



REPUBLIC OF KENYA

**A NATIONAL BIOTECHNOLOGY
DEVELOPMENT POLICY**

2006

TABLE OF CONTENTS

FOREWORD	3
1.0 BACKGROUND	7
1.2. SCOPE OF THE POLICY.....	9
1.3 OBJECTIVES OF THE POLICY.....	10
1.4 METHODOLOGY.....	11
CHAPTER II	12
2.0 PRIORITY AREAS	12
2.1. <i>AGRICULTURAL BIOTECHNOLOGY</i>	12
2.2. <i>EDUCATION</i>	13
2.3. <i>BIORESOURCES</i>	13
2.4. <i>ENVIRONMENTAL BIOTECHNOLOGY</i>	14
2.5. <i>MEDICAL BIOTECHNOLOGY</i>	16
2.6 <i>INDUSTRY AND TRADE</i>	17
CHAPTER III	19
3.0 KEY ISSUES AND POLICY RECOMMENDATIONS	19
3.1 <i>CAPACITY BUILDING & MOBILIZATION OF RESOURCES</i>	19
3.2. <i>FINANCIAL AND BUSINESS SUPPORTS</i>	22
3.3 <i>PUBLIC PROTECTION AND SUPPORT</i>	22
3.4 <i>PUBLIC EDUCATION AND AWARENESS</i>	23
3.5 <i>PUBLIC ACCESS TO INFORMATION</i>	23
3.6 <i>REGIONAL AND INTERNATIONAL COLLABORATION</i>	24
3.7 <i>ETHICS</i>	24
3.8 <i>PROTECTION OF TRADITIONAL KNOWLEDGE AND RESOURCES</i> <i>Error! Bookmark not defined.</i>	
CHAPTER IV	26
4.0 INSTITUTIONAL AND LEGAL FRAMEWORKS, AND POLICY IMPLEMENTATION.....	26
4.1 <i>LEGAL FRAMEWORK</i>	26
4.2 <i>PROPOSED INSTITUTIONAL AND LEGAL FRAMEWORK</i>	26
4.3 <i>POLICY IMPLEMENTATION MECHANISMS</i>	27
CHAPTER V	29
5.0 CONCLUSION.....	29
REFERENCES	30

Foreword

Biotechnology is defined as: (a) the scientific or industrial use of living organisms to make or modify new products or improve existing plants, animals, or microorganisms. The term applies to the technique of gene splicing and, more generally, to other modern technologies such as plant tissue culture, embryo transfer, cell fusion, and fermentation; (b) any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use; (c) interpreted in a narrow sense, a range of different molecular technologies such as gene manipulation and gene transfer, DNA typing, and cloning of plants and animals. These technologies usually aim at enhancing the production and use of the resulting goods and services for the benefit of humankind.

The success of biotechnology has been accentuated through the application of bio-informatics, that is, a combination of Information Technology and biological sciences, especially genetics, genomics, biochemistry, molecular biology, and microbiology.

Advances in genomics have led to modifications of plants and animals with desirable traits for food or other industrial applications. Biotechnology is making the most impact in the areas of agriculture, healthcare, industry and environment. Food insufficiency caused mainly by growth in human population and diminishing crop yields can be successfully addressed through recourse to biotechnology in livestock husbandry and plant agriculture. In this respect, biotechnology is currently applied in the production of food and industrial crops and currently the acreage of land under Genetically Modified (GM) crops worldwide stands at over 52 million ha. This in itself indicates the high rate of adoption and application of this technology. Investment in biotechnology can also lead to enhanced human health and welfare through improved new drugs, development of new and superior diagnostics, therapeutics and applications in preventive medicine.

In the animal production realm, biotechnology allows for the use of transgenic farm animals as sources of biologically activated proteins, bio-pharmaceuticals, as donors in xenotransplantations and for further research in gene therapy, all of which are important applications in human medicine. The beneficial applications of embryo transfer include disease control, transboundary movement of livestock and the provision of sexed sperm and sexed embryos.

With the application of transgenesis in livestock, the benefits of disease resistance, biotechnology-derived vaccines, improved meat, milk and wool quality and protein production in milk and meat (biofarm animals) are significant benefits.

The technology has potential to increase food production through yield improvement, tolerant to biotic and abiotic factors while improving quality. The Government has recognized the role biotechnology can play in poverty reduction, enhancing food security and in the conservation of biodiversity and the environment. The development of a biotechnology and Biosafety policy is one of the measures put in place to chart the vision of the Government on the development and application of biotechnology. This policy will provide those developing and applying the technology a clear framework in which to operate.

While the Government appreciates the role of biotechnology in development, the production of genetically modified products has not been commercialized yet. There is however, some trial work being done on transgenic cassava, maize, cotton and sweet potatoes under containment facilities and development of diagnostic kits for disease detection and vaccines for disease prevention. All these activities have been carried out under the Biosafety Regulations and Guidelines drafted by the National Council for Science and Technology (NCST) in 1998. The NCST is the body charged by the government with the responsibility of implementing the guidelines.

