Biosafety in Africa:
Experiences and best practices

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Important Acronyms

Acronym	Meaning
AATF	African Agriculture Technology Foundation
ABBC	Agricultural Biotechnology & Biosafety Committee
ABNE	African Biosafety Network of Expertise
ABS	Access and Benefit Sharing
ABSD	Agricultural Biotechnology for Sustainable Development
AC	Advisory Committee
AMCOST	African Ministerial Council on Science and Technology
AMCEN	African Ministerial Conference on the Environment
AML	African Model Law
ANB	Agency National Biosecurite
AU	African Union
BCH	Biosafety Clearing House
BMGF	Bill & Melinda Gates Foundation
BRIC	Biotechnology Regional Innovation Centres
CBD	Convention on Biological Diversity
CBSD	Cassava Brown Streak Disease
CEN-SAD	Community of Sahel-Saharan States
CFT	Confined Field Trial
CGIAR	Consultative Group on International Agricultural Research
CILSS	Interstate Committee for Reducing Desertification in the Sahel
CISANET	Civil Society Agriculture Network
CEPA	Centre for Environmental Policy Advocacy
CLI	Crop Life International
CMD	Cassava Mosaic Virus
CNA	Competent National Authority
COMESA	Common Market for Eastern and Southern Africa
COPAGEN	Coalition pour la Protection du Patrimoine génétique africain
CPB	Cartagena Protocol on Biosafety
CSIR	Council for Scientific and Industrial Research
DAES	Department of Fisheries, Department of Agricultural Extension Services
DARS	Department of Agricultural Research Services
DAHLD	Department of Nutrition, Department of Animal Health & Livestock Development
DCD	Department of Crop Development
DNA	Deoxyribonucleic acid
DREA	Department of Rural Economy and Agriculture
DST	Department of Science & Technology
EAC	East African Community
EC	Executive Council
ECOWAS	Economic Community of West African States
EFSA	European Food Safety Authority
FARA	Forum for Agricultural Research in Africa
FAO	Food and Agriculture Organization
FMENV	Federal Ministry of Environment
FRD	Foundation for Research Development, now the National Research Foundation, NRF
GE	Genetically engineered
GEF	Global Environment Facility
GiZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
HRST	Human Resources Science & Technology
HT	Herbicide tolerant
IBC	Institutional Biosafety Committee
ICGEB	International Centre for Genetic Engineering and Biotechnology
IDA	International Development Agency
IFPRI	International Food Policy Research Institute (IFPRI)
INERA	l'institut de l'environnement et de recherches agricoles,
IPPC	International Plant Protection Convention

IR	Insect resistant
ISAAA	International Service for The Acquisition of Agric-biotech Applications
ISF	International Seed Federation
LMO	Living Modified Organism
LUANAR	Lilongwe University of Agriculture and Natural Resources
MDG	Millennium Development Goals
MIBC	Ministerial Institutional Biosafety Committees
MoAFS	Ministry of Agriculture & Food Security
MSU	Michigan State University
MZUNI	University of Mzuzu
NABDA	National Biotechnology Development Agency
NBA	National Biosafety Authority
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NBO	National Biosafety Observatory
NBRC	National Biosafety Regulatory Committee
NCST	National Commission for Science & Technology
NEMA	National Environment Management Act
NEMBA	National Environment Biodiversity Act
NEPAD	New Partnership for Africa's Development
NEPAD/NPCA	New Partnerships for Africa's Development Planning and Coordinating Agency
NEWEST	Nitrogen-use Efficient, Water-use Efficient and Salt Tolerant
NSBC	National Scientific Biosafety Committee
NTO	Non target organism
OIE	World Organization for Animal Health
PBS	Program for Biosafety Systems
PP	Precautionary Principle
PPRSD	Plant Protection and Regulatory Services Directorate
PQs	Plant Quarantine Officers
PRA	Pest Risk Analysis
RIBios	Réseau Interdisciplinaire de Biosécurité
PUB	Public Understanding of Biotechnology (PUB)
RAEIN Africa	Regional Agricultural and Environment Initiatives Network-Africa
REC	Regional Economic Community
RNA	Ribonucleic acid
ToT	Training of Trainer
SAC	Scientific Advisory Committee
SADC	Southern African Development Community
SAGENE	South African Committee for Genetic Experimentation
SOP	Standard Operating Procedure
TAC	Technical Advisory Committee
TBT	Technical Barriers to Trade
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNIMA	University of Malawi
UNPCB	Burkina Cotton Growers' Union
USAID	United States Agency for International Development
VIRCA	Virus Resistant Cassava for Africa
VR	Virus resistant
WAEMU	West African Economic and Monetary Union
WEMA	Water Efficient Maize for Africa
WTO	World Trade Organisation

Foreword

New science and technology continue to play a critical role for enhancing agricultural productivity and economic growth in Africa and all over the world. The New Partnership for Africa's Development (NEPAD) is an initiative of African Union (AU) aimed at stimulating Africa's development. NEPAD Planning and Coordinating Agency (NPCA) programs offer holistic and integrated approaches for sustainable socio-economic development of the continent with a focus on agriculture and food security, climate change and natural resource management, regional integration and infrastructure, human development, as well as cross cutting aspects such as gender and capacity development.

NEPAD Agency has therefore been at the forefront of championing Africa's agricultural agenda for economic empowerment of AU member states. This is particularly important for Africa's development because agriculture continues to be a linchpin of economic growth and transformation in many African countries. Close to 65 per cent of Africa's population relies on agriculture for their livelihood, of which about 90 per cent are small scale farmers (IFPRI[1]). Thus, agricultural growth has been and will remain key to improving livelihoods. There is therefore an urgent need for deliberate efforts at stimulating growth in the agricultural sector in Africa. NEPAD Agency recognizes the pivotal role of new tools of biotechnology for stimulating sustained growth and development of the agricultural sector.

Cognizant of its important role, NPCA, as the technical body of the African Union Commission has prioritized Agriculture and Food Security as one of its six thematic areas for intervention. This is being done through a Comprehensive African Agricultural Development Programme (CAADP) established by the AU assembly in 2003. Through this program, NEPAD Agency hopes to achieve the vision of African leaders to raise agricultural productivity in Africa to at least six percent annually to contribute to poverty alleviation and elimination of hunger in Africa. To achieve this, CAADP requires countries to commit at least 10 percent of their national budgets to agriculture. Since 2003, over thirty countries have signed up to the CAADP Compact and eight have surpassed the 10 percent target (NEPAD Agency). CAADP brings together key players in agriculture – such as African leaders, policy makers, scientists, partners and farmers – to unleash agricultural growth and sustainable development on the continent.

NEW TOOL IN THE TOOLBOX - TRANSFORMING AFRICAN AGRICULTURE THROUGH BIOTECHNOLOGY

Agricultural productivity in Africa is constrained by a multiplicity of challenges requiring multi-prong innovative solutions. To help spearhead agricultural growth and enhance competitiveness, NEPAD facilitates demand-based adoption of safe and useful technologies including modern biotechnology. Indeed, African leaders saw great wisdom in harnessing the enormous potential of biotechnology to transform the agricultural landscape in Africa. In this regard and having at hindsight the controversial nature of this technology, a high level African Panel on Biotechnology (APB) was established through AU and NEPAD, to advise the AU, its Member States and its various organs, on current and emerging issues associated with the development and application of modern biotechnology in agriculture and other priority areas such as human and animal health, industry, forestry and the environment.

The panel report, called ***Freedom to innovate***[2], entreated African leaders to take advantage of biotechnology and outlined key recommendations and strategies to facilitate the process. This report was considered and endorsed by an Extraordinary Conference of the African Ministerial Council on Science and Technology

[1] http://www.ifpri.org/publication/agriculture-s-critical-role-africa-s-development

[2] Freedom to Innovate by Juma and Serageldin (2006) (http://www.nepadst.org/doclibrary/pdfs/biotech_africa_2007.pdf)

AMCOST) leading to the Cairo declaration3 in which African leaders made a commitment to "Establish mechanisms to accelerate and monitor the implementation of the Africa's Science and Technology Consolidated Plan of Action"(3). There is therefore political support at the highest level of governance for the harnessing of science and technology, in this case the enormous potential of traditional and modern biotechnology, in the agricultural transformation agenda being spearheaded by NEPAD.

OVERCOMING THE REGULATORY HURDLES: NEPAD'S 'CO-EVOLUTIONARY APPROACH'

Often, the challenge in accessing new science and technology in Africa is not so much the capacity to utilize the technology, but the lack of capacity to regulate the technology. Modern biotechnology is bound by several international instruments that require technical competence, infrastructure and institutional capacities to use, manage and regulate. Thus, one of the key recommendations of the APB was a co-evolutionary approach in which the technology is developed along with its regulation. To quote recommendation 13;
"*Biotechnology regulations should be based on a case-by-case approach, according to internationally-agreed rules and guidelines. They should adopt the 'co-evolutionary' approach in which the function of regulation is to promote innovation, while at the same time safeguard human health and the environment*" (2).

Weak capacity to regulate biotechnology crops and products is a barrier for African member states to harness its full potential, and there are clear examples to attest to this fact. In this context, through funding from the Bill and Melinda Gates Foundation, the NEPAD Agency in partnership with Michigan State University established the African Biosafety Network of Expertise (ABNE) to support African countries in building functional biosafety systems that will ensure the safe development and deployment of improved biotech crops.

EMPOWERING AFRICAN REGULATORS: BUILDING FUNCTIONAL BIOSAFETY REGULATORY SYSTEMS IN AFRICA

In its brief existence over the last five years, ABNE has gained credibility and experience in working with national governments towards building functional biosafety regulatory systems in Africa. The ABNE service network provides up-to-date training, information, technical assistance and networking opportunities in biosafety to regulators and their support systems.

This book is an outcome of lessons learned by ABNE through on the ground engagement with a number of African countries with varying levels of capacity in biosafety policy and practice. This book has been prepared to highlight progresses made, challenges faced and lessons learnt on issues of biosafety regulation and capacity building towards establishing functional biosafety systems in Africa.

I am delighted to recommend this book to stakeholders, especially regulators and policy makers in Africa, as ABNE has maintained fact-based neutrality and avoided taking positions that are the mandates of the national competent authorities and official advisory committees. It is my sincere hope that this book will help to further strengthen NPCA's efforts in encouraging information sharing and creating awareness among various stakeholders on issues of agricultural biotechnology and biosafety. I encourage readers to provide their feedback to the authors and the ABNE in order to help them improve upon their service provision to national and regional biosafety programmes in Africa.

Dr. Ibrahim Assane Mayaki, CEO, NEPAD Planning and Coordinating Agency (NPCA)

[3] Cairo Declaration: http://www.africa-union.org/root/au/auc/departments/hrst/biosafety/DOC/level1/EXT.AU.EXP.ST.DclI.13(II).Rev1.pdf

Preface

Biosafety involves the reduction and elimination of potential risks resulting from the use of biotechnology and its products. Biosafety has also been defined as the avoidance of risk to human health and safety, and to the protection of the environment, as a result of the use of genetically engineered organisms. A large amount of scientific knowledge and information, therefore, has a direct relevance to biosafety and this can create difficulties for the regulator in the accurate assessment of data in order to come to a rational and objective conclusion and make science-based informed decisions.

During the last quarter of the 20th Century, increased awareness and concern over the accelerating ecological degradation of the global environment culminated in the Convention on Biological Diversity (CBD). The objectives of this Convention were "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources". At that time, the CBD negotiators recognised that biotechnology could contribute to achieving these objectives, if it was developed and used within the necessary safety framework. As a result, procedures were developed to regulate the safe transfer, handling and use of any living modified organism (LMO) resulting from biotechnology that could have an adverse effect on the conservation and sustainable use of biological diversity. These procedures formed the basis of the Cartagena Protocol on Biosafety (CPB). The CPB came into effect in 2003 and since then Parties to the CPB have been busy formulating their national biosafety legislation. This has resulted in a great demand for biosafety-related information, training programmes, and capacity-building projects.

This period of heightened activity in environmental protection was further complicated by the rapid increase in cultivation of genetically engineered (GE) crops. In 2013, the global area planted to GE crops exceeded 175 million ha. From 1996 to 2013 the global area under biotech crops increased from 1.7 million ha to 175 million ha making biotech crops the fastest adopted crop technology in the history of modern agriculture (www.isaaa.org). The number of countries electing to grow biotech crops has been increasing consistently from 6 in 1996 to 27 in 2013. Of the 27 countries growing GE crops in 2013, 19 were developing countries. Another factor complicating the situation has been the public debate on GE Organisms (GEOs - also referred to as Genetically Modified Organisms or GMOs) which relates to the availability of objective, scientific information. Much of the available scientific information regarding GEOs is considered to be confidential by technology developers. In contrast, those in opposition to GMOs have taken to using highly visible and dramatic press announcements that are subjective and inaccurate.

Biosafety regulators and policy makers need to adopt an objective and impartial position in order to compile, coordinate and distribute unbiased and reliable information on biosafety issues. The purpose of this book is to present biosafety regulators and other interested stakeholders with a rational account of the experiences and best practices of selected African countries that have already adopted the cultivation of GE crops or are in the process of adopting them. The experiences of major GE producing countries in Asia such as India and the Philippines are also included for additional information.

The editors hope that the information contained in this book will help those countries wishing to adopt GE crops to formulate an effective and efficient biosafety regulatory framework which will be conducive to the development and implementation of the technology while at the same time providing the necessary safeguards to human and animal health and the environment. The editors would like to thank all those who contributed their time and effort to providing the information contained in the various chapters. We hope that the reader will find this information useful.

Dr. David P. Keetch (Goldamer Consulting cc), Prof. Diran Makinde (NEPAD/African Biosafety Network of Expertise (ABNE), Prof. Karim M. Maredia (Michigan State University), Dr. Cholani K. Weebadde (Michigan State University)

PART 1

BACKGROUND AND INTRODUCTION

Chapter 1. Biosafety issues in food and agricultural systems in Africa

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INTRODUCTION

The term biosafety has been defined as 'the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms' (FAO 2001). Genetically engineered organisms (GEOs/GMOs) are created by transferring genetic material from one organism to another through a process called genetic engineering (GE)[4]. The protein encoded by the introduced gene will confer a particular trait or characteristic to the recipient organism. Across the millennia, selective breeding and other such techniques have been used by humans to transfer genetic material within species complexes. New technologies such as GE permit more controlled gene transfers, and also allow for transfers among completely unrelated species (Philips 2008). The transferred genes or gene sequences are referred to as transgenes, and biotech plants are therefore also known as transgenic plants (the terms GE and transgenic are therefore used interchangeably in this chapter). GE has been used in agriculture to develop crops with increased crop yields; reduced needs for pesticides; enhanced nutrient composition and food quality; enhanced resistance to pests and diseases, and reduced costs for food or drug production, etc. (Takeda & Matsuoka 2008). While the commercial production of biotech crops with various agronomic beneficial traits has opened a new dimension for meeting food security challenges, it has also aroused tremendous debate and concern worldwide (Pretty 2001).

Over the last few years, there has been an increase in research and development in Africa aimed at developing transgenic crops to address constraints to agricultural productivity on the continent. These include projects aimed at developing, amongst many others:

- Insect-resistant (IR) maize in Kenya;
- IR cotton in Ghana, Kenya, Nigeria, South Africa and Uganda;
- Virus-resistant (VR) cassava in Kenya and Uganda;
- Fungus-resistant banana in Uganda;
- VR banana in Egypt;
- Drought-tolerant maize in Kenya, Mozambique, South Africa, Tanzania and Uganda, and;
- Nutritionally-enhanced sorghum in Burkina Faso, Kenya and South Africa (Karembu et al. 2009).

There are also countries that have approved the commercial release of biotech crops, for example IR maize in South Africa and Egypt, and IR cotton in Burkina Faso and South Africa. However, despite the fact that a growing body of evidence continues to document increased crop yields, increased farm income, health and environmental benefits associated with the cultivation of biotech crops (Adenle 2011), there has still been significant debate regarding possible risks to human and animal health, and to the environment, along with associated issues that could arise out of the adoption of such crops. An understanding of biosafety and its related issues is therefore important in helping to make correct decisions when facing and dealing with GE and biotechnology and their products (Lu 2008). This introductory chapter outlines some of the broad biosafety issues pertaining to these technologies that may be pertinent to food and agricultural systems in Africa.

[4] In this book the term GE (genetic engineering) is used instead of GM (genetic modification), GEO (genetically engineered organism) instead of GMO (genetically modified organism) and biotech crop or plant instead of GM crop or plant.

BIOSAFETY ISSUES/CONCERNS REGARDING GE CROPS

Most concerns about biotech crops can be placed into four broad categories - environmental, food safety, legal/policy, and socio-economic - although there are cross-cutting issues which may span more than one of these categories.

Environmental concerns

Environmental concerns relate to the potential impacts on the ecosystem from the adoption of GEOs. These could include the development of resistance/tolerance by target organisms; consequences of gene flow; negative impacts on non-target organisms (NTOs), etc. (Thies and Devare 2007).

Development of resistance/tolerance by target organisms

One of the concerns, with regard to IR transgenic crops, is the likelihood of the development of resistance/tolerance by insect pests to the transgenic compound in the host crops (Thies and Devare 2007), which may result in loss of usefulness of the control strategy. Pests are considered to have developed resistance if they become able to survive on a transgenic insecticidal plant from egg to adult and produce viable offspring (Andow 2008). A number of strategies to delay resistance development have been proposed, including:

- The use of GE varieties expressing very high toxin levels such that any individuals that may develop a degree of tolerance are still killed by the toxin upon consumption;
- Stacking different insect-resistance transgenes together in the same GE variety such that individuals that may not be susceptible to one toxin are killed by a companion toxin with a different mode of action; and
- Strategically planting non-resistant crops or plants nearby as 'refugia' to allow any resistant pest individuals that might develop to mate with non-resistant individuals in order to reduce the frequency of resistance genes in the pest population (Bates *et al.* 2005).

There are concerns that in traditional low input agricultural systems in Africa, whereby farmers save seed, resistance could develop relatively quickly. This is because the plants obtained from the saved seeds of IR transgenic crops may have lower toxin concentrations as compared to the parental generations, and hence permit insects with resistance genes to survive while those lacking the genes are eliminated, gradually resulting in an increase in the number of resistant individuals in the population, thereby hastening the development of resistance. In addition, seed-saving could result in heterogeneous mixtures of GE and non-GE plants in subsequent crops (Fitt et al. 2004), thus exposing the target organisms once more to sub-lethal toxin concentrations and hastening the development of resistance. In principle, however, the high crop diversity which characterises traditional low input agricultural systems in Africa (Boon 2004) should provide suitable refugia for insect-resistant biotech crops. In such systems, it is possible to have a number of non-transgenic crop species in close proximity to GE counterparts. Structured refugia (where areas under GE and non-GE crops are clearly pre-determined, as opposed to random patches of GE *versus* non-GE plants) are however recommended but their use could necessitate a change in agricultural practices. In addition, given the small farm sizes in many parts of Africa, there may be issues regarding the availability of spare land for refugia. Seed mixes (where GE and non-GE seed are pre-mixed prior to planting) have been proposed as one possible way to ensure farmers have sufficient area under refugia, but it is likely that this strategy may actually hasten the rate of resistance development, as discussed above.

Consequences of gene flow

Gene flow refers to the introgression of genes or genetic materials from one plant population into another. There are concerns that the integration of transgenes from a biotech crop into its non-GE counterpart (crop-

to-crop) and/or wild or weedy relatives (crop-to-wild relative) could trigger a range of possible environmental consequences (e.g. the creation of new weeds, and changing the fitness-related characteristics and loss of genetic diversity in the wild relatives of crop landraces caused by crop-crop and crop-to-wild relative transgene flow) (Lu 2008).

Genes introgressing into wild relative populations from crops may accentuate the characteristics of weediness in the wild relatives, leading to greater persistence and invasiveness of the wild relatives. Persistence refers to the tendency of a population to remain in a particular setting, over time after it is introduced. Invasiveness, on the other hand, refers to the ability of a population to spread beyond its introduction site and become established in new locations, where it may out-compete existing populations (Lu 2008). There are concerns, therefore, that if wild or weedy species receive genes which increase their fitness in a given environment then they may become more effective and aggressive weeds. With the advent of herbicide tolerant (HT) crops (those transformed by GE such that they are unharmed when sprayed with a broad-spectrum herbicide whilst crop-infesting weeds are destroyed), there is concern that problematic weeds tolerant to multiple herbicides may develop. In addition, those crop plants that emerge in a field in the following growing season as a result of seed spillage (i.e. volunteers) may develop into aggressive weeds after incorporating such transgenes (Ellstrand 2001). Volunteers may be a special problem in the agricultural crop rotations integral to farming systems in Africa (e.g. in South African cultivation, it is common to have maize-cotton-cowpea rotations).

The introgression of genes from one species into the gene pool of another unrelated species may alter the fitness of wild plants and consequently the dynamics of wild populations in two ways:

1) Cause local extinction of the wild population (in the case of reducing the fitness of wild plants) or;
2) Make the wild population more invasive and competitive (in the case of increasing the fitness of wild plants) (Snow et al. 2005).

The potential of transgenes to increase the invasiveness of a wild species is therefore reliant upon:

1) The presence of sexually-compatible wild relatives; and
2) The resultant impact of the introduced gene.

Prediction of the potential environmental consequences of transgene expression in wild relatives under different circumstances can be done through a systematic risk assessment. From the foregoing it is evident that the potential consequences of gene flow should be the focus of risk assessments, rather than gene flow *per se*. To minimise the possibility of transgene flow, a number of confinement strategies have been developed or proposed, applying physical or biological approaches. Information concerning the location and inter-fertility of compatible relatives, including those of most African crops, is generally available in the scientific literature; whilst information on invasiveness can be obtained from similar sources as well as indigenous knowledge. The most careful evaluation will be needed for those crops that are already invasive or that have invasive sexually-compatible wild relatives (Hancock 2003).

Negative impacts on non-target organisms

A non-target organism (NTO) is a plant or animal other than the one against which a specific GEO has been developed to have protection against. For example, a crop may be engineered for resistance to a specific insect pest (the target) and any other insects would then be considered non-target organisms. NTOs can be classified into the following categories:

- Pollinators and natural enemies of the pest, along with the wider category of beneficial species;
- Soil organisms;
- Non-target herbivores;

- Endangered and other species of conservation concern, and;
- Species which contribute to local biodiversity (Craig et al. 2008).

The potential impacts of GEOs on NTOs could be:

1) Direct toxicity through ingestion of a toxin produced by the biotech plant, or
2) Indirect via multi-trophic food chains, involving, for example, organisms not directly consuming the biotech plant but predating on prey that consume the transgenic plants (Gatehouse et al. 2011).

Possible effects of a biotech crop on NTOs should only be an issue if:

1) The crop has been engineered with a toxin that makes it insect-resistant and there are other organisms present that might be sensitive to the toxin; and
2) The toxin-sensitive organisms can encounter the toxin. NTOs are not expected to be affected by a biotech crop engineered with a trait such as tolerance to herbicide, virus or drought.

Food/Feed safety concerns

Other than the improvements which are intentionally introduced by the genetic modification, concomitant unintended differences may also occur. The latter have been defined as those differences which go beyond the primary expected effect(s) of introducing the target gene(s) (EFSA 2011). Potential adverse effects of GE food/feed which have raised concerns may include: toxicity of GE food/feed; allergenicity to GE food/feed; changes in nutritional value of GE food/feed; and emergence of resistant strains of bacteria (Key et al. 2008).

Toxicity

There is a remote possibility that GE could unintentionally introduce a toxic substance, for example a newly-expressed protein, or elevate the expression of an endogenous toxic substance(s) (Key et al. 2008). Conventional non-GE foods already contain a large number of toxic and potentially toxic products, and so the key question is whether a specific GEO could result in a new hazard. The potential toxicity of the protein expressed in a GE food is an essential component of the requisite safety assessment carried out during product development (Malarkey 2003). The safety assessment requires that the amino acid sequence of a novel protein is demonstrated to be sufficiently dissimilar to known protein toxicants, and that the new protein is rapidly digested under simulated mammalian gastric conditions. Animal bioassays may also be conducted on individual proteins to reveal any potential toxicity.

Allergenicity

Allergic reactions are hypersensitivity responses of the immune system that may occur in sensitive individuals after exposure to certain substances, usually proteins (Bush and Hefle 1996). Concern pertaining to allergenicity relates to:

1) The possibility that genes from known allergens may be inserted into crops not typically associated with allergenicity; and
2) The possibility of creating new, unknown allergens by either inserting novel genes into crops or changing the expression of endogenous proteins (Key et al. 2008).

A number of different organisations have produced guidelines and decision trees to experimentally evaluate allergenic potential (Metcalfe 2003).

Iteration of nutritional value

An unintended effect during the development of a biotech plant may be the lowering of its nutritional quality as compared to its traditional counterpart. This could occur by making nutrients unavailable or

indigestible to humans through the interference of key metabolic pathways and consequently affecting the production of nutritional components, hence compromising the nutritional quality of the product.

Antibiotic resistance marker genes

To facilitate the transformation process, a selectable marker gene conferring, for example, resistance to an antibiotic (e.g. kanamycin, which will kill a normal non-GE plant cell during in vitro culture), is often co-transferred with the gene of interest to allow the discrimination of GE tissue and regeneration of GE plants. There have been concerns that this approach presents a route to increasing the spread of antibiotic resistance to bacterial populations either in the soil or in the human gut after ingestion of GE food (Key et al. 2008). This could then render these antibiotics ineffective and/or make some strains of bacteria untreatable in human therapies. The increase of antibiotic resistance in the human population as a result of GE has yet to be demonstrated empirically. In addition, antibiotic resistance genes were originally isolated from bacteria and are already widespread in the bacterial population. Selection strategies that do not rely on antibiotic resistance have however been developed (Goldstein et al. 2005), and procedures to eliminate the selectable marker from the plant genome once its selection purpose has been fulfilled have also been designed (Hare and Chua 2002). These may be recommended for use in commercial GEOs.

In light of the food/feed safety issues outlined above, it is necessary that GEOs are assessed to determine the biological relevance and potential to cause harm of any intended or unintended differences. This is especially so given that differences between GE and non-GE crops (whether intended or not) may not necessarily be indicative of an adverse effect. Bodies like the Codex Alimentarius Commission, International Life Science Institute, and the Organization of Economic Cooperation Development have developed guidelines to assist the assessment of the safety of GE foods (Malarkey 2003). Generally, the safety assessment of GE plants and derived food and feed follows a comparative approach, i.e. the food and feed are compared with their non-GE counterparts (comparators). The comparators are crops that already have a so-called “history of safe use”. In the comparative safety assessment, the biotech crop and the comparators are assessed in both phenotypic as well as analytical terms, with the aim to identify differences between the two (types of) crops. Subsequent safety assessment steps then focus on any differences that have been identified, to determine whether these detected differences have any (unintended) toxicological and/or nutritional consequences. In practice, if differences have been identified, the subsequent steps of the food and feed safety assessment procedure are decided on a case-by-case basis, depending on the nature of identified difference(s) (Kok et al. 2010).

Legal/policy issues

A biosafety regulatory system should ensure the safe use of GEOs, with no significant risks to humans, animals, and the environment, while acknowledging that zero risk technologies are impossible. Assessing the risks of GEOs is regularly done by national regulatory systems strictly following scientific principles, with some authorities also including socio-economic and even political issues in their biosafety regulation. This last approach has been criticised as being outside of the scope of the risk assessment process, and at the same time, opening the GEO authorisation process to interference by special interest groups (Falck-Zepeda and Zambrano 2011).

National biosafety regulatory systems are the desired outcome of national biosafety laws and policies and attempts to harmonise them (or otherwise) with international agreements. Directly involved in the international regulation of GEOs are two international organisations: the Convention on Biological Diversity (CBD) and the World Trade Organization (WTO). The first specific international legal framework for biosafety regulation came from the Cartagena Protocol on Biosafety (CPB or “the Protocol”) adopted in 2000 as a supplement for the CBD. The Protocol has specifications concerning the safe use and transport of GEOs (or LMOs,] as the Protocol defines them), with the exception of those GEOs used for pharmaceutical production

and those products derived from GEOs that are not intended either for food or feed. The main provisions of the Protocol concern:

- The establishment of procedures for: advanced informed agreement (AIA) between trading Parties;
- Risk assessment;
- Handling, transport, packaging and identification of geos;
- A biosafety clearing house;
- Capacity building, especially for Parties from the developing world;
- Public awareness and participation; socio-economic considerations in decision-making; liability and redress; and
- Compliance (Gupta et al. 2008).

Under the WTO, the agreement on the application of sanitary and phytosanitary (SPS) measures, although not specifically focused on biosafety, concerns food safety as well as animal and plant health, while the technical barriers to trade (TBT) agreement concerns product standards more generally. There are also trade-related aspects of intellectual property rights (TRIPS) agreement setting minimum standards for intellectual property. These WTO agreements allow the member states to set the appropriate level of protection on a case-by-case basis, as long as trade discriminations on similar products are avoided. Similar to the Protocol, the WTO agreements can allow for socio-economic measures, but in very narrowly-defined instances (e.g. damage of production or sales, spreading of pests or diseases). The WTO agreements recommend the use of international standards developed by the Codex Alimentarius Commission, the World Organization for Animal Health (OIE) and the International Plant Protection Convention (Jaffe 2006).

Among the 163 signatories of the CPB, approximately 50 are from Africa (Table 1) yet few of these have biosafety laws and regulations in place. As such, the possibility of a conflict between domestic and international regulations is not yet a significant issue in the region. However, capacity building for biosafety regulators remains a key priority for African states (Obonyo et al. 2011). The main needs centre on: an overall lack of local funding, with too many projects depending on external funds; a general lack of awareness of biosafety issues by the public; a dearth in human capacity with experience in the specialist fields supporting GEO decision-making; the application of overly-stringent precautionary regulations in some countries; and the lack of harmonised biosafety regulations at the regional level (Mtui 2012). With respect to the latter, an attempt at harmonising African biosafety regulation occurred in 2007 with the presentation of the African Model Law on Biosafety in Biotechnology, which however takes a more stringent approach to GEO regulation than the Protocol (Gupta et al. 2008).

Table 1: African countries status on Cartagena Protocol on Biosafety*

Country	Signature	Ratification/accession	Entry into force
Angola		27 February 2009	28 May 2009
Benin	24 May 2000	2 March 2005	31 May 2005
Botswana	1 June 2001	11 June 2002	11 September 2003
Burkina Faso	24 May 2000	4 August 2003	2 November 2003
Burundi		2 October 2008	31 December 2008
Cameroon	9 February 2001	20 February 2003	11 September 2003
Cape Verde		1 November 2005	30 January 2006
Central African Republic	24 May 2000		16 February 2009
Chad	24 May 2000		30 January 2007

Comoros		25 March 2009	23 June 2009
Congo	21 November 2000		11 October 2006
Côte d'Ivoire			
Democratic Republic of the Congo		23 March 2005	21 June 2005
Djibouti		8 April 2002	11 September 2003
Egypt	20 December 2000	23 December 2003	21 March 2004
Equatorial Guinea			
Eritrea		10 March 2005	8 June 2005
Ethiopia	24 May 2000	9 October 2003	7 January 2004
Gabon		2 May 2007	31 July 2007
Gambia	24 May 2000	9 June 2004	7 September 2004
Ghana		30 May 2003	11 September 2003
Guinea	24 May 2000		10 March 2008
Guinea-Bissau			17 August 2010
Kenya	15 May 2000	24 January 2002	11 September 2003
Lesotho		20 September 2001	11 September 2003
Liberia		15 February 2002	11 September 2003
Libya		14 June 2005	12 September 2005
Madagascar	14 September 2000	24 November 2003	22 February 2004
Malawi	24 May 2000		28 May 2009
Mali	4 April 2001	28 August 2002	11 September 2003
Mauritania		22 July 2005	20 October 2005
Mauritius		11 April 2002	11 September 2003
Morocco	25 May 2000		24 July 2011
Mozambique	24 May 2000	21 October 2002	11 September 2003
Namibia	24 May 2000	10 February 2005	11 May 2005
Niger	24 May 2000	30 September 2004	29 December 2004
Nigeria	24 May 2000	15 July 2003	13 October 2003
Rwanda	24 May 2000	22 July 2004	20 October 2004
São Tomé and Príncipe			
Senegal	31 October 2000	8 October 2003	6 January 2004
Seychelles	23 January 2001	13 May 2004	11 August 2004
Sierra Leone			
Somalia			24 October 2010
South Africa		14 August 2003	12 November 2003
Sudan		13 June 2005	11 September 2005

Swaziland		13 January 2006	13 April 2006
Tanzania		24 April 2003	11 September 2003
Togo	24 May 2000	2 July 2004	30 September 2004
Tunisia	19 April 2001	22 January 2003	11 September 2003
Uganda	24 May 2000	30 November 2001	11 September 2003
Zambia		27 April 2004	25 July 2004
Zimbabwe	4 June 2001	25 February 2005	26 May 2005

* http://bch.cbd.int/protocol/parties/

Socio economic issues

Due to their centrality in current biosafety-related debates, socio-economic issues, although mentioned in the category above, are treated separately here. The Protocol gives parties discretion to decide whether or not to include socio-economic considerations in their decision-making processes. Currently, discussions revolve around the need to:

- Agree on a working definition;
- Develop specific methods for assessment;
- Determine the timing for such evaluations (ex ante/ex post), and;
- Establish if socio-economic considerations are to be mandatory or voluntary.

The issues included under the umbrella of socio-economics go beyond the strict interpretation of the term, and concern ethical, philosophical, and even religious issues pertaining to GEOs. However, there are a few regulatory systems that included socio-economic considerations in their specifications e.g. South Africa, and the AU Model Law (Falck-Zepeda and Zambrano 2011).

Beyond the regulatory conundrums, the socio-economic concerns brought by biotech crops in agriculture centre on the possibility of making farmers more vulnerable to market forces as a result of: changes in cost of agriculture and in agricultural practices; monopoly control of seed supply by trans-national companies; profit margins for farmers being squeezed between seed cost and declining world prices; possible replacement and thus loss of existing robust crop varieties and technologies; challenging market dynamics (Sengooba et al. 2009); and the fear of losing entire portions of foreign markets (Paarlberg 2006).

Conclusion

The genetic manipulation or modification of plants and animals to obtain improved products has been practiced for thousands of years. However, modern technology allows a greater specificity in employing genes to facilitate crop improvement. In assessing the safety of such products for humans, animal, and the environment, the public debate has evolved beyond technical scientific risk assessments, to encompass issues such as socio-economics. This chapter has outlined some of the key issues that have dominated public discourses on biosafety issues in Africa. However, given that Africa has varied agricultural systems (agro-ecological conditions, farming systems and types of crops) (Detthier and Effenberger 2011; FAO and World Bank 2001) some of the issues highlighted have pertinence in some settings and less relevance in others. It is therefore prudent to consider the issues on a case-by-case basis, rather than to generalise for all contexts.

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Chapter 2. Transgenic Crops in Africa: Current status and future prospects

DAVID KEETCH

INTRODUCTION

Food production and poverty reduction are among the main goals in efforts to promote socio-economic development in Africa. However, the ability to increase food production through expanding the current area under cultivation, increasing the application of agro-chemicals and extending the use of irrigation is limited. The key for Africa's future is rather to increase the per hectare yield of crops and to achieve this Africa needs to adopt technologies that will raise the production capacity of resource-poor farmers with access to few external inputs.

The use of biotech crops has been identified as one of the technologies that can help Africa increase crop yields and/or reduce production costs and post-harvest loses. However, by 2012 only four African countries had commercialized biotech crops.

A common concern of many national authorities in Africa is that the products of modern biotechnology might affect a nation's health and biodiversity, and thus raise health and environmental safety issues. However, transgenic crops (also known as genetically modified, genetically engineered or biotech crops) such as maize, soybean, rapeseed and cotton are being approved for commercial use in an increasing number of countries. From 1996 to 2013, there was more than a 100-fold increase in the area grown with transgenic crops worldwide, reaching a total of 175.3 million hectares in 2013. At this time there were 19 countries that grew 50 000 hectares or more of biotech crops. These countries were the USA, Brazil, Argentina, India, Canada, China, Paraguay, South Africa, Pakistan, Uruguay, Bolivia, the Philippines, Australia, Burkina Faso, Myanmar, Spain, Mexico, Columbia and Sudan in decreasing order of area of biotech crops cultivated.

Table 1 shows the 2012 global adoption rates for the four principal biotech crops (James 2012) and economic benefits for 1996-2011 and 2011 (Brookes & Barfoot, 2013).

Table 1: 2012 global adoption rates for biotech soybean, maize, cotton and canola and the economic benefits for 1996-2011 and 2011 only.

	Global area planted in 2012			Economic benefits	
Crop	**Total area**	**Area to biotech**	**% biotech**	**1996-2011**	**2011**
Soybean	100 million ha	80.7 million ha	81	$32.2 billion	$3.9 million
Maize	159 million ha	55.1 million ha	35	$30 billion	$8.6 million
Cotton	30 million ha	24.3 million ha	81	$32.5 billion	$6.7 million
Canola	31 million ha	9.2 million ha	30	$3.1 billion	$0.42 million

So far, most commercialisation has focused on these four crops, and the genetic engineering has involved two traits: insect resistance (IR) and herbicide tolerance (HT). Globally, a total of 18 million farmers grew biotech crops in 2013 with 16.5 million or 90% being small resource-poor farmers from developing countries (James, 2013).

The trend for an increase in the global area planted to transgenic crops seems set to continue, given the large range of biotech crops in research and development. In all countries official national approval has to be obtained for the commercial use of a biotech crop – whether for planting and growing or for use in human or animal foods. Such approval is always based on a safety assessment by the national authority, which in turn is based on scientific information regarding the crop, its specific trait and the receiving environment. It is important, therefore, for African governments to implement effective biosafety systems to ensure that good quality safety information is publicly available and, where possible, to adopt international approaches to risk and safety assessment that ensure the efficiency of the risk assessment process. Efficient biosafety systems are also important to protect agricultural and animal biodiversity and minimise unintended effects from influencing agricultural productivity as well as human health.

In developing countries it is common to not only check safety, but to also check the potential socio-economic impact prior to giving approval for release of a biotech crop. Such socio-economic assessments are generally made under the same conditions as the biosafety assessments. The processes for biosafety assessments and biotech crop approvals are developing in tandem and are being implemented in countries around the world. There are also international regulations in place to ensure that biotech crops and their products are transported safely between countries and not released in areas where their health and environmental safety has not been reviewed.

BIOTECH CROPS IN AFRICA

By 2012 four African countries had commercialized biotech crops: South Africa, Burkina Faso, Egypt and Sudan (James. 2012). These four countries together planted 3.2 million hectares (ha) of biotech crops. In 2013, however, only South Africa, Burkina Faso and Sudan grew GM crops as the Egyptian Government placed a temporary planting restriction on Ajeeb YG pending further review.

South Africa

- In 2013, 2.85 million ha of biotech crops were planted compared to 2.9 million ha in 2012.
- The total maize area in 2013 was 2.73 million ha, a slight reduction from 2012 (2.83 million ha) due to drought.
- The area of biotech maize in 2013 was 2.36 million ha compared to 2.42 million ha in 2012
- Over 18 million ha of GE maize (white and yellow) were planted in the period 2001 to 2013 without a single adverse report or a negative effect on human health, animal health or the environment.
- The total area planted to soybeans increased from 500, 000 ha in 2012 to 520, 000 ha in 2013. Of this, the adoption rate of HT soybeans was 92% (478, 000 ha).
- The total cotton area was 8,000 ha, with the adoption rate of GE cotton reaching 100%, 95% of which was the stacked Bt/HT traits and the remainder the HT trait which was used as a mandatory refuge.

Maize

- Of the total maize area of 2.73 million ha, 86.6% or 2.364 million ha were GE.
- Of this 2.364 million ha GE maize, 28.4% or 680, 342 ha were the single Bt gene and 18.2% or 409,032 ha HT. The remainder, 53.4% or 1.274 million ha was planted with stacked Bt/HT traits.
- White maize was planted on 1.580 million ha, 83.7% or 1.322 million ha were GE. Maize with a single Bt gene at 412, 707 hectares, HT trait at 165, 347 ha and Bt/HT stacked traits at 744, 725 ha.
- The yellow maize planting of 1.150 million ha comprised 90.5% or 1.041 million ha of GE, with 25.7% or 267, 635 ha for the single Bt trait, 22.4% or 243, 684 ha for HT, and 50.9% or 530, 065 ha for the stacked Bt/herbicide tolerant traits.

- Three trends have emerged from the collected data:
  1. The adoption rate of biotech maize is very similar for both white and yellow maize.
  2. The adoption rate of traits (insect resistance, herbicide tolerance and stacked) is similar for white and yellow maize.
  3. The adoption rate is reaching saturation. This is because not all maize plantings require Bt insect resistance due to cost saving when pesticide can be applied through overhead irrigation, when necessary. Furthermore, some plantings are not subject to severe stalk borer infestation.
- Over 92% of maize samples tested positive for GE traits, pure GE or co-mingled.
- A niche market has developed for non-GE maize.

Soybean

- In 2013 soybean was planted on 520, 000 ha.
- HT soybean was planted in 478, 000 ha or 92% of the total area planted.

Cotton

- Almost 8, 000 ha was planted to cotton in 2013.
- All of the cotton planted was biotech with 95% stacked (Bt/HT) and 5% RR used in 'refugia'.
- The stacked BtRR (Bollgard®II RR) was replaced with BtRRFlex . Virtually no conventional cotton was grown.

Approval of Biotech Crops

The field trial approvals for 2013 included:

- Biotech maize with drought tolerance;
- Stacked insect resistance/drought tolerance;
- Biotech cotton with insect resistance/drought tolerance;
- Biotech sugarcane with altered sugar ; and
- Cassava.

Economic Benefits

The economic gains from biotech crops for South Africa for the period 1998 to 2013 was US$1.15 billion and US$218.5 million for 2012 alone (Brookes and Barfoot, 2014). Studies have reported farm-level benefits that have translated into increased adoption rates. Yield gains exceeding 40% have been reported to in comparison with conventional cotton in addition to reduced spraying costs by 42%, reduced number of pesticide sprayings from 10 to 4 sprays per season, reduced production costs resulting in higher gross margins ranging from US$ 70–130 /2 ha of cotton (Ismael et al., 2002; Morse et al., 2005; AfricaBio, 2007).

A study by Gouse et al. (2005) on Bt maize involving 368 small-scale and resource-poor farmers compared to 33 commercial farmers was quite revealing. The commercial farmers were grouped into two, those cultivating under irrigation and those under rain-fed production systems. Higher yields were observed for farmers who cultivated under irrigation systems. This group obtained 12.1 MT /ha, an 11% increase over the previous year's yield. These farmers also obtained cost savings in insecticide use of US$18/ha representing a 60% reduction and an increased income of US$117/ha. Farmers who grew Bt maize under rain-fed conditions obtained 3.4 MT/ha, also an 11% yield gain over the previous year's yield. Cost savings on insecticide use for this group was US$7/ha representing a 60% reduction and the combined effect was an increase in income of US$35/ha.

The smallholder Bt maize farmers group was compared to others who grew conventional hybrid and open pollinated maize varieties in terms of yield per hectare (Gouse et al., 2005). Bt maize recorded yield gains of 31% and 134% over conventional hybrids and open-pollinated varieties, respectively. Another study that used longitudinal study over 9-year period (2000 to 2008) reported that small-scale Bt maize farmers in South Africa gained an additional US$ 267 million (Gouse et al., 2008).

Burkina Faso

Cotton is the principal cash crop in Burkina Faso generating over US$ 300 million in annual revenues representing about 60% of the country's export earnings (ICAC, 2006). Despite this achievement, the agricultural sector in the country is beset by a number of challenges including low yields, drought, poor soil, insect pests and lack of infrastructure and inadequate credit. Studies have also reported crop losses in excess of 30% due to insect-pests of cotton (Goze et al., 2003; Vaissayre and Cauquil, 2000).

At the national level, the annual cost for insecticides for the control of cotton bollworms and related insect-pests was around US$ 60 million (Toe, 2003 cited in Karembu 2009). However, insecticides proved ineffective, with losses due to bollworm as high as 40% even with full application of insecticides (Traoré et al., 2006). As a result of this damage, Burkina Faso's cotton production decreased to 0.68 million bales in 2007/08 from 1.3 million bales in 2006/07.

To address this situation and after 5 years of fields trials, approval was granted for the commercial cultivation of Bt cotton. In 2008, Burkina Faso planted approximately 9, 000 hectares of Bt cotton for seed production and initial commercialization, becoming the 10th country globally to grow commercial Bt cotton. Vitale et al. (2008) estimated that cultivation of Bt cotton would result in yield increases of 20% and a decreased need for insecticides that would generate US$ 106 million per year.

Cotton

- In 2012, of a total of 615, 795 ha were planted to cotton, 313, 781 ha or 51%, were planted to Bt cotton. In 2013 a total of 474, 229 ha of Bt cotton were grown.
- There were about 100, 000 Bt cotton farmers in 2012, majority of whom were small-holder resource-poor farmers.
- Burkina Faso started to plant Bt cotton in 2008 with approximately 9, 000 ha, this area increased to 116, 000 ha in 2009, 260, 000 ha in 2010, 247, 000 in 2011, 313, 781 in 2012 and finally 474, 229 ha in 2013.
- The adoption rate of Bt cotton in Burkina Faso has increased from 2% of 475, 000 cotton ha in 2008 to 51% or 313, 781 ha in 2012.

Economic Benefits

In 2009, a survey conducted by Vitale et al. (2010) showed that:

- The yield advantage of Bollgard®II over conventional cotton was 18.9%.
- Yield increase plus labour and insecticide savings (2 rather than 6 sprays) resulted in a gain of US$65.57 per ha compared with conventional cotton; this translated to a 206% increase in cotton income.
- The main benefit of Bollgard®II derives from the increase in yield whereas the reduction of production costs associated with four less insecticide sprays is offset by the higher cost of the seed. Extrapolating from the 2011 data the national benefit for biotech cotton in 2012 was about $30 million.

- In 2011 the average yield increase for Bt cotton over conventional cotton was 19.7% and insecticidal sprays were reduced from 6 to 2. Profit increase by 5% to US$95.25/ha. Extrapolating the data from 2011, the national benefit from Bt cotton in 2012 was about US$30 million.

Egypt

- In 2012, Egypt planted 1, 000 ha of Bt yellow maize (IR MON 810) known in Egypt as Ajeeb YG® compared to 2, 800 ha in 2011. In 2013, Egypt officially did not grow any GM maize due to a temporary restriction imposed by the Egyptian Government.
- Egypt was the first North African state to adopt biotech crops when it planted Bt maize in 2008 on 700 ha.

Maize

- Egypt grew approximately 660,000 hectares of conventional maize in 2010, and imports annually 4.5 million tons of yellow maize valued at US$1.3 billion.
- Of the 660, 000 ha of maize, 160, 000 ha (25%) are yellow maize and 500, 000 ha are white maize.
- The biotech maize hybrid is resistant to three maize insect pest borers (Massoud 2005).
- Field trials that were conducted in Egypt from 2002 to 2007 indicated that the yield of Bt yellow maize could be increased up to 30% over conventional yellow maize hybrids.

Economic Benefits

In 2009, for IR Bt maize there was an increase in yield of US$267 per ha, plus an insecticide saving equivalent to US$89 per ha. This gave a total gain of US$356 per ha, minus the additional cost of seed per ha at US$75 for a net benefit per ha of US$281. Extrapolating from these data, the economic benefits from planting 1, 000 ha of Bt maize in 2012 is about US$281, 000.

Sudan

In 2012, Sudan became the fourth African country to commercialise a biotech crop – Bt cotton.

Cotton

- A total of 20,000 ha of Bt cotton were planted in the Sudan by about 10,000 smallholder farmers.
- The GM cotton variety planted is named “Seeni 1”and was developed in China.
- The availability of GM cotton seed was a limiting factor in 2012, but in 2013 the area tripled from 20,000 ha to 62,000 ha and is expected to expand even further.

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STATUS OF BIOTECH CROPS IN AFRICA

The current status of biotech crops in Africa is shown in Table 2 (James, 2012).

Table 2: The current status of biotech crops in Africa in 2012.

Country	Crop	Trait	Stage
Burkina Faso	Cotton	Insect resistance	Commercialised
	Cowpea	Insect resistance	Field trials
	Sorghum	Insect resistance	Field trial pending
Egypt	Maize	Insect resistance	Temporary restriction
		Insect resistance	Field trials
	Cotton	Insect resistance	Field trials
	Potato	Insect resistance	Field trial postponed
		Viral resistance	Field trial postponed
	Rice	Insect resistance	Greenhouse trials
	Strawberry	Viral resistance	Greenhouse trials
	Sugarcane	Insect resistance	Field trials
		Fungal resistance	Field trials
	Wheat	Drought tolerance	Field trials postponed
		Fungal resistance	Field trials
		Salt tolerance	Field trials postponed
	Tomato	Vial resistance	Greenhouse trials
		Salt tolerance	Greenhouse trials
Ghana	Cowpea	Insect resistance	Trial approval pending
Nigeria	Cowpea	Insect resistance	Field trials
	Cassava	Biofortified	Field trials
	Sorghum	Biofortified	Field trials
Kenya	Maize	Insect resistance	Field trials
		Drought tolerance	Field trials
	Cotton	Insect resistance	Field trials
	Cassava	Viral resistance	Field trials
		Biofortified	Field trials
	Sweet potato	Viral resistance	Field trial pending
	Sorghum	Biofortified	Field trials
Malawi	Cotton	Insect resistance	Field trials
Mozambique	Maize	Drought tolerance	Trial approval pending
Uganda	Cotton	Insect resistance/ herbicide tolerance	Field trials
	Banana	Nematode r5esistance	Field trials
		Bacterial wilt	Field trials
		Biofortified	Field trials
	Maize	Insect resistance	Field trials pending
		Drought tolerance	Field trials
	Cassava	Viral resistance	Field trials
	Sweet Potato	Viral resistance	Field trials pending
		Insect resistance	Greenhouse trials
South Africa	Maize	Insect resistance	Commercialised
		Herbicide tolerance	Commercialised
		Insect resistance/ herbicide tolerance	Commercialised
		Insect resistance	Field trials
		Herbicide tolerance	Field trials
		Insect resistance/ herbicide tolerance	Field trials
		Drought tolerance	Field trials
	Cassava	Starch enhanced	Field trials
	Cotton	Insect resistance	Commercialised

		Herbicide tolerance	Commercialised
		Insect resistance/ herbicide tolerance	Commercialised
		Insect resistance/ herbicide tolerance	Field trials
		Herbicide tolerance	Field trials
	Potato	Insect resistance	Field trials
	Sorghum	Biofortified	Greenhouse trials
	Soybean	Herbicide tolerance	Commercialised
	Sugarcane	Alternative sugar	Field trials
Tanzania	Maize	Drought tolerance	Trial approval pending

FUTURE PROSPECTS

The largest group of potential beneficiary countries that have yet to adopt and benefit from biotech cotton are in sub-Saharan Africa where at least 15 countries, each growing more than 100 000 ha of cotton, for a total of almost 4 million ha of cotton could benefit significantly, plus Egypt in North Africa.

Future prospects for Africa look encouraging with Cameroon, Egypt, Ghana, Kenya, Nigeria, Malawi and Uganda presently conducting field trials with biotech crops. Trials focusing on Africa's priority staple crops, such as maize, cassava, cowpea, banana, sorghum and sweet potato, have made good progress while trials are underway in Kenya, South Africa and Uganda on drought tolerant maize through the WEMA (Water Efficient Maize for Africa) project.

