be used by other developing countries in areas such as information and communication technologies and biotechnology.

Secondly, virtual research activities are faster to build, and can easily be abandoned, rearranged and recreated to meet new challenges. They expose a large number of centres and professionals to new techniques and quickly concentrate limited expertise. They render geographical isolation irrelevant, foster collaboration and stimulate quality research activities. The individual participating laboratories expand their research activities on the basis of the lessons learned and use the tools acquired to create and attract new partnerships and sources of funding.

3.5.5 Tissue culture in the horticulture industry in Kenya and Zambia

Over the last two decades, a booming vegetables and cut flowers industry has developed on the shores of Lake Naivasha in Kenya. The population has expanded from 50,000 to 250,000, the majority of whom are women who have been drawn by the opportunities to participate in the production of vitroplants and cuttings which feed the booming industry. This is a highly valued horticulture industry that is spurred by simple and efficient biotechnology. The industry earns Kenya $300 million to $500 million a year. Similarly, Zambia has become the third African producer and exporter of cut flowers, just behind Kenya and Zimbabwe, after a five-year growth period. Flower acreage is currently estimated at 135 hectares, most of which is planted with over 40 rose varieties. Zambia exports more than 90% of its flowers to the Netherlands. Tissue culture is also used in banana and cassava production among other crops.

The success of these efforts depends also on the quick movement of produce, and the reduction of market barriers and superfluous regulations. It should also be stressed that workers must obtain a fair return from this booming industry in terms of higher wages and better conditions of life (Cowell, 2003). However, it demonstrates the role that biotechnology is playing in industrial development. Extending these benefits to poor farmers remain a challenge.

3.5.6 The case of Biosidus, Argentina

The pharmaceutical company Sidus invested in medical biotechnology in the early 1980s and created a subsidiary, Bio Sidus, which started producing its first biotechnology-derived product, a recombinant erythropoietin (EPO). The company recruited five academic scientists and inaugurated its pilot plant to produce EPO, and the other products followed. In 1993, BioSidus became financially autonomous. Approximately, $35 million was invested in Bio Sidus. Today, BioSidus has a ten-year business plan and may become a public company to be quoted on the stock exchange.

The company's organization has demonstrated, as in the developed countries, that not only good scientists were needed, but also people specialized in marketing, finance, law and regulation. This combination of competences is the key to successfully transforming research results into a marketable product. BioSidus has been awarded several prizes by both the Government and the industry, as well as by the academic circles, to acknowledge its pioneering efforts and success, despite an unfavorable macroeconomic environment (e.g. the hyperinflation period and the present harsh economic crisis prevailing in the country).

In 2002, the annual turnover of BioSidus reached $45 million, which can be considered a good performance compared with other biotechnology companies across the world that received funding for a decade without generating profit. About 75 researchers are working in the company and collaboration linkages have been set up with research teams out of the company and even abroad. The current objective is to collaborate with other biotechnology companies in Latin America and the Caribbean in order to manufacture and commercialize products that are useful for the region.

In 2003, the chairman of BioSidus, Marcelo Argüelles, set out the targets of the current projects: the production of oral vaccines against cholera and typhoid, gene therapy to cure cancer and angiogenesis, and the development of transgenic farm animals to manufacture recombinant biopharmaceuticals (in addition to the production of EPO and interferons).

In August 2002, BioSidus announced the birth of a cloned calf, and two months later that of three transgenic calves expressing the gene for the human growth hormone. These were the results of six years of work aimed at producing human proteins in the milk of farm animals. By 2004, the company may be able to produce the recombinant substance and to transform it into a biopharmaceutical. It is estimated that with a concentration of 1g of protein per litre of milk, a herd of 20 animals would be sufficient to meet the needs of Latin America (the company nevertheless acknowledges that some transgenic goats could produce up to 12g of protein per litre of milk).

3.6 Conclusion

The three cases clearly demonstrate the importance of international alliances in the development of a biotechnology industry. The presence of entrepreneurial persons played an important role in the development of Biocon India and Electric Genetics. Government programmes equally played an important role in the activities of Herber Biotech and Electric Genetics.

In two cases, national Governments played an important role in the development of the firms. In many developing countries, especially in Africa, donors fund a large

proportion of the total research budget. It will require reorientation by both donor agencies and national governments to meet the challenges of establishing biotechnology firms and helping local firms access partnerships outside their national borders.

Chapter IV
International market opportunities

4.1 Global market for biotechnology products and services

Biotechnology products from developing countries are just beginning to enter the international market. Unless the national and international markets are favourable to these products, the benefits and opportunities of biotechnology will be hampered. Areas of great interest and comparative advantage for developing countries include agriculture, mining and industrial processing of raw materials.

Current international market structures may encourage the export of raw materials while some of the biotechnology products may be in the category of semi-processed and processed classification. They may attract higher tariffs and consequently inhibit the expansion of biotechnology in developing countries.

This chapter addresses the current market structure, and the level of trade and market governance in relation to biotechnology. It also seeks to identify market opportunities for developing countries in areas where biotechnology is likely to make a significant difference. The chapter uses reports prepared by CSTD in conjunction with experts.

4.2 Scope of trade[9]

The evolution of market opportunities for biotechnology is difficult to predict, partly because of the nascent nature of the industry, poor public awareness and a lack of concerted efforts to improve the policy environment for the diffusion of biotechnology products. What is likely to emerge, however, is a scenario dominated by niche markets in a wide range of sub-sectors. Furthermore, the blurring of boundaries between agriculture, health and industry makes it difficult to predict potential areas of market expansion. Even though the life science industries model is currently being questioned, the generic nature of the technology suggests that firms that have established a lead in pharmaceutical or agricultural biotechnology are likely to become equally important players in industrial biotechnology.

However, it is clear that industrial biotechnology has a wide range of starting points, which could lead to expansion. For example, enzymes are estimated to hold a world market value of $1.6 billion, of which North America and Europe account for 35 per cent and 31 per cent, respectively. The share of the enzymes market in the textile and detergents sectors shrank, while that in animal feeds, specialty chemicals and food applications increased at least fivefold, between 1992 and 1998.

Asia has the fastest growing market for feed additives, currently estimated to be over $6 billion globally, followed by Latin America. Amino acids and vitamins account for about $3 billion, digestive enhancers for about $1.3 billion and disease-preventing agents for $480 million. It is estimated that the amino acid and digestive enhancers market will continue to grow. The market for probiotics should continue to grow, following the introduction of legislation in Europe and other countries to prohibit the use of antibiotics in animal feed.

However, it is also important to note that a number of the current biotechnological products are more expensive than their traditional equivalents. Biopesticides are still lagging behind chemical pesticides due to target specificity (which is bad for business, but good for the environment), instability and batch (potency) variation. This makes the marketing and production of biopesticides difficult and their use by farmers, households and industry unattractive. They are estimated to be worth about $380 million (or $74 million without *Bacillus thuringiensis*) out of an estimated $8 billion pesticide market.

Bioplastics and biofuels have been more expensive than traditional plastics and petroleum-derived equivalents in developed countries. Although the gains to the environment, made by the use of these products, are hard to determine, bioplastics and biofuels remain worthwhile areas for development, especially since costs of production are dropping. Bioplastics are now commonly used in hospitals and in home products and disposable utensils. Furthermore, the costs of petroleum products in developing and developed countries are different, which makes them attractive in the former. It is along these lines that genetic engineering may increase the value, but reduce the cost of production of these products.

Table IV.1. Market estimates for selected industrial biotechnology products and services

Product	**Current product (examples)**	**Market ($million)**
Enzymes	Liquefying, proteolytic, maltogenic and isomeric enzymes	1,600
Biopesticides	Nematodes, pheromones, natural products and derivatives, and insects	380[#]
Bioplastics	Hospital fibres, straps, cutlery, straws, belts	135 million MT[x]
Nutraceuticals	Dietary supplements, foods (natural/organic/functional), phyto-pharmaceutical	86,000
Biofuels	Fuel additives, methanol, ethanol	2 billion gallons[*]
Bioreactors	Mining, enzymes	NA

Source: Juma and Konde (2002).

1997; represents 1.4 per cent of the pesticide industry.

*The price range is $1-$2 (United States price levels) with subsidies and represents only ethanol.

The influence or impact of biotechnology on industry is likely to increase over the next years, and it will spread from the farm to the manufacturing sector. As new materials with enhancer properties are discovered, the need for better household, industrial and scientific products will grow. Most of the products we touch, wear and see are already produced, in one way or another, through the use of biotechnology-derived products. The development of modern tools (genetic engineering or recombinant DNA technology) will transform many of these processes and products to higher levels of productivity not yet experienced.

4.3 Market structure

Biotechnology powerhouses in developed countries currently dominate the market. The major chemical, oil, agricultural, food and pharmaceutical firms are also major players in biotechnology, which in itself is good for technological development through increased investments. However, there is limited optimism that these firms, which have not been known to transfer technology to developing countries in the past, are unlikely, this time around, to change their attitudes regarding biotechnology development. The market is heavily dominated by the United States and Europe, which have invested in biotechnology infrastructure, human capital and research activities. Other important players include Canada, Japan, Australia, China, India and Cuba.

These countries have some of the leading R&D centres, producers and exporters of biotechnology products. It is possible to determine where many players are located by identifying the major producers and their major consumers, as well as the markets that they serve. Enzymes and plastics give an indication of biotechnology market shares. Most of the industrial enzymes are produced in Europe and the United States, while most of the plastics are consumed in Asia, followed by North America and Europe. Biotechnology application in industry is following trends similar to those observed in agricultural and pharmaceutical sectors, where the major producers develop solutions that are tailored to meet the needs of their markets. This pattern is reinforced by alliances between technology developers and end-users.

4.4 Improving market access

Market access represents the greatest hurdle to international trade and consequently to technology access and acceptance. Although liberalization of markets has increased over the last 50 years following the numerous trade negotiations and integration of economies, many barriers to trade still exist, especially in labour-intensive sectors that are of interest to developing countries. The two major barriers are high tariffs and standards (sanitary and phytosanitary requirements). Agricultural products and industrial product exports to developed countries suffer most from tariff peaks.[10] The EU and Japan have the highest number of tariff peak products for agricultural imports, while the United States and Japan have a high number for industrial and electronic products imports. These products represent about 15 per cent of the exports of least developed countries to the developed countries.

Other than tariff peaks, these products also suffer from tariff escalation. For example, exports of finished textile and clothing products to Canada attract higher tariff levels than raw materials for the same industry. Other products that suffer from incremental applied tariffs by stage production include leather, rubber, metal, wood and paper. These are all products where developing countries have a particular interest (see table IV.2).

Taken together, tariff peaks and tariff escalations hinder the efforts by developing countries to export finished products, thereby reducing diversification and skills accumulation. Because of high levels of subsidies to agriculture and export products in developed countries, most developing countries continue to be marginalized in international trade.[11] In the absence of open markets, it is not surprising that developing countries do not invest heavily in export industries linked to the

processing of raw materials. It is also important to note that tariff barriers in developing countries (such as high input taxes) and subsidies in developed countries increase the cost of production in developing countries.

Table IV.2. Tariff escalation for developing country exports to industrial countries (shown as imports by developed countries in the table)

	Imports (US$ billion)	Share of each stage per cent
Natural-resource-based		
Raw materials	14.6	44
Semi-processed	13.3	40
Finished products	5.5	17
All industrial products		
Raw materials	36.7	22
Semi-processed	36.5	21
Finished products	96.5	57

Sources: World Bank and International Monetary Fund, Washington, DC.

Non-tariff restrictions such as quota allocation, voluntary export restraints and non-automatic licensing continue to affect exports from developing countries. Products affected by these measures include textile, sugar, rubber, minerals, machinery and precious stones in both developing and developed country markets. There are also fears that once these measures are phased out, they are likely to be replaced by other measures such as anti-dumping or other technical barriers.

The requirement for exporters to meet product standards similar to those found in the importing countries is a critical element in international trade. However, if the exporter's home market standards are different from those of the export market, extra cost has to be incurred to meet the demands. Many developing countries do not have sufficient facilities and personnel to meet industrial market demands. Developing countries often import products that are banned in developed countries, while developed countries are more restrictive when it comes to imports from developing countries. The implications of these restrictive measures and other trade inhibitory mechanisms such as countervailing duties, safeguards, customs and administrative red tape on industrial and environmental biotechnology are potentially large. These measures will affect fields such as polymers, fuels, paints, lubricants, fertilizers, plastics, and many other products.

Market access is an essential element of market liberalization, and special efforts are needed to create better trading opportunities for developing countries. In the absence of such improvements, trust in global markets will remain low, and the mistrust is likely to hinder the wider application of emerging technologies such as industrial processing and environmental management.

4.4.1 Potential market gains

Biofertilizers represent an affordable industry for many developing countries. In many African countries, the use of inorganic fertilizer has increased soil acidity, reducing the yield per ton of fertilizer over time. Biofertilizers are relatively inexpensive to manufacture, suitable for small-scale farmers if produced locally (eliminating distribution costs), and the investment in technology is far lower than that of inorganic fertilizers. Biofertilizers have been produced, packaged and sold commercially in India, while in a number of African and Latin American countries, biofertilizers have been produced at national research centers. Most importantly, the demand for biofertilizers has outstripped production in almost all these countries. It is estimated that about $40,000 to $50,000 is required to build a 100-150 metric ton biofertilizer plant. Alternatively, $500,000 for 10 plants in different locations could produce up to 1000-1500 MT to meet the demand by rural farmers. With increased production capacity, biofertilizers have a market locally and possibly internationally.

The increasing urbanization of most developing countries has caused the emergence of problems often thought of as being “Western” (dental caries, diabetes, obesity, cancers and cardiac diseases). As a result, demand for body and health products is rising. It is a rapidly expanding industry that offers growing prospects for both developed and developing countries. Nutraceuticals already have a big market in developed and developing countries. The demand for natural remedies is likely to increase and present a market for developing countries endowed with wide biodiversity.

The agriculture and food industry in many developing countries is still facing quality-related problems, due to their continued use of chemical preservatives and pesticides that many international markets are unwilling to accept. The use of natural products to inhibit bacteria and fungal growth will improve the acceptability of products. Further, most of the enzymes involved are now easy to prepare locally or could be obtained on the international market at a fair price from different sources. The products to be affected will include fruit and vegetable preparations, fish and meat products and fresh grains (e.g. corn) exports.

Textiles and leather constitute another sector where developing countries could expand their exports using biotechnology. Many of the newly industrialized countries in Asia have already registered a marked increase in textile exports. Biotechnology in these areas has been and continues to be used to increase product quality, reduce waste and save energy. With many of the biotechnology companies moving into developing countries in search of new markets, the use of biotechnology in leather and textiles should increase.

The mining sector is the mainstay of many developing countries and its contribution to the economy is often large. The technology currently on the market has focused on the large mining conglomerates that produce copper, gold, zinc, nickel and other

bulky metals. The semi-precious mining sector (the small mining sector, as it is popularly called) has attracted very little attention from technology developers, despite its importance. For example, Ghana's small mining sector earned approximately $140 million in 1995 (United Nations, 1996). This sector could increase its share of earning, if appropriate technology is developed.

