Analysis of the Biosafety System for Biotechnology in Kenya: Application of a Conceptual Framework

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Executive Summary

Kenya is a signatory to the Cartagena Protocol for Biosafety, which offers a set of guidelines regarding the safe handling and use of genetically modified organisms (GMOs). The Protocol also requires signatory countries to develop a regulatory framework and the capacity (in terms of people, expertise, and technology) to undertake risk assessments with regard to the development and use of GMOs. Building capacity in biosafety is thus strategically important for signatory countries, both in meeting obligations under the Protocol and in advancing the successful integration of biotechnology into agricultural research and production.

To facilitate these aims, a conceptual framework was developed, through an initiative instigated by ISNAR, as a tool to aid developing countries in the design and implementation of biosafety systems. This framework identifies five areas as critical to the development of an effective national biosafety system:

1. strong national policies, strategies, and research agendas regarding biotechnology and biosafety;
2. a national inventory and evaluation;
3. the knowledge, skills and capacity to develop and implement a biosafety system;
4. the development of regulations;
5. the implementation of policies.

This country report analyses the status of the national biosafety system in Kenya and also serves to test the suitability of the framework. The report's findings and recommendations may serve as the basis for discussions to strengthen and adapt the biosafety system in Kenya. Some of the main findings are:

- There is a need to develop the biosafety expertise of key government officials within existing regulatory agencies to help them handle increasing volumes of applications.
- There is concern about the entry of transgenic organisms into Kenya outside of regular channels, such as GM grain arriving as food aid, which could subsequently be planted by farmers.
- The National Biosafety Committee (NBC) currently takes a cautious approach to risk assessment. It needs to look at the potential benefits of GMOs and also the risks associated with *not* adopting some GM products for the future productivity and sustainability of agriculture and for the competitiveness of the economy in Kenya.
- As in most countries, public understanding of biotechnology and GM is limited.
- Kenya is well placed to take the lead in biosafety initiatives in the region.

Appropriate recommendations were formulated based on these findings.

Acronyms

ABSF	African Biotechnology Stakeholders Forum
ASARECA	Association for Strengthening Agricultural Research in Eastern and Central Africa
BIO-EARN	The East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development
BTA	Biotechnology Trust Africa
DVS	Department of Veterinary Services
FDA	Food and Drug Administration
GM	genetically modified
GMO	genetically modified organism
IBC	Institutional Biosafety Committee
ICIPE	International Center for Insect Physiology and Ecology
IFPRI	International Food Policy Reasearch Institute
ILRI	International Livestock Research Institute
ISAAA	International Service for the Acquisition of Agribiotechnology Applications
KARI	Kenya Agricultural Research Institute
KBS	Kenya Bureau of Standards
KEPHIS	Kenya Plant Health Inspection Service
LMO	living modified organism
NARO	national agricultural research organization
NBC	National Biosafety Committee
NCST	National Council for Science and Technology
NGO	nongovernmental organization
PHD	Public Health Department
UNEP-GEF	United Nations Environment Programme-Global Environment Facility
USAID	US Agency for International Development
USDA-APHIS	United States Department of Agriculture-Animal and Plant Health Inspection Service
USEPA	United States Environmental Protection Agency

I. Introduction

Kenya was the first country to sign the Cartagena Protocol for Biosafety, in May 2000. The result of five years of international negotiations, the Protocol offers a set of guidelines regarding the safe handling and use of genetically modified organisms (GMOs; also living modified organisms, LMOs). It also requires signatory countries to develop a regulatory framework and the capacity (in terms of people, expertise, and technology) to undertake risk assessments. Building capacity and competence in biosafety are thus strategically important for signatory countries, both in meeting obligations under the Protocol and in advancing the successful integration of biotechnology into agricultural research and production. To date, more than 50 countries have ratified the Protocol, which entered into force in September 2003.

Conceptual Framework for Biosafety Implementation

As the date for compliance with the Cartagena Protocol drew nearer, initiatives within developing countries to design and implement biosafety regulatory systems gained momentum. To capitalize on the experience of countries at more advanced stages of the process, as well as that of providers of capacity building assistance and donor organizations supporting programs aimed at advancing biosafety implementation in the developing world, ISNAR organized an experts' consultation in 2001[1]. The participants' task was to develop a detailed conceptual framework for implementing a national biosafety system, taking into account the breadth of options available. They were asked to identify key decision points in the process and to examine the implications and consequences of the various policy options with respect to future operations of such a system. They worked to identify a range of capacity building activities suitable for countries at different stages of development with respect to biosafety.

The experts identified five elements as being critical to the development and implementation of an effective national biosafety system:

1. strong national policies, strategies, and research agendas regarding biotechnology and biosafety;
2. national inventory and evaluation;
3. the knowledge, skills, and capacity base to develop and implement a biosafety system;
4. development of regulations;
5. implementation of regulations.

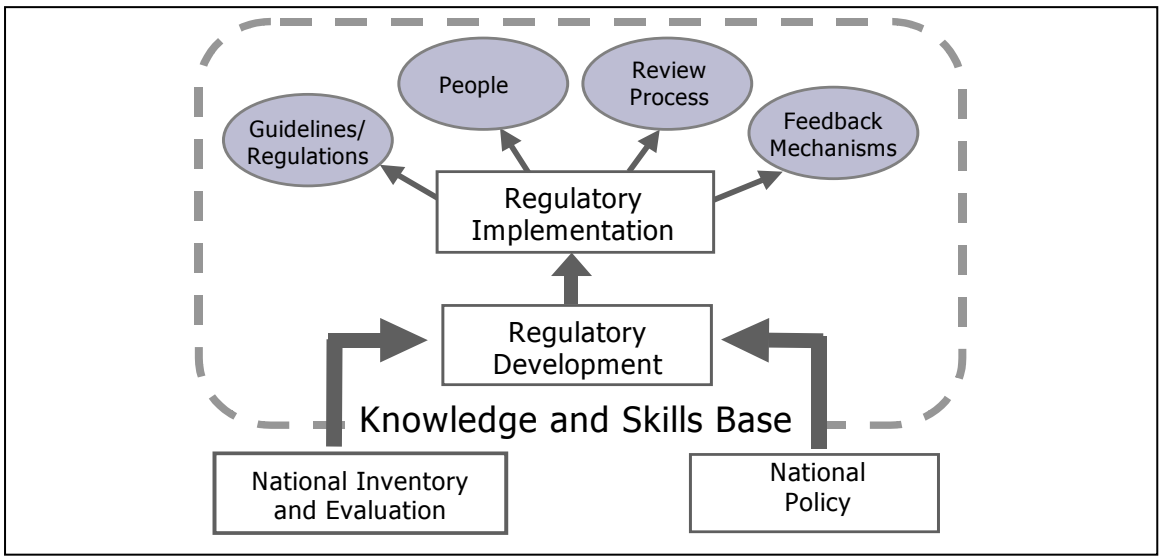
The resultant conceptual framework (figure 1) addresses the regulatory implementation and capacity-building needs of developing countries that are party to the Protocol. If it is applied successfully, client countries will gain a better understanding of the issues and options they face, providers will have a tool that will improve the formulation and delivery of capacity building assistance, and donors may use the framework to focus their capacity building programs for maximum impact. As stated in the introduction to the consultation paper:

> "The framework aims to … provid[e] guidance on the design and implementation of regulatory frameworks and related capacity building initiatives. It is not intended to be a

[1] "A Framework for Biosafety Implementation: A Tool for Building Capacity", held in Washington, DC, USA, July 2001.

common road map for all Parties or countries to follow. Instead, it seeks to clarify critical decision points in the development of a national biosafety framework; choices among policy options; and delineate some of the scientific and social dimensions of these options."[2]

Figure 1. Conceptual framework for biosafety implementation



Framework for the Study

Collaborative ISNAR research studies recently examined the efficacy of biosafety systems in Egypt and Argentina (Madkour et al. 2000; Burachik and Traynor 2001). Each study led to the development of a set of specific recommendations for strengthening the system. The studies reviewed biosafety implementation against a concept which views biosafety systems as having four common elements that, ideally, function to bring about environmentally responsible decision-making regarding the use of GM products (Traynor 1999). These are

- the **regulations or guidelines** clearly define the structure of the biosafety system, the roles and responsibilities of those involved, and how the review process is to operate;
- the **people** involved are knowledgeable and well trained, confident in their ability to make decisions, and supported by their institutions;
- the **review process** is based on up-to-date scientific information; focuses on specific combinations of crop, gene, and environment; promotes appropriate risk management practices; and balances risks against benefits;
- **feedback** mechanisms are used to incorporate new information and revise the system as needed.

[2] The consequences of policy choice on the efficiency and effectiveness of biosafety regulation are presented in more detail in McLean et al. (2002).

[4] Ironically, the vaccine may never be used. A major FAO initiative to eradicate rinderpest in East Africa within eight years is on track to succeed, at which point the vaccine may become irrelevant.

The approach used in this study of Kenya's national biosafety system is similar to that used in previous ISNAR studies. However, in this case the system is viewed in light of the Conceptual Framework developed by the expert consultation, and the elements described therein, as opposed to Traynor's concept. In particular, emphasis is placed on the options available at selected decision points within the following four areas:

- national policies and strategies;
- scientific skills, knowledge and capacity base – locating the science evaluation function;
- development of regulations – (a) legislative framework; (b) transparency and public involvement;
- implementation of regulations – transparency of the risk assessment process and risk assessment decisions.

