

**International Trends
in Modern
Biotechnology: Entry
by and Implications
for African Countries**

John Mugabe

ATPS SPECIAL PAPER SERIES No. 15

Published by the African Technology Policy Studies Network, P.O. Box 10081, 00100
General Post Office, Nairobi, Kenya.

© 2003 African Technology Policy Studies Network (ATPS)

PUBLISHED BY ATPS COMMUNICATIONS DEPARTMENT

Printed by Newtec Concepts
P.O. Box 00800, Westlands
14180 Nairobi, Kenya
Tel: 4449849, Fax: 4450399
newtec@bidii.com

ISBN: 9966-916-31-8

ABOUT THE AFRICAN TECHNOLOGY POLICY STUDIES NETWORK

The African Technology Policy Studies Network (ATPS) is a multi-disciplinary network of researchers, policy makers, actors in the private sector and other end users interested in generating, promoting and strengthening innovative science and technology policies in Africa. With a regional secretariat in Nairobi, the network operates through national chapters in 17 countries, with an expansion plan to cover the entire sub-Saharan Africa.

One of the objectives of the network is to disseminate research results to policy makers, legislators, the organized private sector, civil society, mass media and farmers' groups through publications, dialogue and advocacy. Among its range of publications are the Working Paper Series (WPS), Research Paper Series (RPS), Special Paper Series (SPS) and the Technopolicy Briefs.

Papers published under the ATPS Special Paper Series are those commissioned as concept papers, think pieces, leading conference papers and keynote addresses. In keeping with our knowledge brokerage function, ATPS publishes, with permission of the author(s) or journal editors, papers (published or unpublished) produced by distinguished academics/researchers for a different purpose but judged by ATPS to be of excellent quality. These papers address significant policy questions relevant to the work of ATPS and/or support the Southern voice or an African perspective. We also consider theoretical papers that advance our knowledge of science and technology policy issues.

ATPS is supported by a growing number of donors including the International Development Research Centre (IDRC), the Carnegie Corporation of New York, the Rockefeller Foundation, the World Bank, the OPEC Fund, Ford Foundation, Coca-Cola Eastern Africa, the African Development Bank, *InfoDev*, and the Royal Dutch Government.

Table of Contents

List of Abbreviations and Acronyms	i
List of Tables	iii
Introduction	1
1. International biotechnology development	3
1.1. Trends in research, development and commercialization	3
1.2. The Institutional landscape	5
2. Biotechnology in developing countries	8
2.1. Overview of biotechnology R&D in Africa	8
2.2. Biotechnology R&D in Asia: some examples	12
2.3. Biotechnology in Latin America	15
3. International public policy issues	18
3.1. Public perception	18
3.2. Regulatory Approaches and Capability	19
4. The way forward	22
4.1. Build public confidence and participation	22
4.2. Build and utilize public R&D capacity	23
4.3. Establish and apply regulatory instruments	24
4.4. Build public-private R&D partnerships	25
5. Conclusion	27
References	28

List of Abbreviations and Acronyms

AGERI	Agricultural Genetic Engineering Research Institute
APHIS	Animal and Plant Health Inspection Service
BSE	Bovine Spongiform Encephalopathy
CAS	Chinese Academy of Science
CIGB	Centre for Genetic Engineering and Biotechnology
CMI	Centre for Molecular Immunology
CONABIA	National Biosafety Committee
CTNBio	National Technical Biosafety Committee
CVL	Central Veterinary Laboratory
DAB	Drug Administration Bureau
DNA	Deoxyribonucleic Acid
EPA	Environmental Protection Agency
EPSPS	Enolpyruvateshikimate-3-Phosphatesynthase
EU	European Union
FDA	Food and Drug Administration
GEF	Global Environment Facility
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically Modified Organisms
HGS	Human Genome Sciences
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
ICGEB	International Centre for Genetic Engineering and Biotechnology
IPB	Institute of Plant Breeding
ITSTC	Institute for Tropical and Sub-Tropical Crops
KARI	Kenya Agricultural Research Institute
MABs	Monoclonal Antibodies
NBC	National Biosafety Committee
NBFs	National Biotechnology Funds
NCBP	National Committee on Biosafety of the Philippines
R&D	Research & Development
SAGENE	South African Committee for Genetic Experimentation
SAGPyA	Secretary of Agriculture, Livestock, Fisheries and Food
SSTC	State Science and Technology Commission
UK	United Kingdom

UNEP	United Nations Environmental Programme
UPLB	University of the Philippines in Los Banos
USA	United States of America
USAID	United States Agency for International Development
ZYMV	Zucchini Yellow Mosaic Potyvirus

List of Tables

Table1: Genetically Modified Crops on the Market, 1999	7
Table2: Applications Approved for Field-testing or Commercialization of transgenic plants	13

Introduction

This paper maps global trends in the development, commercialization and application of modern biotechnology and discusses their implications for African countries. It analyzes different policies, laws and agencies that some development countries are establishing to respond to opportunities and challenges that develop the technological system are creating. The paper is stimulated by a variety of factors. First, rapid scientific advances in such areas as genetic engineering and genomics are opening new technological options to address some of the developing world's food production, human health and environmental degradation challenges while at the same time they are generating concerns about potential negative impacts on humanity and nature. Expectations of benefits grow as uncertainty of potential risks increases. Developing countries' policy-makers are thus confronted with the challenge of ensuring that their countries share benefits of the technology while at the same time managing its risks, even anticipated and perceived ones.

Second, the adoption of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and its anticipated entry into force create new international legal obligations on the part of developing countries. For example, these countries will now need to establish biotechnology risk assessment regimes, including scientific and technological competencies to manage the development, transfer and handling of living modified organisms. The effectiveness of their efforts will to a large measure depend on how well they engage in technology forecasting, anticipate new biotechnology processes and upgrade their scientific and technological infrastructure. Risk assessment and management need to be an integral part of biotechnology development. It is those countries that are able to engage effectively in developing and applying the technology that are able to assess and manage its risks.

Third, there is a growing interest and investment by developing countries in biotechnology. Some of these countries are now exporters of genetically modified or living modified organisms. In order to enlarge their economic competitiveness they need to anticipate and invest in new technological trajectories while also responding to risk concerns. Monitoring biotechnology trends should constitute a significant measure of their strategic investment plans and programmes. This paper identifies those technological pathways that African countries should monitor over the coming years.

The first section is about the evolution and growth of modern biotechnology. It also outlines some of the key features of the technology and main international public and private sectors' actors in the development and commercialization of the technology. The second is an overview of the status of

biotechnology R&D in developing countries. The third discusses policy measures that African countries should put in place for them to benefit from advances in biotechnology.

1. International Biotechnology Development

1.1 Trends in Research, Development and Commercialization

Modern biotechnology is a cluster of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (r-DNA) and monoclonal antibody that use living organisms, or their derivatives, to make products or processes. It involves genetic transformation of living matter. Rapid advances in this technology are associated with major scientific breakthroughs of the mid-1970s. Growth in scientific understanding of the nature and functional uses of deoxyribonucleic acid (DNA) made it possible for scientists at Stanford and California universities in the United States of America (USA) to isolate genetic information from a gene of one organism and to insert it into another organism. Essentially DNA from one organism was successfully transferred to another. This is what is now commonly referred to as recombinant DNA technology. The technology has made it possible to incorporate genes from microorganisms into plants, and from plants into animals.

Another scientific breakthrough that formed modern biotechnology is the production of monoclonal antibodies (MAbs) through cell fusion by the UK's Medical Research Council's laboratories in 1975. Prior to this breakthrough pure antibodies could not be produced by conventional techniques. The conventional method of producing anti-bodies for diagnostic and therapeutic purposes is to inject an antigen into an animal to stimulate an immune response and collect antiserum from the animal. This method has a number of limitations including contamination of the antiserum and the limited supply of requisite antisera. The method is also time consuming and relatively expensive. MAb technology has made it relatively easy to identify pathogens and to deliver drugs to destroy pathogenic cells in the human body. They have increased the application of immuno-assays in the diagnosis of bacterial infections that account for at least 30% of deaths in developing countries.