In the future, industrial products such as enzymes, vaccines and some drugs will be produced by plants and animals and will require processing. Developing countries will need to acquire capacity, not only to produce, but also to process products. The international market for industrial enzymes and products is large. It presents an area of interest in which developing countries such as India and China are already involved. For example, the company Maps (India) has registered growth of above 150 per cent per year and is an exporter of industrial enzymes. It should be possible for other developing countries to develop their own industrial products that supply their home industries and compete on the international market.

Integration of the many opportunities to maximize gains and share the risks and benefits of different products is very important. It would be economical to have a milling plant to produce syrup, animal feed, oil, fuel, high protein supplements, flour and fertilizers, among others. The corn refiners in the United States consume about a quarter of the $25 billion corn produce and turn it into syrup, gas (carbon dioxide), alcohol, feed additives and flour. They do not just add value to a product that often remains after exports, but they are a big market for corn. Most of the agricultural programmes in developing countries are affected by lack of a market, and integration could be beneficial. The final products may have an export market.

4.4.2 Potential market losses

The gains outlined above will not occur automatically and evenly. Those firms that invest in biotechnology early enough are the ones that are likely to take advantage of these market opportunities. This may also suggest that large enterprises with an edge in technological innovation stand the best opportunity to make inroads into the emerging markets. But such advances, especially in a world marked by growing industrial inequalities, could trigger market opposition and even resistance to biotechnology. It is therefore important to understand and raise awareness about the market risks posed by the new technologies, in order to appreciate their potential for wider commercialization of biotechnology products.

Market losses are likely to occur in areas where biotechnology products replace conventional sources of raw materials or where chemical processes are replaced by bioprocesses. What is critical is the fact that product substitution is likely to occur. Indeed, the new innovations are expected to have an impact on the composition of products and processes. Equally critical is the design of mechanisms that allow for the wider distribution of benefits and risks. The participation of petro-chemical enterprises in the new technology is essential for the wider diffusion of biotechnology, mainly because perceptions of potential market losses are likely to be high in these sectors.

4.5 Conclusion

The regulation and governance of global markets will dictate the pace of technology diffusion in different areas by developing countries. For example, the market reaction to transgenic foods has undoubtedly influenced the decisions of developing countries to invest in genetic engineering tools as well as commercialization of transgenic food crops. The trend shows that a number of developing nations may be willing to adopt non-food transgenic crops such as transgenic cotton.

Many of the biotechnology products may fall into the category of semi-processed and processed goods that attract high tariffs. If this happens, poor countries are likely to be relegated to primitive biotechnology tools that perpetuate export of low-value unprocessed goods. Therefore, the wider opportunities of biotechnology may not be realized.

It is expected that market forces may lead to product and service dislocations when new technologies displace older ones. However, those whose livelihood is threatened by new technologies become a source or resistance. Therefore, it requires innovative policy tools to manage global and local public goods and services in the face of increased private sector involvement. Provision of incentives that encourage the acquisition of technology by poor countries may be achieved by opening up markets to products from developing countries. Similarly, reduction in subsidies and tariff barriers could help developed and developing countries share the benefits of globalization equitably.

Chapter V
Legal and regulatory policies

5.1 Global governance of biotechnology

From the previous chapters, there is reason for optimism for the future of biotechnology in developing countries. The biotechnology industry is slowly emerging in a few countries while significant research and development capabilities are being developed in many countries. Investment in biotechnology in developing countries and strategic partnership with advanced institutions in developed countries are picking up.

This chapter examines the governance issues at a global level that could help biotechnology live up to its promises. It may be easier to deal with local capacity development than global governance or policy regimes. This has been seen in the past with technical barriers to trade and subsidies. Biotechnology, in addition to the conventional barriers, faces many more challenges that are usually narrowed down to ownership of property rights, conservation and safety concerns.

Here we examine the legal and regulatory regimes on the basis of work done by the Commission on Science and Technology for Development. It analyses the implications of the biosafety and intellectual property rights regimes for the development of a biotechnology industry in developing countries. It also seeks to identify means of harmonizing benefit sharing and inclusion of local communities in the new bioeconomy.

5.1.1 Legal and regulatory policies

Biotechnology is a powerful technology that could easily be developed and abused if it falls into the wrong hands. It is also a technology that requires huge investments and the taking of great economic risks. The natural resources upon which biotechnology innovations are based are often abundant, easy to acquire and decode but the financial resources and skills required to develop the innovations are limited.

Therefore, it is important to identify policies that increase harmonization of the opposing views. Identifying policies that are sensitive to public interests and industrial competitiveness that could be promoted through national priorities may be an important step. The national authorities should adopt policies that will promote innovations and trade, and safeguard the safety of humans, animals, plants and the environment.

5.1.2 International and national policies

International and national policies influencing biotechnology are still in the early stages of development and have not been consolidated into a body of governance. This is partly because the biotechnology industry is an outgrowth of other industrial operations, and as a result, many of the policies that govern the field are derived

from governance of the wider industrial sector. There are, however, exceptional cases where clear policies are being developed to specifically address biotechnology. One of the earliest areas of policy development in biotechnology was the determination of research funding priorities. These broad funding decisions have given way to more specific and targeted approaches by various countries. In the United States, for example, funding for biofuels research is an example of such measures.

Other complementary areas of policy development include the extension of intellectual property rights to cover living forms. This is particularly significant, given the fact that historically, living organisms fell outside the scope of protection of most intellectual property systems. Industry has argued that the absence of intellectual property protection for living organisms undermined funding prospects for biotechnology (Watal, 2000).

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization is the main instrument for the protection of biotechnology innovations. The TRIPS agreement recognizes that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application (see article 13 b)". To encourage innovation around patents the TRIPS agreement encourages full disclosure. It requires the "applicant for a patent [to] disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by persons skilled in the art [using] the applicant's [recommended] best method".

The Agreement also recognizes that nations and firms may waive patents if "[negotiations] on reasonable commercial terms and conditions within a reasonable period of time are unsuccessful and in the case of national emergency, extreme urgency or in cases of public non-commercial use". Whatever the case may be, the patent holder has to be notified.

Differences in interpretation of the TRIPS agreement with respect to biotechnology have emerged and will continue to emerge as new products and services become available. There are strong divisions on what constitute a novel product or process with respect to genes from known organisms. For example, farmers have used the *Bacillus thuringiensis* (bt) to control pests, but some commercial firms and public institutions now own patents on the gene from which the toxin is produced by the organism. It is debatable whether that constitutes novelty. Secondly, the agreement does not provide similar cover for communally owned or traditional knowledge.

Similarly, the agreement does not define what is meant by "micro-organism" nor what constitutes a "national emergency or extreme urgency". For example, private firms and public organizations are embroiled in the meaning of TRIPS and its application to HIV/AIDS, tuberculosis and malaria drugs, given that these diseases constitute a global disaster or emergencency. It is not what it say: but rather what it does not say: the cost of innovation and its relation to market opportunities for innovators as against public emergencies that may extend over a lengthy period of time. In the interim, global funds for research and development efforts on these diseases may provide a cushion but may not substitute individual inventiveness.

On the broader aspects, critics have argued that such property rights are inconsistent with morality and have been too wide (Drahos, 1999). In other words, the extension of intellectual property rights to cover living organisms is seen in some sections of society as being against the public interest (Barton, 2000). In response to these claims, patent offices around the world continue to review the scope of patentability to seek a balance between the demand for protecting inventions and the pressure to safeguard public interest.

Another major area of policy development is the emergence of new rules that seek to govern biological inventions on the basis of their presumed risks to human health and the environment (Wolfenbarger and Phifer, 2000). These policy measures come under the general umbrella of "biosafety" and are the subject matter of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Although the Cartagena Protocol has not yet come into force, it provides a set of policy guidelines that will have implications for the development of biotechnology (Gupta, 2000). One of the most significant features of the protocol is the promulgation of the precautionary principle as a tool for risk management in the face of uncertainty (Soule, 2000). This is a contested field, because of the potential for the principle to be used as an instrument for market protection (Hagen and Weiner, 2000). The critical policy issue here is how to establish an international standard for balancing between safety concerns and international trade.

The application of biotechnology could be enhanced through the adoption of policies that promote the use of cleaner technologies. Such policies could derive their inspiration from international or domestic sustainability norms. Agenda 21 provides one of the most important sources of guidelines for promoting cleaner industrial production. Other international agreements dealing with reductions in chemical pollution, atmospheric pollution and hazardous waste provide policy frameworks for promoting the use of clean biotechnology. There have also been missed opportunities in the international arena. The Convention on Biological Diversity, for example, has devoted the last five years to developing rules for the safe use and handling of biotechnology. However, over that period, little was done to explore areas that could benefit from the new safety rules. The convention's provisions that call upon countries to cooperate in the field of biotechnology still remain dormant.

5.1.3 Moulding responsive intellectual property regimes

Emerging technologies are associated with strong regimes of intellectual property protection. Biotechnology is a particularly interesting area for two reasons. First, the patenting of living forms is a recent development that is specifically linked to policy measures to foster the establishment of the biotechnology industry. There are differences of opinion on the exact impact of patent protection on the evolution of the biotechnology industry. What is evident, however, is that complementary institutions such as venture capital would not have evolved to the extent that they had, without the existence of an intellectual property regime that provides comfort to investors and inventors alike.

In this regard, intellectual property protection has co-evolved with the biotechnology industry and is one of its key institutional attributes. There are, of course, many areas of industrial and environmental biotechnology in developing countries that have developed through the use of public domain technology and have therefore not been

affected by increased intellectual protection barriers. This, however, is going to change as more countries are brought under the auspices of the TRIPS agreement, its successor arrangements and extrajudicial measures.

Trends in agricultural biotechnology suggest that the impact of intellectual property rights on the ability of developing countries to participate in the new bioeconomy varies considerably, depending on the nature of the research, level of technological development and enterprise size. Public sector research programmes remain particularly vulnerable to changes in the intellectual property regime because of their traditional dependence on public domain technologies and lack of knowledge of intellectual property practices.

Although this situation is starting to change, many developing countries are still far from mastering the details of inventive activity. It is paradoxical that for these countries to participate in the new bioeconomy, they will need to establish a certain level of familiarity and compliance with the emerging intellectual property rules. Ironically, however, these same rules might affect their ability to be players in the new bioeconomy.

Furthermore, most developing countries are still in the early stages of technological learning where access to patented technologies is essential for industrial development. The more advanced developing countries need to balance between their interests to have access to protected technologies now, while preserving the possibility that any of their future inventions will be protected. There are no general models that would enable countries to reflect these various balances in one strategy. However, there are specific areas that require policy attention.

First, developing countries will need to ensure that they meet the minimum requirements for intellectual property protection and create suitable environments for inventive activity. In turn, developed countries should help increase the level of trust in the intellectual property system by seeking to balance strong intellectual property protection with the need to broaden the base for technological partnerships with developing countries.

However, the public debate on patenting genetically engineered organisms and, in general, patenting of life remains a points of confrontation, especially in the face of perceived increasing ownership of patents by private corporations in areas previously thought to fall in the public domain. They argue that the concentration of patents in a few large firms constitutes a monopoly over our food production and food security in general. Finding a fair intellectual property protection that takes care of the interests of the poor nations is one of the prerequisites for social acceptance of biotechnology-derived products.

Therefore, a middle ground should seek to provide a balance between the benefits of innovators and mankind as a whole. For example, 14 leading public research institutions and foundations[2] in the United States, specializing in crop improvement

[2] They include University of Wisconsin-Madison, University of California System University of California-Davis, University of California-Riverside, University of Florida, The Ohio State University, Rutgers, The State University of New Jersey, North Carolina State University, Michigan State

and technology transfer, have requested free access to patented biotechnology advances to speed up crop improvement nationally and worldwide. They wish to access current and future patented technologies to facilitate university research aimed at developing new crop varieties. This could overcome dealing with many institutions that own the intellectual rights on different parts of individual organisms or processes and could provide a public database that gives the whole picture of patents owned by the public sector.

Agricultural biotechnology firms are exploring ways of sharing their patented technologies with developing countries under special institutional arrangements, including flexible licensing arrangements. Similar measures may be needed in the field of industrial and environmental biotechnology.

5.1.4 The costs associated with patents

The protection of intellectual property rights is often discussed as though it were a costless exercise and easy to manage. It is often talked of as a natural process of talented and fortunate people. The fees associated with patents also vary from country to country. Establishing a patent on a simple tool such as toothbrush could easily exceed $20,000, while sophisticated innovations such as those based on biotechnology and information technology cost even more. The average cost of an European patent is about Euro 29,800. Therefore, poor countries may have to develop flexible intellectual protection locally and negotiate for fair international favourable fees (see http://www.webpatent.com/costs.htm and http://www.european-patent-office.org/epo/new/kosten_e.pdf).

Over the period of 20 years, the cumulative cost of an industrially useful patent may easily reach $100,000. Similarly, the cost of litigation of a US patent may last for two to three years and cost well over $2 million. Taken together, patents remain an expensive business for poorly funded laboratories in some developing countries.

Patents in developed countries are used as "collateral" for investment. They are very important in attracting investments and sealing business deals. In poor countries the value of patents does not provide the pivotal role seen in developed nations due to a lack of mature venture capital markets and a narrow industrial and technology base. Indeed, poor nations are not even good at imitating, copying or stealing innovations and are rarely the subject of patent litigation.

Patenting is a normal business in developed and well-managed laboratories. Scientists are expected to keep clearly labelled, dated and well-written notebooks containing valuable ideas as they develop and are tested in the laboratories. These notebooks are the property of the laboratory and not the scientists. They form part of the information needed during patenting. Scientists work with laboratory managers or lawyers good at identifying patentable information or materials.

Scientists are expected to take their work seriously and guard against its publication or imitation by others. In many industries, new patentable innovations may not be published until after about a year and half from the date of provisional patent filing

University, Cornell University, Boyce Thompson Institute for Plant Research, Donald Danforth Plant Science Center, Rockefeller Foundation and McKnight Foundation.

to make publication coincide with patent application. This provides a flexible mechanism to incorporate changes in the patent application and avoid extra patent applications in case new knowledge becomes available.

Therefore, patenting is a delicate process that has to be enshrined in the industrial or institutional culture. It requires technology managers or informed scientists/lawyers to maintain patents. Patents, trademarks and trade secrets stay with the firms while people may leave. This makes patents an important lifeline of many knowledge-dependent industries such as biotechnology and pharmaceutical firms.

Recognizing the differences in the role of patents in poor and rich countries may be crucial to appreciation of the opposing views and harmonization of regulations. The market size, the value of the innovation and the ability to lock out competitors have to be considered during patenting. Therefore, it is important to note the different roles patents play as source of innovations and investment and as source revenue for patent regulatory authorities. The fees paid to the patent office go to the national treasury and fees paid to lawyers provide a source of employment.

There are also costs associated with the use of patents owned by others. Currently, many useful genes are covered or protected by patents. The inclusion of these genes in a final product will attract licensing and/or royalty fees. Determining the value of each of these genes or gene fragments may be difficult. Secondly, owners of such patents may also demand higher fees that could increase the cost of the product and make it uncompetitive (see next section). Similarly, owners of patents may refuse to grant permission to use their innovations.