Objectives

The specific objectives of this report are to

1. examine the organization and operation of Kenya's national biosafety system;
2. characterize existing policies, regulations, and capacities for regulatory management and decision making, and identify areas appropriate for further development; and
3. develop a set of recommendations intended to (a) encourage a clear and supportive policy and regulatory environment, (b) increase capacities for meeting national obligations under the Cartagena Protocol for Biosafety, and (c) foster greater biosafety awareness and understanding among stakeholders and the general public.

The Conceptual Framework was developed as a tool to aid developing countries in the design and implementation of biosafety systems but potentially has much wider uses. This study serves to "test" the suitability of the Framework as a tool to aid in the evaluation and analysis of existing biosafety systems.

II. Context for Biosafety

Kenya has been the focus of, or included in, a number of recent reports concerning biotechnology and biosafety (Quemada et al. 2002; Koch 2001; Wekundah and Kabare 2001; Wafula and Kimoro 2001; Thitai et al. 1999). These studies document the resources being allocated to biotechnology research and biosafety implementation. They also show that an atmosphere of cooperation extends across the agencies and committees concerned with these issues and indicate a general willingness within the research community to engage in international collaboration.

Quemada et al. (2002) reviewed biotechnology research at a wide range of national and international institutions in Kenya, such as the Kenya Agricultural Research Institute (KARI), the University of Nairobi, and the International Livestock Research Institute (ILRI). The review shows that while there is the technology base for plant genetic engineering, and that tissue culture and basic molecular biology techniques are regularly used in research, there is still a lack of expertise in genetic engineering. The report includes several recommendations for enhancing national research and development (R&D) capacities, and for strengthening the national biosafety system.

Regulatory Environment

In order to be effective, national biosafety systems need to be compatible with the policies and procedures of other regulatory authorities. Depending on their nature, imported GMOs or GM products may be subject to regulations on, for instance, animal health, quarantine or food safety, as well as biosafety. Administrative jurisdiction, application procedures, and record-keeping requirements pertaining to biosafety need to be coordinated with the other agencies involved in order to minimize confusion and conflicts over administrative authority. In the area of agriculture alone, numerous acts may apply to the importation, use, or sale of GMOs (table 1).

In Kenya, this responsibility falls on the National Council for Science and Technology (NCST), the government agency tasked with overseeing the implementation of biosafety regulations and guidelines. It took the lead in drafting the Regulations and Guidelines for Biosafety in Biotechnology, which were issued in 1998, and established a National Biosafety Committee (NBC). The guidelines are implemented by the following key regulatory agencies.

Kenya Plant Health Inspection Service

The Kenya Plant Health Inspection Service (KEPHIS), administered within the Ministry of Agriculture, is responsible for all aspects of plant health and protection. The agency regulates the import and export of agricultural, horticultural, and forest species through a permit system. It has jurisdiction in phytosanitary matters and routinely inspects any form of plant material arriving at seaports, highway border crossings, and airports. It also has full regulatory authority to seize, turn away, quarantine, or dispose of materials deemed unacceptable for entry into Kenya.

Table 1. Existing legislation that may be applicable to GMOs

Legislation	Purpose	Agency
Agriculture Act, 1955	Development of agriculture; conservation of soil and enhancement of soil fertility; agricultural land development	Ministry of Agriculture
Plant Protection Act, 1971	Prevention of the introduction and spread of diseases and pests destructive to plants	KEPHIS
Seed and Plant Variety Act, 1975	Control of production, processing, testing, certification, marketing, and importation of seeds; protection of plant breeders rights	KEPHIS
Agriculture Produce (Export) Act, 1923	Preparation, manufacture, grading, and inspection of agricultural produce to be exported; registration of abattoirs, dairies, etc.	KEPHIS, KEBS
Suppression of Noxious Weeds Act, 1945	Suppression and eradication of weeds deemed to be noxious	KEPHIS
Pest Control Products Act, 1983	Importation, exportation, manufacture, distribution, and use of products used for pest control	Pest Control Product Board (PCPB)
Crop Production and Livestock Act, 1926	Provisions for control and improvement of crops and livestock, their marketing and processing	Ministry of Agriculture
Animal Diseases Act, 1965	Control of animal diseases	DVS
Fisheries Act, 1968	Preservation of certain fish species; prohibition of certain types of nets and fishing gear; licensing of fishing activities	Fisheries Department
Forest Act, 1942	Establishment, conservation, and control of all activities associated with central forest areas located on unallocated government land	Forest Department
Wildlife Act, 1976	Protection and management of wildlife (animals and vegetation)	KWS
Standards Act, 1974	Safety of all consumer products	KBS
Food, Drugs & Chemical Substances Act, 1965	Protection from harmful or adulterated food, drugs, and other chemical substances (e.g., cosmetics); importation, exportation, processing, and licensing of the above	KBS, PHD
Pharmacy and Poisons Act, 1957	Control of the pharmaceutical profession and trade in drugs and poisons; licensing of persons, premises, drugs, and poisons	Director of Medical Services
Dangerous Drug Act, 1933	Restriction of import and export, manufacture, sale, and use of other dangerous drugs	Director of Medical Services
Pest Control Product Act, 1983	Regulate the importation, export, manufacture, distribution, and use of products used for the control of pests, the organic function of plants and animals, and connected purposes.	Director of Agriculture
Environmental Management and Conservation Act, 1999	To coordinate all development activities and also ensure that environment issues are properly addressed	NEMA
Science and Technology Act, 1980	Advise all government departments on science and technology issues	NCST

As set out in the regulations, KEPHIS inspects and approves containment facilities (laboratories, screenhouses, and quarantine facilities) for handling GMOs. Upon NBC approval of an application to import any quantity of GM material for testing or contained research, a satisfactory inspection report of the receiving facilities is required before an importation permit is issued. The permit stipulates any conditions set by the NBC. KEPHIS conducts site inspections and monitors GMO trials to ensure compliance with conditions set by the NBC. Inspection and monitoring reports are forwarded to the national committee. The agency is empowered by law to discontinue, halt, or cancel a permit due to noncompliance.

Department of Veterinary Services

Animal health matters are regulated by the Department of Veterinary Services (DVS). An example was the importation in 1994 of a recombinant vaccinia virus-based rinderpest vaccine developed by the US Department of Agriculture, which was allowed under a permit from the DVS, which also conducted the testing. In this case the import request did not address the recombinant DNA character of the material; instead the biosafety emphasis was on its potential pathogenicity. DVS required that the vaccine be handled under the same stringent precautions as rinderpest virus itself. Minimum immunization dose studies and very small efficacy trials were conducted under confined conditions. At the conclusion of the studies, immunized animals were put down and the carcasses incinerated. Further testing of the vaccine was delayed pending studies to address whether exposure to the recombinant vaccinia virus might be detrimental to immuno-compromised people. An application for an on-station efficacy trial with 140 animals was to have been submitted to the NBC in 2001. However, funding was not available to pay for the compulsory site inspections prior to the trial.[4]

Kenya Bureau of Standards

The Kenya Bureau of Standards (KBS) is responsible for setting standards for weights and measures, purity, and identity under the Standards Act of 1974. The Act requires that all products for consumers must be safe. It applies to processed foods as well as industrial materials, agricultural commodities, and manufactured goods. KBS sets standards for nutritional content, establishes tolerances for food contaminants and toxicants (e.g., aflatoxin, alkaloids, hydrogen cyanide), administers labeling regulations, and works closely with KEPHIS in relation to sanitary and phytosanitary matters. The Bureau does not regulate or monitor food safety but sets standards with which all foods must comply.

The Bureau's Senior Officer sits on the NBC and is the official delegate to the Codex Alimentarius Commission. Kenya is expected to adopt international standards on labeling, but currently retains the option to set its own. There is an expectation that the Bureau will be requested to detect, identify, and set standards for GM content in commodities and other foods entering Kenya, including food aid. At present, Kenya has neither adequate laboratory facilities for such analyses nor staff with the necessary expertise; training would need to start at an introductory level.

Public Health Department

The Ministry of Health's Public Health Department (PHD) deals with the health and safety aspects of food and feeds. Its role in GM food safety matters has not yet been properly defined. However, clarification of the respective roles of KBS and PHD is expected once the forthcoming biotechnology policy is in place.

Regional Organizations and Programs

Several organizations in eastern and central Africa seek, through regional services and networks, to advance policy development, technical training, stakeholder participation, and information exchange with regard to biosafety. As regional strategies gain importance in influencing biosafety implementation at the national level, these groups may well become the blueprint for cooperation among neighboring countries.

The African Biotechnology Stakeholders Forum

The African Biotechnology Stakeholders Forum (ABSF) is a not-for-profit, apolitical, and nonsectarian association seeking to facilitate communication, improve public understanding, support policy development, and create capacity for information generation and dissemination on biotechnology and related issues. The organization seeks to promote greater collaboration and partnerships with other biotechnology bodies, both in Africa and globally. Based in Kenya, ABSF is expanding its operations into neighboring countries: a focal point in Uganda was established in 2001; an office in Ethiopia became operational in March 2002; and steps are being taken to open an office in Tanzania. ABSF is a leading organization in raising public awareness of biotechnology and biosafety, and ensuring broad consultation about biotechnology implementation in the East Africa region. National focal points will be used to catalyze regional biosafety training and outreach activities. Major funding for ABSF initiatives is being sought through a proposal submitted to the US Agency for International Development (USAID).