The combination of DNA and MAb technologies has revolutionized industrial agriculture and pharmaceuticals and created a wide range of new opportunities for fighting human and livestock diseases. In the early 1980s these technological opportunities were widened by the cloning of a complete bacterial antibody molecule. A United States (US) based firm Genentech developed and reconstituted bacteria protein chains and produced antibody genes¹. These developments sparked renewed interest in bioprocessing, particularly for the formation of complex molecular structures

¹ Klausner, A., 'Genentech Makes Monoclonal Precursors From E. Coli' in *Bio/Technology*, July 1983, p. 396-397.

such as antibodies and proteins. Novel bioprocessing techniques were developed for large-scale production of biotechnology products.

The 1990s witnessed a new wave of scientific advances in biotechnology. The mapping and sequencing of the human genome have given rise to a new scientific enterprise: genomics. Genomics is "the development and application of research tools that uncover and analyze thousands of different molecules at a time".² It has granted scientists and pharmaceutical companies unprecedented access to the molecules of life. Through it, massive amounts of biological information can be converted into electronic form, linking life sciences to information sciences. Human genome map is likely to serve as a guide in the exploration of causes of diseases, and will accelerate development of treatments and cures for many illnesses. By identifying specific genes linked to diseases, scientists and companies will develop genetic tests that can help prevent the onset of illness. Biotechnology firms in the industrialized world are investing considerably in developing treatments for diseases linked to single genes, such as cystic fibrosis. Human Genome Sciences (HGS) one of the world's leading genomics companies has six medicines advanced to human trials and to be potentially submitted to the U.S. Food and Drug Administration for marketing approval around 2005. It has churned out gene-based drugs and therapies to heal chronic wounds, lessen cancer drugs' side effects, and boost the immune system. Prospects of winning wars against such diseases as cancer, tuberculosis, and HIV/AIDS are being enlarged.

Related to genomics is proteomics, the study of how proteins are made, their identification and functioning in the cell is set to be next frontier science in the 2000s. It holds promise of potentially lifesaving medical treatments. This science enables scientists to uncover information on how genes are related to biological functions and diseases. Clinical proteomics is revolutionizing the development of biomarkers for drug development. A protein floating in blood can help predict a disease.³

These scientific discoveries and their commercial application have formed the biotechnology industry. Large corporations in the USA, Europe and Asia have made major investments to adapt these technologies to the production of new pharmaceutical drugs and improved plant varieties. In the pharmaceutical sector there are currently more than 100 biotechnology drugs and vaccines approved by the FDA and more than 350 in the pipeline. The first gene therapy was approved in 1990 to treat Severe Combined Immune Deficiency. Gene therapy techniques for cystic fibrosis have also been approved. DNA probes and MAb diagnostics constitute a large part of biotechnology, at least half of commercialized biotechnology-derived products. By 1996 there were at least 220 diagnostic kits

²Zweiger, G., 2001. *Transducing the Genome: Information, Anarchy, and the Revolution in Biomedical Sciences*, p.xii. McGraw-Hill, New York.

³New York Academy of Sciences, *Academy Update*, March/April 2001.

using monoclonal antibodies and eight using DNA probes on the market. Total sales for MAb products were projected at US\$ 3,800 million in 1998 and US\$ 720 million for DNA diagnostics by 2000.

In agriculture, at least 70 genetically modified (transgenic) varieties of crops were registered for commercial cultivation worldwide in 1999. These include new varieties of cotton, potato, tobacco, tomato and clove. More than 15,000 field trials have been undertaken globally. New genetic modifications of more than 100 plant species are growing in laboratories, greenhouses, or in the field, providing farmers with new agronomic traits, particularly herbicide tolerance and pest resistance. In 2000 the global area under genetically improved crops was 44 million hectares mainly of maize, soya bean, cotton, canola (rapeseed) and potatoes.⁴ Eighty five percent of this area is in North America (USA and Canada) and the remaining 15% in developing countries notably Argentina, China, Mexico and South Africa.

1.2 The Institutional Landscape

Advances in biotechnology have stimulated a variety of institutional arrangements for research, product development, regulation, and commercialization. The private sector is the leading player in biotechnology research globally. A growing number of companies dedicated to biotechnology research have been established in the last decade or so. According to Ernst & Young, in 1997 US companies invested \$9.4 billion in R&D, employed 140,000 people and posted total revenues of \$18 billion. At the same time there were 1,036 European companies working in the life sciences, employing more than 39,000 people directly, with revenues of \$3.1 billion and \$2.2 billion invested in R&D.⁵ In 1999, Monsanto alone allocated some \$1.2 billion for biotechnology research while the National Institutes of Health allocated \$15.6 billion in 1999 for basic bioscience research. In 2000 there were more than 1350 biotechnology companies in the world. Their total sale of products was estimated at US\$13.7 billion. More than 60% of these companies were based in the USA and commanded sales totaling to at least US\$ 10 billion.

In general, three categories of private companies have been responsible for the rapid growth of biotechnology. First are those companies that had already accumulated substantial capabilities in second-generation biotechnology, i.e. in fermentation and products like antibiotics, vaccines and enzymes. The second category is those companies that were specifically created to engage in modern biotechnology and had to build capabilities in such areas as genetic engineering. The last category comprises of those companies that had no prior engagement in biotechnology but perceived the potential of the technology and were willing to invest in its development, sometimes with the aim of diversifying their products. All these companies have played a major role in the development of biotechnology although their strategies and levels of engagement varied across sectors, countries and over time. What is, however, common to all of them is that each had direct association with

⁴UNDP, 2001. *Making New Technologies Work for Human Development*, p. 35. United Nations Development Programme, New York.

⁵Ernst and Young, 1998.

university R&D. The companies that were established to deliberately engage in the technology were in fact born out of university departments by university professors. The other categories of firms relied on universities as sources of scientific knowledge and information. For example, the traditional non-biotechnology companies contracted universities to develop and provide to them basic scientific information and principles in genetic engineering.

National and international public research organizations are also key players in biotechnology R&D. In Western Europe, Japan and the US the mid-1980s saw the emerging of biotechnology programmes to foster national competitiveness in the development and application of the 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 committees⁶. Germany developed the first organized government strategy for biotechnology R&D. Its institutional arrangement comprised of a variety of leading science bodies such as the Max Planck institutes and Fraunhofer institutes. The institutions have dedicated 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.

⁶OECD, 1998.

Table1: Genetically Modified Crops on the Market, 1999

Product traits	Crops
<i>Bt crops</i> are protected against insect damage and reduce pesticide use. Plants produce a protein--toxic only to certain insects--found in a common soil bacterium called <i>Bacillus thuringiensis</i> , or Bt.	corn, cotton, potatoes <i>Future:</i> sunflower, soybean, canola, wheat, tomatoes
<i>Herbicide tolerant crops</i> allow farmers to apply a specific herbicide to control weeds without harm to the crop. Gives farmers greater flexibility in pest management and promotes conservation tillage.	soybean, cotton, corn, canola, rice <i>Future:</i> wheat, sugar beet
<i>Disease resistant crops</i> are aimed against destructive viral plant diseases with the plant equivalent of a "vaccine".	sweet potato, cassava, rice, corn, squash, papaya <i>Future:</i> tomatoes, banana
<i>High-performance cooking oils</i> maintain texture at high temperatures, reduce the need for processing and create healthier food products. The oils are either high oleic or low linoleic. In future , high stearate	sunflower, peanuts and soybeans
<i>Healthier cooking oils</i> have reduced saturated fat.	soybean
<i>Delayed ripening fruits and vegetables</i> have superior flavor, color and texture, are firmer for shipping and stay fresh longer.	tomatoes <i>Future:</i> raspberries, strawberries, cherries, tomatoes, bananas , pineapples
<i>Increased-solids tomatoes</i> have superior taste and texture for processed tomato pastes and sauces.	tomatoes
<i>rBST</i> is a recombinant form of a natural hormone, bovine somatotropin, which causes cows to produce milk. rBST increases milk production by as much as 10-15 percent. It's used to treat over 30 percent of U.S cows	rBST (milk production)
<i>Food enzymes</i> , including a purer, more stable of chymosin used to curdle milk in cheese production. It's used to make 60 percent of hard cheeses. Replaces chymosin of rennet from slaughtered calves stomachs.	chymosin (in cheese) --the first biotechnology product in food
<i>Nutritionally enhanced foods</i> will offer increased levels of nutrients, vitamins and other healthful phytochemicals. Benefits range from helping developing nations meet basic dietary requirements, to boosting disease-fighting and health promoting foods.	<i>Future:</i> protein enhanced sweet potatoes and rice; high vitamin A canola oil; increased antioxidant fruits and vegetables

Source:<http://www.bio.org/food&ag/transgenicprod.html>

2. Biotechnology in Developing Countries

The past two decades have witnessed increased investment in biotechnology research and development (R&D) by a growing number of developing countries. The nature of activities and levels of investment vary from one country to another, and from one sector to another. These initiatives are carried through a variety of institutional forms from laboratories in established national agricultural research bodies, national biotechnology centers, national biotechnology programmes managed in sectoral research agencies, and international research bodies such as those of the Consultative Group of International Agricultural Researchers (CGIAR).