The responsibility of every government is to safeguard its citizens and environment against any development or introduction of any deleterious organisms in whatever form. The development of a biotechnology and Biosafety policy is one of the measures put in place to chart the vision of the Government on the development and application of biotechnology. This policy will provide those developing and applying the technology a clear framework in which to operate in order to address fears on their safety.

In this regard the Government will ensure risk assessment and management is done on all introduced genetically modified material while legislation will be developed to govern and safeguard the use and development of biotechnology products.

The Government will, as a matter of priority, initiate appropriate steps to explore the use of biotechnology for the benefit of Kenyans and, furthermore, ensure that Kenya becomes a key participant in the international biotechnology enterprise within a

decade. This will be pursued through the provision of an enabling environment that responds to the needs of the biotechnology industry, the research and development communities as well as relevant national and international Biosafety concerns.

This policy recognizes that the Government needs to accord any high technology programme a priority rating with commensurate action profile. Through this policy, therefore, the Government commits itself to give priority attention to the provision of relevant infrastructure, framework, facilities and other resources for rapid and safe development and application of biotechnology in industry, agriculture, food, environment, health and research. This will ensure sustainability of the biotechnology industry in Kenya and enhance its international competitiveness, with a strong resolution to promote ethical, environmental and biosafety concerns;

The Government will make adequate provisions for effective and efficient implementation of the policy by, among others, providing appropriate and adequate legal regulatory framework and an enabling environment to attract investors and by also taking actions to accelerate the indigenous acquisition and development of relevant and affordable requisite biotechnology programmes. This is in addition to ensuring that information on the safe use of biotechnology is disseminated to the public and to industry.

In order to achieve sustainable growth of the biotechnology industry, it will be essential to promote indigenous research and development activities and to ensure that bio-resource endowment will be fully and sustainably exploited, through indigenous bio-prospecting of the natural resources for use in agriculture, environment, health and industry.

The Government, therefore, guarantees that a workable Action Plan under the short-term, medium-term and long-term time frames will be kept in view for a systematic and focused implementation of this policy, in collaboration with the private sector and relevant national and international agencies

The policy is structured in eight chapters. Chapter one covers the background; chapter two gives the key issues, policies and guiding principles; and, chapter three details the sectoral policies. Chapter four to eight outline the institutional and legal framework, education, capacity building and public awareness, risk assessment and management, monitoring and evaluation, resource mobilization and the conclusion, respectively.

On behalf of the Ministry of Science and Technology, I thank the National Council for Science and Technology, all individuals, groups and organizations whose valuable contributions were useful in writing this policy document on Biotechnology development in Kenya.

Dr. NOAH WEKESA

MINISTER FOR SCIENCE AND TECHNOLOGY

CHAPTER 1

1.0 BACKGROUND

Biotechnology in simple terms is defined as any technological application that uses living organisms or biological processes or derivatives thereof to make or modify products or processes for specific use. Biotechnology is not new. Thousands of years ago, civilizations were using yeast in bread, beer and wine production and using bacteria to extract minerals from ore. For the past five hundred years, human beings have been selectively breeding crops and animals to improve on their productivity.

Today plant biotechnology encompasses three major areas, plant tissue culture, plant genetic modification (genetic engineering), and molecular breeding or marker-assisted selection. This has resulted in improved yields and quality of crops because plants can be made resistant to diseases and pests, tolerant to drought, salinity and other strenuous environmental conditions. The improvement of domestic animals by selective breeding or cross breeding through assisted reproductive technologies and genetic manipulation could have a positive impact on public health and well-being. Also, the production of recombinant proteins in 'transgenic animal bioreactors' is another application of biotechnology with high value potential. The production of biotechnology derived drugs and vaccines have been a major breakthrough in the control of diseases in humans and animals. Genomics and bio-informatics have a promise to deliver even more benefits following the unraveling of the entire human genetic code. Biotechnology is being used to assess, rejuvenate, and maintain the well being of ecosystems through pollution reduction, and the development of safe manufacturing and disposal processes. In the year 2005, the world hectareage under genetically modified crops stood at 91 million hectares (Clive 2005). Countries that have embraced these biotechnology innovations and applications have brought unprecedented prosperity to their people, for example, the USA has the largest and most profitable biotechnology industry consisting of more than 1,300 companies raising over US\$ 500 billion/year, and providing employment to over 160,000 people. In the year 2004, Argentina, a developing country, realized about US\$ 6.5 billion from GM Soya crop alone (Brooks & Barfoot, 2005). Kenya is ready to learn from these success biotechnology ventures.

The agricultural sector contributes about 25% to the overall GDP. Livestock offers vast opportunities for economic growth especially in the ASAL areas, which have over 50% of livestock. The National development Plan (2002 – 2008) recognises the

following as challenging factors that have contributed to increasing food insecurity and inability to realize full economic potential in the agricultural sector: low farm level productivity, fragmentation of land in the high and medium potential areas into small holdings, expansion of agricultural production into marginal rainfall areas with inappropriate crop varieties, constant droughts and dwindling water sources due to destruction of vegetation and catchment areas, increasing costs of agricultural inputs such as fertilizers, pesticides etc. These are all contributing to chronic food shortages and declining nutrition levels in the population. These are major challenges that require appropriate scientific and biotechnological interventions.