ABSF sponsors short education and awareness programs for journalists, government regulators, parliamentarians, scientists, and other stakeholders; publishes a newsletter; and conducts training workshops aimed at improved communications among all concerned. In December 2001, ABSF brought stakeholders together to discuss Kenya's proposed biosafety policy, and held a second stakeholders meeting in April 2003 to review both the draft policy and biosafety law.

Formal and informal working relationships have been established between ABSF and ISAAA, the BIO-EARN project, ASARECA, AfricaBio, and other groups. For example, ABSF has linked with ISAAA's Nairobi-based AfriCenter to establish a biotechnology information center. Initially, this will be responsible for information dissemination and capacity building in crop biotechnology in eastern and central African countries.

Association for Strengthening Agricultural Research in Eastern and Central Africa

The Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA) is an apolitical organization involving the National Agricultural Research Organizations (NAROs) of ten countries: Burundi, the Democratic Republic of Congo, Eritrea, Ethiopia, Kenya, Madagascar, Rwanda, Sudan, Tanzania, and Uganda. It aims to increase the efficiency of agricultural research in the region so as to facilitate economic growth, food security, and export competitiveness through productive and sustainable agriculture. The organization's recent biotechnology initiative includes two objectives related to biosafety:

- develop consensus on the specific goals, approach, and administration of regional biosafety regulatory development and intellectual property rights;
- determine the mechanism and structure for a regional biosafety initiative under ASARECA.

Regional coordination of biosafety implementation is a long-term goal for ASARECA.

East African Regional Programme and Research Network for Biotechnology, Biosafety, and Biotechnology Policy Development

The East African Regional Programme and Research Network for Biotechnology, Biosafety, and Biotechnology Policy Development (BIO-EARN), funded by the Swedish government, aims to build national capacities and competence in biotechnology, biosafety, and biotechnology policy in Ethiopia, Uganda, Kenya, and Tanzania. The principal objectives of the program are to

- increase institutional and national capacities in using science-based biotechnology, including recombinant DNA techniques (agricultural, industrial, and environmental biotechnology);
- develop national and regional capabilities to assess the risks and benefits of recombinant DNA techniques;
- enable the target countries to develop technologies and policies (including intellectual property rights and access to genetic resources) according to their own needs, abilities, and opportunities.

Key components of the program include graduate student research in biosafety-relevant subjects and the development of a regional biosafety sourcebook to function as a reference and training manual for countries in the region.

Biotechnology Trust Africa

Biotechnology Trust Africa (BTA) is a stakeholders' organization engaged in the development of agricultural biotechnology research priorities, and providing information and training on intellectual property rights. Funding for BTA is provided by the Government of The Netherlands as part of the Kenya/Netherlands Biotechnology Program. Current priorities for the potential application of various biotechnology approaches include micropropagation for crops and trees (mainly to provide clean planting materials); improvement of genetic markers for use in plant breeding; development and evaluation of vaccines and diagnostic kits for livestock diseases; breeding for environmental stress resistance in crops, trees, and livestock; microbial treatment of environmental pollutants; and genetic engineering.

III. National Policies and Strategies

The potential for biotechnology to improve the lives of Kenyan people – and the corresponding need to ensure the technology is used safely – has been evident to government officials since the early 1990s. The introduction of modern biotechnology into Kenya is seen as a way to maximize productivity in agriculture, protect the environment and human health, and stimulate trade, and industry. Requests to import GM materials and the development of genetically engineered products through collaboration with international research institutes prompted the development in 1998 of the Regulations and Guidelines for Biosafety in Biotechnology and of a mechanism for biosafety review – the National Biosafety Committee. However, as in many if not most other countries, the nascent biosafety system was established in the absence of a formal policy and specific legislation on this issue. Nonetheless, a statement in the Regulations (Section IIIc) signals a positive attitude towards the technology:

> "The regulations and guidelines presented are intended to ensure that Kenya benefits from the products of biotechnology with minimum risks to public health and the environment."

Kenyan policymakers are currently working to establish a mechanism to ensure proper direction and coordination of scientific and technological activities to meet the economic and social needs of the country. As described in Section VII, initiatives are under way to update biotechnology and biosafety policy and implement regulations and laws that take into account modern technological issues and continue to conform to international commitments.

Strategic Role of the UNEP-GEF Project

Since 1998, Kenya has benefited from support for its national biosafety system from the United Nations Environment Programme-Global Environment Facility (UNEP-GEF). Kenya participated in the pilot Biosafety Enabling Activity Project, which assisted 18 countries in preparing national biosafety frameworks. As part of this project, a survey was carried out to identify existing applications of modern biotechnology, the extent and impact of releases of GMOs, biosafety, risk assessment and risk management systems, and reviews of existing legislation relevant to biosafety (Thitai et al. 1999). The intention of the UNEP-GEF project was to promote the harmonization of biosafety instruments at subregional, regional, and global levels, as well as the development of greater awareness of the potential benefits and possible risks resulting from modern biotechnology, among a wide spectrum of stakeholders. A regional workshop for Africa was held in Nairobi in November 1998. The first part of the workshop covered issues related to risk assessment and risk management of GMOs, whilst the second part focused on issues related to the transboundary transfer of LMOs, including appropriate mechanisms and methods for the supply and exchange of information regarding biosafety. These activities, together with effective programs conducted by ABSF, have been instrumental in putting biosafety on the national agenda in Kenya.

In the summer of 2002, the NCST began implementing the next phase of the UNEP-GEF project, a three-year activity aimed at the implementation of national biosafety frameworks. The program is organized to achieve a number of strategic goals in biosafety development for Kenya. Key objectives are to

- assist in establishing an office of the NBC;

- support laboratories that are to assist in biosafety assessments (e.g., University of Nairobi, the KARI Biotechnology Centre);
- increase awareness and sensitize stakeholders on biosafety for GM products;
- support public information programs;
- secure adoption of a national biosafety policy and passage of a biosafety law.

The timing and approach of the program make it likely to achieve significant progress in strengthening Kenya's biosafety system and in building human and institutional capacities for biosafety implementation.

IV. Scientific Knowledge, Skills, and Capacity Base

The levels of expertise, knowledge, and experience of the people directly involved in the design and operation of biosafety systems strongly influence the development and implementation of policies, laws, regulations, and review and decision making procedures. When skill and knowledge levels are low, the lack of familiarity and understanding undermines confidence, and biosafety systems are more likely to be highly protective, poorly defined or inconsistent, comparatively rigid, and/or narrowly interpreted. In contrast, when levels of expertise are high there is much more likely to be latitude in regulatory development and more flexibility in implementation.

Kenya is currently the leader in biosafety development among central and eastern African countries and, as such, its experience to date may serve as a resource for neighboring countries seeking to establish their own national systems.

Expertise for Biosafety Review

In contrast to most other countries in the region, Kenya is fortunate in having a small pool of highly educated scientists competent in molecular biology and the use of modern biotechnology techniques (Quemada et al. 2002). However, the limited number of qualified individuals does result in many instances of dual membership on both national and institutional committees.

Institutional Biosafety Committees

Institutional biosafety committees (IBCs) have been established at KARI and the International Center for Insect Physiology and Ecology (ICIPE) to review in-house biotechnology research and GMO release applications prior to submission to the NBC. In accordance with the national biosafety regulations, they include both in-house scientists and external members.

The eight members of the KARI IBC represent the institute's biotechnology and plant protection groups and headquarters, the University of Nairobi, ILRI, the DVS, and KEPHIS. Their levels of experience in biosafety and risk assessment are highly variable. The KARI IBC has recommended to KARI's Director that the institute build technical training in risk assessment and risk management for selected individuals into its GM projects. The committee is meant to meet within 90 days of receipt of an application. However, scheduling conflicts and an overworked Secretary have made it difficult to meet this goal.

The IBC at ICIPE consists of four in-house members plus at least two non-ICIPE members. Currently there are three: representatives of the National Environmental Secretariat, a consumers' organization, and KARI. All in-house members have technical backgrounds and have had some training in risk assessment procedures.

National Biosafety Committee

National Biosafety Committee (NBC) membership is diverse, comprising government regulators, academic scientists, ministry representatives, scientists from research institutes, and representatives from agricultural organizations, nongovernment organizations (NGOs), the Office of the President, and the NCST itself (see table 2). Technical expertise for science-based evaluations resides in the few members drawn from academic and national research institutions. By all accounts, most other members have little direct experience of

biotechnology and biosafety and would benefit from technical training. The committee does, however, have the power to appoint task forces and co-opt individuals with technical expertise, as needed, to provide expert opinions on the risk issues raised by particular applications.

