Review of the Policy, Regulatory Mechanisms and Administration of Biosafety in Eastern and Southern Africa: A study of Kenya, South Africa, Malawi and the ASARECA initiative

Other

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ICRISAT

Prepared for the
International Crops Research Institute for the Semi-Arid Tropics

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Acronyms

AATF	African Agricultural Technology Foundation
ABSF	African Biotechnology Stakeholders Forum
ABSP	African Biosafety Programme
ARC	Agriculture Research Council
ASARECA	Association for Strengthening Agricultural Research in East and Central Africa
AU	African Union
BIO-EARN	Biotechnology East Africa Regional Network
Bio-EROC	Biotechnology – Ecological Research and Outreach Consortium
BRICs	Biotechnology Regional Innovation Centres
BTA	Biotechnology Trust Africa
BTZ	Biotechnology Trust Zimbabwe
CBD	Convention on Biological Diversity
CIMMYT	International Maize and Wheat Improvement Centre
CSIR	Centre for Scientific and Industrial Research
EU	European Union
GMO	Genetically Modified Organism
IARCs	International Agricultural Research Centres
IBC	Institutional Biosafety Committee
ICRISAT	International Crops Research Institute for the Semi Arid Tropics
IPRs	Intellectual Property Rights
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
KARI	Kenya Agricultural Research Institute
KEPHIS	Kenya Plant Health Inspectorate Service
LMOs	Living Modified Organisms
NARIs	National Agricultural Research Institutes
NBC	National Biosafety Committee
NCST	National Council for Science and Technology
OECD	Organisation for Economic Cooperation and Development
R&D	Research and Development
SARB	Southern Africa Regional Biotechnology Programme
SAC	Scientific Advisory Committee
SMMEs	Small, medium and micro enterprises
TRIPs	Trade Related Aspects of Intellectual Property
UNEP/GEF	United Nations Environment Programme/Global Environment Facility
WTO	World Trade Organisation

CONTENTS

Executive Summary

This report summarises the results of a review of the policy, regulatory mechanisms and administration of biosafety in Kenya, Malawi and South Africa and under the ASARECA regional initiative. The report focuses on the current situation and provides insights as to the form that developments in the area of regulation of biotechnology are likely to take.

The first section is an introduction, which provides the definition and scope of biotechnology as used in this report. It provides a brief status of agricultural research; the areas of research and the actors involved in biotechnology in the study countries. With the exception of South Africa, experimentation in transgenic crops is still under development. Most of the current agricultural biotechnology R&D activities focus on improving crop productivity. The actors are mainly National Agriculture Research Institutes, International Agricultural Research Centres and universities. Private sector involvement is in the form of multinational companies.

The second section discusses the frameworks for the regulation of biotechnology. These include international obligations, regional attempts, as well as national efforts in regulating biotechnology in the study countries. Regulation at the national level has been in the form of national policies, national strategies and through legislation. In Kenya and in most countries under the ASARECA initiative, acts of parliament are yet to be enacted. The proposed bill and regulations in Kenya and the proposed regional regulatory structure under ASARECA are discussed with the aim of providing an insight as to the trend regulation in these jurisdictions is likely to take.

The third section is a discussion on institutional arrangements in the field of agricultural biotechnology. Who are the institutional actors? What are the synergies? What is the institutional capacity in terms of human resources and physical infrastructure? This section also explores the commercialisation and innovation attempts in the study countries. It examines public perception and acceptance of modern biotechnology and ends with a brief mention on intellectual property protection in the study countries. South Africa has a developed institutional structure with impressive facilities and adequate human resource capacity. Critical mass in modern biotechnology in the other study countries is yet to be attained. Facilities for experimentation in GM technology are likewise lacking in Kenya, Malawi and other ASARECA countries.

The fourth section summarises the review and presents the way forward. South Africa is best placed to handle applications for testing transgenics such as the rosette-resistant groundnut developed by ICRISAT. A representative from the Malawi biosafety committee should be involved in the testing of the groundnuts in RSA as part of a capacity building exercise and also to pave the way for the testing of the groundnuts in Malawi. In Kenya, there are indications that once an event is approved elsewhere, it is likely to receive timely approval subject to any additional testing that the National Biosafety Board may deem necessary. ICRISAT would have to collaborate with the KARI Institutional Biosafety Committee through which the application to the National Biosafety Committee would be made.

Background to the study

This report aims to provide an overview of the status of biosafety policy, laws and regulations, and implementation issues in Kenya, South Africa and Malawi and under the ASARECA initiative. It is the product of a three-month research assignment commissioned by ICRISAT.

ICRISAT has made significant strides in modern biotechnology research. Of particular relevance to this study is the development of transgenic rosette resistant groundnuts, which await testing. The development of transgenic Bt pigeon pea and soybean trypsin inhibitor is at an advanced stage.

Until recently in Africa, traditional biotechnology (tissue culture and use of molecular markers for breeding and selection) has been the only form of biotechnology used to improve agricultural production. These traditional biotech methods do not require national approval for implementation. Due to potential risks to human health and to the environment, products of modern biotechnology are subject to biosafety laws and require individual approval before they can be tested, deployed and used in a country.

This study seeks to provide the background information on biosafety necessary before the testing and deployment in Africa of transgenic crops developed by ICRISAT.

Methodology

The information in this report was mainly from interviews with key individuals in the field of biotechnology and biosafety. These were sampled by identifying the institutions, organisations, government departments and companies whose work is directly involved in the regulation or application of biotechnology and biosafety in their respective countries. This information was supplemented with library and archival material available from the interviewees, the internet and other information in the form of reports and reviews published from previous studies. Annex I contains the list of interviewees.

Introduction

The application of biotechnology in agriculture offers a wide range of potential benefits directly linked to addressing food insecurity in Africa. It has the potential of greatly improving food production, food quality and alleviating poverty. In a continent with increasing population and decreasing arable land, the role of biotechnology in addressing food needs cannot be gainsaid.

In addition to the benefits that agricultural crops improved through genetic engineering bring, these same crops also raise concerns about their potential long-term effects on human health and the environment. Such concerns have formed the basis for the development and implementation of guidelines on the safe application of biotechnology. There have been international, regional and national initiatives at developing biosafety systems.

At the international level, biosafety emerged as a global priority in Agenda 21[1] and was further enshrined in the Convention on Biological Diversity (CBD)[2]. Protracted negotiations following the adoption of the CBD resulted in the Cartagena Protocol on Biosafety[3]. This was opened up for signature in 2000 and came into force on 11th September 2003.

At the national level, countries have made efforts to establish national biosafety systems. These systems are under development in virtually all countries in Africa. Components of a biosafety system include a policy, legislation, regulations and guidelines and a strategy to implement the policy. Equally important in a biosafety system are institutional arrangements and other implementation mechanisms. These elements work in concert to produce a system that ensures the safe application of biotechnology.

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1. Agenda 21 is a plan of action for sustainable development. It was adopted by the international community at the 1992 Earth Summit in Rio de Janeiro. Agenda 21 was a landmark achievement, incorporating environmental, economic and social concerns into a single framework.
2. Convention on Biological Diversity, (1992), 31 ILM 818 (hereinafter CBD), available at http://www.biodiv.org/
3. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, available at http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf

Regional initiatives have helped facilitate the development of national biosafety systems by providing technical assistance and fora for the exchange of information among countries. Currently countries in Eastern Africa under the Association for Strengthening Agricultural Research in East and Central Africa (ASARECA) have developed templates on which national biosafety systems can be developed. This ensures uniformity of policies and guidelines, which provides other added benefits.

This study aims at analysing the current status of the biosafety environment in Kenya, South Africa, and Malawi. It will examine national policies, legislation and institutional arrangements in regulating biotechnology in each of the three countries. The study will likewise examine regional initiatives in the development of biosafety policy, regulations and guidelines under the ASARECA initiative.

Definition and scope of biotechnology

This report uses the OECD (1999) working definition of biotechnology where biotechnologies are the products namely knowledge, goods and services, arising from the alteration of living or non-living materials through the application of science and technology to living organisms as well as parts, products and models thereof[4]. The techniques used include fermentation, microbial inoculation of plants, plant cell and tissue culture, enzyme technologies, embryo transfer, protoplast fusions, hybridoma or monoclonal antibody technology and rDNA technologies. This definition allows for a focus on products arising from the research continuum between traditional and modern biotechnology.

Status of agricultural research

Biotechnology R&D in the study countries has been ongoing for as long as two decades. South Africa has been involved in biotechnology for over 25 years (Wolson, 2001) while in Kenya, traditional biotechnology, mainly tissue culture, has been used in the production of citrus plants and pyrethrum under a joint initiative by Kenya Agricultural Research Institute (KARI) and the University of Nairobi since the 1980s (Odame, Mbote and Wafula, 2000). Malawi and countries under ASARECA have likewise been involved in tissue culture and molecular breeding for over two decades. Research and development activities in biotechnology have picked up in the region; these vary from country to country depending on funding, expertise and experience (Mpande, 2001).

With the exception of South Africa and Kenya, the study countries are yet to engage in experimentation in transgenic crops. In Africa, South Africa is the most advanced in this field and has already begun commercialising GM crops. At present, there are at least 500 biotechnology projects spread over 7 sectors in South Africa (AfricaBio, 2002). Over 590 applications involving GMO crops have been received and granted by the registrar of the GMO Act; four GM crops have been approved for commercial release[5]. In comparison, it was not until 2000 that modern biotechnology in crop production was used in Kenya; currently, five transgenic crops are in various stages of the approval process by the National Biosafety Committee (BTA, 2002). In Malawi however, only traditional biotechnology is in use; experimentation in transformation is yet to begin. Despite a systematic trend towards adopting selected biotechnology techniques and processes, the uptake of biotechnology in the subregion and in Africa generally has been slow.