HIV/AIDS, which has led to Tuberculosis resurgence, malaria, cancer, diabetes, malnutrition, etc, cause serious health problems with high morbidity and mortality rates. Therefore, there is need for new technologies to facilitate the development of affordable drugs and vaccines and cheap, easy-to-use, low-cost diagnostics for rural clinics and hospitals to support detection and management of these diseases.

Kenya has unique ecosystems ranging from freshwater and soda lakes, coastal freshwater and saltwater marshes, coral reefs, coastal, mangrove and high montane forests to savannahs, and arid and semi arid lands that are renowned for their levels of animal, plant and microorganism species richness and endemism awaiting economic exploitation. Kenya has a rich gene pool comprising of an estimated 35,000 known species of plants, animals and microorganism with unexploited economic potential. However, environmental degradation is a real threat to these biodiversity and therefore, the Government will need appropriate technologies to ensure sustainable utilization and conservation of the threatened biological diversity.

Kenya is currently experiencing a rapid decline in manufacturing industrial development because of inappropriate or declining raw materials, limited and/or constrained technological advancement because of inadequate research and development, and lack of adequate technical and entrepreneurial skills. The manufacturing sector that contributed about 13% of GDP has declined from a growth rate of 3.7% in 1996 to -1.5% in 2000 (NDP 2002-2008). Our ability to penetrate the regional and international markets has been severely constrained by the non-competitiveness of our local products caused by production methods based on outdated technology.

Kenya already has basic infrastructure, training and knowledge bases that can act as a spring board to propel the new revolution in biotechnology. We have a critical

mass of academic and research institutions that are already carrying out biotechnology research and development, currently addressing key traits such as disease, pest and drought tolerance, nutrient enrichment and quality improvement through tissue culture and marker-assisted selection in important staple crops, e.g. banana, Maize, cassava, potato, and sorghum. Other applications include vaccine development and diagnostics in animal research. The immediate challenge is how to boost the infrastructure, scientific and biotechnological capacity, promote entrepreneurship and facilitate effective technology transfer and product development.

In consideration of these challenges and opportunities, the government has certainly identified biotechnology as an appropriate tool and vehicle that can deliver economic gains through intellectual property creation to expand entrepreneurial opportunities for industrial growth, reduction of poverty, and improvement of food security, health, and environmental sustainability. The Government will initiate appropriate steps to nurture platform biotechnologies for the benefit of Kenyans and, ensure that Kenya becomes a key stakeholder in the international biotechnology enterprise within a decade. This will be pursued through a focused approach to basic research, product development and marketing, public protection and support, financial & business support as well as addressing the relevant national and international biosafety concerns.

The policy strategies outlined in this policy document provide well-designed measures for addressing research and development (R&D), and diffusing, transfer and commercialization of technology. This policy acknowledges the need for government to accord any high technology programme a priority rating with commensurate action profile.

1.2. SCOPE OF THE POLICY

Kenya has adopted biotechnology for the purpose of improving the quality of human welfare, maximizing productivity in agriculture and industry and protecting the environment, conserving biodiversity and bioprospecting. This policy seeks to address: Traditional and modern biotechnology; genetically modified organisms that are human food and animal feeds, and pharmaceuticals. The policy covers all biotechnology applications including tissue culture and micropropagation,

biopesticides and biofertilizers, bioremediation, Livestock technology, DNA Marker technology, and genetic engineering.

The policy will be broad based and will cover research, development and use of biotechnology in various fields such as agriculture, environment, human health and industry. The scope of the policy will take cognizance of local and international agreements and protocols such as the Cartagena Protocol on Biosafety, World Trade Agreements, Application of Sanitary and Phytosanitary Measures, the Agreement on Trade Related Aspects of Intellectual Property Rights, International Convention for the Protection of New Varieties of Plants.

The government recognizes that the domestic regulations governing the importation and use of pharmaceuticals, biologicals, food and feeds, may not be adequate. Therefore, the government will facilitate the process of aligning this policy to the regulations and policies governing the importation and use of these products.

1.3 OBJECTIVES OF THE POLICY

The objectives of this policy are:

1. To prioritize, promote, and coordinate research in basic and applied sciences in biotechnology.
2. To promote sustainable industrial development for the production of biotechnology-derived products
3. To create enabling administrative and legal frameworks for biotechnology development and commercialization
4. To develop mechanisms for the provision of sustainable funding for biotechnology research and product development;
5. To facilitate capacity building for Intellectual property access and protection, and biosafety;
6. To support the development and retention of human resources in science, innovation and biotechnology;
7. To stimulate collaboration among public, private sectors and international agencies in order to advance biotechnology both locally and internationally.
8. To establish mechanisms to address ethical issues relating to biotechnology.
9. To stimulate bilateral and multilateral cooperation for biotechnology procurement, development and commercialization.

10. To promote public understanding of the potential benefits of biotechnology.

1.4 METHODOLOGY.

The process of developing the national policy on biotechnology has followed an extensive consultative process thus ensuring public awareness and input. Biotechnology being a multi-sectoral approach, consultation with the ministries directly involved has been extensive as well. Some of the Ministries consulted were those responsible for matters of:

- Education,
- Health,
- Agriculture,
- Trade and Industry,
- Environment and Natural Resources,
- Planning,
- Livestock and Fisheries Development,
- The Attorney- General's Chambers,
- Science and Technology.