Biotech crops have the potential to make a substantial contribution to achieving the 2015 Millennium Development Goals (MDG) of cutting poverty in half, by optimizing crop productivity. This goal can be expedited by public-private sector partnerships, such as the drought tolerant maize for Africa project supported by the Bill and Melinda Gates Foundation.

Globally, there are numerous new products at different stages of research and development. They include:

- Insect resistance – high priority is now being given to the control of sucking insect pests as they have become the top priority now that the previously top priority bollworm pests are effectively controlled by current Bt crops.
- Disease resistance to the pathogens *Fusarium, Rhizoctonia, Pythium* and cotton leaf curl virus.
- Crops that are more resistant to abiotic stress such as drought tolerant maize and cotton that is more tolerant to salinity, high and low temperatures and water logging.
- Crops with greater efficiency to use soil nutrients.
- Cotton with improved fibre, better oil quality and gossypol-free seed.

Climate change is a major threat to sustainable growth and development in Africa, and the achievement of the MDG. According to the Intergovernmental Panel on Climate Change (IPCC 2012), the impact of climate change is expected to be greater in low latitude sub-tropical and tropical developing nations, where farmers have more limited ability to adapt. Africa is particularly vulnerable to the effects of climate change including reduced agricultural production, worsening food security, the increased incidence of flooding, drought and disease and an increased risk of conflict over scarce land and water resources (OECD 2007).

The importance of climate change and concerns about the environment have implications for the future of biotech crops, which contribute to a reduction of greenhouse gases and help mitigate climate change by:

- Reducing carbon dioxide (CO_2) emissions through reduced use of fossil-based fuels, associated with fewer insecticide and herbicide sprays;
- Promoting the use of conservation tillage (need for less or no ploughing facilitated by herbicide tolerant biotech crops) for GE food, feed and fibre crops.

With climate change, droughts, floods, and temperature changes predicted to become more prevalent and more severe in Africa, there will be a need to develop crop varieties and hybrids that are well adapted to more rapid changes in climate. Several biotech tools, including tissue culture, diagnostics, genomics, molecular marker-assisted selection (MAS) and biotech crops can be used collectively to speed up the breeding process.

One factor that is hindering a faster adoption of biotech crops is the current low level of awareness of biotechnology and biosafety in Africa. At present only 12 African countries (Burkina Faso, Ghana, Kenya, Malawi, Mali, Mozambique, Nigeria, South Africa, Tanzania, Togo, Uganda and Zimbabwe) have established regulatory systems, 5 countries are at an interim stage and 32 countries have little or no interest in developing regulatory systems (ABNE, 2012). To counter this situation, vigorous awareness activities are needed. Capacity building for GE and non-GE products must be enhanced. There is also a need for the regional harmonization of biosafety legislation and regulations. It is crucial that Africa accepts biotechnology and develops products that will be appropriate to its needs. Above all, Africa must develop the capacity to be its own spokesperson on the safety and the risks of biotech crops.

CONCLUSION

The capacity of biotech crops to contribute to the sustainability of food production in Africa is significant and it can help the continent overcome the formidable challenges associated with climate change and global warming. Biotech crops can also increase productivity and income, and hence serve as an engine for rural economic growth that can contribute to the alleviation of poverty for Africa's small scale and resource-poor farmers.

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Chapter 3. Environmental biosafety issues associated with GE crops in Africa

MOUSSA SAVADOGO

INTRODUCTION

Africa is endowed with rich and varied biological resources (UNEP 2010). At the same time the continent is faced with environmental challenges that negatively affect its economic progress. Among the most serious environmental concerns are deforestation, desertification, degradation and fragmentation, air and water pollution and loss of soil fertility (http://wikis.lib.ncsu.edu/). These cause a dramatic decline in local biodiversity and such concerns are aggravated by poverty and the need for survival that inevitably lead to the over-exploitation of local natural resources. It is estimated that if such a trend is maintained the environmental problems could double or triple by 2025 when the total population of the continent reaches over one billion (http://www.articlesbase.com/). It is hoped, however, that with the advent of new agricultural technologies including genetic engineering, farmers will have the opportunity to use more efficient practices that will significantly reduce the pressure on the environment through increased agricultural productivity and a reduction of chemical pesticides use. Indeed on the 17th anniversary of the first commercial cultivation of a genetically engineered crop, it was estimated that this technology had contributed globally to a better environment by saving considerable amounts of pesticide active ingredient, reducing CO_2 emissions and conserving biodiversity on millions of hectares of land (James, 2013). Paradoxically, in Africa the adoption of the same technology is being slowed down if not rejected for the same reason – the need to protect the environment that the new agricultural technology will help save. However, African countries such as Burkina Faso, which have taken the lead in adopting Bt cotton, have seen their environmental conditions improve through a significant reduction in the use of chemical pesticides (Vitale et al. 2011).

This chapter briefly reviews the environmental issues, especially those associated with the loss of biodiversity in Africa, the perceptions on the impact of GE crops on the environment, the GE crops of interest to Africa that are either commercially cultivated or under development and the critical information necessary to perform an assessment of their potential for gene flow and weediness.

CRITICAL ENVIRONMENTAL ISSUES IN AFRICA

The environment of sub-Saharan Africa is affected by various factors including deforestation, desertification, degradation and fragmentation, all of which are responsible for a dramatic loss of biodiversity. Deforestation refers to the clearing and destruction of forests in order to create land for agriculture, provide wood for domestic needs of energy and/or create space for building settlements (http://wikis.lib.ncsu.edu/index.php/). It is estimated that about one million km^2 of forest is destroyed every 5 to 10 years and as a result the forest land has declined from 16 million km^2 a century ago to only half today (Braun and Ammann, 2003). Between 1981 and 1990 around 25% of African forested land was converted into agricultural land (Mabogunje, 1995). However in a number of countries, including Nigeria and Niger, governments have been making efforts to mitigate such extensive loss of forest by planting trees and trying to preserve existing ecosystems (Niamey, 2005).

Desertification refers to the expansion of desert conditions as a result of many factors including drought and the overuse of local ecosystems. Degradation refers to the deterioration in the density or structure of vegetation cover or species composition (Mabogunje, 1995). Selective logging without replanting, removal of

plants and trees that are of importance in the life cycle of other species and soil erosion are the main causes of degradation.

Fragmentation is caused by various forms of human intrusion in forest areas, such as road construction. It causes increased vulnerability of natural ecosystems through changes in micro-climates and subsequent loss of native species and invasion by alien species (Mabogunje, 1995).

Deforestation, degradation fragmentation and desertification all cause a sever degradation in natural habitat which is the primary threat to biodiversity, not only in Africa but also globally. In addition to habitat loss, pollution and invasive species are also considered major threats to wild biodiversity (Millennium Ecosystem Assessment 2005).

To protect the environment, the main question for most African governments is how to reverse the loss of biodiversity caused by the destruction of the natural habitat. In answer to this question, Braun and Ammann (2003) suggested that the single most promising way to avoid habitat destruction was to increase farm yields in a process that has been called the "Second Green Revolution."

PERCEIVED CONCERNS ASSOCIATED WITH GE CROPS IN AFRICA

The global community is concerned that modern agricultural biotechnologies such as genetic engineering, like other new technologies, may hold risks for the environment and/or human and animal health. For this reason, crops and products developed through genetic engineering are regulated to the extent of possibly making it the most regulated of all agricultural technologies (Braun and Ammann 2003). Concerns that are generally raised imply that the cultivation of GE crop varieties could negatively impact the environment through unintentional transfer of novel genes and traits to non-GE plants. This could result in the development of herbicide resistant weeds and/or more invasive weed species as well as the development of resistant pests. In addition, more specific concerns have been raised in Africa. It is thought that GE crops might have a negative impact on African traditional crops and land races and on the local biodiversity. This would result in an increased dependency of smallholder farmers on multinational seed companies. Africans fear that such a situation would give multinational companies full control on the continent's genetic resources.

Many other misperceptions and myths are being spread in the continent with regard to GE technology. Some feel that the fact that Cartagena Protocol on Biosafety deals with potential risks means that GE products are risky. Others argue that if GE crops were safe, Europeans would not have adopted their current restrictive attitude. One parliamentarian stated that "we fear this technology and will continue to fear it because it is new and we don't know the long term effects". Another argument insists that Africans' lack the capacity to fully assess and properly manage any risks associated with GE crops. They compare African states with those in developed countries which possess necessary resources to address any issues, should they occur. For example if a particular GE product is found unsafe after it is released to public in developed countries, it is easily recalled; whereas in Africa this may not be possible. In some cases there is expression of lack of trust (Obidimma and Rotman 2012) and advocate the development of "home-made" GE products with the feeling, "Why should it come from outside the continent?" It is also claimed that biodiversity in Africa is very complex that it makes the risk assessment process much more difficult with a higher level of uncertainty (African Union and GIZ, 2011).

KEY PRINCIPLES OF ENVIRONMENTAL RISK ASSESSMENT OF GE CROPS

Extensive scientific research has led to systematic protocols to measure the potential risks posed by GE crops to the environment. Assessment of these risks is based on the logical definition of risk being a function of hazard and exposure. This follows the same fundamental principles as other risk assessment schemes.

Unfortunately, hazard is often perceived to be the only function of risk. However, unless exposure is taken into consideration, hazard is a poor assessment of risk. For example, electricity or fire can be major hazards only if exposure is not carefully controlled.

The typical logical framework designed for risk assessment entails the following key steps:

- Identification of hazards;
- Evaluation of the magnitude and duration of identified hazards;
- Estimation of the likelihood of occurrence of identified hazards; and
- Account for the nature and importance of the scientific uncertainty in each phase of the process.

Thus for each concern raised about a genetically engineered organism (GEO), scientists identify the hazard at the root of the concern; the likelihood that this hazard will materialize; the consequences should it materialize; and whether risk management measures can be applied to reduce any identified risk. When the level of risk is known for all the identified hazards the decision makers determine whether the risk is acceptable for local communities. Biosafety reviewers around the world rigorously follow these logical steps to arrive at credible estimates for risk and to define management measures as proper management of risk leads to safety. African scientists are a part of this network and African decision makers need to trust their national scientists who are working in partnership to achieve international safety standards.

There is consensus that three fundamental questions must be addressed in conducting risk assessments, regardless of where the biotech crop will be grown and the local levels of biodiversity. These are:

1) Whether GE technology will increase plant invasiveness or weediness and cause the transgenes to exhibit a competitive advantage (be more fit) over the natural forms and disturb local ecosystems;
2) Whether GE crops or derived plants will have a negative impact on non-target species present in the environment; and
3) Whether GE crops will negatively impact the non-living components of the environment, damaging or polluting the air, soil or water.

In addressing these concerns there is also consensus that a science-based environmental safety evaluation must focus on:

- The nature of the crop plant;
- The characteristics of the introduced trait;
- The characteristics of the environment where the GE crop will be released; and
- The interactions among these components (Cartagena Protocol on Biosafety 2000; Lu et al., 2012).

Gene movement from GE crops to non-GE relatives, wild or cultivated, is an important consideration, taking into account that the level of gene flow is influenced by the proximity of sexually compatible relatives and the pollination of the biotech crop, especially the degree of outcrossing and the level of viable seed and progeny (Hancock et al., 1996). This information is known for most of the major crop species grown in Africa.

In addition to concerns expressed about the natural environment, biotech crop cultivation has also raised issues about coexistence between GE and non-GE crops and about pest-management. As with pollen flow, guidelines have been developed to address these issues.

CRITICAL INFORMATION FOR THE ESTIMATE OF GENE FLOW AND WEEDINESS POTENTIAL OF GE CROPS IN AFRICA

It is important to note that the GE crops being cultivated or under development in Africa are not new to African scientists or farmers. They are African crops in which specific traits are incorporated to improve their tolerance to pests or abiotic stresses, or to enhance their nutrient content. Only three or four of the

thousands of genes in a GE crop are modified. Wide knowledge and familiarity with these local crops makes it possible to conduct science-based risk assessments focusing on the characteristics of the crop species, the introduced traits and the local environment in which the GE crop will be cultivated.

Each crop species may have compatible relatives in the growing area with which hybridization can occur. Developers, including African scientists, provide information on the potential for outcrossing from a GE crop via pollen flow to other plants of the same species or to wild relatives in the environment. Cultivation of GE crops that do not have wild relatives in Africa does not pose an environmental threat associated with gene flow to wild species. Further risk analysis of the impact of pollen flow is only needed to understand gene flow to the same crop species in the release area. For example, there are no wild relatives of maize in Africa, therefore, pollen flow from GE maize to wild relatives is not an issue. However, Africa is the centre of origin for sorghum, so the impact of pollen flow from GE crops to wild species needs to be addressed wherever wild species are present in growing areas and are sexually compatible.

The mode of pollination, the level of self-fertilization and the viability of seed from outcrossing are important considerations. Sorghum for instance, a predominantly self-pollinated species, outcrosses readily with its sexually compatible wild and weedy relatives when grown in close proximity, have overlapping flowering times and share a common pollination mechanism. This implies that genes from GE sorghum would most likely escape into the native populations. The overarching question here, therefore, is what would be the consequences of such a transgenic trait in the wild and not whether gene flow actually occurs. On the contrary, other self-pollinated crops such as cotton and cowpea have a very low probability of hybridizing with neighbouring relatives, so isolation distances of less than 100 m should effectively prevent pollen-mediated gene flow from GE cowpea. Other species, such as banana and many sweet potato varieties, are predominantly sterile, making hybridization with relatives highly unlikely. Levels of self-fertilization and the viability of hybrid seed are particularly important issues to consider when developing strategies for managing coexistence of GE and non-GE crops.

In performing safety evaluations, newly introduced traits are assessed for their potential to increase plant fitness or produce substances that could be toxic to non-target organisms. Pest resistance traits such as those conferred by Bt genes can only have an environmental impact if the populations of the wild relatives are controlled by the same pests in the natural environment. Nevertheless, it has been recently proved that the widespread adoption of Bt cotton and the subsequent reduction of the usage of broad spectrum insecticides have significantly promoted the biological control services in ecosystems in Northern China (Lu et al., 2012).

Herbicide tolerance traits generally do not increase the fitness of progeny from cross pollination with wild species since herbicides are not applied in unmanaged environments. Abiotic stress tolerance traits such as drought tolerance or salt tolerance may have an environmental impact since they allow crops to grow where they might otherwise have been restricted by the abiotic stress. Typically, nutritionally enhanced traits (e.g. iron, zinc or vitamin A) are not known to produce toxic substances and would, therefore, not be expected to have negative effects on the environment.

EXAMPLES OF GE CROPS IN AFRICA AND THEIR BIOLOGY ELEMENTS NECESSARY FOR THE ESTIMATE OF GENE FLOW AND WEEDINESS POTENTIAL

Following are some genetically engineered crops that are of particular interest to Africans and are either commercially cultivated or under development. The key biological elements necessary for biosafety regulators to assess their potential for gene flow and weediness are also summarized.

Banana (*Musa spp.*)

Bananas are not only a staple food for millions of Africans but also they are a source of income, especially in East and Central Africa (Viljoen, 2010). Currently genetic engineering is being used to improve the level of iron and vitamin A in bananas (Wall 2006) and also to improve yield through enhanced resistance to a number of pests including bacterial wilt, nematodes and weevils (FARA website, http://www.fara-africa.org/biotech-management-africa/; Kasozi, 2010). Transgenic banana trials are taking place in Uganda and Kenya.

Banana has its centre of origin in Southeast Asia, but its primary centre of genetic diversity is in the lowlands of West Africa and South East Asia while the secondary centre of genetic diversity is in East Africa. No close wild relatives and no free-living populations of bananas are found in Africa. Though banana pollen is dispersed by insects, cultivated bananas are sterile triploids and therefore do not outcross. Banana is not propagated by seeds or rhizomes and therefore cannot pose a weed problem. In conclusion, based on almost zero potential for gene flow combined with very low potential for weediness and invasiveness the overall assessment leads to the conclusion that GE bananas have negligible potential impact on the environment as far as gene flow and weediness are concerned . However, its potential impact on non-targets organisms needs to be assessed on a case-by-case basis, taking into account the products of the new gene inserted and the trait conferred.

Cassava (*Manihot esculenta*)

Cassava is a drought and heat tolerant crop that contributes to the food security of millions of people in Sub-Saharan Africa (Hillocks, 2002). Nevertheless, cassava farmers are faced with two major challenges. First, cassava production is hampered by several pests such as the cassava mealybug (Phenacoccus manihoti) and cassava green mite (Mononychellus tanajoa) which can cause up to 80% crop loss. Secondly, cassava roots have a relatively low nutritional value, especially with respect to vitamins and other micronutrients (Sayre et al., 2011) and this is a problem for the millions of people who rely on cassava as a staple food. Efforts are underway using genetic engineering to develop cassava varieties resistant to the Cassava Mosaic Virus (CMD) and Cassava Brown Streak Disease (CBSD) (Taylor et al., 2012) as well as cassava with enhanced vitamin A. Field tests are currently taking place in Uganda, Kenya and Nigeria (Taylor et al., 2012, The Donald Danforth Plant Science Center, www.danforthcenter.org/science/programs/international_programs/bcp/).

In evaluating the potential of GE cassava for gene flow and weediness it is worth noting that cassava originates from South America but has close wild relatives in Africa. Cassava is cross pollinated by insects but

its pollen flow into native relatives is considered highly unlikely because of incompatibility issues and its mode of propagation is by stems cuttings.

Cotton (*Gossypium hirsutum*)

Cotton is the major source of cash income and foreign exchange in Sub-Saharan Africa (Hillocks, 2009), but insect pests, especially cotton bollworms and also weeds constitute the major constraints to cotton production (Hillocks, 1995; Javaid, 1995). Fortunately genetic engineering has allowed the development of not only varieties such as Bt cotton, that are effective against the cotton bollworm, but also a number of varieties tolerant to herbicide. In Africa, Burkina Faso and South Africa have commercialized Bt cotton for some years already. Other countries including Kenya, Uganda, Cameroon and Malawi are currently conducting field testing of Bt cotton varieties.

Cotton has its centre of origin in Central America but several centres of genetic diversity are located in West-Central and Southern Mexico, north-east Africa and Arabia, and Australia (Seelanan, T., A. Schnabel and J.F. Wendel. 1997). Cotton has close wild relatives that are present in Africa, especially in Eastern Somalia and South West Africa. These are *Gossypium herbaceum ssp africanum, G. trifurcatum, G. arboretum, G. anomalum* and *G. triphyllum.* The crop (*G. hirsutum*) and its wild relatives show different numbers of chromosomes as well as other genetic incompatibility barriers. This causes an extremely low possibility of inter-fertility between them. Furthermore, although insects, especially bees, ensure the dispersion of cotton pollen, outcrossing is extremely low due to the fact that cotton is predominantly self-pollinated and the pollen remains viable for less than 30 hours. Cotton is known not to persist in the natural environment and is not naturally invasive, therefore does not pose a weed problem. Moreover cotton is not known to produce substances that are toxic to humans or animals or to be a source of human allergens, therefore GE cotton presents an extremely low potential for gene flow, weediness and invasiveness.

Cowpea (*Vigna unguiculata*)

Cowpeas are drought tolerant crops that provide food and legumes in Sub-Saharan Africa (Langyintuo et al., 2004). While cowpeas are a good source of proteins, vitamins and mineral nutrients (Timko and Singh, 2008), production is limited by a number of insect pests including the pod borer, *Maruca vitrata* (Dugje et al., 2009). GE cowpea lines have been developed to express resistance to the pod borer and are currently undergoing field trial evaluation in Nigeria and Burkina Faso (AATF, 2012). The GE cowpea field trials in Ghana (CSIRO Plant Industry 2010) received regulatory approval in 2013 and are now ready to be commercialised.

Cowpea is native to Central West and Southern Africa and was first domesticated in West Africa. For cultivated cowpea the centre of genetic diversity is West Africa while the centre of genetic diversity for the wild species is South-eastern Africa. The closest wild species of cowpea are *Vigna unguiculata var. rhomboidea , V. unguiculata var. protracta, V. unguiculata var. congolensis, V. unguiculata var. huillensis, V. unguiculata var. ciliolate, V. unguiculata var. grandiflora* and *V. unguiculata var. dekindtiana.* These are found throughout Africa. Cowpeas are highly inter-fertile but do not easily cross because of the high degree of self-pollination which is over 90%. Insects, especially bees and wasps, are the main pollinators of cowpeas. Cowpeas grow fast and can easily shade other competitors within a very short time, but they rarely become dominant in a plant community. Overall, though cultivated cowpea has inter-fertile wild relatives in Africa its potential for gene flow is considered to be low because of its high degree of self-fertilization. Cowpea's potential for weediness/invasiveness is estimated to be moderate because it does not aggressively spread in spite of its fast growth.

Maize (*Zea mays* L.)

Maize is the most widely grown staple crop in Africa providing food for more than 300 million people (Smale *et al*., 2011). Maize production in Sub Saharan Africa, however, faces various constraints amongst which drought is considered one of the most important. Insect pests and diseases are other limiting factors (FARA 2009). Using genetic engineering techniques efforts are currently underway to improve maize productivity through the development of drought tolerant varieties and also varieties with resistance to devastating insect pests and virus diseases such as stem borers and maize streak virus (MSV) (AATF, www.aatf-africa.org/projects/aatf_projects//wema, Mugo et al., 2002; Shepherd et al., 2007; Thomson et al., 2010). A number of GE varieties including MON 87460 have been developed for drought tolerance and are under confined field testing in South Africa, Kenya and Uganda (Thomson et al., 2010).

Maize originates from Mexico, and does not have any compatible wild relatives in Africa. Maize shows a high degree of outcrossing with pollination ensured by wind and insects. Maize does not spread outside agricultural areas and is not invasive. It therefore does not pose a weed problem.

Rice (*Oryza sativa*)

Rice is one of the most rapidly growing food crops in Sub-Saharan Africa, especially in urban areas (WARDA/ FAO/SAA 2008). Rice production is constrained by a number of factors including drought, salinity and limited fertilizer use (AATF, www.aatf-africa.org). Efforts are currently underway using genetic engineering techniques to develop rice varieties that will use the available nitrogen and water more efficiently as well as exhibit tolerance to saline soils (AATF 2012).

Rice is native to the inland delta of the Upper Niger River and has its center of genetic diversity in the West coast of Africa. Rice has a close wild relative in Africa, *Oryza barthii,* which is found in the West coast of

Africa. Rice pollen is dispersed by insects and wind, but the plant is predominantly self-fertilized, with less than 1% of plants being cross-pollinated. Cultivated rice and its wild relatives are compatible and readily produce viable seeds in artificial hybridization. However, under natural conditions, the levels of introgression are very low, and less than 0.01%. Cultivated rice is not naturally invasive, but the wild relative poses a weed problem in agricultural fields. Overall, the potential for gene flow associated with rice is considered very low, due to the high level of self-fertility and the low rate of introgression. However, the potential for invasiveness and weediness is high.

Sorghum (*Sorghum bicolor*)

Sorghum is a staple crop in the semi-arid areas of Africa (Ashok Kumar *et al*., 2010); but, unfortunately sorghum has a low iron and zinc content, low pro-vitamin A and poor protein digestibility (Ng'uni et al., 2011). However, vitamin A deficiency is one of the most prevalent problems in Sub Saharan and is responsible for a high mortality rate. To improve the nutritional status of sorghum, scientists are using genetic engineering to develop biofortified sorghum with improved iron, zinc and pro-vitamin A content, and with higher protein quality and digestibility. The work is being conducted under the African Biofortified Sorghum (ABS) Project (ABS, www.biosorghum.org). Such improved sorghum varieties have been undergoing confined field trial evaluation in Nigeria and Kenya and are planned for South Africa, Burkina Faso and Egypt (Wambugu et al., 2012). Regulatory approval was granted by the National Biosafety Agency in Burkina Faso but the trial has still to commence.

The center of origin and diversity for sorghum is in the Ethiopia-Sudan region of Africa (Kimber, 2000). Gene flow occurs readily between cultivated sorghum and its wild/weedy relatives. Genes from cultivated sorghum, even considered as neutral i.e. without selective advantage or disadvantage, may introgress and persist in wild sorghum populations. Therefore, transgenes from GE cultivated sorghum are likely to be transferred to and persist in the wild populations, as with other genes from conventional cultivated sorghum (Karen et al., 2010). To complete the environmental risk assessment, it is necessary to determine the likelihood or frequency of gene flow to wild relatives, and to assess the consequences when the transgenes enter the wild populations via gene flow (Karen et al., 2010).

Sweet potato (*Ipomoea batatas*)

Sweet potato is a very important food crop that produces large amounts of food per unit area in Sub-Saharan Africa (Mwanga et al., 2011). It is a very good source of carbohydrates, vitamins A, B and C, iron, potassium, zinc, protein and fiber (Low et al., 2009). However, sweet potato production is limited by diseases and pests such as the sweet potato virus disease, *Alternaria* blight, and insect pests like the weevil (*Cylas spp*.) (Mwanga et al., 2011). GE sweet potatoes expressing *Bt cry* proteins for the control of the most important weevil species in East Africa (SASHA, 2012) are being developed. Transgenic sweet potato lines have undergone greenhouse evaluation and await confined field trial evaluation (SASHA, 2012).

Sweet potato is native to Central / South America (Srisuwan, Sihachakr and Siljak-Yakovlev, 2006); but has its center of genetic diversity in East Africa (Ethiopia) (Gichuki, Berenyi, Zhang, Hermann, Schmidt, Glossl and Burg, 2003). Sweet potato does not have close relatives in Africa. Cross-pollination is the main method of reproduction with insects as primary pollen dispersers over very short distances. Sweet potato is not known to be naturally invasive, but it does produce substances (furanoterpenoid) that are toxic to human and animals (Boyd and Wilson 1972). Overall, sweet potato has no potential for gene flow, due to the absence of wild relatives in Africa, as well as for weediness/invasiveness.

PEST MANAGEMENT ISSUES ASSOCIATED WITH GM CROPS IN AFRICA

The development of resistance in target pest populations is a concern for all methods of crop pest management. Resistance to chemical pesticides is well known. The cotton bollworm, *Helicorverpa armigera*, for instance, is the insect species with the highest number of resistance cases reported around the world. Resistance of this insect to chemicals negatively affected the cotton sector in Burkina Faso in the 1990s and prompted the Government of Burkina Faso to explore the use of Bt cotton. Cotton farmers in Mali, Chad, Cameroon and Togo are still facing these resistance issues with chemical pesticides.

Even with GE pest protected crops, resistance to Bt toxins has been reported in a number of countries, including South Africa. This indicates that even with products of agricultural biotechnology resistance can arise; but this situation has been successfully managed using different means of delaying the development of pest resistance including high dose, refugia and gene stacking strategies as well as the adoption of integrated pest management.

COEXISTENCE ISSUES ASSOCIATED WITH GE CROPS IN AFRICA

The issue of coexistence of GE crops with conventional and organic agricultural crop production is not a safety issue. It is market driven and is directly related to choice of consumers and agricultural producers.

The accidental mixing of GE materials with non-GE products, also referred as “adventitious presence”, occurs through physical mixing of seed and pollen. Many countries, including the European Union, have defined acceptable levels of adventitious presence and have determined segregation measures that enable the cultivation of GE crops while protecting farmers from adverse economic consequences of accidental mixing of GE materials.

In Africa, coexistence with GE crops could become an issue for high value cash crops exported to countries where the threshold for adventitious presence has been defined and standards need to be met. However, segregation measures, including isolation distance, can be efficiently applied to meet different thresholds. For each crop species, isolation distances have been defined based on their reproductive biology.

CONCLUSION

The adoption and cultivation of GE crops is growing worldwide thanks to the development of efficient regulatory systems that are able to evaluate the inherent risks and set up appropriate measures to manage those risks. Concerns raised with respect to the safety of the environment are the same all over the world. These concerns centre on whether GE crops and any derived progeny will become more invasive and out-compete other plant species in the environment or whether they will produce substances that could be toxic to non-target organisms. Biosafety guidelines and methodologies have been developed, based on rigorous scientific approaches that carefully assess the identified risks. Knowledge of crop biology and the geographical distribution of wild relatives are key to properly assessing the potential for gene flow and weediness, as part of the environmental risk assessment process. African scientists and farmers have a strong knowledge base having worked with these crops for many decades.

It has been argued that because of the large biological diversity in Africa, assessing potential risks of GEOs would be more complex and the scientific uncertainty will be higher. As a consequence, there is a notion that more precaution should be taken in African countries to deal with any potential risk associated with GEOs. This overly precautionary attitude has denied most African countries access to safe and potentially beneficial modern biotechnology. The risk assessment strategies being used outside of Africa are applicable to this continent and risk assessment can be used effectively for countries with any level of biodiversity. The right question is whether it makes sense for Africa to be denied access to the benefits of modern technology simply because of safety concerns that can be addressed. To what extent other risks would be increased if the benefits offered by advanced agricultural biotechnologies are delayed? Finally, what is the value of biodiversity if it is not protected by sustainable agriculture and used sustainably to support the economic and social growth of local communities?

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Chapter 4. Food safety issues associated with foods derived from Genetically Engineered crops in Africa

ALLAN LIAVOGA

INTRODUCTION

The world's population is estimated to reach the 9 billion by 2050 and Africa is projected to contribute the biggest proportion of this increase. As water scarcity, soil salinity, and other abiotic and biotic stresses continue to increase, compounded by the effects of climate change, the need to produce and maintain high yields of important food crops through techniques such as genetic engineering (GE) will become even more imperative to Africa and the world in general. Genetically engineered food is becoming an increasing part of the global food supply (James, 2012). As Africa cautiously embraces the technology (Okeno et al., 2013), progress is hampered by the perceived safety risks associated with this new gene technology (Ezezika et al., 2012) and corresponding delays in passing regulatory laws and developing regulatory systems. At a global level, there is a general consensus of the food safety issues associated with GE foods and how they are assessed (Codex, 2003). This chapter will discuss the safety issues associated with foods derived from GE crops and point out key considerations in assessing foods derived from these crops to assure safety. A detailed discussion of safety assessments beyond the scope of this chapter but can be found in a number of publications (Snell et al., 2012; EFSA, 2011; ILSI, 2004; Kuiper et al., 2001).

GENETICALLY ENGINEERED FOOD CROPS IN AFRICA

Foods derived from GE organisms are among a number of biotechnological developments intended to improve shelf life, nutritional content, flavour, colour, and texture, as well as agronomic and processing characteristics (NRC, 2004). In Africa, only South Africa, Egypt, Burkina Faso and Sudan have commercialized biotech crops (James, 2012). However, increasing biotechnology research and development activities on important African food crops currently at the experimental phase on the continent attest to a slow but gradual awakening to its possibilities in addressing long standing food and nutrition security challenges in Africa. Table 1 summarizes some of the GE food crops, staple to Africa, that are at various experimental stages – laboratory, greenhouse or confined field trials – in different countries and the different genetic traits that are being introduced (ISAAA, 2012).

Table 1. On-going Biotech Research on Important Food Crops in Africa (ISAAA 2012)

Trait	GE Food Crops	Country
Nutritional enhancement	Sorghum	Burkina Faso, Egypt, Kenya
	Cassava	Egypt, Nigeria
	Banana	Uganda
Herbicide tolerance	Maize	South Africa
Drought tolerance	Maize	Kenya, South Africa, Uganda
Viral resistance	Cassava	Kenya, Uganda
	Sweet potato	Kenya
	Tomato	Egypt
Bacterial resistance	Banana	Uganda
Insect resistance	Maize	Egypt, South Africa
	Cowpea	Burkina Faso, Nigeria
	Sweet potato	Kenya, Uganda
	Pigeon pea	Kenya
	Potato	South Africa

SAFETY ISSUES ASSOCIATED WITH GE FOODS

As far as the safety of foods derived from GE organisms are concerned, the major question to be addressed is "may the improvement of a plant variety through transgenesis result in unintended effects which may impact the consumer and animal health"? The following discussion addresses this question as well as the possibility that the intended changes might also have adverse health effects.

Definition of food safety

According to the United Nation's Food and Agriculture Organization (FAO) and World Health Organization (WHO), food is considered safe if there is reasonable certainty that no harm will result from its consumption under the anticipated conditions of use (FAO/WHO 2000). However, almost any single definition of safe food will be overly simplistic, because food safety is a complex, multifaceted concept (Seward, 2003). Food safety issues are as old as mankind and humans have developed strategies to ensure that the food they eat does not harm them.

An absolute guarantee that a food is safe is virtually impossible. This holds true for foods and ingredients made by conventional methods as well as from GE organisms. All foods are composed of a complex and variable mixture of numerous substances some of which may be toxic to the health of humans if present in sufficient amounts. However, in most cases the foods consumed today are generally viewed as safe, based on their long history of use with no obvious evidence of harm (Constable et al., 2007).

Gene safety

There has been public concern about the health impact of consuming a foreign gene in a food; in this case the new gene or DNA introduced through genetic engineering. In contrast to vertical gene transfer, where DNA is spread from a parent to offspring, horizontal gene transfer is the transfer of DNA between cells of the same generation where genetic material is transferred directly to a living cell or an organism followed by its expression (Kelly et al. 2008). The process of DNA uptake has been extensively reviewed (Dubnau, 1999). The consumption of the transgenic DNA itself is not a threat to the consuming organism since it is quite rapidly degraded in the digestive tract and acts as a nutrient (van den Eede, 2004). In humans, daily dietary intake of nucleic acids in the form of RNA and DNA vary widely but are typically in the range from 0.1 to 1.0 g per day (Flachowsky, 2007). Any concerns over the presence of novel DNA in a GE food consumed in the human diet must take into consideration that this DNA would represent less than 1/250,000 of the total amount of DNA consumed (Lemaux, 2008). In view of this and the digestibility of dietary DNA, the probability of transfer of intact genes from GE plants to mammalian cells is extremely low (WHO, 2000).

The probability of transfer of antibiotic resistance genes present in plant GE varieties as selectable markers to the indigenous gut micro-flora of humans is a second aspect of horizontal gene transfer and one which is of major concern to the public. However, there is general consensus among scientists that this kind of horizontal gene transfer requires several improbable steps and is thus extremely unlikely, though it cannot be entirely excluded (WHO 2000). Furthermore, the antibiotics in question are typically not of clinical importance because resistance genes against these antibiotics already exist in the environment. As a result, any small additional transfer that might occur through transgenic foods would be negligible in both scope and medical impact. However, due to the controversial nature of antibiotic resistance marker genes, there is continuing pressure for product developers to use other selectable markers and indeed other markers are already in use (van den Eede, 2004).

Toxicity and anti-nutrients

Concerns have been raised about the possibility of introducing or elevating naturally occurring toxins or anti-nutritive substances in GE foods to levels that are harmful to human health. All foods, whether or not they

are genetically engineered, carry potentially hazardous substances and as it is currently the case, those without a history of safe use must be properly and prudently assessed to ensure a reasonable degree of safety. The definition of plant inherent toxicants and anti-nutrients is still not entirely harmonized. Usually antinutrients are understood to be substances that inhibit or block important pathways in the metabolism, especially digestion. Antinutrients reduce the maximum utilization of nutrients such as proteins, vitamins or minerals, and consequently may obstruct the optimal exploitation of the nutrients present in a food and decrease its nutritive value (Watzl and Leitzmann, 1995). However, it should be noted that many antinutrients may also be toxic beyond a certain dose, for example oxalate found in amaranth, spinach and tomato may react with calcium and iron in the diet and eventually lead to the formation of kidney stones. Furthermore, most of the deleterious effects of antinutrients are caused by raw plant material and most of the anti-nutritive substances become ineffective by heating, soaking, germination or autoclaving (Novak and Haslerger, 2000).

Naturally occurring toxins are also found in plants and subsequently in food derived thereof; for example cyanogenic glycosides in some staple African food crops including cassava, yams, and sweet potatoes, and glykoalkaloids in potatoes (Noak and Halerger, 2000). The amounts and natural variation of toxic and antinutritive substances in one plant species can differ considerably since they are strongly influenced by the state of ripening, year of production, storage, varietal differences, and growing conditions and also stress or pathogen infection (Ene-Obong, 1995). Literature data sometimes show very wide variations in typical concentrations of inherent plant toxins and antinutrients (Füllgraf, 1989).

The possibility of elevating naturally occurring toxins or anti-nutritive substances or introducing new ones is precluded by the fact that as part of the safety assessment of GE crops, the levels of the naturally occurring toxins in the GE food are compared to those of the conventional food to ensure that these substances are not elevated above their natural levels or no new associated constituents are present. A list of the most frequent and important classes of these constituents, their occurrence and their nutritional effects is given in Table 2.

Table 2. Classes of the most frequent inherent plant toxins and antinutrients (Adopted from Novak and Haslberger, 2000)

Compound	Occurrence	Effects
Cyanogenetic glycosides	Manoik, cassava, yams, sweet potato, fruit, millet, lima beans	Blocking of cell breathing, gastrointestinal symptoms. Influence on carbohydrates and Ca transport. At high intake doses iodine deficiency
Glucosinolates (goitrogen): sinapsin, sinigrin, progoitrin, arachidosid,	Cassava, kale, peanut, soybean, onion, radish, cabbage, mustard seeds	Strumatic effects (forming goiter): thyroid gland increase, thyroxin synthesis, metabolism impairment, ↓iodine absorption, ↓protein digestion
Glykolakaloids (solanine and Tomatine)	Potato, tomato	Inhibition of cholinesterase; gastrointestinal symptoms, haemolysis, inflammation of kidney
Gossypol	Cottonseeds	Binds metals, ↓iron absorption, inhibitor of enzymes
Lectins	Legumes, cereals,	Inflammation and damage of the intestinal epithels, ↓resorption of nutrients and N retention →, ↓ enzyme activity, ↓ B12 and lipid resorption
Oxalate	Spinach, amaranth, tomato	Ca metabolism impairment
Phenols (flavonoids, isoflavone Chlorogen acid)	Vegetables, fruit, cereals, soybeans, potatoes, tea, coffee, plant oils	Destruction or inhibition of thiamine, metal complexes, ↓availability of trace elements, estrogen effects, hypocholesterolaemic activities
Phytate	All plant seeds, cereals, legumes	Complexes: ↓bioavailability of Ca, Mg, Fe, Zn, Cu, Mn, ↓ utilization of protein and starch(↓activity of amylotic and proteolytic enzymes)
Protease inhibitor	Legume seeds, peanut, cereals, rice, maize, potato, apple	Inhibition of trypsin and chymotrypsin, caboxypeptidases and pancreas elastase,↓ digestion of proteins

Compound	Occurrence	Effects
Saponin	Spinach, asparagus, soybean, tea, peanuts	Complexes with proteins and lipoides, haemolytic, gastroenteritis, most saponins harmless
Tannins	Widespread: all fruits, tea, coffee	Inhibition of pancreatic enzymes, cobalamin↓ resorption, ↓ thiamine utilization, ↓ availability of protein and iron

Allergenicity

One particular area of concern with respect to safety of GE foods is the potential introduction of an allergen not previously present or an increase in the level of inherent allergens above the natural range within the crop. A food allergy is a reaction of the immune system to an otherwise harmless food or food component. Food allergies are relatively rare (perhaps 2% of adults suffer from a true food allergy) but they are still of concern because extreme reactions can lead to death through anaphylaxis (Kanny et al., 2001; Sicherer et al., 2004). Overall, approximately 90% of all food allergies are associated with a small number of specific proteins represented by eight major allergenic foods: peanuts, tree nuts, cow's milk, hen's eggs, fish, crustacean, wheat, and soybeans (Metcalfe et al., 1996).

Since the primary product of gene expression is protein and almost all food allergens are proteins (Bush and Hefle, 1996), there exists a possibility that any novel protein introduced into a plant might be an allergen. Also, if a conventional crop that contains allergens is genetically engineered, the GE food may contain those allergens, just as the conventional food does. For example, soy naturally contains proteins that cause an allergic reaction in some people. Unless these specific proteins are removed, they will also be found in GE soy varieties. Therefore, the possibility of introducing new allergens or enhancing the level of existing allergens is a primary concern and subject of extensive food safety evaluations carried out during development of a GE crop.

Unintended effects

Genetic engineering is the newest in a range of genetic modification techniques including traditional hybridization and breeding, and mutation induction by radiation that may be used to alter the genetic composition of plant, animal or microbial organisms to affect a specific result. All these modifications bring about changes that are intended to be beneficial, but also may result in unintended changes. Unintended effects here refer to unexpected alteration(s) beyond the primary expected effect(s) of introducing the targeted gene(s). Unintended effects are not restricted to genetic engineering, traditional breeders observe off-types (undesirable variants) due to unintended effects and they methodologically eliminate these plants through selection during the evaluation process, long before commercialization (NRC, 2004). In addition, unexpected or unintended effects do not imply a health hazard, although obviously a plant expressing novel and unexpected characteristics warrants closer inspection prior to commercial release. Although there have been documented cases of desirable unintended effects in GE crops (Munkvold et al., 1997), this chapter focuses on the undesirable effects.

Genetic engineering is considered a more precise method of altering or introducing genes into a plant compared to most conventional methods e.g. traditional breeding and random mutagenesis, that introduce many uncharacterized genes along with the desired gene(s) or result in multiple mutations of an unknown nature. Even so, there is currently no way to predict the integration region of the gene into the cellular DNA and therefore it is not possible to predict any pleiotropic (multiple) effects of the genetic modification process e.g. through disruption of existing gene or regulatory sequences. Thus, the expression of constituents of crops such as inherent plant toxins, allergens, and antinutrients, and thereby their concentrations in a genetically modified plant, may eventually be influenced by pleiotropic effects (Kuiper, 2001).

Upon random insertion of specific DNA sequences into the plant genome (intended effect), the disruption, modification or silencing of active genes or the activation of silent genes may occur, which may result in the formation of either new metabolites or altered levels of existing metabolites (Novak and Haslberger, 2000). These effects could increase the synthesis and activity of the naturally occurring biochemical metabolic pathways, augmented synthesis caused by increased gene activation, decreased synthesis of catabolism enzymes, or reduced decomposition (Koschatzky and Massfeller, 1994). In addition regulatory elements in the plant DNA can influence the expression of the inserted genes and random insertion events may disrupt or modify the expression of existing genes in the recipient plant. However, it is possible that the activation of genes encoding enzymes in pathways may produce deleterious secondary plant compounds that raises the most concern for food safety (Lang, 1979). Therefore assessment of the unintended effects is an integral component of the safety assessment process.

Nutritional concerns

The risk of health hazards that may be brought about by nutrient excesses, deficits or imbalances as a result of genetic engineering is also an issue that may be of concern and is also addressed before the marketing of foods derived from GE crops. These nutritive issues may arise due to the compositional changes of the food as a result of the genetic modification. The deletion or enhancement of essential nutrients from foods has the potential of influencing the risk of nutrient deficiencies or toxicities, respectively, in a section of the general population, depending on exposure patterns. In this context, it should be noted that to date most of nutrient toxicities are due to elevated nutrient levels in excess of normal physiologic needs, achieved through fortification or due to the excessive consumption of nutrient supplements (NRC, 2004).

SAFETY ASSESSMENT OF FOODS DERIVED FROM GENETIC ENGINEERED CROPS

In order to assure safety, all foods derived through modern biotechnology must undergo a comprehensive safety evaluation as part of the regulatory approval process before entering the market and becoming part of the human or animal food supply (Codex, 2003; FAO, 1996; FAO/WHO, 2000; OECD, 1997; WHO, 1995). The source of the gene is routinely investigated to ensure that the gene product itself has no harmful effects. Furthermore, the safety evaluation process requires the newly expressed product, typically a protein, be investigated to demonstrate that its properties are similar to those of thousands of proteins that are safely consumed on a daily basis and are dissimilar to known toxic proteins.

Substantial equivalence

Safety assessment is structured, step-wise and based on a comparative approach commonly referred to as “substantial equivalence” that was originally proposed by the Organization of Economic Cooperation and Development (OECD, 1993). This concept means comparing a transgenic crop to its nearest isogenic relative using molecular characteristics and agronomic metrics, as well as compositional analysis to determine whether the genetic modification has produced any unintended pleiotropic effects (Sidhu et al., 2000; Ridley et al., 2002; Obert et al., 2004; Herman et al., 2004; McCann et al., 2007; Drury et al., 2008; Lundry et al., 2008).

Animal feeding studies are another way to assess potential adverse pleiotropic effects that may not have been detected from composition testing (Delaney, 2007). However, it is important to note that the assessment of substantial equivalence is not in itself a safety assessment. Rather, it is the first step in the assessment process that provides a platform on which to make a comparison between the GE crop and its traditional counterpart and identify any significant differences. The concept of substantial equivalence is, therefore, considered the starting point of the safety assessment process (Codex, 2003). Careful interpretation and further studies may or may not be necessary to establish safety if biologically significant differences are observed.

Molecular and compositional analysis

To be considered as safe as the conventional counterpart, a modified food would need to be tested to show that the genetic modification had not inadvertently introduced or increased levels of harmful compounds. A detailed description of the molecular characteristics of the recombinant-DNA plant is required. This information includes the composition, integrity and stability of the inserted DNA, the number and genomic location of the single or multiple sites of insertion, and the level of expression of the introduced protein(s) over time and in different tissues and environment. This is important to evaluate the potential effect of the insertions (OECD, 1993).

When the substantial equivalence of GE organisms with their parental organism is analysed, the natural variation in content of inherent plant toxins and antinutrients has to be taken into consideration. Special attention in the analysis of substantial equivalence has to be focused on inherent toxic and anti-nutritive constituents, since genetic modification could affect the expression of gene products not addressed by the genetic modification (unintentional pleiotropic effects) and thereby alter the content of constituents (Kuiper et al., 2001).

Currently, the risk assessment of GE crops includes the analysis of 50-150 analytes that have been identified by OECD (OECD, 2006). If these analytical tests indicate no major differences in the levels of well-known key constituents, the chance of other metabolic alterations leading to the production of significant amounts of other inherent plant toxins and antinutrients is considered unlikely (Belitz and Grosch, 1992).

In addition, '-omics' techniques including transcriptomics, proteomics, and metabolomics have been used as an additional tool for the detection of unintended effects. According to Ricroch et al. (2012), analysis of data from '-omics' profiling publications comparing GE and non-GE crop varieties, with or without intentional metabolic changes, show that transgene insertions produce few unintended effects thus reducing chances of unintended deleterious effect that might occur in the GE crop and/or food. However, such approaches are not required for regulatory purposes.

Animal feeding trials have also been used as a tool to assess unintended effects (Snell et al., 2012), particularly 90-day rodent dietary studies, but Ricroch et al. (2012) suggest that long-term and multigenerational animal studies should only be conducted on a case-by-case basis for GE food/feed safety and nutritional regulatory assessment if some reasonable doubt remains after a 90-day rodent feeding trial. Such feeding studies are currently not a routine requirement for GE safety testing. According to the European Food Safety Authority (EFSA), when molecular, compositional, phenotypic, agronomic and other analyses have demonstrated equivalence of the GE food/feed, animal feeding trials do not necessarily add to the safety assessment (EFSA, 2011). However, animal feeding studies may provide additional and useful information to complement safety and nutritional value assessments of whole GE food and feed, especially when unintended effects are suspected.

Evaluation of protein safety

It is recognized that certain proteins are toxic or allergenic if consumed (Delaney et al., 2008). Therefore, as part of the safety assessment, the safety of the proteins encoded by the introduced genes is evaluated. Proteins are not known to be capable of genotoxic interactions (Pariza and Johnson, 2001), nor are they known to be carcinogenic or teratogenic when consumed in a diet (Delaney et al., 2008). Proteins are structurally quite different from industrial chemicals since they are large macromolecules and their size limits systemic absorption from the gastro-intestinal tract. Unlike most chemicals, proteins are also degraded by proteases which cleave the peptide bonds that hold the protein together (Hammond and Jez, 2011). However, as part of the safety assessment process, data is required to establish whether the newly introduced protein has toxic or allergenic potential.

The safety assessment of proteins includes a bioinformatics analysis of the amino acid sequence to confirm that the protein is not related to known mammalian toxins and allergens, an assessment of the protein's potential for digestion when incubated *in vitro* with proteases, and an evaluation of the protein's history of safe use in food (Delaney et al. 2008). Where appropriate, a dietary risk assessment may also be carried out with the introduced protein to estimate potential human dietary intake (Hammond and Cockburn, 2008). Additional risk characterization is determined on a case-by-case basis and may involve acute (1-14 days) or sub-chronic (at least 90-days) animal feeding toxicological studies (OECD, 1998), depending on the outcome of the previous risk evaluations.

Safety assessment of genetically engineered events combined by conventional breeding

The early commercialized GE crops contained a single event e.g. herbicide tolerance or insect resistance, but the current trend is to combine or "stack" two or more single GE events to provide growers with a combination of traits that increase flexibility and improve performance. This "stacking" can be done using two approaches: by conventional plant breeding, where parents with single GE events are bred to produce progeny with the combined GE events; or by molecular-based methods where two or more traits are simultaneously or sequentially transformed into a recipient crop (Halpin, 2005). Most often, conventional plant breeding is used to combine GE events and in the past several years, multiple new combined GE event crops have been commercialized globally (James, 2009, 2012).

There has been debate on the level of rigor that should be applied to the safety assessment of these stacked GE crops and especially in situations where the individual events have already been approved. There is no global consensus for the regulation of previously approved GE events combined by conventional breeding. Indeed the guidelines provided by Codex do not explicitly address combined GE events generated through conventional breeding (Codex, 2003). Consequently, individual regulatory agencies have devised their own requirements. The regulatory approach taken by US, Canada and Australia/New Zealand does not require additional data for combined GE events by traditional breeding methods that are unlikely to interact (EFSA, 2007; CFIA, 2004; OGTR, 2007). However, other countries including Mexico, Colombia, Taiwan, Philippines, Japan, South Korea, South Africa, and the European Union require additional information (Pilacinski et al., 2011).

The World Health Organization concludes that substantial equivalence should be maintained in a combined GE trait variety if substantial equivalence had been demonstrated for each of the parents (WHO 1995). Additional international groups, including FAO and WHO (FAO/WHO, 1996), the International Seed Federation (ISF, 2005), and Crop Life International (CLI, 2005) similarly advocate basing the safety of combined GM events on the safety of the parental GE events. Pilacinski et al. (2011) argue that additional safety data only become necessary if two or more of the traits present in the combined GE event product are likely to interact in a manner that would in some way change prior safety assessments. In this case, appropriate experiments should be designed to address the anticipated interaction.

CONCLUSION

On a global basis, several organizations, including the FAO, WHO, and OECD, have established the food safety issues to be addressed by the safety assessment of GE foods. There is general consensus among these organizations and other regulatory agencies around the world that GE products are not inherently less safe than those developed by traditional breeding. Further, food safety considerations are similar to those arising from the products of traditional breeding which are subject to different regulations and testing procedures that are much less stringent than those applied to GE products. More rigorous assessment procedures are currently being utilized to evaluate GE products compared to their conventional counterparts to ensure

safety. It is debatable whether this should continue after establishing a reasonable history of safety for some of these GE foods (Herman and Price, 2013).