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4. This definition is similar to that proposed by Cohen (1999).

5. these are (i) insect resistant cotton approved in 1997; (ii) insect resistant maize approved in 1998 (iii) herbicide resistant cotton approved in 2000; (iv) and herbicide resistant soybean approved in 2001.

Areas of research

Most of the current biotechnology R&D activities focus on improving productivity in the agricultural sector (Mpande, 2001). The focus of GMO research and development in South Africa and Kenya are primarily for disease and insect resistance. In Kenya, the modern biotechnology projects include development of sweet potato for resistance against the feathery mottle virus, development of Bt Maize, the testing of Bt Cotton and the testing of mosaic resistant cassava. In South Africa, considerable attention is being paid to fungal and bacterial diseases, improving storage properties of crops, weed control, and yield and quality enhancement (AfricaBio, 2002).

Actors involved in biotechnology

Biotechnology research and development in the study countries is carried out in collaboration with the National Agriculture Research Institutes (NARIs), International Agricultural Research Centres (IARCs) and universities. The NARIs in the ten ASARECA countries are small and vary in size. Agricultural research systems are an important part of a larger agricultural sector, which, in the ECA region, is characterised and dominated by peasant farmers who produce mostly for subsistence. Their type of agriculture is characterised by rudimentary technology, large post-harvest losses, minimal processing and is severely affected by frequently recurring droughts (ASARECA, 2003a)

With the exception of South Africa, private sector investment in the study countries and in Africa generally is minimal. Modern biotechnology however, is being driven mainly through collaboration between national actors and multinational companies.

Traditional biotechnology in the study countries is based on crops specific to their environment. For example, in Kenya, tissue culture for citrus and bananas has been locally developed to address specific constraints in their production. Modern biotechnology on the other hand, is largely based on technology imported from abroad. In South Africa, in spite of biotechnology being in use for 25 years, few local products have been developed. The sectors are largely dependant on imported biotechnology applications with the focus being on commercialisation and industrialisation (Wolson, 2001).

Regulation of biotechnology

Products of traditional biotechnology, i.e. tissue culture and molecular breeding have been in use in the study countries for over two decades. These have not been subject to national approval for their implementation. However, with the advent of modern biotechnology, concerns over the potential long-term effects of transgenic crops to human health and to the environment have come to the fore. These concerns have formed the basis for the development and implementation of guidelines on the safe application of biotechnology. These have translated into international, regional and national initiatives at developing biosafety systems.

International obligations involving biotechnology and biosafety

Globally, the advent of modern biotechnology has focused attention on the development of measures to ensure the safe application of biotechnology. Concern over the effect of biotechnology was expressed as early as 1975 in Asilomar at a meeting of international scientists. The ensuing

debates formed the groundwork for the development of guidelines to address the movement of Genetically Modified Organisms (GMOs) between laboratories, from the laboratories to green houses and from the green houses to fields for trial. Additional biosafety strategies were employed in the early 1990s to address commercialisation of GMOs.

The Convention on Biological Diversity (CBD) was adopted in 1992. This is an international legally binding convention whose objectives are the conservation of biodiversity, the sustainable utilisation of its components and the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. The CBD makes specific provision for the implementation of biosafety measures for the trans-boundary movement of living modified organisms (LMOs)[6].

Culminating from the protracted negotiations following the adoption of the CBD was the Cartagena Protocol on Biosafety. The Protocol was developed out of the recognition that products of genetic modification could pose a risk to both human health and to the environment. The Cartagena Protocol requires countries to provide for the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. It specifically focuses on trans-boundary movement.

The Protocol requires states to establish a national focal point to liase with the Secretariat and to establish competent authorities responsible for administrative functions. It establishes a Biosafety Clearing House Mechanism as a global information centre and a depository of GMO release approvals, their biosafety assessment, permits, registrations and trans-boundary movement of LMOs[7]. Member countries are required to deposit their decisions with the Clearing House and encourage the public to have access to such global information. The Protocol came into force on 11 September 2003.

Table 1: Status of ratification of CBD and CP by study countries[8]

		INTERNATIONAL INSTRUMENTS RELATING TO BIOSAFETY	
	COUNTRIES	Convention on Biological Diversity	Cartagena Protocol
	South Africa	Ratified 02 November 1995	Acceded 14 August 2003
	Malawi	Ratified 02 February 1994	Signed 24 May 2000
ASARECA COUNTRIES	Kenya	Ratified 26 July 1994	Ratified 24 January 2002
	Burundi	Ratified 15 April 1997	Not signed
	DR Congo	Ratified 12 March 1994	Not signed
	Eritrea	Acceded 21 March 1994	Not signed
	Ethiopia	Ratified 5 April 1994	Ratified 09 October 2003
	Madagascar	Ratified 4 March 1996	Signed 14 September 2000
	Rwanda	Ratified 29 May 1996	Signed 24 May 2000
	Sudan	Ratified 30 October 1995	Not signed
	Tanzania	Ratified 08 March 1996	Acceded 24 April 2003
	Uganda	Ratified 08 September1993	Ratified 30 November 2001

SOURCE: CBD Secretariat

6. Article 19(3) 'The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity'.

7. Article 20

8. daily updated version available at http://www.biodiv.org/world/parties.asp?lg=0

Other relevant international regulatory systems include the European Union Regulations, which already have an impact on the study countries. In South Africa for example, companies involved in trade with the EU are required to furnish proof of identity preservation (Wolson, 2001). The Codex Alimentarius Commission is responsible for the setting of world food safety standards and for establishing international labelling regulations, which will affect GM foods.

In 1999 the then OAU drafted the African Model Law on Safety in Biotechnology[9], which was intended to be a regional law on the regulation of biotechnology to be implemented in African countries. The Model Law was fashioned after the Protocol but specifically included aspects that had been omitted from the Protocol such as pharmaceuticals, GMO products and the nature of public participation. Although the Model Law was criticized for hindering the development of biotechnology in Africa (AfricaBio, 2001), it was endorsed by African leaders, in July 2003, at the AU summit in Maputo.

In 2000, a project under the United Nations Environment Programme and Global Environment Fund (UNEP/GEF) was set up to help countries that have signed, acceded or ratified the Cartagena Protocol to establish biosafety frameworks[10]. The project offers funding and expertise to facilitate the development of national decision making frameworks that consider both the safety and socio-economic impact of the application of GMOs and their products on a case by case basis.

Relevant to biotechnology, a number of regional biotechnology and biosafety training programmes in Africa have been conducted. These include:

- Biotechnology East Africa Regional Network (BIO-EARN) funded by the Swedish International Development Agency aims at increasing the institutional and national capacity, facilitating technology development and transfer among others. Twenty-seven trainees have received PhDs under this programme[11]. It focuses mainly on Ethiopia, Kenya, Uganda and Tanzania
- The Regional Biosafety Focal Point for Eastern and Southern Africa, established in 1984, aims at assisting member countries establish national biosafety focal points, develop national biosafety frameworks and create national awareness to biosafety
- African Biotechnology Stakeholders Forum (ABSF) based in Nairobi aims to increase public awareness of biotechnology and biosafety in the region and ensuring broad consultation about biotechnology implementation in regional communities
- Biotechnology Trust Africa (BTA), also based in Nairobi, is funded by the Dutch Government and is aimed at improving IP awareness and protection
- Biotechnology Trust Zimbabwe (BTZ) funded by the Dutch Government and operating from Zimbabwe has surveyed the status of biosafety in East and Southern Africa and set priorities for capacity building in the two regions. It aims at improving biotechnology applications for African farmers
- Southern African Regional Biotechnology Programme (SARB) funded by USAID for capacity building with the main focus on seven Southern African countries
- The UN Food and Agricultural Organisation (FAO), operating from Harare, focuses on food and feed safety reviews of GMOs for SSA
- African Biosafety Programme I (ABSP I), funded by USAID and managed by Michigan State University, focuses on technology transfer and biosafety

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9. Assembly of the Head of States and Government Decision No. AHG/Dec. 164, Council of the Minister Decision No. CM/Dec. 623, July 2001.

10. For further information see http://www.unep.ch/biosafety/

11. www.bio-earn.org

- ABSP II has similar objectives as ABSP I funded by USAID but managed by Cornell University
- Programme for Biosafety (PBS) representing the biosafety part of ABSP funded by USAID
- International Service for the Acquisition of Agri-Biotech Applications (ISAAA) aimed at technology transfer
- African Agricultural Technology Foundation (AATF), funded by Rockefeller Foundation and other donors, aims at facilitating technology transfer to small-scale farmers

At the regional level, the ASARECA Biosafety Project is an example of an initiative aimed at facilitating establishment of a sub-regional biosafety framework. The project, established in 2002, sought to improve the soundness of the biosafety decision-making process in the region by training scientists, members of national biosafety committees and regulators from the ASARECA countries. The sub-regional approach to education and training was seen to foster the harmonisation of technical criteria and procedures. A process whereby national biosafety focal points are to submit biosafety data to ASARECA for review and advice was proposed. This was intended to leverage sub-regional expertise to provide national decision-makers with sound advice on applications for the intentional environmental release of biotechnology products.

The process proposed involved the submission of data by the national biosafety focal points to a committee drawn from a roster of experts from within the sub-region. Advice and recommendation would be provided for the benefit of all member countries. This process was to particularly benefit countries that have neither capacity nor the resources to implement biosafety systems on their own. It would also contribute to a consistent approach to the provision of expert advice.