Within the Ministries, some Government Institutions currently undertaking the role of monitoring and inspection spearheaded the development of this policy. Among them are the Department of Veterinary Science, Department of Public Health, National Environment Management Authority, Kenya Bureau of Standards, Kenya Plant Health Inspectorate Services, Kenya Industrial Property Institute, Pest Control Products Board, Kenya Wildlife Service, and the National Council for Science and Technology.

Apart from the Government taking the lead, other stakeholders involved in the process included the United Nations Environment Programme (UNEP) which facilitated capacity building and promoted public awareness in the field of biotechnology. The civil societies, farmers, scientists, researchers, consumer organizations, development partners Non-governmental and Inter-governmental organizations, the private sector and the general public played key roles in the formulation of the biotechnology policy.

CHAPTER II

2.0 PRIORITY AREAS

2.1. AGRICULTURAL BIOTECHNOLOGY

The Government will adopt productivity enhancing agricultural biotechnologies that can substantially reverse the fast deteriorating food security and nutrition, farm incomes, spawn the agro-industry, and reduce environmental degradation. The Government will therefore focus on the following priority areas to strengthen rural economies:

1. Biotechnologies to develop new plant varieties with beneficial genetic traits for Pest and disease resistance, improved nutritional value, tolerance to drought and salinity. Special attention will be paid to traditional and wild crop plants.
2. Animal reproductive biotechnologies such as artificial insemination, embryo transfer, genetic improvement of local breeds, and somatic cell nuclear transfer (cloning) techniques. Special attention will be paid to the development of livestock that are resistant to diseases, have improved meat, milk or wool quality, can increase proteins in their milk or meat (biopharm animals), or which have characteristics that are environmentally friendly.
3. New plant and animal diagnostic products, improved animal vaccines, biological pesticides, herbicides and fertilizers.

The agricultural biotechnology applications needed include Tissue culture and micro-propagation techniques, DNA marker-based selection systems; Molecular-based diagnostics for pests and diseases; Genetic engineering for development of plants/animals that are resistant to pests and diseases, drought and salinity, and crop plants with enhanced vitamins and amino acids; and Vaccine development, etc.

The Government rates fish, prawn, shrimp, seaweed and oyster farming as a sector with great opportunities (NDP 2002-2008). However, the Government

will call upon the intervention of appropriate technologies to mitigate the following constraints for optimum exploitation of the sector:

1. Restricted range of conditions for farming
2. Inadequate quality fish seed
3. Reduced water volumes

2.2. EDUCATION

Biotechnology is a knowledge-driven and research-intensive industry, and therefore the Government will adopt strategies that strengthen science education at secondary and tertiary levels in order to increase the number of scientists, engineers and technologists for sustainable development of the biotechnology industry. Besides formal education, programs focusing on creating or enhancing awareness will be supported in order to influence a sustainable change in public behaviour and understanding of biotechnology issues. Priority areas that the government will pay attention to include:

- i. Review of curricula at all levels to promote the spirit of scientific inquiry by encouraging independent student projects, taking students on field trips, expert guest lectures; and entrepreneurial skills.
- ii. Strengthening the teaching of biosciences at university level
- iii. Attracting and Retaining talent in biosciences
- iv. Infrastructure development
- v. Informal Public education and awareness programmes

2.3. BIORESOURCES

Kenya's diverse ecosystems support a rich gene pool and endemism estimated at 35,000 identified species. The true extent of this species diversity and its economic value remains unknown. The Government, therefore, recognizes that this rich biodiversity and the traditional knowledge associated with it offer great opportunities for industrial products development through biotechnology interventions. The Government will adequately support the following priority activities for fast economic exploitation of the biodiversity:

1. The development of a centrally managed database on species in different ecosystems and the traditional knowledge associated with the species. Key stakeholders and contributors to the database will

- be universities, research institutions, private companies, and NGOs
2. Molecular characterization and bioprospecting for novel products for development and industrial production. The Government will set up a well-coordinated research fund for this activity.
 3. Establishment of national culture collection centers for microorganisms with potential for novel products development
 4. Accelerate the establishment of viable *in-situ* and *ex-situ* (Gene banks) conservation centers. Tissue culture technology will be used to regenerate endangered indigenous plant species. To accelerate this process, the government will set up regional tissue culture facilities, backed by adequate human resources to achieve this objective
 5. Focused exploitation of fauna, flora and microbes in marine and extreme habitats for novel genes for development of osmo-tolerant crops, enzymes, biopolymers, marine pollution biosensors, bioactive molecules, etc.

2.4. ENVIRONMENTAL BIOTECHNOLOGY

The precautionary approach contained in Principle 15 of the Rio declaration on Environment and Development forms the basis for biotechnology development. This policy will ensure an adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms that may have an adverse effect on the environment.