From past and recent publications (EC, 2010; Lemaux, 2008; Cockburn, 2002) and as far as the author is aware, for the past 16 years that GE foods have been consumed there has not been a single documented case to indicate that these foods pose any greater risk than their conventional counterparts to humans and animals that consume them. Although this cannot exclude low-level or rare events that might not have been recorded, it would be reasonable to suppose that the current regulatory framework for evaluating food safety has been effective in ensuring that the GE foods currently in the market are as safe as their conventional counterparts. However, vigilance should be maintained as more GE crops continue to be developed. It is important that African scientists and regulators have access to the available GE food safety literature. The ability of African regulators to understand these safety issues, and evaluate and provide scientific opinion to decision makers on the safety of GE crops will, in-part, determine the rate of adoption of this technology. This, in turn, will impact the continent's ability to address the food and nutrition security challenges afflicting it.

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Chapter 5. Legislative and policy issues associated with GE crops in Africa

JULIUS MUGWAGWA AND BETTY KIPLAGAT

INTRODUCTION

Biotechnology, defined broadly as the use of living organisms or parts thereof in the production of goods and services, has revolutionized many human endeavours that rely on biological processes. Activities in agriculture, health, environment and industry have had a radical facelift as a result of developments in biotechnology. These developments have brought together advances in disciplines such as engineering, chemistry and biology, to hasten processes, and to enable the development of processes and products that were not imaginable before the advent of these technologies. African countries are employing various levels of biotechnology (as detailed elsewhere in this book) in a wide range of fields, which include agriculture, environment management, forestry, health care and industry. The potential of the technology to deal with some of the challenges facing the countries of Africa has been documented in national development strategies, especially agricultural, science and technology and industrial policies, and some steps have been taken towards harnessing the technology.

As they wrestle with the perennial challenge of feeding their populations, African countries have had to contend with the contested benefits and risks presented by new technologies such as gene-based biotechnologies (Birner and Linacre, 2008). Indeed, like elsewhere in the world, African countries have engaged in the debate on the pros and cons of modern biotechnologies and products thereof for a greater part of the last two decades (Paarlberg, 2000). However, for African countries, the debate continues to change irreversibly and fundamentally in content and nature as a result of situations such as food emergencies which force countries to make decisions in the face of regulatory uncertainty and humanitarian crises (Mugwagwa, 2008). The debate continuously reveals the limited preparedness within countries, and the continent in general, to deal with these crises despite the many years of individual and collective efforts to develop and implement effective regulatory systems. Meanwhile, the fact that there is no unanimity at sub-national, national and continental levels on the technology and how to regulate just adds to more confusion to an already disorderly situation. This chapter identifies and discusses some of the legislative and policy activities to harness and effectively regulate modern biotechnology across Africa.

THE NEED FOR BIOSAFETY LEGISLATION

From a biological science perspective, the concept of biological safety (or biosafety) has paralleled the development of the science of microbiology and its extension into new and related areas (e.g. tissue culture, recombinant DNA, animal studies, among others). The knowledge and skill gained by microbiologists to isolate, manipulate and propagate pathogenic microorganisms required parallel development of containment principles, facility design, and practices and procedures to prevent occupational infections in the biomedical environment or release of the organisms to the environment. However, as used under the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD), the concept of biosafety refers to the legal actions that an importing country is entitled to take under international environmental law with the aim of protecting the biological diversity of its conventional plants and animals against the risk of contamination through imported varieties or species consisting of so-called Living Modified Organisms (LMOs) (cf. Mackenzie et al., 2003). These actions consist primarily of preventive or precautionary trade measures. Such restrictions or bans include the elaboration, negotiation and implementation of pertinent standards, and the institutionalization and international ‘harmonization’ of the

related regulatory framework and procedures. They also take into consideration the legally less clearly circumscribed concerns over related public health issues and socio-economic considerations. All these provisions aim at a non-hierarchical and mutually supportive relationship with other international agreements, especially with World Trade Organisation (WTO) rules, with the Codex Alimentarius Commission standards on food safety and with the International Plant Protection Convention.

The Biosafety Protocol

The Cartagena Protocol on Biosafety was adopted in January 2000 as a supplement to the Convention on Biological Diversity (CBD) to serve as the global framework on biosafety. The Protocol addresses the safe handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity, taking into account risks to human health and focusing specifically on transboundary movements (CBD Secretariat, 2007). Countries are given authority by the Protocol to assess the risks posed by LMOs before they accept them. Their acceptance or rejection of the products is enshrined in the advance informed agreement, and the precautionary approach emphasised by the Protocol. A communication mechanism for exchange of information and experiences on biosafety with the world community is provided via the Biosafety Clearing House (BCH) Mechanism.

The Protocol makes it clear that Parties to the Protocol must develop or have access to the ‘‘necessary capacities to act on and respond to their rights and obligations’’. National capacities are seen as a necessary prerequisite for the successful implementation of the Protocol, hence many national, regional and international agencies have been engaged in assisting countries, singly or in groups, to develop the necessary technical and regulatory capacities. The efforts of the three supranational organisations are seen as some of these many efforts towards equipping countries for implementation of the Protocol and strengthening their risk management and decision-making with respect to biosafety.

Even before the advent of the CPB, there were many efforts to build regulatory and technical capacity in African countries for the development, enforcement and safe use of biotechnology. However, since its entry into force in September 2003, the Protocol has served as a key driver of both national and international processes in the handling of products of modern biotechnology. In addition, and looking specifically at countries in Sub-Saharan Africa, many policy and regulation models used elsewhere in the world have been adopted by key stakeholders, governments and organisations as a basis for policy development (e.g. the ISNAR and UNEP models and the African Model Law on Safety in Biotechnology, cf. Paarlberg, 2000). Lessons have also been drawn from the European and American experiences.

LOCAL LEVEL REALITIES FOR BIOSAFETY

Biosafety is a collective term used in reference to policy frameworks and actions for assessment and management of the safe application of modern biotechnology, frequently referred to as “genetic engineering.” Concepts of safety are applied with respect to hazards that modern biotechnology may pose to human and animal health as well as to the environment. The risks include related non-technological concerns of a social, ethical or political nature (Persley et al., 1993; Persley and Doyle, 1999). In this context therefore, biosafety is a concept that is being applied to regulate situations in which products of biotechnology are introduced into the environment directly as genetically engineered crops, animals and microbes or through derived products such as food, cosmetics, drugs and other biologicals. Biosafety is, therefore, applicable to the food industry, public health, agriculture and the environment, where it is applied in research, production, conservation, marketing and trade.

Among the key issues and realities for biosafety are that while there is a significant level of agreement on the potential risks associated with GE technology - for example, environmental risks from gene flow to non-cultivated plants, agronomic risks from resistance problems in the GE crops and in weeds, co-existence challenges between fields of farmers using GE crops and those not using them; among others - there is still considerable disagreement within and across countries regarding the importance of these risks and the scientific possibilities for adequately assessing and addressing them (Birner and Linacre, 2008). Add to this the disagreements on the so-called non-scientific issues, such as labelling of food and feed derived from GE crops, and socio-economic issues around the technology, and one begins to understand the emergence of a continuum of regulatory systems, ranging from the 'stringent' EU system on one end to the 'permissive' US system on the other end (Levidow et al., 1996, Paarlberg, 2000). As noted by Arcuri (2001), a 'regulatory divide' has emerged, championed by 'technocrats' on one hand, who believe in a rational application of the science to identify and manage the risks; and a 'deliberative' philosophy on the other hand, which embeds scientific knowledge within policy and societal debates (Birner and Linacre, 2008). African countries have to contend with these realities in their efforts to harness and effectively regulate the technology.

DEVELOPING AND IMPLEMENTING NATIONAL BIOSAFETY SYSTEMS

According to the UNEP-GEF Project, a national biosafety framework is a system of legal, technical and administrative mechanisms established to address the safety of modern biotechnology. Biosafety frameworks can be tailor-made to meet specific country needs but the main three tenets that must be present in any biosafety regulatory system are:

- An administrative system to handle application for permits for releases and research on GEOs/LMOs;
- A decision making system including risk assessment and management for the release of GEO/LMOs;
- Mechanisms for public participation.

Article 2(1) of the Cartagena Protocol on Biosafety requires each party to take the necessary and appropriate legal, administrative and other measures to implement its obligations. It further states that parties shall ensure that the development, handling and transport, use, transfer and release of any GEO/LMO is undertaken in a manner that prevents or reduces risks to biological diversity, taking into account risk to human health.

The main purpose of a biosafety system is three-fold. It enables a country to:

- Make informed choices on decisions to import GEOs/LMOs,
- Devise tools to assess, evaluate and manage potential adverse effects associated with transboundary movement, transit, handling and use of GEOs/LMOs on conservation and sustainable use of biological diversity accounting for risks to human health as well as socio-economic considerations
- Meet the international requirements of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

THE POLICY ENVIRONMENT

Public policies are statements of intent on what is to be done by states or agencies, and they are defined as outcomes of interactions between the states or agencies and civil society (Ushewokunze-Obatolu, 2005). Policies are therefore intended to serve the public interest. They are expressed as acts of parliament or regulations that attempt to state in very clear and specific terms, what is to be done under various circumstances surrounding an issue. Policies may further be explained for relevance through statutory instruments, guidelines, strategy documents and action plans. Policy-making in most African countries has tended to be prescriptive and top-down rather than participatory with the public. This is due to the low level of literacy of the general population, ignorance about the purpose of policies and regulations, the absence of skills in participatory development techniques and the anxiety by administrations to bring about changes without committing too much time and financial resources, thereby implementing by force rather than by

voluntary co-operation. While a top-down approach may have worked with most past policies, development of biotechnology/biosafety policies in many African countries has ushered in a new era where consultative processes have become the norm rather than the exception (Mugwagwa et al., 2013). This has introduced inertia and momentum in the processes, but overall, there is agreement that for the adoption of this technology, there is need for it to be well understood by the public.

Biotechnology policies should strike a balance between promoting research, development and applications and ensuring human safety, national security and biodiversity conservation. Modern biotechnology is not sector specific - it includes the entrepreneurial life sciences/biotech companies that use modern biotechnological techniques to develop products or services, research institutions, regulatory bodies and standards development bodies, traders and consumers, among others. An ideal country policy environment will thus need to strengthen and balance the capabilities of these various stakeholders in their contribution to and derivation of benefits from modern biotechnology (Mugwagwa and Makinde, 2012). Realising this goal is not only in the outputs, but also in the processes of coming up with the policies, both of which should be reflective of local contextual realities.

The problems that biotechnology addresses are social, present and economic, in the domains of food availability, nutritional quality, enhanced yields, incomes, entrepreneurship, reduced cost of inputs, and reduced costs and predictable availability and quality of vaccines and drugs. A wide range of stakeholders thus needs to understand the implications of the technology in order to accept and promote its products (Ushewokunze-Obatolu, 2005). Due attention is therefore required to these factors if effective policies are to be developed and, with the support of the public, to be executed through self-policing and self-regulation.

LEGAL ISSUES TO CONSIDER

There are many legal issues that a country will encounter when it attempts to implement and comply with the Cartagena Protocol on Biosafety (Kiplagat, 2009).

Liability and Redress

Liability is the obligation of a legal entity, such as a person, corporation, or government office, to provide compensation for damage caused by an action of that legal entity for which that legal entity is responsible. Liability will arise when an action contravenes legal rules and causes damage. There is a causal link between the action and the damage and responsibility for the action can be attributed to that legal entity. Within the context of the Cartagena Protocol, liability and redress refers to whether there should be an international liability and redress system for any environmental damage caused by a transboundary movement of an LMO. Currently, there is a significant difference in ideologies between countries who favour a strict liability regime, and those who favour a liability and redress regime that takes cognizance of existing liability and regimes within the legal systems of member states (Kiplagat, 2009).

If a country opts to develop a separate national liability and redress regime to deal specifically with living modified organisms, the specific challenges will be defining exactly what constitutes damage, determining an adequate timeline for ascertaining damages, and defining who should be liable for the determined damages. A country might also opt to use its existing liability and redress regime for environmental damage. This issue, however, will remain uncertain for countries until the debate on the international regime for the Cartagena Protocol is finalized.

Socio-economic Considerations

The Cartagena Protocol allows the possibility of including socio-economic considerations in biosafety regulatory approval processes for LMOs. Article 26 of the Protocol provides that Parties may take into

account socio-economic considerations in reaching a decision on import of LMOs, but only to the extent consistent with that country's other international obligations. These obligations could include any international agreements and treaties that a country is party to. The Protocol further limits what may be taken into account by describing socio-economic considerations as those "arising from the impacts of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities."

By definition, socio-economic assessments are *ex-ante*—before the fact procedures—for those products in the regulatory approval process. There may be some cases where a biosafety regulatory system may require post-release monitoring and evaluation of socio-economic impacts, but this instance clearly falls under the realm of *ex-post* assessments, where there is a long and well-established literature and experience for assessments after environmental release (Kiplagat, 2009).

The Protocol in itself does not define socio-economic considerations and the interpretation of this Article has been left to individual parties. If a country decides to include socio-economic considerations in its regulatory process, a clear definition on what issues will constitute socio-economic considerations and how they will be factored into the decision making process should be included in the law, regulations or guidelines.

Public Participation

Article 23 of the Cartagena Protocol encourages Parties to "promote and facilitate public awareness, education and participation in the safe transfer, handling and use of LMOs…" The Protocol further provides for consultation with the public to be part of decision-making and necessarily unique to each country's legal system and regulations. In addition, any public participation that is permitted in a country with respect to biosafety decision making should not differ in any material way from participation permitted in that country on other matters that may impact conservation and sustainable use of biodiversity. The legal challenge will be to ensure issues on public participation with regard to implementation of the Cartagena Protocol will be treated in the same manner as any other public participation mechanism currently in use within a country.

As the Cartagena Protocol does not give guidance on the public participation procedures to be used in the decision-making process, it is important that when engaging in public dialogue each country should consider the level of education, the language of communication and the medium to be used.

Transparency and Confidentiality

Article 21 of the Cartagena Protocol allows certain information provided by a notifier (applicant) to be treated as confidential. The Protocol provides that the name and address of the notifier; a general description of the living modified organism or organisms; a summary of the risk assessment; and any methods and plans for emergency response shall not be treated as confidential. This information is considered to be information that must be supplied in the public interest. The onus is on the notifier to specify the information it considered to be treated as confidential.

However, not all information identified by the applicant as "confidential" qualifies to be treated as such. Countries need to provide clear guidelines on confidentiality in their laws and regulations since this issue is linked to transparency. Information that may have an adverse economic impact on the business of the developer should be kept confidential as this information may provide a competitor an unfair advantage. Trade secrets, the gene construct and the efficacy data are types of information considered to be confidential material. The location of field trials and the personal information of the applicant are also treated as confidential in most instances. Countries should strive to reach a balance on what information can

be kept confidential and what should be made available to the public. The public needs to be educated on why some information will remain confidential as this is important in the decision-making process.

Transparency is an integral part of a regulatory process as it ensures that the regulatory process within the country is clear to the applicant, the Government, regulators and the general public. Countries should therefore ensure that the regulatory process has legal rules that set forth the application process, including the information required on the application, the parties involved and the office responsible for the activities to be undertaken. Those regulations or guidelines should ensure that decisions are availed to both the applicant and the public. A mechanism of how the application and decision documents can be made available to all interested parties should also be developed. The legal challenge will be to create a balance between the competing interest of the applicant and the information to be available to the public.

CONCLUSION

The challenge for African countries will be to ensure that the laws developed address issues that have not been clearly defined by the Cartagena Protocol yet are important in its implementation at the national level. Clear and concise rules will go a long way in ensuring an adequate level of protection for transboundary movement of LMOs. Overall, countries should enhance their policy and regulatory capacities in order to be able to unpack and confront the challenges facing development and implementation of biosafety systems. There is a need for a more nuanced and context-driven approach to biosafety as a platform for raising stakes for success and making best use of available resources. Failure to adequately define and delimit policy and legislative issues and embed them within a science-based assessment of biosafety causes more harm than good to efforts by countries to develop and implement biosafety systems.

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Chapter 6. Socio-economic issues associated with GE crops in Africa

SAM TIMPO

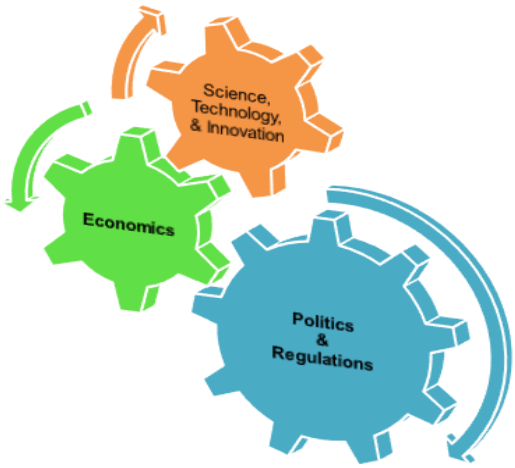
INTRODUCTION

The challenge of the new millennium is to provide solutions for a growing population including attaining food security and food safety, managing climate change and the limited fossil fuel resources while combating disease, hunger, malnutrition, poverty, and inequity. The nature of the challenge is not only to increase global future production but also increase it *where it is mostly needed by those who need it most…with special focus on smallholder farmers, women and rural households and their access to land, water and high quality seeds … and other modern inputs* (FAO, 2008). This resonates particularly with Africa, a continent recognized for its high agricultural potential yet low productivity characterized by low product diversity and the existence of biotic and abiotic stresses. As a consequence, Africa is a net importer of food. The three basic economic problems to resolve for any system are what to produce, how to produce it and who gets what is produced. Concerning how to produce to meet societal needs, modern biotechnology has been identified as a tool for agricultural productivity and food security in meeting the global needs for food, feed, fiber, and fuel. Proponents argue that biotechnology could be used to address challenges that have been difficult to resolve using conventional approaches.

The NEPAD Planning and Coordinating Agency, among other objectives, seeks to eradicate poverty, place African countries on a path of sustainable growth and development and halt the marginalization of Africa in the globalization process and enhance its full and beneficial integration into the global economy. A thriving African bioeconomy within the global market place is possible if premised on enabling biosafety laws and an ability to make timely and appropriate regulatory decisions. Economics is one of the key drivers of change within a bioeconomy and plays a major role in assessing and improving a regulatory process (Figure 1).

Figure 1: Drivers of Change

Africa urgently needs strategic repositioning in the modern era of technological advancement and bioinformatics.

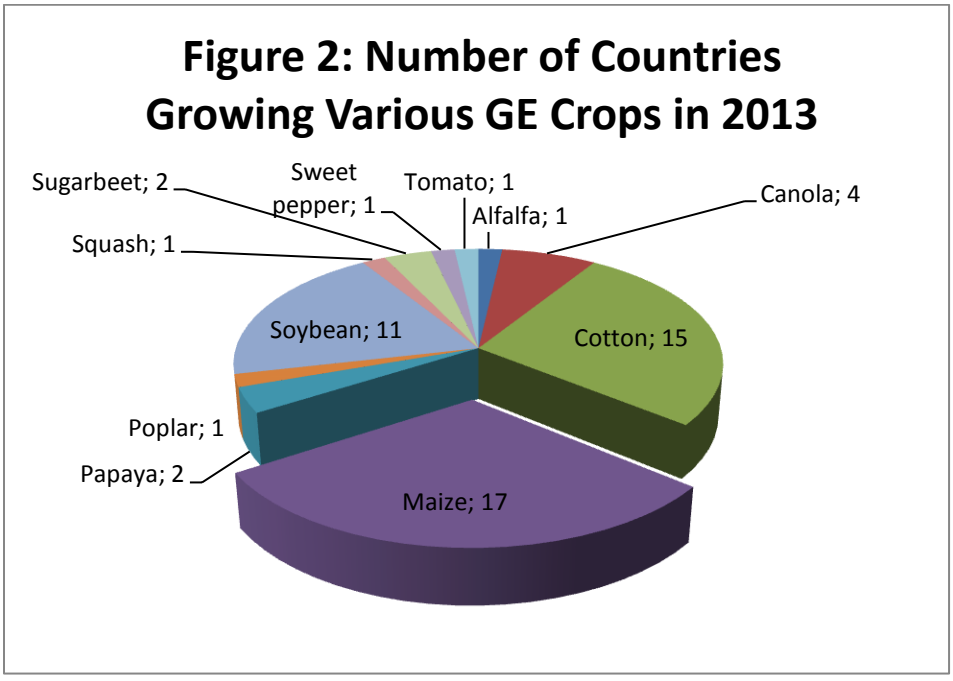


SOCIO-ECONOMIC BENEFITS AND CONCERNS FOR ADOPTION OF GE CROPS

Area under biotech crops and the number of countries and farmers planting biotech crops globally have been monitored since commercialization in 1996. James (2013) in his annual report on the global status of commercialized GE crops observes an annual growth rate of 6% for the 18-year period of commercial cultivation and that there was a more than 100-fold increase in biotech crop area from 1.7 million hectares (ha) in 1996 to 175.2 million ha in 2013. By 2013, 18 million farmers in 27 countries of which more than 90%

were resource-poor farmers in developing countries had planted GE crops. The report estimates that the global value of the biotech crop market in 2012 was US$14.84 billion and this represented 23% of the US$64.62 billion global crop protection market. The share of biotech crop seeds in the estimated US$34 billion global commercial seed market was 35% in 2012 (James, 2013). This valuation of the global biotech crop market was based on both the sale price of biotech seed and associated technology fees. Brookes and Barfoot (2009) also noted that the direct global farm income benefit from biotech crops was $10.1 billion in 2007 and that since 1996, farm incomes have increased by $44.1 billion. About $20.5 billion of the total cumulative farm income benefit (46.5%) was attributed primarily to yield gains and to some extent facilitation of a second crop while the remaining 53.5% was due to reductions in the cost of production. The contribution of GE insect resistance technology to the observed yield gains was estimated at 68% while GE herbicide tolerance contributed the remainder.

Of the 27 countries that commercially cultivated GE crops, 19 were from developing countries while 8 were industrial countries. The cumulative economic benefits from 1996 – 2012 for developing countries was US$59 billion compared to US$57.9 billion (46.5%) for industrial countries. For 2012, the economic benefit for developing countries was US$8.6 billion and US$10.1 billion for industrial countries (Brookes and Barfoot 2014, forthcoming; cited in James 2013). The US had the largest share of global biotech crop plantings in 2013 accounting for 70.1 million hectares. Other major growers were Brazil with 40.3 million ha, and Argentina with 24.4 million ha. Other notable mentions were India, Canada, China, Paraguay, South Africa and Pakistan. The eleven GE crops deployed in 2013 were alfalfa, canola, cotton, maize, papaya, poplar, soybean, squash, sugar beet, sweet pepper and tomato. Of these, maize, cotton and soybean were the most cropped in terms of number of adopter countries (Figure 2).



Source of data: James 2013

The three crop traits adopted were herbicide tolerance, insect resistance, and stacked traits. Available statistics suggest stacked double and triple traits appear to be increasingly more popular with farmers compared to insect resistance traits alone. Double stacks conferred pest resistance and herbicide tolerance while the triple stacks conferred resistance to two insect pests plus herbicide tolerance**.** In 2013, 13 countries planted 47 million hectares to GE crops with stacked traits (James 2013)**.**

Some Continent Specific Statistics

Currently, farmers in the US grow more GE soybean, maize, cotton and canola than conventional varieties. The scenario is not different in Canada for GE soybean, maize, and canola. The benefits accruing to adopter farmers in these countries are well documented (see James, 2009; Brookes and Barfoot, 2009). Five EU countries namely Spain, Portugal, Czech Republic, Slovakia and Romania planted a total of 148,013 hectares of biotech Bt maize in 2013. Spain alone accounted for 93% of this total.

At present, only 3 African countries (South Africa, Burkina Faso, and lately Sudan) commercially cultivate GE crops. From an initial 197,000 hectares in 2001, the area planted to GM crops by South Africa increased over the years to 2.85 million hectares in 2013. Of the three GM crops grown, Bt maize is the leading crop in terms of hectarage under cultivation with a share of 82.9 per cent of all GM crops. In 2013, Bt maize occupied 86.6 per cent of all land cultivated to maize, be it conventional or GM with HT soybeans occupying 92% of total area of 520, 000 ha planted to soybeans while the total area of 8, 000 ha under cotton represented a 100% adoption rate. The net benefits from biotech crops for South Africa was estimated at US$98 million in 2011 while the accumulated benefits from 1998 to 2011 was US$922 million (Brookes and Barfoot, 2009). Maize accounted for US$891.1 million, soybean US$34.4 million and cotton US$7 million of these accumulated benefits. Cotton is the leading cash crop in Burkina Faso and is second only to gold as an export commodity. The sector however was beset with pest control issues in the 1990s with reported crop losses between 30 to 90% in some growing areas (Goze et al., 2003; Vaissayre and Cauquil, 2000; personal communication, 2013). Pyrethroid resistance was observed in major pests with more than €3 million loss in 1998 and increased number of insecticidal sprays from 6 up to 12 with decreased effectiveness. To address resistance to pesticides and decreased cotton production, Burkina Faso adopted Bt cotton. In 2008, 8,500 ha was planted to Bt cotton for certified seed production and a modest 15,000 ha planted. Area under cultivation increased to 125,000 ha in 2009 and by 2013, to 474,229 ha. Sudan commenced Bt cotton commercialization in 2012 and put 20,000 ha under cultivation. This increased to 62,000 ha in 2013.

Brookes and Barfoot (2009) report that both small- and large-scale farmers have adopted GE crops and that the size of operation appears not to influence adoption. The four leading countries growing GE crops in Asia are India, China, Pakistan and the Philippines. In India where Bt cotton remains the only commercialized GE crop, 11 million hectares was planted by small-scale farmers to the crop in 2013. With an adoption rate of 93%, India enhanced farm income by US$3.2 billion in 2011 and by US$12.6 billion for the period 2002 – 2011. For the 7.1 million small- and resource-poor farmers who benefited from cultivating Bt cotton in China, studies conducted by the Center for Chinese Agricultural Policy (CCAP) indicated that, on the average, small-scale farmers increased their yield by 9.6%, reduced insecticide use by 60% (which had positive implications for both the environment and the farmers' health), and generated a substantial US$220/ha increase in farm income (James, 2009) and in 2013, 7.5 million small resource poor farmers in China grew 4.2 million hectares of Bt cotton. Small-scale farmers who grew Bt maize in the Philippines were also reported to have gained from the crop in 2008. A socio-economic impact study reported that these farmers gained an additional farm income from Bt maize of about US$135 per hectare during the dry season and about US$125 per hectare during the wet season of the 2003-2004 crop year (James 2009).

Reasons for the fast adoption

For any agricultural technology, benefits are usually quantified in monetary terms. However, non-monetary benefit considerations including ease of operation, time savings, and lesser exposure to chemicals also inform farmer decisions (Fernandez-Cornejo and Caswell, 2006). Consequently, farmers' adoption of new technologies is influenced by both monetary and non-monetary expectations of net benefits. Farmers normally choose technologies and practices that they expect to earn the greatest benefits based on yield performance, taste and preferences, farm characteristics, savings in management time, demand for

produce/product, and costs. The observed annual increments and growth in global biotech crop adoption have been attributed to a number of factors including continued increases in the number of countries growing GE crops (adopter countries), additional crop acreage deployment in adopter countries, the introduction of new GE crops and traits, farm profitability, and the introduction of stacked or multi traits (James, 2009; Brookes and Barfoot, 2009).

Similar considerations have driven the rapid increase in the adoption of GE crop varieties in countries that commercialized cultivation. Beyond farm profitability, other less quantifiable (non-pecuniary) benefits have been observed to have had important influences for technology adoption (Brookes and Barfoot, 2009). These benefits have received mention across adopter countries by farmers and were attributed to herbicide tolerant (HT) and insect resistant (IR) crops (Boxes 1 & 2).

Box 1: Herbicide tolerant crops

Factors influencing farmer adoption of herbicide tolerant crops include:

- Ease of use associated with broad-spectrum, post-emergent herbicides and the increased/longer time window for spraying;
- Reduction in damage to crop arising from the application of post-emergent herbicide;
- Ability to use alternative production technologies such as no/reduced tillage practices ;
- Time and fuel savings from the adoption of no/reduced till compared to equivalent conventional crop husbandry practices;
- Ease of weed control leading to cleaner crops hence reduced harvesting costs, and time spent for harvesting. Resultant effect is improved harvest quality and premium price for quality;
- Avoidance of potential damage from soil-incorporated residual herbicides in follow-on crops;
- Improved quality of family life arising from social benefits derived from time savings made from crop husbandry practices.

Sources: Brooke & Barfoot 2009; James, 2009; Karembou *et al.* 2009; Personal communication 2008 - 2013

Box 2: Insect resistant crops

Factors influencing farmer adoption of insect resistant crops include:

- Reduced risks from crop loss associated with insect pests;
- Convenience associated with less time spent on crop walking and/or applying insecticides;
- Savings in fuel use – mainly associated with less spraying;
- Savings in the use of machinery (for spraying and possibly reduced harvesting times);
- Improved quality (e.g. lower levels of mycotoxins in GE IR maize);
- Improved health and safety for farmers and farm workers (from reduced handling and use of pesticides);
- Easier crop husbandry practices;
- Facilitated second crop cultivation;
- Triggered subsidiary benefits for bee keepers as fewer bees were now lost to insecticide spraying;
- Improved family welfare and education for women and children.

Sources: Brooke & Barfoot, 2009; James, 2009; Karembu *et al.*, 2009; Personal communication 2008 - 2013

Yet despite this rapid growth, the industry has been beset by a wide-ranging and often emotionally charged debate on issues pertaining to the environment, human health, economics, ethics and politics. The socio-economic concerns include dependence of farmers on large corporations for seed; unaffordable planting materials; possible unsuitability of GE crops for small-scale farm operations and for resource poor farmers (interestingly 90% of GE crop farmers are small-scale and resource-poor farmers in developing countries);

unethical patenting of life; possible limited access and increased price of seeds due to technology fees; lack of food distribution infrastructure rather than simply producing more; products needed in developing countries not being developed due to market or profit considerations; and developing countries having to eat food others had rejected. It must however be noted that these concerns are not peculiar to GE crops but rather are challenges inherent in the agricultural sector. Discussions on and in-depth analysis of the benefits and perceived risks associated with GE crops are required but have been hindered by lack of information, lack of access to impact assessment analyses and in some cases misperceptions. The goal of public policy is to maximize the welfare of all its citizens and biosafety regulation can help achieve that by providing certainty, stability and disciplinary rigor to the social framework required for risk assessment, management and communication.

Socio-economic Considerations in Biosafety

Regulation has been central to the debate on the use of agricultural biotechnology due to possible safety implications for the environment and human health on one-hand and non-safety implications including socio-economic considerations on the other. Defined as a principle, rule, or law designed to govern conduct, regulations play a critical role in achieving broad socio-economic goals, including assuring safety, achieving equitable distribution of income, ensuring public confidence, improving efficiency of resource allocation, and protecting rights of ownership. In the same vein, biosafety regulations are expected to enable countries to protect human health and the environment while harnessing the benefits of modern biotechnology. However, such outcomes can only be achieved if countries implement functional biosafety regulatory systems. Consequently, the Cartagena Protocol on Biosafety, a legally binding international agreement, negotiated, concluded, and adopted in the framework of the Convention on Biological Diversity, was established to guide parties in developing systems for the environmentally sound management of modern biotechnology practices, focusing specifically on trans-boundary movement of living modified organisms (LMOs) and their impact on biodiversity.

Article 26 of the Cartagena Protocol on Biosafety allows Parties to the Protocol to consider the inclusion of socio-economic considerations in biosafety approval processes and decision making for living modified organisms. Article 26 of the Protocol states that:

1) The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.
2) The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

A close examination of the provisions of this article reveals that it is fraught with implementational challenges having been cast in a language of constructive ambiguity that presents a number of caveats. These are:

1) Lack of a clear understanding of the *meaning* of socio-economic considerations in biosafety because the Protocol does not define what these considerations are;
2) Regulators' *lack of information* on the socio-economic impacts of biotechnology; and
3) Lack of clarity on the *process* of incorporating socio-economic considerations in actual decision-making.

Consequently, it is unclear what socio-economic considerations (SECs) are, when they are required, what information should be used for the analysis, how that analysis should be done, and by whom. In addition, a strict interpretation of the text in the Cartagena Protocol suggests an implementation scope that is limited to

impacts of living modified organisms (LMOs) on biodiversity, especially on indigenous and local communities. Nevertheless, the language in some national legislation suggests a broad and undefined inclusion of all socio-economic considerations of LMOs. The Protocol also states that the inclusion of socioeconomic considerations must be consistent with other international obligations. While it is possible for a country to include socioeconomic considerations in its national biosafety regulatory system, it will require a significant amount of work to specify all the details in its laws and regulations that are needed to make the analysis of those considerations consistent with international obligations as well as fair and transparent to biosafety stakeholders (Jaffe 2005, Falck-Zepeda 2009).

Recognizing the implementational challenges, a survey[5] on the application of and experience in the use of socio-economic considerations in biosafety decision-making as provided for in Article 26 of the Cartagena Protocol on Biosafety Scoping exercise on socio-economic considerations (SECs) in biosafety decision-making was commissioned. The survey included capturing experiences of Parties with SECs and the preparation of a draft outline for a toolkit module on socio-economic considerations. The survey was conducted from Oct 14, 2009 to Nov 13, 2009 in English, French and Spanish. A total of 578 completed surveys were received from individuals and organizations. Respondents identified the following as most important socio-economic issues:

- Food security
- Health-related impacts
- Coexistence of LMOs
- Impacts on market access
- Compliance with biosafety measures
- Macro-economic impacts
- Impacts on biodiversity
- Economic impacts of changes in pest prevalence
- Farmers' rights
- Intellectual Property Rights
- Impacts on consumer choice
- Use of pesticides and herbicides
- Cultural aspects
- Labour and employment
- Land tenure
- Gender impacts
- Rural-urban migration

Socio-economic considerations are non-safety issues of importance to African countries but must be appropriately placed within the decision-making process.

Ranking of the level of agreement with statements concerning the evaluation of SECs	
Rank	Statement
1	"Socio-economic considerations should be included in all decision-making frameworks for LMOs."
2	"Decisions concerning LMOs should incorporate socio-economic information at the same time as scientific risk assessment information is being considered."
3	"Socio-economic considerations should be undertaken separately from scientific risk assessments of LMOs."
4	"Socio-economic considerations should be part of the scientific risk assessment of LMOs."
5	"Decisions concerning LMOs should incorporate socio-economic information only after scientific risk assessment information has been considered."

[5] UNEP/CBD/BS/COP-MOP/5/INF/10

For inclusion in a methodological toolkit, respondents listed the following assessment methods in order of importance:

- Cost effectiveness
- Macroeconomic impacts
- Cultural, ethical assessment
- Property right assessment
- Benefit-cost assessment
- Economic risk assessment

When asked whether they had ever taken SEC arising from impact of LMOs on the conservation and sustainable use of biological diversity for decision on imports, 29% indicated having done so, 15% had only in some cases and 40% had not.

Regarding if they had cooperated with other Parties on research and information exchange on any socio-economic impacts of LMOs, only 7% had done so. Twenty-seven percent had done so to a limited extent while a staggering 66% per cent had not at all.

Parties to the Cartagena Protocol on Biosafety agreed further discussions were required for conceptual clarity on socioeconomic issues associated with decision-making on LMOs and that Parties that may wish to consider socioeconomic factors in reaching decisions will require assistance in that regard. Consequently, it was agreed to convene a group of experts to develop conceptual clarity on socioeconomic considerations and to convene online discussion groups and regional online real-time conferences to facilitate exchange of views, information and experiences on the issue. COP-MOP 6 therefore established an Ad-hoc Technical Expert Group (AHTEG) on socio-economic considerations (SECs) to:

- Examine the outcomes of the online discussion group, the regional online real-time conferences, and the global overview of information, in order to develop, drawing upon the outcomes, conceptual clarity on socio-economic considerations; and
- Submit a report for consideration by COP-MOP 7.

The AHTEG on SECs recognized there was no single agreed definition for socio-economic considerations hence adopted a descriptive approach to reach conceptual clarity and went ahead to propose elements of a framework that could be adapted as deemed appropriate to national and regional specificities and consistent with international obligations

The AHTEG on SECs noted that any list of elements of SECs would be indicative and non-exhaustive but should be informed by existing experiences and information which would then contribute to the future development of guidelines on SECs.

Framework for Socio-economic Impact Assessment (SIA)

Socio-economic considerations are crucial in safeguarding the interests of indigenous and local communities in technology adoption. However, a lack of comprehension of the regulations governing the inclusion of socio-economic considerations by stakeholders could translate to socio-economic assessments becoming an obstacle to the development and transfer of safe and efficacious products to farmers (Falck-Zepeda, 2009). For biosafety approval processes, assessment of such considerations will require a mechanism for identifying positive and negative socio-economic impacts. Doing this requires a framework that is accessible, transparent, reproducible, predictable, and science-based to ensure that SIA will not become an obstacle to the safe development and transfer of products to end users. The socio-economic impact data could have the social impact component including acceptability, vulnerability, access, gender equity, loss of traditional knowledge, appropriateness, culture, ethics, and religion while the economic impact component covers cost-

benefit analysis, cost of application, cost of compliance with biosafety regulations, cost of new planting material and impact on trade.

Functional, effective, and efficient biosafety systems are required for the safe and sustainable access to modern biotechnology products.

The major phases in a GE product development that potentially represent regulatory decision points in a functional biosafety system are the laboratory, greenhouse, confined field trial, commercialization and post-commercialization stages. The central issue is to determine the stage at which to include socio-economic considerations since socioeconomic assessments could be ex-ante i.e. before the fact/event or ex-post i.e. after the fact/event. For biosafety approval processes, socioeconomic assessments tend to be ex-ante and therein lies a limitation regarding methods for assessment. Equally important is whether to have socioeconomic considerations inbuilt into the biosafety decision-making process or have a process that separates risk and socio-economic impact assessments but utilizes SIA before a decision is made (Falck-Zepeda, 2009).

REGULATORY COSTS

Risk and cost considerations bound biosafety assessments and biotechnology decision-making processes (Viscusi, Vernon, and Harrington, 2000). It is also noteworthy that the time value of money lost from regulatory approval delays tend to be greater than the cost of compliance itself (Bayer et al., 2008). The high cost of generating adequate data for regulatory purposes, maintaining functional biosafety regulatory structures, and ensuring regulatory compliance is well documented (Bayer et al., 2010; Bradford et al., 2006; Jaffe, 2005). In the specific instance of discovery, development and authorization of a new biotech crop or trait, the cost is estimated to be US$136 million (McDougall, 2011). A regulatory system must be established in a manner that it is workable, science-based, cost efficient, and does not compromise on acceptable safety standards. Only relevant regulatory data should be requested at any stage of the regulatory process and the regulatory structures and requirements should be efficient and commensurate with the level of risk posed by GEOs. Thus there is the need to clearly define data needs and establish acceptable data sources and methods of validation.

Most African countries and institutions lack the financial and technical resources for mandatory risk assessment and compliance monitoring. However, a false and detrimental premise in establishing regulations is the assumption that foreign multinational companies will be the only developers and users of the technology and will offset the high regulatory costs with profits from approved products. This assumption penalizes public institutions that are interested in applying GEOs that focus on crops and traits of national and regional interest. Many public research institutions in Africa have partnered with foreign public and private counterparts to undertake GE R&D activities, but the products of these initiatives never reach African farmers primarily because of the prohibitive cost of regulatory approval and the long delays associated with regulatory decisions.

A useful regulation is one that ensures an adequate level of safety and enables access to safe new products that will benefit local communities.

An additional cost mitigation consideration would be the acceptance of regulatory food safety data from other countries and environmental data from regions with similar agro-ecological systems. If farmers and consumers in Africa are to benefit from improved planting materials, there is the need to build regulatory systems that are an incentive for investment.

Key issues that can lead to disagreement and stymie progress towards implementing functional regulatory frameworks include:

terminology differences; inconsistency with international obligations; inclusion of socio-economic issues; labelling of GE products; and choice of liability and redress regime. Considering that most African countries are parties to the Cartagena Protocol on Biosafety, consistency with provisions of the Protocol is of prime importance and consensus documents from the Protocol can be used to help establish harmonised regulations or processes.

CONCLUSIONS

Regulations are critical for the adoption of good science and for deriving benefits from modern biotechnology without compromising on safety to the environment and humans. For any human endeavour, the adoption of a technological innovation implies a certain amount of risk and managing this risk is an important component of decision-making. Ultimately, a regulatory decision has to be made, and the scientific assessment will have to be balanced against the cost/benefit analysis in risk management.

National biosafety regulatory systems in considering socio-economic issues should address definitional issues and spell out the decision-making rules and regulations upfront and these must be consistent with international obligations. Also needed is a clear indication of when and how "socio-economic considerations" will be analyzed and factored into the decision-making process. Designing a clear, adequate, fair, transparent, efficient and workable national biosafety system requires a significant amount of work and resources. Information exchange on best practices could be useful as a starting point. Currently no blueprint exists on how these issues should be addressed but then it is important for the national regulatory systems to note these challenges and fashion out a workable process that is agreed upon by biosafety stakeholders.

A thriving African bioeconomy within the global market place is possible if based on enabling biosafety laws and an ability to make timely and appropriate regulatory decisions. Functional regulatory systems that demonstrate government leadership in the technology, assure the public safety, ensure public confidence, facilitate public research and corporate collaboration, and promote investment by industry are needed to attain socio-economic goals such as achieving equitable distribution of income, improving efficiency of resource allocation, and protecting rights of ownership. The AU-NEPAD Agency's African Biosafety Network of Expertise (ABNE) is partnering with other biosafety service providers to assist build functional regulatory systems in Africa. ABNE is achieving this goal by empowering African regulators and policy- and decision-makers by providing science/evidence-based biosafety information, technical assistance and training that will ensure the safe use and management of agricultural biotechnology and the effectual participation of African countries in the global bioeconomy.

Africa urgently needs strategic repositioning in the modern era of technological advancement and bioinformatics.

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Chapter 7. Biosafety regulatory systems in Africa

E. JANE MORRIS

INTRODUCTION

At the start of this chapter it seems logical ask the question "why does Africa need biosafety regulation anyway?" Biotechnology and biosafety go hand in hand, and countries cannot develop their biotechnology sector (at least insofar as Genetically Engineered Organisms (GEOs), alternatively known as Living Modified Organisms (LMOs) are concerned, without at the same time ensuring safety. However the majority of African countries are recipients of technology developed elsewhere, and have limited capacity to develop their own biotechnology products. This is starting to change, with Kenya, Uganda, Egypt and South Africa leading the way in biotechnology research, yet even in those countries no GEOs developed by local researchers have reached the stage of commercialization.

The wide range of available biotechnology techniques has only recently started to be taken up by African researchers. Although GEOs continue to attract attention, there are many other emerging technologies with relevance to Africa. These include not only more widely known techniques such as marker assisted selection and mutation breeding, but also new techniques such as RNAi, zinc finger nucleases etc. Biosafety regulation may be seen as a means to ensure governability of the technology, although the rapid pace of technology development threatens to leave the regulatory systems behind. Nevertheless, by managing the uncertain risks, the technology's benefits for society can be realized (Todt and Lujan 2008). Regulation can also facilitate the process of technology selection, through comparative risk-benefit assessment to facilitate choice between alternative technologies (Morris 2011).

A HISTORICAL PERSPECTIVE

South Africa is probably the most advanced country on the continent in terms of biotechnology research, and was the first country in Africa to enact biosafety regulations. The factors driving this process are informative (Morris 1995). In the early days of genetic engineering, in 1978 an advisory committee known as the South African Committee for Genetic Experimentation (SAGENE) was established. Although this committee initially dealt with laboratory containment issues, its mandate was later widened to include environmental release. Applications for importation of genetically engineered (GE) seeds received by the Department of Agriculture were sent to SAGENE for consideration before permission for importation was granted. The first request for field trial approval of genetically engineered cotton was received by SAGENE in 1990, and a number of other approvals followed subsequently. The limitations of SAGENE became apparent when research on GE crops within South Africa developed to the stage where confined field trials were needed. As an advisory body, SAGENE had no power to make decisions. The Department of Agriculture could apply its plant and quarantine control legislation to imports, but had no power to regulate activities when importation was not involved. This led to a realisation that additional legislation was necessary. As a result of the political turmoil in South Africa there were some delays in developing new legislation, but the Genetically Modified Organisms Act (South African Department of Agriculture 1997) was finally passed and implemented in 1999 when regulations were published. The initiative to develop legislation came from scientists working in the field, who needed an appropriate regulatory environment to facilitate their work.

The South African situation stands in stark contrast to that of most other African countries. Much of the early push to develop biosafety regulations in those countries came through the development of the Cartagena Protocol on Biosafety (CPB) (Secretariat of the Convention on Biological Diversity 2000), amid concerns that developing countries would become testing grounds for novel and potentially risky substances that they had neither the capacity nor the regulatory frameworks in place to deal with (Gupta 2010). Although African policy makers expressed early concern over GEOs, these concerns surfaced in the public mind at the time of the food aid crisis in 2002 (Clapp 2005). African policy makers' concerns were partially influenced by concerns in Europe over GEOs, as well as a mistrust of the motives of multinational seed companies. During the regional drought in Southern Africa at that time, African governments became concerned about the potential health, environmental and trade effects of importing food aid (Eicher et al. 2006). Biosafety legislation that was developed as a result of these pressures therefore tended to be preventative in nature; the Biosafety Act of Zambia (Government of Zambia 2007) and the Biosafety Proclamation of Ethiopia (Government of Ethiopia 2009) are extreme examples of this.

Some African countries have subsequently developed biosafety legislation in response to other pressures. Burkina Faso wanted to facilitate the local introduction of GE cotton to revive its flagging economy (Vitale et al. 2010), while countries such as Kenya, Uganda and Nigeria have been promoting their own development of biotechnology capacity and have been pushing ahead with confined field trials.

The availability of capacity-building funding from the Global Environment Facility (GEF) for developing countries to draft National Biosafety Framework (NBF) documents after the CPB entered into force in 2003, was another reason for countries to develop biosafety regulations, even though a number of these countries at that stage had little knowledge of, or interest in, biotechnology or biosafety. As discussed in the GEF evaluation report (GEF 2006), the CPB does not prescribe the immediate need for comprehensive legislation, stating instead:

- As an alternative to immediate development of a law addressing the "introduction of LMOs", parties may decide to directly use article 10 of the protocol, adopting it by reference as an interim measure for implementing the protocol.
- As an alternative, to develop a streamlined decision-making process to address LMOs used as food, feed, or for processing (LMO-FFPs), parties may decide to directly utilize the provisions of article 11.6 of the protocol in the same way.
- Nevertheless the development of draft legislation was seen by most countries as an important component of their NBFs, even though this did not necessarily proceed further once the GEF funding was exhausted.

It is therefore clear that there have been many different underlying reasons behind the development of biosafety regulation in Africa, which at the same time have led to differing approaches to the issue.

CURRENT STATUS

A summary of the current status in each African country is provided in Table 1.

Table 1

Status of GM technology and regulations in Africa

Country	Draft National Biosafety Framework	Enacted Biosafety Legislation	Draft Biosafety Bill	Biotechnology/ biosafety policy	Approved GM laboratory research	Confined field trials	General Release Approval
Algeria	Yes	Yes	N/A	Yes	Yes	No	No
Angola	No	No	No	No (GM moratorium)	No	No	No
Benin	Yes	No	No	No (GM moratorium recently lifted)	No	No	No
Botswana	Yes	No	Under development	Yes	No	No	No
Burkina Faso	Yes	Yes	N/A	Yes	Yes	Yes	Yes
Burundi	Yes	No	Yes	Yes	No	No	No
Cameroon	Yes	Yes	N/A	Yes	Yes	Yes	No
Cape Verde	Yes	No	No	No	No	No	No
Central African Republic	Yes	No	No	No	No	No	No
Chad	Yes	No	No	No	No	No	No
Comoros	Yes	No	No	Yes	No	No	No
Congo	Yes	No	No	No	No	No	No
Côte d'Ivoire	Yes	No	Yes	No	No	No	No
Democratic Republic of the Congo	Yes	No	Yes	Yes (draft)	No	No	No
Djibouti	Yes	No	No	Yes (draft)	No	No	No
Egypt	Yes	Yes	N/A	Yes	Yes	Yes	Yes but official ban on GE maize
Equatorial Guinea	No	No	No	No	No	No	No
Eritrea	Yes	No	Yes	Yes	No	No	No
Ethiopia	Yes	Yes	N/A	No	No	No	No
Gabon	Yes	No	No	No	No	No	No
Gambia	Yes	No	No	No	No	No	No
Ghana	Yes	Yes nearing full implementation	N/A	No	Yes	Yes	No
Guinea	Yes	No	No	No	No	No	No
Guinea-Bissau	Yes	No	Yes	No	No	No	No
Kenya	Yes	Yes	N/A	Yes	Yes	Yes	No (current ban on GE food products)
Lesotho	Yes	No	Yes	Yes	No	No	No
Liberia	Yes	No	Yes	Yes (draft)	No	No	No
Libya	Yes	No	No	No	No	No	No
Madagascar	Yes	No	Yes	Yes	No	No	No
Malawi	No	Yes	N/A	Yes	Yes	Yes	No
Mali	Yes	Yes (decree)	N/A	No	No	No	No

Mauritania	Yes	No	No	No	No	No	No
Mauritius	Yes	Yes	N/A	Yes	Yes	No	No
Morocco	Yes	No	Yes	No	No	No	No
Mozambique	Yes	Yes (decree)	Yes	Under development	No	No	No
Namibia	Yes	Yes	N/A	Yes	Yes	No	No
Niger	Yes	No	No	No	No	No	No
Nigeria	Yes	Yes but awaiting presidential approval	N/A	Yes	Yes	Yes	No
Rwanda	Yes	No	Yes	Yes	No	No	No
Säo Tomé and Principe	Yes	No	No	No	No	No	No
Senegal	Yes	Yes but not yet fully functional	N/A	No	No	No	No
Seychelles	Yes	No	Yes	Yes	No	No	No
Sierra Leone	Yes	No	No	Yes (draft)	No	No	No
Somalia	No	No	No	No	No	No	No
South Africa	Yes	Yes	N/A	Yes	Yes	Yes	Yes
Sudan	Yes	Yes	N/A	No	No	Yes	Yes
Swaziland	Yes	Yes but not yet functional	N/A	Yes	No	No	No
Tanzania	Yes	Yes	N/A	Yes	Yes	No	No
Togo	Yes	Yes but not yet functional	N/A	No	No	No	No
Tunisia	No	No	Yes	No	Yes	No	No
Uganda	Yes	No but approval likely	Yes	Yes	Yes	Yes	No
Zambia	Yes	Yes	N/A	Yes	No	No	No
Zimbabwe	Yes	Yes	N/A	Yes	Yes	Yes (2002-2006)	No

Note: The information in this table is gathered from a multitude of sources, too numerous to cite. The data are correct according to the best information available to the author, but it is possible that there may be some minor inaccuracies.

As of February 2014, the only countries in Africa that have not yet ratified or acceded to the CPB are Côte d'Ivoire, Equatorial Guinea, Säo Tomé and Principe, and Sierra Leone,. Also as of February 2014, there are 56 signatories to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (Secretariat of the Convention on Biodiversity 2011), hereafter termed the "Supplementary Protocol", of which 13 are from Africa.

It is therefore clear that the majority of African countries are taking the CPB as the basis for their biosafety regulatory systems. In line with the requirements of the CPB, most African countries have adopted the Precautionary Principle (PP) in their regulatory systems, despite the many criticisms as summarized by Vlek (2010), who points to its inherent pessimism regarding uncertain risks.

African Model Law on Biosafety

The African Model Law (AML) embodies a strict view of the PP. The PP as framed in Principle 15 of the Rio Declaration (United Nations Conference on Environment and Development (UNCED) 1992), and adopted in the CPB text states:

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation.