The Project was also to establish a roster of sub-regional scientific and socio-economic expertise to support biosafety decision-making in the region. It sought to establish a program of biosafety research to address sub-regional risk assessment and risk management knowledge gaps. This was to facilitate the funding of research that is likely to inform and assist national authorities in making science based decisions about the effects on biodiversity of introducing GMOs into the environment of another ASARECA member country.

With respect to harmonisation, ASARECA seeks to promote the development of regional templates on related policies, guidelines and procedures within ASARECA countries. Each country is to model their national policies and legislation along these templates subject to variations to suit their unique needs. The result is expected to be harmonised biosafety procedures in the region.

The regional approach to regulation of biotechnology was born out of the recognition that capacity was lacking in ASARECA countries and that the biosafety review process is costly, repetitive and requires specific trained expertise, which is lacking in most ASARECA countries. Given the scarce resources in the sub-region, the approach aims at ensuring that duplication and overlap in findings in the sub-region do not occur.

It is proposed that a regional biosafety support service centre and a scientific experts' committee to review applications and make recommendations be set up. This would facilitate regional reviews of applications; provide a platform for regional interaction in biosafety, initiate and monitor regional biosafety research, and coordinate with other regional players.

There have been priority-setting initiatives under the biotechnology project. Reports have been prepared to assist in setting priorities for the biotechnology program[12].

[12.] See Johanson, A & Ives C., 2001, An Inventory of Agricultural Biotechnology for the East and Central Africa Region, Agricultural Biotechnology Support Programme, Michigan State University and Johanson, A., 2002, Agricultural Biotechnology in the ASARECA Region: Priorities for Research, Agricultural Biotechnology Support Programme, Michigan State University

Intellectual property

Intellectual property rights (IPRs) form an important component in the practice and implementation of biotechnology. Intellectual property issues are coming to the fore and countries will sooner than later have to address Intellectual Property (IP) under their national laws and policies. The Agreement on Trade Related Aspects of Intellectual Property (TRIPs Agreement) under the World Trade Organisation (WTO) requires WTO member countries to formulate legislation protecting IP. In addition to developing national biosafety systems, countries must also develop concomitant policy, legal and institutional frameworks for the protection of IPRs especially in the context of biotechnology.

National frameworks for the regulation of biotechnology

A national biosafety system traditionally consists of a national strategy, national policy, legislation, regulations and guidelines. In most cases, the policy and strategy should precede the legislation, whose implementation would be made possible by the promulgation of regulations and the formulation of guidelines.

National policies

The function of a national policy in any sector is *inter alia*, to outline the nation's objectives in the particular sector. A policy forms the spirit of subsequent national action in the particular and other related sectors.

None of the study countries has a national policy on biotechnology or biosafety. Matters related to biotechnology are referred to in policies in other sectors the most common being the Science and Technology (S&T) policies. Malawi has a comprehensive S&T policy[13], which acknowledges the potential of biotechnology in revolutionising production systems in agriculture and observes that Malawi has not taken full advantage of the opportunities offered by biotechnology and that there has been no special effort to further develop national competencies in this emerging technology. Although the Malawi S&T policy does not address biotechnology specifically, it commends the government's effort to develop a legal framework governing biosafety issues in Malawi. The S&T Policy lists the strategies to be adopted in order to promote the development of Malawi's interests in the field of biotechnology. These are to:

- establish and strengthen centres of excellence in specific areas of biotechnology;
- increase awareness in biotechnology and its potential impact on socio-economic development through demonstration and training centres;
- intensify the development of the human resource capacity in biotechnology;
- establish a national programme of action for promotion and adoption of biotechnology;
- establish capacity to monitor and evaluate biosafety issues in the economy; and to
- establish programmes of international cooperation in biotechnology.

In South Africa and Kenya, the situation is similar. Issues relating to biotechnology and biosafety have generally been addressed in the national science and technology policy. Kenya has a broad science and technology policy but lacks a specific national policy and legal framework on biotechnology. Likewise, South Africa does not have a national policy on biotechnology. National

13. The 2002 National Science and Technology Policy

policies on areas that are related to biotechnology and biosafety such as the environment and agriculture, do not focus much attention on biotechnology and biosafety save for perhaps the National Policy on the Conservation and Sustainable Use of Biodiversity which expresses the need to adopt measures to regulate the use, handling, transfer and release of GMOs. The 1996 White paper on Science and Technology underscores its role in promoting South Africa's economy and recognises its benefits in the improvement of the livelihoods of South Africans. It however, only identifies biotechnology as an area of collaboration both nationally and internationally and across various partners.

Policy formulation in the area of biotechnology is characterised by ad hoc policy related statements and national pronouncements, which are indicative of the political recognition of the opportunities offered by biotechnology. In the study countries, these pronouncements stop at that with the exception of South Africa, which has formulated a biotechnology strategy. This serves as a clear sign of the government's willingness and commitment to embrace biotechnology.

The lack of a specific biotechnology policy results in ineffective prioritising of needs. This is responsible for fragmented research since these efforts are not aligned to stipulated national priorities. Biotechnology R&D is therefore evolving in a policy vacuum. This has led to fragmentation and poor communication of the biotechnology R&D agenda among various stakeholders. For example, most of the biotech initiatives reflect interests of concerned individuals and particular institutions. There are little inter-organisational interactions and modern biotechnology activities are influenced by institutional preferences and donor funding and are not necessarily guided by or aligned to national priorities (Anyango and Shiundu, 1999).

While biotechnology advances at a rapid pace in the western world, it has yet to find proper grounding in Africa. The governments in the study countries, save for South Africa, have not played a major role in facilitating consultation and negotiations among different stakeholders in order to set priorities for biotechnology R&D. The lack of national priority setting and political will to implement biosafety reflects a lack of awareness of biotechnology and its impact at all levels beginning with policy makers. In Malawi, lack of resources for organising seminars, awareness campaigns etc was also cited as a major obstacle to the formation of a policy on biotechnology and biosafety.

Efforts are however, underway to develop biosafety policies. In Kenya, the National Council for Science and Technology (NCST) has drafted a national biotechnology policy, which awaits adoption. The draft Biotechnology Development and Biosafety Policy is to be discussed at a stakeholders' meeting to be held in late 2003.

The draft policy has a wide scope that extends to public awareness, legal framework, intellectual property issues, capacity for biotechnology R&D, institutional framework to coordinate biotech efforts, funding, safety issues and protection of indigenous resources and knowledge. The policy is to be presented to the committee of Permanent Secretaries and it is expected that it will be approved by the end of 2003.

In Malawi, a workshop organised by the Environmental Affairs Department and the Biotechnology-Ecological Research and Outreach Consortium (Bio-EROC) in April 2003 brought together biotechnology and biosafety experts and stakeholders with the aim of providing a forum for the development of a biosafety regulatory framework for Malawi and to draw strategies leading to the implementation of the Biosafety Act[14]. The participants agreed that a working group should be constituted comprising representatives from Commerce and Industry, Agriculture, Health,

[14.] Report on the National Biosafety Regulatory Framework Workshop, Lilongwe, 28 April 2003

Labour and Environmental Affairs by 30th September 2003. The working group is to formulate terms of reference for the retention of a consultant to lead the process of developing a biosafety policy for the country. The consultant should have been engaged by 30th October 2003, submit the first draft by May 2004 and the final draft by August 2004, followed by a stakeholders meeting in September 2004. A final Biosafety Policy document is scheduled to be available by October 31st 2004.

Although South Africa has no biotechnology or biosafety policy, there however is a Policy on GMO Consignments in Transit. The aim of the Policy is stated as to serve as a framework to promote the safe transit of GMOs through South Africa. This is especially necessary given the fact that South Africa is often utilised for logistic and shipment of food consignments destined for aid to southern African countries during emergencies. These consignments may contain GMOs whose events have not been approved in South Africa. The policy lays the requirements and the procedure to be followed in such cases.

National biotechnology and biosafety strategies

Of all the study countries, only South Africa has a National Biosafety Strategy. In spite of South Africa's long history in the use of biotechnology and the large number of biotechnology-embracing projects, it was determined that RSA had failed to maximize on the potential of third generation biotechnology and that very few products and processes were under commercialisation. The limiting factors were identified as including the lack of infrastructure for R&D, institutional capacity, business support and management for start-up technology companies, lack of technology platforms in S&T coordination of policies and programmes, lack of collaboration and funding for innovative ideas. In response to this, the Department of Science and Technology embarked on a study that resulted in the drafting and gazettement of the National Biotechnology Strategy for South Africa in November 2001.

The Strategy identifies gaps and suggests interventions that can be used to ensure that the potential of biotechnology is harnessed for the benefit of the economy and to improve the livelihooods of South Africans. The recommendations are in two categories: new institutional arrangements and specific actions to be taken by government departments. The strategy recommends the establishment of a Biotechnology Advisory Committee under the Cabinet's Economics Cluster which would be responsible for the implementation of the strategy, the coordination of biotechnology R&D, and alignment with national priorities.

Different means by which the government can influence the development of biotechnology are identified in the stragety. These include the legal framework, the funding mechanisms, the creation of new infrastructure and institutional arrangements, and the construction of research capacity through appropriate human resource development. Certain interventions from the government are listed. Key among these is the creation of biotechnology regional innovation centres (BRICs) which would serve as nuclei for the development of biotechnology platforms that would address the gap between research and innovation, the formation of a National Bioinformatics Network, the promotion of Public Understanding of Biotechnology, conducting a biotechnology audit of South Africa, and the development of a Biobank.

The South African government has pledged to increase R&D spending from 0.27% to 1% of national GDP (Maistry, 2003). The funds are to be channeled into operational objectives as outlined in the strategy. The Biotechnology Strategies Unit under the Department of Science and Technology is mandated with the implementation of the strategy through the management of new institutional and infrastructural arrangements, coordination of biotechnology research and development and ensuring that R&D is aligned with national priorities.