2.1. Overview of Biotechnology R&D in Africa

African countries can be grouped into four categories in terms of their investment and engagement in biotechnology R&D. The first group of countries is that involved in more sophisticated biotechnology activities, those pertaining to the development and commercialization of genetically modified organisms. This group consists of Egypt and South Africa. The second group is those countries engaged in the research and development of genetically modified organisms, and with some products at field-testing stage. It includes Kenya, Nigeria and Zimbabwe. The third group is those countries largely involved in tissue and cell culture applications. This includes Ghana, Tanzania and Uganda. The last group is of those countries that are not engaged in biotechnology. This group includes Ethiopia, Rwanda and many of the region's countries.

South Africa and Egypt are biotechnology leaders in the region. With considerable scientific infrastructure, the two countries have growing investment in biotechnology and are commercializing some of their products. South Africa's biotechnology R&D focus is on genetic engineering of cereals: barley, lupins, maize, millet, ornamentals, sorghum, soybean, sugarcane, sunflowers, vegetables wheat, as well as on molecular marker applications of: diagnostic for pathogen detection; cultivar identification potatoes, sweet potato, ornamentals, cassava, cereals, seed-lot purity testing cereals; marker assisted selection in maize, tomato, and markers for disease resistance in wheat. The first field trials for genetically modified crops were initiated in 1990, while conditional commercial release permits were granted in 1997. The country has now commercialized insect-resistant maize and insect-resistant cotton. Other genetically modified crops expected to reach the market within the next couple of years include barley, soya, wheat, and sunflower seed. By end of 2000, 41 GMO field trials had been conducted in South Africa.

The country has enacted legislation to regulate the development, importation and application of genetically modified organisms. The Genetically Modified Organisms Act (GMO Act)⁷ was passed in 1997, and regulations for its implementation were adopted in 1999. According to the legislation, no person may import or export from the Republic of South Africa, or develop, produce, use, release or distribute any GMO in the Republic of South Africa, other than under a permit for undertaking such an activity⁸. Such permit is to be issued after a technical assessment and risk analysis report has been submitted by the applicant and has been approved by the Executive Council. The GMO Regulations⁹ provide that an applicant shall notify the public of any proposed release of GMOs prior to the application for a permit for such release. Public notifications shall be in the form of a standard notice published in the printed media informing the public of the intended release¹⁰. The South African Committee For Genetic Experimentation (SAGENE), a scientific advisory committee, has been monitoring and advising on GMO development and release.

Section 2 of the GMO Act defines scope for its application. It provides that the "Act shall apply to the genetic modifications of organisms; the development, production, release, use and application of genetically modified organisms (including virus and bacteriophages); and the use of gene therapy." Excluded from the scope of application are techniques involving human gene therapy, techniques in which rDNA molecules or genetically modified organisms are not employed.

Under section 5(a) any applicant requiring to develop, produce, use or apply genetically modified organisms "or to release such organisms into the environment, to submit to the Council through the registrar, an assessment of the risk and, where required, an assessment of the impact on the environment of such development, production, use, application or release ..." Section 5(k) gives authority to the Executive Council of Genetically Modified Organisms to "promote co-operation between the Republic and any other country with regard to research, development and technology transfer in the field of the genetic modification of organisms." This provision is largely a reflection of the country's aspiration to continue to invest in modern biotechnology with emphasis on the development of and trade in genetically modified organisms.

South Africa's biosafety law contains other provisions covering such areas as determination of risks and liability (section 17 para 2) and confidentiality and disclosure of information on risks and nature of genetically modified organism(s) (section 18). The law as whole should be carefully reviewed to establish the extent to which its provisions are in conformity with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

⁷Act 15 of 1997

⁸Section 14(2)(1), which is subject to the provisions of sub-section (2)

⁹Section 6(1)

¹⁰Section 6(2)

Egypt has invested considerably in genetic engineering of potatoes, cotton, maize and tomatoes. The country has at least 3000 scientists active in biotechnology-related fields and more than US\$ 100 million annually allocated to biotechnology R&D projects. It is focused on genetic engineering for crop improvement. The Agricultural Genetic Engineering Research Institute (AGERI) has conducted genetic transformation of cotton, cucurbits, maize, potato, and tomato. With funding from the United States Agency for International Development (USAID) it undertook genome mapping of tomato and rapeseed. The Centre for Genetic Engineering and Tissue Culture at Menoufiya University has transferred *Bacillus thuringiensis* (Bt) toxin genes into cotton. Similar R&D are being conducted by Cairo University's Centre for Genetic Engineering at the Faculty of Agriculture where Bt genes have been inserted into Egyptian clover.

Between 1994 and 1998 trials of GMO maize, cotton, potato, tomato and squash were conducted under greenhouse containment at the AGERI. During the same period field trials of GMO squash resistant to Zucchini Yellow Mosaic Virus (ZYMV), GMO potato resistant to potato tuber moth virus and GMO tomato resistant to tomato yellow leaf curl virus were conducted by the AGERI. Recently the Government of Egypt and Monsanto entered into agreement to field test and to subsequently commercialize cotton with Bollard Bt gene. The country has also imported genetically modified pharmaceutical products. These products include Actrapid 40 U HM/ml (human insulin) produced by Novo Nordisk, Roferon-A (Interferon alfa-21) produced by La Roche and Pronivel 2000 LU (Recombinant human erythropoietin) by Laboratorio Elea Argentina.

In 1995 Egypt instituted biosafety regulations. Two decrees, Ministerial Decree No. 85 of January 25, 1995 and Ministerial Decree No. 136 of February 7, 1995 establish both procedures and institutional arrangements for regulating the development and application of modern biotechnology and its products, and more specifically for approving field testing of GMOs. Procedures for commercializing GMO crops were instituted in 1998 by Ministerial Decree No. 1648. Between 1996 and 2000, 34 GMO field trials were conducted in the country.

Kenya's biotechnology R&D efforts have concentrated on the application of tissue culture to improve the production of food crops. For example, the Kenya Agricultural Research Institute (KARI) is collaborating with the Institute for Tropical and Sub-Tropical Crops (ITSC) based in South Africa to micro-propagate or develop pathogen-free banana planting material. This involves rapid and sterile multiplication of banana plantlets by *in vitro* propagation. In 1991 KARI in partnership with Monsanto Inc. launched a project on the application of genetic engineering to develop sweet potato resistant to Feathery Mottle virus. Monsanto developed a protein responsible for virus resistance and donated it to KARI for use royalty free. There are also efforts at KARI with support of the Novartis Foundation and CYMMIT to develop Bt maize.

In 1998 Kenya adopted regulations and guidelines for biosafety. These, the *Regulations and Guidelines for Biosafety in Biotechnology for Kenya*¹¹, explicitly recognize the role that biotechnology can play in the economic transformation of the country. They lay down procedures for field and contained testing of genetically modified organisms. A National Biosafety Committee (NBC) administered by the National Council for Science and Technology was established to implement the regulations and guidelines. It is the authority responsible for granting approvals for GMO testing, import and export. The Committee has approved field- testing of the Bt maize and the GMO sweet potato.