Identifying these costs, engaging in negotiations and seeking professional advice early in the research and development of the product are very important. It will help in making a realistic market value of patents, seeking optional sources and establishing new relationships between owners of innovations and users. Seeking interventions by teams that have a good relation with both the user and owner of patent(s) may bring down the cost.

5.1.5 Patent regimes and industrial innovations

Some argue that patents encourage innovations, while others maintain that patents could hurt technological development. Patents on genes have encouraged private funding in research and development activities, motivated scientists to innovate, and research institutions such as universities to benefit from their work (Krattiger, 2002). Consequently, the number of patents granted to universities and other public institutions has increased. Similarly, the number of technology transfer and commercialization offices in research institutions has increased as well.

However, many of the downstream patents (such as those on genes) are beginning to work against innovations in developed countries (Shapiro, 2001). It may soon reach a stage where to develop one drug, a firm will have to get permission from many institutions, some of which may be unwilling. Working around one or two patented genes may be easier than working around five or more protected genes.

These views were summed by Peter Ringrose, Chief Scientist at Bristol-Myers as follows: "there are more than 50 proteins possibly involved in cancer that the

company [Bristol-Myers] was not working on because the patent holders either would not allow it or were demanding unreasonable royalties" (Thompson, 2002). Some patents may be good for innovations while other may not.

There is a growing recognition that genes may soon become unpatentable as they will either fail the non-obviousness or utility requirement. As more genomes become fully sequenced and the tools to analyse genomes become standard practice in laboratories, it will be difficulty to satisfy the law's requirement that inventions be non-obvious to persons with ordinary skill (Steinberg, 2000).

Inventors are required to know the properties and application of their discovery (utility claim). Currently, patent offices may accept computer-aid sequence comparison to predict the properties of an unknown gene with known ones. However, this may predict the biochemical function but not the biological process it may be involved in.

Indeed, patent offices are refining their patent guidelines, increasing the stringency of the rules. Currently, claims on ESTs as probes (previously acceptable) may be rejected while claims on single nucleotide sequence differences (single nucleotide polymorphisms (SNPs) as markers may be accepted. Indeed, just how much information is needed to satisfy the utility requirement is questionable.

Some of the cases that may be regarded as preludes to what lies ahead include:

1. Millennium Pharmaceuticals discovered a leptin receptor that could be used in weight control in 1995. It filed and got a patent but the gene turned out to be a longer version of a gene patented by Progenitor.

2. The Human Genome Sciences Inc is the patent holder to CCR5 gene and its products. After the patent was issued, the gene was found to be a cellular receptor for HIV while the patent does not mention HIV. Other firms have applied for patents based on the CCR5 application in AIDS-related issues.

3. Chiron has a patent on hepatitis C virus (HCV) and Roche holds rights to the polymerase chain reaction-based nucleic acid technology (NAT) diagnostic system. In order to create a diagnostic kit that detects HCV as well, Roche needed Chiron's licence. After a lengthy court battle, the two firms agreed on a settlement where by Roche paid Chiron $85 million plus royalties. Consumers were also affected by the decision to charge royalties per test instead of per kit.

Pharmaceutical firms that produce antiviral drugs against HIV/AIDs will remember the year 2001 for the demonstrations in Africa against patent monopolies. In South Africa, pharmaceutical firms and governments were dragged to court in an effort to bring down the cost of these therapies and make them accessible through parallel importation or local production of generic forms. In a bid to protect their patents, firms entered into agreements with some countries in Africa and Latin America to supply the drugs at a lower than market price in poor nations.

Therefore, IPR issues were perceived as being between developed and developing nations. However, 29 State attorneys in the United States may be suing Bristol-Myers, arguing that the company benefited and cheated consumers by blocking

generic forms of its anticancer drug, paclitaxel. This case, which hinges on extension of patents by minor alterations and legal technicality, will be very interesting. It was claimed, in 2000, that a generic paclitaxel would have cost $.07 per milligram compared with Bristol-Myers price of $6.09 per milligram (For a review see SPAN (Stop Patient Abuse Now), http://www.spancoalition.org/.) The company claims to have spent $1 billion in research and development activities while opponents point to public funds at different stages of development.

The significance of this development is that extension of patents may not be easy to get whether the cases are won or lost in courts. It also shows that patents issues are not just about developed and developing countries. While patents confer temporary monopoly rights over knowledge and products, issues of equity may be gaining ground. Above all, patent issues are not limited to biotechnology.

These developments should help guide developing countries in modelling their patent regimes to encourage innovations and competition. Developed countries equally have to worry about the effect of patents on future research without discouraging investment in research and development. They also show that patent rules have to be monitored to conform to demands in changes in science and technology development.

5.2 Protection of traditional knowledge

The importance of indigenous or traditional knowledge (TK) in the lives of local communities is well recognized. Instruments seeking protection of TK are based on the recognition that benefits derived from innovations or technology associated with such knowledge should accrue to the local community. It may be important to note that this line of thought becomes clearer and stronger as the biotechnology revolution is primarily based on plants and other raw materials that are a source of livelihood for many poor societies.

Many country reports called for the conservation and protection of TK by harnessing forests, animals and plants. It is argued that modern science and technology does not seem to recognize the importance of TK. It is important to note the difference between TK that is under threat of exploitation by commercial interests and that which is being lost due modernization of local societies.

Indeed, every document on TK has mentioned the development of a *sui generis* or unique IPR regime. The definition or building blocks of such an IPR regime remains vague and proposals on possible models are rare to find. However, that is not surprising as TK, like most knowledge, is continually evolving, broadly owned, widely practised and all-encompassing. The boundary between TK and modern innovations becomes unclear as societies begin to modernize.

Some of the recommendations include documentation of TK, protection through customary or traditional law, designing a TK-responsive IPR regime, inclusion of TK in a modern IPR system and instruments for benefit sharing from products and services derived from TK.[12] What is lacking is a system for classifying public domain TK from non-public domain TK. The highly valued non-public-domain TK may be included in an IPR regime while most of the common TK may have to be documented for the good of mankind. Encouraging developed and developing

countries to equally document and protect TK may help in crafting an IPR regime that appreciates the importance of TK.

International regimes for protection of traditional knowledge are still in development. The Convention on Biological Diversity (CBD) is the only internationally legally binding instrument that explicitly refers to the protection of TK. Article 8(j) states that: "Respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices".

Many other international organizations, such as UNCTAD, the Food and Agricultural Organization (FAO), the World Health Organization (WHO), the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), have all been involved in studies seeking to develop mechanisms for the protection of traditional knowledge. Almost all these organizations advocate *sui generis* legislation to protect TK whose elements may include: (i) ancestral community rights over TK; (ii) collective ownership of rights; (iii) distinguishing rights over genetic resources (vested in the State) and rights over knowledge associated with such resources (vested in local and indigenous custodians); and (iv) use of genetic resources implies use of associated TK (WIPO, 2001).

The Organization of African Unity (OAU) has drafted the "African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources". The Third World Network (1996) proposed a model of a Community Intellectual Rights Act aimed at protecting the innovation and intellectual knowledge of local communities. The United Nations Educational, Scientific and Cultural Organization (UNESCO), WIPO "Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions" could be extended beyond folklore to encompass other types of traditional knowledge.

The development of an internationally recognized regime(s) to protect traditional knowledge and share the benefits arising from its exploitation may be important. However, educating the local communities on the importance of preserving traditional knowledge should include incentives for further innovations. The latter is important for the survival of local societies and could lead to increased cooperation between scientists or industry and local societies to develop even better products of higher value and benefits to the societies concerned. Indeed, traditional knowledge has to continuously evolve to meet new challenges or risks becoming irrelevant or being forgotten. Despite these developments, country reports have not shown inclusion of these measures in national or international legal regimes for the protection of intellectual property rights (UNCTAD, 2001).

5.2.1 The role of traditional knowledge in the health sector of nations

The Organization of African Unity declared 2001-2010 as the decade for traditional medicine at its Summit in Lusaka, Zambia, in 2001. There is a growing recognition that the first line of defence in fighting health-related problems in Africa is the use of

herbal medicine. Approximately, 80 per cent of the African population is estimated to depend on or use herbal medicine.

There is also a growing market for herbal related medicines in many developed and developing nations. The Convention on Biological Diversity estimates that global sales of herbal medicines reached $60 billion in 2000. Countries such as Japan saw herbal sale increase from $1 billion in 1991 to $2.4 billion in 2000. Similarly, the sales in the United Kingdom increased from $92 million in 1994 to $159 million in 2000. The US herbal medicines market stood at $5.4 billion in 2000, up from $1.6 billion in 1994.

Surveys in Belgium, Denmark and Viet Nam found satisfaction and an approval rating of herbal medicines equal to or higher than 77 per cent. Only 7 per cent of the respondents considered themselves not cured by herbal medicine and 1 per cent indicated their condition had worsened. These are impressive levels of satisfaction in the face of the freedom and latitude that traditional medicine practice enjoys.

Despite these achievements, many developed and developing countries do not have legislations that protect or promote the use of herbal medicine. Biotechnology has rekindled the interest in traditional knowledge that may be of industrial use. It may be possible to coax plants to produce the therapeutic ingredient in an active, easy to purify and increased quantities. There is also a general belief that many more life-saving ingredients have not yet been discovered.

5.3 Cases of IPR related to traditional knowledge

Traditional knowledge suffers from a lack of individual ownership. It is knowledge that passes through trusted family members and close friends. Often the same preparation is used by different societies in different countries, thus making it difficult to identify the inventor. Since it is shared, community knowledge cannot be said to be new. Therefore, it only meets one of the basic requirements (utility) of patent regimes but often fails to meet novelty and inventiveness.

Each society has a set of knowledge that is often vested and practised only by trusted people such as traditional healers. It resides in one or few individuals that pass the knowledge to trusted member(s). Like patents, this knowledge is a source of livelihood and expensive to acquire. There is also common traditional knowledge that is vital to the survival of the village or community. This includes knowledge needed to produce food, heal common ailments, produce common wares and arts, and build homes.

Patenting traditional knowledge to ensure its protection and utility is important. However, high-value traditional knowledge is protected through secrets. The common traditional knowledge is owned by the community and does not expire. Anyone who comes to live in this society may acquire the common traditional knowledge if desired.

While it is possible to patent the composition, extraction and preparation methods, and treatment tools, identifying the original inventor is difficult. The search for a flexible and responsive regulatory regime for protection of traditional knowledge has not gone beyond creation of databases and benefit sharing. Perhaps enabling the

communities to work with scientists to add value to traditional knowledge through identification of active ingredients, novel preparation methods and new treatment regimes could help meet some of the patent or utility model requirements. Similarly, greater value may be obtained through the application of advanced technology to increase the quality and quantity of the products. The local communities could then become suppliers of raw materials and recipients of royalties on products sale and licensing fees.

5.3.1 Development of Jeevani drug based on traditional knowledge of the Kani people of India

Indian scientists on an expedition in 1987 observed that their Kani guides ate a fruit that energized them. Efforts by the scientists to get hold of the source of the fruits were met with resistance as the Kani traditional knowledge was kept secret and vested in tribal physicians, the Plathi. It took persuasion and skilful negotiation with the tribal leaders to obtain the information.

The scientists extracted 12 active ingredients from the Arogyappacha (*Trichopus zeylanicus*) plant. The scientists were members of the Tropical Botanical Garden and Research Institute (TBGRI). TBGRI licensed the products and their preparation methods to an Indian commercial firm, Arya Vaidya Pharmacy Ltd, with interests in herbal formulations. The firm began pilot phase production of the drug, Jeevani, using raw materials (leaves of the plant) supplied by the community.

The Kani community was entitled to 50 per cent of the licence fee and 50 per cent of royalties gained by TBGRI from the drug. A trust was established to manage the community funds gained from the technology. The early beneficiaries were the individuals that divulged the information as an encouragement or reward for their participation. The same individuals were also members of the trust management team.

The community could have gained extra benefits if the cultivation of this shade-loving plant had been allowed. An estimated 500 to 1,000 families would have been employed to supply leaves to the firm. The firm was willing to provide seed funds to the families to enable cultivation to take off. However, the forestry officers declined to give permission to the Kani community to grow the plant. The decision was later changed through reclassification of the plant by the forestry conservation division.

It was noted that legitimization of intellectual property did not translate into legitimate benefit sharing. It is believed that the inclusion of the forestry team in the early stages would have enabled the plant to be cultivated by the Kani community. However, commercial efforts to smuggle the plants increased and the Kani leadership involvement gave sufficient grounds for the decision of forestry officers.

The case demonstrates that addition of value to traditional knowledge may be the key to ensuring its protection. Inclusion of the stakeholders from the beginning may determine the success of the project but increases the number of beneficiaries. Early negotiations on the benefits of the different stakeholders, their role and share may be vital to smooth operation or collaboration between private and public interests.

The case also shows that traditional knowledge is not freely available. However, in the face of commercial interests and financial incentives most of this knowledge could be lost. The tying of conservation efforts to commercial use of genetic resources is important but requires significant sensitization of the community. The existence of a body with conservation interests and the scientific capability to isolate and identify the different active ingredients played a key role in legitimizing the intellectual property rights of traditional knowledge.

5.3.2 The case of HIV vaccine patent between the University of Nairobi and Oxford University

A team of University of Nairobi scientists worked with a group of prostitutes that they believed might have been exposed to HIV but remained negative throughout their practice over a number of years. They figured out that the immune systems of the individuals may have been eliminating the HIV virus that causes AIDS.

To carry out detailed studies, they worked with a team at Oxford University and together got funding from the International AIDS Vaccine Initiative (IAVI). All the detailed studies at molecular level, including designing of the vaccine, took place at Oxford University. In 1999, the project was preparing to move to trials.

In 2000, the team at Oxford decided to patent the vaccine candidate molecule to protect the initiative from being taken over. A patent was issued in the names of the Oxford scientists as inventors but never mentioned any of the Kenyan scientists. The media got wind of it and questioned the morality of such a step.

Although the situation was redressed and the University of Nairobi scientists are shown as co-claimants to the patent, the case left more questions than answers. When exactly was the invention made and what is the invention? Is the inventor of this vaccine the one who developed the idea or the ones that designed the vaccine? Of the final products value how much is due to the idea and initial investigations, molecular analyses and designs? Similarly, do the prostitutes that provided the samples have any claim to the invention or its proceeds?

While this is a modern state-of-the-art case it highlights some of the difficulties in dealing with traditional knowledge and benefit-sharing. One would have expected that small teams of highly qualified and informed people would have easily avoided the bad publicity. Therefore, dealing with larger communities may be more difficult and similarly benefit sharing could become complicated. However, these cases provide a good model of collaboration between communities and firms in a bid to protect traditional knowledge and share the benefit from their resources.

Similarly, when a natural product has given rise to an effective marketable drug, for example the anti-tumour substances extracted from the Madagascar periwinkle, under CBD, the value of traditional knowledge and/or biological resource has to be factored. However, after years of research and development activities, it may be difficult to estimate the share of the contribution of the natural substance initially used as share of the final product value (Boisvert, 2003).