Efforts will be made to ensure that the potential benefits of biotechnology for sustainable utilization and conservation of environmental resources are tapped while ensuring the necessary biosafety measures are put in place. Applications requiring use of modern biotechnology for all purposes, including for environmental protection, bioremediation, as well as biodiversity conservation and bioprospecting will be subject to approval by any designated authority, in addition to fulfilling the requirements of the Environment Management and Coordination Act, 1999.

The Government will ensure environmental sustainability by developing and adopting appropriate biotechnologies to address:

1. Monitoring environmental pollution
2. Eco-restoration of degraded habitats

3. A forestation and reforestation
4. Bioremediation of wastes
5. Control of biological invasions
6. The potential for value-added products from biomass

Environmental biotechnology applications will include Tissue culture and micro-propagation techniques, Bioremediation, and genetic engineering. Rules and guidelines regarding the solid waste and wastewater treatment through biotechnology will be evaluated on case by case.

2.4.1 Risk Assessment & Management

Arising from the need for the Government to maintain the public trust at a high level through impartiality, integrity and transparency of its decision making process with respect to Genetically Modified Organisms, there is critical requirement to enhance mechanisms to adequately assess the safety of, and to identify and develop appropriate management practices to minimize potential risks to human health and the environment associated with, such products. The Government will institutionalise risk assessment and risk management in collaboration with other relevant stakeholders.

The Government will ensure that scientific risk assessment and management is undertaken on genetically modified organisms to be released into the environment for research, field trials and commercialization. This will be supported by an efficient monitoring system to be established. In this regard an adequate capacity & knowledge base will be put in place at all times to ensure that adequate risk assessment is carried out and proper risk management measures are provided for to adequately and appropriately address any potential risks. The risk assessment will focus on scientific consideration of evidence of the potential for adverse effect as provided for in Article 15 of Cartagena Protocol and any non-science issues will be separated from the risk assessment process. The bodies engaged in biotechnology will be required to carry out internal risk assessments commensurate with the scale of biotechnology activity.

2.4.2 Monitoring and Evaluation

For any programme, monitoring & evaluation promotes efficiency, accountability & transparency. Adequate provisions for supervision, monitoring and enforcement of approved standards will be incorporated into

the action plan to ensure that biotechnology projects and programmes are identified, planned, implemented and monitored in line with existing government policies. To this end, the Government will ensure that there is adequate inter-sectoral collaboration so as to avoid overlap on the roles of various agencies (such as Director of Veterinary Services, Kenya Plant Health Inspectorate Service, Kenya Bureau of Standards, Department of Public Health, National Environmental Management Authority) in regulating the introduction, development and use of biotechnology and its products. These regulatory institutions will re-orientate their policies, rules, regulations and services in order to enable them adopt their added roles of regulating the novel products processed using biotechnology.

Legal mechanisms will be developed for continuous monitoring and evaluation of research and use of genetically modified organisms. Monitoring will start from the onset of a programme right through to the commercialization of the products. It will therefore include monitoring and evaluating approvals, trials & releases; inspections; LMO disposal; and for labeling in supermarkets & other outlets. The post commercialization evaluation will ensure that the programme has been successfully undertaken and the impacts adequately assessed and understood.

The monitoring and evaluation process will be the primary responsibility of the government through the proposed National Biosafety Authority (NBA), which will work in conjunction with the relevant government regulatory institutions ensuring adherence to the relevant laws.

The monitoring and evaluation system adopted for this policy will be designed to provide feedback to stakeholders to facilitate appropriate decisions on future implementation and review of the policy.

2.5. MEDICAL BIOTECHNOLOGY

HIV/AIDS, Tuberculosis and other respiratory infections, Malaria, and malnutrition are key diseases with high mortality rates in Kenya. At global level, biotechnology has delivered clear benefits for improved medicines and healthcare. Genomics promise to deliver even more benefits following the unraveling of the entire human genetic code. The Government will make use of these medical biotechnologies to develop affordable and easily accessible

tools for disease prevention, drugs and vaccines, and diagnostic tools, especially for rural clinics and hospitals to support detection and management of these diseases.

In order to realize fast and meaningful economic benefits from medical biotechnology the Government will focus on the following areas:

1. Basic and applied research in Bioinformatics, molecular and cellular biology, genomics, proteomics, stem cell biology (strictly using ethically obtained stem cells only), and other new platform biotechnologies as appropriate.
2. Development of molecular diagnostics, recombinant vaccines, combinatorial chemistry, vaccine and drug delivery systems, etc.
3. Development of traditional herbal medicines into superior industrial therapeutic products
4. Screening of biodiversity components for bioactive compounds for value added therapeutic products

Health and nutrition related genetically modified organisms that are shown to be beneficial to human health, approved and in use in the country of origin would be allowed for use in Kenya under the laid down procedures. However, the Government will safeguard the health of Kenyans by ensuring that the products brought into the country meet the required standards, and are safe for human use as stipulated in the proposed Biosafety Act. These genetically modified organisms include, but not limited to, vaccines, vitamins, hormones, diagnostic kits and naked DNA.

Kenya will not allow any activities or research dealings involving human cloning, or use of unethically procured stem cells.