The implementation of the strategy will no doubt stimulate growth and commercialisation of biotechnology in South Africa. The strategy promotes local and foreign investment and the BRICs are likely to aid in raising human capacity levels in biotechnology.

Legal regulatory framework

Under national systems, policy can be implemented in different ways. New legislation can be enacted, existing legislation can be reviewed to accommodate the proposed policy and finally, a non-legislative means such as a ministerial decree can be used. Policy can also be implemented though a combination of these.

Agricultural biotechnology in the sub-region has focused on the development of new plant varieties, their derived livestock feed and human food products, and animal vaccines or diagnostics produced using modern biotechnology. Ministries of agriculture, health, or the environment have traditionally regulated the conventional forms of products of these processes. In choosing a legislative approach to implementing biosafety, some countries have chosen to develop new regulations under existing science and technology Acts or Statutes.

This type of legislation was originally designed primarily for the purposes of creating and governing research agencies. The implementation of new regulations therefore, must be a two-step process. First the existing legislation must be amended to provide the necessary authority to create such regulations, and then the regulations must be drafted and promulgated. As the legislative amendment requires Parliamentary approval, the risk with this approach is that it may be nearly as lengthy as creating a new Act of Parliament and the accompanying regulations.

Implementing biosafety requires an inspection and enforcement capability normally not provided for under S&T legislation. Hence there is the need to either create a new inspection service for that purpose, which may not be cost effective, or to delegate inspection and compliance enforcement to another agency with those powers for example under the ministries of Agriculture or Environment. Therefore, although adaptation of existing laws avoids the necessity of drafting new laws, it however can lead to redundancy and bureaucratic delays. It would also require the harmonisation of the different sectoral laws to ensure that they are consistent with the policy. This may result in side lining new policy that is to be incorporated in the existing laws.

In most sectors, the norm is to have an enabling statute, implementing regulations and finally guidelines. The current status on legal regulation of biotechnology in Kenya is a departure from this norm. There exists no overarching legal framework for the safe application of biotechnology. Kenya has not enacted any laws that specifically address biotechnology issues. Biosafety regulations and legislation are only incidentally incorporated in various sectoral statutes. There has been no attempt to date to harmonize these provisions. In the first place, an overall policy on biotechnology, to which these scattered provisions are to be aligned, is missing.

The application of biotechnology in Kenya is regulated by the 1998 Regulations and Guidelines. These lack an enabling statute. While non-legislative means such as a ministerial decree are faster and simpler to issue and are more readily amended or replaced, there are enforcement constraints. Without an enabling statute, the guidelines may lack substance. It is, for example, legally difficult to prosecute one who contravenes the guidelines as they lack the weight and enforcement power of government regulatory authorities. A good biosafety system must provide for an effective enforcement mechanism that will secure the enforcement of rights as provided under the law.

With respect to legislative regulation of biotechnology, the study countries are in different stages although virtually all are yet to develop and implement framework laws and supporting regulations.

As mentioned, Kenya does not have legislation on biotechnology or biosafety but has been relying on the 1998 Regulations and Guidelines.

The Regulations and Guidelines cover research on recombinant DNA, categorized experiments, plant biosafety, quarantine procedures, containment and field experimentation. Other areas such as the deliberate release of GMOs, the importation of biotechnology products and sanctions to ensure compliance with biosafety measures are also addressed.

The regulations describe the steps to be followed to develop a national biosafety system. The government designated the National Council for Science and Technology (NCST) as the authority to oversee the coordination and implementation of biosafety Regulations and Guidelines. Its secretariat, the inter-agency National Biosafety Committee (NBC), draws up policies and procedures and vets research applications to ensure responsible application of biotechnology in Kenya. The NBC has been operational since 1998. Currently, five transgenic crops are in various stages of the approval process by the NBC.

Statutes which mention certain aspects of biotechnology and biosafety in Kenya include: the Agricultural Produce (Export) Act, Cap 319; the Crop Production and Livestock Act, cap 321; the Plant Protection Act, Cap 324; the Suppression of Noxious Weeds Act, Cap 325; the Seeds and Plant Varieties Act, Cap 326; and the Environmental Management and Coordination Act No. 8 of 1999.

This fragmentation of non-specific provisions on biosafety across various statutes is what exists in Kenya today. Recognizing the need for an overarching legal framework on biotechnology, the NCST constituted a task force to prepare a biosafety bill and draft regulations and guidelines in biosafety for biotechnology. The draft Biosafety Bill establishes the National Biosafety Authority whose functions include formulating and implementing policies, plans and programmes for the development of biosafety in Kenya; overseeing the formulation of standard provisions governing rights and obligations of biosafety institutions; promoting efficiency in the development of biosafety through the establishment of appropriate institutional linkages and promoting and encouraging the use of environmentally friendly technologies.

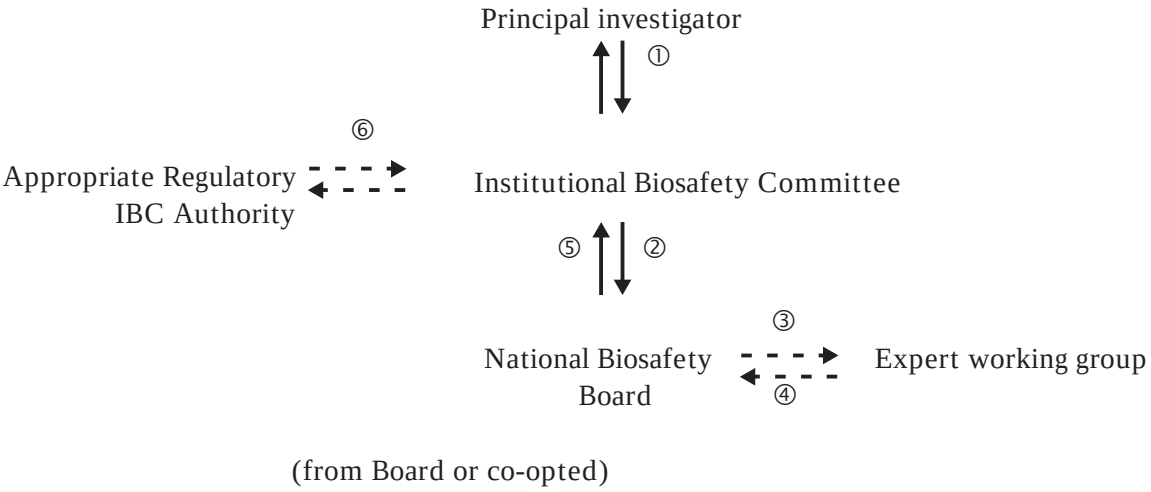

Figure 1: The proposed procedure for experimenting in genetic transformation under the Kenyan Biosafety Bill

1. The applicant submits his proposal to the Institutional Biosafety Committee (IBC)
2. The IBC assesses the application and forwards it together with the evaluation to the Board for further assessment
3. On receipt of the application, the Board forms an expert working group
4. The working group assesses the proposal and may seek additional information from the applicant. On completion of the assessment, the working group submits its recommendation to the Board.
5. The Board returns its report to the IBC
6. The IBC in consultation with the appropriate regulatory agency shall make the changes recommended by the Board.

In South Africa, the Genetically Modified Organisms Act, No. 15 of 1997 (the GMO Act) regulates biotechnology. The objectives of the Act are to promote the safe application of biotechnology, to protect the environment and to provide a risk assessment mechanism. The most salient features of the Act include the provision for a multi-ministerial decision-making process, the conducting of independent risk assessments by the scientific experts on a case by case basis and the accommodation of public input through the invitation for comment on GMO applications published in the print media.

Table 2: GMO permits issued by the Registrar under the SA GMO Act from Dec 1999 to June 2003[1]

Applications	*1999*	*2000*	*2001*	*2002*	*2003*
Commodity import	1	6	3	37	4
Import	0	50	64	58	19
Field trials	2	45	61	50	1
Export	0	3	22	36	34
Transit	0	0	0	2	1
Animal Feed/ Food	0	6	1	17	4
General Release	0	1	3	1	1
Commodity clearance	0	0	6	4	0
Contained use	0	11	1	2	1
Greenhouse trials	0	0	2	1	0
Commercial planting	0	0	9	11	8
TOTAL	3	122	172	219	73

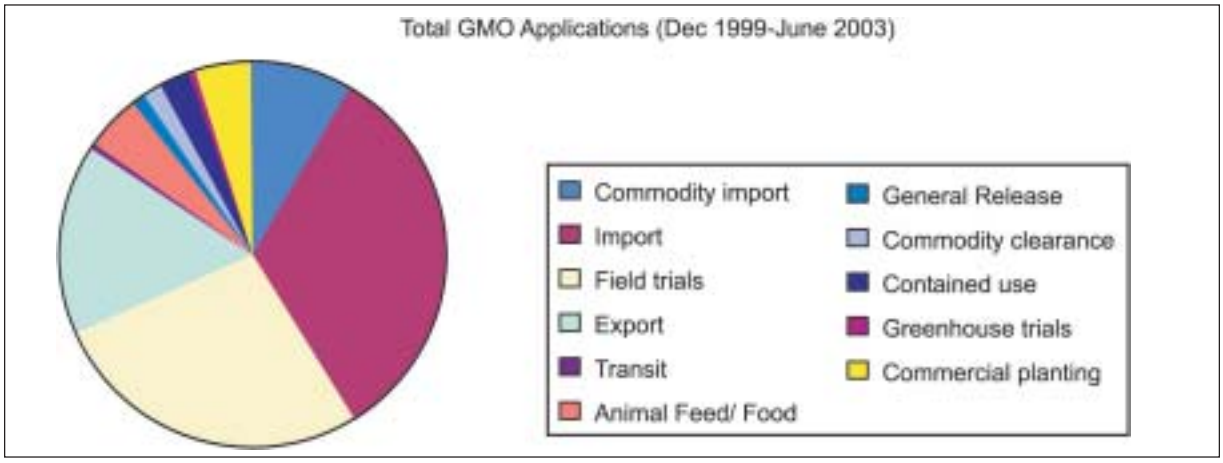

Figure 2: Total GMO Applications under the RSA GMO Act (Dec 1999 to June 2003)

A total of about 590 applications from December 1999 to June 2003 have been handled by the Registrar's office most being for importing GM materials (see Table 2 and Figure 2).