5.4 National initiatives to protect traditional knowledge

Few panel members were able to report significant developments in their own countries in respect of intellectual property protection for traditional knowledge. In fact, many countries have first to undertake a substantial amount of research in order to fully assess their genetic resources and the traditional knowledge associated with them.

5.4.1 Traditional knowledge protection in Peru

The country has established a register of collective knowledge related to biological resources that are being compiled. Access to the register, when it is complete, will require the permission of the indigenous people from whom the knowledge is obtained. Furthermore, commercial use of the knowledge will be allowed only through licensing agreements. The Andean Pact introduced a broad-spectrum biodiversity regime in 1996 called Andean Community Decision 391.

This strategy regulates access agreements for genetic resources and traditional knowledge, and provides for contractually agreed benefit-sharing in respect of the traditional knowledge components of bioprospecting activities. However, the Andean Community is also considering the introduction of a new *sui generis* system to legally protect traditional knowledge. One purpose of this system would be to encourage the holders of the knowledge to make it available as a database.

5.4.2 Efforts of other countries to protect traditional knowledge

In Jamaica, for example, ethnomedical and ethnobotanical research has started to facilitate the recording/preservation of traditional pharmacological knowledge. In other countries, such as *Sri Lanka,* where initiatives are under way to develop legislation on access to genetic resources and benefit-sharing as part of CBD implementation, progress has been reported to be slow.

The *Costa Rican* Biodiversity Law, introduced in 1994, is a broad protection regime, which establishes procedures for accessing both genetic resources and associated knowledge and practices. Under this law, bioprospecting agreements must ensure that consent is obtained from the custodians of the genetic resources and knowledge, and that profits from their use are equitably distributed.

5.5 Intellectual property rights in developing countries: National experiences

5.5.1 The intellectual property rights regime in Romania

The State Office for Inventions and Trademark (OSIM) and the Romanian Office for Copyright Protection (ROC) are the two bodies responsible for the protection, registration and use of intellectual property rights (IPRs) in Romania. The OSIM deals with international intellectual property regimes, protection of innovations and industrial knowledge, while ROC registers, monitors and enforces compliance with trademarks as well as related rights. These rights are enshrined in various legislations that relate to unfair competition, patents, integrated circuits and copyright.

However, the country is still undertaking a review of the intellectual property rights legislation to meet the requirements of WTO and TRIPS. The legal regime in Romania is well advanced in meeting the minimum requirements of international organizations.

Romania offers patent protection on crop varieties that are new, distinct, homogeneous and stable, and have a generic denomination for identification. The protection is offered to the inventor, employer or organization that commissioned the work resulting in the improvement.

Patents are registered with OSIM, which publishes the innovation in the official Bulletin for Industrial Property. In case of plants, the patents on crop varieties are protected for 25 years or 30 years for fruit trees and vines. In case of infringement, complaints may be lodged with OSIM after publication. However, personal, non-commercial and experimental use is allowed. The law also allows the use of protected varieties as starting material in research and development activities.

If the patent holder decides to exclusively license the innovation, a new registration in the National Register for Protected Varieties Patents at OSIM and another publication is required. Non-exclusive licensing contracts may be published as well. In the event of failure to utilize the patent within five years, OSIM may issue a compulsory licence of the innovation or if the innovation is of public interest to other interested parties. However, this does not stop the patent holder from licensing or utilizing the innovation. If aggrieved, redress may be sought through the Court of Bucharest and the Court of Appeals of Bucharest.

5.5.2 Intellectual property rights in the Republic of Korea

The intellectual property rights regime in the Republic of Korea is very mature. By 1998, about 50,596 patents had been issued to residents in various fields. The country ranked seventh in terms of patents granted to residents, fourth in annual compound percentage change for patents issued to residents, twentieth for patents in use and thirty-eighth in patent protection out of 46 countries surveyed for the period 1994 and 1995.

The number of patents issued for biotechnology-related fields has continued to grow at an annual average rate of about 15 per cent. About 222 patents were granted for biotechnology-related innovations in 1991 and this number reached 530 by 1997. Table V.1 shows the number of patents granted between 1994 and 1997 to residents and non-residents.

The major national patenting institutions include the Korean Institute of Science and Technology (KIST), LG Chemicals and Cheil Chedang. The major patenting foreign firms include Hoechst AG (Germany), Eli Lilly (United States) and Misui Doaz (Japan). Table V.2 shows some of the main patent seeking firms and their areas of interest.

Table V.1. Patenting trends in biotechnology

	1994	**1995**	**1996**	**1997**
Residents	564	489	551	530
Foreigners	541	635	731	871
Total	1105	1124	1282	1401

Source: Korean Patent Office.

Table V.2. Some of the main patenting biomedical firms

Name	**Grants**	**Percentage**	**Technology areas**
Residents	***1031***	***39.3***	
Kist	152	5.8	Anti-cancer, virus antigens, enzyme-related, interleukins
Cheil Chedang	152	5.8	Enzyme-related, vaccines, amino acids, anti-cancer and antifungal agents
LG Chemicals	62	2.4	Interferons, EPO, G-CSF
Foreign	***1595***	***60.7***	
Hoechst AG	58	2.2	Recombinant proteins e.g. insulin
Eli Lilly	48	1.9	Recombinant proteins and antibodies
Misui Doaz	38	1.4	Amino acids inducers, insulin
Total	**2626**		

Source: KINITI (1999), Development and Patenting Trends of Biomedicals.

For innovations to be patented, they must involve an inventive step, and be industrially useful and new. Patents are generally valid for 20 years or 15 years in the case of utility models. Utility models are issued on innovations that are useful and new but the inventive step is smaller than is needed for traditional patents. Upon request by the holder, patents may be extended for an additional five years, especially on pharmaceutical products.

5.5.3 Intellectual property protection in Paraguay

The country had already introduced a plant breeders' rights regime before the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement came into force. The Seeds and Varieties Protection Act was introduced in 1994. This law protects the intellectual property rights (IPRs) of plant breeders for a period of between 15 and 18 years, although under this law, protected varieties can be used as a base for the research and development of new varieties, and farmers have the right to re-use saved seed.

In 1995, the law was presented to the Union for the Protection of New Varieties of Plants (UPOV) for analysis. UPOV approved Paraguay's membership of the organization in 1997.

5.5.4 Intellectual property regulations in Jamaica

The country is in the process of upgrading its IPR regime. It has recently become a signatory to the Paris Convention of 1883 (revised six times), which permits the filing for a patent in many countries at the same time. National legislation on plant varieties protection is being drafted, guided by the UPOV model.

The Jamaican report showed that concerns have been expressed as the drafting of this legislation is thought to be driven by external pressures rather than local needs. Furthermore, it is taking up scarce resources, and it is still unclear whether these investments will be justified in respect of socio-economic development. It was noted that there are too few local innovations to justify the investment of such resources to mainly attract foreign technology or investment.

5.6 Biosafety regimes in developing countries: National experiences

5.6.1 Biosafety in the Russian Federation

The Russian Federation has used and developed significant biotechnology capacity over a long time, especially in the defence system. For this reason, it has attached great emphasis to the development and use of living modified organisms (LMOs). The public appreciates the fact that benefits may be accrued from the use of biotechnology-related products and services but also recognizes the risks posed by these products.

To address this dichotomy, an Act was passed in 1996 to regulate the use, generation and movements of LMOs. In 2000, the Act was updated to include gene therapy-related activities, such as the use of virus vectors. The main aim of the legislation is to meet the concerns of the public and those of innovators.

In addition, an inter-ministerial committee was formed to address biotechnology-related issues in agriculture, health, environment, economic and legal requirements. This committee was charged with the responsibility of creating the infrastructure and policies needed to harness the safe use of biotechnology products and services.

There are also three bioethics committees at the Federal level that address the ethics of biotechnology-related protocols, such as human cloning. These committees are mainly influenced by orthodox religious considerations, cultural values and political views. However, they provide a more balanced representation of the public and are relatively transparent. For example, a committee comprising prominent biotechnologists, physicians, lawyers, philosophers and government officials among others recommended a temporary ban on human cloning.

The Russian system seeks to build on an all-inclusive approach that brings together the scientific community, government and the public to reach some common ground. This is useful in informing the public about the biosafety measures that may allay some of the fears and help government, industry and scientists predict the likely public perception. It may also help communication of new advances in science and technology to the public and enable their participation in decision-making.

5.6.2 Biosafety regime in Ghana

Biosafety protocols in Ghana are still in their infancy. Ghana developed draft legislation on biosafety in 2000. The major players in the original development of the biosafety regulation were the Biotechnology and Nuclear Agriculture Research Institute (BNARI), the University of Ghana, the Ghana Institute of Biologists and the Ministry of Environment, Science and Technology.

During the United Nations Environmental Programme-Global Environmental Facility (UNEP-GEF) project, BNARI was selected as the National Focal Point for biosafety coordination in Ghana. However, BNARI faced difficulties in fulfilling the task because it lacked effective institutional structures for operation. With the support of DFID and the Ministry of Environment, Science and Technology, the Biotechnology Development Programme was developed in collaboration with the University of Strathclyde's School of Environment. The project partly aimed at reaching a consensus on the appropriate biosafety regulatory regimes for Ghana.

A 13-member National Biosafety Council was inaugurated in 2000, drawing expertise from academia, research institutions, ministries, professional bodies and industrial organizations. The main objectives of the Council were to develop biosafety policies, regulations and procedures, coordinate and monitor biotechnology activities, build human and institutional biosafety capacity and participate in regional and international biosafety forums.

The draft legislation in Ghana is a hybrid of local interests and international experiences mainly of other developing countries, such as South Africa and Costa Rica. A local biosafety-clearing house has been established to enable the exchange of technical and scientific biosafety-related information.

5.6.3 Biosafety regulations in Pakistan

A new regime for biosafety has been developed which includes very comprehensive guidelines on procedures for various risk categories, together with the institutional structures for their implementation. These proposals, which are in draft form, are currently being circulated and are publicly available for comment.

Biotechnology was first developed in centres of excellence. After some time, these centres wished to undertake field trials, and firms from outside the country also wanted to start field trials under local conditions for their transgenic seeds. The present draft biosafety regime was developed in response to these demands. There have been no releases of GMOs in the country as of 2001.

5.6.4 Biosafety policies in Sri Lanka

The Ministry of Environment has appointed committees to study issues related to biosafety and bioethics, but so far no regulatory mechanisms have been introduced. With respect to controlling the importation of GMOs, existing seed import controls and capacity are insufficient. For example, the regulatory agencies involved do not have sufficient laboratory facilities. However, within the country, as of 2001 there was no research directed at developing transgenic plants.

5.6.5 Biosafety regulations in Slovakia

A slightly different approach to biosafety has been taken in Slovakia, where a cross-sectoral Slovak Commission for the Convention on Biological Diversity has the mandate to support biosafety initiatives. Legislation has not yet been introduced, and it was suggested that, in the interim, EU laws on GMOs be observed. In the meantime, the Commission has obtained for distribution a translation of the International Technical Guidelines on Safety in Biotechnology, prepared by the United Nations Environment Programme (UNEP). Under the national programme, implementation of legislative measures is scheduled, as a priority, for the first phase in 2001–2003.

5.6.6 Biosafety policies in Romania

Biosafety regulations with respect to genetically modified organisms (GMOs) are relatively new and mainly address the agricultural sector. The other sectors such as the pharmaceutical, industrial and environment are still governed by older regulations. The Government decree of 1997 provides the regulatory regime for products and services likely to endanger life, health work, security and the environment.

A government decree of 2000 established the regime for obtaining, testing, use and commercialization of genetically modified organisms through the National Commission on Biological Safety (NCBS). It is responsible with containment use, testing, creation and multiplication of GMOs, and their environmental release. It is also charged with risk assessment and management.

The trade in genetically modified organisms requires prior notification and preliminary documented agreement especially if the products and services are intended for environmental pre-lease or release. The products have to be packaged securely, labelled, transported and manipulated according to agreed procedures. By the same token, the NCBS is required to protect IPRs and other undisclosed information, and provide measures related to emergency situations. Importation is only allowed once the risk is assessed and procedures to manage any identified risks are developed.

The unintended introduction of GMOs in Romania requires the Commission to make arrangements to contain and/or eliminate the GMO, and NCBS may invoke any relevant international legal regime available. If the GMO is introduced illegally into Romania, NCBS would request the originating country to ship back the consignment at its own expense. NCBS may also invoke any relevant international regulations to contain the situation or to ensure that such incidences do not arise.

NCBS is composed of 19 members, of whom 12 are drawn from the Romanian Academy of Sciences, the Academy of Medical Sciences, the Academy of Agricultural and Forestry Sciences and other biomedical related organizations while 7 are drawn from environment, health, agriculture and food-related public institutions and government ministries. These arrangements are in compliance with European Union directives.

5.6.7 Biosafety regimes in Latin America and the Caribbean

One report (presented at the panel meeting in Tunis in 2000) indicated that the majority (63 per cent) of countries in the Latin American region have not yet formulated and implemented biosafety regulations. These countries include the Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Venezuela and most of the Caribbean countries. Among the countries that have introduced specific measures to manage biosafety, wide differences with respect to the scope of regulations, the approach taken (that is, the development of an entirely new regime, or building on existing regulations), the institutional arrangements and mandates for implementation, and the types of regulatory mechanism used were noted. Biosafety Committees or Commissions have been set up in some countries.

Their membership tends to draw from a wide range of agencies, including ministries (especially agriculture, health, environment, commerce, and foreign relations), the scientific community, civil society, agricultural producers, non-governmental organizations, consumers, environmentalists and the private sector. Except in Brazil, these Committees act in an advisory capacity only. In Brazil, in addition to making recommendations to ministries, the Technical Commission for Biosafety has the final decision to authorize or prohibit field trials.

In Paraguay, an inter-institutional Biosafety Commission has been in place since 1997, and procedures have been established for it to handle applications for the release of genetically modified organisms. The Commission, which is made up of representatives from the Ministries of Agriculture and Health, universities and non-governmental organizations, acts in an advisory capacity to the two key ministries that have the authority to authorize or reject applications. As of July 2000, only one such application had been received - for the experimental release of several herbicide-tolerant soybean varieties - and was approved.

In Cuba, a National Centre for Biological Safety was established in 1996 under the Ministry of Science, Technology and Environment. This body is responsible for coordination and implementation of regulations and agreements on biosafety. Other relevant organizations and programmes are at the Centre for the State Control of Medicine Quality, the National System for Veterinary Medicine and the National System of Plant Health.

In 1999, a Decree on Biological Safety was passed which regulates the use, storage, handling, transport, import and export of biological agents, including genetically modified organisms and DNA fragments. In the same year, the Government established an Official List of Biological Agents affecting humans, animal and plants, including their classification into risk groups. In 2001, the General Rule on Biological Safety, which establishes the functions and procedures for biosafety organizations and officers, including procedures for handling and moving samples, was established.

An authorization procedure has been approved to regulate applications for approval of releases of biological agents, including the granting of licences. Furthermore, Cuba has already introduced university course modules in biosafety, including specialized modules in respect of human health, veterinary medicine and plant

health. In addition, a Master's level degree course in biosafety has recently been approved.