Zimbabwe's Central Veterinary Laboratory (CVL) is involved in the production of both attenuated and recombinant DNA vaccines. It is also involved in the diagnosis and culture of both animal and poultry pathogens. The CVL uses recombinant *Escherichia coli* to express proteins from genes of interest. It has some of the capability for genomics and proteomics.

In 2000 Zimbabwe enacted biosafety regulations. The Research (Biosafety) Regulations, Statutory Instrument 20 of 2000, regulate the development and application of modern biotechnology in general, and genetically modified organisms in particular. Section 3 of the law defines the scope of application. It stipulates that the "regulations shall apply to:

- (i) techniques in which recombinant DNA molecules or genetically modified organisms are employed in *in vitro* fertilization in human beings and animals; or conjunction, ...transformation or any other natural process; or polyploid induction;
- (ii) techniques in which genetically modified organisms as recipient or parental organisms are employed in mutagenesis; or the construction and use of somatic hybridoma cells; or ...any activities involving genetically modified organisms that are declared by the Council in terms of ...to constitute potentially harmful research or undertakings."

Zimbabwe's biosafety law places a lot of emphasis on institutional or agency aspects. The law, as we shall show below, creates institutional arrangements for managing biosafety at national and individual agency levels. Its coverage of such issues as risk assessment procedures, application of the precautionary principle, liability and redress, convergence with national and international trade laws, and information exchange is fairly general. The law requires the National Biosafety Board (established by section 4) to formulate detailed biosafety guidelines and standards as well as a long-term policy for safety in biotechnology. It is largely a technology management instrument and places emphasis on the promotion of biotechnology R&D.

Cameroon has also invested in the development of national biosafety legislation. With financial support from the Global Environment Facility (GEF) through UNEP the country by January 1999 had

¹¹Republic of Kenya 1998. *Regulations and Guidelines for Biosafety in Biotechnology for Kenya*. National Council for Science and Technology (NCST), Nairobi.

a draft bill on safety in biotechnology. The draft bill, prepared under the leadership of the Ministry of the Environment and Forestry, has three objectives to:

- (i) provide a framework and guidelines for the safe, ethical and responsible research and development in modern biotechnology;
- (ii) provide a framework for assessing, managing or controlling the risks associated with the use, release and transboundary movement of living modified organisms or organisms with novel traits resulting from modern biotechnology which are likely to have an adverse environmental impact that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human and animal health, their socio-economic impacts, while maximizing the advantages of the technology; and
- (iii) create a National Biosafety Authority charged with the overall supervision of the implementation of this law and regulations in collaboration with existing competent administrations."

Article 2 of Cameroon's draft bill defines scope of its application. It excludes organisms developed with the aid of cell technology, modified plants obtained by means of

2.2 Biotechnology R&D in Asia: Some Examples

Many of the Asian countries are investing in biotechnology R&D and some have already put GMO products on the market. China is one of the Asian leaders in biotechnology. The country has dedicated its economic, scientific and technological resources to R&D in such areas as the development of pest resistant GMO cotton, recombinant drugs, and gene therapy of malignant tumors. The Chinese Academy of Science (CAS) Molecular Biotechnology Research Laboratory is the main body dedicated to R&D in plant genetic engineering. By mid 1998 GMO tomato, sweet pepper and petunia developed by Chinese universities had been approved for commercialization while several other GMO crops were being field tested in the country. Monsanto has commercialized Bt cotton in China. In 1999, 26 applications for commercializing GMO crops (multiple varieties of cotton, tomato, rice, green pepper and petunia) were approved.¹² By 2000 China was the second largest producer and exporter of Bt maize, accounting for 21% of the total acreage.¹³

There are more than 200 companies most involved in commercial biotechnology activities in China. Thirty companies have obtained the required approvals to manufacture 12 kinds of human therapeutic biotechnology products. Some of the multinational companies either operating in China or exporting products to China include Pasteur Merieux Connaught, Sanofi Biological Serums and Vaccins, SmithKline Beecham Biologicals, Merck Sharp and Dhome, Upjohn Schering-Plough, Baxter, Amgen,

¹²Paarlberg, R. 2000. *Governing the GM Crop Revolution: Policy Choices for Developing Countries*. International Food Policy Research Institute.

¹³Carpenter, J. and Gianessi, L. 2001. *Agricultural Biotechnology: Updated Benefit Estimates*. National Centre for Food and Agricultural Policy, Washington, D.C.

Kirin and Novo Nordisk in the field of medical biotechnology and Monsanto, and Delta and Pine Land in the field of plant biotechnology. Some of the domestic companies involved in medical biotechnology production/marketing activities are China Pharmaceutical Company, China National Bio-product Company and China Medical and Equipment Company.

Table 2: Applications approved for field-testing or commercialisation of transgenic plants

Plants	Field Trials	Commercialization
Rice	6	1
Maize	2	—
Soybean	2	—
Cotton	7	2
Tobacco	4	—
Potato	6	—
Tomato	3	1
Green Pepper	1	—
Chili Pepper	1	—
Tropical fruit	1	—
Flower	—	1
Poplar tree	1	—
Total	34	5

Source: Carl E. Pary, 1999. 'Public and Private Collaboration on Plant Biotechnology in China', *Agbioforum*, January, 1999

China developed and adopted the safety administration regulation on genetic engineering in 1993. This instrument aims at promoting biotechnology R&D while ensuring that products of genetic engineering are safe to human life and the environment. The State Science and Technology Commission (SSTC) of China is responsible for promoting the implementation of the regulations. In 1996 the Ministry of Agriculture issued the safety administration implementation regulation on agricultural biological genetic engineering. This is an explicit regulatory regime for risk assessment and management of agricultural products of genetic engineering.

All medical biotechnology products, including pharmaceuticals, imported into or manufactured in China are regulated by the Drug Administration Bureau (DAB) under the Ministry of Health. Based on laboratory reports prepared by the National Institute for the Control of Pharmaceutical and Biological Products (NICPBP), the DAB's bioproducts division recommends approval or rejection of license applications. DAB also controls authorization procedures for clinical trials of pharmaceuticals.

India is also devoting a growing portion of its R&D budget to biotechnology. Specific areas of investment include the development of insect resistant transgenic rice plant, development of *transgenic brassica*

for fungal resistance, development of transgenic plants of chickpea, and use of anti sense RNA to delay fruit ripening. The first GMO testing in India was done in 1994-95, when *Brassica juncea* plant containing the barnase genes were planted at Gurgaon near Delhi to assess the extent of pollen escape. Since then several GMO field and contained trials have been conducted. Monsanto has conducted Bt cotton trials in India. It has, also is conducting bollgard Bt trials, Proagro PGS is testing mustard. Trials of GMO potato, cauliflower, rice, and tobacco have also done.

Monsanto has formed a joint venture with Indian Company Mahyco to create Mahyco-Monsanto Biotech Private Limited (MMB). MMB is actively engaged in developing Bollgard insect resistant cotton in Indian hybrids. Monsanto has invested about \$100 million in India in agrochemicals and other industrial activities.

India has established biotechnology and GMO regulatory measures. In 1994 the Department of Biotechnology, revised its earlier guidelines of 1990 titled "Revised Guidelines for Safety in Biotechnology". The revised guidelines aimed at regulating large-scale production and deliberate release of GMOs, plants, animals and products into the environment, shipment and importation of GMOs for laboratory research.

Korea has a dynamic and growing biotechnology industry. The importance of this industry is manifested in the size of its total financial contributions to biotechnology R&D and its products sales. Private biotechnology industry's investment in biotechnology grew at an average annual rate of 44.5 percent in the 1980s and early 1990s. During this period the development of vaccines and diagnostics received at least 60% of the country's investment in biotechnology R&D. ¹⁴ In the later part of the 1990s Korean firms began investing in more agricultural biotechnology. Green cross, Heungnong seeds, Joongang seeds, and Seoul seeds are among the leading companies in agricultural biotechnology R&D.

The country has instituted regulatory measures for safe development and application of biotechnology. In 1997, the Ministry of Health and Welfare promulgated the guidelines for recombinant DNA experiment covering physical and biological containment for small and large-scale experiments, proper handling of rDNA molecules including storage and movement of rDNA organisms, safety control measures and safety evaluation procedures. The Ministry of Agriculture is preparing the guidelines for experiment and handling of rDNA organisms in agriculture, forestry and livestock.