Other legislation of relevance to biotechnology in food and agriculture in South Africa include: The Environment Conservation Act, No. 73 of 1989; The Foodstuffs, Cosmetics and Disinfectants Act, No. 54 of 1971; The National Environmental Management Act, No. 107 of 1998; The Agricultural Pests Act, No. 36 of 1983; The Plant Improvement Act, No. 53 of 1976; Animal Improvement Act, No. 62 of 1998; and The Plant Breeders' Rights Act, No. 15 of 1976.

In Malawi, the Biosafety Act was passed by Parliament in October 2002 but it is yet to be implemented. The scope of the Act extends to the genetic modification of organisms, the importation, development, production, testing, release, use and application of GMOs as well as the use of gene therapy in humans and animals[15]. The Act is to be administered by the Minister in charge of Environmental Affairs assisted by appointed officers whose duties and functions are spelt out by the Act[16]. Efforts are currently underway to implement the Act through the establishment of the Biosafety secretariat and the appointment of other officers. To date, no applications for GM crops have been made in Malawi.

Under ASARECA, different countries have approached regulation of biotechnology differently.

Components of a national biosafety framework

The components of a national biosafety framework traditionally include:

(i) an administrative office that coordinates the application process. This office is the entry point for all applications relating to GMOs and is usually a government department such as that charged with matters relating to the environment, agriculture or science and technology.

(ii) a scientific advisory committee with a wide range of scientific expertise to cope with the diversity of case-by-case assessments is essential. This body advises government, industry and the public on the safe application of biotechnology. Scientific reviews are carried out on a case-by-case basis. As such, constitution of the review team needs to be flexible (Koch, 2001).

(iii) the decision-making body which should represent interests of all national sectors. The decision-making process should allow for public input and should address socio-economic aspects regarding to the application of biotechnology.

The national biosafety process should address issues such as biosafety communication, public participation and non-safety issues in order to increase the acceptability of the products of the technology by the public. Examples of other issues that should be addressed in biosafety systems include processes and activities: contained GMO research in laboratories and green houses; experimental field trials; commercial scale introduction of GMOs; labelling options; marketing and advertising of GMOs; products; imports; animals; plants; seeds; livestock feeds; agricultural commodities; processed food products; drugs and therapeutic products to name but a few. Table 5 and 6 summarise the issues considered necessary in developing biosafety systems in ASARECA countries.

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15. section 3

16. sections 4, 5 and 6

Table 3: current legislative approaches within ASARECA member countries*

Item	DR Congo	Kenya	Madagascar	Rwanda	Sudan	Tanzania	Uganda
New GMO-specific legislation	Yes	Yes			Yes		
Does the proposed competent authority have existing inspection and enforcement powers?	Draft legislation exists Legal authority under Minister of Agriculture Creation of cross ministerial Biosafety Advisory Committee (Agriculture, Environment, Health)	Biosafety Bill New competent authority: National Biosafety Authority (under Minister of S&T) New inspection staff Mixture of new and existing inspection activities.			At the drafting stage Likely under the Ministry of S&T Creation of National Biosafety Board		
Will existing legislation/regulations require amending to delegate authority?	Inspection staff to be created	New Act will supersede all existing affected Acts					
Utilise existing legislation with adapted or amended regulations (relevant Acts & competent authorities, & the affected processes or products)		Using the Decree on Environmental Impact (only covers importation) Ministry of Environment & the National Office for Environment	Using existing Decrees (National Environmental Bill & Decrees under the Ministry of Agriculture)			Using existing legislation (Science & Technology Act)	Planning to use the Uganda National Council for Science and Technology Statute Draft National Biosafety Regulations are prepared
Does the competent authority have existing inspection & enforcement powers?		Receipt & processing of applications Nothing (yet) regarding domestic development of GMOs					
Interim procedures that have/will be put in place while legislative/regulatory amendments are progressing.				Not aware of any			Guidelines on Biosafety and Biotechnology are in place (Prepared by UNCST)

Source: ASARECA 2003a

* Information on Burundi, Ethiopia and Eritrea was not available

Table 4: status of biosafety regulation in the study countries

		Basic Framework	Policy	Strategy	Legislation	Regulations & guidelines	Institutional framework
ASARECA COUNTRIES	Burundi	No	No	No	No	No	No
	DR Congo	No	No	No	Draft Bill	No	No
	Eritrea	No	No	No	No	No	No
	Ethiopia	No	Draft policy under preparation	No	Draft under preparation	No	No
	Kenya	Yes	Draft Policy	No	Draft Bill	Interim regulations	Yes
	Madagascar	No	No	No	Using existing decree on EIA	No	No
	Rwanda	No	No	No	Plans to use existing decree	No	No
	Sudan	No	No	No	Bill is being drafted	No	No
	Tanzania	Yes	Draft Policy	No	Using existing legislation	Regulations under the Commission for S&T	Yes
	Uganda	Yes	Draft Biotechnology Policy Draft Biosafety Policy	No	No	Regulations under the National Council for S&T Interim guidelines under preparation	Yes
	Malawi	No	No	No	Yes	No	No
	South Africa	Yes	No	Yes	Yes	Yes	Yes

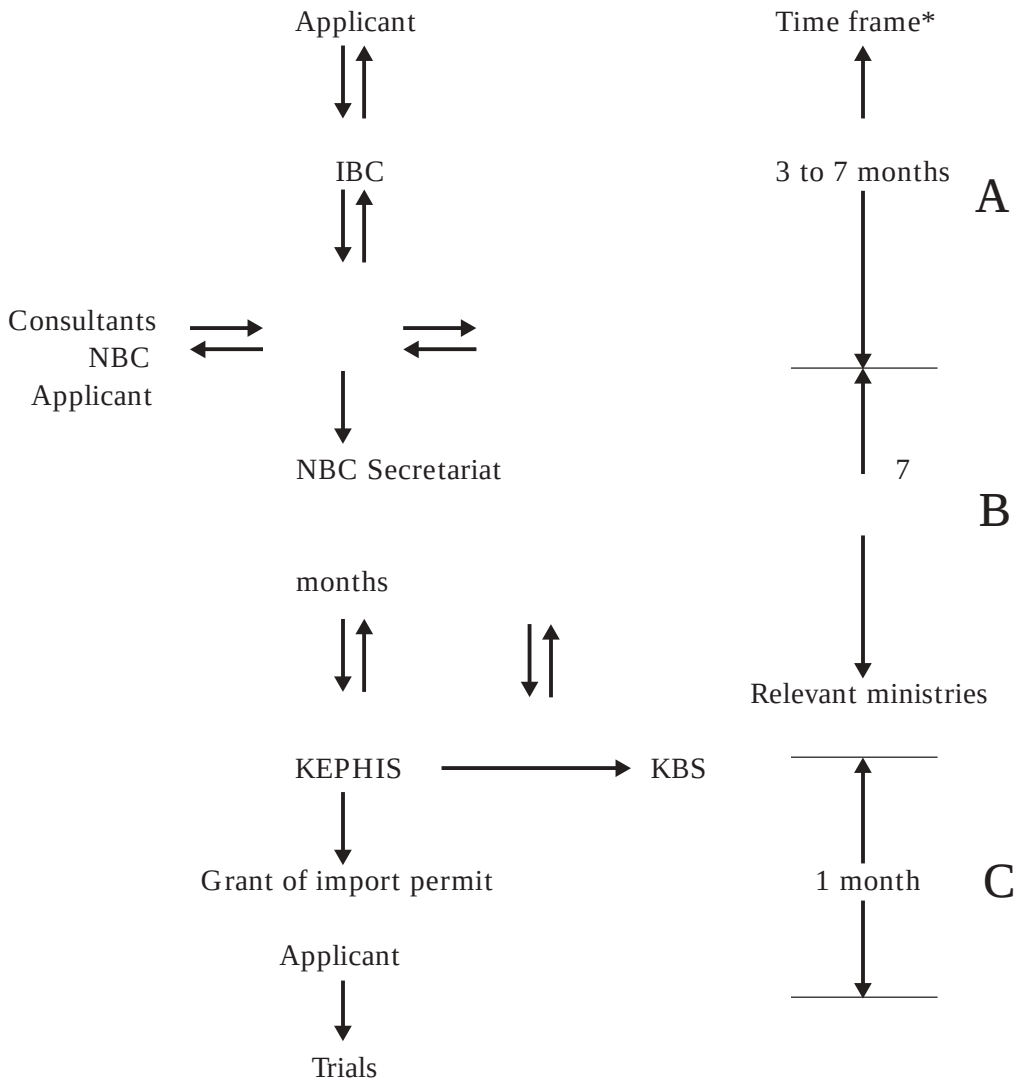
Decision making process and the time frame

The process for handling applications for experimentation in GM crops in the study countries incorporates the three levels mentioned above: the administrative office, scientific review process and the final decision-making. In Kenya, the current process is represented in Figure 3.