5.6.8 Development of biosafety regulations in the Republic of Korea

Although the promotion and development of biotechnology in the Country is more than two decades old, biosafety regulations with respect to biotechnology products and service received official attention by 2000. The Bioengineering Safety Law was drafted in 2000 and was expected to come into force in October 2001. Earlier efforts to rekindle biosafety issues in 1997 were not taken very seriously by the legislature as it was seen to be too pessimistic and contrary to the promotion of biotechnology development. It was believed then that transgenic organisms would become part of the biotechnology industrial revolution and strict rules would hamper development.

After 2000, biosafety has been viewed as necessary to protect human, animal, plant and environmental health. Similarly, biosafety may be important in trade with other countries that are parties to the Cartagena Protocol on Biosafety.

The draft legislation prepared by the Ministry of Science and Technology proposes the formation of a Bioengineering Safety Committee composed of 15-20 members chaired by the Prime Minister. Of this, 9 members would be drawn from interested ministries and departments, while the remainder would come from professional organizations and non-governmental institutions.

The draft legislation requires the Government to develop five-year conservation plans and grant permission and inspection of bioengineering firms or institutions. It also requires firms to seek permits from the Government before any person or organization imports, exports, uses and commercializes living modified organisms. Finally, the Government is required to establish, through a relevant ministry, an agency for evaluation of biosafety standards.

5.6.9 Argentina

Since 1991, Argentina has continuously developed a biosafety regulatory system for genetically engineered organisms, mainly crops, that is effective, rational and respected. The Agricultural Directorate, within the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPYA), is responsible for the overall regulation of the use of transgenic organisms in field tests, unconfined releases and commercial application. This Directorate encompasses the National Advisory Commission on Agricultural Biotechnology (CONABIA), the National Institute of Seeds (INASE), and the National Agrifood Health and Quality Service (SENASA).

CONABIA is the advisory body entrusted with proposing and applying environmental release guidelines for transgenic organisms in greenhouses, field trials, unconfined release and recombinant DNA products intended for animal health (e.g., recombinant vaccines). Therefore, the main activity of CONABIA is science-based environmental risk assessment of the action(s) proposed by the applicant. CONABIA prescribes what biosafety measures should be taken in addition to those proposed by the applicant, if any.

CONABIA is composed of representatives of various government agencies, the private sector, professional societies and academic institutions. A representative of

the Secretariat of Natural Resources and Environmental Policy joined in 2000. The Ministry of Health will also be represented in CONABIA. However, consumer and environmental non-governmental organizations are not represented since CONABIA is a technical advisory group.

Once a transgenic plant has been sufficiently field-tested, the applicant may request that the crop be flexibilized, i.e. approved for unconfined (usually large-scale) planting for certain specified uses (e.g. export, off-season seed multiplication not to be sold in the country, pre-commercial multiplication pending variety registration). Flexibilization does not constitute approval for commercial release within Argentina but only entails unconfined, usually large-scale, planting for the purposes mentioned above.

CONABIA's risk assessment for flexibilization evaluates the transgenic crop's potential outcrossing and weedness, horizontal transfer or gene exchange with other organisms, phenotypic expression and genotypic stability, pathogenicity to other organisms, potential to produce hazards in the environment, and potential harmful effects on humans, including allergenicity and eventual development of resistance in host populations. Food-related issues must also be addressed by the applicants requesting flexibilization.

Current guidelines for food-safety approval are based on the concept of substantial equivalence. In general, it compares the contents of natural toxic compounds, nutritional elements and the effect of processing and modifications on bioavailability of major and/or micronutrients between that of the transgenic organism and its conventional one. It also includes studies on the toxicological, allergenicity, carcinogenic and teratogenic of introduced protein(s).

SENASA guidelines are along those being developed by the Codex Committee on Food Biotechnology. Information on genetically engineered animals, genetics or embryos, and testing animals under contained or controlled conditions, are conducted under permit from SENASA and CONABIA. Data obtained from experiments carried out in other countries are also acceptable. CONABIA's review leads to a recommendation to the SAGPYA indicating approval or rejection of the request. If commercialization approval is granted, the applicant is responsible for the safety of the food derived from transgenic organisms as well as monitoring of the quality and consistency of the food so derived. The authorized transgenic-derived food is to be reassessed periodically.

The Directorate of Agri-Food Marketing (DNMA) conducts a final review that determines possible commercialization. The DNMA's decision determines which transgenic crop varieties seed companies can sell to Argentine farmers. The applicant must apply to INASE for a New Variety Registration as required by regulations controlling proprietary and commercial practices in the seed industry before actual sale. Where the crop contains endotoxin (e.g., pest-protected crops) or is herbicide-tolerant, commercialization requires specific authorization from SENASA.

While acknowledging the relevance and effectiveness of this system, the International Service for National Agricultural Research (Burachik and Traynor, 2002) recommended that the strengthening of national and institutional policies, the

modification of biosafety procedures to enhance transparency, strengthening of the scientific base for decision making, investment in human capacity-building and the design and implementation of a coordinated programme to address public awareness and acceptance. All these elements are important in ensuring that the system is capable of handling future biosafety challenges.

5.7 Strengthening regulatory institutions

There are two sets of regulatory issues that deserve attention under the new bioeconomy. The first set is related to international trade in living modified organisms. The second set of regulatory issues involves measures that are designed to facilitate the adoption of industrial and environmental biotechnology. Industrial biotechnology regulations may be similar to those in agricultural or pharmaceutical industries, depending on the products, but have so far remained and will remain less controversial, for at least two reasons. Firstly, biotechnology products used in process management (e.g. enzymes in textile and leather processing) do not become part of the final product (cloth or shoes). Secondly, the enzymes do not have any ability to transfer the gene sequence from which they were produced to any other life forms. Industry is likely to recycle or degrade the waste prior to discharge. Therefore, the main issue will be batch contamination and the quality of the discharge.

The potential environmental benefit of industrial biotechnology makes it attractive to those who are interested in promoting the transition towards sustainability. Incremental innovations as well as new design concepts will help make these technologies competitive with their conventional counterparts. Such cost reduction is important, especially with biofuels and bioplastics that are not yet competitive with petroleum-derived equivalents. However, the use of transgenic organisms in food processing, biofertilizers and waste treatment will be more controversial than in bioplastics and biofuels. The kinds of concerns expressed in agricultural biotechnology may arise here and should be treated in the same way.

Evidence from the current efforts to implement the Cartagena Protocol on Biosafety shows that building regulatory capacity for biotechnology is a complex process requiring considerable external assistance for most developing countries. Those countries that have capacity in biotechnology research are also in a better position to design and implement regulatory systems. This view suggests that the growth of regulatory capabilities in developing countries will remain uneven and will be sensitive to cost factors. There are numerous models for reducing regulatory costs, including regional centres, mutual recognition arrangements, cost-sharing agreements between government and industry.

Another area that might require special attention is the use of environmental regulation to promote industrial sustainability. This regulatory field is relatively new, but it offers opportunities for expanding the adoption of environmentally sound biotechnologies. The main limiting factor is the low level of use of environmental regulations to promote the adoption of alternative technologies in developing countries. Also related to this are measures that seek to reduce the consumption of non-renewable raw materials and replace them with bioproducts. Environmentally sound legislation that is enforceable could be a source of innovation.

5.8 Conclusion

There is very little attention paid to the needs of local markets in developing countries. Significant attention is paid to addressing the most urgent and often difficult problems whose answers may not be easy to find. For example, the use of biopesticides and biofertilizers by resource-poor farmers may be just as effective as transgenic crops. The area cultivated is often small per farmer and the growing period is often seasonal. It is therefore possible to prepare sufficiently to meet the demand. Reports have shown that where biofertilizers have been tried, demand has outstripped production.

While the export market is important, biotechnology has to help the development of local products and services for the local market. This is very important to the elimination of poverty and improvement in the quality of life. The case of Cuba has shown that combining the strength of domestic resources (human and financial) and external help (strategic partnerships and training opportunities) is vital in generating products and services for domestic and export markets.

Export market conditions and requirements will influence technology adoption and diffusion. If products that are developed using biotechnology application encounter additional costs, such as high tariffs and other regulatory costs, further development will be hampered. However, efforts to identify product lines that will be significantly enhanced or make substantial savings in terms of financial, environmental and time considerations should be encouraged. Such steps are important as biotechnology applications will enhance existing production capabilities and products quality.

Chapter VI
Public awareness and participation

6.1. The public and biotechnology policy

Public participation in setting national development agenda is receiving significant interest. There are many non-government organizations (NGOs) that focus on different aspects of development issues especially those likely to have some social and economic implications for local communities.

Following the democratization and liberalization of national economies and political systems, the numbers of local NGOs have grown in some developing countries. Despite this development, there are few NGOs that specifically focus on science and technology for development. The increased influence of science and technology in economic competitiveness and social development has not been well received by the public.

The technology divide, magnified by the difference in the level of digitization, communication and genetics, is constantly widening the gap between the poor and the rich countries. This has contributed to the negative attention that globalization and trade have often attracted. Technology is seen as the agent of globalization or tool for exploitation rather than development. In such an environment, constructive dialogue may be difficult to achieve. The opportunities and benefits of advanced technologies will continue to elude the poor.

6.1.1 Current public awareness and participation regimes

Public attitude is important in dictating the policy options of industry, government, NGOs and regulators (Salter, 2002). Positive public attitudes may increase the chances of political support, funding, adoption and appreciation. Therefore, self-interest dictates that public and private organizations cultivate a positive public image of their activities.

The institutions with vested interests tend to drive public awareness campaigns. Identifying the interests or passion for those involved in public awareness is just as important as the process itself. Public awareness may be difficult and expensive when the subject is new and complex.

Public participation requires as a minimum ability of the various stakeholders to freely air their opinions, respect the views of others, patiently listen to the arguments and evaluate the criticisms. However, at national level, it is important to identify stakeholders, their interests and common goals. Therefore, mechanisms for delivering and receiving information should be designed to increase the scope of common interests and reduce differences.

Public awareness and participation in agricultural biotechnology, especially GMOs, have been characterized by a failure in these basic principles resulting in a breakdown of trust among different stakeholders. Neither those in favour nor against tolerate and appreciate dissenting views, possibly out of self-interest. This situation makes constructive dialogue difficult.

The debate on GMOs has buried the wider application of biotechnology in other areas of great interest to developing countries. These include enhancement in industrial processing, improvement in product quality, improvement in human and animal health and reduction in cost of production. The benefits of biotechnology are immense but remain overshadowed.

Developing campaigns that sensitize Governments, industries and researchers about the opportunities and benefits of biotechnology will determine the success of biotechnology development in poor countries. Helping them to achieve these goals will be very important. The acceptance of some biotechnology processes and products may increase familiarity with the technology and lead to wider acceptance of other biotechnology products. The needs of developing countries to acquire the technology and that of developed countries to expand their market become inseparable.

6.2 Bridging the information gap

Deliberate and sustained strategies should focus on separating the technology from its products. Public awareness of the set of technologies that constitute biotechnologies is very important in decision-making. A basic understanding of the techniques is required, especially by the main stakeholders and policy makers, to appreciate the opportunities.

Unfortunately, there is a large (technological) information gap between the developed and developing countries, among the scientists, policy makers, media and other stakeholders within countries, and between regulators and industry. The ability of any of these groups to articulate biotechnology issues may be limited to self-interest, and people with limited sources of information can be misleading as they access resources with a similar viewpoint.

This information gap may have to be closed by building working groups of scientists, regulators, industrialists and policy makers. Those with working knowledge of biotechnology become advisers to those with limited experience in the field. Industry will bring the commercial interests and scientists the technical experiences that could help Governments make informed decisions. Such teams may be well placed to conduct public awareness campaigns and encourage participation. See table VI.1 for some of the basic ways of raising public awareness and participation.

Current policies being developed by many countries target the trade in products and technology developed and owned by firms of other nations. Interactive networks or teams, where members of the team may have some common projects, services and products, may encourage support for forward-looking policies and equitable sharing of benefits. This may also consolidate the ownership of policies.

Unfortunately, lessons of successful public awareness and participation campaigns that have achieved significant positive results for the technology are hard to find. For example, countries that are major producers of transgenic food crops may not have conducted sustained public debate beyond advertisements. Switzerland is one country where a referendum was held following bans of several GMO trials. The bans were defeated by a popular vote in favour of trials.

Table VI.1. Some questions for public awareness creation

Some of the basic questions	Examples of reasons
Why conducts the campaign?	Educate the population, solicit feedback/input from the public, seek public support
Who is the public?	Consumers, voters, policy makers, professional groups, employers
Who conducts the campaigns?	Governments, professional teams, pressure groups, industry, municipalities
What mechanisms may be used?	Public rallies, consensus conferences, workshops, radio, television, internet, handouts, posters
Who provides the mechanisms?	Government, industry, pressure groups, professional teams
Why should they provide these resources?	They need to sell their message, passion for the subject at hand, committed to the cause, need to know public attitude, modify public perception
How much should they know?	Enough to form an opinion, sufficient to participate in decision-making, enough basic science understanding
Are they telling the whole truth?	Perhaps. (Have they lied, mishandled the truth, withheld some critical details and wrongly accused others before, and how often? Are there other trustworthy sources?)
When is it enough?	When consensus is reached or decision made

Source: UNCTAD (2001).

6.2.1 Effective communication of opportunities, risks, and benefits

Trust in regulators has been affected by lack of decisions, indecisions and, to some extent, the past track record of regulatory failures. Unless regulatory bodies are seen to be competent, vigilant and protective of public interest, trust will continue to be eroded. It is difficult for untrustworthy regulators to communicate effectively.

Developing countries should employ trusted institutions to communicate. This entails building bodies composed of organizations that are knowledgeable and trusted to communicate the benefits, opportunities and risks of different processes, products and services of biotechnology.

Clarity and honesty of the message are important (Aerni, 2001). For example, how do we communicate the opportunities that lie in the use of biotechnology to enhance

industrial competitiveness and the quality of products, increase food production, create wealth and jobs, and reduce disease burden and poverty? Currently, there is very little attention paid to the opportunities of using biotechnology in industry and environments. This may be the responsibility of interested Governments. Yet communicating opportunities and benefits has not been very effective as these tend to be overshadowed by risks and concerns.

The benefits to people lie in the products and services, assuming that the opportunities have been exploited. These may include healthier foods, effective drugs, lower energy consumption and increased foreign exchange earning among others. Others have argued that acceptability of biotechnology products has not been successful partly because the opportunities are in the hands of only a few countries.

The risks of biotechnology are communicated very poorly too. They are communicated in a way that makes them unique, hence the need for caution. The risks are looked at in isolation. For example, the European Commission suspended all trials of GMOs following the publication that the pollen from *bt*-corn killed monarch (butterfly) caterpillars. One would have thought that regulators would have been excited that the innovation was effective. It was not new knowledge as any effective pesticide against corn borer worms may have done the same. Such a decision may have been interpreted as "transgenic crops were producing a unique poison that kills insects indiscriminately". It is not what is communicated but how the public interprets it.

6.3 Public awareness and participation; country experiences

6.3.1 Public awareness and participation in Ghana[13]

Ghana embarked on an 18-month public awareness and participation campaign on issues pertaining to biotechnology in 1999. This participatory project was called the Biotechnology Development Programme (BDP). The programme aimed at identifying biotechnology development goals, local capacity, barriers and other ingredients needed to achieve set targets and activities designed to build public awareness and involvement.