Other Asian countries are engaged in the development, importation and export of GMOs. By early 2000 Indonesia had five GMO crops approved for field trials. They are Bt cotton, corn, roundup ready

¹⁴Acharya, R. and Mugabe, J. 1995.

cotton, roundup ready corn and roundup ready soybean. Thailand has approved several field trials and commercialization of GMO products. For example, in 1994 it approved application by Calgene Fresh Company to conduct a field test GMO *Flavr Savr* tomato. By 1996 *Flavr Savr* tomato had been approved for commercialization in Thailand.

Indonesia has commercialized Bt cotton. It has more than 4,000 hectares of this crop grown in the South. The government approved contained and field trials of this Bt cotton in 1998 and 1999 respectively. Trials were conducted by the Monsanto in collaboration with Hasanuddin University in South Sulawesi and Universitas Gadjah Mada (UGM).

Malaysia has also received and approved GMOs for field trials and commercialization. In October 1996, the Malaysian government received an application for the import of transgenic soybean for food and feed. This was the first application to be reviewed by the country's Genetic Manipulation Advisory Committee (GMAC). The glyphosate-tolerant "Roundup Ready Soybean", line 40-3-2, containing enolpyruvate shikimate-3-phosphate synthase (EPSPS) gene derived from *Agrobacterium sp.*

The Philippines has had several applications for field trials and commercialization of GMO crops. In 1999 two multinational companies, Agroseed Corp. and Pioneer Hi-bred Philippines Inc., applied for permits to conduct field trials of Bt maize with resistance against Asiatic corn borer. The companies are to conduct these trials in collaboration with the Institute of Plant Breeding (IPB) of the University of the Philippines in Los Banos (UPLB). The country has a body of policies aimed at regulating the development, importation, transfer and use of GMOs. In 1990 an executive order was issued by the President to establish the National Committee on Biosafety of the Philippines (NCBP). In 1991, the NCBP and the Department of Science and Technology developed and published national biosafety guidelines.

2.3 Biotechnology in Latin America

In Latin America, leading actors in biotechnology include Argentina, Brazil and Cuba. Argentina is one of the major exporters of genetically modified crops. It is estimated that GMO soybean occupies 40% of the land area under soybean cultivation in the country. The number of GMO field trials has considerably increased over the last few years. Between 1991 and 1994 42 field trials were approved. In 1995 alone 36 were approved and 78 in 1997 and 90 in 1998. 44% of the field trials carried out in 1998 were performed with maize, 27% with sunflower, 13% for soybeans and 5% for cotton, as well as rice and wheat.

Argentina has instituted regulatory measures for the safe development and application of biotechnology in general and GMOs in particular. It has policies, procedures and institutional arrangements to regulate the development, importation and export of GMO products. The country uses GMO specific legislation and implicit laws covering veterinary products and seeds. There are explicit regulations on contained use, deliberate release and commercialisation of GMOs. These

are contained in Resolutions of the Secretary of Agriculture, Livestock, Fisheries and Food (SAGPyA) No. 656 of 1992, No. 837 of 1993, and No. 289 of 1997. Additional regulations apply to human safety of foods and food ingredients containing GMOs. These are deposited in SAGPyA No. 511 of 1998. The regulations focus on the properties of the new trait and not on the process used to develop a particular GMO.

The National Biosafety Committee (CONABIA) established in 1991 by the SAGPyA to provide advice and oversee the implementation of biosafety regulations. It reviews applications for testing and commercialising GMOs in the country. CONABIA recommends to SAGPyA whether to approve or disapprove applications. Final decisions are made by SAGPyA. It is the one that also grants permits for GMO testing and commercialisation.

Cuba has also invested considerably in modern biotechnology. In 1998 the Government of Cuba allocated a budget of US\$ 50-70 million to biotechnology R&D with emphasis on the development of GMO products. The country's biotechnology R&D activities are conducted and coordinated by the Centre for Genetic Engineering and Biotechnology (CIGB) and the Centre for Molecular Immunology (CMI). With modern production facilities and highly trained personnel, the CIGB has devoted its efforts to the development of new products using recombinant DNA techniques. Its products include the production of hepatitis-B vaccine and a vaccine (on trial) against the HIV. Cuba is also engaged in the production of GMO crops. The country has enacted legislation to regulate the development, testing and commercialization as well as import and export of GMOs. Decree No. 190 of 1999 spells policies and scientific procedures for assessing risks and regulating GMOs

In Brazil, until July 1999, 112 institutions have been awarded permits to work on GMOs research. The Brazilian government holds a peculiar position distinctive from other Latin American countries, having set up a legally binding regulatory system for the sustainable development of biotechnology considering biodiversity issues and the preservation of biological species along with fundamental biosafety questions. Brazilian biosafety regulation establishes guidelines for the contained use of genetic engineering techniques and for field trials with Genetically Modified Organisms (GMOs), managed by the National Technical Biosafety Committee. Therefore, the Brazilian regulatory framework is then similar to the European regulatory system, since it considers the control of DNA technology distinctively from other technological processes.

Based on the Law Project of the then Senator Marco Maciel and after five years of negotiations within the regulatory instances of the government, in 1995 the Brazilian Biosafety Law was set up and the National Technical Biosafety Committee (CTNBio) created: Law 8974 /95. The President has made a few sanctions to the law, on the chapter referring to the link of CTNBio to the Presidency. This veto was explained since the creation of public institutions is of exclusive competence of the Executive Government and since the law did not include the participation of environmental protection groups, consumer protection agencies and representatives from the industry and workers' health.

Among the main characteristics of Brazilian Biosafety Law 8974/95, it is worth pointing out the main differences from other countries' regulation:

- Emphasises the technique used in the genetic modification, regarding how the organism has been modified through DNA/RNA recombinant techniques. Note that the regulation in many countries focuses only the resulting phenotype and/or the environment where field trials will be conducted.

3. International Public Policy Issues

3.1 Public Perception

Public perception of modern biotechnology is one of the factors that now influence the direction of innovation in, including commercialization of, the technology. It varies from one country to another, and from one region to another. It is largely influenced by values and psychological factors as well as public confidence in scientific agencies responsible for risk assessment and management. It is also influenced by information from industry, governments, scientists, public interest groups, and the media. Regulatory and scientific agencies are expected to conduct objective risk assessment and to provide the public with factual information on the nature of risks and benefits of a particular biotechnology product or process.

Most of the assessments or studies of public perception of biotechnology have been conducted in developed countries. However, efforts are now being made to assess public attitudes to the technology in such countries as the Philippines and Mexico¹⁵. These studies show that although the level of developing countries' public awareness of and concern about GMO are lower than in the developed countries, they are not nonexistent. The current debate on the impacts of genetically modified organisms tends to assume that developing countries' publics are not aware of and concerned about biotechnology—its positive and negative impacts. In a recent paper Aerni argues that:

The transatlantic debate is strongly dominated by Western perceptions about the risks and benefits of this technology and how developing countries should solve their agricultural problems. Very often, stakeholders in public debates in Western countries are NGO leaders or academic professors from developing countries who fit their view or interests and invite them to speak for the developing countries as a whole. But, apart from the fact that these experts cannot represent the view of their own country, ... There is not just a single developing country perspective but several, each reflecting the particular social, political, economic and cultural circumstances.¹⁶

¹⁵See Aerni, P. 2001. *Public Attitudes Towards Agricultural Biotechnology in Developing Countries: A Comparison between Mexico and the Philippines*. Science, Technology and Innovation Discussion Paper No. 10. Cambridge, MA, USA: Centre for International Development.

¹⁶See Aerni, P. 2001. *Public Attitudes Towards Agricultural Biotechnology in Developing Countries: A Comparison between Mexico and the Philippines*, p. 10. Science, Technology and Innovation Discussion Paper No. 10. Cambridge, MA, USA: Centre for International Development.

Recent media attention in Europe has increased public debate and controversy over the safety of GM crops and foods generally. In the UK the debate may have been aggravated by the bovine spongiform encephalopathy (BSE) and traces of *Escherichia coli* found in meat products. The BSE crisis undermined public confidence in UK's institutions responsible for regulating safety of foods. In Europe there is growing public hostility to GMO products.