2.6 INDUSTRY AND TRADE

The Government's current plan (NDP 2002 – 2008) is to improve the performance of the industrial sub-sector by:

1. Acquisition and dissemination of appropriate technology
2. Value addition to primary commodities.

The Government will therefore support safe platform biotechnologies to convert the local bioresources into biofuels, fine and bulk chemicals, bioplastics, pharmaceuticals, enzymes, vitamins, biofertilizers, food processing, etc. The Government will take the following actions:

1. Develop initiatives that will attract major investment in biotechnology research and product development from local and international companies
2. Promote industrial skills development
3. Provide a conducive environment for small and medium size biotechnology products businesses
4. Ensure high quality standards, and competitiveness of products on local and international markets.

Industrial applications of biotechnology will be in line with the proposed Biosafety Act. The development of modern biotechnology products will not be at the expense of environmental degradation.

CHAPTER III

3.0 KEY ISSUES AND POLICY RECOMMENDATIONS

3.1 CAPACITY BUILDING & MOBILIZATION OF RESOURCES

The first priority for Kenya is to build endogenous scientific and biotechnological capacity including human resource and research infrastructure as part of the national planning strategy. It is through the availability of such capacity that Kenya will be able to manage biotechnology acquisition, absorption and diffusion of activities relevant to development. The government will take the following proactive actions:

3.1.1 Human resource development

Biotechnology is a knowledge-driven industry that requires appropriate human resource development for its success. For sustainable biotechnology development, formal education and technical training for capacity building will be provided at the primary, secondary and tertiary levels. Lessons learned from the developed world prove that industrial development benefits immensely from university training and research activities, and therefore, the government proposes to take the following actions:

1. Cause public universities to adopt crosscutting curricula that promote, among others, innovation, product development and entrepreneurial skills.
2. Facilitate adequate funding and the acquisition of the state-of-the-art facilities for modern pedagogy and cutting-edge research.
3. Facilitate a crash programme for upgrading of existing 'classical' bioscience scientists and technologists in molecular and cellular

genetics, tools of biotechnology, and entrepreneurial skills through short training courses.

4. Establish a post-doctoral fellowship scheme
5. Promote International partnerships. The government will stimulate and strengthen international linkage with institutions at the leading edge of biotechnology for knowledge generation and acquisition of cutting-edge biotechnologies.
6. The government will ensure retention of highly trained experts in biosciences, engineering and biotechnology through availability of jobs and competitive remuneration packages; and fast tracking of human resource needs at public research institutes and universities.

3.1.2 Infrastructure, Facilities and Equipment

Biotechnological research and development is largely laboratory based and characterized by high operational costs. It requires special containment facilities, high quality water supply, uninterrupted electricity supply, expensive equipment, and ready and frequent access to perishable consumables. Modern communication systems including telephones, fax, e-mail and Internet are critical components in the acquisition and exchange of knowledge among R & D institutions. Generally, Kenya has a reasonable amount of equipment to undertake effective biotechnology work. However, equipment, consumables, and funds for donor-supported projects are made inaccessible to other scientists who are not part of the project, even when they are in the same institutes/laboratory. In view of these handicaps, the Government proposes to take the following actions to resolve these operational problems:

- a. The Government, through the National Biotechnology Enterprise Programme will put in place mechanisms to create linkages and networks among public Research Institutes and Universities for optimum access and utilization of available resources.
- b. Enhancement of public – private, NGO, IGO partnerships for acquisition of equipment and consumables.
- c. Support initiatives for the establishment of biotechnology parks at R & D institutions as incubators to stimulate the growth of

small- and medium-size businesses with potential to mature into high-technology companies.

3.1.3 Prioritization and Coordination of Research and Development

Currently, the biotechnology related research and development (R&D) programmes going on at public Research Institutes and Universities, and International research centres in Kenya are not coordinated. Each institution has its own research agenda and priorities, and at different stages of application of biotechnological processes. In order to realize maximum economic returns and to eliminate the possibility of unnecessary and wasteful duplication of effort, the government will establish a National Biotechnology Enterprise Programme consisting of:

- a. A National Commission on Biotechnology to consolidate and maximize on available resources for institutions engaged in training, and R&D through:
 - i. The identification and implementation of national priority areas for R&D
 - ii. Provision of advice/guidance on and/or supervision of the allocation of primary resources and responsibilities to public R&D Institutes and Universities
 - iii. Tracking and evaluation of inventions, patents and commercialization of discoveries
 - iv. Identifying and linking Research and Development centres of excellence and the private sector actors.

- b. A National Biotechnology Education Centre whose functions shall be:
 - i. To coordinate and facilitate training
 - ii. To develop and maintain bioscience research, innovation and biotechnology database
 - iii. Develop and maintain a National culture collection

- c. A National Biosafety Authority to be responsible for safe acquisition, development and commercialisation of biotechnology and its products thereof.

3.2. FINANCIAL AND BUSINESS SUPPORTS

The Government, in partnership with the private sector and development partners, will create funding mechanisms for firms or consortia of firms and research institutions to undertake focused research on development of new products and production techniques, improvement of existing products and processes, and upgrading product quality and strengthening innovative capacity. The government proposes to take the following financial support initiatives:

- a. Create incentives to encourage partnerships between public research institutes and universities, and the private sector for the purpose of attracting private-sector investment in biotechnology-based start-up firms. Incentives include but not limited to subsidies on private-sector capital investment, tax exemptions/holidays, etc.
- b. Waiver of taxes on research materials and equipment
- c. Encourage specialized technological financing agencies to provide loans to firms or consortia and research institutions.
- d. Direct public budgetary allocation to biotechnology research and development.