Table 2. Agencies and organizations currently represented on the NBC

- Ministry of Agriculture and Rural Development
- Ministry of Health
- Consumers Information Network
- Kenya Plant Health Inspection Service
- Kenya Industrial Property Office
- Kenya Bureau of Standards
- Institutional Biosafety Committees
- Kenya Agricultural Research Institute
- International Livestock Research Institute
- Kenyatta University
- Kenya Medical Research Institute
- Ministry of Education Science and Technology
- National Environment Management Authority
- Kenya National Farmers Union
- Seed Trade Association of Kenya
- Biotechnology Trust Africa
- Ministry of Trade and Industry
- Department of Research Development
- University of Nairobi
- Kenya Wildlife Service
- African Biotechnology Stakeholders Forum
- National Council for Science and Technology

Options and Choices: Locating the science evaluation function

Options for composition of NBC membership

There is no universal standard for the composition and membership of national biosafety committees, which vary widely from one country to another. Government regulatory bureaucracies in larger countries may have sufficient scientific and technical expertise to conduct science-based evaluations internally, as is the case in Canada and the United States. The governments of most developing countries, however, are relatively small and have fewer technical specialists in their ranks. National committees are made up of ministry representatives and other government officials, few of whom have a technical background. Under these circumstances, committees typically rely on an external advisory group to conduct scientific reviews. Advisory groups comprise experts drawn from relevant scientific disciplines. Their findings and recommendations are presented to the national committee for further action.

Kenya takes a combined approach: the national committee includes both government officials, with little or no technical background, and scientists from research institutes and universities, who have the necessary expertise to conduct rigorous scientific assessments. The technically competent members of the NBC perform the scientific biosafety evaluations with the ad hoc support of expert advisors as needed. This arrangement ensures a science-based approach to risk assessment within the context of a government committee.

Options for division of responsibility for reviews

Responsibility for reviews can either be consolidated within a single body or distributed among relevant departments and ministries.

In Kenya, responsibility for all reviews is held by the NBC, which operates as a function of the NCST. No individual ministry, department or regulatory agency has an independent review committee. To date, no technical food safety reviews have been conducted and it is not yet clear how the matter will be handled. Determining who has authority over food safety in relation to biosecurity and implementing procedures for food safety analyses is an issue that needs to be resolved as a matter of urgency.

V. Development of Regulations

Recombinant DNA research in the early 1990s stimulated awareness of biotechnology and biosafety issues within Kenya's research and regulatory communities. Growing awareness among government officials and policymakers led to the development of the Regulations and Guidelines for Biosafety in Biotechnology, issued in 1998. The regulations apply to biotechnology research conducted in controlled conditions for applications in agriculture, medicine, industry, and the environment. They address the use of genetically engineered plants in laboratory, screenhouse, and confined field conditions, as well as in small-scale field trials. Annexes to the guidelines describe a detailed step-by-step approach to risk assessment, measures for risk management and control, containment specifications, procedures for deliberate release, importation requirements, principles of good industrial large-scale practice, good laboratory practice, and sanctions to promote compliance. However, these regulations are not exhaustive, since they prescribe only minimum standards.

Options and Choices: Legislative framework

Options for implementation of legislation

Differing legal or administrative frameworks have been used as the foundation of biosafety systems in different countries. A country that decides to develop a mandatory biosafety system has two choices when it comes to establishing legally binding regulations: (1) develop a new act and regulations specifically to address GMOs or (2) regulate GMOs under existing legal instruments. Examples of countries with new laws include South Africa and Australia, whilst Canada and the USA apply existing legislation, or adaptations of existing legislation. Examples of countries using "nonlegislative" instruments, such as ministerial decrees, include Argentina and Egypt. The resulting systems differ in complexity, timeliness, flexibility, and cost. Each approach has advantages and drawbacks, all of which need to be considered when deciding which to use.

A new law, conveying the power of enforcement to regulatory authorities, may be written to address precisely what needs to be regulated. However, enacting new legislation is time-consuming and expensive, and is subject to a supportive political climate. Adaptation of existing laws, as has been done in the United States, avoids the drawbacks of drafting new laws but can lead to regulatory gaps and redundancies[5]. In comparison, a ministerial decree is faster and simpler to issue, and is more readily amended or replaced. However, without regulatory authority behind it there is no way of enforcing compliance.

Kenya used existing legislation, the Science and Technology Act 1980, as the framework for the biosafety regulations issued in 1998. The Act provides for the establishment of a mechanism to coordinate and advise the government on all matters of science, technology, and research related to national development, and for the establishment of relevant research institutes. The Ministry of Education, Science, and Technology administers the Act but it does not carry regulatory authority and therefore has no means to enforce compliance with the regulations. Although there have been no flagrant violations to date, the lack of enforcement authority is widely seen as a shortcoming in the current system.

[5] For example, in the US, products such as Bt potatoes cannot be marketed until cleared by three separate regulatory agencies: USDA-APHIS for environmental safety, USEPA for use of a plant that has pesticidal properties, and the FDA for food and feed safety.

Centralized vs. *distributed authority*

The mandate for biosafety may be vested within a single government agency exclusively tasked with regulating products of biotechnology (e.g., a gene technology regulatory office), or it may be distributed among diverse agencies in accordance with their existing responsibilities (e.g., departments of health, agriculture and/or environment). Kenya's situation is typical, in that biosafety matters concern several ministries and regulatory agencies.

The NCST was established under the Science and Technology Act 1980. Its main function is to advise government and public officials on all issues concerning science and technology. The Council has been designated to oversee the development and implementation of national biosafety regulations and to serve as the Secretariat of the National Biosafety Committee.

VI. Implementation of Regulations

A biosafety system's functionality – its ability to allow access to new technologies in ways that do not impose unacceptable risks on people or the environment – is determined by the nature of the regulations and the manner in which they are implemented. It is dependent on having coherent, operational mechanisms for application, review, and decision-making and is enabled or limited by the competence of those involved. Stakeholder and public participation confers credibility, as does open and timely access to and dissemination of information.

The National Biosafety Committee is the most visible implementing agency for Kenya's regulations. Since its inception in 1998, the NBC has approved a small number of import and release applications. Four were seeking to import GM material: a sweet potato variety resistant to sweet potato feathery mottle virus, Bt maize intended for breeding purposes, Bt cotton, and a recombinant vaccine against rinderpest. Applications to conduct small-scale field trials under quarantine have been approved for the sweet potatoes, Bt cotton, and a recombinant vaccine against Rift Valley Fever virus in sheep. Applications to import leaves of Bt maize to test for nontarget effects on Kenyan insect species, to import and grow transgenic carnations, and for construction of a Level II greenhouse are still pending.

Options and Choices: Transparency of Biosafety Reviews and Decision Making

Internal vs. *external reviews and/or supplementary opinions*

The NBC can draw on external expertise and resources as necessary in the course of its deliberations. A schematic drawing of the current approval and decision-making process is shown in Figure 2. The process is as follows:

1. Applications from national research organizations (for example, KARI) to import or release GMOs are submitted to the relevant IBC where they undergo technical review.
2. Upon IBC approval, the application is forwarded to the NBC together with minutes of the IBC meeting.
3. A technical subcommittee of the NBC examines scientific details of the application and reports to the full committee. In the course of its discussions, the committee may request additional information from the applicant.
4. NBC deliberations must reach consensus before the Chair makes a ruling on the application. If a member disagrees that sufficient evidence has been presented to justify an approval, no ruling is made at that point. The Chair requests the applicant to provide additional information in order to satisfy the member's concern. At the same time, the Chair consults with experts on the issue so that at the committee's next meeting, added information from the applicant and consulting experts allow a final ruling to be made. Recommendations for approval or denial and any conditions or requirements with which the applicant must comply are recorded in the minutes of the meeting.
5. The NBC Chair forwards the minutes and the application for final authorization. The Secretary then informs the applicant of the approval and of any terms or conditions placed on it. Depending on the nature of the GMO, copies are sent to the respective regulatory officials:
    - GM crops – Director of Agriculture, Ministry of Agriculture and Rural Development

- GM animals, vaccines – Director of Veterinary Science, Ministry of Agriculture and Rural Development
- Industrial GM organisms – Permanent Secretary, Ministry of Industry and Trade
- GM foods – Permanent Secretary, Ministry of Health.

6. In the case of imported material, the Secretary sends a letter informing KEPHIS of the approval and requesting the agency to issue a permit for importation.