Genetically modified foods challenge traditional European ideas about food. Europeans simply regard biotechnology with suspicion, at least where their food is concerned. ...All the talk of Frankenfoods in the United Kingdom has left its mark. Because of the public's response, the European approval procedures for GMOs are stringent and thorough. ...European resistance to the introduction of GMOs is so strong that approval has practically come to a stop. Europe is faced with a crisis, voters do not want GMOs and do not believe in assurances of their safety. As a result, Europe is in danger of rejecting this new science of biotechnology despite its enormous potential for good.¹⁷

The European anti-biotechnology stance may influence some of the developing countries' policies. It is likely to have irreversible consequences for the entire field of biotechnology and its potential benefits for the poor in developing countries.

The participation of developing countries in the ongoing debate on biotechnology should be influenced and informed by their own aspirations, needs and perceptions of this technology. It should evolve as these countries gain a better understanding of the technology, and as their R&D efforts generate new products and processes, and as they experiment with biosafety regulations to assess and manage risks. What is of concern is that the growing uncertainty and anxiety over GMO products in Europe may undermine their current investments in R&D. Again the challenge is one of building regulatory measures and capability that promote investment in the technology while ensuring that science-based risk assessment form the basis for decision-making.

3.2 Regulatory Approaches and Capability

The above review of the status of biotechnology demonstrates that there is a correlation between investment in R&D and the formulation and implementation of regulatory measures for biosafety. Countries that have more established biotechnology R&D programmes and are either commercializing and/or testing GMOs also possess relatively developed biosafety instruments. The review also shows that countries have either formulated single explicit or use several regulatory instruments. Many of the developing countries involved in biotechnology R&D have adopted explicit biosafety regulations and established specific agencies or committees on biosafety.

¹⁷Richardson, J. 2000. 'EU Agricultural Policies and Implications for Agrobiotechnology', p. 81 in *AgBioForum*, Volume 3, Number 2&3, 2000.

There are marked differences in developed countries' regulatory approaches. In 1986 the US adopted the "Coordinated Framework for the Regulation of Products of Biotechnology" that created a strong federal commitment to the safe development of the products of biotechnology from the laboratory, through field-testing and development, and to commercialization. This framework is founded on the principle of substantial equivalence—that any risks from biotechnology products are the same in kind to those of similar products. USA regulatory agencies are the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services, and the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture. APHIS regulates the development and field-testing of GMO plants and microorganisms. It reviews environmental and agricultural safety of the GMOs. The FDA is responsible for assessing food safety and nutritional aspects of new plant varieties. It requires that GMO foods meet the same standards as is required of all other foods. EPA handles safety of pesticides and establishes tolerance standards or levels for substances used as pesticides in food and feed. It is also responsible for issuing permits for field testing of GMO plants with pesticidal traits.

The European Union's (EU's) main instrument for regulating the development, testing and commercialization of GMOs has evolved since the early 1990s. The Directive 90/220/EEC on the deliberate release of genetically modified organisms requires an assessment of environmental impact and promotes a step-by-step approach in granting approvals for release of GMOs. It requires an importer or manufacturer to submit a notification to the national component authority of a Member State where the GMO is to be first placed on the market before releasing it into the environment. The notification must contain information on product, and dossier of all risk assessment conducted on the product. EU's risk assessment approach takes into account how the product was developed, including the processes of generating a GMO product. Austria, France and Germany have invoked Article 16 (safety clause) of the Directive 90/220/EEC to temporarily ban the commercialization of GMO corn and oilseed in their economies.

The US and EU regulatory approaches differ in two ways. First, while the US focuses on regulating the end product, the EU tends to regulate the whole process of biotechnology R&D and commercialization of products. Secondly, "US policies tend to be more supply-driven, while EU policies are demand-driven, dominated by consumer concerns. Thus, efficiency of production is the presiding goal in the US. In the EU, on the other hand, emphasis is on quality aspects, both of products and of production methods".¹⁸

Many of the developing countries are instituting biosafety frameworks [several of them with financial support from the Global Environment Facility (GEF)] with procedures and institutional arrangements

¹⁸Haniotis, T. 2000. 'Regulating Agri-Food Production in the US and the EU', p. 84 in *AgBioForum* Volume 3, Number 2&3, 2000.

for regulating the development, testing and commercialization, including importation of GMOs. While the developed world (particularly in the US) regulatory measures are now mainly for purposes of promoting knowledge-intensive biotechnology industry to expand national competitiveness in the global economy and ensure environmental safety, biosafety frameworks of many developing countries are not being introduced with the goal of promoting industry but mainly for risk assessment and environmental management. In terms of the explicit goals of their regulatory regimes, developing countries can be categorized into three groups. The first is a group of countries that aspire to develop domestic biotechnology through national public R&D and/or by creating incentives for the participation of multinationals as sources of technology. These countries have relatively liberal regulations. They also have more explicit regulatory institutional arrangements. They include Argentina, Brazil, Cuba, Egypt, South Africa, India and Zimbabwe.

A second group of countries is that which has adopted more defensive measures to assess and regulate the development, testing and commercialization of biotechnology. "Generally, in these countries norms in any form (voluntary or mandatory) are accompanied by regulatory inertia due to the competing jurisdictions of the authorities involved, pressure from interest groups, or inability to take informed decisions. Regulatory oversight in terms of monitoring or enforcement is absent in most cases",¹⁹ Ethiopia is an example of this group.

The third group is that of countries where there is no domestic high level biotechnology R&D and no established commercialization of GMOs by external agencies, and with no explicit regulatory measures. In this group are a large number of African countries, for example Burundi, Sudan, and Tanzania.

The first category of countries is likely to attract private investment and activity in GMO development, testing and commercialization. It will also witness rising rates of technology transfer as such companies as Monsanto establish local presence start socializing with local public R&D actors. These countries' capability for and public confidence in GMO regulation may grow as they engage in intense biotechnology R&D and an incremental further revision and development of their regulatory systems.

On the whole, there are many developing countries with regulatory systems. Their approaches vary and capabilities differ. However, many of these countries are faced with challenges of strengthening their regulatory systems to respond to domestic and international demands. In general terms, they suffer from inadequate financial and human resources and young (and in many cases absence of or existing of weak agencies) regulatory institutional arrangements. It is this context that developing countries must make decisions on GMOs and move into implementing the Cartagena Protocol on biosafety to the convention on biological diversity.

¹⁹ Tzotzos, G. 1999. 'Regulation of Biotechnology in LDCs', p. 214 in *AgBioForum* Volume 2, Number 3&4, 1999.

4. The Way Forward For Africa

How then should African countries respond to the opportunities and challenges posed by genetic engineering? We suggest that these countries should establish broad-based platforms to mobilize the public and scientific communities to build confidence in the technological advances associated with genetic engineering. In addition, they will need to identify their specific national priorities in food production and harness the growing body of science and innovations in genetic engineering to address specific problems. Public R&D agencies and policies dedicated to genetic engineering as well as partnerships with private industry will be crucial, and lastly African countries will need develop and implement regulatory measures to manage any environmental, economic, health and social risks associated with genetic engineering. Below we expound on each of the actions.

4.1. Build Public Confidence and Participation

Science in general and genetic engineering in particular are not evolving in a socio-political vacuum. The African public and politicians have (or should have) a direct interest in scientific advances and technological developments associated with genetic engineering, yet they are not participating in the GM debate. In many countries of the region there are obstacles to citizens' participation in the debate on the impacts of GM crops and the potential role of genetic engineering in solving food insecurity. Considerable institutional space in the debate has been taken by isolated groups of non-governmental organizations opposed to GM crops and purporting to speak for the African rural poor, and groups of scientists who espouse the benefits of the new technology for the poor. It is unlikely that the two groups—anti and pro GM crops groups have the attention of millions of farmers in Africa. The general public and farmers in particular are not informed about the nature of the technology, its potential benefits and risks, and rarely do they participate in deciding on what crops or problems biotechnology research and development should focus on.