From the interviews conducted, time frame A was cited as being the most prone to administrative delays. The lack of coordination between the IBC and the NBC results in further delay. The review process under the NBC likewise is not always within the stipulated time limit. For example, it took three years to obtain an import permit in the case of the KARI/Monsanto virus resistant sweet potato (KARI, 2001). It may be argued that Kenya developed biosafety regulations fairly recently and is therefore still acquiring experience. The IRMA project has also experienced administrative delays most of which have been within the time frame A (KARI and CIMMYT, 2001). Large committee membership in both the IBC and the NBC with diverse professional backgrounds that hinder timely convening of meetings has been cited as one of the main reasons for administrative delays within time frames A and B.

Most interviewees however stated that once the NBC had approved applications, the grant of import permits from KEPHIS was within reasonable time.

The Executive Committee meets every six to eight weeks. An applicant must therefore make his application to coincide with this meeting otherwise he may loose a considerable amount of time. It takes 90 days to process permits and 180 days for the commercial release of GM crops. The registrar however may require additional information or clarification from the applicant. No time limit is allocated for this process. The effect of this is that applications are subject to administrative delays. This has led to unpredictability regarding the time taken to grant a permit. The relative lack of expertise among members of the Executive Council coupled with the requirement that a majority of the Scientific Advisory Committee (SAC) be present for the taking of decisions serves to further complicate and prolong the process.



*according to the draft Regulations and Guidelines, the NBB (the draft Regulations and Guidelines establish the National Biosafety Board as opposed to the existing National Biosafety Council; all other references to NBC remain the same) from the date of receipt of the application, shall take a maximum of 30 days to acknowledge receipt, 60 days to assess application for correctness of information, 90 days to deliberate on the application, 150 days to inform applicant of the decision and 210 days to confirm the grant of the application.

Figure 3: The current procedure in Kenya for approval of GMO trials using GMO material constructed abroad

The approval process takes into account repeat applications; approvals on these can be granted within a week. The SAC does not review applications that have been previously approved. Similarly, an application for a GM crop that has gone through the system in another country and has been approved is likely to be processed more quickly.

The Act has been hailed as one that facilitates for a consultative process. By the time a decision is made, there has been input from the applicant, the scientific audits from the SAC and its committees, the public through the mechanism provided using the print media and from national concerns as tendered by the six ministerial representatives. It has however come under considerable attack from the growing anti-biotech groups. Some of the criticisms levelled against it include the omission to cover GMO products, the exclusion of the civil society from decision

making, that public participation is not adequately provided for, that liability is placed on users of GMOs rather than the developers to name but a few (Mayet, 2001). It should be noted that South Africa has a notable anti-biotech movement and the adoption of GM technology by the public may be influenced by the information disseminated by both pro and anti-biotech movements. In addition to the criticisms levelled against the Act by the anti GM movement, the registrar's office charged with the implementation of the Act has likewise been criticized as lacking expertise, experience and capacity.

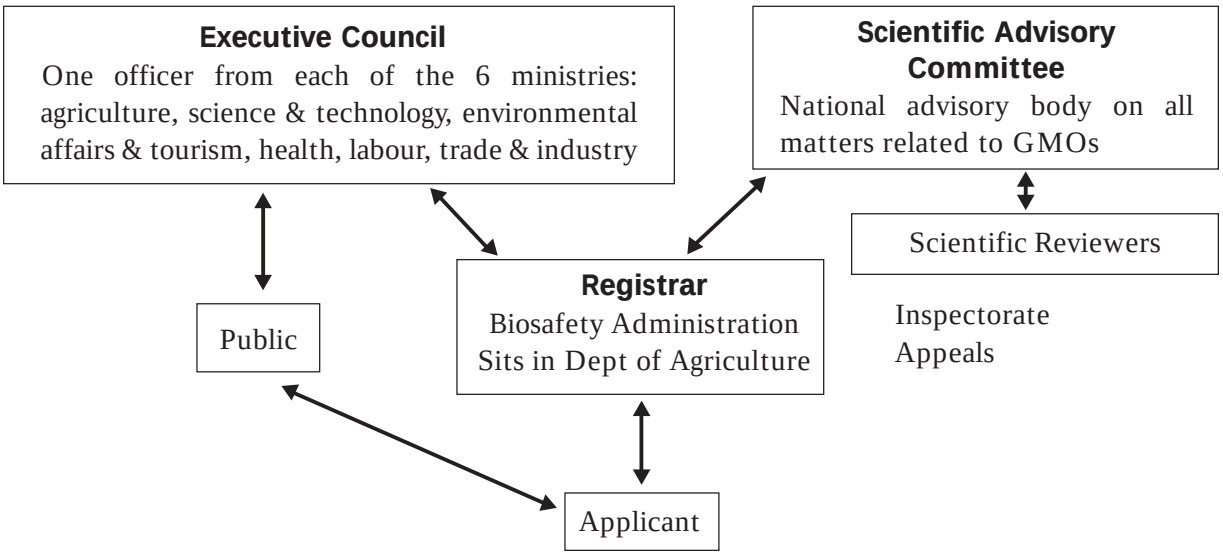


Figure 4: Decision-making process under the South African GMO Act.

Regional approach under ASARECA

The Biotechnology industry is a research-intensive industry requiring a lot of financial resources. The high amount of funding required calls for cooperation and the sharing of human, financial and technological capital. This is yet to be achieved in ASARECA. Member countries are still in the process of setting up national biosafety regimes.

Biosafety review may result in duplication within a region where applications relating to GMOs are made to more than one country in a region. A regional approach in biosafety would minimise duplication and maximise the cost benefit ratio of the risk assessment process.

Biotechnology relies heavily on knowledge flows between and among those involved in its application. A regional approach to biosafety would facilitate the sharing of information. Existing information from risk assessments in other countries need not be repeated. Subsequent countries entertaining applications for the approval of events would benefit from the information already existing although they would be free to require further information and assessments to address biosafety issues specific to their national needs, socio-economic issues and civil society concerns.

GMOs found to be safe for human food or animal feed in one country are likely to be found to be safe in other countries. Safety reviewers however owe it to their communities to assess the events according to the prescribed safety review process. A regional approach to such reviews would result in a decision endorsed by safety experts in the region thereby making it acceptable in the various countries forming the region.

Table 5: Issues addressed by the ASARECA member countries

ISSUE	Kenya	Uganda	Tanzania	Ethiopia	Madagascar	Burundi	Sudan	Rwanda	Eritrea	DR Congo
Regulations & guidelines	Yes	Yes	Yes(Draft)	No	No	No	No	No	No	No
Institutional framework[17]	Yes	Yes	Yes	No	No	No	No	No	No	No
Safety measures	Yes	Yes	Yes	No	No	No	No	No	No	No
Procedures of handling requests	Yes	Yes	Yes	No	No	No	No	No	No	No
Regulatory proceduresDev't & use of natural GMOs	Yes	Yes	Yes	No	No	No	No	No	No	No
Importation of biotech products	Yes	Yes	Yes	No	No	No	No	No	No	No
- Laboratory infrastructure & practices	Yes	Yes	Yes	No	No	No	No	No	No	No
- Containment of biotech products	Yes	Yes	Yes	No	No	No	No	No	No	No
- Commercial release of GMO	Yes	Yes	Yes	No	No	No	No	No	No	No
- Notification	Yes	Yes	Yes	No	No	No	No	No	No	No
- Compliance with the regulations & guidelines	Yes	Yes	Yes	No	No	No	No	No	No	No
- After release monitoring and feed back mechanism	No	No	No	No	No	No	No	No	No	No
GuidelinesLaboratory Research - Safety levels - Safety precautions - Fast aid - Medical structure	Yes	Yes	Yes	No	No	No	No	No	No	No
Containment/confinement (Lab. Green house, Field)	Yes	Yes	Yes	No	No	No	No	No	No	No
Commercialisation & Release	Yes	Yes	Yes	No	No	No	No	No	No	No
Importation/ Acquisition	Yes	Yes	Yes	No	No	No	No	No	No	No

Source: ASARECA 2003b

[17] Most institutions are dealing with modern biotechnology but do not have Institutional Biosafety Committees.

Table 6: Legislative objectives with respect to biosafety – activities and products for which regulation is believed necessary*

Item	DR Congo	Kenya	Madagascar	Rwanda	Sudan	Tanzania	Uganda
Processes and Activities							
Contained GMO research in laboratories and greenhouses	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Experimental field trials of GMOs, or small scale environmental introductions	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Commercial scale introductions of GMOs into agriculture	Yes	Yes	yes	yes	yes	Yes	Yes
Environmental introductions of genetically modified micro organisms	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Labelling - options: based on *content* of GMOs, or based on *derived* from GMOs even though product does not contain GMOs.)	Yes	Process (derived from) – noProduct (contains) – yes	Process – no Product – yes	Process – no Product – yes		Process – no Product – yes	Process – no Product – yes
Marketing/advertising of GMOs	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Domestic Movement/Transport of approved products	No	No	No	No	No	No	No
Products							
Imports	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Exports	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Animals	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Plants, seeds	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Livestock feeds containing GMOs	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fertilisers containing GMOs	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Commodities (agricultural)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Processed food products	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Drugs and therapeutic products	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Medical devices	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Veterinary biologics (vaccines, diagnostics, etc)	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Source: ASARECA 2003a

*information on Burundi, Ethiopia and Eritrea was not available

Although human capacity in biotechnology has been growing in the sub region, critical mass of experts in biotechnology and biosafety is yet to be attained. Regional cooperation would enable countries with low human capacity levels to benefit from collaboration with those countries, which have a higher level of biosafety capacity. This applies to laboratory facilities as well.