The AML was first developed in 2001 but its contents have been controversial because of the strict nature of its provisions, which apply not only to living GEOs (i.e. LMOs) but equally also to the products of GEOs. In spite of this, the African Union (AU) and others have urged that the AML should be adopted as the basis of biosafety legislation by all African countries (Andanda 2009). In an attempt to gain greater acceptance of the AML, and to use it as a basis for harmonizing the positions of African countries on biosafety, there has been some attempt at revising the AML (African Union 2007). The most recent draft of the revised AML (African Union 2011a) however remains extremely strict, and goes far beyond the requirements of the CPB. Its provisions continue to apply equally not only to LMOs but also to sterile organisms and products of GEOs.

The revised AML also requires mandatory labelling of both GEOs and products of GEOs, including the relevant traits and characteristics of the organism. Taken to extremes, this would require not only segregation of GEOs from non-GEOs throughout the production process, but could also require segregation of different GE events in order to ensure that labels adequately reflect the particular traits that might be included in (for example) a cotton shirt.

The AML also addresses the issue of Liability and Redress, which has been the subject of intensive international negotiations resulting in the finalization of the Supplementary Protocol in 2011. The Supplementary Protocol applies specifically to "significant" damage, which is defined to include such items as:

a) The long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time;
b) The extent of the qualitative or quantitative changes that adversely affect the components of biological diversity;
c) The reduction of the ability of components of biological diversity to provide goods and services;
d) The extent of any adverse effects on human health in the context of the Protocol.

In contrast the revised AML makes no reference to the significance of any harm, and extends the liability to both direct and indirect effects.

However both the Supplementary Protocol and the AML "place the burden of proof on the claimant, meaning the more resources and knowledge a country has the more it will be able to apply the supplementary protocol effectively" (Komen 2012).

It can be unequivocally stated that the adoption of this strict AML will do little to stimulate the adoption of GEOs or the development of modern biotechnology within the countries concerned. As an example, the AML requires that experiments with locally produced GEOs must be carried out in "complete containment", presumably Biosafety Level 4 – regardless of the results of any risk assessment and the fact that few if any countries in Africa have such facilities. The approach of the AML, although promoted by the AU, seems to be at odds with the report of the AU's own High Level African Panel on Modern Biotechnology (African Union 2006) that "the AU should adopt the 'co-evolutionary' approach in which the function of regulation is to promote innovation, while at the same time safeguarding human health and the environment" and the recent support of African Ministers of Agriculture Science and Technology who endorsed the need "to take advantage of modern technologies such as biotechnology" (FARA Secretariat 2012).

The development of laws, regulations, guidelines or policies relating to biotechnology and biosafety is an ongoing process in many African countries. Progress has been documented at various stages, (Makinde et al. 2009; Mtui 2012; USDA 2011; Wafula et al. 2012; ABNE 2012, 2013, 2014). It is perhaps not surprising that the African countries have been a strong driving force in the development of the CPB (Egziabher 2007). The African Group's position placed an emphasis on the likelihood that biotech products could result in social and economic dislocations in the global south (Andrée 2005), and hoped that a Biosafety Protocol could help mitigate these disruptions. There were also hopes that the CPB would place added burdens on countries exporting goods to Africa rather than on the receiving countries, hoping to "shift the burden of testing to the exporting countries" (Garton et al. 2006). Despite this, there has been a lack of political commitment to implement the requirements of the Protocol through the development of national legislation. It may be that many countries expected the international instruments of the CPB to remove their responsibilities at national level.

COMPONENTS OF A BIOSAFETY REGULATORY SYSTEM

For countries in Africa to have a workable biosafety regulatory system, the passing of a Biosafety Act or equivalent, or the modification of existing legislation to take account of biosafety issues, is just the start of a long process. The CPB does not require specifically that new legislation is introduced, but it does require some decision making processes to be put in place, which in the majority of cases lead to legislation. Capacity needs to be built at many levels. The NBFs developed under the CPB did make progress in setting the scene to a greater or lesser extent depending on the country, but were insufficient to ensure that a full regulatory system was in place. Obonyo et al. (2011) point out that in most African countries there are many gaps in expertise necessary to implement a workable biosafety regulatory system. Even in South Africa, the country with the most experience on the African continent, many of the issues highlighted below have not yet been fully resolved, leading to ongoing conflicts and uncertainties.

Some of the components of an ideal functioning biosafety regulatory system are discussed below.

National Policy

A national policy is required to frame a country's unified approach to biotechnology and biosafety. Problems arise when one sector of government has a positive approach to the development of biotechnology (often led by ministries responsible for agriculture or science), whereas other ministries (often those responsible for the environment or trade) adopt a negative view. This has happened, for example in South Africa, where the Department of Science and Technology is responsible for the National Biotechnology Strategy (and the more recent Bioeconomy Strategy), while the Department of Agriculture administers the GMO Act, but the Department of Environment Affairs is responsible for the administration of the CPB, as well as for the National Environment Management Act (NEMA) and the National Environment Biodiversity Act (NEMBA) (South African Department of Environment Affairs 1998; 2004). NEMA and NEMBA collectively confer the ability to block the issuing of permits for release of GMOs applied for under the GMO Act. The diversity of approaches of different government departments leads to considerable uncertainty and can be considered partially to blame for regulatory delays and poor decision making (Janssen van Rijssen et al. 2013).

Legislation

Although some countries are operating with interim existing sectorial legislation (Wafula et al. 2012), the majority of countries in Africa are moving towards new biosafety legislation, with varying degrees of success. "Inexpertly drafted legislation that ….creates insufficient or legally uncertain permits and

processes, for example - may deter external investors and importers from future attempts to act within the country" (Global Environment Facility, 2006). Legislation comprises not only an approved Act governing biosafety, but also associated Regulations and Guidelines. The government ministry responsible for any new legislation must be agreed and confirmed, and that ministry is then responsible for drafting the Regulations that are required to bring the Act into force. It is not uncommon for there to be a delay of some years between the passing of an Act and its coming into force. The wording of the Act and Regulations should be aligned with the approach outlined in the Policy.

Administrative arrangements

Biosafety legislation is meaningless if there is no appointed body to administer the legislation, with appropriate resources at its disposal. There needs to be a central point where application forms are developed and disseminated, and where applications can be received and processed. The processes for handling applications, for receiving inputs on risk assessments, and for the final approvals and issuing of permits need to be defined. There also needs to be a clear mechanism by which applicants who are dissatisfied with the results of their application can apply for recourse, usually through an appeals process. There must be a central point where reports are received and evaluated, and where monitoring processes are undertaken to ensure adherence to permit requirements.

Risk assessors and agreed approach to risk assessment

Those involved in risk assessment are usually scientific experts who are independent from the decision-making process. In many African countries there is a scarcity of experts with the required expertise, but additional international expertise may be available if required. Experts should however be provided with a clear mandate and should follow an agreed methodology. The risk assessment may be undertaken with different perspectives, eg with the intention of complete risk avoidance (Townsend 2006), or through a risk-benefit assessment (Morris 2011). The comparative risks of alternative options for action need to be taken into account. An initial framing step can give direction regarding hazards and identified priorities (e.g. this is where discussions should take place regarding the importance of food security verses the importance of protection of biodiversity). The recommendations may be different depending on the context in which the assessment is undertaken. However the international context, and the country's adherence to international regulatory requirements such as the CPB, should also be taken into account.

Risk managers and decision makers

Whereas risk assessors are usually scientists operating in an advisory capacity, eventually a decision has to be made as to whether the activity with GEOs/LMOs will be permitted, and if so under what conditions. This puts the burden of responsibility on to government officials. The relevant government officials therefore require training and need adequate support to give them confidence in making decisions. Lack of confidence on the part of government officials is usually reflected in ongoing requests for additional information, delays in issuing permits, or outright rejection of applications.

Extension services

Extension officers play a vital role in introducing the technology to the farmers and advising on "best practice". They need to be trained in all aspects of the application of GE technology in order to ensure that farmers apply it to best effect. In many developing countries the extension system is unfortunately weak.

Agricultural inspectors

Agricultural inspectors are usually government employees, who inspect the process of growing and making of agricultural products. They can play a vital role in monitoring and inspection, provided they are mandated to do so and are appropriately trained to know what to look for.

Risk communicators

It is apparent that for any project involving GEOs to be successfully implemented, effective risk communication within the country is essential (Wangalachi et al. 2011). Communication and dissemination of accurate information appropriate to the audience is critical to reducing negative perception, building trust and winning public confidence in the technology.

Customs officials

Customs officials have an essential role to play insofar as the CPB is concerned, since its primary focus is on transboundary movement of LMOs. The five key roles and responsibilities of customs officers have been described as:

(i) ensuring that LMO imports and exports have proper approvals before they are cleared;
(ii) ensuring that LMO shipments are accompanied with appropriate documentation;
(iii) inspecting incoming shipments of LMOs to verify the actual content and cross-check them against the accompanying documentation;
(iv) detecting illegal or unintentional transboundary movements; and
(v) reporting to relevant authorities information concerning shipments of LMOs arriving at the ports of entry (UNEP 2009).

In most cases the roles of Customs officials will be confined to (i) and (ii) above, since the process of physical verification of actual content is time consuming and costly. If the importing country has accepted that certain GE events are permitted, then appropriate documentation is normally sufficient. Actual testing of shipments to verify the content requires clarification on (a) sampling techniques, (b) agreed threshold levels, (c) statistical significance, (d) labelling requirements (see below), (d) testing methodology and (e) procedures for dealing with stacked events. Experience to date in South Africa shows that most international shipments are accepted on the basis of accompanying documentation, and GEO testing facilities are not utilized to full capacity.

Trained farmers

For farmers are to gain maximum benefit from GE seeds, they must also implement good farming practices. The currently available GE traits still require the use of good agronomic practices. Unfortunately where farmers are unable to access credit for purchase of fertilizers and other inputs, they may fail to reap the benefits of GE crops. Farmers need to understand the reasoning behind the biosafety requirements such as the need to plant non-transgenic refugia around pesticide-resistant crops to prevent the emergence of pesticide-resistant insects. Instances where there has been failure of insect resistance have been linked to lack of adherence to permit requirements particularly in the small-scale farmer environment (Kruger et al. 2009).

Agreed approach on labelling

Gruère and Rao (2007) point out the range of different labelling options, from voluntary labelling to mandatory labelling of all processed products derived from GEOs. "Countries may require labeling for a list of particular food ingredients or all ingredients that include detectable transgenic material; highly processed products derived from GE ingredients, even without quantifiable presence of transgenic material; animal feed; additives and flavourings; meat and animal products fed with GM feed; food sold at caterers and restaurants; and unpackaged food."

Threshold levels for labelling need to be established (do they apply to each ingredient, to each transgenic event or to the food product as a whole?) and the content of labels needs to be specified. If the requirements are to be enforced by testing, then only products with detectable and quantifiable traces of GE materials or ingredients should be required to carry a label. But if the labelling requirements specify that any product derived from GEOs will have to be labelled, despite the lack of detectable transgenic DNA or protein, then document-based identity preservation systems that track or identify GEOs (or the lack of GEOs) from their origin to their final packaged form will be required.

Bouet et al. (2010) demonstrated the negative effects on trade and food prices that would result from introducing strict labelling requirements for LMOs intended for food, feed or processing. Strict labelling would require that all shipments of LMOs are labelled as "does contain" LMOs and must be accompanied by a list of all GE events present in the shipment. This would require testing of each shipment to verify the accuracy of the list. Providing precise information on each shipment would have a significant cost implication.

Involvement of multiple actors in the supply chain

Farmers, handlers, processors, distributors, and retailers all have to deal with the realities of GEOs in the supply chain. These role players may have to make segregation decisions, with associated costs (Desquilbet and Bullock 2009), based on regulatory requirements, labelling requirements and on market preferences (organic or conventional, GE or conventional, etc).
It is clear from the above that it is not enough just to have legislation, but that all the role players need to be in place to ensure that legislation can be effectively implemented within an overall policy framework.

DO BIOSAFETY REGULATORY SYSTEMS FACILITATE BIOTECHNOLOGY DEVELOPMENT?

The fact of having a regulatory framework in place is unfortunately not sufficient to ensure that biotechnology development takes place or that biotechnology products are taken up by the countries concerned (Kingiri 2011). In the majority of countries in Africa, GEOs developed by multinational companies are likely to gain regulatory approval ahead of those developed through local technology, even though such products were not initially targeted towards the African situation. Even where the regulatory framework is intended to encourage local development, or implementation of internationally developed biotechnology products, some ongoing barriers to implementation exist, as identified by Kingiri:

- Lack of ongoing funding to ensure regulatory systems are sustainable
- The need for integration of multiple actors with multiple agendas
- Limited access to credit to buy expensive GE seed
- Informal seed trade and possible breach of intellectual property rights
- Inadequate capacity to enforce regulations
- Inadequate inspection and monitoring capacity
- Lack of public awareness

Additional limitations identified by Timpo (2011) are:

- Limited human resources with expertise in biotechnology/biosafety
- Lack of access to accurate information
- Inadequate infrastructure
- Lack of viable seed industries
- Nascent public-private sector partnerships
- Weak linkages between industry and R&D institutions

These limitations pose a major concern to the development of biotechnology and biosafety in Africa, and need to be addressed through broad infrastructure development programmes within the region. Until these barriers are overcome, commercially available GEOs/LMOs are unlikely to be widely adopted by both large and small scale farmers. Nevertheless, there are considerable opportunities to enhance agricultural production in Africa, provided that both the infrastructural and regulatory hurdles can be overcome.

REGIONAL HARMONIZATION STATUS

It is generally recognized that regional harmonization of biosafety regulation is advantageous (Morris 2008). Although the main reasons for harmonization are centred around formal and informal trade issues, there are also a number of research initiatives involving development of GEOs that are being undertaken at a regional level and involve field trials in more than one country. Some of these were outlined by Thomson et al. 2010. They include African Biofortified Sorghum (ABS), Water Efficient Maize for Africa (WEMA), BioCassava Plus (BC+) (Adenle et al. 2012) and Virus Resistant Cassava for Africa (VIRCA) (Taylor et al. 2012).

At the level of the African Union (AU), there is a clear recognition of the advantages of regional harmonization, although there is also an acknowledgment of the complexities. The AU standpoint is laid out in the 2011 Biosafety Report document (African Union 2011b). In support of the AU, the African Biosafety Network of Expertise (ABNE) is an initiative established by the AU/NEPAD's Office of Science and Technology to build functional biosafety systems in Africa (ABNE 2012).
In moves towards harmonizing biosafety regulation amongst trading blocs, there are a number of sub-Saharan African initiatives aimed at developing regional biosafety policies and guidelines. The West Africa Regional Biosafety Project is funded by the Global Environment Fund (GEF) and the International Development Agency (IDA). It forms part of the West African Economic and Monetary Union (WAEMU) Regional Program for Biosafety. This project has developed a draft regional biosafety regulatory framework, and national and regional consultation workshops have been held. There is an ongoing dialogue with the Economic Community of West African States (ECOWAS) and with the Interstate Committee for Reducing Desertification in the Sahel (CILSS) (World Bank 2012).
The Common Market for Eastern and Southern Africa (COMESA) has developed policies on commercial planting, trade and emergency aid in GEOs and a roadmap to guide development of national biosafety frameworks (Juma 2011;Wafula et al. 2012). These policies were developed with the assistance of USAID Program for Biosafety Systems (PBS) program, and following national consultations were endorsed at the fifth Joint Meeting of Ministers of Agriculture, Environment and Natural Resouces in September 2013 (Chambers 2013).

Harmonization in the Southern African Development Community (SADC) may be more challenging, given the divergent positions of SADC members towards the technology (Mugwagwa 2011). At the sub-regional level, guidelines were drafted and adopted in 2003, through the SADC Advisory Committee on Biotechnology and Biosafety, but there appears to have been little or no progress towards implementation.

WHAT ARE THE INFLUENCES ON REGULATORY DECISIONS?

Although risk assessment is essentially a scientific process, African decision makers often take into account a broader range of issues including socio-economic considerations. A framework for decision support can be helpful to enable decision makers to take a wide range of risks and benefits into account in a structured way (Morris 2011).

The multinational companies such as Monsanto are often accused of influencing the regulators in Africa and elsewhere to adopt GE technology against their better judgement. This has been termed "regulatory capture", which occurs when a state regulatory agency, created to act in the public interest, instead advances the commercial or special interests that dominate the industry or sector it is charged with regulating (Adams et al. 2007; see also the summary on Wikipedia http://en.wikipedia.org/wiki/Regulatory_capture). However even where the multinationals have played a significant role, such as in the adoption of GE cotton in Burkina Faso, the benefits to farmers and to the economy are apparent (Vitale et al. 2010). In South Africa, the economic benefits of GE maize and cotton have been analysed (Gouse et al. 2005; Gouse 2009) and shown to be positive overall.

Despite this evidence, many African countries are resistant to the idea of permitting activities with GEOs to take place in their countries. The danger of loss of exports to Europe has been frequently cited as a negative factor in such decisions, yet Paarlberg (2006) has demonstrated unequivocally that African countries cannot use the excuse of loss of exports to Europe as a reason to impose preventative GE regulations. He states that "by far the largest share of the possibly GE exports….go to other African states". The potentially negative impact on intra-Africa trade has been cited as a rationale for harmonization of regulatory systems within Africa (Morris 2008). This emphasizes the need for African countries to establish their regulatory systems based on a clear policy towards GEOs. Gruère and Sengupta (2009) and Gruère and Takeshima (2012) have shown that unjustified threats from European or other importers who set GE-free private standards can have a significant influence on regulatory decision making. The lack of a well informed and rationally considered regulatory policy for GEOs can "potentially push policy makers to support irrational and likely detrimental decisions" (Gruère and Sengupta 2009).

It is to be hoped that in future more African regulators will support a rational approach to decision making based on much more than the "fear factor" which continues to dominate the debate and has led some countries to impose a complete GE moratorium.

CONCLUSION

While African countries continue the GE debate, the technology is moving forward. The definition of a "Genetically Emgineered Organism" continues to develop with the introduction of some of the new technologies mentioned earlier in this chapter. Indeed, RNAi technology has already been adopted in the VIRCA project. It is imperative that regulators in African countries should not be seen to "bury their heads in the sand", but should take the lead in determining the best way forward to enhance agricultural production and promote food security.

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PART 2

COUNTRY CASE STUDIES IN AFRICA

Chapter 8. Case study - South Africa

JULIAN JAFTHA

INTRODUCTION

By the time South Africa (SA) ratified the Cartagena Protocol on Biosafety ("the Protocol"), the country already had a fully functional regulatory framework to manage the use of genetically engineered organisms. To fully comply with the provisions of the Protocol, SA affected the required amendments to the principle legislation, the Genetically Modified Organisms Act, 1997.

GENETICALLY MODIFIED ORGANISMS ACT

The Genetically Modified Organisms Act, 1997 prescribes two tiers of decision-making - an Advisory Committee and the Executive Council. The Advisory Committee evaluates the risk assessment and risk management data of a proposed activity and subsequently makes a specific recommendation to the Executive Council.

Composition of the Advisory Committee

Section 10 of the GMO Act makes provision for the establishment of an Advisory Committee (AC). The AC consists of not more than ten persons appointed by the Minister of Agriculture, Forestry & Fisheries, after the recommendation of the Executive Council (EC).

Functions of the Advisory Committee

The AC is responsible for the scientific evaluation and safety assessment of all applications for GEO activities, as it relates to food, feed and environmental impact, following which a recommendation is submitted to the Executive Council. Furthermore; the AC acts as the national advisory body on all matters concerning or related to GEOs. The AC also advices, on request or of its own accord, the Minister, the EC, the registrar, other Ministries and appropriate bodies, on matters concerning the GEOs.

Composition of the Executive Council

Regulatory consideration of activities involving GEOs require decisions by different government authorities and may include those concerned with the environment, agriculture, health, trade, etc. In support of the coherent policy approach adopted by South Africa, the Act empowers the Minister of Agriculture to appoint members to the Executive Council. These members are nominees from departments of Agriculture1, Science & Technology, Environmental Affairs, Health, Labour, Trade & Industry, Arts & Culture and Water Affairs & Forestry. The inclusion of the latter two departments as members of the Executive Council was prompted by Article 26 of the Protocol and the possible developments in the field of indigenous knowledge and genetic modification in the aquaculture and forestry sectors, respectively.

Nomination of the respective departmental representatives is the prerogative of the relevant heads of those departments, however, section 3(2)(c) of the GMO Act sets one condition: they "shall have knowledge of the implications of genetically modified organism with regard to the sector represented by his or her department", including any existing policies and legislation applicable within that sector. The provision significantly limits the Minister of Agriculture's discretion on the appointment of the members of the

[1] Department of Agriculture now known as Department of Agriculture, Forestry & Fisheries; Department of Water Affairs & Forestry now known as Department of Water Affairs.

Executive Council. However, this deficiency is remedied by section 6(2) of the GMO Act which empowers the Minister of Agriculture to remove any member of the Executive Council if he/she is of the opinion that such a member is no longer competent to fulfil his or her function or being guilty of any form of misconduct. Mindful of different scientific disciplines involved in addressing potential risks associated with the application of genetically engineered organisms, the Executive Council is also empowered to co-opt any knowledgeable person in a specific field of science to either serve on the Council or advise the Council on relevant matters.

Furthermore, if the need for access to additional expertise is temporary in nature, the Council is also empowered [section 5(2) of the GMO Act] to invite written comments from knowledgeable persons.

The Executive Council also includes the Chairperson of the Advisory Committee. This Chairperson presents Advisory Committee's recommendations on applications received to the Executive Council and further serves as a resource on technical matters.

Powers and duties of the Council

Section 3(1) of the GMO Act established the Executive Council as a juristic body therefore this body has acquired certain rights, duties and capacities. A complete delegation of power is granted to the Executive Council to decide on all matters related to the use of GEOs. This means that the Council is empowered to decide on all applications without the involvement of the Minister of Agriculture. One should, however, not think that the Minister has no control over the body. He/she still exercise control over the Council by approving:

- Regulations which clearly outlines the application and decision-making processes or procedures
- Guidelines for activities involving genetically engineered organisms

In addition, section 5(l) places a further burden on the Council to notify the Minister of any approval granted under the Act. In any administrative system, it remains good practice to ensure sufficient flow of information is maintained between the delegator and the delegate. In the South African context, this is achieved through internal reporting structures or briefing notes to the Minister of Agriculture. This is especially useful if and when a decision (including both approvals and denials) is made of a GEO of which there is no or limited precedence.

The Council's objective may be broadly defined as advising the Minister of Agriculture on all aspects concerning genetically engineered organisms. More specifically this advisory function can be categorised as follows:

- Advising the Minister on:
    - Relevant bilateral, regional or multilateral agreements or arrangements in an attempt to maintain the same level of protection of human and animal health and the environment as provided for in the Protocol.
    - Prohibitions of certain activities involving GEOs.
    - Measures to be undertaken to avoid accidents and to minimize any adverse impact on the conservation and sustainable use of biological diversity, including risks to human and animal health.
    - The appointment of members to the Advisory Committee.
- Determines the administrative actions and related processes, including
    - The process to be followed in submitting an application for consideration
    - Which factors to consider in evaluating an application
    - Setting the conditions and restrictions under which an activity may proceed
    - Delegating the registrar to extend an activity, previously authorised by the executive council

- The steps to be taken in the event of an unintentional transboundary movement or any other contravention

Decision-making process

The GMO Act prescribes that decisions within the scope of the Act will be made at the meetings of the Council. The Chairperson of the Council is empowered to determine the time and place of the meetings of the Council. Special meetings may, however, be convened at the request of the Minister or on a written request from at least two members of the Council.

In determining the timelines for the decision-making procedure, South Africa followed the timeliness as outlined in the Cartagena Protocol on Biosafety. The most extended being 270 days for commercialization and use as food and feed, 120 days for contained use and field trials and 30 days for importation of GEOs which have been approved for commercialization or use as food and feed. Adherence to these timelines is often not achieved due to administrative delays, additional questions and concerns by the Advisory Committee and or Council.

Mindful of many interrelated processes and the respective government departments involved, meetings of the Council are held once every two months. The Executive Council remains mindful that this schedule is extremely important to allow a swift initiation (importation, planting, etc.) of an activity as soon as a positive decision is received. As a result, meetings dates are clearly communicated to applicants and detailed schedules made available which outline the respective due dates for submission of applications for a possible consideration at a specific meeting. There are obviously no guarantees that a decision will be reached at a specific Council meeting due to delays along the chain of decision-making.

PUBLIC INVOLVEMENT IN THE DECISION-MAKING PROCESS

Applicants are required to undertake public notifications for all activities involving GEOs in field trials, use as food and feed or full commercialisation. The content of these notifications are clearly prescribed and include at a minimum, a general description of the intended activity, the kind of modification involved, the receiving environment, etc. The extent of the public notification is also prescribed, with general release and use as food and feed applications requiring more extensive publication than limited field trial release. The Registrar is the contact point for accessing a copy of the application of which the confidential business information had been removed and the point for submission of comments.

The Executive Council considers the public inputs received through these notifications in its decision-making process. Where appropriate, the Council could request the Advisory Committee and or the Applicant to respond to relevant and potentially valid concerns.

Over the past few years, comments received have been restricted to interest groups and a few individuals on the application of field trials, commercialization and use as food or feed. Comments from individuals often reflect those expressed by interest groups.

Often applicants and interested and affected parties request an opportunity to make oral presentations to the Council on a specific application. The Act does not allow for this and to date, no such requests have been granted. The Council may, however, request experts in a specific field relevant to the application of GEO or other regulatory authorities to address the Council on a specific subject. Individual departments represented on the Council, nevertheless, have the freedom to allow interested and potentially affected parties to make oral presentations.

COMMUNICATION OF THE DECISIONS TAKEN UNDER THE ACT

The GMO Act does not prescribe specific processes to be followed when communicating decisions made under this Act, however, the Registrar plays a key role in the overall communication process. This does not release the decision-makers from the obligation of communicating decisions taken under the GMO Act as the right to lawful, reasonable and procedurally fair administrative action is enshrined in South Africa's Constitution. This constitutional right provision was enacted through the Promotion of Administrative Justice Act of 2000 which aims to support and create a culture of efficient administration and good governance.

Applicants are usually informed of decisions of the Executive Council within two weeks after a decision was reached. Upon approval of the minutes of Council's meetings, a copy of the minutes is published on the department's website. In this version of the minutes, all confidential deliberations are removed but it remains sufficiently detailed to inform interested and affected parties of the applications considered and decided upon. Currently, work is being undertaken to compile a formal decision document which will also be made available in a facilitated manner. To date, this has not been possible due to capacity constraints. A list of all permits issued under the Act is also published on the department's website.

South Africa also has active anti-GMO lobby groups who have an interest in all decisions taken under the Act as well the reasons for such decisions. Although the Executive Council remains committed to communicating with all stakeholders, it remains a challenge to satisfactorily communicate with these groups. Currently, information and reasons for decisions may be accessed via the Promotion of Access to Information Act of 2000. Several interested and affected groups feel that this is an onerous process. Several efforts are underway to use current IT infrastructure more effectively to further facilitate access to relevant information.

Chapter 9. Case study - Burkina Faso

MOUSSA SAVADOGO

INTRODUCTION

By joining 15 other member states of African Union to establish the African Biotechnology Agency in 1992, at an early stage Burkina Faso showed interest in modern biotechnology as a crucial tool for improving the agricultural production in the country. Agriculture contributes almost 40% of the Burkina Faso GDP and provides employment to 85-90% of the country's total population. Cotton is the main cash crop from which over 2.2 million people derive their income (Vitale et al. 2011)**.** However, crop damage caused by insect pests has threatened the country's cotton sector for many years. The development of resistance to chemicals peaked in the 1990s and became a major issue. This caused the cotton production to drop drastically from 300, 000 tons in 2007 to 154,000 tons in 2008 (Karembu et al. 2010). Different strategies with varying numbers and intervals between chemical sprays were tried but without success. Finally the government, through a partnership with Monsanto, decided to explore the use of Bt cotton. At the same time, stakeholders realized that the use of biotechnology must go hand-in-hand with biosafety measures as required by the Cartagena Protocol on Biosafety (CPB).

BACKGROUND

The Government of Burkina Faso signed the Cartagena Protocol on Biosafety in May 2000 and ratified it in August 2003[2]. Then in June 2004, the government adopted *Décret No 2004-62/PRES/PM/MECV/MAHRH/MS* which prescribed national rules to regulate the movement, experimentation and use of GEOs in contained facilities as well as in confined field trials. Later, the national rules were amended and translated into a biosafety law (*Loi n°005-2006/AN portant régime de sécurité en matière de biotechnologie au Burkina Faso*) that was enacted on March 17, 2006. Before this, the national biosafety rules enabled the country to start confined field trials of Bt cotton in 2003. Like the biosafety laws of many other countries in Africa, the Burkina Faso law takes after the African Model Law, with a very broad scope covering not only GEOs but also

[2] http://bch.cbd.int/about/countryprofile.shtml?country=bf

its' derived products and related activities. The Biosafety Law covers the areas of risk prevention measures, ethical considerations (*Loi n°005-2006/AN portant régime de sécurité en matière de biotechnologie au Burkina Faso*), mechanisms for risk assessment, risk management, risk communication and risk control when using modern biotechnology and its products.

In 2010, Burkina Faso actively participated in the negotiations and the adoption of the Nagoya-Kula Lumpur Supplementary Protocol on liability and redress. In 2010 the government also started to review the biosafety law. A draft was developed by the biosafety agency and submitted to parliament in August 2011. However, the review process had not been sufficiently participatory to obtain feedback from key players such as the cotton growers and technology developers. As a result, the draft law included provisions for strict liability as well as damage associated with socio-economic and cultural impacts. Had the draft been accepted by parliament, there could have been implications on the private sector to continue developing biotechnology applications and products. Therefore, it was decided to postpone the adoption of the draft in order to allow various stakeholders time to request clarifications and amend the draft before sending for approval by the parliament. NEPAD-ABNE was requested to provide assistance and played a significant role in revising the draft law. The revised Law was adopted by the National Assembly in December 2012 as as "*Loi No 064-2012/AN portant régime de sécurité en matière de Biotechnologie*". On the same day, December 20, 2012, the National Assembly ratified the Nagoya Kuala Lumpur Supplementary Protocol on liability and redress.

REGULATORY SYSTEM IN BURKINA FASO

To date, Burkina Faso is the only francophone West African country to have a functioning biosafety regulatory system that has approved the commercial release and use of GE products (Sylla and Dong 2010). The Biosafety Law adopted in 2006 governs the regulatory regime in Burkina Faso (*Loi n°005-2006/AN portant régime en matière de biotechnologie au Burkina Faso 2007)*. It originated from the national biosafety rules (*Règles nationales de biosécurité*) adopted in 2004. Four institutions were established to enforce the biosafety regime in Burkina Faso, namely the National Biosafety Agency (ANB), the National Scientific Biosafety Committee (NSBC), the National Biosafety Observatory (NBO) and the Ministerial Institutional Biosafety Committees (MIBC). The ANB is the deliberative competent authority while the NSBC and the NBO are consultative bodies (*Loi n°005-2006/AN portant régime en matière de biotechnologie au Burkina Faso 2007)*. Establishment of Institutional Biosafety Committees was envisioned by the law but this section of law was never implemented; and has since been removed from the revised law ("*Loi No 064-2012/AN portant régime de sécurité en matière de Biotechnologie*").

The core role of the competent authority is to handle applications and make recommendations for decisions. Decision documents are prepared by the ANB, based on report from the NSBC that is composed of 12 members selected from various governmental ministries.

The NBO has a mandate to oversee a breadth of activities related to modern biotechnology, and especially to facilitate the public participation in the decision making process. Public consultation and awareness are fully part of the NBO's agenda. This body is composed of 33 members selected from governmental institutions and the civil society.

It is worth noting that the ANB was established initially under the Ministry of Environment. It was then transferred to the Ministry for Higher Education & Scientific Research in 2009. In 2011, the Ministry for Higher Education & Scientific Research was divided into two ministries; the Ministry for Science & Innovation and the Ministry for Secondary & Higher Education. Since then the ANB has moved to the Ministry for Science & Innovation. In addition to its core role of setting standards, handling applications, granting approvals for field trials and commercial use, monitoring and inspection of trials sites, laboratories and other

facilities, the ANB also carries out an array of other activities including training, public information, awareness, sensitization and consultation. Awareness is of special importance, for example, in 2010 the ANB launched a program to translate the biosafety law into the most commonly spoken languages in cotton growing areas and also to train farmers on the use and management of GEOs (Sylla and Dong 2010). In addition, thousands of people, including students, representatives of local administrative and religious communities as well as customs officials have benefited from the awareness activities conducted by the ANB. This program was partially sponsored by the *West Africa Cotton Improvement Program* (WACIP) (Sylla and Dong 2010).

GENETICALLY ENGINEERED CROPS APPROVED IN BURKINA FASO

Five GE events have been approved in Burkina Faso from more than 29 applications that have been submitted. Approved events include insect resistant cotton and cowpea, herbicide tolerant cotton, nutritionally enhanced sorghum and a modified fungus for the control of the malaria transmitting mosquitoes.

Commercial release of Bt cotton

Burkina Faso started to grow Bt cotton commercially in 2008 after a joint venture with Monsanto that started in 2001. Burkina Faso thus became the 10th country in the world to grow Bt cotton commercially (Karembu et al. 2010).

Figure 2. Six to eight chemical sprays were yearly applied by Burkinabe cotton farmers against cotton pests.

Various factors prompted Burkina Faso to adopt Bt cotton. These included the high cost of pest management which was continuously increasing from year to year due to the development of pest resistance to chemical pesticides, especially the cotton bollworm, *Helicoverpa armigera*, to pyrethroids resulting in 30 to 60% yield losses. Every year about US$ 60 million were spent on insecticides for the control of cotton bollworms and related insects (Karembu et al. 2010). Environmental pollution and the danger to the health of cotton growers were considered as additional mitigating factors. “After spending the day spraying these chemicals, you invariably catch a bad cold and a heavy headache,” said Mr. Karim Traore, President of the Burkina Cotton Growers’ Union (UNPCB) during a study tour to Burkina Faso by Tanzanian delegates in November 2012.

The adoption of Bt cotton was very fast in Burkina Faso, from an initial area of approximately 8,500 hectares in 2008 to 400,000 hectares in 2010 (Karembu et al. 2010, Vitale et al. 2011). There was a 247% increase of area planted to Bt cotton from 2009/2010 to 2010/2011 (Sylla and Dong 2010). Data collected from field trials and producers surveys showed that Bt cotton has increased cotton yields by an average of 21.3%, and increased income by $106.14 per ha (Vitale et al. 2011). It also allowed for a significant reduction in the number of applied pesticides sprays, from 6 or 8 to 2. These were

Figure 1. Youths return to cotton fields thanks to Bt technology.

considered to be the major driver for the quick adoption of Bt cotton by most farmers. Cotton farmers also justified their choice for Bt cotton from the benefits gained in better health for themselves and their families. "I have adopted Bt cotton because I want my children to keep farming and stay healthy," said Mr. Francois Traore, the former president of the Burkina Faso cotton growers' union (UNPCB). It is worth noting that young people in the rural areas had started leaving cotton farms because of the laborious nature of the work and the risk of poisoning associated with the application of pesticide sprays.

Figure 3. Mr. Francois Traore, a cotton farmer, says "I have adopted Bt cotton because I want my children to keep farming and remain healthy."

In Burkina Faso, the deployment of GE cotton seed follows the same pathway as the conventional seed that has been followed for decades. This involves the agricultural research institute (INERA), the national cotton company SOFITEX (*Société Burkinabe des Fibres Textiles*) and a number of farmers specialized in seed production. Nevertheless, Bt seed management and handling recently faced serious challenges. Maintaining a good level of seed purity over the years has been difficult; and as a result, several plots that were supposed to be planted with Bt seed were found damaged by bollworm causing serious yields losses. Investigations revealed that this was due to a mixture of Bt and non-Bt seeds (http://www.nepadbiosafety.net/bt-cotton-in-burkina-faso). Such a mixture may have been deliberately caused by farmers or by accident during transportation. As a matter of fact, a number of farmers had mistakenly thought that when grown side by side Bt plants also protected the neighbouring non-Bt cotton plants from pests. In order to avoid a reoccurrence, measures were immediately taken to strengthen the seed quality control measures. In addition, the cotton company developed a seed scheme that included more specialized training targeted at all the stakeholders involved (http://www.nepadbiosafety.net/bt-cotton-in-burkina-faso). This incident clearly indicates the need for more proactive stewardship actions to be carried out by product developers together with all the partnering players.

Confined filed trials of stacked cotton

Confined field trials are now being conducted with the Monsanto Bt cotton variety, Bollgard II® with Roundup Ready Flex, combining insect resistance and herbicide control traits.

Confined field trials of Bt cowpea

Cowpeas are cultivated on 12.5 million hectares in Africa and consumed by about 200 million people (Sylla and Dong 2010). In cowpeas, the legume pod borer, *Maruca vitrata*, can cause yield loses of between 50% and 80%. To address this problem, a regional project is being implemented in partnership with the African Agriculture Technology Foundation (AATF) to test the efficacy of Bt against this insect pest. Initially the project involves three West African countries - Nigeria, Burkina Faso and Ghana. In Burkina Faso, confined field trials started in 2011 by the agricultural research institute INERA at the Farakoba Research Station at Bobo-Dioulasso. Nigeria has already completed three years of confined field trials while Ghana initiated the trials in 2013 for Bt cowpea.

Approval for confined field trial of biofortifed sorghum

In 2010, an application was approved in Burkina Faso for a confined field trial with sorghum engineered to express increased levels of vitamin A, zinc and iron. However, the trials are yet to start.

Trial with the fungus, Metarhizium robertsii

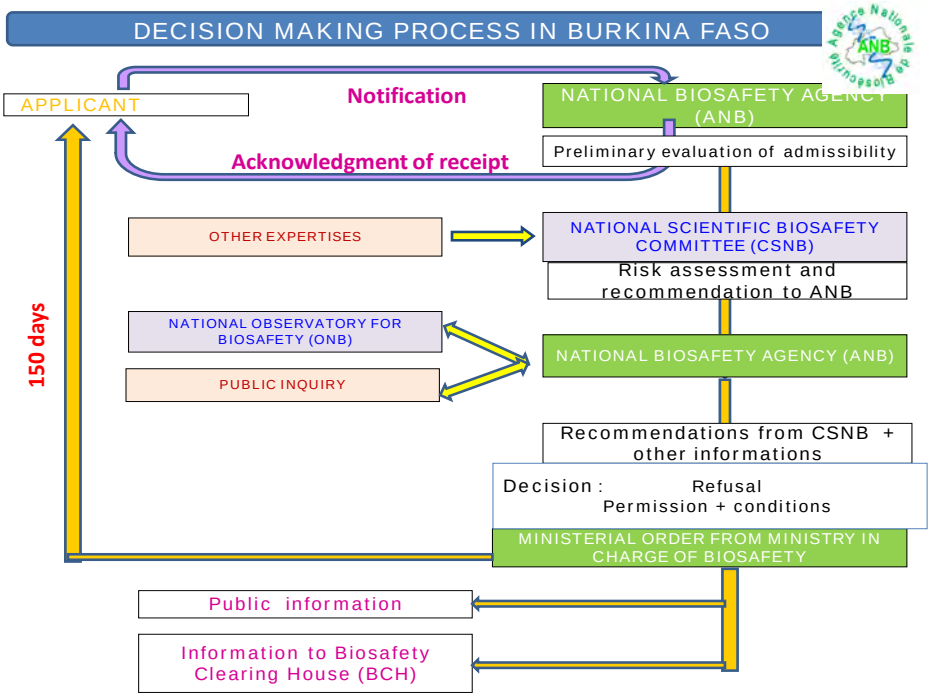
Approval has been granted to the Centre Muraz at Bobo-Dioulasso to conduct experiments, in collaboration with the University of Maryland and University of John Hopkins, on the genetically engineered entomopathogenic fungus, *Metarhizium robertsii,* for the control of the malaria transmitting mosquito, *Anopheles gambiae*. The trial is yet to start.

APPLICATION REVIEW PROCESS IN BURKINA FASO

In Burkina Faso, the application review process broadly follows the recommendations of the Cartagena Protocol on Biosafety. Figure 4 summarizes the key steps of the process. Any application for import, export or release of a GEO is subject to a written notification addressed to the competent national authority. All documentation and information necessary for a notification are set out in a decree of the ministerial council. The competent national authority may request any additional information deemed necessary to make a decision. Burkina Faso law also states that the applicant must provide the competent authority with evidence that he/she has the means to fulfill the obligations of a notification otherwise the application is rejected.

The competent national authority must provide the applicant with a final decision within 150 days of receipt of the application. A copy of the final decision is also sent to the Biosafety Clearing House (BCH). In the case of an application being rejected, the competent national authority is required to motivate its decision. Any decision may be revoked, suspended or have additional conditions imposed, if the competent national authority subsequently obtains new or additional information on the GEO.

Figure 4: Summary of the application review process in Burkina Faso (Source: National Biosafety Agency, Burkina Faso)



According to The Burkina Faso Biosafety law, risk assessment must take into account the precautionary principle. Labelling of GMOs is mandatory in Burkina Faso. Any GEO intended for general release or markets in the country, either imported or produced locally developed, must be packaged and labelled on forgery-

proof paper to ensure the protection of ethical and cultural values and avoid risks to the environment, human and animal health. Labels must state, “Products based on GMOs” or “Contains GMOs”. The competent national authority in consultation with other concerned authorities may set additional requirements. Wording and terms for labels are set by the decree of the Ministers Council. With respect to Liability and redress, the previous biosafety regulations in Burkina Faso sought to safeguard farmers from being liable for the payment of compensation should serious damage be caused by a GE crop. Based on this, there was a need to find ways to identify those who may be considered as liable and have the financial capacity to make restitution. With the current law however, efforts have been made to take into account most of the provisions of the Nagoya Kuala Lumpur supplementary protocol on liability and redress and there is a definite move towards the adoption of fault based liability.

CONCLUSION

The Burkina Faso experience provides a good example of how the political will could make a positive contribution towards the adoption and development of agricultural biotechnology in an African country. Cotton production is the backbone of the national economy. Introduction of improved cotton varieties that were genetically engineered for insect resistance revived the cotton industry that was severely affected by pests developing resistance to chemical pesticides declining yields. The private sector partnered with national scientists to develop a legal framework for the safe use of the technology. In Burkina Faso, therefore, the development of a national biotechnology policy preceded the development of biosafety regulations.

After 4 years of implementation of the biosafety regulations, the national competent authority decided in 2010 to amend the law to ensure a more effective protection of people’s health and the environment, and also to provide a better channel for the determination of liability in the case of any damage. This amendment process almost led to the establishment of more restrictive biosafety regulations that would have made it difficult for most product developers, including private sector promoters and national scientists, to operate. Fortunately, local cotton farmers and other stakeholders in the cotton value chain together with the support of several international organizations managed to get the amendment process back on track. This experience has shown that the progress and achievements in the fields of biosafety and biotechnology could be lost if efforts are not continuously made to protect them.

Parties that oppose modern biotechnology are continuously working to stop and reverse the development of enabling legislation. It is clear that the fight for the safe and responsible use of modern biotechnology in developing countries has not been won. Awareness, sensitization and other capacity building activities must therefore continue so that science-based decisions can be made on the safe use of biotechnology.

Risk assessment is based on scientific data, but risk management measures and related regulatory decisions are sometimes influenced by non-safety issues. In particular, there are some overly precautionary measures applied to field trials such as the CFT for Bt cowpea in Burkina Faso which appear to have no scientific justification but have been set to please particular activist groups. In Burkina Faso, anti GE activists fully participated in the public consultation meetings organized by the competent national authority and sometimes were even given privileged roles and considerations. On the other hand, when farmers met on their farms to discuss Bt cotton they showed complete confidence in the technology. But the same farmers are skeptical when discussing issues related to liability and redress in meetings with decision makers to the extent that they support the provisions to hold liable GE products developers and promoters.

Although the adoption of Bt cotton in Burkina Faso was fast, efforts to build trust between the key stakeholders in agricultural biotechnology in the country needs to be pursued. Like in many other African countries, public regulators and lawmakers in Burkina Faso still hold negative perceptions of the technology

promoters in the private sector. This conforms to the overarching conclusions reached by the studies of Obidimma and Rotman (2012). As a matter of fact, until recently Monsanto representatives based in Burkina Faso were denied access to activities including training workshops conducted by the national regulatory body. Many stakeholders are still suspicious of private sector involvement.

Another challenge to building functional biosafety systems is how to reconcile the concept of national sovereignty with the provisions contained in international treaties. Legislators sometimes put much emphasis on national sovereignty and claim complete freedom to take measures.

Based on the experience gained over many years, Burkina Faso is now playing a major role in the development of biosafety systems in the West African sub-region and even the continent. For instance, in order to encourage harmonization in the development of biosafety systems in the sub region, Burkina Faso has taken a loan from the World Bank to build a biosafety laboratory that is expected to serve all eight member states of the West African Economy Monetary Union (WAEMU). The construction of this structure started in November 2012. Burkina Faso also granted the NEPAD Planning and Coordinating Agency permission to establish the first node of the African Biosafety Network of Expertise (ABNE) in Ouagadougou. Currently the country offers study tours to regulators, decision makers and farmers from various African countries. In addition, the Polytechnic University of Bobo-Dioulasso was recently selected to host a biosafety short course to benefit francophone regulators, scientists and students from the entire West African region. This short course was held in November 2013 in partnership with the ABNE and Michigan State University (MSU). More than forty participants from eleven countries attended.

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6. Loi no 064-2012/AN portant régime de sécurité en matière de biotechnologie 2013
7. BF Btcowpea-Decision En.pdf
8. BF Bt cowpea – Risk Assessment FR. Pdf
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Chapter 10. Case study - Kenya

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INTRODUCTION

Biotechnology is believed to hold great promise for increasing food production (Karembu et al. 2009; Juma 2011; Chambers 2013) and because of this considerable effort has been expended by many African countries, Kenya included, to set up regulatory frameworks to support the responsible and safe use of this technology (Karembu et al. 2009). Tapping into the potential of modern biotechnology, whilst ensuring that the health of humans, animals and the environment is safeguarded, requires a dynamic and functional regulatory regime. The need to have biosafety frameworks and laws to govern the safe use of biotechnology has its genesis in the provisions of the Convention on Biological Diversity (CBD). Paragraph 3 of Article 19 of the Convention states that parties will consider the need to develop a protocol that would govern the safe transfer, handling and use of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biodiversity (UNEP 1992). In the East African region, for example, the need to have biosafety laws that would control, regulate and promote the safe use of biotechnology and its products has inherently been there given that trade and other informal movements of agricultural products have been taking place beyond country borders in the region (Sengooba 2009).

After the Conference of the Parties to the CBD adopted the Cartagena Protocol on Biosafety in January 2000 as a supplementary agreement to the Convention, Kenya made history by becoming the first country in the world to sign the Protocol in May 2000 (Wafula et al. 2008, Karembu et al. 2010). Kenya then ratified the Protocol in 2002 and thereafter became a Party to the Protocol (Wafula et al. 2008). By doing this Kenya bound itself to the Protocol's provisions which among other things obligated each member Country to develop and implement a National Biosafety Framework (Karembu et al. 2008a, Karembu et al. 2010). However, domesticating the protocols into national legislation proved rather elusive for Kenya (Karembu et al. 2010) and it was only after the country was selected as one of the pilot projects for the UNEP Global Environmental Facility (UNEP-GEF) biosafety project in 2001 (Karembu et al. 2008b) that some movement started in this direction. Through the UNEP-GEF project, international experts came to Kenya and conducted several capacity building initiatives on biosafety including risk assessment and decision-making procedures (Karembu et al. 2008b) and through these, Kenya also received significant support to develop its own National Biosafety System (ISAAA 2007). With this, the foundation was laid for the development of a National Biotechnology Policy and Biosafety Law (Karembu et al. 2008b), two documents that form the cornerstones of Kenya's national biotechnology and regulatory system.

A comprehensive policy to guide research, development and commercialisation of modern biotechnology products is an important first step in defining a country's biotechnology agenda (Karembu et al. 2009). Within the context of the UNEP-GEF project, a draft of a comprehensive policy on Biotechnology and Biosafety was developed in 2003 (Kameri-Mbote 2005) which later, in 2006, after much debate and discussion, was presented to and approved by Cabinet as Kenya's National Biotechnology Development Policy (ISAAA 2007; Wafula et al. 2008, Karembu et al. 2010). In this policy, the Government's vision and commitment towards the promotion and application of biotechnology was articulated as well as the need to introduce adequate biosafety measures that would ensure maximization of the benefits of biotechnology while minimizing any potential risks (Wafula et al. 2008). The approval of the policy cleared the way for fast-tracking the enactment of biosafety and biotechnology laws to enable Kenya to comply with the international instruments governing the development and trade in biotechnology products (ISAAA 2007).

REGULATORY SYSTEM IN KENYA

A comprehensive national policy that facilitates technology transfer and adoption is essential to harness the potential of any technology. In the case of agricultural biotechnology, a strong policy environment for agriculture, new technologies, resource conservation, and related areas would facilitate the adoption of modern biotechnology and serve as a template for establishing a functional regulatory regime (Chambers 2013). Research on genetically engineered organisms (GEOs) had, for a long time, been guided by scattered pieces of legislation (Karembu *et al.* 2010) and only in the early 1990's did a formal biosafety policy toward genetically engineered crops start emerging (Paarlberg 2001). The first institutional biosafety guidelines in Kenya were developed in 1992 by the Kenya Agricultural Research Institute (KARI) with help from the United States Agency for International Developments (USAID) and the new Agricultural Biotechnology for Sustainable Development (ABSD) project (Paarlberg 2001). In 1995 the National Council for Science & Technology (NCST) started developing the National Biosafety Guidelines and Regulations under the Science & Technology Act Cap.250 of the Laws of Kenya (NCST 1998). The draft Guidelines and Regulations were issued in 1998 and among other things made provision for the establishment of a National Biosafety Committee (NBC) whose membership comprised of representatives from both the public and private sector and was mandated to oversee the coordination and implementation of biosafety issues (NCST 1998). However, the Guidelines and Regulations lacked adequate legal backing since they were not promulgated into law. Nevertheless the NBC started applying the Guidelines and Regulations to review and approve applications to introduce modern biotechnology products into Kenya, but within the scope of the existing legislation (Wafula et al. 2008).

The process of drafting the Kenyan biosafety law started in 2002 under the leadership of the NCST (Wafula et al*.* 2008; Wafula 2009) and involved rigorous and extensive consultations with a mix of stakeholders that included parliamentarians, scientists, legal experts, policy makers, the media and civil society (Wafula 2009; Wafula et al*.* 2011). Kenya needed a biosafety law to guide and manage the GEO research that was already underway and to facilitate the eventual commercialization of products that were undergoing confined field trials (Karembu et al. 2010). The Biotechnology policy of 2006 had already highlighted the need to embrace genetic modification. However, there was no law or regulations to guide this work. In fact it seemed absurd that whereas transgenic cotton and maize were fast approaching the commercial phase, there was a lacuna in the legal framework needed to carry this process forward since the only existing legislation i.e. the Science & Technology Act (1980) lacked substantive provisions to take the research process to the next stage of commercialization (Karembu et al. 2010). The task of drafting the law was met with a myriad of challenges and obstacles but mercifully by July 2002 a draft Bill was produced by a team of experts working under the leadership of the NCST (Karembu et al. 2010). However, the parliamentary debate on the Bill and the processes it had to go through in Parliament became victim to time and circumstances and Parliament was prorogued before the Bill could be passed into law (Karembu *et al.* 2010). The Bill was reintroduced into Parliament as Biosafety Bill 2008 (Wafula et al. 2008) and after much debate was eventually passed in December 2008 (Karembu et al*.* 2010) and signed into law in February 2009.