With the intensifying debate on GM crops, confusing counter claims from pro- and anti-GM activists, and often passive reactions by African governments, the public is likely to lose confidence in the scientific enterprise and overall decision-making authorities. What are required in the region today are processes that will legitimately bring the voices of the public to inform and change the focus and content of the current debate. Three actions that should be taken to build public participation and confidence are:

- (a) Well-structured and objective assessment of African public perceptions of and/or opinions on genetic engineering and GM products should be undertaken. Such assessments must be accompanied by organized activities to provide the public with reliable and adequate information on the nature of the technology and its products.
- (b) Have public stakeholders; the youth, women, farmers and other social groups, legitimately represented on bodies that are charged with regulating GM import, development and commercialization. Currently, it is difficult to determine the legitimate loci of GM decision-making in many countries of sub-Saharan Africa. Even where biosafety frameworks have been developed and adopted (e.g. Kenya and Zimbabwe), political institutions have either ignored these and have often made policy pronouncements that are not necessarily founded on science and informed by public opinion. What is required is the review and determination of appropriate decision-making mechanisms. Such mechanisms should have representation from all stakeholders including farmers, consumers, environmentalists and religious bodies.

If genetic engineering is to improve food production in Africa it should be guided to co-evolve with local social and economic production systems. Appropriate social and economic institutions will be required to articulate demand for the technology and to act as 'watchdogs' for its responsible application. It is in this regard that we are proposing the establishment of broad-based platforms that enlarge public confidence in genetic engineering through open participation in priority setting and decision-making.

4.2. Build and Utilize Public R&D Capacity

To harness and benefit from advances in genetic engineering as well as to manage any risks African countries need to build a diverse range of human and institutional capacities. They require expertise in such areas as molecular biology, biochemical engineering, plant breeding and bioinformatics. They also need national agencies or institutes dedicated to the conduct and management of genetic engineering. Currently many African countries do not have such agencies. Their limited investments in genetic engineering and biotechnology tend to be in the form of projects scattered across the institutional landscape. This is in sharp contrast to the organization of biotechnology and genetic engineering activities in such countries as Cuba, China, India and the US where special centers devoted to genetic engineering have been established. It is probably only in Egypt, Nigeria and South Africa where agencies dedicated to biotechnology are found.

It is crucial that each African country identifies and implements measures to build dedicated biotechnology agencies. Such efforts may focus on identifying a few national institutes with potential, and providing political support and financial resources to such institutes to grow into national centers of excellence in genetic engineering for food production. These centers should focus on specific priority problems identified through public participation. They need significant and predictable funding and should have explicit links to private sector. In addition to research, they should devote their attention to training of scientists in such new science fields as genomics.

The establishment of national centers of excellence in genetic engineering needs to go hand in hand with the creation of appropriate mechanisms to finance R&D. Current funding of biotechnology R&D is still relatively low to enable African countries to effectively engage in genetic engineering. For example, an assessment by Falconi in 1999 showed that Indonesia's total expenditure for the 1985-96 was US\$ 18.7 million while Kenya spent about \$3.0 million. Nigeria and South Africa are increasing their financial investment in biotechnology and genetic engineering. Nigeria's Federal Government now provides the National Biotechnology Development Agency with an average of US\$ 263 million per year for the next three years as a start-up grant. South Africa's new biotechnology strategy commits more than US\$ 300 million per year from government to finance a variety of biotechnology initiatives. Other countries of the region need to invest more in genetic engineering. Some of them may wish to create special funding mechanisms, possibly National Biotechnology Funds (NBFs) for R&D. Such mechanisms would mobilize domestic and international public and private finance to support specific priority research and innovation activities that target the improvement of food production.

4.3. Establish and Apply Regulatory Instruments

Many African countries lack coherent regulatory instruments and institutions for risk management in relation to genetic engineering. Where instruments have been formulated and adopted by governments, there are weak institutional arrangements for enforcement of regulatory procedures. As a result, there is no consensus on how best to respond to global developments in genetic engineering and, particularly, whether to allow the importation and/or development of GM crops. The current controversy over GM food aid to Zambia and Zimbabwe clearly demonstrates the importance of governments instituting and applying regulatory instruments as well as risk assessment and management procedures.

In June 2002 the government of Zimbabwe rejected a consignment of 17,500 tonnes of maize from the US because it was not certified free of genetically modified material. The government was concerned that some of the grains would be planted and thus releasing GM into the environment and potentially undermining the country's exports to the European Union and other countries that have banned GM foods.²⁰ Zambia also rejected GM maize from the USA citing potential human health risks. This is despite assurance from the US administration that the maize had been tested and proven to be safe.

There are many interest groups engaged in the debate on whether African countries should accept GM food. These range of groups of scientists to activists. What is of concern is that they have focused no or very little attention on how best to use existing national, regional and international regulatory instruments to make informed decisions. In some cases some may be exploiting such situations as

²⁰ Zimbabwe's government recently accepted the GM maize after protracted controversy and diplomatic interventions from the USA and the World Food Programme.

political uncertainty and economic instability to promote narrow agendas to deny the public choice and to undermine national learning from the application of risk assessment and management instruments. In Zimbabwe for example the debate acquired an intense political tone and locus of decision-making become full of intense diplomatic interventions denying local scientists and national regulatory authority space to engage in risk assessment. Our survey and consultations with relevant government officials and scientists show that the government did not in a procedural way apply provisions of national biosafety regulations. The Research (Biosafety) Regulations Statutory Instrument 20 of 2000, regulates the development and application of modern biotechnology in general, and genetically modified organisms in particular. The law vests responsibility for risk assessment with the National Biosafety Board (established by section 4). This Board did not get an opportunity to conduct scientific analysis of the GM maize offered by the US.

Risk management and making decisions on the development, importation and use of GM crops are knowledge intensive responsibilities that require the participation of scientists and consumers. Appropriate regulatory instruments should guide these processes. Such instruments should enable countries to invoke the precautionary principle without denying them with opportunities to address short-term and urgent needs, particularly in terms of access to and provision of food to the hungry. They should create institutional arrangements that mobilize domestic and international science to make informed decisions.

There is need to build national capacity to assess and respond to risks as well as to tap benefits generated by genetic engineering. Such initiatives as the capacity building programme of the International Center for Genetic Engineering and Biotechnology (ICGEB) will play a major role in building the capacity of African countries to conduct risk assessment. The ICGEB is engaged in the building of national capacity in industrial, agricultural, pharmaceutical, animal and human health biotechnology. The ICGEB has now more than 30 affiliated centers around the world some of which have emerged into centers of excellence in genetic engineering.

4.4. Build Public-Private R&D Partnerships

A large and growing portion of the scientific information and investments in genetic engineering are held by private sector mainly in the industrialized world. According to Ernst & Young, for example, in 1997 US companies invested \$9.4 billion in R&D, employed 140,000 people and posted total revenues of \$18 billion. At the same time there were 1,036 European companies working in the life sciences, employing more than 39,000 people directly, with revenues of \$3.1 billion and \$2.2 billion invested in R&D.²¹ For public research institutions in Africa to access this information they will need to create strategic links with or to the private companies in the industrialized countries. The second reason

²¹See Falconi, C. 1999 for Ernest and Young data.

has to do with the fact that commercialization of biotechnology is effectively achieved with the participation of private sector. The economic history of public R&D in many parts of the world demonstrates that public agencies have limited capacity to engage in the commercialization of new innovations. They often require private entrepreneurs to take their innovations into the economic domain.

Another good reason is that private biotechnology companies are potential new sources of financial resources for biotechnology R&D in Africa. The historical evolution of biotechnology in such countries as the US, Germany and Japan vividly demonstrates, the role of companies as sources of finance for biotechnology R&D. In Japan biotechnology companies have financed biotechnology R&D through such arrangements as venture capital. In the US they have provided finances to university departments and scientists to undertake specific research on contract basis. Countries of Africa may wish to explore and exploit financial opportunities associated with partnering with private companies.