To achieve these objectives, building public awareness and participation in the programme were perceived to be important. Farmers, scientists, policy makers and industrialists among other stakeholders drove the programme. Public awareness and participation was viewed as an important aspect in generating sufficient political will and popularization of biotechnology.

This participatory approach was meant to address setting priorities for biotechnology development in health and agriculture. It was also intended to improve information flows among stakeholders, institutions and the public. This approach was adopted to promote development of biotechnology networks and partnerships.

To achieve public awareness, the BDP published newspaper feature articles. Some scientists and representatives of private biotechnology industries made favourable independent comments on the articles. The project also published a newsletter called ***Biotech Ghana,*** which was distributed to stakeholders, including the media.

In addition, press conferences and workshops were held to sensitize the public on biotechnology issues. These received significant attention in newspapers, and on television and radio. The Ghana News Agency (GNA) also carried some of the information generated by BDP on its websites. However, the media articles tended to lack substantive content and the interest was short-lived.

The effectiveness of the various models or tools for delivering information and enabling the public to make an input into the biotechnology development agenda was analysed. The two major dailies are estimated to have a total circulation of 230,000 for a population of 18 million. Therefore, publication of a biotechnology article is likely to reach a small but sizeable fraction of the population. In addition, science stories were generally relegated to inside pages and there was no control on what got in or how it was published.

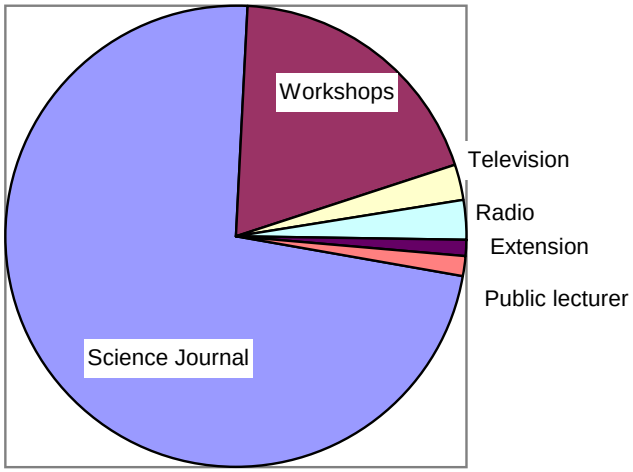
Workshops and conferences were found to offer a better education to stakeholders. They provided a teaching and learning environment where questions were asked and answers provided in an interactive manner. The inputs from various stakeholders was easily noted and analysed. Unfortunately, there was limitation of space and the number of stakeholders that could be gathered in one place at any point in time.

Personal appearances on television and radio programmes were also found to be effective if scheduled. Unscheduled interviews could easily lead to misrepresentation of the facts by the press. These benefited policy makers who try to learn the dynamics of biotechnology to help them communicate effectively. However, scheduled interviews were often pre-paid programmes and fairly costly.

Many challenges were faced in reconciling the interests of scientists and the media personnel. For example, the sources of media stories were predominantly reports from the staff media (52.2 per cent) followed by government and institutional briefs (13.9 per cent). The summary of the study is shown in figure VI.1.

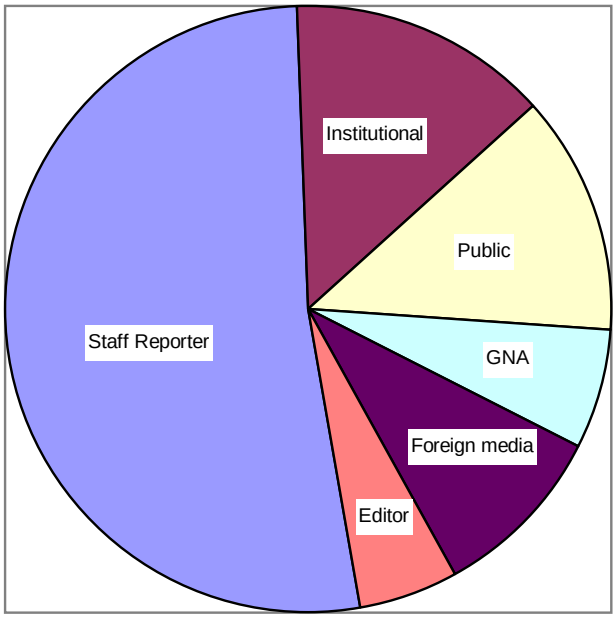
Local media staff rarely consulted scientists and did not publish stories from scientific publications. Local scientists' choice of communication channel was tailored towards peers. Most scientists chose scientific journals as their preferred communication platform followed by scientific conferences and workshops (see figure VI.2). However, most scientists indicated that their findings were targeted at peers (31.5 per cent), policy makers (21 per cent) and the public (18.5 per cent) (see figure VI.3).

Figure VI.1. Channel for Science communication in Ghana



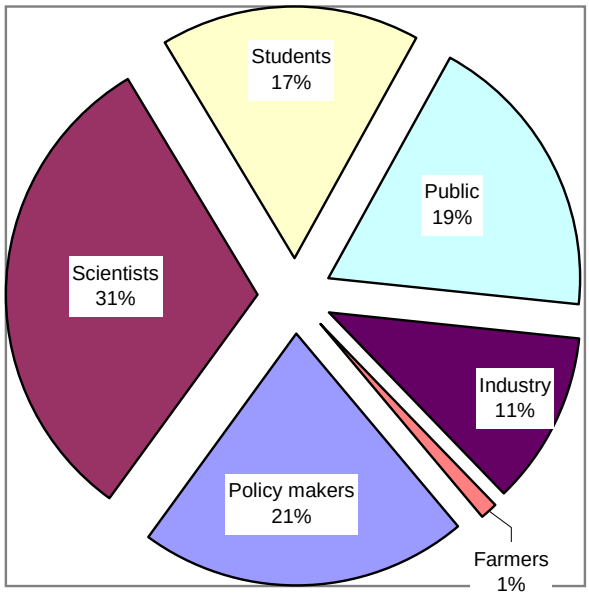
Source: Ghana biotechnology report.

Figure VI.2. Sources of media stories



Source: Ghana biotechnology report.

Figure VI.3. Target groups for scientific data



Source: Ghana biotechnology country report.

The project encountered numerous other interesting problems. Some NGOs and firms did not see themselves as stakeholders. Others, though appointed to serve on the committee, chose not to attend meetings. Scientists and the media generally thought that the public was not interested in science. It was also found that scientists, just like journalists, did not practise exactly what they intended to diffuse. It was not surprising that science stories were on the decline in the media. Many journalists in Ghana are not trained or experienced science reporters while scientists were too busy to concern themselves with science communication.

In the case of biotechnology, the sensational stories carried most of the airtime on television, radio shows and on the front pages of newspapers. It is the captive, sensational and snappy stories that sell newspapers and command airtime, and not boring, long and information-packed sentences that are difficult to understand.

It was difficult to conclude that the public awareness programme in Ghana accomplished all its targets. However, biotechnology received greater government support than before. The Government allocated $350,000 for capacity-building in biotechnology. It also constituted the National Biosafety Committee, refined its draft legislation and developed biosafety guidelines.

An increased exchange of information between scientists was observed. The Council for Scientific and Industrial Research created a biotechnology working committee to address capacity-building issues and collaboration among the various stakeholders.

However, Ghana found itself under pressure to define public policy for biotechnology applications, especially genetic engineering. Many international groups were lobbying the Government to take a precautionary approach to biotechnology. In such an environment, discussions of the benefits and risks of biotechnology objectively was hard to achieve.

6.3. 2 The Russian Federation

The report of the Russian Federation expressed concern that some interest groups tend to emphasize the perceived risks of biotechnology and its products to the general public. This has contributed to an increasingly discerning global public who now want greater reassurance from the scientific community concerning the safety of new products. This tends to place increased responsibility on scientists themselves, and may force the development of new scientific criteria for risk assessment.

The role of the State, as the regulator of both scientific research and its commercial applications, is key to bridging the gap between the scientific community and the general public. In the Russian Federation, several ministries are working together with the Russian Academy of Sciences to build a legal framework for biotechnology. A federal Act was introduced in 1996 to regulate the use of genetic engineering. This Act, which is subject to updates and amendments as new areas of technology develop (for example, gene therapy), has been implemented with transparency and public access to biosafety information.

A new Act, "On a temporary ban on human cloning", now in preparation, resulted from a participatory process involving research scientists, medical practitioners, lawyers, philosophers and ministry officials. The inclusion of philosophers indicates that the ethical questions related to some areas of biotechnology are taken very seriously – in fact, there are three bioethics Committees at the Federal level. However, to date, the public has not specifically been targeted for participation in decision-making. Mechanisms through which the public can make inputs into decision-making would be useful.

6.3.3 The Philippines

The primary agency promoting capacity-building in biotechnology is the Department of Science and Technology (DOST). DOST has a twin-track policy approach: one area of policy covers exploiting the opportunities presented by biotechnology, particularly in agriculture and natural resources; and the other addresses the possible risks to human and environmental health. Within this framework, DOST is encouraging greater participation at sectoral level and also initiating programmes aimed at enhancing public awareness. This is commensurate with participatory approaches in other areas, such as the Ministry of Agriculture's "Agriculture for the Masses" programme.

One of the sectoral planning councils under DOST - the Philippine Council for Agriculture, Forestry and Natural Resource Research and Development (PCARRD)

had in 2000 - started a programme of information, education and communication strategies. To date this has involved the production and dissemination of materials, and the establishment of a biotechnology database. Its proposed activities for the medium term (to 2004) include awareness-building seminars at national and local level for different groups of stakeholders (legislators, farmers, etc.), and increased education about biotechnology through TV, radio and exhibitions.

One of the objectives of PCARRD in implementing this programme of activities is greater public acceptance of biotechnology, particularly in respect of field trials of GM crops, and in generating opposition to a proposed ban on the release of GMOs into the environment. In April 2000, PCARRD and the Biotechnology Association of the Philippines jointly coordinated a workshop on "Information Campaign Strategies for Biotechnology." It was recognized, at this workshop, that PCARRD's activities have so far not been able to effect a real counter-balance to the anti-GMO lobby in the Philippines. A bill, "Genetically Engineered Food Right to Know Act", currently under preparation, will require mandatory labelling of food and food products containing GMOs.

6.3.4 Portugal

In Portugal, a public survey on attitudes towards science was conducted in 2000, which produced some interesting results. When presented with three statements concerning the levels of awareness and participation wanted by the public in respect of science, the largest respondent group (43 per cent) felt that the public should be made more aware of scientific developments. A smaller group (31 per cent) felt that not only should awareness be enhanced, but also that the public should actively participate in decision-making. A sizeable minority (13 per cent) felt that science was so specialized that only experts should be involved in it.

In respect of biotechnology, or more specifically, transgenic foods, 81 per cent of those who participated in the survey did not know anything about them. This compared with 41 per cent in respect of air pollution, and 62 per cent for the greenhouse effect, both of which have been debated in the public arena for much longer. The indications from the survey show that the majority of the respondents do not feel well informed about biotechnology, and would like to be informed, but do not necessarily want to participate in decision-making.

The survey report noted that the public debate on GMOs is relatively low-key, compared with other countries in Europe. The Ministry of Science and Technology is directing its awareness-raising activities mainly towards students, particularly through an umbrella programme called 'Science Alive', which involves teachers, scientific institutions and companies. However, a network of interactive science centres is also being built up.

In respect of public participation in policy-making, it is apparently not an issue of concern at the present time. The survey indicated that only a minority of the public feels that it is needed. It was noted with interest that the anti-GMO lobby within the NGOs has not promoted public participation. At present the authorization for the use and release of GMOs in Portugal does not necessarily include public hearings, although these are an optional part of the authorization process.

6.3.5 Tunisia

In Tunisia, no GMOs have been released outside the research environment as yet, though there is some question as to whether imported animal feed may contain genetically modified corn or soya. It was noted that there is a wide gap between the knowledge embodied in the new technologies and the general public's capacity to understand complex science. Therefore, public choice in respect of biotechnology would be affected by many other factors than just raising the level of technological education in the country.

Other key factors included cultural and religious values, expected socio-economic benefits, confidence in risk management, and other national social and economic policies. Using public acceptance of two other areas of scientific application (organ transplantation, and medically assisted human reproduction) as a guide, the report from Tunisia derived some lessons for building public awareness about genetic modification. Organ transplants were legally accepted in the country, where political will for acceptance was greater than expressed public need, whereas medically assisted reproduction has been limited due to religious considerations, despite public pressure for its acceptance.

It was observed that political will may perhaps provide a greater impetus for information dissemination, legislation and institution-building than public need for the technology. In respect of biotechnology, neither public demand nor a significant national economic need for the technology has yet been demonstrated. Despite recognition of the importance of the technology, the conditions for its promotion in the public arena are, therefore, not particularly favourable at the moment.

6.3.5 Austria

In Austria, public awareness about modern biotechnology is relatively high, perhaps in part because a referendum on gene technology in agriculture was conducted quite recently. However, the problem is that awareness is biased towards fear of perceived risks than being based on scientific information, and therefore this "awareness" has not led to greater acceptability of the technology.

There is no shortage of balanced information available. For example, several ministries provide information which can be accessed by the public, and a comprehensive website[14] exists which contains links to publications by national and international organizations and by individual scientists. But this balanced information is not promoted effectively to the public through the mass media, which tends to highlight the polarized views of anti-GMO activists and the biotechnology industry.

In the long term, the most effective and sustainable way to enhance awareness about the opportunities and risks emerging from gene technology is through the school education system. In the shorter term, there is a need to find ways to improve communication between scientists and government agencies, on the one hand, and the mass media on the other. Even then, this in itself may be insufficient for balanced scientific information to be given prominence in the popular press, or to be broadcast at peak TV viewing (or radio listening) times. The Government may need to

introduce other political or financial measures to enhance public awareness that is based on balanced and dispassionate information.

6.3.6 Greece

Despite being without a significant market for GM seed and with only one major research institution involved in modern biotechnology, Greece has a fairly well informed public according to the most recent Eurobarometer survey on public attitudes towards biotechnology. Whilst public acceptance of biotechnology has not been systematically studied in the country, press reports and the Eurobarometer results suggest that the public in Greece is very sceptical about the technology and its potential to contribute to future welfare and sustainable development.

Acceptance seems to be higher for medical applications than for food production and manufacture. This may well be due to a tendency to favour traditional food products and processes, but also because of a lack of trust in political agencies seeking to promote the technologies. Bioethics committees have been established in the Ministries of Health, Environment and Development, which form the General Secretariat for research and technology in Greece. Further, a National Committee on Bioethics, comprising senior academics of wide-ranging disciplines, has been set up directly under the office of the Prime Minister. All these committees are mandated to address policy issues and provide policy advice.

The Greek Bioethics Committee, based at the Ministry of Development, is further mandated to promote public awareness through a variety of mechanisms, including participation in public events and dissemination of information via the Internet. However, whilst it has issued opinions on biotechnology-related matters, it has been less successful in its aim of enhancing public awareness. The Ministry of Agriculture has so far reacted only defensively (in respect of raising public awareness), issuing press releases when challenged by environmental lobbies.