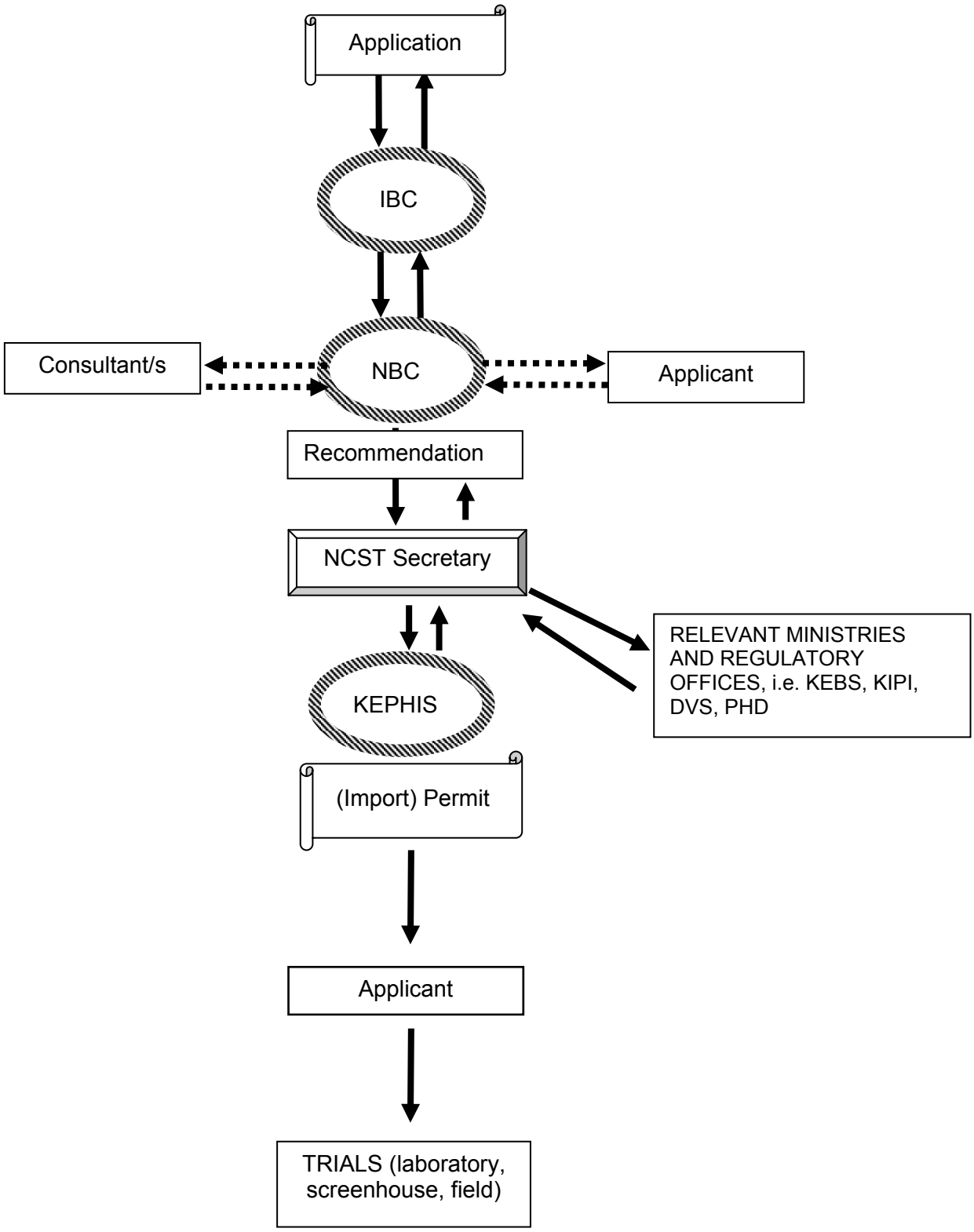
The turnaround times for applications to be considered remain unacceptably long for those involved. Approval of the first two applications took 3 years and 18 months respectively. The delays are accounted for by a combination of factors: unfamiliarity with the technology tends to make reviewers cautious; the busy schedules of the senior Ministry representatives on the committee make it difficult to meet regularly; the questions on the application form tend to be general rather than specific, leading to repeated cycles of requests for additional information; and, finally, the NBC lacks adequate funds to facilitate regular meetings.

Publication of deliberations and decisions; information available before or after the fact

Limited documentation is made of NBC meetings. No notes are taken of the discussion during application reviews, and no written summary of findings is made. The minutes record the names of those present, comments on the previous meeting's minutes prior to adoption, and current business to be discussed. Additional information or clarifications on a pending application are recorded, together with specific advice to the applicant arising from the committee's conclusions and a recommendation regarding the decision.

All documents relevant to NBC reviews – application materials, additional information, conclusions, and recommendations – are available to all committee members. Copies are sent to the relevant regulatory office, the chairman of NBC, and the chairman of the relevant institutional biosafety committee. Officials with a relevant interest in the subject at hand may see the conclusions and recommendations. Neither outcomes from NBC meetings nor upcoming business are announced to the general public.

Figure 2. Approval Process for GMO Trials in Kenya



VII. Pending Changes in the Biosafety System

Biotechnology and Biosafety Policy

Kenya signed the Cartagena Protocol for Biosafety in May 2000 and ratified it in January 2002. In December 2001, a regional stakeholders meeting was held to introduce biotechnology and its applications to participants. The outcomes of this meeting were disseminated through newspaper articles and publication of the proceedings. A second stakeholders meeting in June 2002 addressed biosafety, intellectual property rights, and Kenya's regulations and guidelines under the revised Science and Technology Act of 1980. Following discussions regarding the possibility of developing a new biosafety law, a consensus emerged among the stakeholders that, before proceeding with such a law, a biotechnology policy needed to be put in place.

A draft policy document for biotechnology and biosafety has subsequently been developed by a task force drawn from all institutes using biotechnology, under the auspices of the NCST. The document's scope is expected to embrace four broad areas:

- Regulatory matters: the environment, conservation, crop and animal protection, biosafety, ethics, standards, and consumers' rights. It will seek to provide (1) a framework for the proper development of biotechnology products in accord with principles and guidelines intended to safeguard public health and the environment; (2) the basic environment needed to secure adequate safety in the application of GMOs to various industrial processes, including manufacturing, agriculture, food, environment, health, and research; and (3) guidance for communicating information to stakeholders and the general public on the use of biotechnology to produce food for human consumption.
- Research and development: animal vaccine development, animal and plant disease diagnosis, plant protection, plant and animal breeding, food and feed technology, the environment, research funding, manpower development, institutional strengthening, and the assessment of biotechnology status. It will (1) promote additional research regarding the potential economic and environmental benefits and risks of using biotechnology to produce food and other products; and (2) activate a series of competitive research initiatives.
- Production and utilization: seed production, quality control and propagation material quality, privatization, trade and commercialization, capacity building, and industry environment.
- Coordination and collaboration: technology transfer, internal collaboration, international institutional collaboration, and the participation of farmers in research.

Internal and external experts will review the draft policy document, which will be subject to revision following stakeholder meetings before the NCST submits a final draft to the Parliamentary Committee for Science, Technology and the Environment for its consideration. Subsequently it will be taken to the Attorney General for official transmission to Parliament. Approval of the policy is a high priority within the NCST, which hopes to bring it before Parliament and have it approved by the end of 2003. Once in place, the policy will be reviewed regularly and modified when necessary.

Revised Regulations

In July 2002, the NCST assembled an eight-member national task force to address gaps and limitations in the regulations. The primary task was to expand the document's scope beyond small-scale field testing to cover field releases, and to deal with issues relating to the commercialization of GM products. As a result, in addition to laboratory and screenhouse trials and small-scale confined field tests, two categories of field releases are now to be incorporated into the regulations: unconfined releases subject to monitoring, and commercial releases no longer subject to monitoring (applicable to imports and exports).

At the same time, an accumulation of useful feedback from users of the regulations prompted the task force to decide to give the regulations an overall update. After reviewing the document, they recommended that new text be added introducing GMOs and the products of modern biotechnology; detailing procedures for the introduction of these products (verification tests); and discussing both environmental issues associated with field and commercial releases, and socioeconomic and ethical issues. They also suggested some new topics to be added to the introduction: new developments in biotechnology, including the benefits; definitions of key terms; a discussion of the risks associated with modern biotechnology; objectives of the regulations; laws under which the regulations are implemented; the process for implementation; and the link between these national regulations and international obligations, such as those under the World Trade Organization (WTO) and Cartagena Protocol.

Significantly, the task force will also address socioeconomic impacts and ethical issues should a GMO become a commercial product, using input from stakeholders.

The revised regulations are expected to present a set of criteria and guiding principles for handling GMO applications. Some of these are described below, with the proviso that terms in the final draft may differ from those presented here.

- The NBC will find ways of integrating public input into the decision making process. Where a proposed GMO activity is found to be against socioeconomic or ethical interests, the request for approval will be denied irrespective of the application's rating on risk analysis issues.

- Organizations and people involved in biotechnology operations will be expected to exercise prudence, responsibility, and innovation in the maintenance and enhancement of safety standards. Provisions will be made to terminate an activity if negligence or any deviation from conditions set by the NBC is found to contribute to risks to human health and the environment. Compliance with the regulations should, where appropriate, be enforced through legal sanctions and penalties.

- Updated procedures for biosafety review will include an assessment of the capacity and readiness of the applicant to conduct monitoring and inspection of GMO sites during and after the activity. The task force has reviewed the suitability of existing biotechnology facilities in Kenya. Under the new regulations, relevant regulatory agencies will assess facilities for biosafety containment or confinement to ascertain whether they are adequate.

- The revised regulations will employ a new application form that comes with a checklist to help applicants assemble all the required data prior to submission. GM products will be

categorized according to their potential adverse effects to both human health and the environment. Nonhazardous products will be listed in an exempt category; hazardous or potentially hazardous products will be in a nonexempt category. In order to add transparency to the review process, the technical reviewers will score applications. This may also help to maintain consistency in the reviews. Records for each GMO application will be kept by the Secretariat.

Biosafety Act

The Science and Technology Act 1980 is the legislative umbrella under which biosafety regulations were first developed. The Act does not confer regulatory authority to the NCST or NBC, so there is at present no legal weight behind the regulations. The absence of biosafety legislation is seen as a critical weakness that undermines the legitimacy of biosafety decisions and precludes taking measures to ensure regulatory compliance. A biosafety law is widely viewed as essential to protect national interests and gain public acceptance.

Once drafts of the proposed biotechnology and biosafety policy and revised regulations had been made available, in late 2002, a legal task force was appointed to move the processes forward. The legal team's terms of reference include:

- review, update, and finalize the draft policy on biotechnology and biosafety;
- review existing laws as they relate to biotechnology and biosafety;
- identify elements for incorporation in the Biosafety Act and prepare a draft bill;
- prepare and hold a two-day consultation among members of NBC and other relevant stakeholders to examine and discuss the draft policy and bill; and
- prepare the documents for discussion at a stakeholders workshop in spring 2003.