Proposed regional biosafety structure

A workshop on Biodiversity, Biotechnology and Biosafety for East and Central Africa organised by the Global Biodiversity Institute, in August 2001, brought together 46 delegates from eight ASARECA countries with the aim of considering a structure for a regional biosafety initiative. The proposed structure is represented in Figure 5 :

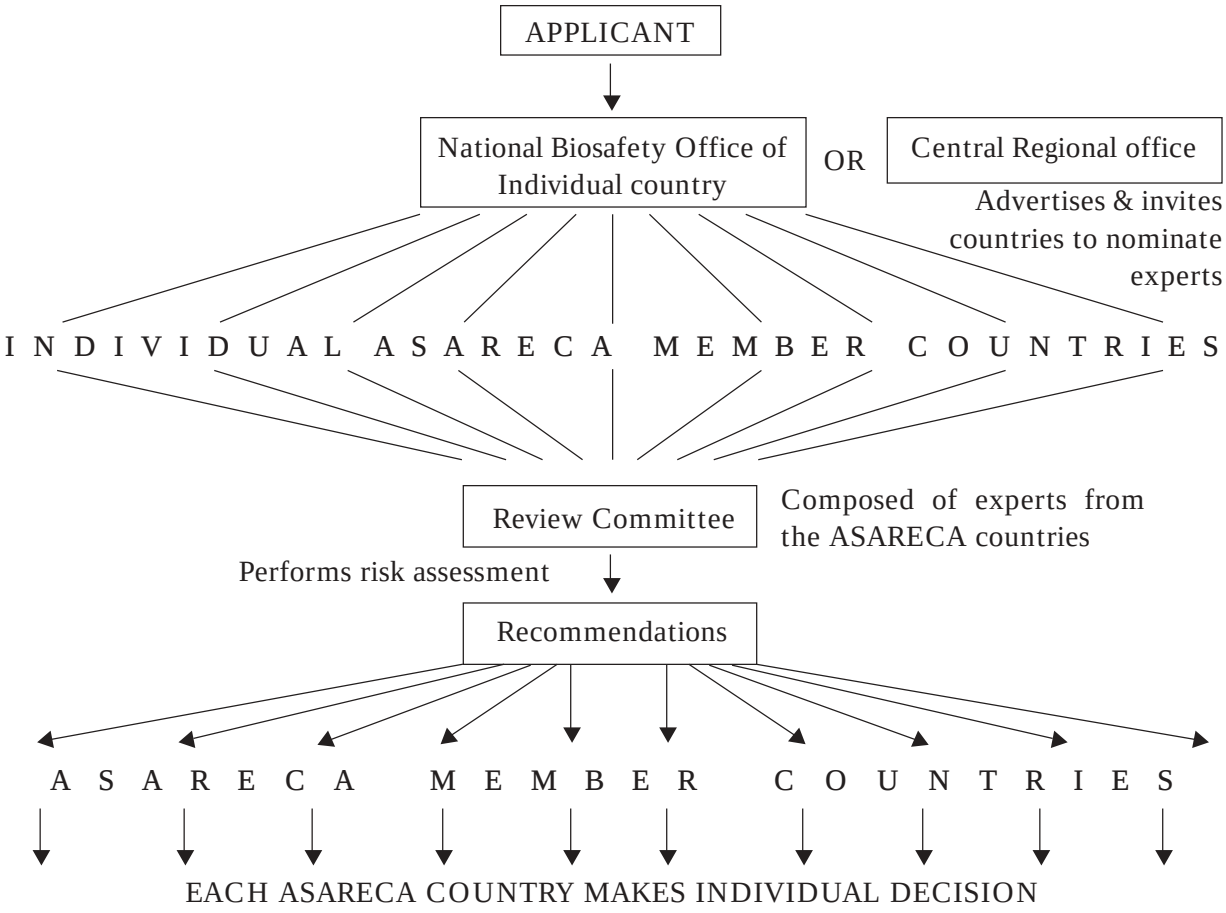


Figure 5: The proposed structure of a regional biosafety system

The format of the regional biosafety initiative requires further consultation within the region, especially as each country gains experience with handling biosafety applications, regulation and risk assessment. Many of the responsibilities lie with the national framework but when a functioning regional support structure is in place much of the day-to-day administration and responsibility could be transferred to this central office. As of now, countries are still developing their national biosafety frameworks and it will take a while before a regional framework is operational.

Institutional arrangements

Any decision to establish a biosafety system must address two important questions: what kind of institutions - research, social, political and economic - should be established to enable a country to engage in the biotechnology industry? Secondly, what capacities are required to assess risks in biotechnology and to effectively manage those risks?

Institutional actors in biotechnology

The study countries particularly Kenya and South Africa have well-established systems of national agricultural research. The NARS are characterized by public goods research, use of conventional technology, and centralised and hierarchical organisation. The institutions in this national system include national agricultural research institutes, academic institutions, NGOs, producer associations and farmers' associations and other community based organisations. In South Africa, institutional actors in biotechnology R&D include academic institutions, public research institutions, and industry. Academic institutions constitute the largest group of participants in agricultural biotechnology. They are engaged in both basic and applied research. Public research institutions include science councils such as the CSIR, which have the largest share of funding. In Kenya, modern biotechnology is dominated by the Kenya Agricultural Research Institute (KARI), universities and international agricultural research institutes (IARCs).

Industry is however, increasingly taking part in the area of modern biotechnology particularly in South Africa and in Kenya. However, it is mainly multinational companies that are involved. In Malawi, there is low representation of private companies and venture capital is non-existent.

Although there is some level of collaboration among the various actors in the study countries, there has not been full exploitation of organisational synergies. In South Africa, institutional linkages exist between universities, both local and international, and South African institutions. These linkages are characterized by information and material exchange. There are other limited collaborations between national research institutes, international organisations, government departments, NGOs and the private sector. The need for improved institutional linkages was expressed by those interviewed. The situation is similar in Kenya while in Malawi, even in the use and application of traditional biotechnology, synergies between those involved have not been developed. As a result, the activities are uncoordinated and generation and exchange of information, on which biotechnology so heavily relies, is lacking. Given the pervasive nature of biotechnology, a multidisciplinary approach to application and regulation of biotechnology is inevitable. This means that there must be collaboration between researchers, lawyers, engineers, information technology experts, market researchers, business experts and other professionals. This is yet to be fully achieved in the study countries.

Capacity

Building capacity in biosafety is strategically important to successfully integrate biotechnology into agricultural research. The successful application of biotechnology requires an adequate infrastructure, a vital component of which is capacity. Capacity for implementation of biosafety should be seen in the broader context of human capacity, financial resources and institutional and infrastructural capabilities.

The study countries have built human resource capacity in traditional biotechnology over the years. Kenya and South Africa have capacity for tissue culture and marker-assisted biotechnology. Currently,

there are numerous projects involving tissue culture and marker assisted technology in Kenya, most of which are being conducted under KARI and departments in national universities (BTA, 2002).

With the exception of South Africa, there is a dearth of capacity for molecular biotechnology and risk assessment. In Kenya, the majority of scientists have basic scientific knowledge in genetics and molecular biology, they however lack practical experience to effectively apply their existing knowledge to modern biotechnology (Odame *et al.*, 2000). The biosafety system is yet to attain a critical mass of researchers that is required to engage in molecular transformation technology.

There are a significant number of scientists with postgraduate qualifications in South Africa. In 1998, the figure was estimated at 1200 - 20% of which had PhD qualifications and 20% with MSc. degrees (Wolson, 2001). The highest concentration of qualified individuals is found in academic institutions. Loss of graduates and staff from the system has however lately been of concern as qualified personnel seek greener pastures in the private sector and abroad. A shortcoming highlighted in the decision making process is that of lack of expertise and capacity in those charged with the duty of administration of the GMO Act and among decision-makers in government. In Kenya, there are competent officers charged with the administration of the Regulations and Guidelines, however, as the number of proposals increase, additional competent personnel will be needed to handle applications, make decisions, process reports and perform other information management tasks. Capacity has to be increased and maintained to address the increasing need as research in biotechnology takes off.

Malawi has a low stock of science and technology personnel[18]. The National Science and Technology Policy requires Malawi to take significant strides in improving her stock of S&T human resources. With the exception of the S&T policy, which in any case addresses S&T needs generally and not biotechnology specifically, government and research institutions in Malawi and in the study countries do not have specific training strategies for building national capacity in biotechnology, intellectual property rights and biosafety. In Kenya and South Africa, research institutions have incorporated their training needs within the framework of individual research programmes (Odame *et al.*, 2000), while in Malawi, no institutional strategies for addressing capacity were identified. Capacity needs begin from the policy level, through the whole value chain ending with the end user of the technology. Capacity among policy makers particularly in Kenya, Malawi and in the ASARECA countries needs to be addressed urgently. Research and Development also lacks adequate trained and skilled persons. Capacity is likewise needed and in auxiliary fields such as intellectual property rights. Similarly, the levels of awareness creation, and the distributive system all require the input of trained persons.

The level of funding in biotechnology is low in the study countries with the exception of South Africa where there is significant investment in biotechnology. In Kenya, the National Biosafety Council charged with the administration of the Biosafety Regulations and Guidelines does not have any budgetary support from the government. It is an ad-hoc committee that is financed by the applicants. In Malawi, lack of financial resources was cited as a major setback in the development of capacity and undertaking initiatives for the formulation of the national biotechnology policy and strategy. Due to lack of sufficient public funds, public institutions rely heavily on international donors.

Venture capital in the study countries has not taken root. In South Africa however, there are some public and private sources of funding for start-up companies wishing to engage in biotechnology.

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18. The National Science and Technology 2002 estimate S&T personnel at 42 per million of the population against the recommended minimum target of 200 per million in 1980.