5. Conclusion

This paper has given a general sense of trends in biotechnology development and commercialization and drawn out some of the policy implications for developing countries. It has shown that a growing number of developing countries are already investing in related R&D, and some are exporters of genetically modified products. Their success in acquiring and sustaining global markets for their biotechnology is dependent on public perceptions of the technology, its risks and the nature and level of public confidence in national regulatory regimes. Countries of Africa should eschew the either/or, pro and anti- sentiments and erect scientific and technological foundations for harnessing benefits of the new science while at the same time reducing risks. It is through their own investment in genetic engineering that they are able to make informed decisions on which specific GM crops to import or accept as part of any food aid. Furthermore, with increased investment in genetic engineering that targets specific food production challenges, it may be possible to build the basis for food security in the region: reducing dependency on food aid. Africa requires genetic engineering as part and parcel of its endogenous scientific and technological development.

References

- Avramovic, M. 1996. *An Affordable Development? Biotechnology, Economics and the Implications for the Third World*. Zed Books, London.
- Brenner, C. and Komen, J. 1994. *International Initiatives in Biotechnology for Developing Country Agriculture: Promises and Problems*. Development Centre Studies, OECD, Paris.
- Brenner, C. and Komen, J. eds., 1996. *Integrating Biotechnology in Agriculture: Incentives, Constraints and Country Experiences*. Report of a Policy Seminar for West Asia and North Africa. International Service for National Agricultural Research (ISNAR).
- Bunders, J. ed. 1990. *Biotechnology for Small-Scale Farmers in Developing Countries*. VU University Press, Amsterdam.
- Byerlee, D. and Fischer, K. 2001. 'Accessing Modern Science: Policy and Institutional Options for Agricultural Biotechnology in Developing Countries'. Unpublished manuscript.
- Cohen, J. 2000. 'Harnessing Biotechnology for the Poor: Challenges Ahead Regarding Biosafety and Capacity Building'. Background Report Prepared for the United Nations Development Programme (UNDP) Human Development Report 2001.
- Dembo, D. and Morehouse, W. 1987. *Trends in Biotechnology Development and Transfer*. United Nations Industrial Development Organization (UNIDO), Technology Trends Series No. 6.
- Falconi, C. 1999. 'Agricultural Biotechnology Research Indicators and Managerial Considerations in Four Developing Countries', p. 24-37 in Cohen, J.I. ed. 1999. *Managing Agricultural Biotechnology—Addressing Research Program Needs and Policy Implications*. CAB International.
- Farrington, J. 1989. *Agricultural Biotechnology: Prospects for the Third World*. Overseas Development Institute, London.
- Fransman, M., 1991. *Biotechnology: Generation, diffusion and policy, An Interpretive Survey*. UNU/INTECH Working Paper No. 1.
- Izquierdo, J. and de la Riva, 2000. 'Plant Biotechnology and Food Security in Latin America and the Caribbean', in the *Electronic Journal of Biotechnology*, Vol. 3 No. 1.
- Juma, C. 1989. *The Gene Hunters: Biotechnology and the Scramble for Seeds*. Zed Books, London.
- Juma, C., J. Mugabe, and P. Kameri-Mbote, eds. 1995. *Coming to Life: Biotechnology in African Economic Recovery*. Nairobi: Acts Press.
- Kenney, M. 1986. *Biotechnology: The University-Industrial Complex*. New Haven, Yale University Press.
- Komen, J. 1999. 'International Collaboration in Agricultural Biotechnology', p.110-127 in Cohen, J.I. ed. 1999. *Managing Agricultural Biotechnology—Addressing Research Program Needs and Policy Implications*. CAB International.

- Krimsky, S. 1982. *Genetic Alchemy: The Social History of the Recombinant DNA Controversy*. MIT Press, Boston.
- Lall, S. 1989. *National Capabilities to Master Technological Change: A First Look at Selected Developing Countries*. Paper prepared for the OECD, Paris.
- MacKenzie, D., 2000. *International Comparison of Regulatory Frameworks for Food Products of Biotechnology*. Report Prepared for the Canadian Biotechnology Advisory Committee.
- Mugabe, J. 2000. *Biotechnology in Developing Countries and Economies in Transition*. Paper Prepared for the United Nations Conference on Trade and Development (UNCTAD), Geneva, Switzerland.
- National Academy of Sciences, 2000. *Transgenic Plants and World Agriculture*. National Academy Press, Washington, D.C.
- OECD 1989. *Technology and Global Competition: The Challenge for Newly Industrializing Countries*. Organization for Economic Cooperation and Development: Paris.
- Orsenigo, L. 1989. *The Emergence of Biotechnology*. Pinter Publishers, London.
- OECD, 1998. *Biotechnology and the Changing Role of Government*. Organization for Economic Cooperation and Development, Paris, France.
- OECD, 2000. *Genetically Modified Foods: Widening the Debate on Health and Safety*. Report of the OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods. Organization for Economic Cooperation and Development, Paris.
- OTA 1992. *Biotechnology in a Global Economy*. Office of Technology Assessment of the United States of America, Washington DC.
- Paarlberg, R. 2000. *Governing the GM Crop Revolution: Policy Choices for Developing Countries*. International Food Policy Research Institute (IFPRI), Washington, D.C.
- Sasson, A. 1988. *Biotechnologies and Development*, United Nations Educational, Scientific and Cultural Organization (UNESCO).
- UNCTAD. 1990. *Transfer and Development of Technology in Developing Countries: A Compendium of Policy Issues*. New York: United Nations Conference on Trade and Development.
- United Nations. 2001. 'Synthesis Report on the CSTD Panels on National Capacity Building in Biotechnology'. United Nations Economic and Social Council, New York.
- United Nations (1992), *Agenda 21*. Report of the United Nations Conference on Environment and Development.
- United Nations 1992. *Biotechnology and Development: Expanding the Capacity to Produce Food*. United Nations, New York.
- Warhurst, A. 1989. *New Directions for Empirical Policy Research in Biotechnology*. Paper presented at the International Symposium on Biotechnology for Sustainable Development, March 1989, African Centre for Technology Studies, Nairobi.
- Wiegele, T. 1991. *Biotechnology and International Relations: The Political Dimensions*. University of Florida Press, Gainesville.
- World Commission on Environment and Development (WCED) 1987. *Our Common Future*. Oxford: Oxford University Press.

Other Publications in the ATPS Special Paper Series

Special Paper Series 1

Globalization and Technology: Africa's Participation and Perspectives: Concept Paper and Research Agenda by Melvin Ayogu & Osita Ogbu (2002)

Special Paper Series 2

Globalization, Markets for Technology and the Relevance of Innovation Policies in Developing Economies by Sunil Mani (2002)

Special Paper Series 3

Biotechnology in sub-Saharan Africa: Towards a Policy Research Agenda by John Mugabe (2000)

Special Paper Series 4

The Impact of Globalization in sub-Saharan Africa Countries by Mwindace N. Siamwiza (2002)

Special Paper Series 5

A Blueprint for Developing National ICT Policy in Africa by Clement Dzionu (2002)

Special Paper Series 6

Impact of Foreign Direct Investment (FDI) on Technology Transfer in Africa by Moses M. Ikiara (2002)

Special Paper Series 7

Pursuing Technology Policy Research in sub-Saharan Africa: Reflections on the Dimensions, Applications and Implications of a Methodological Framework by M.H. Khalil-Tammy (2002)

Special Paper Series 8

African Response to the Information Communication Technology Revolution by G. Olalere Ajayi (2002)

Special Paper Series 9

Information and Communication Technologies (ICTs): Poverty Alleviation and Universal Access Policies by Andrew Dymond & Sonja Oestmann (2002)

Special Paper Series 10

ICT Human Resource Development in Africa: Challenges, Strategies and Options by T.M. Waema (2002).

Special Paper Series 11

Applications of ICTs in Africa: Development of Knowledge Workers in Centres of Learning by John Muraguri Waibochi (2002).

Special Paper Series 12

State of Science and Technology Capacity in sub-Saharan Africa by Khalil-Timamy (2002).

Special Paper Series 13

Strengthening National Information and Communication Technology Policy in Africa: Governance, Equity and Institutional Issues by Melvin Ayogu

Special Paper Series 14

A Science Agenda from An African Perspective by Turner T. Isoun

Dr. John Mugabe is the Executive Secretary of the African Commission on Science and Technology, South Africa and the Science Policy Advisor to the New Partnership for Africa's Development (NEPAD).