3.3 PUBLIC PROTECTION AND SUPPORT

3.3.1 Intellectual Property Rights

Protecting Intellectual Property Rights (IPR) is a critical aspect of biotechnology innovation, and ensuring effective public and private sector participation in research and product development. In the 2002 – 2008 National Development Plan, the Government identified lack of awareness of Intellectual Property Rights as key constraint in the development of industry. In order to remove this obstacle, the Government will institute the following interventions:

1. Develop capacity for effective management of intellectual property
2. Training of scientists
3. Improve accessibility to IPR services by scientists
4. Establish a Government fund to support the filing of patents from public research institutions.

3.1.2 Protection of Traditional Knowledge and Resources

The Government recognizes the existing policies and legislation on protection of traditional knowledge and resources. Where gaps exist the government will review the legislation and align this policy to the policy on royalties, patenting, access to information and benefit sharing of issues relating to biotechnology.

3.3.2 Products from genetically modified organisms

All products containing engineered genes or derived from genetically engineered organisms that are locally developed or imported must meet the requirements of the laws of Kenya governing Biosafety, Environment, Phytosanitary, Sanitary, Food and Pharmaceutical standards.

3.4 PUBLIC EDUCATION AND AWARENESS

Availability and access to information is paramount in the development and management of biotechnology. The Government will put in place mechanisms to spread awareness about the investment opportunities in biotechnology for the public and the entrepreneurial community. The government will avail information to stakeholders from introduction to commercialisation of products of modern biotechnology. The trader through the relevant government organisation will provide this information giving scientific details on their products to the consumers. The public will have a right not only to participate in decisions affecting the management and status of the environment but also to institute legal proceedings in vindication of the public interest. There are four basic elements to the principal of public awareness and participation that the Government will adopt:

- Creation of public awareness on biotechnology issues and investment opportunities
- Access to information held by public authorities;
- Participation in decision making process;
- Access to judicial and administrative provisions.

3.5 PUBLIC ACCESS TO INFORMATION

The Government will ensure that information on the development and use of the technology is accurately and efficiently disseminated to the public and

industry to allow them to make informed choices on its application while being guaranteed of their traditional methods of production. For any generation or development of a product of modern biotechnology there will be adequate information on the extent of modification, effect on environment and consumer safety.

3.6 REGIONAL AND INTERNATIONAL COLLABORATION

In promoting the acquisition of technology and implementation of biotechnology activities, the Government will seek regional and international partnership specifically to:

1. Harness international expertise and platform technologies
2. Finance of biotechnology
3. Build regional innovation systems and market access.
4. Enhance collaboration with relevant national, regional and international agencies to ensure that biotechnology and its products meet the required safety and ethical standards.

3.7 ETHICS

The Government recognizes the need to enhance agricultural output and therefore encourages the use of biotechnology to address specific problems where alternatives are not available. Socially, biotechnology cuts across species in the transfer of genes, which could have negative impacts on dietary preferences of cultural or religious groups. Farmers in Kenya normally plant farm-saved seeds. Consumers also have preferences on what to consume and this right will be guaranteed. Ethically, the developers of the technology will be bound to use biotechnology in a way acceptable to society. Notwithstanding that the Government recognizes the need to enhance the quality of human health and nutrition through the application of innovations in biotechnology, the Government will not allow the use of science to propagate unethical practices. In this respect, socially negative trends in biotechnology development like human cloning, use of stem cells obtained unethically and the introduction, use or release into Kenya of any genetically modified organisms that have terminator sequences will not be allowed. Groups with special interests such as the farmers who practice organic

farming will continue enjoying their freedom to practice their farming systems unhindered.

Release of genetically modified organisms will be undertaken in compliance with the Biosafety Act and only after careful and comprehensive risk assessment and ethical considerations. Each institution involved in biotechnology research and product development shall consult the National Biosafety Authority to provide guidance and advice to researchers, regulatory agents, and the public on ethical issues arising or likely to arise from the science and the products thereof.

CHAPTER IV

4.0 INSTITUTIONAL AND LEGAL FRAMEWORKS, AND POLICY IMPLEMENTATION

4.1 LEGAL FRAMEWORK

The different elements of modern biotechnology are scattered in different pieces of legislation. There is therefore need to develop a new legislation that will address all aspects of modern biotechnology. The Government in implementing this policy shall review and harmonize the statutory mandates of existing institutions with the view of enhancing the implementation of this policy. The new legislation on biosafety will cover the development, control & impact of biotechnology, which takes into account international regulations & treaties. It will govern all experiments, field trials, and commercialization of genetically modified organisms and will provide for containment facilities consistent with the level of potential risk. Finally, the legislation will define a liability regime for damage resulting from the use of modern biotechnology.