COMMERCIALISATION OF GEOS IN KENYA

The Biosafety Act allows the marketing and release into the environment of approved GEOs and their products. This is controlled by the Biosafety (environmental release) Regulations. Until now, there has been no release into the environment of any GE crop but several crops are in the pipeline for release with the confined field trials on Bt cotton, Bt maize and virus resistant cassava at an advanced stage. Confined field trials have also started on bacterial wilt resistant banana, nematode resistant yam, and bio-fortified sorghum. The interest in the Government exploring all possible strategies to food sufficiency is real, and overrides the fears raised about GE in the country.

One of the functions of the NBA, according to its strategic plan (NBA SP 2011-2015) is to establish a transparent, science-based and predictable process for reviewing and making decisions on the development, transfer, handling and use of GEOs and release activities. The reaction of the public over the commercialisation and marketing of GEOs has been met with high emotion both for those anxious to embrace the technology as well as those opposed to it. This calls for care and sensitivity in handling GEO issues in Kenya. Awareness creation on Biosafety is helping the public view GEOs from a positive perspective. It is therefore expected that any GE crop that passes the risk assessment should be released without much opposition.

APPLICATION PROCESS IN KENYA

In 1999, the NCST proposed a National Biosafety Act in an attempt to anchor the Guidelines and Regulations to the Environment Management and Coordination Act of 1999 (Kameri-Mbote 2005), which was then the only legislation that contained regulatory provisions for environmental releases (Karembu et al. 2009). The proposed Act was, however, never adopted and this left the draft Guidelines and Regulations as the only blueprint the NBC could use to make decisions on any GEO work (Kameri-Mbote 2005). In 1999, these Guidelines were used by the NBC to approve, for example, contained and confined field trials for Insect-Resistant maize and cotton (Wafula et al. 2008). In 2009, the Biosafety Act was signed into law which led to the establishment of the National Biosafety Authority (NBA). This Authority is mandated to ensure safety to human and animal health, and provide adequate protection of the environment from harmful effects that may result from genetically engineered organisms. Thus it regulates all activities involving GEOs in food, feed, research, industry, trade and environmental release. Three sets of regulations have been published to guide the implementation of the Biosafety law. These include the Biosafety (contained use) regulations, the Biosafety (environmental release) regulations, and the Biosafety (import, export and transit) regulations which were finalized for publication and gazetted on 15th August 2011 (Kenya Gazette 2011a, b, c). The fourth set, the Biosafety (labelling) regulations were signed on June 2012. Kenya is now fully compliant with all the international requirements on the development and utilization of biotechnology (Crop Biotech Update 2011) and has joined the ranks of many countries worldwide that are already applying modern agricultural biotechnology (Karembu et al. 2010) technology.

Application for research on a GEO in contained use and confined field trials

The Biosafety (contained use) regulations guide activities involving GEOs under containment and confined field trials. They are applied during research to GEOs in the laboratory, greenhouse and growth chamber and confined field trials. Institutional Biosafety Committees (IBCs) are regulated under these guidelines. The objective of these regulations is to ensure that any potential adverse effects of GEOs are addressed to protect human health and the environment when conducting contained use activities (Kenya Gazette 2011a). These regulations guide the assessment of the suitability of site for contained use after determining the containment level for laboratory, greenhouse or screen house activities. They also give the appropriate measures to be applied to confined field trials.

All applicants have to complete a prescribed form and submit it to the NBA. The NBA secretariat then scrutinizes the form for completeness before sending it for review by experts and relevant regulatory agencies.

Once the review is complete, a recommendation is made to the Board of Management of the NBA. The Board then either approves or rejects the application based on the assessment of the scientific evidence by the secretariat and the experts. This process takes a maximum 90 days from date of application, provided all the required information is submitted. To date all applicants and the NBA have worked together harmoniously and the process is proceeding well.

Application for commercialisation of GE crops

In Kenya, genetically engineered crops are commercialised under the Biosafety (Environmental release) regulations. These regulations also cover activities involving release of GEOs into the environment and marketing (Kenya Gazette 2011c). They ensure that any potential adverse effects of GEOs are addressed in order to protect human health and the environment when conducting an environmental release; i.e. when GE crops and their products are available to the public. The application forms to commercialise a GEO are posted on the NBA website. The procedure for processing the application is set out in the Kenya Gazette (2011c).

Applicants normally submit their forms to the secretariat of the NBA and the process from application to approval or rejection status should not take more than 90 days according to the time limit set by the NBA. Strategies have also been put in place to ensure integrity during the development, handling and transfer of GEOs (NBA SP 2011-2015)

CONCLUSION

The Biosafety Act received Presidential approval in February 2009 (Wafula 2009) and is known as the Kenya Biosafety Act, 2009. The passing of this Act was considered a major achievement and it holds a number of useful lessons for African countries which are in the process of enacting similar biosafety legislation (Wafula et al. 2011). The process of implementing the Act has met with mixed reaction both from the public and researchers. The National Biosafety Authority has had to deal with this situation under sometimes very challenging conditions.

The major lesson learnt is that building consensus on biosafety issues is an almost impossible task. However, the non-partisan position of the NBA Board and Secretariat in carrying out relevant activities that involve GEOs has helped to reduce the antagonism that would have inevitably built up among and within stakeholder groups. At the present time the Biosafety regulatory system in Kenya is well established and serves as an example of a system that has been well thought out and that should be emulated by others.

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Chapter 11. Case study - Uganda

ANNET NAMUDDU AND JULIUS ECURU

INTRODUCTION

Ugandan government recognizes biotechnology as a tool for addressing agricultural challenges and enhancing economic development for improved livelihoods of the poor. Biotechnology is included as one of the strategies for agricultural modernization and poverty eradication. As a way to improve agricultural productivity, biotechnology research in Uganda is being conducted to address agricultural challenges such as pests, diseases and abiotic stresses like drought, and improve nutritional content of staple crops (Ecuru & Naluyima, 2010). Uganda is one of the leading countries in Africa using modern biotechnology in agricultural research and development with over 10 confined field trials of genetically engineered crops at various national agricultural research institutes. With this trend, commercialization of modern biotechnology derived crops could be imminent. Thus the need for a functional science based biosafety regulatory framework.

BIOSAFETY REGULATION IN UGANDA

In 1993, Uganda ratified the Convention on Biological Diversity (CBD) and thereafter the Cartagena Protocol in Biosafety (CPB) in 2001. CPB is an international binding agreement that requires Uganda to establish a functional national biosafety regulatory system. In 2003, the National Planning Authority responsible for the overall national planning also set biosafety as a required strategic input into the biotechnology planning process. The Cartagena Protocol's scope is transboundary movement, transit, handing and use of all living modified organisms (LMOs) that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risk to human health (article 4). In line with this, Uganda approved the National Biotechnology and Biosafety Policy in 2008 to ensure safe application of modern biotechnology for improvement of livelihood and the country's economy. The proposed law, The National Biotechnology and Biosafety Bill 2012 to operationalize the policy was also gazetted and tabled in parliament in February 2013.

There are also other laws, which have implications for biosafety. Some of these include: Drugs Act that sets standards for drugs; the Plant Protection Act, which is a phytosanitary law that regulates the introduction of exotic plants and micro-organisms; and the Public Health Act that sets standards for sanitation, vaccination and prevention of infectious diseases.

The CPB requires its' member countries to designate competent authorities and national focal points. Uganda's Ministry of Environment is the national focal point for purposes of the CPB to the CBD. The ministry is responsible for matters related to transboundary movement of GEOs into and out of Uganda, as well as the national biosafety clearing house. When performing its functions, the national focal point receives information regarding biotechnology and biosafety from the competent authority, the Uganda National Council for Science and Technology (UNCST), formed in 1990 under the Ministry of Finance, Planning and Economic Development (MFPED). UNCST falls under MFPED because biotechnology and biosafety cut across many disciplines, and economic development and transformation of the country depends on science and technology. UNCST is the lead body for biosafety policy development. When executing biotechnology and biosafety activities, the competent authority works with the National Biosafety Committee (NBC) established by UNCST in 1997. The NBC is the main national body for biosafety matters under the UNCST and is appointed by the Minister of MFPED on recommendation by the competent authority. The NBC provides technical advice on biosafety issues to the government and maintains links with institutions doing biotech

work. It is composed of 15 members drawn from a heterogeneous pool of experts from relevant disciplines including the end users of the genetic engineering technology.

UNCST with regard to modern biotechnology is responsible for developing and implementing the national biosafety framework to manage potential risks associated with LMOs under UNCST Act Cap. 209. The NBC established in accordance with Article 14 of the UNCST Act Cap. 209, assists the competent authority with general supervision and control over dealings in LMOs ensuring safety to human and animal health, and protection of the environment based on internationally proven scientific information.

UNCST houses the national biosafety office, which is the central facility to manage, support and effect environmental and health safety in the use of modern biotechnology. It is the focal point for biosafety matters in Uganda and serves as the primary contact point for national, regional and international biosafety activities. The biosafety office recruits *ad hoc* expertise for technical assistance to the NBC as needed. Acting as the bridge between the NBC, government officials and applicants, the office facilitates biosafety reviews and decision making, regulatory inspections and monitoring, reporting and record keeping. The office developed guiding documents such as standard operating procedures (SOPs) for contained and confined experiments; national guidelines for: containment, regulation of research with genetically engineered organisms (GEOs) and microbes, confined field trials, field experiments involving genetically engineered plants; procedures and forms for field experiments with GEOs; biosafety inspection manual for field experiments involving GEOs; and cop specific compliance handbooks on bananas, cotton and maize.

OTHER MINISTRIES AND AUTHORITIES RESPONSIBLE FOR BIOSAFETY IN UGANDA

Ministry of Agriculture, Animal Industry and Fisheries (MAAIF)

The mandate of MAAIF includes formulating, reviewing and implementing policies and regulations in the agriculture sector, and providing technical guidance, support and backstopping for local governments. In terms of biosafety, MAAIF is in charge of Phytosanitary Service, National Seed Certification Service, Control of Agricultural Chemical service, Uganda Veterinary service, Fisheries Inspectorate, and Food and Nutrition Council. The Phytosanitary Service (PS) is in charge of clearing plant imports, and for the case of GEOs, the PS refers the matter first to the NBC which gives approval, after which the PS clears the importation but remains with the responsibility to monitor and report on the performance of the GEO as part of its regulatory mandate.

Uganda National Bureau of Standards (UNBS)

It provides services in product certification, import/export shipment inspection, product testing, calibration and standards documentation across all industrial sectors. UNBS is the competent authority for food safety with respect to standards for sanitation, composition and nutritional content. It handles matters related to *Codex Alimentarius*, including standards for labeling packaged foods. The responsibilities of UNBS in the National Food Safety Strategic Plan include; protecting the health and safety of Ugandan people against hazards related to locally produced and imported food products, protecting consumers' interests, and ensuring equity in the market. UNBS is responsible for assessing GM food products in consultation with the NBC.

Ministry of Health (MoH)

The mandate of MoH in terms of biosafety is to provide a safety policy oversight and management in development and application of all biotechnologies involving pharmaceuticals, nutrition products and related public health issues.

National Drug Authority (NDA)

One of the key roles of NDA is to regulate human and veterinary biotech products mainly vaccines. In addition, MoH in consultation with key stakeholders in the food and medicines industries and the National Planning Authority have decided in principle to strengthen NDA by giving it more mandate to handle issues of food quality and safety. The mandate will be extended to regulate cosmetics, medical/veterinary devices, and health care products, and public health products, chemicals for public health use, vaccines, blood and biological products under the new National Food and Drugs Authority (NFDA). The process of acquiring government approval is on-going.

Ministry of Trade, Tourism and Industries

Its key role is standardization and trade in products involving recombinant DNA technology, and industrial use e.g. bioleaching of cobalt. It focuses on trade policy and regulation.

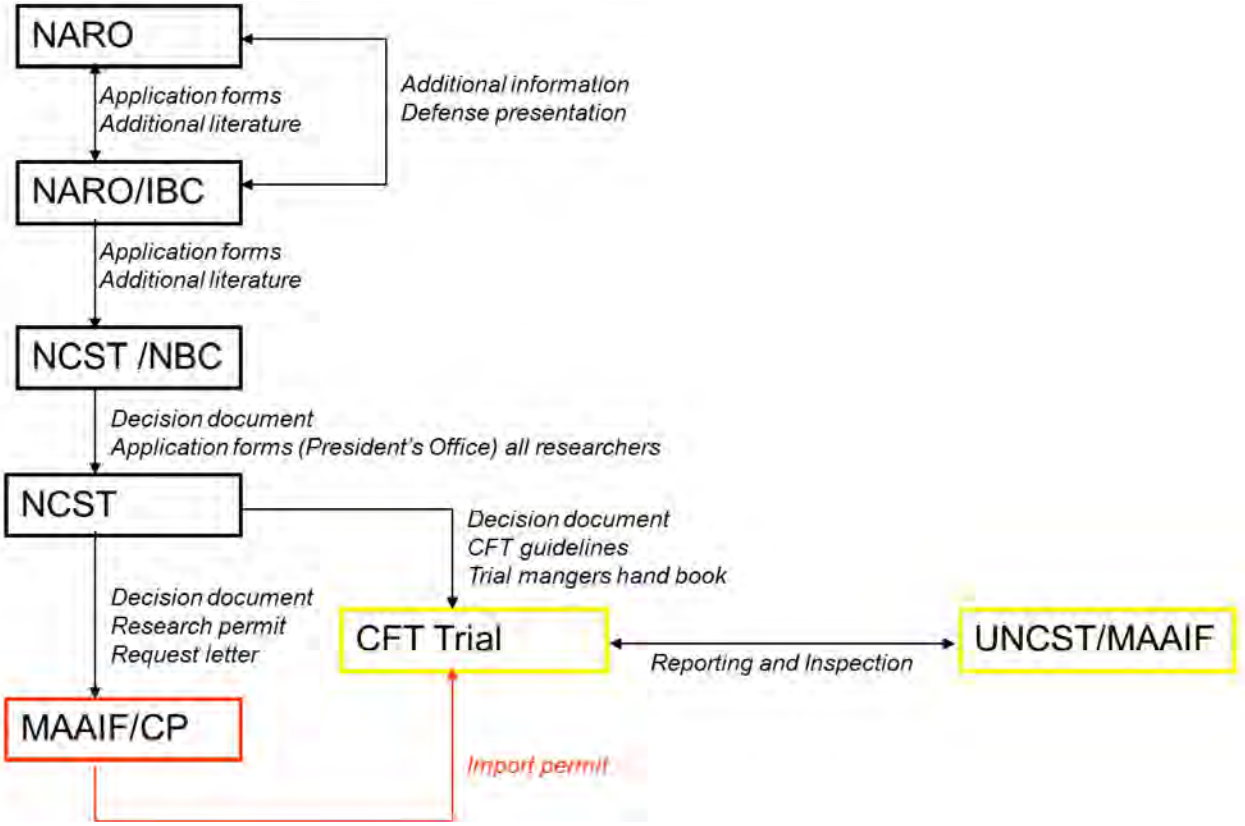
THE REGULATORY PROCESS FOR CARRYING OUT BIOTECHNOLOGY RESEARCH

Only national entities are mandated to carry out modern biotechnology activities under the guidelines provided by the competent authority. These national entities engaged in biotechnology and biosafety research include the National Agricultural Research Organisation (NARO) and Makerere University and are required to establish the Institutional Biosafety Committee (IBC), which is approved by the UNCST. The formation of the IBC is guided by the National Biotechnology and Biosafety policy.

The IBC receives applications for laboratory experiments and contained testing from research institutions. The IBC then notifies the UNCST which gives directions regarding the applications, either in approval or disapproval. The approvals or denials are based on scientific justification. UNCST is responsible for issuing permits for carrying out research on GEOs. If materials to be tested in containment are to be imported, the scientist/applicant sends an application to the IBC which notifies UNCST. UNCST then provides the relevant information to MAAIF on whether to issue an import permit or not. Prior to conducting laboratory and contained research, the IBC inspects the infrastructure of the research institution to ensure that measures are in place to minimise risk to human health and environment arising from genetically engineered organisms. The IBC regularly reviews, monitors and supervises laboratory experiments, contained and confined testing. IBC also makes recommendations to the UNCST with respect to applications for confined field testing. The IBC ensures that research is conducted in accordance with the guidelines by the UNCST. The NBC also visits the research institution to ensure that the guidelines by the UNCST are followed when conducting research.

The NBC reviews and makes recommendations on the confined field trial applications received by the UNCST from the applicant. The NBC is mainly involved in confined field trials because that is the major activity present in agricultural biotechnology, as Uganda moves towards embracing the benefits of modern biotechnology. In case materials to be tested are to be imported, the scientist/applicant notifies UNCST through the IBC, which provides information to the Ministry of Agriculture Animal Industries and Fisheries (MAAIF) on whether the applicant is permitted to carry out such research. MAAIF then issues a certified import permit through its Quarantine and Inspection Services. Prior to planting a confined field trial, inspectors from UNCST/NBC visit the trial to ensure that the recommended isolation distances, fencing, security, and infrastructure for destruction of transgenics upon completion are taken care of. During planting and termination of the confined field trial, inspectors from UNCST/NBC are always present to ensure that guidelines are followed accordingly.

Figure 1. Uganda's agricultural biotechnology regulatory process



BIOTECHOLOGY RESEARCH AND DEVELOPMENT

Uganda is the regional leader in East Africa and role model in conducting confined field trials using the existing legislation (Komen and Wafula, 2013). Research in modern biotechnology is mainly carried out by the National Agricultural Research System, for instance NARO and Makerere University. NARO's public research institutes actively involved in biotechnology research include the National Agricultural Research Laboratories (NARL) and the National Crops Resources Research Institute (NaCRRI). Research is on-going on Uganda's major staple crops (bananas, cassava, maize, sweet potatoes and rice) and commercial crop (cotton). There are also a few private commercial tissue culture laboratories working on bananas, coffee, sweet potatoes and pineapples (Chambers, 2013).

The genetic engineering technologies being evaluated in confined field trials include bananas, cassava, maize and rice. Sweet potatoes are under greenhouse containment. Researchers continue to produce GM plants with new gene technologies. The high level of genetic engineering activity in the laboratory, greenhouse and confined field trials identifies Uganda as one of the leading countries in Africa with practical biotechnology and biosafety experience (Chambers, 2013).

Table 1: GM crops under development

Crop	Trait	Stage	Partners
Bananas	Bacterial wilt resistance	CFT, second season	NARO, IITA, AATF
	Pro-vitamin A, iron	CFT, first season	NARO, QUT
	Nematode and weevil resistance	CFT, first season	NARO, Univ. of Leeds
Cassava	CMD, CBSD resistance	CFT, second season	NARO, DDPSC, IITA
Cotton	Bollworm resistance and herbicide tolerance	CFT, third season	NARO

Maize	Drought tolerance	CFT, second season	NARO, AATF
Rice	NUE, salt tolerance, water use efficiency	CFT, first season	NARO, AATF
Sweet potato	Weevil resistance	Greenhouse containment	NARO, CIP

AATF: African Agriculture Technology Foundation; CFT: Confined Field Trial; CIP: International Potato Center; DDPSC: Donald Danforth Plant Science Center; IITA: International Institute for Tropical Agriculture; NARO: National Agricultural Research Organisation; NUE: Nitrogen Use Efficiency; QUT: Queensland University of Technology (Australia).

Note: Funders are not included.

Figure 2. Confined field trial for transgenic bananas in Kawanda (Source: Bashaija Henry)

Figure 3. Confined field trial for transgenic drought tolerant maize in Kasese (Source: Lominda Afedraru)

BIOSAFETY POLICY OVERVIEW

Uganda benefited from the donor funded project, United Nations Environment Programme-Global Environment Facility (UNEP-GEF) that contributed towards the development of the National Biosafety Framework (Sengooba *et al*., 2005). The Program for Biosafety Systems, which is a USAID funded project managed by IFPRI established in 2004 has been instrumental in providing technical and logistical support in the development of the biosafety regulatory framework. It has provided support in: establishment of biosafety policies, regulatory capacity building in national agencies, establishment of biosafety regulations, guidelines and procedures, and biotechnology and biosafety awareness (Sengooba and Oloka, 2012).

There has been political support from the President of Uganda and members of parliament for modern biotechnology. In 2003 during the opening of the National Agricultural Biotechnology Center at Kawanda, the president announced his support for use of modern biotechnology to improve agricultural productivity and the livelihood of the poor (Sengooba et al., 2005). During the first Biennial National Biosafety Conference in July 2013, the members of parliament present showed that there was urgent need for the National Biotechnology and Biosafety Bill, 2012 to be enacted into law for Ugandans to benefit from modern biotechnology. Despite political support, the bill is taking longer than anticipated to be enacted into law.

CONCLUSION

Uganda needs the National Biotechnology and Biosafety Bill enacted into law to provide a more coherent system, which also provides legal certainty with respect to biotechnology research, product development and commercialization. There is need to strengthen the national capacity for biosafety monitoring and enforcement, and develop appropriate biosafety training programs for regulators to maintain sustainable technical expertise.

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Chapter 12. Case study - Ghana

GODWIN LEMGO AND SAMUEL TIMPO

INTRODUCTION

Biotechnology is considered a promising technology for attaining food security and improving livelihoods in Ghana (STI policy, 2000). This is part of a broader government policy to promote the use of innovative and modern technologies (including biotechnology) to address problems in agriculture, health and industry and clearly outlined in Ghana's Biotechnology Policy (derived from the Science, Technology and Innovation policy of Ghana). This policy direction is further strengthened by a constitutional obligation on government to promote agriculture and industrial growth whiles ensuring that the environment and the natural resources of Ghana are protected (NBF, 2004). It is however documented that the development of biotechnology on the African continent is lagging behind other continents due in part to the lack of adequate and functional regulatory systems for the technology and Ghana is no exception (Juma & Seralgeldin, 2007). Thus, to fulfil her policy direction and constitutional mandate, Ghana developed a management system to provide a regulatory environment for a sustainable and safe use of biotechnology.

Brief historical perspectives

In May 2003, the government of Ghana ratified the Cartagena Protocol on Biosafety (CPB). This international instrument mandated the Ghanaian government to institute biosafety measures as deemed adequate to protect the environment from any potential harm that may emanate from harnessing the enormous potentials of modern biotechnology as spelt out in the strategic thrust areas of Ghana's national biotechnology policy of 2000 (including agriculture, health and therapeutics, environmental management, bioinformatics).

Prior to this, in 2002, Ghana commenced work on its biosafety management system under the United Nations Environmental Program – Global Environment Facility (UNEP-GEF) project. The outcome was the development in 2004 of Ghana's National Biosafety Framework (NBF). This framework consisted of a Government policy on biosafety, a regulatory system (including a biosafety bill and a set of biosafety guidelines and regulations), an administrative system, a decision making system, and a mechanism for information sharing and public participation (NBF, 2004). In developing the Framework, Ghana was guided by its constitutional obligations of promoting agriculture and industry in a framework of sound environmental management and other sustainable management practices (NBF, 2004). However, it wasn't until December 2011 that Ghana's biosafety bill which was required to domesticate the CPB and provide legal underpinning to the management system outlined in the NBF was signed into law (Act 831, 2011).

Whiles awaiting the passage of the Biosafety Bill into law, Ghana passed the Biosafety (Management of Biotechnology) Regulations, 2007 (legislative instrument - LI 1887) to regulate contained use and confined trials of genetically engineered organisms (GEOs) for research purposes (but not commercial releases). This legal instrument was derived from the parent act of the Council for Scientific and Industrial Research (CSIR) [CSIR Act No. 521] and was meant to be an interim measure to stimulate research.

The biosafety regulatory structure in Ghana

Legal mandate

There are currently two legal instruments that address issues of biotechnology directly. These are the LI 1887 and the Biosafety Act, 2011 (Act No. 831). The LI 1887 was passed as an interim measure prior to the passage of the biosafety Act No. 831 and is still in force mainly because the Biosafety Act No. 831 is yet to be fully operational three years after it was signed into law. This is due to the absence of the regulations needed to implement the Act. Consequently, the LI 1887 has yet to be repealed and so is the regulatory structure established by it. However, the LI 1887 has a limited scope of research and does not support commercial release of transgenic organisms.

The Biosafety Act, 2011 (Act No. 831) has a much broader scope that includes deliberate environmental release for the purpose of commercialization. When fully operational, the biosafety act will be the parent law to operationalize Ghana's biosafety framework.

There are however, existing plant, animal and food safety laws with relevant provisions that have a direct bearing on the management of biotechnology in Ghana. These include the Environmental Protection Act (Act No. 490), Food and Drugs Law, 1992 (P.N.D.C.L. 305B) and its amendments; Prevention and Control of Pests and Diseases of Plants Act (Act No. 307), Pesticides Control and Management Act (Act No. 528), Plant Varieties Bill, Diseases of Animals Act, Local Government Act (Act No. 462), Exportation & Importation Laws, etc. (NBF, 2004).

Institutional arrangements

The Ghana Biosafety Regulatory system is a coordinated framework with a coordinating agency, the National Biosafety Authority (NBA), whilst monitoring and enforcement issues are handled by the existing regulatory agencies including; the Food and Drugs Authority (FDA), the Veterinary Services Directorate (VSD), the Plant Protection and Regulatory Services Directorate (PPRSD), the Environmental Protection Agency (EPA), The Customs Division of the Ghana Revenue Authority (GRA) and the Local Government Authority.

The NBA is established by the Biosafety Act, 2011 (Act No. 831) as the administrative body that will manage the implementation of all issues related to Biotechnology in Ghana. The governing body of the NBA is a Board whose chairman and members are yet to be appointed by the Executive President and so is the chief executive officer of the NBA. The NBA and its Board will be responsible for biosafety decision making in Ghana. In the interim, all biosafety related matters and decision making lies with the National Biosafety Committee (NBC) established by the LI 1887 which also forms the legal basis for its operations. In October 2009, the Ministry of Environment, Science, Technology and Innovation (MESTI) endorsed the mandate of the NBC to receive and process applications on GEOs for contained use and for the conduct of confined field trials (CFTs).

MESTI is the Competent National Authority (CNA) for biosafety in Ghana and has an overarching supervisory role over the NBA. It provides the NBA with broad policy directions and political support. Currently, the NBA exists as a Biosafety Secretariat established by the LI 1887 to coordinate biosafety related activities and to handle applications for contained and confined use of GEOs in Ghana. This secretariat is housed in the MESTI and is expected to metamorphose into the NBA in the near future when the Board of the NBA is inaugurated.

Also established under the Act is a technical advisory committee (TAC) to provide technical support to the NBA. The TAC members are drawn from regulatory agencies, private sector, academia, and research

institutes, and represent all the varied expertise/competencies required to conduct a scientific risk assessment. The report of the TAC feeds into the decision making process.

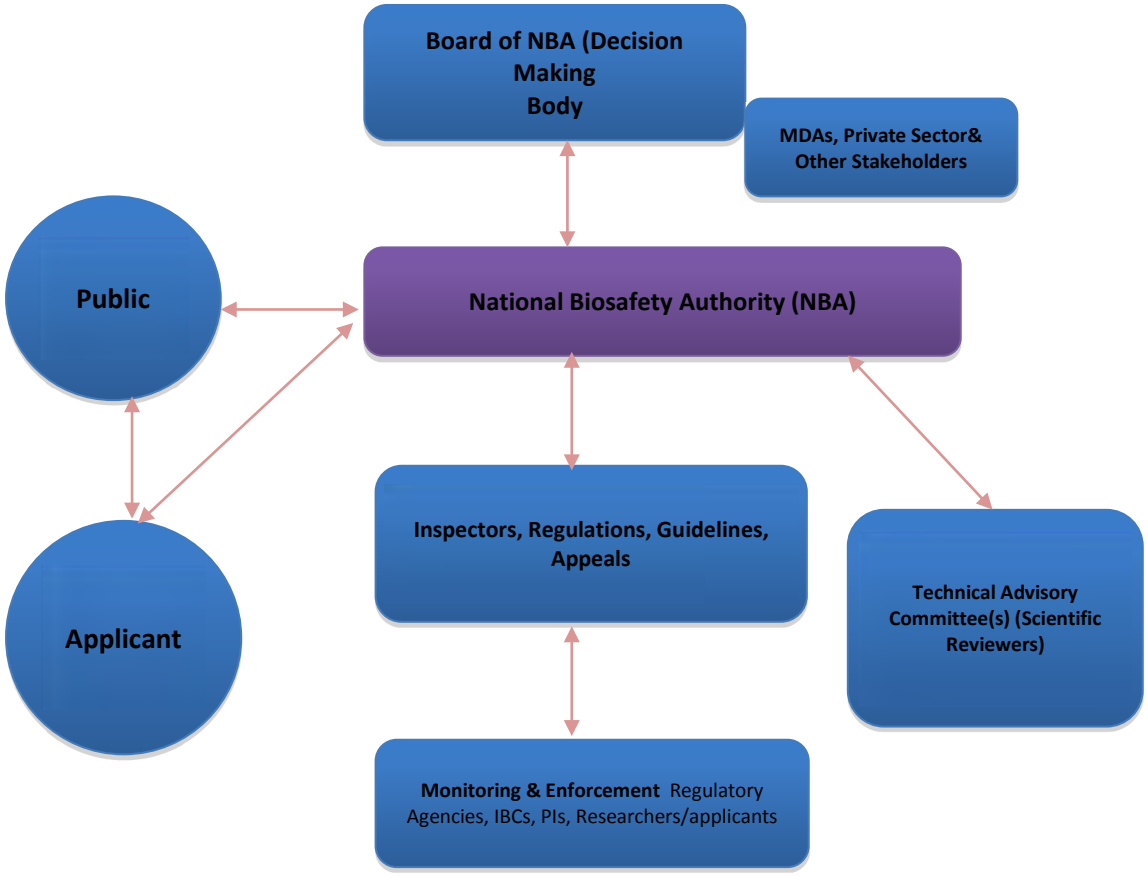
Under the current institutional arrangement, every institution involved in biotechnology development is required to establish an Institutional Biosafety Committee (IBC). IBCs serve as a bridge between institutions (applicants) and the NBA and perform functions ranging from application review to inspections, monitoring and compliance. They are considered the "first safety valve" and the "eye of the NBA in the institution" and may be designated by the NBA to perform certain functions on its behalf. A schematic representation of the institutional arrangements established by the Biosafety Act No. 831 is shown in Figure 1 below.

Inspectorate functions

The regulatory system in Ghana recommends a two-tier inspection, monitoring and compliance system; first by the institutions involved and secondly by national inspectorate services. At the institutional level, IBCs are mandated to conduct routine monitoring and report as appropriate to the NBA. Currently, two IBCs have been certified by the NBC including the IBCs of the Savannah Agriculture Research Institute (SARI) located in Tamale (Northern Region of Ghana) and the Crops Research Institute (CRI) located in Kumasi. A third IBC, that of the Biotechnology and Nuclear Agriculture Research Institute (BNARI) is under consideration by the NBC for certification.

At the national level, and in accordance with the various biosafety legal instruments, biosafety inspectorate functions fall under the mandates of existing regulatory agencies. This implies that biosafety inspectors are designated by their respective institutions and are certified and trained by the NBA for inspectorate and compliance functions on a case-by-case basis.

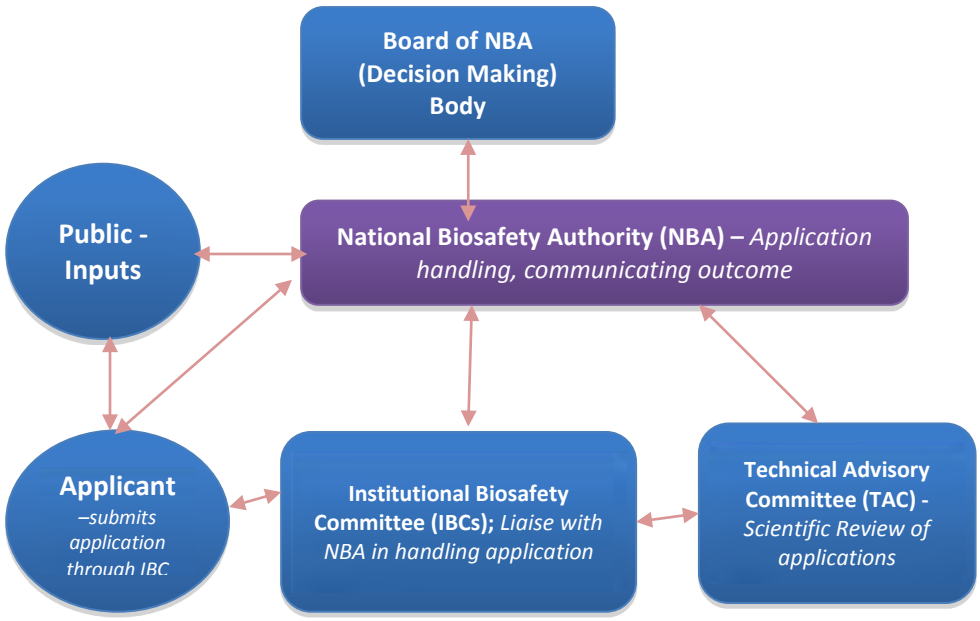
Figure 1. Schematic diagram of the regulatory system in Ghana (Source: NBF)



Application and approval process in Ghana

In accordance with the Biosafety Act 2011, Act No. 831 and the Legislative Instrument, LI 1887, the introduction into the environment of genetically modified organisms is prohibited unless with prior written approval of the NBA. A formal approval process has to be followed involving application review and decision making. The NBA (currently the NBC) is mandated to receive all applications for introduction of GEOs into the environment (either for commercial purpose or research), import/export and for transit. These applications have to be submitted to the NBA through IBCs. This implies that foreign entities would necessarily have to liaise with local counterparts in Ghana for an application to be submitted especially in the case of research. The contents of such applications are outlined in schedule III of the Biosafety Act, 2011 (Act No. 831) except for exports which require an advanced informed agreement (AIA) and transit (to be spelt out in the implementing regulations).

Applications received by the NBA (or NBC) are vetted for administrative completeness and the TAC is constituted to perform a technical review (risk assessment). This is entirely a safety assessment exercise and a recommendation report of the TAC forms the scientific basis to aid the decision making process by the Board of the NBA. However, in reaching a final decision, the Board is mandated to also take into account i) national policy and needs; ii) relevant public comments and iii) socioeconomic considerations. Currently, decision making in Ghana is by consensus, which means that each Board member has to be in agreement with the decision. These decisions are then published in government gazette and the public is notified. There are currently no fee regimes in Ghana with regards to any of the applications. This is expected to be spelt out in the implementing regulations to be passed. This will allow the NBA to charge fees for application handling, review and issuance of permits.



Capacity gaps – factors that impeded Ghana's progress

The biosafety management system established under the UNEP-GEF program and the subsequent interim measures established under the LI 1887 of 2007 did not automatically translate into functionality. As an example, Ghana received its first application for confined trials of biotech crops in 2010. However, this application was not processed until late 2012. Several factors accounted for this delay. Among them were i)

the absence of logistics to make the Biosafety secretariat functional, ii) inadequate experience and expertise in biosafety administration, iii) low critical mass of biosafety expertise in all the institutions involved in implementing the biosafety management systems, iv) absence of information and technical support services and v) limited capacity for communication and public engagement. In fact, these capacity gaps slowed down progress so much that it was unclear if the government was indeed interested in harnessing the potentials of biotechnology.

Bridging the gap – ABNE's Biosafety Capacity Building in Ghana

Several biosafety initiatives have been involved in biosafety capacity building in Ghana in an attempt to bridge this capacity gap. These efforts obviously started under the UNEP-GEF capacity building program for Ghana from 2002 to 2004. The USAID-sponsored Program for Biosafety Systems (PBS), implemented by a consortium led by the International Food Policy Research Institute (IFPRI), also played a significant role in developing the underlying legal framework for biotechnology and biosafety policy in Ghana in 2004-2008 (GAIN report, 2013).

In 2009, the African Biosafety Network of Expertise (ABNE) was formed under the auspices of the NEPAD Planning and Coordinating Agency (NPCA) of the African Union with the aim of assisting AU member states to establish functional biosafety systems for regulating biotechnology. Ghana was one of the priority countries of ABNE. Cognizant of prior progress made in Ghana, the existing political will and the capacity gaps identified during an in-country consultative process in 2009, ABNE commenced its capacity building efforts in Ghana in 2010, targeted at stakeholders involved in biosafety management in Ghana including the NBA/NBC, the TAC, certified IBCs, state regulatory agencies charged with biosafety inspection, monitoring and compliance, the media and other vital stakeholders. These interventions have been in the form of a) logistical support to make the Biosafety secretariat functional, b) Human resources capacity building, and c) Provision of technical support and expertise. ABNE worked closely with MESTI and the biosafety secretariat to ensure that Ghana overcame prevailing challenges to establish an adequate and functional regulatory system.

Three strategic goals underpinned ABNE's intervention in Ghana (ABNE, 2013). The first is the *creation of an enabling policy, legal and institutional environment for biosafety regulation.* This was to ensure that Ghana's biosafety management framework/system had adequate legal mandate through the passage and promulgation of workable legal instruments to regulate the technology. ABNE sensitized Ghanaian law makers, provided technical assistance to and shared best practices with the NBC and stakeholders working on the biosafety act and its implementing regulations.

To implement the law effectively, an effective administrative system was required for efficient coordination. This required a functional biosafety secretariat. ABNE supported MESTI to equip the biosafety secretariat with office logistics in November 2010 and followed it up with a series of capacity building activities for staff of the secretariat and the NBC on biosafety administration, application handling and decision making.

Also cognizant that there are a number of existing institutions with mandates for some aspects of biosafety management in Ghana, ABNE is engaging MESTI to develop and operationalize a mechanism for cooperation and coordination among institutions. It is important that all institutions involved in biosafety management in Ghana understand their roles and mandates and have memoranda of understanding (MOUs) amongst themselves. This is necessary for the system to run smoothly and efficiently.

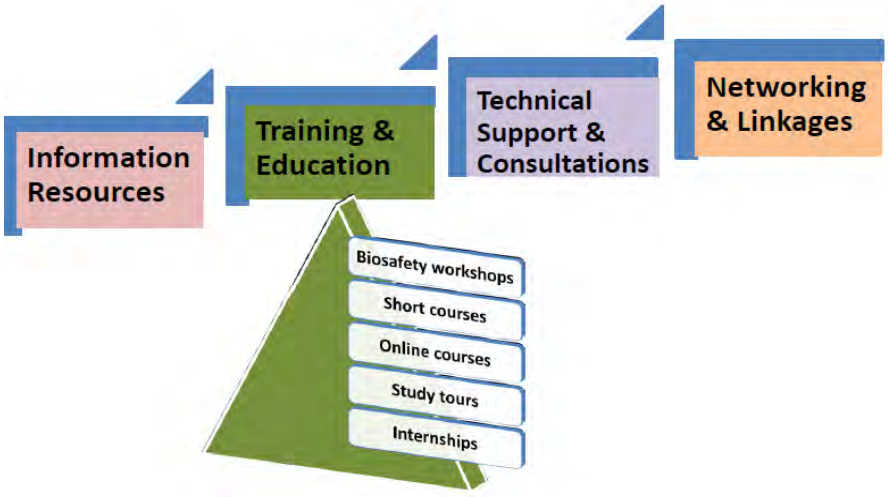
The second goal is *empowering a critical mass of regulators, policy and decision makers with improved competencies.* An effective regulatory system requires a good mass of human resource with good technical competence to assess risks, propose risk management measures and ensure effective discharge of

inspectorate, monitoring and compliance functions. Through ABNE's service delivery platforms (See fig. 3 below), key stakeholders (including NBC, IBCs, TAC, biosafety inspectors, regulatory agencies) were identified and empowered with key competences and skills required to make the biosafety system functional, including risk analysis (i.e. risk assessment, risk management, risk communication), dossier evaluation, decision making, inspections, monitoring and compliance. These were sustained, strategically planned and practical in-country trainings with regular follow-ups designed to boost their competence and confidence.

Finally, the third goal is *enhancing competence and mechanisms for biosafety communication.* Public awareness and participation in biosafety decision making is a key characteristic of a good biosafety management system. To promote awareness, stimulate public participation and to ensure effective risk communication and emergency response, there is a need for continuous engagement amongst all stakeholders. This is essential to ensure transparency, stimulate national ownership and public confidence in the regulatory system. Realizing the significance of this, the competent authority initiated measures to develop a national biosafety communication strategy. ABNE has been supporting this process together with other biosafety initiatives operating in Ghana.

In 2012, the PBS program in Ghana was reactivated to continue with its assistance with biosafety capacity building in Ghana. This coincided with the commencement of the second phase of the UNEP-GEF program for capacity building in Ghana (dubbed the implementation phase). In 2013, the biosafety unit of the International Centre for Genetic Engineering and Biotechnology (ICGEB) also commenced biosafety capacity building in Ghana. This brought the number of biosafety initiatives operating in Ghana to four (4), thus requiring some level of coordination to ensure synergies and avoid duplications. This coordination effort, led by ABNE, has resulted in very successful partnerships in Ghana.

Figure 3: ABNE service delivery platforms



Status of biosafety in Ghana

Ghana's biosafety regulatory system is gradually evolving towards full functionality. The system possesses the components and characteristics of a functional and protective biosafety system as outlined as follows; it is comprehensive, transparent, participatory (has provisions), flexible and adaptable, efficient, has adequate legal authority, has clear safety standards, has proportionate risk-based review systems and has provisions for post-approval oversight (Jafe G, 2006).

Biosafety governance

Even though existing plant and animal health and food safety laws contained some provisions (non-specific) that could be used to regulate GEOs, Ghana opted to pass a biosafety-specific law to provide adequate legal authority for the regulation of biotechnology in the country. Ghana's biosafety law has been assent by the president. The law is considered user friendly and does not contain any strict liability provisions (GAIN report, 2013). Instead, it relies on the fault-based system to be administered under existing liability and redress regimes. Currently, the biosafety secretariat is coordinating efforts to have the draft implementing regulations finalized and passed by the Parliament of Ghana. This is the final piece of the puzzle missing in Ghana's legal regime for biosafety management. The draft regulations will be submitted for cabinet approval and subsequently laid in parliament to mature. MESTI is also currently taking steps to put in place the appropriate governance structures established by the biosafety act 831. A concept note for the operationalization of the NBA has been developed and approved by the sector minister. Consequently, a search party has been constituted to select and interview candidates for the position of CEO of the NBA. The Ghana Atomic Energy Commission has made available an office building for use by the NBA. The Board of the NBA has also been constituted by the competent authority and the members are currently awaiting inauguration by the president.

Permits for field trial

The regulatory regime in Ghana is fluidly processing and making sound science-based regulatory decisions on applications for confined and multi-location trial of crops derived from modern biotechnology. In 2012 and early 2013, three (3) CFT applications including that of Insect resistant cowpea (Bt Cowpea), High protein Sweet Potato and N-use efficiency, Water –use efficiency, Salt Tolerant (NEWEST) Rice were processed by the Biosafety secretariat, reviewed by the TAC and a determination made by the NBC. This was followed closely by the review and decision making on an application for a Multi-location trial of Bt Cotton. These applications were submitted by the Savanna Agriculture Research Institute (SARI) and the Crop Research Institute (CRI) both of the Council for Scientific and Industrial Research (CSIR) of Ghana. In the first quarter of 2014, the system processed two more applications for confined trials of Herbicide tolerant (HT) Cotton and a stacked event (HT x Bt). This brings the total of applications processed for confined trials to six (6).

This is an indication that the Ghanaian regulatory system is maturing and increasing in confidence and experience. Some of the regulatory decisions emanating from Ghana are unprecedented for a relatively young system. For instance, Ghana considered years of regulatory data on single site trials of cotton in Burkina Faso to opt for a multi-location trial of Bt cotton instead of repeating the single site confined trials. The bases for this decision were the facts that the Bt Cotton variety to be tested has been commercialized in Burkina and the cotton regions of Ghana share a similar agro-ecology with the ones in Burkina. There was therefore no need for Ghana to start all over with many years of confined field trials. Ghana is perhaps the first in the sub-region to port data from their neighbors for decision making. Till date, no permit has been granted for any commercial release of GEOs into the environment or for placement of GEOs on the market for food/feed or processing.

GM Rice (Nitrogen Use Efficiency – NUE) Trial at CSIR-SARI, KUMASI

Multi-Locational Trial of Bt Cotton – Kpalkore Site, Tamale, Ghana

Capacity for risk analysis, inspections, monitoring and compliance

Ghana is gradually building up a critical mass of regulators and policy makers with competence and confidence to review applications, make decision and to do a post-approval monitoring. The nation currently has a reasonable pool of expertise that can be drawn for implementing the biosafety framework. Ministries, departments and agencies (MDAs) involved in biosafety management are taking steps to build human capacity in biosafety management. The NBC and TAC have adequate expertise and have received further training and exposure to do a scientific evaluation and to successfully make a decision on applications. Biosafety inspectors have also been designated by responsible ministries, departments and agencies (MDAs) and have subsequently been trained for biosafety inspections and monitoring functions. In additions, two IBCs have been certified and trained to conduct biosafety monitoring in their institutions. These stakeholders are being empowered through training opportunities provided by biosafety service providers in Ghana. For instance, under the capacity building partnership with ABNE, about 329 stakeholders in Ghana were empowered from 2010 to 2013 through ABNE's capacity building platforms.

Biosafety communication strategy developed

Considering the significance placed on public participation in biosafety decision making and its contribution to making the Ghanaian system transparent and participatory, a communication strategy has been developed under the coordinative effort of the secretariat and with technical guidance from ABNE and ICGEB. This strategy document is expected to facilitate biosafety communication in general and public awareness creation. In addition, communication materials detailing the setup of the biosafety system in

Ghana, the key documents on biosafety and the process flow for application processing were also developed and disseminated to the general public and other stakeholders.

Growing regional influence

Ghana is also showing a steady regional influence in terms of biosafety management within the Economic Community of West African States (ECOWAS) sub-region. In an attempt to stimulate a harmonization of biosafety regulation in the ECOWAS bloc, some detrimental provisions were introduced which if adopted would derail any success made in Ghana and the sub-region as a whole. Ghana, during the national consultation process produced a position paper to point out the irregularities within the ECOWAS regulations and requested amendments. This is another example of the nation's growing maturity in the biosafety space.

Challenges and lessons learnt

Notwithstanding the notable achievements and the legitimate mandate of the National Biosafety Committee (NBC) which has been steering affairs so far, the absence of a National Biosafety Authority (NBA) has been a key missing link in biosafety administration in Ghana. Fortunately, Ghana has demonstrated strong commitment and significant political will towards establishing a National Biosafety Authority (NBA) including the inauguration of the Board members. This however has not translated into budgetary support to the biosafety secretariat for biosafety functions. There is little or no fund committed from government to biosafety functions in Ghana. Ghana like many other African countries is totally reliant on donors for budgetary assistance. There is an urgent need for government to own and support the process budget wise.

Biosafety capacity building can be an expensive endeavor. It is absolutely necessary to have the right target participants that will be useful to the country process when trained. Working with the competent authority and closely with the biosafety secretariat is very valuable in this regard. Not only does it ensure national ownership of the capacity building effort, it also facilitates government buy-in and ensures that the right participants are selected. In doing so, there is often the temptation for biosafety initiatives to engage in one-off activities with no clear follow-up plans which is clearly ineffective. Instead, sustained efforts, clear follow-up plans and continued in-country engagements have been impactful in Ghana. It is important that national requests for capacity building are matched with capacity gaps and considered in order of priority and desired impact. Some requests maybe the right ones but at the wrong time.

One key lesson learnt is the need to analyze and ensure that all important stakeholders are involved in the process of building a safety management system. When stakeholders feel left out of the process, they most often turn out to oppose and fight the system. This was recently illustrated by a farmer group in Ghana.

Ensuring political buy-in is essential for successful capacity building. However, political leadership in Ghana, as is generally the case in Africa, is most often fluid with high turn-overs. It is therefore important to carry along the technocrats. This will ensure continuity and sustainability.

With regulatory progress and increasing functionality comes growing misinformation through anti-biotech activism. A general lack of awareness amongst key stakeholders has made them vulnerable to misinformation and Ghana intends to address this by providing a platform for enhanced stakeholder understanding and participation in biosafety processes and policy development.

SUGGESTED FURTHER READINGS

1) Ghana Science, Technology and Innovation Policy, 2000
2) Biosafety (Management Of Biotechnology) Regulations, 2007 (Legislative Instrument 1887)
3) Biosafety act, 2011 (Act No. 831)

4) National Biosafety Framework (NBF).
5) NBF Administrative Guidelines.
6) Guidelines for Public Participation information Sharing and Access to Justice with Respect to Genetically Modified Organisms.
7) Regional Mechanisms for Harmonization on Biosafety Activities (Survey report I).
8) Existing Legislative and legal Instruments Related to Biotechnology in Ghana (Survey report II).
9) Programmes for safe use of Biotechnology/biosafety and existing status of biotechnology and LMOs in Ghana (Survey report III).
10) Introduction to Biosafety Guidelines.
11) Guidelines on Risk Assessment of Genetically Modified Organisms in Ghana.
12) Biosafety Guidelines for Laboratory & Field Work.
13) Movement of Regulated Materials and Commercial Releases.

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Chapter 13. Case study - Nigeria

RUFUS EGBABA AND DIRAN MAKINDE

INTRODUCTION

Nigeria occupies a total land area of 923 768 km^2 and has a population of over 120 million people. By virtue of its geographical position, its variable climate and physical features the country is endowed with a very rich biodiversity (4^{th} Nigeria National Biodiversity Report 2010). At the current annual growth rate of 2.8% the demand for food, fuel-wood and other biological resources is expected to increase and this will lead to greater pressure on the land, water and other resources. The high rate of population growth also threatens biodiversity. Most of the rural poor derive their livelihood from the exploitation of wild species of plants and animals while the urban populations benefit from the use of the country's biological resources, particularly in the construction industry.

Although Nigeria derives about 80% of its income from oil, agriculture contributes about 38% of the Gross Domestic Product. About 70% of the population derives its livelihood from agriculture, and the national economy is characterized by a large rural-based traditional sector.

Nigeria has over 250 ethnic groups each with a rich cultural heritage. This diversity of cultures has a considerable impact on biodiversity utilization and the level of protection. Natural and man-made threats include over-exploitation as well as the direct and indirect erosion of biodiversity in the country. Nigeria needs to apply eco –friendly technologies that can enhance the economy and the environment.

Convention on Biological Diversity (CBD)

Nigeria signed the Convention on Biological Diversity in 1992 and ratified it in 1994. The country has since actively participated in the activities of the Convention and is committed to its objectives.

Nigeria signed (2002) and ratified (2003) the Cartagena Protocol on Biosafety (CPB) which is intended to conserve biological diversity from the adverse impact of Living Modified Organisms (LMOs). Nigeria also signed the Supplementary Biosafety Protocol on Liability and Redress of the Cartagena Protocol on Biosafety in 2012. Nigeria, therefore, accords a very high priority to the successful implementation of all the articles of the Convention and the Protocol as a responsible member of the global community and in pursuit of sustainable development.