The draft bill is currently going through the same cycle of revision and approval as the policy document, with the aim being to have the Act approved by Parliament by the end of 2003. The legal task force will also work to incorporate terms and requirements under the Cartagena Protocol into other national laws.

VIII. Findings and Conclusions

The national biosafety system in Kenya is undergoing substantive changes that represent major advancements in its evolution. The government's vision with regard to the development and application of biotechnology is set out in the draft policy document on biotechnology and biosafety that is currently under consideration. The document defines appropriate steps to exploit biotechnology for the benefit of Kenyans and to ensure that Kenya becomes a key participant in the international biotechnology scene within a decade. It calls for the provision of an enabling environment that responds to the needs of the biotechnology industry and to the R&D community, as well as to relevant national and international biosafety concerns.

The draft Biosafety Act provides the legal and institutional framework for the development of biotechnology applications and biosafety standards. The Act includes provisions to establish a National Biosafety Board, sets out its membership and duties, and fully empowers the Board with legal authority to perform its functions. The legislation will be taken to Parliament before the end of 2003.

In the midst of these changes, and prior to finalization of the policy and legislation, a number of important findings have been made in the course of this study.

1. The national context for implementing biosafety is poorly defined at present. There appears to be little systematic knowledge of such factors as
   - existing mechanisms for the development of public policy, legislation, and regulations;
   - existing human, financial, and scientific infrastructure;
   - the status of biotechnology research and development, including programs for the safe use and handling of GMOs;
   - existing mechanisms for regional cooperation and regulatory harmonization;
   - existing capacity building programs;
   - the role of civil society in the process of policy and regulatory development;
   - administrative and enforcement capacity.

2. Key government officials recognize the need to develop biosafety expertise within existing regulatory agencies. The people interviewed (see Annex 1) placed a great deal of emphasis on the need for practical, technical training for field inspectors, monitors, and laboratory technicians. Government support for the necessary training, however, is not available, nor likely to be for the foreseeable future.
3. NBC members (and others) have concerns about the entry of transgenic organisms into the country outside of regular channels, e.g., without undergoing biosafety review. It is possible, for example, that grain arriving as food aid may reach the hands of farmers and be planted, without having undergone an environmental safety review.
4. In general, the NBC takes a cautious, narrowly focused approach to risk assessment. Its reviews focus on risk alone and give no consideration to the benefits that the use of GMOs could bring, nor to the risks of disallowing GMOs and therefore continuing to use conventional varieties and agronomic practices.
5. A summary of NBC deliberations on applications is not made; there is no record of what questions or issues were examined, no summary of pertinent findings, no technical

justification to support the committee's conclusions, or how the recommendation was reached. The same is true for IBCs. The lack of documentation could put the committees' work on trial should some problem arise from an approved activity.

6. Although a formal mechanism for public participation in biosafety decision-making is not clearly defined, public input into NBC reviews is obtained by having representatives of several NGOs sit on the committee. Task groups drafting the biotechnology and biosafety policy and the biosafety bill, and working to update the biosafety regulations, have included representatives of the academic, private, and nongovernmental sectors.
7. As in most countries, the general public in Kenya has little understanding of biotechnology, GMOs, and GM foods. These subjects have been addressed in the media and in several public awareness workshops, but a strategic plan for informing and communicating with the public is not yet in place. Few people outside the biotechnology/biosafety community are aware that processed foods or food aid coming from Argentina or the U.S. almost certainly have a GM content. The potential for the public to react with anger when this type of information leaks out is high.

IX. Recommendations

Since its inception in 1995, with the granting of ad hoc approval and a permit to import a recombinant animal vaccine, Kenya's biosafety system has evolved to comprise a national committee and several institutional committees, a set of guidelines and regulations, and a functional process for conducting environmental safety evaluations. As a result, Kenya has emerged as a regional leader in the use of biotechnology in agricultural research and the small-scale testing of GMOs released into the environment.

Although the biosafety system is operational, only a handful of applications have thus far been approved. A few GMO field tests have been conducted, but large-scale commercial releases are not expected in the near term. There is a need to strengthen parts of the system so that it operates more efficiently. This will include increasing the capacity for conducting biosafety reviews, and increasing public involvement. The following recommendations are based on the findings given above.

1. The NBC can expect the volume and variability of applications to increase. Scientists will seek to import a broadening range of GM research materials; companies will request approval for small- and large-scale trials of new GM crop varieties developed elsewhere; and genes will be moved into local crop varieties, which must then undergo testing. Many committee members expressed their interest in opportunities for additional training, considering this necessary if they were to perform their duties more effectively. The NCST and the NBC should work together to develop a strategy for increasing the competence and confidence of biosafety reviewers. Elements of such a strategy may include:
   - requiring new committee members to undergo training on biosafety concepts and issues, risk assessment and risk management principles and procedures, and public communications skills;
   - active recruitment and mentoring of potential candidates for membership;
   - an ongoing effort to maintain appropriate scientific expertise within the committee;
   - elevation of NBC membership to be an official part of members' work responsibilities, with suitable monetary compensation.
2. The pending policy for biotechnology and biosafety should be compatible with other policy objectives related to food, agriculture, the environment, and sustainable development. It should form the basis for developing specific legislation and/or regulations that lead to the design and implementation of the structural elements necessary for risk analysis, inspection, monitoring, and enforcement. The policy should also be used as the basis for developing a biotechnology strategy that articulates goals for the integration of biotechnology in national agricultural research programs and priorities. The national policy, biosafety legislation, biotechnology strategy, and biosafety regulations and guidelines should present a consistent and coherent national approach to the technology.
3. The NBC Secretariat is the logical cornerstone of many biosafety activities. It is recommended that the following come under its purview:
   - *Regional and subregional approaches to biosafety.* As indicated in the Cartagena Protocol, mechanisms are needed for information sharing and for harmonizing legal and regulatory requirements in order to manage the transfer of GMOs across national borders. Kenya is in a position to take the lead in regional initiatives. It is

recommended that the Secretariat form a task force to explore mechanisms for coordination and cooperation in technical and administrative functions. This effort should complement and build on activities under ASARECA, UNEP-GEF, BIO-EARN, ABSF, and other programs operating in the region.

- *Dissemination of information.* The Secretariat should be the primary information node for biotechnology and biosafety. It should organize and conduct programs to inform government officials and work closely with ABSF and similar organizations to plan and coordinate public information campaigns. It should work directly with national designated focal points to facilitate coordination with activities related to the UNEP-GEF program and the Biosafety Clearing House mechanism.
- *Coordination of training.* The Secretariat should take the lead in organizing technical training programs intended to increase the knowledge and competence of NBC members, improve the skills of government regulators so that they are better able to carry out their biosafety responsibilities, and increase the communications skills of people who talk with the media and general public.

4. Reliance on donor-sponsored capacity building programs is an unsustainable approach to strengthening and maintaining an effective and credible biosafety system. The work of an advisory committee can be hampered when members are volunteers (or appointees) who have limited time to devote to biosafety activities. Meetings may be limited to only a few times per year due to scheduling difficulties. If the system is to be seen as a legitimate part of the government's remit, the NBC Secretariat must be institutionalized as a permanent office within the NCST. It must have secure funding to support its own operations and those of the NBC.

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Annex I. List of Interviewees for the Kenya Biosafety Study (held September 2002)

1. Prof. G. K. King'oriah Government Advisor	NCST Executive Secretary Email: ncst@insightkenya.com
2. Dr. Benjamin Odhiambo Research Scientist	KARI Email: bodhiambo@skyweb.co.ke
3. Mrs. Cecilia Nzau Policy Advisor	DRD Email: nzaucecilia@yahoo.com
4. Dr. Phelix Majiwa Research Scientist	ILRI Email: p.majiwa@cgiar.org
5. Mrs. Grace Thitai Scientist	KWS Email: thitaigrw@yahoo.com
6. Dr. Ellie Osir Research Scientist	ICIPE Email: eosir@icipe.org
7. Mr. J. K. Ng'eno Policy Advisor	NBC Email: moadap@kenyaweb.com
8. Dr. Wilson Songa Government Regulator	KEPHIS Email: kephis@nbnet.co.ke
9. Prof. James Ochanda UNEP-GEF Project Manager	University of Nairobi Email: jochanda@uonbi.ac.ke
10. Mr. J. Keeru Government Regulator	KEBS Email: jkeeru@kebs.org
11. Mr. S. J. Ochieng	Consumers Information Network (CIN) Email: cin@insightkenya.com
12. Mr. H. K. Macharia National Biosafety Coordinator	NCST Email: ncstnbo@insightkenya.com

ANNEX II: Draft National Policy on Biotechnology and Biosafety in Kenya

Chapter 1 (May 2003 version)

1.1 Foreword

Biotechnology is defined as a package of techniques that employs organisms, or parts of organisms, to make or modify products, to improve plants and animals, or to develop microorganisms for specific applications. These techniques 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 bioinformatics, that is, a combination of information technology (IT) and biological sciences, especially genetics, genomics, biochemistry, molecular biology, and microbiology. Biotechnology is currently making the most impact in the areas of agriculture, healthcare, industry, and environment.