4.2 PROPOSED INSTITUTIONAL AND LEGAL FRAMEWORK.

Legislative response to biotechnology issues in Kenya has been characterized by fragmented and uncoordinated sectoral legal regimes with inherent deficiencies. This policy recommends efficient coordination of the relevant regulatory institutions involved in the handling of food safety, Sanitary and Phytosanitary issues as mandated under the following Acts: Science and Technology Act Cap 250; Environmental Management and Coordination Act Cap Standards Act Cap 496; Food, drugs and chemical substances Act Cap 254; Public Health Act Cap 242; Plant Protection under KEPHIS legal Notice No. 350 of 1996; Animal Diseases Act Cap 364, Public Health and

Environment Management and Coordination Acts No. 8 of 1999.

The flexibility will be achieved through investing relevant authorities with wide regulatory powers to promulgate subsidiary legislation addressing specific biotechnology issues and completing the generality of the framework statute. In addition, the proposed framework law will provide a basis and a reference point for the co-ordination of sectoral activities and harmonization of sectoral legal regimes.

The effective implementation of Biosafety legislation presupposes the existence of appropriate institutional arrangements and process. The sectoral approach to biotechnology management has had the effect of diffusing power and responsibility to diverse government departments without any institutional mechanisms for co-ordination. Jurisdictional overlaps and conflicts have inevitably arisen thereby inhibiting not only the effective implementation of sustainable development policies but also law enforcement. To address this, the Government will put in place a National Biosafety Authority. This Authority will be the central coordinating and implementation body and will work together with the relevant Government regulatory institutions to ensure adherence to laws & regulations. The functions of the Authority shall include: providing guidance on biosafety and related legal matters on biotechnology, establish linkages with institutions and Institutional Biosafety Committees (IBCs) according to the guiding principles of this policy, creating links with appropriate standards bodies, facilitating biosafety planning and articulation of policy, ensure co-ordination of the various sectors and harmonization of sectoral policies, and to provide technical advice to government departments and agencies.

4.3 POLICY IMPLEMENTATION MECHANISMS

Finally, the Government will make adequate provisions for effective and efficient implementation of this policy. It will ensure that a workable action plan under the short-term, medium-term and long-term time frames will be developed in view of a systematic and focused implementation of the biotechnology policy.

The Government will regularly review existing policy, legal and administrative mechanisms on biotechnology in order to ensure that the development and

use of biotechnology remains focused and in line with national, regional and international obligations. The sectoral approach to biotechnology management has had the effect of diffusing power and responsibility to diverse government departments without any institutional mechanisms for coordination. Jurisdictional overlaps and conflicts have inevitably arisen thereby inhibiting not only the effective implementation of sustainable development policies but also law enforcement. Towards this end it is recommended that a National Commission on Biotechnology be created to oversee the implementation of the biotechnology policy. In terms of biosafety the Government will establish National Biosafety Authority which will work closely with the National Commission on Biotechnology.

CHAPTER V

5.0 CONCLUSION

The policy defines a well-designed mainstream biotechnology roadmap that should effectively guide the country into a pre-eminent position of a knowledge-based economy that reflects the co-evolutionary dynamics of biotechnology. The speed at which the country will drive towards world-class biotechnology to gain real mileage in food security and nutrition, affordable health, and industrial growth for the overall sustainable economic growth and poverty alleviation, will be determined by our commitment to, and accuracy of strategic action plans and timelines for the implementation of this policy.

The Government's position and commitment to provide an enabling environment for the acquisition and development of the biotechnology industry for fast exploitation of the immense potential in agriculture, environment, bioresources, health, and manufacturing industry is clear. This commitment is well articulated in priority areas and the policy recommendations that are linked to them.

The policy also appreciates the need for prioritization as a critical step to strategic investment in biotechnology and also the need for institutional articulation and coordination in order to mobilize and optimally utilize available resources. The policy implementation will rely on a requisite capacity in terms of financial, human resource, infrastructure and information. In all this, capacity building at all levels will be crucial to ensure the success of this policy. This calls for concerted efforts by all stakeholders to play an active role in creating a capacity which is commensurate with the priorities identified for the social and economic growth of the nation. The policy identifies the gaps and challenges which can be addressed through creation of endogenous capacity that is supported by indigenous knowledge and innovations. Further, the transfer of appropriate and affordable technology will be promoted in line with the objectives of this policy. There is clear recognition of the importance of fostering collaboration at local, region and

international levels for the furtherance of the objectives of this policy.

Regular monitoring and evaluation will be necessary to assess the achievements on each policy recommendation for prompt identification and implementation of remedial action on activities that require policy adjustments. Consequent to this, the policy will be reviewed from time to time to ensure that it continues to support biotechnology development.

REFERENCES

- 1 Kenya Gazette Supplement, ACTS, (2000). Environmental Management and Coordination Act, 1999.
- 2 Republic of Kenya (2000). National Development Plan 2002 – 2008
- 3 James, C. 2005. Global Status of Commercialized Biotech/GM Crops: 2005. ISAAA Briefs No. 34. ISAAA: Ithaca, NY.
- 4 Brooks & Barfoot (2005). GM Crops: The Global economic & Environmental Impact 1996 – 2004. PG Economics UK. www.pgeconomics.co.uk