Nigerian Biodiversity

The 4^{th} Nigeria National Biodiversity Report (2010) records that Nigeria is endowed with a wide variety of plant and animal species. About 7,895 plant species have been identified in 338 families and 2,215 genera. There are some 22,000 vertebrate and invertebrate species which include about 20,000 insect species, 1,000 bird species, 1,000 fish species, 247 mammal species and 123 reptile species. Of these animals about 0.14% are threatened and 0.22% are endangered. About 1,489 species of micro-organisms have also been identified. All of these animal and plant species occur in abundance within the country's vegetation zones that range from mangrove swamps along the coast in the south to the arid Sahel in the north.

The Regulatory System

The Federal Ministry of Environment is the National Focal Point and the Competent National Authority (CNA) on biosafety in Nigeria. The CNA is mandated for the safe management of modern biotechnology including research, development, introduction and the use of the products of modern biotechnology – the genetically engineered organisms (GEOs). This responsibility is carried out by the Biosafety Unit in the Federal Ministry of Environment.

Modern biotechnology, though it has great potential benefits, also could have potential risks to the environment and human health if not properly managed. It is on this note that Nigeria has adopted biosafety as a tool for the safe handling, use and transit of GEOs. Nigeria has adopted biotechnology, including modern biotechnology, as one of the approaches to achieve sustainable development in all sectors of the economy, but especially to address challenges that have been difficult to resolve using conventional methods.

With the advent of modern biotechnology, GEOs and their products, coupled with their perceived risks to the environment and human health, Nigeria joined the group of nations that adopted precautionary safety measures by signing and ratifying the Cartagena Protocol on Biosafety (Biosafety system in Nigeria 2011). The conscious decision to regulate modern biotechnology also began when local research workers became competent in modern biotechnology and appreciated the possible risks that the technology and its products could pose to the environment and human health.

Nigeria's extensive biodiversity must be conserved and used in a sustainable manner. The regulation of modern biotechnology should manage the technology in such a way that it will improve food production, medicine/health, industrial growth and protect the environment. With this object in mind, biosafety issues have become a major focus of the Federal Ministry of Environment.

MODERN BIOTECHNOLOGY IN NIGERIA

The importance of biotechnology to Nigeria was stressed when President Chief Olusegun Obasanjo (2002) said that the "Acquisition of biotechnology now is crucial for poverty eradication and food security in Nigeria. The 21st Century will be biological and diverse with biotechnology being the kingpin of the process." To foster the development of biotechnology in Nigeria a National Biotechnology Policy and National Biotechnology Development Agency have been created within the Federal Ministry of Science & Technology. Another agency, the Agricultural Research Council of Nigeria, has also been tasked with promoting biotechnology activities in the agricultural sector.

Some institutions in Nigeria have been identified as having the potential to carry out modern biotechnology research. Three institutes applied for and have been accredited (themselves and their containment facilities), to conduct modern biotechnology research. They are the:

- National Root Crops Research Institute, Umudike,
- Institute for Agricultural Research, Zaria, and
- Federal University of Technology, Akure.

Currently confined field trials (CFTs) on GEOs are ongoing or just being completed at the:

- National Root Crops Research Institute, Umudike - There are two CFT events, bio-fortified cassava with increased vitamin A and bio-fortified cassava with an increased bio-availability of iron.
- Institute for Agricultural Research, Zaria - There are two CFT events at this Institute, sorghum with increased bio-availability of zinc, iron, protein and vitamin A and cowpea resistant against the soybean pod borer, *Maruca vitrata*.

The CFTs are being carried out as a prelude to the expansion of modern biotechnology research. Nigeria wishes to use modern biotechnology to:

- Produce plants that can reduce greenhouse gases and mitigate the effects of climate change;
- Develop plants that have a greater tolerance to abiotic stress in marginal environments;
- Improve the growth and productivity of plants and animals;
- Improve food quantity, quality, nutritional content and consistency for healthier living;
- Produce new breeds of crops and animals;
- Reduce the use of chemical pesticides and herbicides;
- Reduce the area of farming land;
- Improve the health sector,
- Promote environmental sustainability;
- Encourage industrial development,
- Create more jobs and wealth.

Biosafety in Nigeria

The biosafety system in Nigeria aims to:

- Minimize or eliminate the risks of modern biotechnology on the environment, biodiversity and human health by providing policies, laws and guidelines
- Determine in advance if there is any risk to human health or the environment if a particular GEO is released and prevent such a risk;
- Anticipate when a given GEO or any of its product(s) will become a risk if it becomes part of the national diet;
- Safely harness the benefits of modern biotechnology;
- Prevent Nigeria from becoming a dumping ground for unregulated GEOs which may endanger the environment or human health.
- Protect the populace from any adverse socio-economic consequences of GEOs, especially among small scale farming communities;
- Determine whether a GEO actually produces the benefits it was designed to provide, and
- ensure, as far as possible, that no risks occur if GEOs are transported intentionally or unintentionally, Between different ecosystems and countries;
- Reaffirm Nigeria's commitment to the aims and objectives of the CBD and CPB.

Evolution of biosafety in Nigeria

Biosafety Guidelines

Nigeria started its biosafety activities with the development of guidelines.

- 1994 Biosafety Guidelines - These Guidelines were developed by the Federal Ministry of Agriculture specifically for the agricultural sector before the CPB. It was, however, not put into practice because it did not meet the required biosafety standards.
- 2001 National Biosafety Guidelines - These guidelines were developed with the participation of the relevant stakeholders, government agencies, non-governmental organizations and experts in biodiversity conservation, biotechnology and biosafety. They were developed after the signing of the CPB and were aligned with the contents of the Protocol.
- National Biosafety Framework (NBF) - The CBD identified the emergence of Genetically Engineered Organisms (GEOs)/Living Modified Organisms (LMOs) as a group of organisms produced by modern biotechnology that needed special attention because of the perceived risks to the conservation and sustainable use of biodiversity and human health. The CBD requested the negotiation of a biosafety protocol (the CPB), which Nigeria signed and ratified in 2000 and 2003, respectively. In line with the

CPB, which requires member states to develop national administrative and legal frameworks as a means of incorporating the Protocol into domestic legislation, Nigeria developed a National Biosafety Framework (NBF) in 2006. The NBF consists of a Biosafety Bill and Biosafety Policy. It ensures the safe practice of modern biotechnology as well as the handling and use of GEOs that may pose a risk to the conservation and sustainable use of biodiversity, taking into account human health. The NBF covers:

- Laboratory and field research in modern biotechnology.
- Current and future applications of modern biotechnology in agriculture, human and veterinary medicine, food/feed and beverage production, industry, environmental management (e.g. bioremediation, industrial and domestic waste management).
- A regulatory system including:
  - Notification
  - Information transfer and review
  - Risk assessment, including socio-economic impact and ethical consideration
  - Monitoring and enforcement measures relevant to import, export, trans-boundary movement of GEOs, laboratory and field testing/use of GEOs including handling, containment disposal, control, monitoring and release.
  - Ensuring that any GEO product that might be eaten by humans and/ or animals is safe to eat.
- Occupational safety in the workplace where genetic engineering procedures are used or products handled
- Labelling of GEOs in food/feed produced locally, sold domestically or imported.
- Any other measures that may be required for the safe use of GEOs while protecting human health, the environment and national biodiversity.
- Promotion of public awareness on biosafety involving policy makers, legislators, administrators, the organized private sector, industry and rural communities.
- Development and establishment of a comprehensive and up-to-date database and infrastructure for information exchange to enable risk assessments, the evaluation of products and provision of a mechanism to enable the transmission of advanced informed agreement.

- National Biosafety Bill - The National Biosafety Bill provides for an Act to establish the National Biosafety Management Agency that will be responsible for providing a regulatory framework as well as institutional and administrative mechanisms for safety measures for the application of modern biotechnology so as to prevent any risk to human health, animals, plants and environment; and for related matters (National Biosafety Management Bill 2011).
- The domestication of the CPB will enable Nigeria to:
  - Exercise its sovereign right over all natural resources with the authority to regulate the practice of modern biotechnology and the handling, use and transport of GEOs (Biosafety system in Nigeria, 2011)
  - Harness the potential that modern technology offers in the fields of food production, medicine/health, industrial growth, environmental protection, job and wealth creation.
  - Create a regulatory biosafety regime to prevent Nigeria from becoming a dumping ground for unregulated GEOs and their products,
  - Allay fears of the populace on the socio-economic consequences of modern biotechnology, especially among the small scale farmers.
  - Give credence to modern biotechnology and GEOs.

NIGERIA AND GLOBAL BIOSAFETY

Nigeria accords high priority to the successful implementation of the CPB and all UN resolutions which significantly reduce the risks of modern biotechnology on the conservation and sustainable utilization of biodiversity and taking into account risk to human health. The country has also attended meetings of Parties to the CPB (COP-MOP) and been active in the Biosafety Clearing House (BCH) as a means of information exchange on biosafety issues. At the 5th Meeting of the Conference of Parties to the Convention on Biological Diversity which served as a meeting of Parties to the CPB on October 2010, Nigeria accepted the adoption of a Supplementary Protocol on Liability and Redress, known as Nagoya-Kuala Lumpur supplementary Protocol on Liability and Redress. Nigeria signed the Supplementary Protocol in 2012.

To further strengthen the Nigerian biosafety system, the country is currently being supported by the Global Environment Facility (GEF) with funds for the development of capacity to implement the National Biosafety Framework following the initial support for the development of Nigeria National Biosafety Framework (NBF).

In West African sub-region, Nigeria was one of the countries that supported the development of a common ECOWAS Biosafety Regulation. In Africa, Nigeria has also participated in biosafety initiatives and programmes to promote regional biosafety.

The UNEP/GEF has signed an MOU with Nigeria to develop the capacity to facilitate the exchange of scientific, technical, environmental and legal information, and experience with GEOs/LMOs (Biosafety Clearing House) (http//:www.bch.biodiv.int). Nigeria has the following biosafety website - http://ng.biosafetyclearinghouse.net.

CURRENT BIOSAFETY INSTITUTIONAL ARRANGEMENTS IN NIGERIA

- Federal Ministry of Environment (FMENV) - Is the Competent National Authority (CNA) and the National Focal Point on Biosafety in Nigeria
- Biosafety Unit – Is the office in the FMENV that manages biosafety issues on behalf of the Ministry.
- National Biosafety Committee (NBC) - Is the Committee that reviews biosafety applications and advises the Honourable Minister of Environment. It also advises the Minister on general biosafety matters.
- National Biosafety Technical sub-committees - These are *ad-hoc* committees on Agriculture, Environment, Health and Industry which carry out detailed reviews of biosafety applications and advise the NBC.
- Institutional Biosafety Committee (IBC) - Is the committee responsible for biosafety matters at institutional level and deals with the use of modern biotechnology in research and development.

Functions of the Biosafety Unit

- To propose, for the approval of the Minister, the overall policy on issues of biosafety in Nigeria;
- To implement the provisions of the CBD and CPB on matters relating to GEOs;
- To develop risk management plans and strategies to protecting human health, biological diversity and the environment from any risks associated with GMOs
- To take samples and carry out laboratory analyses of crops, products or materials to determine whether they contain GEOs and ensure compliance with the Biosafety Act;
- To accept and verify applications in respect of GEOs and keep records of all approvals and unapproved applications
- To carry out any action necessary to ensure the compliance with the legal obligations set forth in the Biosafety Act, including but not limited to
    - the inspection of facilities, conducting activities with GEOs covered by the Biosafety Act,

    - the collection and analysis of samples of materials covered by the Biosafety Act,
    - the monitoring of human health and the environment to determine the effects of GEOs regulated by the Biosafety Act
- To carry out and maintain inventory of laboratories with the physical and human capacity to conduct modern biotechnology research ;
- To monitor the activities of institutional committees and biosafety officers;
- To carry out public awareness and enlightenment programs on Biosafety;
- To carry out capacity building activities;
- To liaise with the Secretariat of the CBD and the Biosafety Clearing House with respect to the administrative functions required under the CPB;
- To carry out such other duties as may be necessary for the full discharge of its functions under Biosafety and other related Acts (Nigeria National Biosafety Policy 2006).

CURRENT BIOSAFETY INSTRUMENTS IN NIGERIA

- Biosafety Policy
- The CPB and the Supplementary Protocol on Liability and Redress;
- Biosafety application form,
- Biosafety Containment Facilities Guidelines,
- Accreditation of Institute application form,
- Certification of a Biosafety Containment Facility form,
- Confined Field Trial Monitoring and Inspection Manual,
- GEOs import/shipment form,
- National Biosafety Guidelines,
- National Biosafety Risk Analysis Framework,
- Decision document
- Biosafety Bill awaiting Presidential assent.

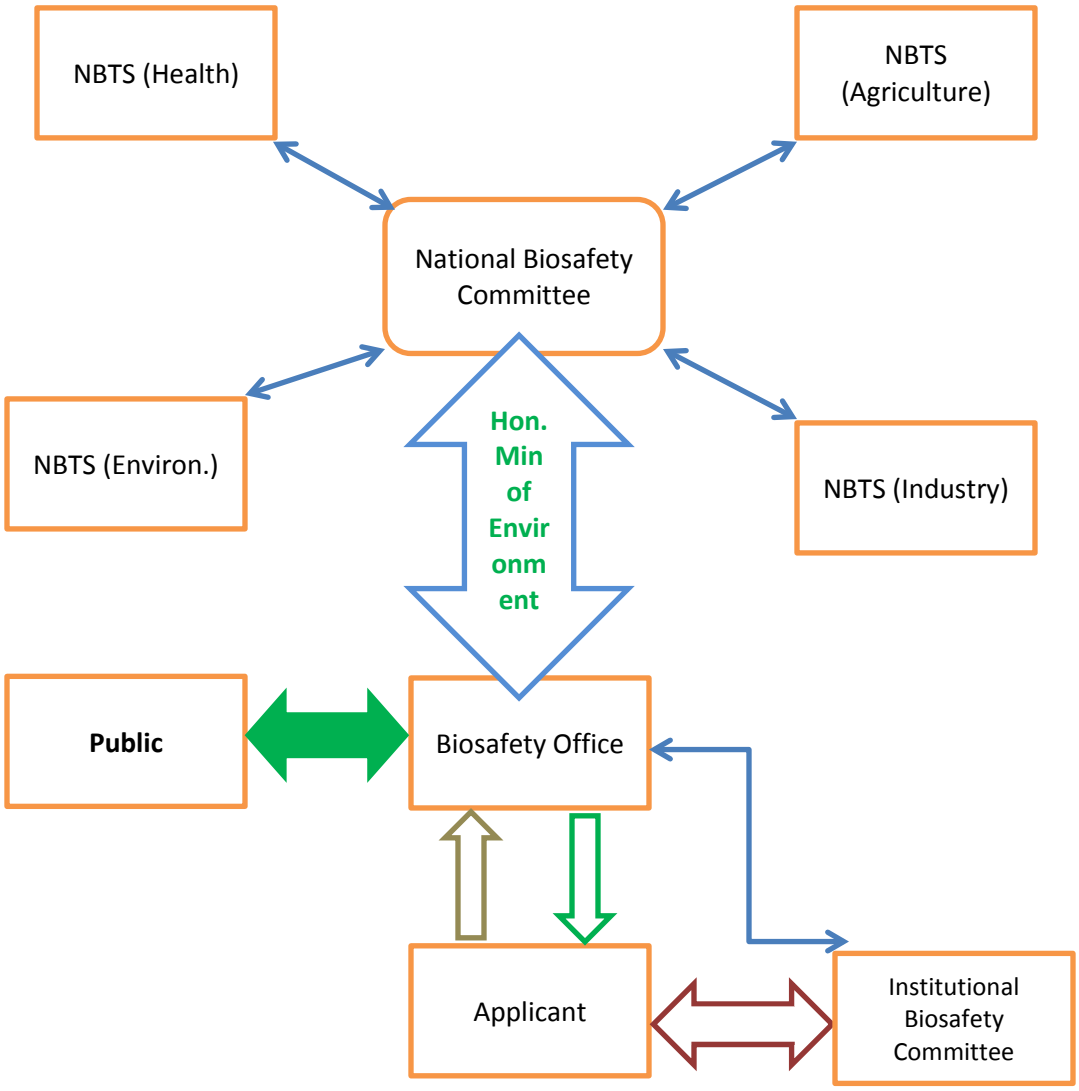
Procedures for the Approval of a Biosafety application

The following procedure is followed in the application and processing of biosafety applications:

- Accreditation of Institution/Organization: Any organization/institution that intends to do modern biotechnology research, develop or work with GEOs must obtain accreditation from the Federal Ministry of Environment
- Certification of a Containment/Storage Facility: Any organization/institution that intends to carry out modern biotechnology research, develop or work with GEOs must obtain a certificate for its biosafety containment facility from the Federal Ministry of Environment;
- Completion of application form and submission: Any individual, organization or institution that intends to work with GEOs must complete an application form and forward it to the Honourable Minister of Environment, Abuja. All applications must contain a risk analysis which includes a risk assessment, risk management and risk communication.
- Acknowledgement of Application: Every application is acknowledged with 90 days from the date of receipt. The Biosafety Unit checks the application for completeness before acknowledgement,
- The National Biosafety Committee (NBC) meets to review the application and constitute a National Biosafety Technical Sub-committee (NBTS);
- NBTS reviews the application and submits a recommendation to the NBC,
- Public Participation,
- The NBC meets and takes a decision on the application. It then advises the Honourable Minister of Environment,
- The Honourable Minister of Environment takes a decision on the application,

- A decision document is prepared by the Biosafety Unit and sent to the applicant within 270 days of receipt of the application. If approved, the Biosafety Unit will inspect the containment facility periodically,
- A copy of the decision is sent to the Biosafety Clearing House.

The biosafety decision-making pathway is depicted in the following diagrams.



CHALLENGES TO BIOSAFETY IN NIGERIA

The major challenges of biosafety in Nigeria include:

- The lack of a Biosafety Law
- An inadequate knowledge of biosafety by the public,
- Misconceptions about modern biotechnology and GEOs,
- Inadequate capacity for biosafety risk assessment, risk management, monitoring and enforcement,
- Issues surrounding Liability and Redress ,
- Control of the distribution of GEOs,

- The traceability of GEOs,
- The co-existence of GEOs and non-GEOs
- Packaging, transport ,storage, handling, in relation to GEOs and their products
- The purity of GEO products,
- Inadequate funding of biosafety activities,
- The lack of operational vehicles,
- The lack of operational biosafety guidelines ,
- Inadequate training

THE WAY FORWARD FOR NIGERIA

- Funding the activities of the Biosafety Unit by making provision in the national budget
- Developing operational biosafety guidelines
- The provision of operational vehicles
- The approval of the Biosafety Bill
- Continuous local and foreign trainings for the staff of the Biosafety Unit.

CONCLUSION

The development of the national biosafety system followed a process in which the public and private sectors both participated. The introduction of a National Biosafety law has created a Biosafety Regulatory Regime to ensure a safe and secure environment for the use, handling and transport of GEOs that takes into account the safety to human health and the environment. This will in turn open a new avenue for the use of modern biotechnology as a tool for national development in the fields of agriculture, industry, health and environmental sustainability that will lead to employment generation and wealth creation.

END NOTES

1) Federal Ministry of Environment 'Biosafety system in Nigeria': 2011, p. 5.
2) Federal Ministry of Environment, The 4th Nigeria National Biodiversity Report: 2010, pp.13-14.
3) Nigeria National Biosafety Policy: 2006, p.6.
4) Nigeria Biosafety Management Bill:2011, p5

Chapter 14. Case study - Malawi

WISDOM CHANGADEYA AND BONEFACE MUKOKO

INTRODUCTION

Malawi, as an agro-based economy, has applied traditional biotechnologies for a long time without biosafety legislation, as has been the case in most other African countries. The history of biosafety in Malawi in relation to modern biotechnology is directly linked to the first import of genetically engineered maize into the country in 2001-2002 when there was a famine due to drought. The maize consignment was in the form of a grain donation from the United States of America. Since the country did not have legislation for allowing importation of genetically engineered organisms (GEOs) at the time, a Biosafety bill was drafted, debated and passed into law in parliament in 2002. The GE maize was distributed to the public for consumption in form of flour to avoid the replanting of the kernels as the importation was only approved on condition that all the grain would be milled and distributed as flour. There were, however, cases where un-milled grain was distributed due to inadequate milling facilities and other logistical challenges.

The Biosafety Act (2002) provides for a Biosafety regulatory framework, which in turn provides for an institutional framework for its application consisting of the following:

- National Biosafety Regulatory Committee
- Reviewers
- Inspectors
- Biosafety Registrar.

In 2004, the Danforth Plant Science Center (USA) developed an application for a confined field trial in Malawi of cassava with resistance to Cassava Mosaic Disease (CMD). The application was never submitted to the biosafety registrar because the Department of Agricultural Research Services (DARS), which was to partner with Danforth Plant Science Center, did not agree to do the field trials citing lack of capacity to conduct the trial. This meant that the biosafety regulatory system as provided for in Biosafety Act (2002) was never tested though biotechnology and biosafety stakeholders had agreed prior to this application that the Biosafety Act (2002) and its provisions was a basic minimum required for the regulatory system to handle applications in the absence of a National Biotechnology and Biosafety Policy and other necessary regulatory instruments.

Since 2002, the Malawi government has generally adopted a positive attitude towards biotechnology and has consequently put in place appropriate Biosafety measures to reap the benefits offered by the technology. The country signed the Cartagena Protocol on Biosafety in May 2000 and ratified the same in 2009. In line with the requirements of the Protocol, the Malawi Parliament enacted the Biosafety Act in October 2002 which centres mainly on GEOs and is administered by the Minister responsible for Environmental Affairs. Over the years, the country has seen a number of biosafety regulatory instruments, committees and personnel being put in place through public appointments, experts' consultancies, stakeholders consultative meetings, training workshops with funding from various sources including the Government of Malawi, Program for Biosafety Systems (PBS), AfricaBio, UNEP, International Service for The Acquisition of Agric-biotech Application (ISAAA) among others.

CURRENT STATUS OF BIOSAFETY IN MALAWI

Malawi has legislation and a legal framework for the promotion and safe use of biotechnology (Biosafety) and its products comprising the Biosafety Act of 2002, Biosafety (Management of Genetically Modified Organisms) Regulations, 2007, the National Biotechnology and Biosafety Policy (2008), the National Biosafety Regulatory Committee (NBRC) (2008) and the Malawi Biotechnology Guidelines (2009). The Biosafety Regulatory Framework is housed at the Department of Environmental Affairs (EAD).

The country also has Standard Operating Procedure (SOP) documents necessary for the safe conduct of confined field trials namely Confined Field Trial Guidelines and the Trial Manager's and Inspector's Handbook. These SOPs were developed in anticipation of the approval of applications for confined field trials involving Insect resistant (Bt) and Herbicide tolerant (Ht) cotton submitted by Bunda College of Agriculture of the Lilongwe University of Agriculture and Natural Resources (LUANAR) to the Biosafety Registrar, Environmental Affairs Department.

Among the several provisions in the National Biotechnology and Biosafety Policy are the delineation of roles and responsibilities at government ministerial level as well as at R&D and other service delivery institutional levels. In the policy, the mandate of promoting and developing biotechnology in Malawi is vested in the National Commission for Science & Technology (NCST). The NCST therefore hosts the National Biotechnology Committee which is responsible for promoting biotechnology, public awareness and coordination of biotechnology research and development. On the other hand, the Department of Environmental Affairs (EAD) is responsible for regulation of biotechnology which entails receiving and reviewing biotechnology applications and issuing of licences or permits and hosts the National Biosafety Regulatory Committee (NBRC). In addition, there is a third set of public institutions that are responsible to provide regulatory and enforcement services of biotechnology and biosafety in the country. The mandate for these institutions is provided through the regulatory provisions contained in the various Acts that established them. These include, the Ministry of Agriculture & Food Security; Ministry of Industry & Trade; Ministry of Health; Malawi Bureau of Standards; Pharmacy & Medicines Board; Pesticides Control Board; Seed Services Unit; Plant Protection Unit; Ministry of Labour; Fisheries Department; Environmental Affairs Department; Forestry Department; National Herbarium & Botanic Gardens of Malawi; Department of National Parks & Wildlife; Ministry of Local Government; Ministry of Women & Child Welfare; and Malawi Investment Promotion Agency.

Detailed responsibilities of various institutions are given below.

National Commission for Science and Technology (NCST)

National Commission for Science & Technology is the lead/coordinating institution for the National Biotechnology and Biosafety Policy. Its responsibilities are as follows:

- Promoting and coordinating biotechnology research and development in the country;
- Conducting public awareness on biotechnology in general and benefits and risks of modern biotechnology in particular;
- Mobilising resources for biotechnology research and development, capacity building and public awareness;
- Facilitating development of national priorities on biotechnology research and development;
- Developing biotechnology research and development programme;
- Facilitating periodic review of the National Biotechnology and Biosafety Policy;
- Facilitating inter-departmental cooperation and participation in implementation of the policy and the identified priorities;
- Mobilising local and international support for biotechnology programmes in the country;

- Undertaking monitoring and evaluation of biotechnology programmes in the country;
- Hosting the Biosafety Clearing House Mechanism (CHM); and
- Servicing the National Biotechnology Committee as its Secretariat.

Environmental Affairs Department (EAD)

The Environmental Affairs Department has the following responsibilities:

- Receiving and processing GEO applications for review by the National Biosafety Regulatory Committee;
- Processing and issuing permits and licences after final approval by the Minister Responsible for Environment;
- Appointing biosafety inspectors from within Environmental Affairs Department (EAD) or without depending on the nature of the application and submitting all approvals or rejections to the inspectorate;
- Mobilising funding for biosafety research in order to build capacity in risk assessment, risk management and risk reporting;
- Serving as focal point for biosafety issues in Malawi and communicating with relevant international organizations;
- Serving as a focal point for the Convention on Biological Diversity (CBD) and the Cartagena Protocol;
- Serving as biosafety competent authority;
- Ensuring participation by all key stakeholders in biosafety decision-making;
- Facilitating development and review of Biosafety Regulations and Guidelines for contained experiments, confined field trials, commercial releases, food safety, storage, labelling and transportation of GEOs; and
- Servicing the National Biosafety Regulatory Committee as its Secretariat

Regulatory and Service Institutions

These institutions have the following responsibilities:

- Setting standards;
- Undertaking risk assessment and any other relevant assessments; and
- Inspecting GEO field trials and any facilities undertaking activities related to modern biotechnologies in order to ensure compliance with conditions for approval for an application.

Technical Committees of the NCST, EAD and Ministry of Agriculture and Food Security

Promotion and regulation of biotechnology in the country are delivered through the works of two committees, namely, the National Biotechnology Committee and the National Biosafety Regulatory Committee. The responsibilities of the two committees are spelt out in the Policy as follows:

National Biotechnology Committee

The Committee is responsible for the following:

- Advising the National Commission for Science and Technology (NCST) on biotechnology research, commercialisation, capacity building, and public awareness;
- Developing policy and guidelines on all biotechnology developments in Malawi;
- Setting national priorities for biotechnology research and development;
- Developing and coordinating the national programme for research, development and commercialization of biotechnology in Malawi; and
- Mobilising funding for biotechnology programmes.

National Biosafety Regulatory Committee

The committee is responsible for the following:

- Developing and publicising regulations, guidelines and standard operating procedures for contained experiments, confined field trials, commercial releases, food safety, storage, labelling and transportation of GEOs;
- Reviewing GEO applications based on advice from reviewers and make recommendations to the Minister for final approval;
- Reviewing risk assessment reports;
- Referring applications for licences or permits to appropriate reviewers for assessment and recommendation; and
- Mobilising resources for biosafety programmes.

Agricultural Biotechnology & Biosafety Committee

The Ministry of Agriculture & Food Security has also established its institutional biosafety committee known as the Agricultural Biotechnology & Biosafety Committee (ABBC) which is technically and financially supported by the Ministry of Agriculture & Food Security (MoAFS). It draws membership from various government ministries, departments and non-governmental organisations such as Ministry of Agriculture & Food Security (MoAFS), Ministry of Justice, Department of Agricultural Research Services (DARS), Environmental Affairs Department (EAD), National Commission for Science & Technology (NCST), Department of Fisheries, Department of Agricultural Extension Services (DAES), Department of Crop Development (DCD), Department of Nutrition, Department of Animal Health & Livestock Development (DAHLD) Department of Land Resources, University of Malawi (UNIMA), University of Mzuzu (MZUNI), Seed Co Malawi, Civil Society Agriculture Network (CISANET) and Centre for Environmental Policy Advocacy (CEPA).

The committee was formed to guide and provide leadership in biotechnology development in the agricultural sector. The committee also ensures that it owns biotechnology programmes in Malawi with international partners providing support and collaborating in the development of biotechnology programmes suitable for the country.

Its responsibilities are as follows:

- To identify and facilitate the development of priority areas for agricultural biotechnology and biosafety programmes in Malawi
- To promote capacity building in institutions for research, monitoring, risk assessment and management of biotechnology and biosafety activities and their associated products
- To coordinate, promote and carry out publicity and awareness of agriculture biotechnology and biosafety activities
- To advise agricultural institutions on biosafety requirements for undertaking biotechnology activities
- To formulate work plans and budgets for the operations of the committee
- To formulate guidelines in conducting GEO and other biotechnology and biosafety research/inspection
- To facilitate training in agricultural biotechnology and biosafety
- To facilitate the development of an information system for agriculture biotechnological and biosafety
- To forge linkages with National Biotechnology Committee (NBC) and National Biosafety & Regulatory Committee (NBRC)
- To forge linkages with regional and international agricultural biotechnology and biosafety organizations

- To mobilize resources for the operations of the committee and implementation of the committee's programmes
- To participate in local and international fora on agricultural biotechnology and Biosafety activities
- To formulate and periodically review guidelines on the minimum expertise and infrastructure requirements for agricultural biotechnology and biosafety applications
- To monitor and evaluate agricultural Biotechnology and biosafety activities and associated products.

An analysis of the terms of references of ABBC shows that the mandate of the committee duplicates the work of the Biotechnology Committee of the NCST and the National Biosafety Regulatory Committee (NBRC).

ACHIEVEMENTS

The biosafety regulatory system in Malawi has registered a number of achievements over the years since the enactment of the Biosafety bill in 2002 as follows:

- The legislation and legal framework for the promotion and safe use (Biosafety) of biotechnology and its products is in place.
- The institutional arrangement for biosafety as stipulated in the Biosafety Act (2002) is in place though official designation the biosafety registrar is yet to be done.
- The Nation Biosafety Regulatory Committee members, prospective Reviewers and Inspectors have been trained.
- The first GE crop confined field trial (CFT) started in January 2013 in accordance with all regulatory requirements as provided for in the Biosafety Act (2002), the Biosafety (Management of Genetically Modified Organisms) Regulations (2007) and The Malawi Biotechnology Guidelines (2009). The CFT involved cotton (*Gossypium hirsutum*) with the event MON15985 (insect resistant) and was conducted at Bunda College of Agriculture of the Lilongwe University of Agriculture and Natural Resources (LUANAR). The Principal Investigator was Professor Moses Kwatapa who worked with a team of well-trained experts based at Bunda College.
- The biosafety regulatory system and process has been tried and tested through the approval and conduct of the first ever GE crop confined field trial.

CHALLENGES

Though the biosafety regulatory system in Malawi has had some success, it has experienced its fair share of challenges ranging from the lack of cooperation by technical institutions to low technical capacity of the regulatory system. For example:

The first Confined field trial application review and approval process took too long. Bunda College of Agriculture, through Professor Moses Kwapata, submitted an application for Bt cotton CFT in 2009, but it was only approved in August 2011. The delay was attributed to lack of capacity to review the application by the National Biosafety Regulatory Committee and ABBC which were consulted as a technical review committee.

The unwillingness by the Ministry of Agriculture & Food Security to conduct the CFT before its biotechnology roadmap was implemented. This was evident by the "refusal" by the Ministry to host the CFT at Chitedze Agricultural Research Station and ABBC to review the application under the pretext of no capacity. The Ministry's biotechnology roadmap for introduction of GEOs in Malawi stipulated that the issues raised in the road map should be first addressed before any GEOs would be allowed in the country. Central among the issues was the need to build the Ministry's biotechnology and biosafety capacity both human and infrastructural. This would involve training of people in the Ministry in the areas of biotechnology and biosafety as well as building and equipping a biotechnology laboratory at Chitedze Agricultural Research Station.

Gaps in the instructions to the applicant on what constitutes a single application. The review process was also delayed because of the state of the Bt cotton application in its first form. The NBRC sent back the application to the applicant before reviewing it because the applicant had submitted a single application when two different events were applied for. The application had cotton insect resistance and herbicide tolerance as new characteristics for assessment. The applicant felt that this was a single application since the genes involved were stacked but the NBRC considered it an application of two events. It took some time for the applicant to submit two separate applications for review.

Lack of government budget for the regulatory authority to train regulatory personnel such as reviewers, the NBRC and inspectors. This was evident by the regulatory authority's over-reliance on other donors for funding of training sessions which meant that training of regulators would not be done on time.

CONCLUSION

Several lessons have been learnt through the process of implementing the biosafety regulatory framework in Malawi, including the following:

The advancement of biotechnology and biosafety in developing countries requires sufficient political will. In Malawi, because of the will of political leadership by the then State President Dr. Bakili Muluzi, to take presumably risky decisions, it was possible to import GE maize to avert hunger in 2002 which eventually opened a way for future testing of Bt cotton because the country had reference to some GE crop in the past unlike other countries which refused donation of GE maize in 2002.

Political will was also another key factor for the approval of the first CFT in Malawi. The leadership of the late President Professor Bingu wa Muthalika spoke openly about the need to use biotechnology to enhance crop production in the country. Biotechnology still has the backing of the present political leadership as demonstrated by the first state of the nation address made in Malawi Parliament by the incumbent State President her Excellency Dr. Joyce Banda in June 2012. In her address, she highlighted biotechnology as one of the tools for improving agricultural production in Malawi.

Investment into a biosafety regulatory system yields results. Malawi's final approval and conduct of the first confined field trial has been possible because of a huge investment in form of financial resources for putting up the required regulatory instruments, training regulators, reviewers, inspectors and raising awareness of the general public on biotechnology.

Persistence is essential if a country will ever conduct its first GE crop confined field trial. The road to the first GE crop field trial has been long and frustrating in Malawi but because of the consistent support from both national and international stakeholders, the first CFT has been conducted.

Use of cash GE crops like cotton in the first CFT seems to be easily acceptable than use of a food crop. The suggested GE cassava field trial in 2004 did not take place because the masses including scientists were sceptical of the technology and would not easily try it on their staple food.

Universities are potential alternatives to national agricultural programs in spearheading biotechnology development in a country. The experience in Malawi was that the Ministry of Agriculture and Food Security' Department of Agricultural Research Services (DARS) was reluctant to lead conducting of the first CFT in the country. Bunda College of Agriculture of the Lilongwe University of Agriculture & Natural Resources took the challenge and conducted the first ever GE crop CFT in Malawi.

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Chapter 15. Case study - Ethiopia

WOLDEYESUS SINEBO

INTRODUCTION

Ethiopia, with a population of about 95 million, is one of the low income and most populous countries in Africa. The country has an agricultural economy prone to environmental hazards making it vulnerable to periodic droughts. Agriculture contributes for about 80% of the total employment and 41% of the GDP. Although agriculture is the prime economic activity, agricultural productivity is constrained by fragility of the ecosystem, high frequency of drought and low technological capability (Diao, 2005; MEA, 2005). Because of this, Ethiopia needs to adopt an increasing array of knowledge-intensive technologies including modern biotechnology to spearhead its economic development. On this note, already sufficient evidence on economic benefits and safety of genetically engineered (GE) crops has accumulated the world over with immense benefits to smallholder farmers in developing countries including in China and India (Qaim and Zilberman, 2003; Kathage and Kaim, 2012; Lu et al., 2012).

In recent years, Ethiopia has become one of the fastest emerging economies in the African continent (Friedman, 2013; Schuman, 2014). The country has laid a significant undertaking of infrastructural development in its ambitious five year Growth and Transformation Plan. Agricultural development is the center-piece of economic transformation with light industries such as textiles and leather industry expected to lead this process of transformation. Adoption of technologies particularly in agriculture including modern biotechnology is thought to speed up this process of economic transformation. Noting this, the government of Ethiopia has encouraged the process by building a national agricultural biotechnology laboratory at Holetta Agricultural Research Center and by issuing a Biosafety Proclamation to enable the adoption of modern biotechnology while ensuring safety to the environment and human health. Ethiopia ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in July 2003 (FDRE, 2003) and issued its Biosafety Proclamation No.655./2009 in September 2009 (FDRE, 2009). However, the Biosafety Proclamation has not lived up to the expectation because of unworkable provisions, which constrained researchers from acquiring and testing of relevant technologies for possible general release (Abraham, 2013; Demissie and Muchie, 2014). In addition, the international technology providers have now and then explicitly expressed their unwillingness to engage in Ethiopia because of these negative provisions in the Ethiopian Biosafety Proclamation (Abraham, 2013).

Ethiopia's Biosafety Proclamation theoretically presumes the adoption of the spirit of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. However, the Proclamation misses the important fact that the Protocol was meant to provide an enabling environment for countries to derive maximum benefit from modern biotechnology while minimizing potential risks to the environment and human health (Secretariat of the Convention on Biological Diversity, 2000). Rather Ethiopia's Biosafety Proclamation was manifestly crafted by the then influential anti-GE Environmental Protection Authority's leadership to ward off agricultural applications of GE. Because of these preconceived beginnings, adequate space was not given for consultation and hearing of dissenting voices during the course of development of the Proclamation (Abraham, 2013). Hence the Proclamation has served more as an instrument for effective banning of genetic engineering research and use in agriculture than a regulatory tool for adoption of the technology while keeping potential risks to the minimum.

Applications of Modern Biotechnology in Ethiopian Agriculture

Developments in biotechnology and agricultural biotechnology in Ethiopia were reviewed by Sbhatu (2010), Abraham (2009) and Sinebo et al. (n.d.). Ethiopia has some incipient capacity in non-transgenic forms of modern biotechnology such as tissue culture and molecular marker technologies in agriculture. However, Ethiopia does not yet have noticeable genetic engineering R&D or commercialization of products. In Ethiopia, both the local and international private sector has now and then approached the agricultural research and development institutions for the introduction of GE crop varieties, notably Bt cotton. Also, the Government of Ethiopia has had a keen interest on GE crops particularly Bt cotton for a long time now. Ethiopian government instructed its Ministry of Agriculture to test and possibly release Bt cotton around year 2008. Based on this order, the Environmental Protection Authority gave the permission for Ethiopian Institute of Agricultural Research (EIAR) to import Bt cotton seeds into the country for testing in 2008. However, this was also a moment when the prohibitive Biosafety Proclamation was at an advanced stage of development. Hence, technology providers who had already had access to the draft proclamation refused to engage in the country denying the opportunity to test and commercialize the technology in Ethiopia. Following the gazetting of the Biosafety Proclamation in September 2009, both researchers and technology providers met an impasse; with hope only radiating since initiation of the revision of the Biosafety Proclamation in late 2012.

Although Ethiopia has never declined food aid on account of being GE, the country through its Environmental Protection Agency (EPA) had been a vocal opinion leader in Africa against GE grains destined for consumption or GE seeds for environmental release. In fact, Ethiopia through its EPA was one of the notable negotiators of the Cartagena Protocol on Biosafety and one of the architects of the restrictive African Model Law on Biosafety. Despite this, research and development institutions in Ethiopia such as the EIAR, Ministry of Science and Technology (MoST), the Ministry of Agriculture (MoA), and the seed industry have consistently foreseen a role for GE seed technology in the country. Although imminent change is in the horizon, the country continues to trade the precautionary approach to recombinant DNA (rDNA) technology destined for environmental release.

Ethiopia has diverse agro-ecological systems with a range of challenges and opportunities. Provided that a functional biosafety system is put in place, Ethiopia has a potentially large acreage of cultivable land that could benefit from the currently available GE crop traits including insect resistance and herbicide tolerance. For instance, in maize based systems where soil erosion is a common feature, herbicide tolerance trait should enable minimum tillage enhancing the sustainability of fragile cropping systems. In rain fed and irrigated systems where cotton is a major crop, the Bt trait can offer a competitive edge enhancing productivity and production. Ethiopia has a large swath of virgin land in lowland humid and sub-humid areas that are suitable for the production of warm season crops such as soybean, maize and cotton. However, in such areas labor is in low supply and weeds are critical agricultural problem. Herbicide tolerant crops such as soybean, maize and cotton should enhance investment, increase agricultural production and productivity and stimulate regional and national economic growth, in the end enhancing the wellbeing of communities.

The Ethiopian Biosafety Proclamation and its Pitfalls

Institutional set up

In Ethiopia, biosafety policy and regulatory issues initially came under the realm of the Environmental Protection Authority (EPA). EPA was established under the Ministry of Natural Resources Development and Environmental Protection, in May 1994. Later, EPA as environmental regulatory and monitoring body was reestablished as an independent institution in 2002 by proclamation No. 295/2002. The EPA morphed into the Ministry of Environment and Forestry (MoEF) in 2013 taking, in its fold, the role of forest regulatory and development aspects from the Ministry of Agriculture. The Ministry is tasked with the development of

environmental policies, strategies, laws and standards and supporting their implementation to foster sustainable socio-economic development and environmental safety.

The organizational structure of the MoEF encompasses a Minster and two State Minsters: one for Environment and the other for Forestry. Biosafety regulatory affairs fall under the State Minster for Environment. At present, there are two personnel actively involved on biosafety regulatory issues in the Ministry, one of whom is the focal person for the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The structure does not yet have a national biosafety committee or national biosafety experts actively engaged with biosafety issues so to speak. Hence the system, as it is, is largely non-functional. Of recent, this shortcoming has been well noted by concerned authorities at the Ministry and there is a great interest to overhaul the entire setting to make it functional.

The Proclamation Drafting Process

The context in which the current Biosafety Proclamation was developed and the problems associated with the process have been discussed by Abraham (2013). Apparently, the Environmental Protection Authority marshalled the course of the draft Proclamation singlehandedly from the beginning to the passing of the bill by the country's Parliament. The EPA formed a national steering committee consisting of 33 institutions to draft the Proclamation. The committee largely represented public intuitions and included only two environmental NGOs and a consumers' association. Neither domestic nor international private sector who were potential users or suppliers of biotechnology seeds were represented in the committee. Farmers associations were also not included. The committee was largely symbolic as the drafting process was entirely done by consultants who were hired and guided by the EPA. In national meetings to discuss the draft Proclamation, institutions such as the EIAR and Addis Ababa University expressed their concerns but were not able to influence the course to make the Proclamation balanced in such a way as to enable access to the technology while ensuring safety to the environment.

The EPA ensured that it developed the Proclamation and it was made the national focal point and the national competent authority. From the beginning, the EPA effectively marginalized key stakeholders from agricultural research, education and development institutions. Hence the Proclamation lacked the all-important national consensus and, therefore, stretched between the opposing poles of environmental stewards and development vanguards.

Obviously, those seeking a functional biosafety regulation were not as well organized as those backing the strictly precautionary and prohibitive approach. In retrospect, however, it is difficult to adjudge that pro-biotechnology stakeholders should have worked better to challenge the draft Proclamation before it was presented to and assented by the Parliament. In the first place, the EPA whose guiding principle was strict precaution was better informed and resourced. In fact, the Director of the EPA was the architect of the African Model Law on Biosafety and also a highly regarded negotiator of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. He, more than anybody in the country, was well informed about and well-connected to the global anti-GMO campaign. To the dismay of the pro-biotechnology group, he was also more likely to have been better listened to domestically. Secondly, the external environment the world over was not helping as the campaign against GEOs was even stronger than it is at present.

Major Drawbacks of the Proclamation

Limitations related to functionality of the biosafety Proclamation have been discussed in Abraham (2013). First, the Advanced Informed Agreement in the Proclamation is broad in scope including not only GEOs destined for intentional environmental release but also GE grain for food and feed uses and any rDNA laboratory work which is not of any significant potential risk. Abraham (2013) argued that the Proclamation is so prohibitive that it does not allow the conduct of simple laboratory procedures for research and

education whose aim is not the development of GEOs, without seeking approval from the Environmental Protection Authority.

Second, socio-economic considerations on risk assessment and decision making were overly elaborate and included risks which are broad and not-so-easy to measure such as risks to culture and local and national economy. In addition, the reach of these provisions were further broadened in the accompanying Directives meant for implementation of the Proclamation, making any initiative for GEO R&D exceedingly daunting. Socioeconomic risks enumerated in the Directives, for instance, included potential adverse effects on "substitution of traditional crops and products or indigenous technologies and effects on religious and ethical values, including those affecting other countries" (Abraham, 2013).

Thirdly, perhaps one of the most frustrating provisions in the Proclamation was the requirement that the applicant submit an assurance signed by the competent authority of the GEO exporting country that the exporting country "takes full responsibility for the accuracy and completeness of information" contained in the application. This, besides exceeding the provision in the Cartagena Protocol, is simply impractical as no country would rationally be willing to assume full responsibility for another country to benefit from a technology developed by a transnational company.

Fourthly, according to the proclamation and the accompanying Directives, the EPA is everything on biosafety matters including the national focal point and the national competent authority. Lack of clear provisions for an independent body such as national biosafety committee to evaluate and make recommendations on GEO applications leaves no room for rational decision making normally expected from a functional biosafety system. In addition, the cumbersome requirement that applicants provide adequate guarantee and insurance for potential damages from GEO activities are grossly probative discouraging technological innovation in the field of modern biotechnology.

Revision of the Biosafety Proclamation

As was described above, Ethiopia's Biosafety Proclamation has not served so far as a useful regulatory instrument for the adoption of modern biotechnology while keeping potential risks to the minimum. The Proclamation has failed to harmonize the development ambitions of the country and environmental protection goals. It has failed to create a shared vision among the various government institutions with respect to sustainable economic development in the country. Furthermore, Ethiopia's Biosafety Proclamation has crippled the drive for technological learning and has scared away potential investment from the country. As a result, the country's lofty goal of realizing middle income status through agriculture-led industrialization by enhancing the supply of agricultural raw materials to nascent industries has been jeopardized.

Cognizant of this fact, the government has taken positive measures towards the revision of the prohibitive provisions in the Biosafety Proclamation. The prime movers of this change of course have been agricultural research and development institutions and universities. They were prompted by the unwilling stance of the international private sector to work in an environment where the country's biosafety regulation is not conducive for biotechnology investment. In the face of these apparent needs, the Ministry of Environment and Forestry (MoEF) has been compelled to start the process of revision of the Biosafety Proclamation.

Apparently, MoEF, the Ministry mandated with setting environmental regulations and standards, has been given a second chance to make the process participatory, transparent and inclusive in the best interest of the public and the country. The Ministry should take this opportunity to garner as wide lessons as possible from countries with functional biosafety systems and develop a regulation that serves Ethiopia's best interests. The revision besides removing the constraints noted above and elsewhere (Abraham, 2013) should decisively address functionality and capability of the current setup particularly with respect to application handling,

review, risk assessment and decision making. In this regard, the Proclamation should provide for the establishment of a National Biosafety Committee which in turn may draw up on the advice of technical experts for informed decision making. In addition, the Proclamation should encourage the establishment of Institutional Biosafety Committees. Moreover, the implementing regulations should be made in line with best practices deriving lessons from countries with functional biosafety systems.

Interim measures and biosafety capacity building needs

The fact that Ethiopian Government has interest in adopting Bt cotton technology necessitates sharing of experiences from other countries on interim measures such as executive order that would create an enabling environment for the rapid introduction and testing of trait-bearing varieties while the revision of the proclamation and implementing regulations are underway. In this regard, NEPAD Agency ABNE can share its rich experience from Africa and elsewhere.

Of several African countries where GE crops have been commercialized, it was the imperatives of adopting the technology which has driven the growth and development of functional biosafety systems. In Burkina Faso, the need to fast track the testing and adoption of Bt cotton necessitated the issuance of an executive order before the biosafety law was put in place. Even after the biosafety law was issued, it had limitations until it was finally revised in 2012 to make it optimal. Sudan issued its biosafety law in 2010 and commercialized Bt cotton in 2012. However, the biosafety law is not yet functional because of lack of implementing regulations. In other African countries like Uganda and Nigeria, confined field trials of GE crops are underway without the passage of biosafety laws.

Ethiopia has sought and received some technical assistance on building functional regulatory system for modern biotechnology. One such support was given by a team of NEPAD Agency ABNE and Michigan State University which visited the country from December 1- 8, 2012. The team after conversing with a number of institutions and sharing ideas with a range of stakeholders made some recommendations in a report entitled ***Assessment of Biotechnology and Biosafety Capacity in Ethiopia***. The report was submitted to the Agricultural Transformation Agency of Ethiopia in early 2013.

The recommendations included the need for supporting:

- Provision of technical and legal support for the revision of the Biosafety Proclamation
- Training of biosafety regulators
- Public awareness creation on biotechnology and biosafety
- Biosafety regulatory study tours

As has been done in several countries in Africa, NEPAD Agency ABNE may support one-on-one consultations or conduct small group workshops to render technical and legal assistance to ensure that the revised proclamation is in line with international best policies and practices.

With regard to training, ABNE in collaboration with Michigan State University (MSU) has started offering training opportunities for Ethiopian regulators through biosafety short courses at MSU and in Africa. In the year 2013, one lawyer had attended a biosafety and biotechnology short course for lawyers at Michigan State University. Two biosafety regulators and one researcher attended a biosafety short course conducted at Makerere University, Uganda in July 2014. In addition, MSU through the ABNE project sponsored three officials selected from the Ministry of Environment and Forestry, the Ministry of Agriculture and the Ministry of Science and Technology to attend biosafety and biotechnology short courses that took place at MSU in August and September 2014. These officials are expected to brief their ministries on their observations and they help chart the course of action vis-à-vis biotechnology regulation in Ethiopia. Overall in the future, such training opportunities should expand to create a critical mass of biosafety policy makers, regulators and

experts with adequate skills in biosafety policy making, administration, risk assessment, operation and functioning of biosafety committees, review of biosafety applications, standard operating procedures (SOPs) and guidelines.

Given the cloud of doubt on biotechnology in Ethiopia (Zane, 2003), the importance of regulatory study tours for policy makers and regulators to the countries with functional biosafety systems cannot be overemphasized to instill confidence. So far one regulator and one policy maker have received regulatory study tour opportunities in South Africa (in 2014) and India (in 2013), respectively.

Looking ahead

In Ethiopia, lack of appropriate policy for technological innovation had been one of the underlying reasons for its long run state of economic backwardness in the past. But with massive expansion of tertiary education over the last two decades, this has been changing. The country's economy has been in consistent upswing trajectory for over a decade now. Maintaining this positive turnaround requires concerted multidimensional efforts including further technological upgrading in primary sectors of economic importance.

Agriculture-led economic transformation is the centerpiece of the current economic policy in Ethiopia. Adoption of conventional and cutting-edge technologies in agriculture including modern biotechnology offers a potentially handy tool for rapid economic transformation of the country. The Ethiopian Government has increasingly understood the importance of adopting modern biotechnology, specifically GE crops to enhance the supply of agricultural raw materials to its nascent industry. However, making use of modern biotechnology requires a regulatory system that is functional, flexible and responsive to the needs of the country. The Biosafety Proclamation of 2009 has not been able to meet these touchstones (Demissie and Muchie, 2014). To resolve this quandary, the Government has taken steps for the revision of the Biosafety Proclamation to make it functional. It is likely that imminent change is in the horizon. However, it would be premature to assume that the playing ground has been decisively altered.