Advances in genomics have led to modifications of plants and animals with desirable traits for food or other industrial applications. 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.

However, there are several ethical and social issues of importance to be considered in any national biotechnology development programme. Investment in biotechnology can lead to enhanced human health and welfare through improved new drugs, development of new and superior diagnostics, therapeutics, and applications in preventive medicine.

Biotechnology is a science which is proving useful to human beings in the areas of food and medical supplies. In the realm of agriculture, biotechnology is currently applied in the production of food and industrial crops and the acreage of land under genetically modified (GM) crops worldwide at present stands at about 52 million ha. This in itself indicates the high rate of adoption and application of this technology.

The technology has potential to increase food production through yield improvement and greater tolerance to biotic and abiotic factors whilst also improving quality. Kenya has recognized the role biotechnology can play in poverty reduction, enhancing food security, and in the conservation of biodiversity and the environment.

Studies have been conducted on some GM products to allay fears about their safety. The development of a biotechnology and biosafety policy is one of the measures put in place to chart the vision of the Government of Kenya on the development and application of biotechnology. This policy document provides those developing and applying such technology with a clear framework in which to operate by addressing the safe development and use of biotechnology.

While Kenya appreciates the role of biotechnology in development, nothing has been done to commercialize the production of GM products. However, trials of Bt maize and sweet

potatoes are being performed under containment facilities, and diagnostic kits for disease detection and vaccines for disease prevention are being developed. All these activities fall under the existing 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.

Whilst the Government realizes and appreciates the benefits of modern biotechnology, it has the responsibility of safeguarding its citizens and environment against introduction or development of any deleterious organisms, in whatever form. In this regard the Government shall ensure risk assessment and management of all introduced GM material while legislation will be developed to govern and safeguard the use and development of biotechnology products.

1.2 Mission Statement

Kenya should, 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 scene.

This will be pursued through the provision of an enabling environment that responds to the needs of resource poor farmers, industry, research and development (R&D) communities, as well as relevant national and international biosafety concerns.

1.3 Policy Overview

The national policy on biotechnology acknowledges the need for the Government to accord any high-technology programme a high priority rating with a commensurate action profile. As such, this policy is designed to address the following points, amongst others:

i. the Government is to give priority attention to the provision of relevant infrastructure and facilities for rapid development of biotechnology in Kenya;

ii. provision of an appropriate and adequate legal regulatory framework and an enabling environment to attract investment for the growth of our national biotechnology industry;

iii. strong emphasis is to be placed on the following R&D priority areas:
   a. food and agriculture,
   b. human health,
   c. industry,
   d. environment,
   e. bioresources development;

iv. actions are to be taken to accelerate the acquisition and development of relevant and affordable requisite biotechnology programmes in Kenya;

v. promotion of indigenous R&D activities to enhance creativity and innovations in biotechnology critical to the growth and sustenance of the biotechnology industry;

vi. ensure that there is adequate funding for this vital technology in order to enjoy the corresponding payoffs;

vii. ensure greater national commitment to capacity building for sustainability of the biotechnology industry in Kenya and enhance its international competitiveness, with a strong resolution to promote ethical, environmental, and biosafety concerns;

viii. promote collaboration between public institutions and the private sector and relevant national and international agencies to advance the course of this industry locally and internationally;

ix. make adequate provisions for effective and efficient implementation of the policy;

x. Kenya's bioresource endowment and comparative and competitive advantages are to be fully and sustainably exploited, through indigenous bioprospecting of these natural resources for use in agriculture, environment, health, and industry;

xi. a workable Action Plan over the short-, medium-, and long-term is to be implemented to enable a systematic and focused implementation of the biotechnology policy;

xii. biotechnology being a multisectoral technology requires a 3-tier organizational structure: Ministers Council, National Biotechnology Technical Committee (to advise the Ministers Council), and National Biotechnology Development Agency (Management).

1.4 Introduction

Biotechnology is defined as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use. Biotechnology includes, for example, the use of molecular markers, gene manipulation and transfer, vegetative reproduction of crops and trees, embryo transfer, and artificial insemination.

Modern biotechnology includes the application of:

- in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- fusion of cells beyond the taxonomic family.

These techniques overcome natural physiological reproductive or recombination barriers that have limited traditional breeding and selection.

Biotechnology evolved from traditional practices such as breeding and fermentation. Novel technologies are needed to solve specific problems in human health, agriculture, environment, and industry. Biotechnology research in Kenya focuses on these problems.

Some of the current applications can be classified into the following broad categories: vaccines, diagnostics, therapeutics, biofertilizers, biopesticides, tissue culture, molecular markers, and genetic engineering. The majority of these activities use first and second generation biotechnologies. Kenya needs the capacity to develop and use modern biotechnologies, including genomics, bioinformatics, and genetic engineering, and to apply them effectively in addressing problems of national priority.

1.5 Biotechnology and Development

In Africa, biotechnology offers an opportunity to develop and deploy sound technologies as a means of attaining sustainable development to achieve food security, poverty alleviation, improved agroindustrial and health products, as well as socioeconomic improvements. In developed countries, farmers have adopted biotechnology more quickly than any other agricultural technology. The technology is also increasingly being used in the areas of medicine and pharmaceuticals, and in industrial applications. Indeed in developed countries, especially North America and Europe, biotechnology industries are receiving millions of dollars of investment.

The adoption and development of biotechnologies in Africa is extremely slow. This is predominantly due to lack of effective government policies supportive of the development and application of biotechnology.

1.6 Biosafety Issues

Biosafety as a concept refers to the need to protect human health and the environment from possible adverse effects of the products of modern biotechnology. While it is recognized that modern biotechnology has the potential to contribute toward the improvement of human well-being, particularly in enhancing food production and health care, there is growing public concern over the potential adverse effects of the technology and its products to human health and the environment.

These concerns stem from uncertainties about the actual behaviour of genetically modified organisms in the natural environment. Issues such as the possibility of horizontal gene transfer occurring and leading to serious adverse effects on the environment and associated risks to human health; use of modern biotechnology and its products for antisocial purposes, such as production of biological weapons; and the right of individuals to know and decide on the use of the products of modern biotechnology have necessitated the need for the institution of safety measures in the development and application of modern biotechnology and the commercialization of its products.

The main objective of these safety measures is to ensure an adequate level of protection of human health and the environment from adverse effects of modern biotechnology and its products. This can be achieved though safe transfer, handling, and use of modern biotechnology and its products.

Products of modern biotechnology are becoming increasingly available in the global market and there is real possibility of such products finding their way into Kenya. The country must therefore have a clear policy outlining the necessary biosafety measures.

1.7 Objectives

1.7.1 Objectives of the biotechnology policy

The objectives of this policy are

- to provide a framework for safe development and application of biotechnology;
- to list priorities for a national plan of action in areas such as research and training in biotechnology, processing of biotechnology products, regulatory requirements in biosafety, and intellectual property rights;

- to provide the basic conditions for securing adequate safety in the development, application and utilization of GMOs (resulting from recombinant DNA technology) in various industrial processes, including manufacturing, agriculture, food, environment, health, and research;
- to ensure that information on biotechnology is disseminated to the public and to industry on the safe use of biotechnology;
- to update the Law in matters relating to biotechnological advances and to ensure laws continue to conform with international obligations and commitments;
- to provide for the establishment of a mechanism that ensures the proper coordination of scientific and technological activities to meet economic and social needs;
- to provide resources for investment to ensure effective implementation of the policy and subsequent strategies and programmes;
- to ensure that Kenya becomes self-reliant in the development and production of biotechnology-derived products and services critical to the national economy;
- to ensure that Kenyans have access to, and benefit from, safe, ethical, and profitable uses of biotechnology-based products and services.

1.8 Scope of the Policy

The purpose of embracing modern biotechnology in Kenya is to improve the quality of human welfare, maximize productivity in agriculture and industry, and protect the environment. The scope of this policy extends to

- traditional and modern biotechnology
- public awareness on biotechnology
- legal framework for safety in biotechnology
- funding for biotechnology related activities
- capacity for biotechnology R&D and application
- public and private sector linkages
- ethical and IPR issues
- establishment of an institutional framework to coordinate biotechnology
- ensuring that institutions and actors involved in biotechnology are well coordinated and focused.

Within the provisions of the policy, it will be possible to make clear arrangements for marketing and utilization of biotechnology products, to have transparent material transfer agreements (MTAs) and intellectual property regimes (IPRs), and to develop a national strategic plan for the biotechnology industry. Furthermore, it will be possible to make provisions for funding of biotechnology activities, to develop the requisite human resources, build adequate infrastructure for biotechnology R&D, protect indigenous resources and knowledge, and to strengthen information systems that ensure participation of the stakeholders at all stages of biotechnology R&D.

ANNEX III: Draft Revised Biosafety Regulations and Guidelines

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EXECUTIVE SUMMARY

This document provides the regulations and guidelines for biosafety in biotechnology applications in Kenya. These procedures will be widely applied by research managers, policymakers, producers, and consumers to ensure safe use of modern biotechnology and its products. Biosafety describes the recognized procedures and policies in ensuring safe application of modern biotechnology and use of its products. This is expected to protect human health and the environment from possible adverse effects of modern biotechnology. Although modern biotechnology has provided new opportunities in promoting human well-being in enhancing food production, agricultural developments, and health care, it also has the potential to have adverse effects on both human health and the environment. It is this dual potential of modern biotechnology that has elicited concern for the need to establish mechanisms for safety measures to ensure biosafety in biotechnology applications and use of its products.