6.3.7 Indonesia

In Indonesia, the environmental groups opposed to genetic engineering have stimulated public debate and therefore, arguably, raised public awareness, driving the public into participating in the policy arena. The debate has so far centred on the commercial planting of imported transgenic cottonseed through the local subsidiary of a transnational corporation. The seed had been authorized for commercial planting by the National Commission for Food and Agricultural Biosafety (NCFAB), and the farmers reported a substantial increase in yield from the new seed.

However, since the public debate intensified, the Ministry of State for the Environment has suggested that commercial planting of transgenic seed should be halted, though contained research could continue. Farmers and private firms have publicly opposed this directive. Both the Ministry of State for Research and Technology (MSRT), and the Indonesian Science Academy have issued statements supporting the use and development of biotechnology.

The Indonesian Parliament has initiated programmes to provide public access to objective information. The MSRT conducts routine scientific briefings for members of Parliament, the press and the public on transgenic products. In Indonesia's case,

the Government has tried to react to public controversy based on extreme positions taken by commercial interests and NGOs, respectively, by intervening as a supplier of balanced information.

6.3.8 Paraguay

In Paraguay, whilst public awareness has been raised through the national and international media, there does not seem to be a high level of public interest in, or concern about, biotechnology. Despite a lack of public concern, it was agreed in 2000 to maintain the existing moratorium on the commercial use of GMOs until clearer scientific evidence on their alleged risks emerges.

Whilst there is as yet no central national policy on biotechnology, sectoral ministries have developed their own policies and positions. Public awareness raising activities are being implemented, for example through the Biosafety Commission, which has been organizing information workshops since 1998.

6.3.9 Uganda

In Uganda, apart from a small minority of scientists, there was a general lack of awareness about biotechnology. Whilst there is recognition at sectoral level that biotechnology may provide the means to improve crop yields, increase disease and pest resistance, contribute significantly to improve human healthcare provision and enhance animal health, there is also significant concern about the potential negative impacts of the technology. However, little is understood beyond this outline of opportunities and challenges, and there is a perceived need for awareness raising in general. The National Biosafety Committee, already established, may be the best national body to undertake this task, but it is likely to be severely constrained by resource problems.

Box.VI.1. General observations

It was agreed that greater public awareness about biotechnology is needed, though it is evident from European countries' experiences that greater awareness does not necessarily lead to increased public appreciation of the science behind biotechnology. This seems to be largely because the dominant messages reaching the general public, mostly through the mass media, are clearly biased against biotechnology, especially in respect of agriculture. Provision of balanced information was necessary, but not sufficient, to restore the balance between perceived risks and expected benefits.

There is a need to ensure that the information actually reaches the public. Journalists are unlikely to take the responsibility for seeking out and transmitting balanced science stories. Scientists, with support and encouragement from their employers and Governments, could play a key role in actively seeking channels of communication to disseminate their findings.

The Commission called on Governments to raise public awareness about biotechnology through public debate, rallies, seminars, conferences, education system and the media among others. However, in many countries, there is a perceived lack of public interest in science. It was suggested that a gradual building

up of an improved science culture within developing countries' formal and informal education systems may be required. Similarly, simplifying the scientific language for easy digestion by non-scientists may increase public interest.

It was recognized that an uninformed public of consumers and, perhaps, voters may have an adverse impact on the application of biotechnology if they do not trust Governments, firms and scientists. National Governments, international organizations, the media, specialists and NGOs can play key roles here, both by providing balanced information and by establishing and supporting a public forum for open and transparent dialogue on the potential opportunities and challenges related to biotechnology.

6.4 Managing economic risks and benefits

Much of the discussion about the risks of biotechnology concerns environmental and health issues. The failure to manage economic risks and benefits effectively is one of the main sources of resistance to the adoption of new technologies. There are institutions that deal with some aspects of risk and benefit management, such as anti-trust legislation. But these do not address the seemingly benign cases of product displacement. Generally, such adjustments are considered to be part of the evolution of markets. However, the pace and scale at which they happen could become a threat to the diffusion of the very technology that brings about new benefits. The use of pest-resistant crops, for example, could be seen as offering a wide range of economic and health benefits. But those who rely on the chemical industry for their livelihoods are likely to be direct and indirect sources of resistance to the new technology.

An early effort to identify potential winners and losers is an important part of the technology development strategy. It should be possible to manage both the risks and the benefits in a way that allows for relatively smooth technological transitions. Managing technological transition is not easy, partly because of the competitive nature of market behaviour and the dominant view of losses as part of the institution of free markets. However, in the absence of measures that reduce radical market impacts, resistance to new technologies is likely to emerge and undermine the potential benefits to society.

6.5 Social acceptance of biotechnology

6.5.1 Social acceptance of transgenic crops

Governments, farmers, consumers and, to a lesser extent, scientists disagree fundamentally on the risks and benefits of transgenic crops. The reasons for opposition include safety, ownership (patents) of life, the influence and role of multinational firms and economic muscle or control (transgenic crops being another way of controlling food supply, and a threat to agricultural diversity) and the neglect of interest of small-scale and poor farmers. Therefore, social acceptance is not simply based on the strength of scientific evidence and perceived benefits and risks but also issue of self-empowerment. For example, consumers wish to choose what they eat, farmers what they grow, Governments what they regulate and citizens what science they support. Consequently, all these stakeholders (or at least a majority of them) should agree on the dissemination of transgenic crops.

The debate is also based on differing views of nature. For example, Europeans in general regard their countryside as a place where people live and not as somewhere apart, and attach great importance to regional cuisines, making food a strong element of local identity. However, in the United States, although there are regional recipes, there is not a strong tradition of local brands but more about brand consistency, making products of major restaurant companies predictable. Although food in Europe travels great distances from farm to the table, Europeans think of their food as a product of the countryside in which they live. Perhaps it is the perceived industrialization of food production that makes Europeans uncomfortable, not so much the tinkering with genes (Raynes, 2003)

There is also concern about the risk to reasoned discussions and, possibly even to, democracy. For example, the World Trade Organization (WTO) regime recognizes threat to human health or the environment as the basis on which a country can refuse to admit a product. Countries cannot openly express the full range of their concerns about transgenic crops because such fears have no legal standing in WTO. This could force nations to inflate concerns about human health and the environment. Without an open debate, democratic decision-making would not occur easily. Although solutions are hard to find, avoiding the cultural issues that lie behind the public arguments may not be helpful (Raynes, 2003).

Arguably, biotechnology applications could help meet food security issues affecting a number of developing countries, especially Africa. However, the current transgenic crops on the market were not developed to help feed the developing world, although they may help the commodity sector in a number of them. There are only a few major public sector programmes that target crops and livestock of interest to developing countries because about 70% of investment in agricultural biotechnology R&D comes from the private sector. From the early 1990s major biotechnology firms targeted products for lucrative markets of Western Europe, the United States and Canada that made infinite promises about profit.

A similar dedication to develop genetically improved lines of African staple crops such as sorghum, cassava, yams, pearl millet, pigeon pea, chickpea, groundnut and cowpea would make a big impact and possibly increase yields 10% to 15%, if properly adopted and adapted. For example, transgenic rice varieties, developed through technologies patented by private firms, have the potential to improve yields by as much as 20% by resisting disease, and yet no field testing is under way (Piore, 2003).

The acceptance of transgenic crops varies widely between and across nations. For example, in one 1999 study by Environics International, 79% of Chinese held a favourable view of agricultural biotechnology to create pest-resistant crops, a percentage even higher than the 78% registered in the United States, and 63% of Japanese and 36% of British (holding similar views). A more recent survey of Beijing residents found that a large majority of shoppers were quite willing to buy transgenic foodstuffs, with many even willing to pay a premium for such products if there were noticeable benefits. Such attitudes facilitate the Government's plans for expanded use of transgenic crops. The lack of consumer benefits is another reason for resistance.

The World Bank is launching a three-year review of all agricultural technologies used around the globe from transgenic crops to organic farming. "The key question about any review of transgenic organisms is: does it have the full ownership of the scientific community and those who make decisions about biotechnology", Bank's chief scientist, Bob Watson, said. The review will involve various biotechnology stakeholders, such as scientists, firm executives, farmers, consumers and NGOs (Mason, 2003).

6.5.2 Social acceptance of medical biotechnology

In the case of medical application, many people agree that health care is a top priority and anything that may improve it is more than welcome, especially if it affects individuals directly and independently. In addition, access to drugs, diagnostics and vaccines remains limited for many life-threatening illnesses. Medical biotechnology is likely to improve the accuracy and speed of diagnosis of diseases and identification of pathogens, and the prevention (through efficient, cheap and safe vaccines) and management of ilnesses (new drugs and genetic profiles).

For these and other reasons, medical applications find significant support even when they are controversial. Geron, a firm involved in medical research, has worked out how to lead embryonic stem cells to turn into seven different types of normal cell lines that may be used to repair damaged tissue (heart, muscle, pancreas, bone, brain, spinal injuries and liver). This could solve rejection of organs or tissue derived from stem cells of another organism.

Box. VI.2 The case of Molly Nash and Franconi's (anaemia) disorder

Molly Nash (8 years in 2003) was born with a rare disorder, Franconi's anaemia, which causes bone-marrow cells to fail. Molly needed new cells from a donor who is an almost exact genetic map. Pre-implantation genetic diagnosis (PGD), a test performed using embryonic cells, was used to save Molly. With the help of PGD, Molly's parents conceived their son Adam, 2.5 years old in 2003, who successfully donated umbilical-cord blood to save his sister's life.

However, PGD is transforming reproductive medicine by giving parents unprecedented control over what genes their offspring will have. The fear is that as other aspects of reproductive technology improve, PGD may be misused. The process starts with a single human stem cell, plucked from a three-day-old embryo or less. Although many clinics in London, Chicago, Tel Aviv and Brussels offer the PGD service, a controversy is building up since the cells come from fertility clinics, where would-be parents have their eggs harvested, fertilized and grown in the laboratory. By day three, the egg cell may divide, on average, into only six stem cells. To find out if it carries the genes for Tay-Sachs or cystic fibrosis or sickle cell anemia, the laboratory's researchers and technicians analyse the DNA.

The number of people on lists for organ transplant remains high, but few viable organs are available to save these lives. Work is on going to coax stem cells to grow into organs, overcome rejections of organs from other animals (e.g. pigs) and target ailing tissues/the organ's ability to regenerate. Despites impressive results, there is no consensus on the use of embryonic cells and the limits to which such use is permitted. In 2002, the EU adopted a moratorium on the Commission's funding of

research on embryonic stem cells until clear-cut and strict ethical rules have been set up. The United States has also curtailed Federal funding for embryonic research. In addition, the UN postponed a decision on human cloning in 2003. However, the United Kingdom, Singapore and China are among countries with more liberal regulation on embryonic research.
The development of research on adult stem cells, spurred by therapeutic aims, may raise more formidable problems than those aimed at forbidding destruction or creation of embryos. There is not a clear definition of an embryo in science. Ethical reflection and debates seems to be based on the representation of life which the continuous discoveries put in question. At the same time, people want therapies without ethical dilemmas, the absence of risk without questioning our representations of life (Renard and Bonniot de Ruisselet, 2003).
Throughout history, mankind has continuously revised the ethical codes to meet new challenges. The continuous creation of knowledge, innovation and technologies requires the design of new procedures and the participation of academic, professional associations and legislatures. Inevitably, the accumulation of biological knowledge and its wide application will place a share of responsibility among the stakeholders (Renard and Bonniot de Ruisselet, 2003).
Gene therapy, on the other hand, is highly supported despite the risks it possesses. For instance, treatment of Parkinson's disease via gene therapy was tested for the first time on humans on 18 August 2003. It consists of injection into the brain of a virus carrying the gene for the synthesis of dopamine (whose absence causes the disease). The scientific community is divided about this approach, which some neurologists consider highly risky. The results were expected within two months after the initial injection. Some recent gene therapy experiments dealing with the repair of major deficiencies of the immune system were interrupted after the death of the patients. The causes of fatality are being sought, and experiments might be resumed if safety is ensured. On the other hand, extending gene therapy to germ cells to stop the disease being passed on is controversial, because of its eugenic approach.

6.5.3 Acceptance of GM crops for food and pharmaceutical production

Biopharming, which critics call Pharmageddon, worry consumer advocates, who fear that crop products carrying drugs, vaccines and industrial chemicals will end up on their dinner tables. This fear is heightened by the discovery of transgenic maize variety containing a vaccine against pig diarrhoea in a soya field that had been used previous as testing site by ProdiGene. USDA Animal and Plant Health Inspection Service (APHIS) instructed ProdiGene, Inc., to remove the maize plants from the field. Despite the fact the plants had no viable seeds, it constituted a failure by the firms to destroy all the crops as demanded in field trials.

However, the soybeans were harvested before all of the transgenic maize was removed to a storage facility. The soybeans had to be stopped from entering the human or animal food chains. Another breach of the US regulations was discovered at a ProdiGene, Inc., test site in Iowa in September 2002 and the maize plants were removed from the field earlier in the season. The contaminated soya batches did not enter the human or animal food-supply chain.

ProdiGene, Inc., was fined more than $3 million for breaching the Plant Protection Act and paid a civil penalty of $250,000 as well as reimbursing the USDA for all costs for collecting and destroying the contaminated soybeans, and cleaning the

storage facility and all equipment. ProdiGene, Inc., also agreed to a $1 million bond and higher compliance standards, including additional approvals before field testing and harvesting transgenic material. The company was expected to develop a written compliance programme with the USDA to ensure that its employees, agents, cooperators and managers are aware of, and comply with, the Plant Protection Act, federal regulations and permit conditions. Such lapses reinforce fears that managing the segregation of transgenics for industrial chemicals crops meant for food may not be feasible.

The concerns in biopharming are similar to those of GM food plants and animals. Issues of gene flow, resistance to drugs, contamination of non-GM plants and animal and biodiversity concerns plague both GMOs for food and pharmaceuticals or industrial chemicals. Some key players, including Monsanto Co. and Dow Agrosciences, have chosen to grow their pharma-maize in isolated areas, such as Arizona, California and Washington State, instead of the Corn Belt. In response to these breaches, the USDA created a new Biotechnology Regulatory Services (BRS) Unit within the Animal and Plant Health Inspection Service (APHIS) for regulating and facilitating biotechnology. Draft guidance to industry on drugs, biologicals and medical devices derived from bioengineered plants for use in humans and animals was published in September 2002. The USDA also set up a new unit in the Foreign Agricultural Service to deal with biotechnology trade issues.

Gene escape from a biopharmed crop towards a conventional one would occur only if a certain gene from the crop confers a selective advantage on the recipient or has the ability to reproduce. However, many plant varieties for biopharming are less fit and less able to proliferate than conventional ones. However, various countries are putting in place legislation and guidelines for biopharming, with a high degree of responsibility of being placed on the firms.

6.5.4 Social acceptance of industrial biotechnology

Industrial biotechnology enjoys a positive social acceptance because it is environmentally friendly and contributes to sustainable development. By providing new materials and fuels that are not derived from petrochemical processes, by improving and enhancing the bioremediation of water, soils and ecosystems at large, and by trying to use less fossil-fuel energy, industrial biotechnology may become acceptable to all.