To help the country reap benefits from safe agricultural biotechnologies, specifically GE crop varieties, NEPAD Agency ABNE can assist the country through training and technical backstopping in broad areas of biosafety regulation. In the short term, ABNE may focus on provision of inputs and experiences in setting up workable biosafety regulations and on training in the basics of building of functional biosafety systems including biosafety administration, application handling, risk assessment and decision making for confined field trials. To this end, continuous and consistent engagement with the Ministry of Environment and Forestry, Ministry of Agriculture, Ministry of Science and Technology and the Agricultural Transformation Agency of Ethiopia may help lay an enduring functional biosafety platform in the country. In addition, sensitization of members of the Standing Committees for Agriculture, Environment, and Science and Technology at the House of Peoples Representatives should help establish a sustainable biosafety/biotechnology knowledge platform for informed decision-making.

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PART 3

INTERNATIONAL EXPERIENCES FROM DEVELOPING COUNTRIES

Chapter 16. Biosafety regulatory system in India

NIDHI P. CHANANA

INTRODUCTION

Since the late 1980s, technological progress and policy reforms opened up new opportunities for growth in India's seed and agricultural biotechnology industries but to date Bt cotton is the only genetically engineered crop currently approved for commercial cultivation. From 2002, the Indian Government has approved six Bt cotton events for commercial cultivation but the country does not commercially produce genetically engineered (GE) animals, including cloned animals or products derived from GE animals for commercial production.

India's biotech regulatory system has been on a regressive pathway starting 2010 with the Ministry of Environment & Forests (MoEF) announcing a moratorium on the approval of Bt eggplant in February. This was followed by the Genetic Evaluation and Approval Committee (GEAC) introducing new procedures for authorizing biotech crop field trials in July 2011 and the Supreme Court (SC) of India appointing a Technical Expert Committee (TEC) in October 2012 to review and recommend biosafety risk assessment studies for genetically engineered crops.

Some public policymakers and decision makers are confident that the current situation can be reversed, arguing that the right combination of new technological solutions and progressive policy reforms will stimulate a significant increase in private investment in productivity-enhancing products and services.

CURRENT STATUS OF BIOTECHNOLOGY IN INDIA

At present Bt cotton is the only genetically engineered crop approved for commercial cultivation in India with 1,128 hybrids of Bt cotton having been approved in various states such as Haryana, Punjab, Gujarat Madhya Pradesh, Maharashtra, Andhra Pradesh, Karnataka and Tamil Nadu.

Bt brinjal was developed by the Mahyco seed company using the Cry1Ac gene to give resistance against lepidopteron insects, especially the brinjal fruit and shoot borer. This transgenic event was introgressed by plant breeding into various local varieties by the University of Agricultural Sciences (UAS) and Tamil Nadu Agricultural University (TNAU). After two expert committees had given their recommendations about the biosafety of this crop (2006 and 2009), the GEAC approved Bt brinjal for commercialization on 14 October 2009. Following concerns raised by some scientists, farmers and anti-GM activists, the Government of India announced on 9 February 2010 that more time was needed before releasing Bt brinjal. Furthermore, the Environment Minister imposed a moratorium on the release of transgenic brinjal hybrid. Mahyco was accused of bio-piracy of local germplasm in respect of at least 10 brinjal varieties from the states of Karnataka and Tamil Nadu without prior consent of the National Biodiversity Authority and state biodiversity boards.

Many other crops have been genetically engineered with various traits and have reached the field trial stage. Table 1 gives the annual list of crops under various stages of field trials developed by different institutes between 2006 and 2013.

Table 1. An annual record of transgenic crops under field trials with details of foreign genes/events and the institutes involved from 2006 to 2013. (http://igmoris.nic.in/field_trials.asp)

Year	Crop	Trait	Company Name	Trial	Gene/Event
2013	Corn	Insect resistance	Monsanto India Ltd.	BRL-I 2nd year	*cry2Ab2 &cry1A.105* genes (Event MON 89034)
		Insect resistance herbicide tolerance	Syngenta Biosciences Pvt Ltd.	BRL-1	events Bt11, GA21 and stack of Bt11 x GA21
		Insect resistance herbicide tolerance	Syngenta Biosciences Pvt Ltd.	BRL-1 2nd year	Bt11, GA21 and stack event of Bt11 x GA21
		Insect resistance herbicide tolerance	Syngenta Biosciences Pvt Ltd.	Seed Increase	Bt11 and GA21
	Cotton	Herbicide tolerance	Bayer Bioscience Pvt Ltd	BRL-I (2nd season)	*2mepsps* (Event GHB 614)
	Maize	Herbicide tolerance	Monsanto India Ltd.	BRL-I 2nd year	*cp4epsps* (Event NK603)
	Cotton	Herbicide tolerance	MAHYCO	BRL-I 2nd year	*cp4epsps/* MON 88913
2012	Corn	Insect resistance herbicide tolerance	Syngenta Biosciences Pvt Ltd.	BRL-1	Bt11, GA21 and stack event of Bt11 x GA21
		Insect resistance herbicide tolerance	Pioneer Overseas Corporation	BRL-1 2nd year	*cry1F & cp4epsps* genes [stacked events TC1507 x NK603 (DAS-01507-1 x MON-00603-6)]
		Insect resistance herbicide tolerance	Pioneer Overseas Corporation	BRL-1	*cry1F, cry1Ab & cp4epsps* genes [stacked events TC1507 x MON 810 x NK603
	Cotton	Herbicide tolerance	Bayer Bioscience Pvt Ltd	BRL-1	*2mepsps*(Event GHB 614)
		Herbicide tolerant	Bayer Bioscience Pvt Ltd.	Exptal seed Production	*2mEPSPS*gene (Event GHB 614)
	Maize	Herbicide tolerance	Monsanto India Ltd.	BRL-1	*cp4epsps* (Event NK603)
		Insect resistance	Monsanto India Ltd.	BRL-1	*MON 89034*
	Rice	Herbicide tolerance	EI Dupont India Pvt Ltd.	Event Selection	*SPT1 rice containing Zm-AA1, Os-Msca1 and DsRed2*
		Herbicide tolerance	EI Dupont India Pvt. Ltd.	Event selection	*SPT6 Rice (Oryza sativa L.) events containing Zm-AA1, Os-Msca1 and DsRed2*
		Herbicide tolerance	EI Dupont India Pvt Ltd.	Event selection	*13 SPT transgenic Rice (Oryza sativa L.) events containing Zm-AA1, Os-Msca1 and DsRed2*
		Herbicide tolerance	EI Dupont India Pvt Ltd.	Event selection	*SPT1 construct and two events generated using SPT6 construct*
	Cotton	Herbicide tolerance	MAHYCO	BRL-1	*cp4epsps/* MON 88913
2011	Castor	Insect resistance	DOR	Eventselection	4 events containing *cry1Ec* and *cry1Aa* genes
	Corn	Insect resistance herbicide tolerant	Syngenta Biosciences Pvt Ltd.	BRL-I 2nd year trial	GA21 event *(cry1Ab & mepsps* genes)
		Insect resistance herbicide tolerant	Pioneer Overseas Corporation	BRL-I 2nd year trial	*cry1F, cp4epsps & PAT*genes [stacked events TC1507 x NK603
	Cotton	Insect resistance herbicide tolerant	Bayer Bioscience Pvt Ltd.	Event Selection	stacked events – GHB 119 (*cry2Ae/ PAT)* & T304-40 (*cry1Ab/PAT)*

	Mustard	Male sterile female inbred rice lines	University of Delhi South Campus	BRL-I 2nd year trial	*barnase, barsar and bar*genes [events bn 3.6 (Barnase line) and modbs 2.99 (Barstar line)]
	Rice	Insect resistance	EI Dupont India Pvt. Ltd	Event selection	20 events generated using SPT1 construct, of BC2 generation expressing OS-MSCA1, ZM-AA1 and DsRed2 protein
		Insect resistance	EI Dupont India Pvt. Ltd	Event selection	20 events generated using SPT6 construct, expressing OS-MSCA1, ZM-AA1 and DsRed2 protein
		Insect resistance herbicide tolerant	Bayer Bioscience Pvt Ltd.	Event selection under nethouse	*cry1Ab, cry1Ca* and *bar*
		Male sterile female inbred rice lines.	EI Dupont India Pvt. Ltd	Event selection	Hybrid Rice SPT maintainer events using the SPT1 construct of BC4 generation containing three genes, *Zm-AA1, Os-Msca1,* and *DsRed2*
		Yield enhancement	BASF India Limited	Seed production	80 transgenic rice (*Oryza sativa*) events containing RPD5-11
	Cotton	Herbicide tolerant	Maharashtra Hybrid Seeds Company Ltd	BRL-1	*cp4epsps* gene (Event MON 88913)
	Rubber	Abiotic tolerance	Rubber Research Institute of India	BRL-1 (Not conducted**)**	Hb. SOD-L1 & L2
	Sorghum	Insect resistance	Directorate of Sorghum Research	BRL-1	2 events containing *cry1B* genes
2010	Brinjal	Insect resistance	IIVR	Event selection in net house	*cry1Ac*
	Cauliflower and cabbage	Insect resistance and herbicide tolerant	Nunhems India Pvt Ltd	Net house (Discontinued)	3 events for cauliflower and 3 events from cabbage containing *cry1Ba, cry1Ca*and *bar* genes.
		Insect resistance and herbicide tolerant	Nunhems India Pvt Ltd	Event selection in net house (Discontinued)	*cry1Ba, cry1Ca*and *bar*
	Corn	Insect resistance	Dow AgroSciences India Pvt. Ltd.	BRL-I second year	*cry1F* (event TC 1507) gene
		Insect resistance	Syngenta Biosciences Pvt. Ltd	BRL-I	*cry1Ab* gene (Event Bt11)
		Insect resistance herbicide tolerance	Monsanto India Ltd.	BRL-I second year	Stacked *cry2Ab2* and*cry1A.105* genes
		Insect resistance herbicide tolerance	Monsanto India Ltd.	Seed production	Events MON 89034 x NK603
	Cotton	Herbicide tolerant	Bayer Bioscience Pvt. Ltd	Event Selection	7 hybrids containing*2mEPSPS*
	Groundnut	Abiotic tolerance/drought resistance	UAS	Event selection	3 Events over expressing *DREB1A* for stress tolerance
		Abiotic tolerance/drought resistance	UAS	Event selection	5 Events over expressing *DREB1B* for stress tolerance
		Fungal resistance	ICRISAT	Event selection in net house	9 events containing chitinase gene
		Virus resistance	ICRISAT	Event selection in net house	11events containing coat protein gene of tobacco streak virus

	Rice	Male sterile female inbred rice lines.	EI Dupont India Pvt. Ltd	Event selection	9 events containing Os-Msca1 gene
			EI Dupont India Pvt. Ltd		Hybrid Rice SPT maintainer events generated using the 1) SPT1 construct and 2) SPT6 constructs containing *Os-MSCA1, ZM-AA1* and*DsRED2*
			EI Dupont India Pvt. Ltd		Hybrid Rice SPT maintainer events generated using the SPT1 of BC2 generation and DKC 320 of BC1 generation
	Maize	Insect resistance herbicide tolerance	Pioneer Overseas Corporation	BRL-I second year	*cry1F & PAT* and *CP4EPS PS* genes
	Mustard	Abiotic tolerance	NRCPB	BRL-1	event Omb5-B
		Male sterile female inbred rice lines	University of Delhi South Campus	BRL-1	hybrid DMH11with *barnase, barstar* and *bar*[and modbs 2.99 (Barstar line)]
		Male sterile female inbred rice lines	University of Delhi South Campus	experimental seed production, environmental safety	hybrid DMH-11with *barnase, barsar* and *bar*[events bn 3.6 (Barnase line) and modbs 2.99 (Barstar line)]
	Rice	Insect resistance	Metahelix Life Sciences Pvt. Ltd.	Event selection	MHR01 to MHR566 with *cry1Ac* and*cry1Ab*
		Insect resistance herbicide tolerant	Bayer Bioscience Pvt Ltd.	Event selection	56 Bt rice lines events containing *cry1Ab, cry1Ca & bar* genes.
			Bayer Bioscience Pvt Ltd.		4 Bt rice lines containing *cry1Ab, cry1Ca* and *bar* genes
	Sorghum	drought resistance	CRIDA	Event selection	7 genotypes with Events containing *mtID* gene
	Sugarcane	Insect resistance	Sugarcane Breeding Institute	Event selection	10 events containing *cry1Ab* gene
	Tomato	Delayed fruit ripening	NRCPB	Event selection	transgenic tomato events namely ACS3-9 and ACS 7-9 containing *antisense ACC synthase 2*
		Insect resistance	IIVR	Event selection in net house	8 events containing*cry1Ac*
		Virus resistance	IIHR	Event selection	16 events resistant to Tospo virus (PBNV)
		Virus resistance	IIHR	Event selection	30 events resistant to TLCV
		Virus resistance	IIHR	Event selection	9 events combined resistant to TLCV and Tospo (PBNV)
	Watermelon	Virus resistance	IIHR	Event selection	8 events resistant to WBNV
2009	Brinjal	Insect resistance	Bejo Sheetal Seeds Pvt. Ltd.	BRL-I	*cry1Fa1* (Event 142)
			UAS	Seed multiplication	*cry1Ac*
	Cabbage and cauliflower	Insect resistance	Nunhems India Pvt. Ltd.	Net house (Discontinued)	*cry1Ba, cry1Ca*and *bar*
	Chickpea	Insect resistance	NRCPB		*cry2Aa*
	Corn	Insect resistance	Dow Agrosciences India Pvt. Ltd.	BRL-I	*cry1F* (event TC1507)
		Insect resistance herbicide tolerance	Monsanto India Ltd.	BRL-I second year	Stacked *cry2Ab2*and cryA.105 &*CP4EPSPS*
		Insect resistance herbicide tolerance	Pioneer Overseas Corporation	BRL-I	Stacked *cry1F* and *CP4EPSPS* (stacked event of C1507XNK603)
	Groundnut	Virus resistance	ICRISAT	Event selection	Coat protein gene (cp) of tobacco streak virus against peanut stem Necrosis Disease and Rchit gene for resistance against *Aspergillus*
	Potato	Disease resistance	CPRI		RB gene for conferring resistance to late blight
		Reduction in cold-induced	CPRI		vacuolar acid and invertase 7 RNAi-transgenic events

		sweetening and chip colour improvement			
		Transgenic dwarf potato	CPRI	Event selection	*GA20 Oxidase1*- 10 Events
	Rice	Insect resistance	Bayer Bioscience Pvt. Ltd.	Event selection	*cry 1Ab, cry 1Ca & bar*
		Insect resistance	MAHYCO		20 Bt Rice events namely containing *cry2Ab*
	Cotton	Insect resistance herbicide tolerance	MAHYCO	BRL- second year	Stacked *cry1Ac & cry2Ab* and*CP4EPSPS*
	Sorghum	Insect resistance	National Research Centre for Sorghum	BRL-1	*cry1B gene NRCSCRY1B event 4 and NRCSCRY 1B event 19*
2008	Cauliflower	Insect resistance	Sungro Seeds Research Ltd.	BRL-I	*cry1Ac*
	Corn	Insect resistance herbicide tolerance	Monsanto India Ltd.	BRL-I	Stacked *cry2Ab2* and *cryA.105*& *CP4EPSPS*
	Cotton	Insect resistance herbicide tolerance	MAHYCO	BRL-I	*cry1Ac & cry2Ab* (MON 15985) and *CP4EPSPS* (MON 88913)
	Rice	Insect resistance	Bayer Bioscience Pvt. Ltd.	Event selection	*cry 1 Ab, cry 1Ca & bar*
	Tomato	Increased lycopene content	Avesthagen Ltd.	Event selection	unedited *NAD9*
2007	Brinjal	Insect resistance	MAHYCO	LST	*cry 1 Ac*
		Insect resistance	UAS	MLRT	*cry 1 Ac*
		Insect resistance	Sungro Seeds	MLRT	*cry 1 Ac*
		Insect resistance	TNAU	MLRT	*cry 1 Ac*
	Cotton	Insect resistance herbicide tolerance	MAHYCO	MLRT	stacked *cry1Ac, cry2Ab* and *CP4EPSPS*
	Okra	Insect resistance	MAHYCO	MLRT	*cry1Ac*
	Rice	Insect resistance	MAHYCO	MLRT	*cry1Ac*
2006	Brinjal	Insect resistance	IARI, New Delhi		*cry1Aa and cry1Aabc*
		Insect resistance	Sungro Seeds Ltd,		*cry1Ac*
		Insect resistance	Mahyco, Mumbai		*cry1Ac*
	Cabbage	Insect resistance	Nunhems India Pvt. Ltd.,		*cry1Ba and cry1Ca*
	Castor	Insect resistance	DOR		*cry1Aa and cry1Ec*
	Cauliflower	Insect resistance	Sungro Seeds Ltd,		*cry1Ac, cry1Ba and cry1Ca*
		Insect resistance	Nunhems Pvt ltd.,		*cry1Ac, cry1Ba and cry1Ca*
	Corn	Insect resistance	Monsanto,		*cry1Ab gene (Mon 810 event)*
	Groundnut	Fungal resistance	ICRISAT		*chitinase gene from rice (Rchit)*
	Okra	Insect resistance	Mahyco,		*cry1Ac, cry2Ab*
	Potato	Fungal resistance	CPRI		*RB gene from Solanum bulbocastanum*
	Rice	Insect resistance	IARI		*cry1B-cry1Aa fusion gene*
		Fungal resistance	TNAU		*rice chitinase (chi11) or tobacco osmotin gene*
		Insect resistance	Mahyco,		*cry1Ac, cry2Ab*
	Tomato	Virus resistance	IARI,		*antisense replicase gene of tomoto leaf curl virus*
		Insect resistance	Mahyco,		*cry1Ac*

Table 2. List of commercially approved recombinant therapeutics approved for marketing in India (http://igmoris.nic.in/commercial_release.asp)

S.No.	Molecules	Therapeutic applications
1.	Human insulin	Diabetes
2.	Erythropoietin	Treatment of anaemia
3.	Hepatitis B vaccine (recombinant surface antigen based)	Immunization against Hepatitis B
4.	Human growth hormone	Deficiency of growth hormone in children
5.	Interleukin 2	Renal cell carcinoma
6.	Interleukin 11	Thrombocytopenia
7.	Granulocyte Colony Stimulating Factor	Chemotherapy induced neutropenia
8.	Granulocyte Macrophage Colony Stimulating Factor	Chemotherapy induced neutropenia
9.	Interferon 2Alpha	Chronic myeloid leukemia
10.	Interferon 2Beta	Chronic myeloid leukemia, Hepatitis B and Hepatitis C
11.	Interferons Gamma	Chronic granulomatous disease and Severe malignant osteopetrosis
12.	Streptokinase	Acute myocardial infarction
13.	Tissue Plasminogen Activator	Acute myocardial infarction
14.	Blood factor VIII	Haemophilia type A
15.	Follicle stimulating hormone	Reproductive disorders
16.	Teriparatide (Forteo)	Osteoporosis
17.	Drerecogin (Xigris) alpha	Severe sepsis
18.	Platelet Derived Growth Factor (PDGF)	Bone marrow induction and osteoblasts proliferation
19.	Epidermal Growth factor (EGF)	Mitogenesis and organ morphogenesis
20.	Eptacogalpha (r-F VIIa) r-coagulation factor	Haemorrhages, congenital or acquired hemophilia

THE BIOSAFETY REGULATORY SYSTEM IN INDIA

Organization of Biosafety regulatory system at the national, state, district and institutional levels in India

A key piece of the Indian legislation on biotechnology (known as the “Biosafety rules” or ”the Rules of 1989” states “The norms of the Environment (Protection) Act provides the legal background to the Rules for Manufacturing, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells”. The Biosafety Rules deal with the research, manufacturing, importation, usage and storage of microorganisms, gene technology products and products made from genetically engineered microorganisms.

In 1990, the Department of Biotechnology enacted the Recombinant DNA Safety Guidelines supplementing the Biosafety Rules.66, which have been revised on two occasions (1994 - Revised Guidelines for Safety in Biotechnology, and 1998 - Revised Guidelines for Research in Transgenic Plants). These guidelines are crucial for conducting rDNA research activities, experimentation, quality control and importation of products resulting from biotechnology. A set of guidelines for conducting field trials of regulated genetically engineered plants and Standard Operating Procedures (SOPs) were approved by the Review Committee of Genetic Manipulation (RCGM) and GEAC in June 2008. The Guidelines describe the application process and general requirements for confined field trials and the SOPs for transport, storage, management, harvest/termination and post-harvest management during the conduct of the trials.

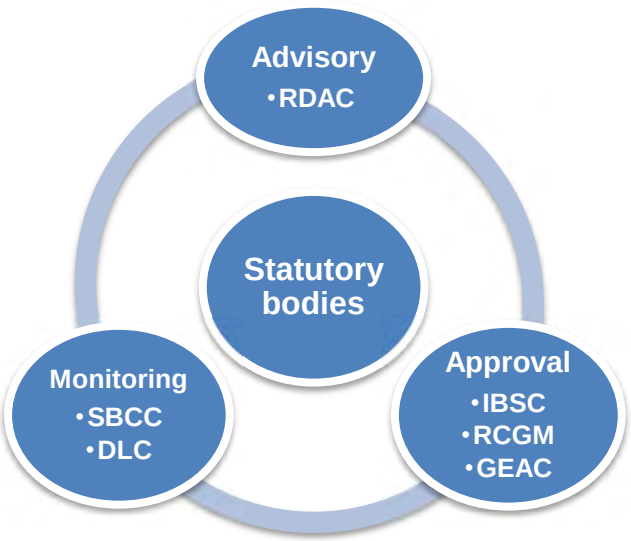

Figure 1. Diagram of the biosafety regulatory framework of India.

The roles and functions of the various committees involved are given below.

Approval bodies

Institutional Biosafety Committee (IBSC) – The main functions of the IBSC are:

- To note, examine and approve proposals involving r-DNA work; to ensure adherence of r-DNA Safety Guidelines- 1990 of Government; inspection of containment facilities at R&D and production units and to inform the RCGM about the facilities;
- To prepare emergency plan according to guidelines;
- To approve experiments utilizing the organisms and genetic elements from Risk Group I and II organisms up to laboratory fermentation 20 litres capacity with intimation to RCGM; for using organisms falling in Risk Group III & above, recommend to RCGM for approval to conduct laboratory studies;
- To recommend for import/ exchange of GEOs/LMOs/transgenic seeds, vectors, gene constructs, plasmids, etc., for research purposes;
- To inform DLC and SBCC as well as GEAC about the experiments wherever needed; to act as a nodal point for interaction with statutory bodies; to ensure experimentation at designated location taking into account of approved protocols etc.
- To examine the description of the target gene and source; nucleotide sequence and amino acid sequence of target gene and the target protein; the composition of the vector used; schematic diagram of the expression cassette; restriction map of vector indicating the location of the target gene; cloning strategy; description of the host cell line including genera and species; risks involved in handling of cell line; methods of maintenance of cell line; classification of the host cell line as per the guidelines;
- To approve category I & II experiments, as per the Guidelines 1998 of Department of Biotechnology (DBT), up to greenhouse level with intimation to RCGM in category III & above experiments, RCGM to approve conduct lab & greenhouse studies. To recommend all open field experiments in any of the categories, for any purpose (biosafety studies, seed increase experiments, agronomic studies, etc.) for the approval of RCGM.
- To examine protocols for toxicity/allergenicity studies as per national and international guidelines and their recommendations to RCGM

Review Committee on Genetic Manipulation (RCGM) - The RCGM, under the Department of Biotechnology, Ministry of Science & Technology, shall function for a period of three years from the date of notification and meet once in a month or as and when required. The functions of the RCGM are:

- To monitor the safety related aspects in respect of ongoing recombinant DNA (r-DNA) projects and activities involving Genetically Engineered (GE) organisms/hazardous microorganisms. All ongoing projects including high risk category and confined field experiments shall be reviewed by RCGM to ensure that adequate precautions and containment conditions are complied with as per the Guidelines and Standard Operating Procedures (SOPs) issued by DBT from time to time.
- To lay down procedures restricting or prohibiting production, sale, importation and use of such GE organisms or products thereof for research and applications as mentioned in the schedule of Rules, 1989.
- To produce manuals and guidelines specifying procedures for regulatory processes with respect to activities involving GE organisms in research, use and application including industry with a view to ensure safety to human, animal and environment health.
- To issue the clearance letters/permits for import or exchange of genes, DNA fragments, vectors, plasmids, cosmids, etiologic agents and transgenic organisms or germplasm(s) including transformed calli, seeds, plants and plant parts for research use only. It will also take note of all such commercially available agents which are acquired from commercial sources through IBSC.
- To act as the regulatory body for receiving and reviewing the applications to conduct confined field trials (such as event selection trials, Biosafety Research Level I trials (BRL-I), pollen flow studies or any other trial involving GE organisms) and recommend appropriate studies to be conducted for data generation for biosafety assessment as per the decision of the GEAC for its authorization.
- To authorize, on case-by-case basis, applicants to use bioreactors to produce sufficient material/end-products of GE organisms required for conducting pre-clinical studies and other relevant data generation including the use of capacity over and above. This will include the authority to produce sufficient quantities of GE organism/plant product(s) for generating safety data in appropriate animals, as appropriate on case-by-case basis.
- To generate, examine or invite the research projects, proposals for capacity building and training courses in biosafety, creation of information systems/data banks in electronic media, websites etc. for financial support and recommend the same to DBT for furthering the cause of generating specific biosafety data related to use of GEOs and strengthening infrastructure facilities & dissemination of information on biosafety rules, regulations and guidelines in the country.
- To invite, induct or appoint special experts in their individual capacities on a case by case basis.
- To constitute subgroups of its members or subcommittees involving experts for specific functions or seek advice on specific matters from other external experts and these subgroups/subcommittees may visit periodically the experimental sites where r-DNA projects and activities involving GE organisms/ hazardous microorganisms are being pursued to ensure that adequate safety measures have been taken as per the guidelines and compliance of SOPs.

***Adhoc S*ub-Committees of RCGM** formed to date:

- Sub-Committee for finalizing the protocols for biosafety studies on transgenic brinjal, okra, tomato, cauliflower and cabbage.
- Sub-Committee for review and finalization of the protocol on safety (toxicity and allergenicity) studies on new transgenic crops in regulatory pipeline.
- Sub-Committee for finalizing the protocols for biosafety studies on transgenic maize.
- Sub-Committee for finalizing the protocols for biosafety studies on legumes (groundnut, redgram, pigeonpea, chickpea and other pulses).
- Sub-Committee for formulation of detailed biosafety guidelines for millets.

- Sub-committee for finalizing the protocols for genotype ID through DNA fingerprinting and prescribing standard molecular markers for cotton hybrids for inventory purposes and field trial assessment, based on parental lines and for biosafety assessment for various vegetable crops

Genetic Evaluation and Approval Committee (GEAC) - This Committee, is a Statutory Body under the Ministry of Environment & Forests, and is active for a period of three years, from the date of issue of this notification, to carry out the following functions:

- To approve activities involving large-scale use of hazardous living microorganisms and recombinants in research and industrial production from the environmental angle
- To approve proposals relating to the release of genetically engineered organisms and products into the environment including experimental field trials
- To be responsible for the approval of proposals involving the use of living modified organisms in the risk category III and above in the manufacture/import of recombinant Pharma products or where the end product of the recombinant Pharma products *per se* is a living modified organism.
- To co-opt other members/experts to the GEAC
- To appoint subgroups/sub-committees/expert committee to undertake specific activities related to compliance of biosafety.

Advisory bodies

Recombinant DNA Advisory Committee (RDAC) – The main functions of this Committee are:

- To review developments in biotechnology at national and international level.
- To recommend suitable and appropriate safety regulations for India in r-DNA research, use and applications.

Monitoring bodies

State Biotechnology Co-Ordination Committee (SBCC) – The main functions of this Committee are:

- To inspect, investigate and to take punitive action in case of violations of statutory provisions through the State Pollution Control Board or the Directorate of Health etc.
- To review periodically the safety and control measures in various institutions handling GEOs.
- To act as nodal agency at State level to assess the damage, if any, due to release of GEOs and to take on site control measures.

District Level Committee (DLC) – This committee's main functions are:

- To monitor the safety regulations in installations.
- To inspect, investigate and report to the SBCC or the GEAC about compliance or non-compliance of r-DNA guidelines or violations under EPA.
- To act as nodal agency at District level to assess the damage, if any, due to release of GMOs and to take on site control measures.

Monitoring-cum-Evaluation Committee (MEC) – This committee's main functions are:

- To visit field experimental site(s) and to constitute, if necessary, monitoring team(s) approved by the RCGM for the purpose of collecting scientific information on the comparative agronomic advantages of the transgenic plants.
- To prepare formats for collecting scientific information on transgenic crops in limited field trials based on the experimental design approved by the RCGM.
- To advise, from time to time, the RCGM on the risks and benefits of the transgenic plants under trial and to suggest new experimental design(s) to the RCGM and also assist in collecting, consolidating

and analyzing the field data for evaluating the environmental risks emanating from the transgenic plants.

- To apprise the RCGM on those transgenic crops, which are environmentally safe and economically viable for recommending the same to the GEAC for consideration for release into the environment.
- To undertake field visits to the experimental site(s) approved by the GEAC for the purpose of collecting scientific information, based on specific requests made by the GEAC.

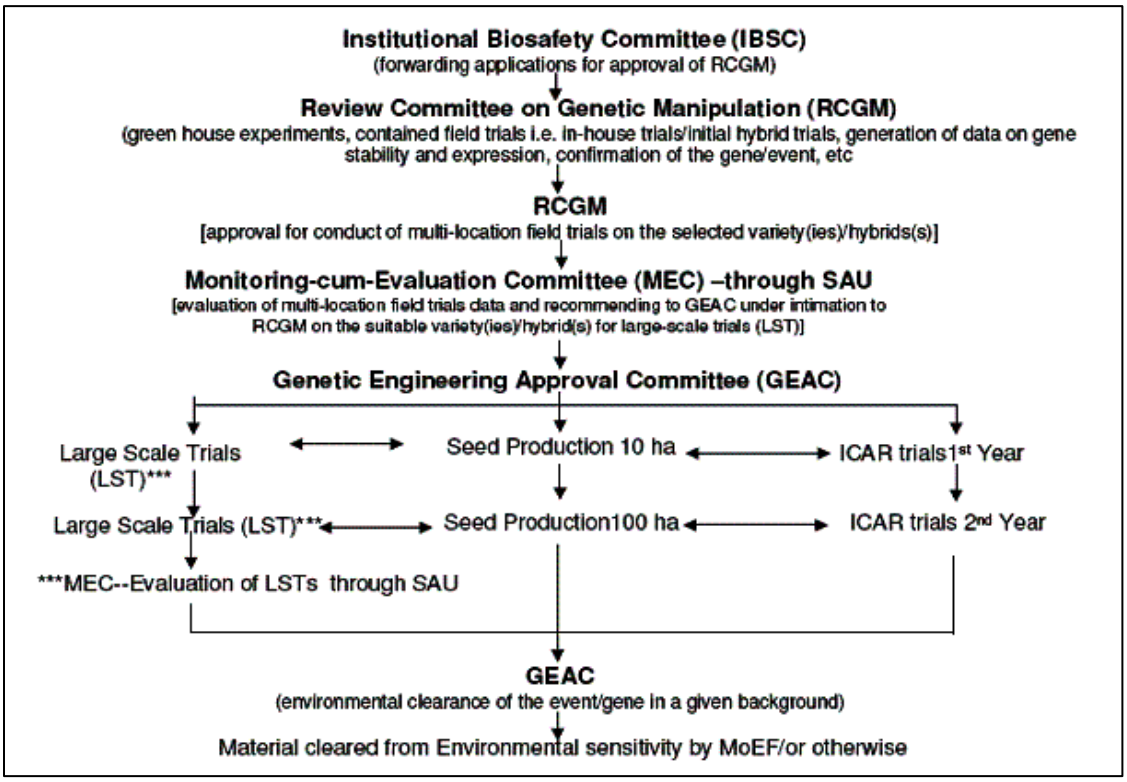

Figure 2. The step-wise process for obtaining approval for rDNA activities in India. (http://dbtbiosafety.nic.in/)

Key agencies involved with the Biosafety and their roles and responsibilities

Biotechnology is a cross-cutting, inter-ministerial activity, since several ministries conduct activities in the biotech field - the Ministry of Science & Technology, the Ministry of Agriculture, the Ministry of Health and the Ministry of Human Resource& Development. There are also a number of agencies under the authority of these Ministries - the Department of Biotechnology, the Indian Council of Medical Research, the Council of Scientific & Industrial Research, the Indian Council of Agricultural Research and the National Biodiversity Authority.

Department of Biotechnology (DBT) - Established in 1986, the DBT is the nodal agency under the Ministry of Science and Technology entrusted with the task of formulating policies in this specific field. The Department of Biotechnology provides support to researchers and national industry through facilities, human resource development and bioinformatics programs.

Indian Council of Medical Research (ICMR) – The ICMR was established at the beginning of the 20th century and is presently under the responsibility of the Ministry of Health and Family Planning. The ICMR is responsible for all biomedical research in India related to human health and formulates, promotes and coordinates medical research in a way that matches national health priorities. The Council also supervises a

broad network of research centres and institutes. It conducts normative functions and has adopted guidelines on different matters. In the field of modern biotechnology, it adopted guidelines for stem cell research and therapy and, in view of their potential impact on health, on biotechnology and genetically-modified seeds and food.

Indian Council of Agricultural Research (ICAR) - The ICAR, which was established in 1929, falls under the authority of the Ministry of Agriculture and is attached to the Department of Agricultural Research & Education. The ICAR is a key agency because it coordinates and manages research and education in agriculture, animal sciences and fisheries, activities of the utmost importance in India. In the field of biotechnology, the ICAR controls the National Bureau of Plant Genetic Resources and is responsible for the control of the importation and quarantine of transgenic planting material.

Biotech Consortium India Limited (BCIL) - The BCIL provides linkages amongst research institutions, industry, government and funding institutions, to facilitate accelerated commercialization of biotechnology. The Company is engaged in technology transfer, project consultancy, fund syndication, information dissemination and manpower training and placement related to biotechnology.

The Ministry of Environment & Forests (MoEF) – The MoEF is the nodal agency in the administrative structure of the Central Government for the planning, promotion, co-ordination and overseeing the implementation of India's environmental and forestry policies and programmes.

National Biodiversity Authority - The National Biodiversity Authority was established in 2003 in terms of Section 8 of the National Biodiversity Act. It has both an advisory and regulatory role, since it advises the government of India on biodiversity preservation and equitable sharing of benefits and, on the other hand, regulates access to biological resources for research and/or commercial purposes. Moreover, it also intervenes on behalf of the Indian Government in patent-opposition procedures in cases of patents applied for or obtained without prior informed consent and on mutually agreed terms.

CURRENT BIOSAFETY REGULATIONS AND GUIDELINES IN INDIA

India is party to several international treaties that directly impact on biotechnology regulation and management. In the field of international trade law, Indian is signatory to the Agreement establishing the World Trade Organization (WTO); therefore all relevant policies are framed according to the WTO covered agreements and especially three agreements:

- the Technical Barriers to Trade Agreement, which prescribes the adjustment of national regulations to international standards, something which can be of relevance in case of standards aimed at safeguarding the quality, biosafety and efficacy of biotechnological products; and
- the TRIPS agreement, which prescribes the patentability of inventions in any field of technology, including microorganisms.
- the Sanitary and Phytosanitary Agreement, which establishes WTO rules on food safety and animal and plant health measures.

In 1990, the Department of Biotechnology enacted the Recombinant DNA Safety Guidelines supplementing the Biosafety Rules.66, which was revised on two occasions (1994, Revised Guidelines for Safety in Biotechnology and 1998, Revised Guidelines for Research in Transgenic Plants). These guidelines are crucial for conducting rDNA research activities, experimentation, quality control and importation of products resulting from biotechnology.

The National Biodiversity Act of 2002 and the Biological Diversity Rules are aimed at implementing the Convention on Biological Diversity (CBD). The National Biotechnology Act states that its goal is the

conservation, sustainable utilization and equitable sharing of the benefits that result from genetic resources. In order to achieve its goals, the Act provides for access and benefit sharing mechanisms (including the disclosure of origin of the genetic material) and incorporates conservation principles. The Act also created a new institution: the National Biodiversity Authority. Other important norms influencing activities in the biotechnology field are the Protection of Plant Varieties & Farmers' Rights Act 2001 (provides plant breeders with rights over new plant varieties), the Indian Patent Act (particularly important Section 3(d), regarding patentability criteria), Biosecurity Regulations, the Seed Act and the Prevention of Food Adulteration Act.

In order to establish a single window mechanism to provide approvals for GEOs, The Ministry of Agriculture, Government of India, constituted a Task Force on the Application of Agricultural Biotechnology under the chairmanship of Prof. M.S. Swaminathan which, in 2004, recommended the establishment of an autonomous and statutory National Biotechnology Regulatory Authority (NBRA) which would be an independent, autonomous and professionally led body. The Task Force on Recombinant Pharma constituted by MoEF made similar recommendation in 2005 under the Chairmanship of Dr. R.A. Mashelkar. In 2005, a draft National Biotechnology Development Strategy was published by DBT and the establishment of a National Biotechnology Regulatory Authority with four separate divisions was recommended.

In November 2007, the Indian government approved the National Biotechnology Development Strategy (NBDS). It was a much awaited policy document, which devised a comprehensive ten year road map for the Indian biotech sector, and put forward proposals that could greatly change the Indian biotechnology regulatory landscape. The NBDS was the outcome of two years of consultations with several stakeholders during which the government held meetings with ministries, universities, private companies, research institutes, international bodies and consumer associations.

The general goals defined in the NBDS include development of human resources, strengthening of the infrastructure and promotion of trade and industry. To accomplish these goals, the NBDS identified several actions, the most important being the creation of a new National Biotechnology Regulatory Authority. According to the Draft Establishment Plan for the NBRA, it would be headed by an eminent biotechnologist as chairman, supported by two advisory bodies:

- The Inter-Ministerial Advisory Board (IMAB) and
- The National Biotechnology Advisory Council (NBAC).

The IMAB would provide the NBRA with independent, strategic advice from several stakeholders on developments in modern biotechnology, while NBAC would seek to foster coordination among Central Government ministries in the implementation of India's national biotechnology regulatory system.

In July 2008, the National Biotechnology Regulatory Act was drafted to establish the NBRA under the Department of Biotechnology. This draft establishment plan and "Draft National Biotechnology Regulatory Bill, 2008" was prepared by a Consultative Committee of experts. This piece of legislation identified the core goal of the agency as safeguarding "the health and safety of the people of India and to protect the environment by identifying risks posed by, or as a result of, modern biotechnology, and managing those risks through regulating the safe development and deployment of biotechnology products and processes". Feedback was collected from all concerned stakeholders by requests placed on websites as well as organizing regional consultations by BCIL.

This Bill was renamed as Biotechnology Regulatory Authority of India (BRAI) Bill (2009). By April 2010, the NBRA had not been created, although the Indian government affirmed at that time that it would be established by the first quarter of 2010. The proposed scope of the NBRA activities raised a lot of criticism. Some criticized the limitation of the concept of 'biotechnology' to genetic engineering and, more precisely, its activities to those involving genetic engineering. Another objection was to the responsibility of the

Authority to achieve consistency between national and international standards. It was unclear which 'countries' standards should be considered, those adopted in the USA, Japan or the EU or only those adopted by international organizations.

In 2012 the Bill, which had faced widespread opposition both inside and outside Parliament on its intent and content, was sent to the Parliamentary Standing Committee for consideration. The Parliamentary Standing Committee on Agriculture (PSCA) found that while India is a signatory to a number of international agreements with respect to the protection of biodiversity and ensuring health and environmental safety from GEOs, the necessary scientific expertise, infrastructure and manpower for ensuring compliance had not been put into place. In August 2012, the PSCA tabled a report that consulted all stakeholders and examined the BRAI Bill against the standard regulatory frameworks elsewhere in the world. It observed that "regulating biotechnology is too small a focus in the vast canvas of biodiversity, environment, human and livestock health, etc. and a multitude of other such related issues". The panel recommended "setting up of an all-encompassing Biosafety Authority through an Act of Parliament, which is extensively discussed and debated amongst all stakeholders, before acquiring shape of the law", adding that "unless and until such an authority is in place, any further movement in regard to transgenics in agriculture crops will obviously be fraught with unknown consequences".

The PSCA, therefore, recommended the government come up with a fresh road map for ensuring food security in the coming years without jeopardizing the vast biodiversity of the country and compromising with the safety of human and livestock health. Also, the PSCA unanimously felt that the government should take decisive action on the recommendations of this report and rethink its decision of introducing transgenics in agriculture as a sustainable way forward.

In May 2012, the Supreme Court constituted a Technical Expert Committee (TEC) comprising six eminent scientists with fixed terms of reference that were agreed to and signed by the government and the petitioner. This committee recommended a ban on all field trials of transgenic crops. While recommending the ban, the committee said the trials should not take place until certain conditions were satisfied. The conditions included designating specific sites for conducting field trials and putting in place sufficient mechanisms for monitoring the trials. A panel of scientists, qualified in evaluation of the biosafety data of GE crops, should be engaged to scrutinize and analyze safety data. It also called for a mandatory requirement for preliminary biosafety tests prior to the field trials; including sub-chronic toxicity in small animals. The TEC also recommended that the regulatory body be located in the MoEF and the Ministry of Health & Family Welfare as the *Biotechnology Regulatory Authority of India* (*BRAI*) under the Ministry of Science & Technology would clearly result in a conflict of interest. Hence, a 10-year moratorium on field trials on Bt brinjal came into existence.

The BRAI Bill was tabled in the lower house of Parliament by the Minister for Science & Technology, in April 2013. In July, the TEC came down heavily upon the current regulatory mechanism and advised against any further field trials until the serious lapses were rectified. Owing to increasing public pressure, the PSCA extended the time for submission of views and suggestions on the proposed law.

In February 2014, the Minister of Environment & Forests announced that the file was cleared as the GEAC's decision was not bound by the Supreme Court's moratorium on field trials and the companies and agriculture research institutes could go ahead with scientific field trials of different transgenic varieties of GM crops which had got clearance from the GEAC in March 2013. However, the trials could only start after approval had been obtained from the respective state authorities.

The GEAC also scheduled a meeting for March 2014 to consider other applications that have been pending for almost two years.

Experience of Bt cotton in India - Post commercialization Biosafety issues

Very few studies have been carried out in India on the post commercialization biosafety issues related to non-target organisms and secondary pest development, but the most significant ones are cited below.

In India, as per the direction of DBT, several studies relating to biosafety were conducted (Manjunath TM, http://www.agbioworld.org/biotech-info/articles/biotech-art/safety-bt-cotton.html). Feed-safety studies of Bt cottonseed meal were carried out with goats, buffalos, cows, rabbits, birds and fish at the Industrial Toxicological Research Institute; National Dairy Research Institute; Central Institute of Fisheries Education; Central Avian Research Institute; National Institute of Nutrition and Govind Vallabh Pant University for Agriculture and Technology. The results revealed that animals fed with Bt-cottonseed meal showed no ill-effects and were comparable to control animals in the various tests. These studies showed that Bt cottonseed meal was substantially equivalent to its non-Bt counterpart. Studies were also conducted on the effect of leachate from Bt cotton plant on soil rhizosphere and non-rhizosphere microflora, soil collembola and earthworms. The results showed no difference between the soils obtained from Bt and non-Bt plants.

Lawo et al. (2009) assessed the performance of cotton aphids (*Aphis gossypii* Glover), when grown on three Indian Bt (Cry1Ac) cotton varieties (MECH 12, MECH 162, MECH 184) and their non-transformed near isolines in climate chambers. They also examined the presence of Bt protein in the aphids and analyzed the sugar composition of aphid honeydew to evaluate its suitability for honeydew-feeders. They observed that plant transformation did not have any influence on aphid performance. However, some variation was observed among the three cotton varieties which might partly be explained by the variation in trichome density. None of the aphid samples contained Bt protein. As a consequence, natural enemies that feed on aphids are not exposed to the Cry protein. A significant difference in the sugar composition of aphid honeydew was detected among cotton varieties as well as between transformed and non-transformed plants. However, it is questionable if this variation is of ecological relevance, especially as honeydew is not the only sugar source parasitoids feed on in cotton fields. The study concluded that Bt cotton poses a negligible risk for aphid antagonists and that aphids should remain under natural control in Bt cotton fields.

Sharma et al (2007) studied the effects of transgenic cotton with *cry1Ac* gene on the natural enemies of cotton bollworm under field and laboratory conditions. There was no apparent effect of transgenic cotton on the relative abundance of predatory spiders (*Clubiona* sp. and *Neoscona* sp.), coccinellid (*Cheilomenes sexmaculatus* Fab.), and the chrysopid (*Chrysoperla carnea* Stephens). However, the abundance of these arthropods was quite low in insecticide protected plots towards end of the cropping season. There was a significant reduction in cocoon formation and adult emergence of the ichneumonid parasitoid, *Campoletis chlorideae* Uchnida reared on *H. armigera* larvae fed on the leaves of transgenic cottons before and after parasitization. However, no *Bt* toxins were detected in *H. armigera* larvae and the parasitoid cocoons with ELISA. There was a slight reduction in adult weight and fecundity, and prolongation of the larval period when the parasitoid was raised on *H. armigera* larvae fed on the leaves of transgenic cotton before and after parasitization. Survival and development of *C. chlorideae* was also poor when *H. armigera* larvae were fed on the leaves of cotton hybrid Mech 184. The adverse effects of transgenic cotton on survival and development of *C. chlorideae* were largely due to early mortality and possibly poor nutritional quality of *H. armigera* larvae due to toxic effects of the transgene.

Dhillon et al. (2012) studied the efficacy of Bt cotton for the management of bollworms and their effects on non-target insects under insecticide protected and unprotected conditions. It was found that *Helicoverpa armigera* and *Earias vittella* damage was significantly lower in Bt than in non-Bt cotton, while no significant differences were observed in egg-laying by *H. armigera*. The populations of major non-target sucking insect pests such as *Amrasca biguttula biguttula, Bemisia tabaci*, *Aphis gossypii*, *Oxycarenus laetus*, *Dysdercus koenigii* and *Nezara viridula* and the generalist predators, viz *Cheilomenes sexmaculatus*, *Chrysopa* spp., and spiders did not differ significantly between Bt and non-Bt cotton. Insecticide application resulted in

resurgence of cotton aphid and whitefly, possibly because of elimination of natural enemies or better growth of plants under protected conditions. Abundance of bollworms, non-target pests, and generalist predators was significantly greater before insecticide sprays than after insecticide application, except in a few cases.

Hanchinal (2010) also carried out a survey, seasonal fluctuation of mealy bug, and its natural enemies, crop loss assessment, estimation of economic injury loss, biology of mealy bug, biology of the predator and efficacy of insecticides including biological agents against mealy bugs for two years in Bt cotton.

Significant reduction in usage of insecticide especially broad spectrum organophosphates and pyrethroids has given scope for emergence of new pests. Mirid bugs either found earlier or newer ones have assumed key status demanding couple of sprays during flowering phase. Diverse Bt events with ability to contain all bollworm species and other Lepidoptera would be ideal in the Indian context. (https://www.icac.org/tis/regional_networks/asian_network/meeting_5/documents/papers/PapUdikeriS.pdf).

THE NATIONAL BUREAU OF PLANT GENETIC RESOURCES (NBPGR)

The National Bureau of Plant Genetic Resources (NBPGR) has been actively involved in testing of transgenes in imported transgenic material since 2000. From 1999, it has been executing the DBT funded project "National Containment/Quarantine facility for testing of Transgenic Material" under which a State-of- Art National Containment Facility of CL-4 level was established. The total number of imported transgenic planting material kept in Gene bank (1997-till date) is around 172 imports of 14 crops constituting 5,112 accessions.

The transgenic testing laboratory for PCR based testing of imported transgenic lines is presently known as the Referral Centre for Molecular Diagnosis of Transgenic Planting Materials. Salient achievements of the centre are listed below.

Loop mediated Isothermal amplification (LAMP) assays: These have been developed for detection of GEOs for the first time in India. This easy to use assay enables visual detection, and when combined with an efficient DNA extraction method, can be used at the port of the entry by the custom officials or on-site in farmer's fields, as it does not require laboratory equipment and specialized expertise.

Technology developed for initial screening of GE crops: Multiplex PCR-based and LAMP assays for initial screening of GE crops for simultaneous amplification of screening elements to check/verify the GE status of a sample irrespective of the crop and GE trait:

- Hexaplex PCR assay for simultaneous detection of six marker genes, *i.e.*, *aadA, bar, hpt, nptII, pat* and *uidA.*
- Heptaplex PCR assay simultaneously amplifying marker genes; *nptII, aadA, pat, uid A* and regulatory elements, *viz*., *CaMV* 35S, *nos* promoters and *nos* terminator.
- LAMP assays for *CaMV* 35S and commonly used marker genes have been developed for on-site screening for the GM status of planting material at the ports of entry or on farmers' fields when combined with efficient DNA extraction method.

Technology developed for detection and identification of GM crops:

- **Technology for detection of commercialized *Bt* Cotton events:** Decaplex PCR technology has been developed to differentiate and to check the adulterants in two major commercialized *Bt* cotton events in India, *viz*., MON531 (Bollgard® I)and MON15985 (Bollgard® II). Recently, another decaplex PCR method differentiating five commercialized events of *Bt* cotton, *viz*., MON531, MON15985, Event1, GFM-*cry1A* and MLS-9124 has been developed with limit of detection (LOD) up to 0.1-0.01%.

- **Technology developed for detection of *Bt* Brinjal:** Event-specific conventional and real-time PCR assays with LOD up to 0.01% have been developed for detection of *B*t brinjal event EE1.
- **Technology developed for detection of Ten GE crops:** Multiplex PCR assays to detect and identify specific transgenic elements in ten GE crops, *viz.* cotton, soybean, maize, mustard, rice, brinjal, cauliflower, okra, tomato and potato have been developed.
- **Technology developed for quantitative analysis of 20 GE events in six GE crops:** Real-time PCR assays targeting specific events/constructs/transgenes have been developed using *Taq*Man and SYBR®-Green I chemistry, in simplex and multiplex formats for 24 GM events in six crops, *viz.,* cotton, maize, rice, brinjal, tomato and cauliflower.

These developed diagnostic/detection assays would benefit a broad range of stakeholders, including consumers, regulatory bodies and the agri-biotech industry as they would:

- help to ensure public confidence in both the technology and the ability to regulate effectively,
- assist in risk assessment and risk management specifically pertaining to gene flow studies,
- assist in post release monitoring and
- solve legal disputes if they arise (Randhawa et al, 2009; 2010a, 2010b; 2011, Randhawa and Singh, 2012; Randhawa et al. 2012, 2013a, 2013b).

Transfer and Commercialization of Technologies and patents: DNA-based GE detection technologies have been transferred to:

- Basmati Export Development Foundation (BEDF), APEDA, Meerut on non-exclusive basis.
- Amar Immunodiagnostics Pvt Ltd. Hyderabad, in May 2010, on non-exclusive basis.
- 2011 Patent No. 245749: Process enabling simultaneous detection of two transgenes in transgenic maize.
- 2012 Patent No. 254341: Process enabling simultaneous detection of two transgenes namely human serum albumin (HSA) and bar genes in transgenic wheat.