The Cartagena Protocol on Safety in Biotechnology was formulated and adopted in January 2000 as a supplement to the Convention on Biological Diversity (CBD). The Protocol encourages the environmentally sound application of biotechnology, making it possible to derive maximum benefits from biotechnology while minimizing the risks to the environment and human health. Thus the protocol addresses the safe transfer, handling, and use of living modified organisms (LMOs), their potential adverse effects on biodiversity, and their transboundary movements. The Protocol underscores the need for risk assessment as a prerequisite to biosafety. As a result, the development of a national policy on biosafety strategy, inventory, and evaluation is of paramount importance. The Protocol was opened for signatures in May 2000 during the fifth conference of parties (COP5) to the CBD. Kenya ratified the Cartagena Protocol on Biosafety in January 2002 and is currently spearheading its domestication into national law through the development of a biotechnology policy.

Kenya considers the development of a biotechnology policy important because it will subsequently provide the framework for safe development and application of this technology in the country. The policy being developed will provide the modalities for biotechnology applications, information dissemination to the public, updating the laws which have a bearing on matters related to biotechnology advances, as well as coordinating scientific and technological activities. The policy integrates both traditional and modern biotechnology, and covers public awareness, the legal framework, capacity building, public and private sector partnerships, as well as intellectual property rights.

The regulations and guidelines cover research on recombinant DNA, categorized experiments, plant biosafety, quarantine procedures, containment, and field experimentation. Other areas covered include deliberate release of GMOs, importation of biotechnology products, and sanctions that ensure compliance with safety measures for biotechnology. This document further reviews the general development of modern biotechnology by outlining its benefits in the fields of agriculture, medicine, industry, and the environment. In these areas, biotechnology products such as diagnostic kits, vaccines, biofertilizers, and biopesticides have already been released for commercial use. New biological control agents devised by the use of genetic modifications have also been released. Many experimental field trials of potentially useful plant varieties developed using genetic engineering have been conducted in a number of countries. The most promising of these materials will hopefully be released as improved plant varieties. However, their release and use will have to follow prescribed guidelines. Uncertainties concerning the behaviour of GMOs and the flow of transferred traits form the basis for the formulation of safety regulations and guidelines.

This document prescribes a series of steps that shall be followed in establishing the national biosafety system. Firstly, the Government has designated the National Council for Science and Technology (NCST) as the authority which will oversee the coordination and implementation of biosafety regulations and guidelines, through the establishment of an interagency National Biosafety Committee (NBC). The NBC draws up policies and procedures and vets research applications to ensure responsible use of modern biotechnology in Kenya. The NBC, which has been operational since 1998, coordinates the establishment of institutional biosafety committees (IBCs) in those organizations undertaking biotechnology research, production, and utilization in Kenya.

Biotechnology applications, development, and use may pose risks to human health and the environment. Therefore, Kenya must institute appropriate safety measures to govern all developments in modern biotechnology. The guidelines require organizations and people involved in biotechnology operations to be fully familiar with the potential risks to which biotechnology products expose the society and the environment. This will enable them to make proper judgments on the safety arrangements to be implemented. They are required to develop safety measures as a basis for undertaking biotechnology operations. Such safety measures include risk assessment procedures, risk management, and use of appropriate control measures, among others. The successful application of safety measures depends upon accuracy of operations, competence, and timely assessment and dissemination of information. Stakeholders involved in biotechnology activities shall handle biosafety information in a transparent manner and shall operate within the conditions defined by the NBC while applications are being assessed. The interests of the public shall be safeguarded.

Regulations and guidelines are set tools for ensuring the application of prescribed safety measures in biotechnology. These regulations and guidelines are expected to enhance

effectiveness in the use of new products and ensure safety to human health and the environment. Compliance with the regulations and guidelines will be enforced by the NBC, IBCs, and other relevant government institutions. This will ensure that Kenya draws maximum benefit from modern biotechnology while minimizing the risks.

These regulations seek to minimize potential risks during development, importation, and release of biotechnology products. They also set standards for good laboratory practice and containment procedures in order to limit the spread of such products. However, these regulations are not exhaustive since they only prescribe minimum standards. Organizations and other stakeholders involved in biotechnology operations are expected to exercise prudence, responsibility, and innovativeness in the maintenance and enhancement of safety standards. Compliance with the regulations and guidelines should, where appropriate, be enforced through penal as well as other sanctions under the legal system. Furthermore, the regulatory procedures have been categorized according to their potential for causing adverse effects to both human health and the environment. Nonhazardous products are listed under the exemption category while hazardous products are in the nonexemption category.

In addition, the suitability of existing biotechnology facilities in Kenya has been reviewed. Good laboratory practice involving biotechnology research such as genetic manipulation has been recommended. Biotechnology laboratories should be designed appropriately to limit the spread of hazardous GMOs. Biosafety levels have been developed for adoption of biotechnology work in accordance with varying degrees of exposure. Biosafety levels one and two can be applied under basic facilities, while biosafety levels three and four require higher physical containment facilities. Thus, the appropriate equipment must be put in place in order to undertake biotechnology work as specified in the various levels. Both physical and biological containment facilities must be applied while doing the work, as well as during importation, release, commercialization, and post-release of biotechnology products.

The relevant institutions should therefore endeavor to enforce the present regulations and guidelines for biosafety in Kenya as this will enable the country to safely explore new opportunities created by biotechnology to maximize benefits. These instruments are, however, expected to be dynamic as new innovations for industrialization are anticipated in the future. The regulations shall be subjected to review whenever the need arises.

1. INTRODUCTION

1.1. General Aspects

Biotechnology offers great potential for improvements in the welfare and general health of humankind in various ways. It has become an important component of economic impetus, helping to provide practical solutions to global problems of health care, food supply, energy, waste treatment, and industrial regeneration. It is also a powerful agent for environmental restoration and protection. Some uses of biotechnology have been known for generations; indeed, such uses have been exploited for many years in areas of classical plant and animal breeding, food fermentation, vaccine production, and biological control.

In the 1970s scientists developed techniques for manipulating genes so that they could cut and join DNA from different organisms to create recombinant DNA (r-DNA). Such DNA, when transferred into an organism, confers the organism with new genetic potential: it becomes a genetically modified organism (GMO). This form of biotechnology, generally

referred to as modern biotechnology, has been practiced for over two decades. The terms genetic modification and genetic engineering, both of which are included in the concept of biotechnology, describe the application of the new biotechnology to living organisms in order to reach certain practical research goals, and to produce goods and services with commercial applications.

Genetic engineering techniques, coupled with advances in methodologies for the production of monoclonal antibodies and cell and tissue culture, have revolutionized the field of biotechnology. Through the use of these methods it is possible to modify many genetic attributes of animals, plants, and microorganisms, thus creating transgenic organisms.

These capabilities present tremendous potential in many novel experiments and applications that could benefit humankind. However, they could also pose danger and, therefore, have generated a sense of concern among both scientists and the public. National governments are considering safeguards to ensure the benefits of biotechnology are maximized, while hazards to the health and welfare of humans and possible damage to the environment are minimized. Consequently, efforts have been made to establish how activities in this field can be performed safely. A flexible, well-reasoned, scientific basis for safe use of biotechnology needs to be provided so that tests of GMOs can be performed only when they are deemed safe. However, before this can be done, relevant issues and information must be considered and it should be determined whether enough is known to evaluate the relative safety or risk of introduction of such organisms. The overriding goal is to ensure that the products of biotechnology made within or introduced into the country are used safely to the benefit of all. Therefore, guidelines need to be formulated for effective regulation of work involving genetic modification of organisms.

Biosafety is generally used to describe policies and procedures adopted to ensure safe application of biotechnology to benefit humankind through applications in medicine, agriculture, and the environment, without endangering public health or the environment. Biosafety guidelines, so formulated, must be appropriate to the country concerned.

In Kenya, biotechnology is being applied in the fields of agriculture, medicine, industry, and environment. Biotechnological activities are presently conducted by individual institutions both in private and public sectors, according to their operative institutional research policies and mandates. These developments, together with the opportunities offered by the introduction into the country of biotechnology products imported from elsewhere, emphasize the need to formulate appropriate regulatory guidelines to streamline and thus facilitate the activities. The National Biosafety Committee (NBC) formed within this framework will oversee compliance with the biotechnology and biosafety guidelines.

1.2. Scope

(i) The scope of these regulations and guidelines covers areas of research and development involving GMOs, genetic transformation of plants, the use of all aspects of recombinant DNA technology, and the release of microbes, plants, animals, or biological products derived by genetic modification.

(ii) This document elaborates on developments in biotechnology, guiding principles for handling GMO applications, safety measures, the institutional framework, regulatory procedures, and mechanisms for handling GMO applications.

(iii) The objectives of the national guidelines for biosafety are to

a. promote opportunities for the application and exploitation of products of biotechnology for the general well being of humanity;

b. ensure public and environmental safety, particularly in accident prevention, containment, and waste disposal, when GMOs are used in research development or industrial processes or ultimately released for commercial purposes;

c. determine the measures for risk assessment, management, and monitoring of operations involving GMOs, recombinant DNA technology, and products arising from the use of these.