Intricately linked to financial resources and capacity is the physical infrastructure to implement biosafety. Resources such as appropriate facilities and equipment to carry out risk assessment and management are crucial to the implementation of biosafety. In respect to facilities, Kenya has numerous labs in the long established KARI stations and in academic institutions. However, as applications for research and use of modern biotech increase, these facilities will have to be upgraded with more efficient and appropriate biotechnology tools. With regard to modern biotechnology, a green house to handle GM crops is currently under construction at KARI's Biotechnology Centre in Nairobi. The green house has a Biosafety Level 2 specification and is a culmination of the maturity of the insect resistant maize project (IRMA) under CIMMYT in collaboration with KARI. It is expected that construction of the green house will be completed by the end of 2003. The recently launched Biosciences Initiative, a facility that is to be hosted at ILRI's headquarters in Nairobi, will no doubt contribute to increasing the capacity in terms of human resource and in infra structure as labs and other facilities for experimentation in molecular biotechnology are constructed.

South Africa has the most advanced physical infrastructure for biotechnology in Africa. There are specialized and expensive scientific equipment in some institutions. Several institutions involved in biotechnology have well-equipped facilities. An example is the CSIR Bio/Chemtek whose biotechnology unit boasts comprehensively equipped laboratories for molecular biotechnology, microbial propagation and plant tissue culture. It has green house facilities for transgenic crop trials. It offers services in DNA fingerprinting for plant and microbial genetic identification, characterization and verification, marker assisted selection in crop breeding programmes, GMO testing for foodstuffs and tissue culture services. The division has adequate human capacity to engage in biotechnology research having about 311 scientists and technicians about 40 of whom are senior scientists engaged in genetic transformation. The Agriculture Research Council (ARC) likely boasts experience and specialised capacity in conducting field trials.

Other constraints in the development of biotechnology include poor infrastructure. Modern communication systems are lacking in the study countries with perhaps the exception of South Africa. Biotechnology heavily relies on knowledge flows. Poor information technology - manifested in underdeveloped modern communication systems, access to email and internet - impedes the acquisition and exchange of necessary and relevant information vital in biotechnology.

Commercialisation and innovation

Among the study countries, only South Africa has achieved the commercialisation of biotechnology. In Kenya, the most developed GM crop, the sweet potato for resistance against the feathery mottle virus developed by KARI and Monsanto, is still at the field trials stage. In Malawi, experimentation of GM crops has not commenced. There is likely to be increased commercialisation of biotechnology in South Africa owing to the implementation of the National Strategy. The Strategy provides for the formation of BRICs, the National Bioinformatics Network, Public Understanding of Biotechnology, and Biobank among other programmes whose main objective or ultimate impact is to facilitate the commercialisation of biotechnology products and to increase capacity in the same.

Consortia made up of academic institutions, private companies and research councils make up the BRICs. There are currently 3 BRICs representing specific regions in the country. These BRICs receive funding from the government. Their goal is to address the gap existing between research

and innovation. Research and development, entrepreneurial services, technology platforms, intellectual property management, capacity development and business incubation are emphasised, funded, stimulated and facilitated under the BRICs the result being that viable businesses result from the research and resources available.

Other actors in the South Africa biotechnology landscape with activities likely to influence commercialisation and innovation include the GODISA programme which aims at increasing economic growth and employment creation through the enhancement of technological innovation, improvement in productivity and accelerated international competitiveness of South African small, medium and micro Enterprises (SMMEs). The programme supports an Innovation Support Centre, a Technology Demonstration Centre, and six Technology Incubators. Plans are underway for further funding of more technology incubators.

Venture capital has not taken much root in South Africa. There are however some public and private sources of funding for start-up companies wishing to engage in biotechnology. These include HBD Venture Capital, Bioventures, Brait Private Equity, Support Programme for Industrial Innovation, Technology and Human Resources for Industry Innovation, Industrial Development Corporation, Innovation Fund and Catalyst Innovations to name but a few.

Public perception and acceptance of biotechnology

Public awareness and understanding of biotechnology has great implications on the acceptance of products of biotechnology. The public in the study countries is largely unaware of the potential benefits and risks of the biotechnology. There is little to no effort by the governments and others involved in biotechnology to educate the public and raise awareness. In Malawi, there have been a few initiatives at addressing the situation mainly championed by Bio-EROC. In South Africa, where there is a growing anti-biotechnology movement, the government has included in its National Biotechnology Strategy a Public Understanding of Biotechnology (PUB) programme that aims to promote the understanding of biotechnology by disseminating factual, unbiased information.

Intellectual property

Issues of intellectual property rights (IPRs) are beyond the scope of this report but deserve brief mention. IPRs in agricultural research go beyond the conventional plant variety protection framework to patent legislation and its coverage of biological materials and processes, as well as issues about the countries' enforcement capacities. IPRs raise a new and distinct management challenge for existing research institutions, since they are generally not well equipped to deal with proprietary knowledge. This is with regard to the lack of negotiating skills and the limitations of the administrative and bureaucratic systems they have to deal with in the acquisition and protection of IPRs. At the national level, lack of IP policy, legislation on IP, effective enforcement mechanisms and capacity are some of the constraints that are increasingly impacting on agricultural research and transfer of technology. Countries must address these issues to fulfil their international obligations under the WTO TRIPs Agreement.

South Africa has five acts of parliament addressing intellectual property. These are the Patent, Trademark, Copyright, Registered Designs and Plant Breeders' Rights Acts. All are administered by the Department of Trade and Industry with the exception of the Plant Breeders' Rights Act, which is under the Department of Agriculture. However, this legislation is not clear about

biotechnology products and processes (OECD, 2003). The Patent office is a non-examining office. Nevertheless, the courts are considered to deal competently with intellectual property litigation (Wolson, 2001). In Malawi, intellectual property legislation comprises the Patents Act, 1958, the Registered Designs Act, 1958; the Trade Marks Act, 1958 and the Copyright Act, 1989. In Kenya, biotechnology inventions are protected under the Industrial Property Act, no. 3 of 2001.

In spite of having these statutes, IP protection in the study countries is weak. The general legal, policy and institutional framework for the protection of intellectual property particularly in the context of biotechnology is still far from adequate and is straddled with financial, technological and socio-economic constraints.

Summary and the way forward

With the exception of South Africa, the regulatory framework for biotechnology is still under development in the study countries. In Kenya, there is a draft Biotechnology Policy and the Biotechnology Development and Biosafety Bill, both of which are yet to be adopted. There are however Regulations and Guidelines which have been in place since 1998. Although lacking the force of law, these have enjoyed the goodwill of those involved in biotechnology and have facilitated the experimentation with genetic material in Kenya. Currently, there are applications involving five crops that have been made under these Regulations and Guidelines. They are however also under review to ensure their consistency with international requirements and with the proposed Bill and Policy. In Malawi, although there is a Biosafety Act, the implementing structure is not yet in place. Although respondents expressed an eagerness to start processing applications, it may not be practical at the moment as the biosafety secretariat and other administrative officers are yet to be appointed. South Africa is by far the most advanced in modern biotechnology. There is a working framework for the testing of GM crops under which numerous applications have been made since the implementation of the GMO Act in 1999. Under the ASARECA initiative, efforts are underway to develop a regional biosafety framework although emphasis, at this stage, is in developing uniform templates along which individual national frameworks are to be modelled. The regional biosafety framework is still in the conceptual stages. Applicants as of now will have to apply for the testing or commercialisation of GMOs in those countries that have a working biosafety framework.

With regard to human resource capacity and facilities, South Africa has the best infrastructure in place. There are many qualified scientists engaged in modern biotechnology. Institutional linkages between actors although requiring improvement are by far the most advanced in the study countries. Critical mass of qualified scientists engaging in modern biotechnology is yet to be achieved in Kenya. The same applies to Malawi, which likewise has limited capacity even in traditional biotechnology.

Way forward

Given the efficient framework, the excellent facilities and enough human resource capacity, South Africa is best placed to handle applications for testing the rosette resistant groundnut developed by ICRISAT. CSIR Bio/Chemtek boasts comprehensively equipped laboratories and offers services in GMO testing. The ARC has vast experience and capacity in conducting field trials and would be best placed to take on the testing at the field trial stage.

There is indication from Kenya that technologies once approved in South Africa are likely to receive timely approval although they have to undergo additional testing should the Biosafety Board deem it necessary. In the case of Malawi, lack of resources and capacity was cited as being the main set back to development of a functioning biosafety framework. It may be worth engaging persons in the biosafety committee in a collaboration where they would be involved in the testing of the rosette resistant groundnut in RSA as part of a capacity building exercise. These persons would subsequently import that knowledge to the biosafety system in Malawi and would serve as a link with the ICRISAT application when it is made in Malawi. In the case of Kenya, ICRISAT will have to collaborate with the KARI Institutional Biosafety Committee (IBC) through which the application to the National Biosafety Committee is to be made.

With regard to procedural aspects, the application process in South Africa is relatively shorter than that in Kenya. However, the time taken for conducting the laboratory tests, experimentation under contained facilities, confined field trials and national field trials could take as much as 10 years and would be a costly exercise. ICRISAT will have to take this into account in determining if such an investment is worthwhile.

Other aspects such as the social and economic impacts, which are beyond the scope of this study shall also have to be taken into account as these have implications on the deployment and acceptability of the GM crops in the market. Public awareness and matters relating to sensitising farmers and their communities have to be considered.

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The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) is a non-profit, non-political, international organization for science-based agricultural development. ICRISAT conducts research on sorghum, pearl millet, chickpea, pigeonpea and groundnut – crops that support the livelihoods of the poorest of the poor in the semi-arid tropics encompassing 48 countries. ICRISAT also shares information and knowledge through capacity building, publications and ICTs. Established in 1972, it is one of 15 Centers supported by the Consultative Group on International Agricultural Research (CGIAR).

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