Industrial biotechnology benefits from the fact that it may simplify processing, improve efficiency, reduce waste production and increase productivity. It meets both the demands of shareholders by being cost-effective and profitable, and those of environmental advocates by being environmentally friendly. Therefore, firms may be compelled to adopt industrial biotechnology applications because of their simplicity, reduced initial investment capital and flexibility or legal requirements rather than because they are environmentally friendly (OECD, 2001).

However, the release into the environment of genetically-modified organisms used in industrial biotechnology application raises fears about their potential impact on biological diversity. That is why the industrialists are rather using them in confined environments, such as their factories and greenhouses under strict biosafety regulations.

6.6 Conclusion

Public trust in science, and particularly biotechnology, cannot be achieved without open communication about the potential or perceived risks associated with the technology. Dialogue with the public, policy makers and the scientific community, and listening to, and taking account of, public concerns and recommendations may be required.

Public awareness and participation need to be planned, deliberate and sustained to achieve maximum impact. This is likely to be costly in the short term but justifiable in the long run. In countries where budgets are fairly restrictive, financing of biotechnology will only take place if decision-makers appreciate the opportunities and benefits of biotechnology.

In developed countries, scientific literacy is considered to be very low, despite easy access to higher education, the mass media and other sources of information about science. For developing countries, then, the task of building greater scientific awareness will not be an easy one. It will depend on the ability and willingness of many different groups of people, particularly policy makers, the scientific community and the public themselves, to participate. To improve information flows and engage in meaningful dialogue, the choice of the most appropriate and cost-effective mechanisms to promote public awareness and to facilitate public participation in decision-making will be important, especially in poor countries.

There is overwhelming evidence that public awareness and understanding does not lead to public acceptance. Despite the spirited debates and demonstrations, and the abundant information on biotechnology, on television, in the print media and on the Internet, attitudes towards biotechnology have not changed much over the last few years. The segments of populations that support or oppose the technology have remained unchanged.

National Governments often seem to make choices of which biotechnology fields and products are allowed on the basis of other factors rather than science alone. The ability to be seen to regulate and the comparative opportunities biotechnology offers to local societies seem to be the major influencing factors.

The levels of transgenic maize acreage in the United States in 2001 was reduced because the European corn borer infestation in 2000 was low and farmers did not see the need to pay a premium in the absence of high levels of the pest (James, 2002). National Governments seem to make similar arguments in allowing commercialization of transgenic crops. Many developing countries, especially those whose prime market(s) are sceptical of GMOs, will not adopt the technology unless the benefits are significant.

While Governments will be making these policy decisions, the public may interpret decisions to ban certain transgenic crops to mean that these crops are unsafe. Similarly, Governments that would not allow commercialization of certain transgenic crops (e.g. maize) are unlike to allow trade in products of such a crop. This may be the situation being witnessed with transgenic crop adoption.

The ray of hope comes from the promotion of biotechnology in general. As biotechnology products penetrate all aspects of production, processing and communication, the myths may reduce and familiarity may increase. Biotechnology still enjoys significant support in medical and industrial applications. The field of environmental biotechnology is also growing fairly fast too.

Winning public trust is very important in generating public awareness. Many developing countries do not seem to have trustworthy regulators. The regulators are often perceived as not being very competent owing to lack of skilled personnel, facilities and funding. Governments must act in a timely fashion to improve public awareness and participation in biotechnology.

Chapter VII
Possible development models

7.1 The achievements

Biotechnology is revolutionizing agricultural, medical, industrial and environmental research and development. As indicated in the various cases highlighted in this report, some developing countries have taken strides to be considered frontrunners. Their size may not match that of developed nations, but they have impressed and attracted the interest of developed countries' firms. They serve as signals of the coming of age of the biotechnology industry in developing countries.

The cases of Brazil, Cuba, India, Ghana and the Republic of Korea provide excellent examples of ingenious ways of achieving and managing technical change within their national resources by building local capacity and strategic alliances with leading nations. It is possible to help other countries to emulate, but not necessarily copy, their strategies.

These results are far from being considered impressive as some developing countries are yet to join the bioeconomy. However, the presence of regional leaders gives hope that "proximity" may help accelerate use of biotechnology by countries lagging behind. Combined with regional integration, neighbouring countries or countries belonging to the same regional grouping may adopt similar strategies.

This process could be hastened if regional bodies are involved in science and technology, helping the "weaker neighbours" to have a stake. So far, this strategy is working well in North America, Europe and Asia. Unless countries have something to lose or gain they are unlikely to be proactive in their perception of biotechnology products and services.

7.2 Use of technological niches to develop biotechnology

The use of technological niches to quickly develop facilities and human resource is highlighted in the case of ONSA, Brazil, which created the virtual genomic institute. In many countries, all the resources would have been put in one centre, experts hired from the outside or contracts given to laboratories in developed countries. The case clearly demonstrated the importance of the careful design of incentives and support structures in motivating and increasing performance. All the laboratories that were associated with ONSA acquired the ability to generate high-quality data.

Identifying a technology that could help a number of centres interact with each other, share facilities and human resources, and the benefits is important. Technologies for genome sequencing, bio-prospecting, breeding and bioinformatics are among many others that could be exploited to train skilled manpower, upgrade facilities and generate useful products at an economic price.

In combination with market niches, technological niches could be economically and socially beneficial. For example, the high demand for flowers and green vegetables in developed countries has created a lucrative market for products from developing countries. Even in time of starvation, this sector remains very strong. Technologies such as biofertilizers and biopesticides targeting this market would provide an added advantage. Extra jobs and wealth will be generated.

Currently, technology niches are not even on the agenda of countries and development agents in poor countries. While it is important to focus on the most difficult problems, widely used products and services, and socially or politically significant issues such as vaccine development, developing countries do not have any competitive edge in some of these areas. These niches provide an opportunity from which biotechnology may grow and alliances may be developed to later take on the more challenging and complex tasks.

7.3 Development of national biotechnology programmes

Many developing countries do not have biotechnology programmes that clearly state the goals, when they should be achieved and the levels of productivity expected. National biotechnology programmme should be separate from the Biosafety Commissions to minimize conflicts of interest, independence and fair representation of biotechnology.

The national programme could benefit from professionals at home and abroad. Given the improvements in communications, huge amounts of work could be accomplished without the need for special buildings or structures. The Government could be represented at a high level, preferably a minister or deputy minister, and interested donors at a high level as well. The rest of the team could come from industry and academic/research institutions with interests in the development of biotechnology.

This team could work with other experts to develop training programmes to meet the goals set. It should also ensure that biotechnology is included in technical assistance and other bilateral and multilateral agreements. Mechanisms for financing and technology acquisition could be developed, marketed and/or negotiated.

7.3.1 Establishing industries using incubators

Incubator facilities in research institutions and universities remain very popular. They are important in commercializing research products, especially in countries without mature venture capital markets. They are also important in attracting finance as projects are likely to be funded if linked to incubator facilities that have acquired a good reputation rather than in isolation. Incubator facilities may have to be developed inside or within walking distance of research centres such as universities.

Incubator facilities reduce the cost of space, research and development, and professional advice. They also increase information flow, recombination of ideas and expansion of knowledge horizon. They may also benefit from government incentives, such as tax relief on equipment, rentals and salaries. For these reasons, they could help increase the survival and generation of new firms. However, the

success of incubators has to be measured by the number of successful firms graduated rather than the number of firms in tenancy.

7.3.2 Building interactive teams for industrial development

Although the idea of bringing industries, academia and Governments together is a highly favoured model (the triple helix), implementation remains loosely articulated. Poor countries have another powerful player, donors, that is not often included and yet donors influence policy decisions, financing and marketing or access to technologies. Inclusion of donors in the triple helix model or the national innovation system model violates the basis of these models. Donors (in developing countries) are rarely national, governmental, industrial or academic in nature to fit these models.

Inclusion of the role of donors in development of a biotechnology industry is important. Interactive teams formed around specific projects could include donors and government as financing and technology transfer entities, industry as product developers and academia as researchers and human resource developers. Therefore, identifying projects that could allow the various public and private institutions to make some contribution and realize benefits (social, economic or political) may be vital to the creation of interactive teams. Once a start has been made, different players will identify other areas of collaboration.

Agricultural biotechnology in poor countries, especially Africa, has suffered from fragmentation. National agricultural research systems (NARS) are largely agricultural research institutions that are owned by Governments and work in isolation (away from academic and industrial institutions). The agricultural extension and marketing services are independent from research facilities. Therefore, the flow of new innovations to farmers is slow.

To solve this problem, many research institutions have taken on the role of extension services and marketing firms. Unfortunately, their small size and limited financial and communication systems are working against this one-in-all model. It would seem reasonable to integrate extension services and agricultural marketing firms in order to increase specialization and commercialization of products as well as receive feedback.

7.3.3 Policies for biotechnology industrial development

Government policies that explicitly indicate the intention to develop a biotechnology-based industry are important in accomplishing any of the above tasks. These include policies that provide incentives for the initiation of biotechnology-related programmes in universities, encourage ownership and protection of intellectual property rights, promote the commercialization of technologies and provide incentives to industry. In addition, government policies should encourage the formation of strategic partnerships between different players in the economy and outside the country.

Governments could help in acquiring technologies needed to build a biotechnology industry. Cuba, for example, sourced technologies from friendly Governments. Other countries could do the same. Establishment of public venture capital is important in

ensuring that technologies that can not be acquired freely may be bought at a negotiated price, and that products developed are successfully commercialized.

7.4 Conclusion

Future biotechnology products and services are likely to improve the quality of life even in developing countries. Products and services developed for markets in the North may find applications in the South. The cost of biological research is likely to become affordable for developing countries to develop their own products. The increase in information exchange and access will empower innovators and the public to seek better products and services.

Unless the formal and informal educational systems are refocused to meet the current and future challenges, developing countries will lose most of their current market to developed countries and countries with economies in transition. This is based on the fact that the technology market is imperfect, poorly characterized and highly regulated in favour of developers. Identifying the best, cost-effective and useful technology is difficult and time-consuming, while the fast turnover of technology makes even new technology platforms become obsolete, sometimes before products and services are generated.

The role of technology in industrial competitiveness is now well established and is a distinguishing agent between the poor and the rich. The replacement of older technology products and services with newer ones is part of the free market. These forces are not restricted to biotechnology alone nor are they new. For example, the sisal market was taken by synthetic fibres, while artificial sweeteners and syrups have displaced some of the sugar market. Similarly, technology that enables crops and animals to perform well in environments previously thought to be hostile will spell gains and losses for different societies that depend on them.

Therefore, biotechnology may have to be sold in a way that enables all countries to see themselves as winners. The lessons from transgenic crops and animals should serve as a source of new strategies. Rather than stand out, benefit sharing could be achieved by buying into national or local seed companies. It could also help elevate the profile of multinationals and their local partners, and share the risks.

However, these could only be achieved if developing countries become part of the revolution. Developing countries may have been left behind but options for catching-up remain open. Developed countries, especially those that work in developing countries, should provide technological and industrial leadership.

Notes

[1] Based on an ad hoc expert group meeting held from 15 to16 November 2001 on 'industrial and environmental applications of biotechnology in developing countries, prepared in conjunction with CSTD, and Calestous Juma and Victor Konde.

[2] Based on transgenic maize adoption by farmers, in terms of acreage, which increased significantly until 1999 and has since stalled or reduced slightly. Some attribute this to the low infestation of the European corn borer in 1999 and 2000. It is also possible that the uncertainty of market availability for transgenic maize may be influencing adoption. This reduction occurred in the United States of America, where crop marketing is well organized. Developing countries seem to be making similar choices.

[3] Based on "Biotechnology in developing countries and countries with economies in transition; Strategic capacity building considerations", series paper prepared by the United Nations Conference on Trade and Development in collaboration with J. Mugabe for the first CSTD panel on national capacity-building held from 11 to 13 April 2000.

[4] Based on a country report presented by the representative of Republic of Korea at the first CSTD panel on national capacity-building in biotechnology, held in Tehran, Islamic Republic of Iran, from 11 to 13 April 2000.

[5] China's genome project gets enthusiastic support, *People's Daily*, 7 July 2000.

[6] Source: FAOSTA (http://apps.fao.org)

[7] Based on an ad hoc expert group meeting held from 15 to16 November 2001 on industrial and environmental applications of biotechnology in developing countries, prepared in conjunction with CSTD, and Calestous Juma and Victor Konde.

[8] It is suitable for production of up to 150, 000 tonnes per annum.

[9] Based on an ad hoc expert group meeting held from 15 to 16 November 2001 on industrial and environmental applications of biotechnology in developing countries, prepared in conjunction with CSTD, and Calestous Juma and Victor Konde.

[10] Peak tariffs are tariffs of 15% or higher, or three times the tariff in developed countries. Tariff escalation refers to increasing tariff with level of downstream processing.

[11] OECD support to agriculture is estimated at $1 billion per day (see Inge Kaul, Katell Le Goulven and Mirjam Schnupf, Financing Global Public Goods: Policy Experience and Future Challenges [via www.undp.org] and van Beers, Cees, and André de Moor (2001) *Public Subsidies and Policy Failures: How Subsidies Distort the Natural Environment, Equity and Trade, and How to Reform Them*, Cheltenham, UK: Edward Elgar Publishing.

[12] See World Intellectual Property Organization (WIPO) report of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 2001 WIPO/GRTKF/IC/1/10, and World Health Organization (WHO) 2002-2005 Global strategy on traditional and alternative medicine, accessible via www.who.int/inf/en/pr-2002-38.html.

[13] Based on a national report presented at the CSTD panel on public awareness and participation in science policy making and dialogue held in Tunis, Tunisia, from 11 to 14 November 2000.

[14] At URL: http://www.gentechnik.gov.at

[15] 1. Despite the high levels of HIV/AIDS cases in developing countries and the numbers of unwanted pregnancies, the use of male condoms had such a stigma that no one was willing to buy or sell them. It has taken years of spirited and sustained public awareness campaigns and discussions for the general public to accept. However, most religious groups still oppose the use of condoms.

2. Sex technologies have attracted significant opposition. For example, the use of pills that eliminate fertilized embryos have been opposed by anti-abortion groups. Similarly, male fertility control pills are not on the market mainly for two reasons: (i) women will not trust men to take them; and (ii) men are unlikely to take them. However, in some developing countries such pills will not even be allowed to be on the shelves.

3. The argument that those opposed to GMOs have a choice of many foods has been proved wrong. GMOs have attracted negative feeling in developing countries except where political leaders see the benefits. Future technology may face similar opposition based on cultural, political, ethical and religious views that tend to be far stronger in developing nations than developed nations. With improved information access, exchange of ideas and experiences increasingly becomes global, and this may therefore change.

[16] It is often difficult for developing countries to take sides. The battle over transgenic crops shows developing countries failing to take decisions that place them in a confrontation with one of their developed partners, especially those influencing trade arrangements. Empowering them to make independent decisions may be crucial, but for now developed nations have to be sensitive to the needs of poor countries while pursuing their national interests.

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