Consultancy Services for developing expertise in the area of GEO Testing and Designing of GE Testing laboratory as per international Standards ISO/IEC 17025:2005

- Such services are being provided to Punjab Biotechnology Incubator (PBTI), (Agri and Food Testing Laboratory), Mohali and Basmati Export Development Foundation (BEDF), Modipuram, Meerut.
- These services are also provided by some private labs such as SGS and Bioserve Biotechnologies (India) Pvt Ltd.

AGENCIES RESPONSIBLE FOR GE FOOD SAFETY IN INDIA

- The Ministry of Health and Family Welfare (MoHFW) is primarily responsible with ensuring the availability of food that is safe. In 2006, the Food Standards and Safety Act, 2006 was promulgated. This Act will be implemented by the Food Safety and Standards Authority and includes genetically modified foods within the definition of food under the Act.
- The Bureau of Indian Standards (BIS) has also initiated a program to develop draft Indian standards for GE foods.
- The Indian Council of Medical Research (ICMR), in its capacity as the scientific and technical advisory body to MoHFW, has formulated these guidelines to establish the safety assessment procedures for foods derived from GE plants taking into consideration the international *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC 2003).

The Food Safety and Standards Authority of India (FSSAI) is empowered to regulate genetically engineered foods in terms of the Food Safety and Standards Act, 2006. The FSSAI intended to meet its regulatory obligations by implementing a safety assessment and approval process for GE foods that uses the existing regulatory capacity within the Government of India, notably within DBT, MoEF and the Indian Council of

Medical Research (ICMR). This body also prepared a document on Operationalizing the Regulation of GE Foods in India in which the proposed responsibilities of the FSSAI in the regulation of GE organisms in India includes food safety assessment of GE foods (viable and processed) as well as approval for commercial release of GE foods (processed). However, in the highlights of the Review of the FSSAI's Activities in 2010-2011, it mentioned that though the provisions of Food Safety and Standards Act include GE food, the government was considering the establishment of the Biotechnology Regulatory Authority of India (BRAI) as the nodal point for regulating GE food. Consequently, the FSSAI has not operationalized the provisions relating to GE food but would continue to be responsible for the labelling and other safety related issues of GE food.

BIOSAFETY RESOURCES AVAILABLE IN INDIA

The Biotech Consortium India Limited (BCIL) started working in the area of biosafety in 1998. Since then it has worked closely with concerned ministries such as the MOEF, DBT, Ministry of Agriculture, ICMR etc., state governments, universities, research institutions, industry and other concerned agencies. Among its biosafety activities, it has used multiple tool coverage, viz. national/international, regional/state level events, technical trainings, websites, newsletters, publication etc. for ensuring wider coverage and outreach, as well as conducted a training needs assessment survey to ensure structured approach and planning (Ahuja 2012).

The BCIL developed the Indian GMO Research Information System (IGMORIS), a web based database on research on GEOs supported by Department of Biotechnology developed with the purpose of making available objective and realistic scientific information relating to GEOs and products commercialized as well as under research (http://igmoris.nic.in/).

The DBT biosafety regulatory website (http://dbtbiosafety.nic.in) has also been developed by BCIL to facilitate and disseminate the statutory requirements to be adhered to by the researchers in the R&D work using modern biotechnology tools. As an ongoing process, DBT continues to bring out the latest information and modifications/amendments in the guidelines etc. from time to time. All the relevant Acts, Rules, Guidelines, proformas are available. The detailed stepwise procedures to be adopted for development of GEOs as of date can be viewed or downloaded from this website. In addition to information exchange, the website also provides tracking of regulatory clearance applications to RCGMS and e-monitoring of IBSCs. It also disseminates two newsletters, namely Biosafety Newsletter, a quarterly by MoEF and SABP Newsletter.

BCIL is also the in-country partner of South Asia Biosafety Program, an international developmental program implemented by Centre for Environmental Risk Assessment (CERA-ILSI) in India and Bangladesh to identify and respond to technical training needs for food, feed and environmental safety assessment as well as develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.

BCIL has also come out with several publications and CDs as well on biosafety such as various guidelines for handling and use of GEOs in English and vernacular languages as well as a series of crop specific biology documents on cotton, okra, maize and rice. They have also developed the Biosafety Information Kit.

FUTURE OF BIOTECHNOLOGY AND BIOSAFETY IN INDIA

It is clear that the 'modern biotech revolution' in India will terminate from a lack of a facilitating public policy to a fundamental component for the delivery of technology to smallholder farmers. Therefore, public misunderstanding about safety and ownership of innovative technologies must be dispelled in order to reach to smallholder farmers in India and other developing countries. To maximize the benefits of the revolutionary new genetics (Swaminathan, 2012) and at the same time minimize risks, a number of policy and regulatory steps have to be taken, either to re-establish the functioning of the current regulatory system

or implement a new regulatory framework that can provide smallholder farmers access to genetically enhanced crops (Bhagirath Choudhary et al.2014) . The first option requires the government to reverse many of its political decisions. The second option requires establishing a new regulatory framework by enacting a new law by the Parliament of India that has the following characteristics:

- Purpose – that is, a system that allows the government to make informed decisions, weighing potential benefits against risks.
- Clear, transparent and predictable - that is, decisions based on sound science, clear rules for public information, criteria and time limits for decision-making.
- Non-political - that is, approvals are given by an intergovernmental body, of which the members are experts in relevant fields, nominated by the ministries involved and other relevant government bodies.
- Efficient – that is, reducing the number of different bodies involved in the decision-making process to a minimum.
- Consistent – that is, compling with international obligations and practices, such as definitions (e.g., GMO/LMO), regulatory categories (e.g., contained use, environmental release, placing on the market) and decision criteria based on sound science.
- Clear transition provisions with regard to ongoing activities, and repealing existing laws and regulations, to avoid duplication.

According to Damodran (2005), single window initiatives in the field of biosafety regulations should not only be vertically stacked but also horizontally broad-based with both civil society and industry associations accorded their due role in decision-making processes.

In conclusion, it is vital for the nation to direct agricultural growth with the help of technical expertise and institutional capacity that have been built with meticulous efforts and huge investments over a period of time so that it moves towards self-sufficiency.

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Chapter 17. Biosafety regulatory system in The Philippines

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INTRODUCTION

The Philippines is classified as one of the biotech mega countries with a production area of at least 50,000 hectares of genetically engineered crops (James 2011). Filipino farmers have reaped the benefits from this new technology and on a macro-level, the country as well. The Philippine government recognized the potential of biotechnology in contributing to economic development as early as 1979 as well as the need for biosafety regulations to go alongside biotechnology research. Foresight became the key to the creation of an enabling environment that has allowed the Philippines to reach its current position in terms of the adoption rate of GE crops.

EARLY BIOTECHNOLOGY AND BIOSAFETY INITIATIVES

The first institutionalized foray of the Philippines into biotechnology research and development was during the time of President Ferdinand Marcos. In 1979, a national institute to focus on biotechnology R&D was established at the University of the Philippines Los Baños which is now known as the National Institute of Molecular Biology and Biotechnology (BIOTECH). During the term of President Corazon C. Aquino, the National Committee on Biosafety of the Philippines (NCBP) was established to help the country harness the benefits of biotechnology while at the same ensuring its safe and responsible use. Under the Administration of President Fidel Ramos, the Agriculture & Fisheries Modernization Act (RA 8435 S-1997) was signed. This Act was intended to modernize the agricultural and fishery sectors by transforming them from resource-based to technology-based industries. Further in 2000, during the administration of President Joseph Estrada, a national policy on the use of biotechnology as a strategy to improve agricultural production, modernize Philippine agriculture and enhance rural development was approved. The NCBP was further strengthened and broadened through the approval of Executive Order No. 514 by President Gloria Macapagal-Arroyo who also approved a policy statement on the safe and responsible use of modern biotechnology. Furthermore, Presidential Proclamation 1414 of 2007 designated the third week of November every year as the National Biotechnology Week.

Under the present administration of President Benigno S. Aquino III, biotechnology R&D is generously supported by the Department of Science & Technology and the Department of Agriculture. The Philippines is, therefore, reaping the benefits of the consistent recognition of its leaders for the potential of biotechnology and the need for biosafety regulations.

EARLY RECOGNITION OF THE NEED FOR BIOSAFETY REGULATIONS

Interest in biosafety started when research workers at the University of the Philippines Los Baños (UPLB) and the International Rice Research Institute (IRRI) started using modern biotechnology tools. It was the scientists themselves who expressed the need for biosafety regulations (Mendoza et al. 2009). In 1987, a Joint Committee by IRRI and UPLB was formed under the leadership of National Scientist Dolores Ramirez. The committee reviewed existing guidelines from several countries and focused on the process and not the products. After a series of presentations and reviews, the draft guidelines were submitted to the National Academy of Science and Technology (NAST) with the recommendation that it takes the lead in getting the guidelines nationally adopted. The NAST conducted further consultations and submitted a draft to the Department of Science & Technology (DOST). The recommendations of the DOST led to the issuance by President Corazon C. Aquino of Executive Order (EO) 430 , Constituting the National Committee on Biosafety of the Philippines (NCBP) and for Other Purposes in 1990 (Mendoza et al. 2009).

The first biosafety regulation in Asia

Under EO 430, the NCBP was tasked with identifying and evaluating potential risks and recommend measures to minimize these risks; formulate and review national policies and guidelines on biosafety such as the safe conduct of work on genetic engineering. The Philippine Biosafety Guidelines were issued in 1991 and they provided risk assessment guidelines for the introduction, movement and field releases of GEOs. The Philippines regulates GE crops by transformation event. The NCBP under EO 430 was chaired by the DOST Undersecretary for Research & Development. It had scientist members as well as representatives from the Departments of Agriculture, Environment & Natural Resources and Health.

Department of Agriculture Administrative Order 8, preparing for commercial propagation of GE crops

By 2001, with the advancement in research and development, it was realized that biosafety regulations would have to be formulated to meet the needs of the time. The Department of Agriculture (DA) Administrative Order (AO) 8, Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology, was signed in 2002. Through DA AO 08 2002, field trials and commercialization would be handled by the Bureau of Plant Industry (BPI). Having represented DA in the NCBP, BPI personnel are technically equipped in biosafety evaluation and the agency has police power to implement the regulations through the existing Plant Quarantine Act. Four activities are regulated in this AO namely:

- importation for contained use,
- importation for direct use for food/feed/processing,
- conduct of field experiments, and
- release of seeds for propagation.

Another feature of AO 8 is that the permit for propagation is renewed every five years until the GE crop is deregulated.

Executive Order 514, Strengthening the NCBP

The Philippines became a beneficiary of the United Nations Environment Program/Global Environment Facility (UNEP/GEF) Global Project on Development of National Biosafety Frameworks. The Philippines formulated its current National Biosafety Framework after consultations with various sectors (Halos et al. 2004).

EO 514, Establishing the National Biosafety Framework, Prescribing Guidelines for its Implementation, Strengthening the National Committee on Biosafety of the Philippines, and for Other Purposes, was signed in 2006 by the then President Gloria Macapagal-Arroyo. Under EO 514, the membership of the NCBP was expanded to include the Secretaries (or their representatives) of the Departments of Foreign Affairs, Trade and Industry and Local Government. The NCBP became the lead agency to coordinate and harmonize inter-agency and multi-sector efforts to develop biosafety policies in the country. It is now chaired by the Secretary of the Department of Science & Technology with other Department Secretaries (or their representatives), scientists, and stakeholder group representatives as members. Risk assessment was given to duly designated Competent National Authorities (CNAs), the Departments of Agriculture, Environment & Natural Resources, Health and Science & Technology with their respective mandates.

Ratification of the Cartagena Protocol on Biosafety

The Philippines is a Party to the Cartagena Protocol on Biosafety. The Instrument of ratification was signed in November 2004, it was concurred by the Philippine Senate on August 14, 2006 and entered into force on January 8, 2007. By being a Party to the Cartagena Protocol it became mandatory for importing and

exporting entities to declare Living Modified Organism (LMO) content of materials for transboundary movement. (Mendoza et al. 2009).

Further, the Philippines actively participated in the negotiations leading to the adoption of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety by the COP/MOP of the CBD in 2010 in Japan.

THE FIRST BIOSAFETY EVALUATION: BT MAIZE

The Philippines' first experience with a GE crop was Bt maize (MON 810). The proposal for contained testing was submitted to the National Committee on Biosafety of the Philippines (NCBP) by the Institute of Plant Breeding - University of the Philippines Los Baños. The contained test was conducted in 1996 at the CL4 containment facility of the IRRI to test Bt maize against the Asiatic Corn Borer (ACB), *Ostrinia furnacalis* Guenee (Fernandez et al. 1997).

To determine the efficacy of Bt maize to ACB in the field, a limited confined field test was conducted in 1999. This was done in the approved experimental site in General Santos City in Mindanao. (www.ncbp.dost.gov.ph). The next step was to determine the efficacy of Bt maize against ACB under the different climatic conditions in the Philippines. Monsanto Philippines conducted multi-location trials after the NCBP approved the proposal in 2001. Pioneer Hi-bred Philippines conducted another set of multi-location trials during the 2002-2003 planting season (Ebora et al. 2005). Prior to its implementation, all of these experiments were subjected to rigorous environmental risk assessments conducted by the technology developers, regulatory agency and scientists who were members of the Scientific and Technical Review Panel of DA-BPI. One of the main features of the Philippine biosafety regulation is the active involvement of the Institutional Biosafety Committee where a community representative is one of the members in the risk assessment process.

Promoting Public Acceptance

Parallel to the regulatory approvals that Bt maize was going through, public reaction to it was also gathering momentum. Being the first GE crop to be propagated in the country, Bt maize was expectedly met with controversy. A combination of communication efforts and a robust regulatory process were instrumental in gaining sufficient public acceptance.

The conduct of the first contained tests inside the high level containment facility may be partially attributed to the strong opposition of some Non-Government Organizations (NGOs). For the confined field trials, the proponents agreed with local government officials to enhance their isolation measures by detasseling the plants and erecting a 3 meter plastic barrier in addition to the 500 meter isolation distance that was already devised (Cariño 2009).

At the time that tests were being conducted, debates were occurring in the various forms of media. Major events that happened at this time were the uprooting of the Bt maize field trial site in August 2001 and a hunger strike in front of the Department of Agriculture. Scientists undertook the task of explaining the scientific basis of the risk and benefits of the technology using existing reviews (Panopio and Navarro 2011). During these times, different sectors played various roles to ensure that scientifically accurate information reached the stakeholders. The academic community stepped out of their laboratories and contributed to the communication efforts led by the Philippines' National Academy of Science and Technology (NAST). Scientific and professional organizations highlighted the role of biotechnology in agriculture, environment and health in their annual conferences. Some members of the religious sector gave positive statements about biotechnology as it may address the needs of poor farmers. Farmer groups, in turn spoke out about the possible use of biotech to increase farm productivity, and food, feed and fiber security. Regulators explained

to the public that policies were in place and GE products were rigorously assessed for safety before they were allowed to be commercialized. The importance of the media was also recognized, thus capacity building for the media was conducted to enable them to accurately report on technical matters. (Panopio and Navarro 2011).

A study by Juanillo (2003) determined that consumers, extension workers and policy makers generally exhibited moderate attitudes towards biotechnology. It was also stated that Philippine stakeholders generally held an overwhelmingly moderate position on agricultural biotechnology. This was partially attributed to the study's other finding that the stakeholders did not have enough understanding on the topic to take a definite position. Another study in 2006, determined that generally respondents had a positive perception on agricultural biotechnology. However, the study also determined that further education of the public was still necessary (Torres 2006).

GE CROP ADOPTION: INCREASING USE, REAPING THE BENEFITS

After the initial planting of Bt maize (MON 810) in 2002, herbicide tolerant maize and the stack of the two traits were approved for commercialization in 2006. Between 2008 and 2011, the stack was widely planted. In 2011, a pyramided crop was approved for commercialization. Pyramiding is the use of two or more toxins in the same variety. The idea is that one toxin would kill the individual insects that are resistant to the companion toxin. It is a way to manage resistance to Bt and other toxins. The strategy is intended to reduce refuge requirements (Roush, 1998).

As of June 7, 2012, the Philippines has five single trait transformation events and three stacked trait products approved for propagation and 61 single event and combined trait products approved for direct use (www.bpi.da.gov.ph).

The land area planted to GE maize has increased from 10,000 hectares in 2003 to 685,000 hectares in 2012 (DA - BPI data). There are an estimated 322,000 small scale farmers growing an average of two hectares in 2011 (James, 2011). Studies have also shown that GE maize farmers have benefited economically through their use of the transgenic crop.

A study by Yorobe and Quicoy (2006) conducted during the 2003 to 2004 planting seasons showed that Bt maize farmers had a yield advantage of 34% over the non-Bt users. In terms of pesticide cost, Bt maize farmers spent PHP 156/hectare or only 48% of what non Bt maize farmers were spending, which was PHP 324/hectare. The use of Bt maize resulted in an increase in total revenue of PHP 14,849 (approximately US$ 270) per hectare.

Gonzales (2009), with data from 2003 to 2008 planting seasons using Bt, RR and the stacked trait GE maize, determined that yield for GE maize farmers was higher by 4% to 34%. The income advantage of biotech maize farmers was 3% to 75% higher during the wet season and 1% to 75% higher during the dry season.

The decision by farmers to adopt biotech maize was influenced primarily by economic factors, followed by agronomic and social factors. The higher income has allowed them to pay off debts, acquire education for their children, purchase material possession and others. A non-material benefit was the peace of mind that their crops would not be attacked by the corn borer (Torres, 2012). It was also reported that there are substantial improvements in maize productivity while area planted to maize has remained constant. Philippine maize productivity has improved from PHP 22 million in 1998 to PHP 88 million in 2011 at current prices or PHP 25 million in 1998 to PHP 46 million in 2011 at constant prices (Serrano, 2012).

Post approval monitoring

The Philippines continues to monitor GE crops through their commercialization period. An Insect Resistance Management (IRM) plan is part of the approval process for pest protected GE crops in order to delay, if not prevent the development of resistance and prolong the usefulness of the technology. Post approval monitoring is done through the Regional Crop Protection Centers of the Department of Agriculture and is regulated through the issuance of Memorandum Circulars and Special Orders by the Bureau of Plant Industry (BPI). The IRM plan takes into consideration the local conditions and the farming system. Local studies are conducted and data generated are used in decision making and providing guidance for the policies that need to be put in place. These studies include farmers' attitude towards refuge strategies; monitoring of resistance in the Asiatic Corn Borer (ACB), ACB biology, ovipositional preference and alternate hosts, ACB predators and parasites and dispersal of Bt pollen and its impact on non-target insects. Filipino researchers conduct studies under local conditions to generate data in support of policy formulation and implementation (Palizada 2011).

Perhaps the most crucial resource in having an effective biosafety system is the human resource. Ultimately, it is the regulators who will make the decisions based on their knowledge and confidence. The NCBP itself recognizes this and has conducted 27 workshops, training-seminars, round table discussions and similar activities from 1993 to 2007 (Mendoza et al. 2009). Similarly, the Program for Biosafety Systems (PBS) in the Philippines has conducted capacity building activities in-line with the mandates of the CNAs. These were designed with the biosafety focal persons of the Departments thus ensuring that the program will meet the needs of the regulators.

Public Sector GE Crops

It is expected that public sector GE crops will be approved for commercialization in the near future. The two that are most likely to be approved are Golden Rice and the Bt eggplant.

In the Philippines, approximately 1.7 million children aged 6 months to 5 years are affected by Vitamin A deficiency. It also affects 1 out of 10 pregnant women. Golden Rice contains beta carotene which is converted to Vitamin A when eaten thus addressing the problem. (Golden Rice Network, 2012).

Eggplant is the dominant vegetable in the Philippines in terms of area cultivated and output. In 2011, area harvested to eggplant totalled 21,377 hectares valued at PHP 4.22 billion. The most damaging pest to eggplant is the fruit and shoot borer (FSB), *Leucinodes orbonalis*. The FSB could damage up to 100% of the yield. Bt eggplant is meant to control the pest and reduce pesticide use (Panopio and Mercado 2012).

CONCLUSION

The Philippines was quick to see the potential of biotechnology and the need to regulate it responsibly with a functional and responsive biosafety system. The nation's small-scale farmers have benefited from the use of modern biotechnology but as with any new technology, fresh challenges are arising. The country has been able to meet these challenges through regulations formulated through the active involvement of various stakeholders and strengthened by data generated by local researcher workers. Capacity building of regulators and sustained information campaigns are crucial to the greater understanding of the technology and its ultimate public acceptance.

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PART 4

CAPACITY BUILDING IN BIOSAFETY IN AFRICA

Chapter 17. Capacity building in biosafety: NEPAD/ABNE approach to building functional biosafety systems in Africa

CHOLANI WEEBADDE, KARIM MAREDIA AND DIRAN MAKINDE

INTRODUCTION

The global population has reached 7 billion people and is expected to grow to around 9 billion by 2050. Africa has reached a population of 1 billion and continues to grow. There are mounting pressures to feed the growing global population on a sustainable basis, especially in Sub-Saharan Africa. The challenges of food security will be further impacted by the potential adverse effects of climate change, rising energy needs as well as the intense depletion of natural resources. In this context, the tools of modern biotechnology and genetic engineering are expected to play a pivotal role in addressing the food security and other emerging challenges in Africa and globally.

Genetic engineering is a powerful technology that enables scientists to move useful genes and traits from one species to another to improve crops. When genes are obtained from unrelated species and engineered into crops for better performance, the public is often concerned about the safety of products of modern biotechnology for humans, animals and the environment. Currently there is a lot of controversy and debate on the products of modern biotechnology in Africa and other parts of the world. In this context, functional regulatory systems are critical to evaluate the potential risks of biotech products including food, feed and environmental safety.

Since first planted in 1996, the area under genetically engineered (GE) crops (also referred to as biotech crops and GM crops) has increased more than 100-fold making it the “fastest adopted crop technology in the recent history” (Clive James, 2013). Reducing hunger and poverty remains a key priority of African governments. Policy makers and leaders in Africa are discussing and considering utilization of biotechnology tools for enhancing agricultural productivity towards food and nutritional security and economic growth. Many governments are putting regulatory frameworks and appropriate policies in place to regulate biotech crops and products. They are also keen to develop a critical mass of well-trained regulators, access science-based information and technical assistance to strengthen and implement regulatory frameworks and policies.

CURRENT STATUS OF BIOTECH CROPS IN AFRICA

Many African governments are taking positive steps by granting regulatory approvals for confined field trials (CFTs) and/or commercial planting of biotech crops. Out of the 54 member states, 22 countries have biosafety laws, regulations, guidelines or policies in place related to genetic engineering and modern biotechnology. Of these countries, four (South Africa, Burkina Faso, Sudan and Egypt) have reviewed applications for commercialization of biotech products and approved commercial plantings of specific GE crops (James, 2012). There was significant increase in the area planted under Bt cotton in both Burkina Faso (over 50% increase from 2012) and Sudan (tripled compared to 2012). While the area under GE crops remained about the same in South Africa, pending a government review, Egypt did not plant GE maize in 2013 (James, 2013). Along with these countries, an additional seven countries; Cameroon, Egypt, Ghana, Kenya, Malawi, Nigeria and Uganda, have reviewed, approved and conducting CFTs. Traits considered in the GE crops that are commercialized or undergoing field trials are either farmer oriented (resistance to insects and diseases, tolerance to herbicides, drought or salinity and agronomic performance) or consumer oriented (nutrient enhancement). Table 1 shows a summary of the countries that are making decisions on GE crops.

Table 1. Current status of biotechnology crops in Africa

GM Crop and Trait\Country	South Africa	Burkina Faso	Egypt	Kenya	Uganda	Nigeria	Malawi	Cameroon	Ghana	Sudan
Commercially approved										
1. Cotton – Insect resistance	X	X								X
2. Cotton – Insect resistance and herbicide tolerance	X									
3. Maize – Insect resistance	X		X*							
4. Maize – Herbicide tolerance	X									
5. Maize – Insect resistance and herbicide tolerance	X									
6. Soybean – Herbicide tolerance	X									
Greenhouse trials (GHT), Confined Field Trials (X) that are conducted (C), approved (A) or Pending approval (P)										
1. Cotton – Insect resistance	X(C)	X(C)		X(C)	X(C)		X(C)	X(C)		
2. Cotton – Herbicide tolerance		X(C)			X(C)					
3. Cotton – Insect resistance and herbicide tolerance	X(C)									
4. Cotton – Salt tolerance										
5. Maize – Insect resistance	X(C)		X(C)	X(C)						
6. Maize – Herbicide tolerance	X (C)									
7. Maize – Insect resistance and herbicide tolerance	X(C)									
8. Maize – Virus resistance	X(C)									
9. Drought tolerant maize	X(C)			X(P)	X (C)					
10. Soybean –Herbicide tolerance	X(C)									
11. Banana – fungal resistance					X(C)					
12. Banana – Nutrient enhancement					X(P)					
13. Cowpea – Insect resistance		X(C)				X(C)			X(C)	
14. Cassava – Virus resistance				X(C)	X(A)					
15. Cassava - Nutrient enhancement	X(C)					X(C)				
16. Sweet Potato - Nutrient enhancement									GHT	
17. Sorghum - Nutrient enhancement	GHT	X(P)		GHT		X(C)				
18. Sweet potato – Virus resistance				X(C)						
19. Sweet potato – Weevil resistance					X(P)					
20. Potato – Insect resistance	X(C)									
21. Sugar cane – Alternative sugar	X(C)									
22. Wheat – Drought tolerance			X(C)							
23. Wheat – Fungal resistance			GHT							
24. Cucumber – Virus resistance			X(C)							
25. Melon – Virus resistance			X(C)							
26. Potato – Virus resistance			X(C)							
27. NEWEST Rice									X(C)	

CURRENT STATUS OF REGULATORY SYSTEMS IN AFRICA

Having signed the Cartagena Protocol on Biosafety (CPB), many countries in Africa have developed or are in the process of developing National Biosafety Frameworks (NBFs) with technical support and funding from various biosafety service providers. The objective of having a NBF is to develop capacity to evaluate the safety of GE crops and products using the international best practices.

For establishing the NBFs, the current capacity of each country was evaluated. In developing biosafety capacity, who takes the ownership of the process, on what context the capacity building should operate on, time considerations, who will be involved, and, what tools would be used were considered. Given that the countries in Africa are at different levels of biotechnology and biosafety regulatory capacity, efforts at developing NBFs varied among countries across the continent.

The countries that took a lead in developing the NBFs were the ones that were keen on developing or adopting GE crops and products for commercial purposes and for enhancing food security. It was necessary for the countries to understand how and at what levels the safety of GE crops and products can be evaluated and regulated before the approvals for general release are granted.

KEY ELEMENTS OF A FUNCTIONAL BIOSAFETY SYSTEM

A functional biosafety regulatory system should enable science-based decision making on the development, deployment and importation of biotechnology products, be predictable and clear to stakeholders, be flexible towards adopting new technologies, be transparent and take into consideration input from public and other stakeholders and, consist of policies and implementing regulations that are workable. Without such a system in place, the research using genetic engineering and modern biotechnology cannot move beyond the laboratory and the large and long-term investments made on technology development will not bear fruits in terms of delivering final products to smallholder farmers. Therefore, in order to ensure safe deployment of biotech crops for the benefit of African farmers and consumers, it is essential that functional regulatory systems are established where by science-based informed decisions can be made on the development and deployment of biotech crops and products.

Figure 1 indicates the steps in the Biosafety regulatory approval process. Regulators in National Biosafety Systems include members of the National Biosafety Committees (NBCs), Institutional Biosafety Committees (IBCs) and Plant Quarantine Officers (PQs) as well as technical teams that support these committees. The role of these regulators is to make decisions on the safety of GE crops along the development and commercialization from the laboratory and greenhouse levels (IBCs) all the way up to confined field trials and general release (NBCs) including decisions to be made on the food imports and trans-boundary

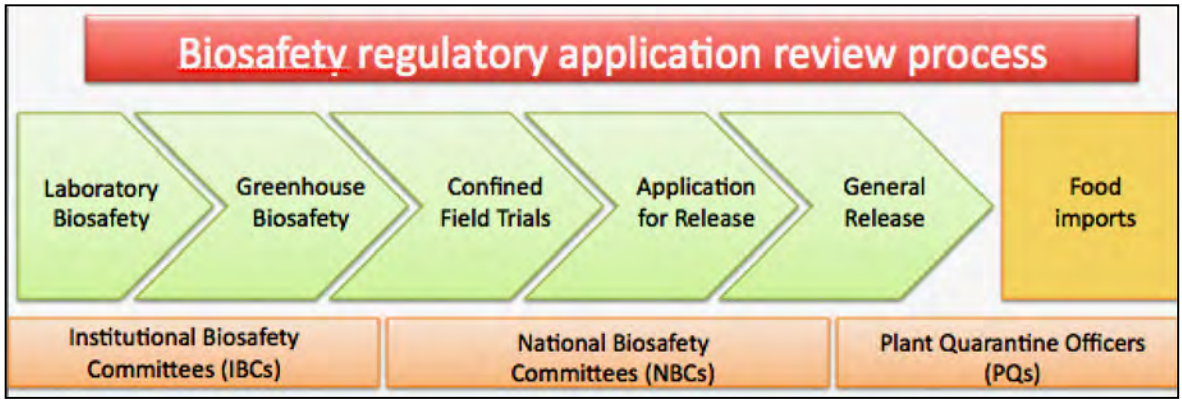


Figure 1: The steps in the Biosafety regulatory approval process.

science-based informed decisions in a transparent manner. However, there has not been a systematic approach to empowering regulators on science-based decision-making on the safety of GE crops and products. This has led to a delay in the regulatory application review process not only in Africa but also in many parts of the developing world.

CONCEPTUALIZING AND ESTABLISHING THE AFRICAN BIOSAFETY NETWORK OF EXPERTISE (ABNE)

Why ABNE was established

Over the past few years, there have been positive developments in many African countries in terms of accessing new tools of biotechnology for crop improvement. While biotechnology research and applications are moving forward in Africa, inadequate biotechnology policies and regulatory frameworks are delaying the decision-making process. To improve this situation, African leaders adopted a co-evolutionary approach to advance science and technology on the continent where the function of regulations would be to promote new innovations, while safeguarding human health and the environment. In other words, it is necessary that the regulators and policy-makers are well informed and empowered to make science-based regulatory decisions on products of research and development efforts including those derived from genetic engineering and modern biotechnology.

In 2008, following the recommendations contained in the publication "Freedom to Innovate" (http://belfercenter.ksg.harvard.edu/files/freedom_innovate_au-nepad_aug2007.pdf), the AU/NEPAD conceptualized the African Biosafety Network of Expertise (ABNE) as a continent-wide resource to provide biosafety services to African regulators and empower them with science-based information and up to date training to make informed decisions on the biotech crops and products. After a one-year design, planning and preparation phase, the ABNE service network was launched in 2010. The goal of ABNE is to build functional biosafety systems in African countries to ensure safe use and management of agricultural biotechnology crops and products. The ultimate goal of ABNE is to enhance agricultural productivity and livelihoods of smallholder farmers, while safeguarding human health and the environment.

How ABNE was established

Planning phase

ABNE was established through a consultative process with diverse stakeholders including high-level government officials, policy makers, regulators, scientists and academic specialists, NGOs, private sector, farmers, and consumer organizations. The Bill and Melinda Gates foundation (BMGF) awarded a one-year planning grant to NEPAD and Michigan State University (MSU) to jointly establish ABNE. As an international partner of NEPAD, MSU has been closely working with the ABNE.
The establishment of ABNE was officially endorsed by the African governments and was approved by the African Ministerial Council on Science and Technology (AMCOST) in 2008 to promote advancement of science and technology for agricultural development in Africa. During the planning phase, as a part of the consultative process, country visits and surveys were conducted to identify biosafety needs and gaps of African regulators and design biosafety services that are tailored to meet these needs.

Burkina Faso was identified as a suitable location for the first node to serve as the secretariat of the ABNE service network. A host country agreement was signed between NEPAD Agency and the Burkina Faso government to accommodate the first ABNE Node on the campus of the University of Ouagadougou. Establishment of the ABNE service network was guided by a six-member Technical Advisory Committee (TAC) appointed by AU/NEPAD representing all of the five sub regions of Africa. A representative of the African Union also serves on the TAC.

The team building process for the ABNE service network included a one-year long-term training of four young scholars from Africa at Michigan State University. The four scholars represented backgrounds in four key areas of biosafety and biotechnology including environmental safety, food safety, socio-economic, and legal/policy aspects.

As indicated earlier, multiple approaches were undertaken to obtain input from African regulators to determine their biosafety needs and gaps towards making informed decisions on GE crops and products. The approaches included:

- Face-to-face consultations in 17 different countries that had functional or interim biosafety frameworks,
- Survey instruments,
- A review of past assessments on biosafety capacity building needs conducted by various projects and service providers, and
- An Africa-wide regional workshop with regulators and stakeholders to verify the findings from the first three approaches used.

A summary of the biosafety needs and gaps revealed by these assessments are presented below.

- Provide access to science-based information on the environmental biosafety and food safety aspects of biotechnology products, in addition to information on the socio-economic impact of agricultural biotechnology products.
- Establish systems for the handling and review of biosafety applications including:
    - Adapting biosafety administrative processes to specific national systems
    - Developing Standard Operating Procedures (SOPs) for handling and review of biosafety applications
    - Providing technical assistance in making national biosafety secretariats operational
- Provide training and capacity building for regulators (members of NBCs, IBCs, and PQs) in risk analysis encompassing risk assessment, risk management and risk communication, including:
    - Interpretation of environmental biosafety and food safety data submitted to regulatory institutions, including applications for confined field trials (CFTs), commercial releases, and importation of food and feed
    - SOPs and guidelines for risk assessment, risk management and risk communication
- Facilitate networking and interactions among regulators within and between countries, and enhance interactions between regulators and scientists.

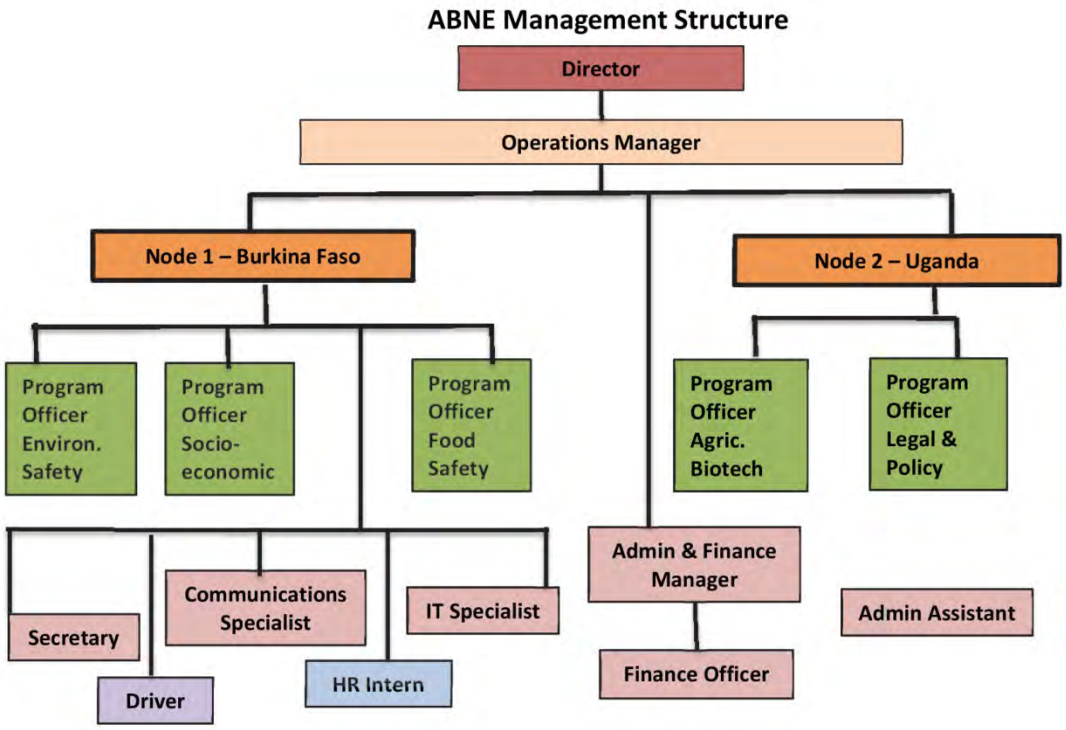
Based on the biosafety needs identified through the consultative process, a five-year implementation plan was developed by the NEPAD-MSU Partnership and submitted to the BMGF. This plan was approved and a five-year grant was awarded in July 2009 for the implementation of ABNE service network.

Implementation phase – Operation of the ABNE service network

ABNE was implemented as an Africa-based, Africa-owned and Africa-led initiative with the overall goal of building functional biosafety systems in Africa. From the onset, it was decided that ABNE would serve as a "network of expertise," like the hubs and spokes of a wheel, to serve regulators on the African continent for optimizing the use of existing expertise and capacity. The ABNE services include biosafety information resources, technical consultations, training and education, and networking/linkages opportunities to empower regulators and policy makers with science-based information. These services are targeted to the members of National Biosafety Committees (NBCs), Institutional Biosafety Committees (IBCs), and Plant Quarantine Officers (PQs). The ABNE services are offered by a team of biosafety specialists based at ABNE first node in Burkina Faso and later in Uganda, in collaboration with national governments, regional

economic bodies, NPCA's African Biosciences Initiative (ABI) networks and other biosafety service providers. The Burkina Faso node was established in 2009 and the Uganda node was established in 2012.

Figure 2. An organogram illustrating the structure of ABNE management and staff.



International partners and links to other biosafety service providers

Michigan State University is the first international partner of ABNE. MSU has a long-standing commitment to working in Africa and building institutional capacity and human resources. MSU also has a strong commitment to harnessing new science and technologies and has a global network that is actively engaged in international agricultural research and development.

The ABNE service network also collaborates with other service providers and has developed memoranda of understanding (MoU) with a number of Biotechnology and Biosafety service providers in Africa and internationally. ABNE has signed MoUs with ISAAA, IFPRI/PBS, AATF, FARA/SABIMA, NABDA (Nigeria), CSIR (Ghana), AfricaBio, ICGEB. In addition, as a step towards offering and institutionalizing Biosafety training and education in Africa, ABNE has also signed or is in the process of signing MoUs with three African Universities in West and East Africa regions. These collaborations help enhance and expand ABNE services and training opportunities for regulators as well as bringing synergy and avoiding duplication of efforts.

Services offered by the ABNE network

The consultations and surveys with African regulators confirmed not only that the countries in Africa are at various levels of biosafety and biotechnology capacity, but also that even within the same country, the level of understanding of biosafety and biotechnology issues varied among the regulators and the agencies. The ABNE services are, therefore, based on the needs identified by the African regulators and policy makers

during the consultative process; as such they are demand-driven by member states. These needs are constantly evolving as the countries progress in terms of their use and management of biotechnology.

In addition, the networking activities of ABNE facilitate policy dialogue through participation of African regulators and decision makers in various fora and conferences at national, regional and international levels.

Information services – web site, policy briefs, publications

One of the greatest limitations that African regulators face is not having access to up-to-date science-based information on the environmental safety, food safety and other aspects of biotechnology. Understanding this limitation, ABNE provides access to scientific information to regulators and other stakeholders through their website at www.nepadbiosafety.net. In addition, ABNE develops policy briefs on regulatory aspects that are relevant to biotechnology and biosafety developments in Africa. These policy briefs are shared with African regulators through the electronic and print media and are also made available through the ABNE website at http://www.nepadbiosafety.net/policy-briefs.

ABNE hosts a documentation unit at its node in Ouagadougou, Burkina Faso that houses various publications and regulatory documents relevant to Africa. Furthermore, ABNE develops and updates information on the current status of biosafety in its focus countries ("ABNE in Africa" document at http://www.nepadbiosafety.net/abne/wp-content/uploads/2014/01/ABNE-in-Africa-2014.pdf). ABNE also develops and distributes newsletters and news bulletins that inform African regulators on the activities implemented by the ABNE service network.

Technical support – consultations

ABNE has critically evaluated the various needs of its focus countries and provides technical assistance either through focused workshops or one-on-one technical consultations. These interventions assist countries to step over the hurdles they are often faced with when developing functional regulatory systems. At the request of national governments, over the past four years, ABNE has provided a number of technical consultations towards the development of SOPs for handling and review of biosafety applications, drafting guidelines and regulations, and developing administrative processes for biosafety applications.

Training – workshops, short courses, study tours, internships conducted in Africa, and internationally

Biotechnology and biosafety are emerging areas. The background of members serving on NBCs, IBCs and PQs are diverse and many members have limited understanding and knowledge of biotechnology and biosafety. ABNE, therefore, has developed a basket of different training programs to cater for the variety of regulators of different countries and their various needs. Depending on the specific need, regulators have the opportunity to participate in workshops, short courses, internship opportunities and study tours within or outside Africa. Programs outside of Africa provide regulators with a wide range of biosafety and biotechnology experiences from around the world, especially in countries where the GE crops have been commercialized. Through more than 100 programs implemented during the past four years, ABNE has trained over 2200 regulators, policy makers and other relevant stakeholders that are part of the national biosafety regulatory systems in 11 focus countries in Africa.

As the countries in Africa move forward on biotechnology and biosafety, the need and demand for training is growing. To meet this growing need, the NEPAD-MSU partnership initiated a "training of trainer" (ToT) program to design and offer biosafety training programs for regulators and other stakeholders through African universities. The first and second of these short courses were offered at the Polytechnic University of Bobo-Dioulasso in Burkina Faso and at the Makerere University in November 2013 and July 2014,

respectively. These courses mainly focused on regulators and other stakeholders from 11 African countries. A Similar program is soon to be offered at the University of Ghana, Legon.

Networking – participation in international meetings and fora

Countries in Africa and around the world have accumulated a wealth of biosafety and biotechnology experiences and resources. Regulators from different countries can benefit from each other's information and experiences. ABNE provides networking opportunities to African regulators in various international meetings, fora and conferences. These networking opportunities also allow regulators to provide input on policy issues related to Africa. For example, ABNE has sponsored regulators' participation at important international meetings such as ISBGMO and COP-MOP where regulators from all over the world share their experiences and provide input on policy dialogue. ABNE has also organized special side events at international meetings on issues relevant to biotechnology in Africa. Furthermore, ABNE organizes a biannual Regulator-Scientist forum where key scientists and regulators get an opportunity to discuss scientific and regulatory issues pertaining to the new developments in the biotechnology field.

CASE STUDIES OF ABNE SERVICES OFFERED TO SPECIFIC COUNTRIES

Burkina Faso

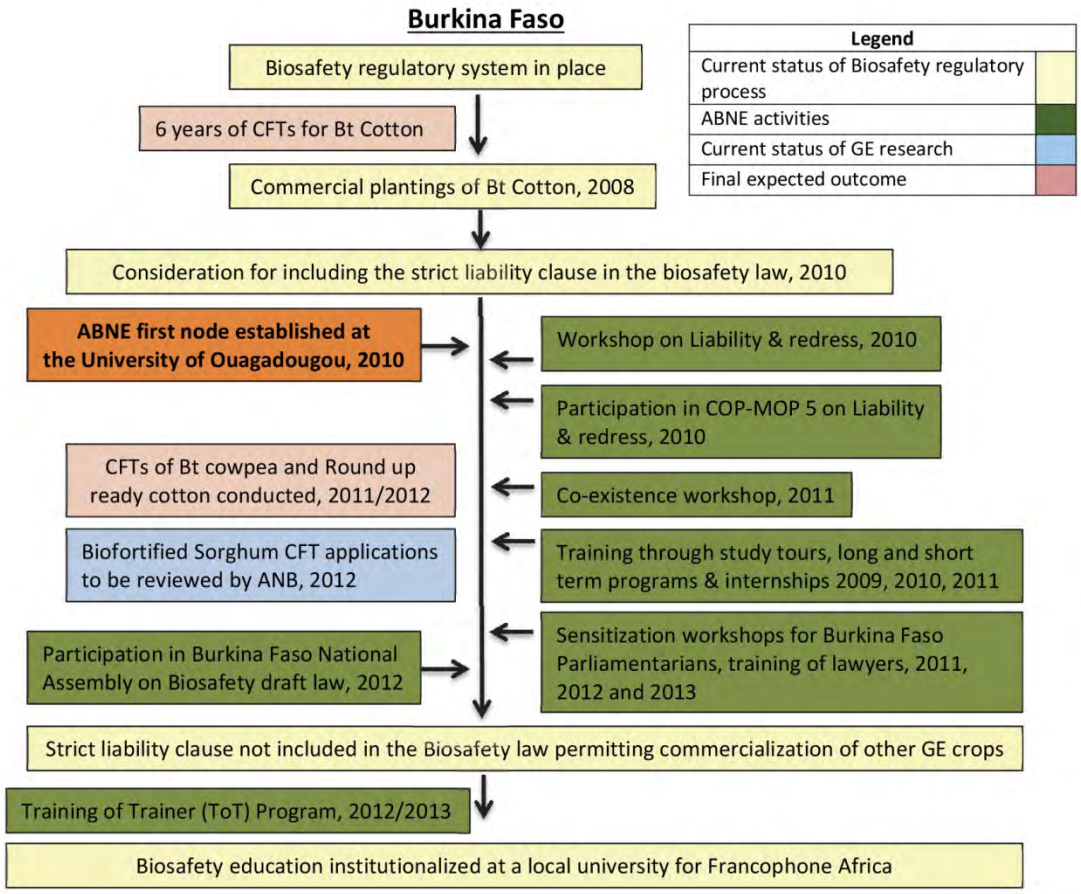
Burkina Faso is one of four countries in Africa that has approved commercial planting of GE crops. Farmers in Burkina Faso have been growing Bt cotton since 2008. The Biosafety Agency (Agency National Biosecurite or ANB) houses the NBC in Burkina Faso. In addition to Bt cotton, confined field trials are currently ongoing for *Maruca*-resistant cowpea and RoundupReady® cotton.

ABNE has been providing assistance to ANB towards enhancing their regulatory capacity. A number of training workshops, study tours and technical consultations have been provided to regulators in Burkina Faso (see Figure 3) and so far close to 400 regulators and other relevant stakeholders have directly benefited from ABNE services. Being the only country in West Africa with commercial plantings of Bt cotton, ABNE has facilitated study tours involving regulators from other countries in Africa to visit Burkina Faso to see Bt cotton in farmer's fields, interact with small-scale farmers and regulators to benefit from their experience.

Upon a request from the government of Burkina Faso, ABNE provided technical assistance in reviewing the country's revised biosafety law and made suggestions to bring it in line with international best practices by including the provisions of the Nagoya-Kuala Lumpur Supplementary Protocol on Biosafety. As a result, the country now has a fully workable policy that could potentially become a model for other francophone countries in the West Africa sub- region. ABNE is currently assisting the government of Burkina Faso in the inspection, monitoring and compliance of CFTs for food crops such as Bt cowpea and in the development of implementing regulations and the national biosafety communications strategy.

To help expand training and educational opportunities for regulators and decision makers, ABNE established a biosafety short course at the University of Polytechnic in Bobo-Dioulasso (PUB) in collaboration with the Agricultural Research Institute (INERA). To initiate this effort, two members from these two institutions worked closely with the ABNE team and MSU faculty members under the Training of Trainer (ToT) program and assisted in institutionalizing biosafety education and training at the university. A summary of the biotechnology and biosafety environment in Burkina Faso and the role that ABNE has played is illustrated in Figure 3.

Figure 3. ABNE's interventions in Burkina Faso

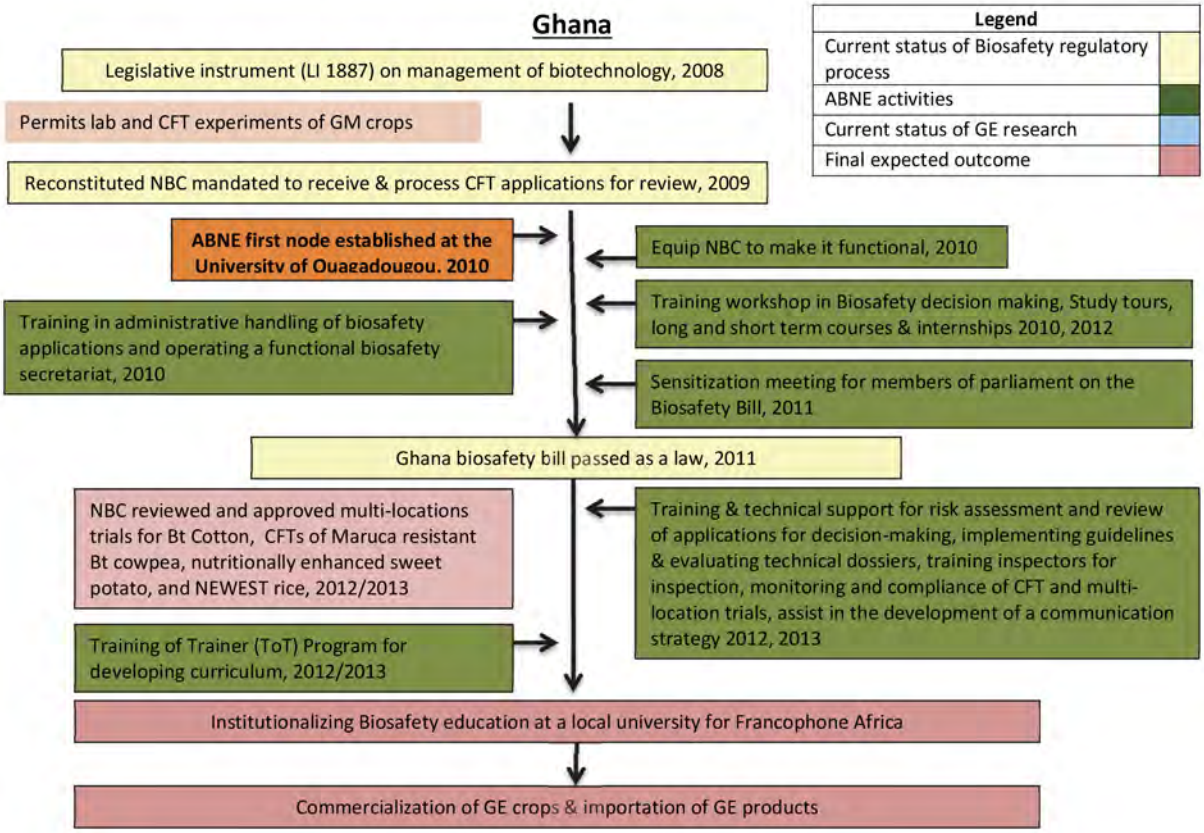


Ghana

The government of Ghana is taking positive steps towards moving biotechnology applications forward in key food security crops. In this context, ABNE is making a concerted effort to enhance Ghana's regulatory capacity for assessing safety of Biotech crops. Recently, the NBC of Ghana approved three CFT applications including *Maruca*-resistant Bt cowpea, nutritionally enhanced sweet potato, and the Nitrogen-use Efficient, Water-use Efficient and Salt Tolerant (NEWEST) rice.

During the past three years, ABNE has provided a diverse set of services to regulators in Ghana (see Figure 4). Thus far, more than 300 regulators, policy makers and other relevant stakeholders from Ghana have directly benefitted from ABNE services. ABNE's activities in Ghana have focused on providing strategic guidance on developing implementing guidelines and evaluating technical dossiers. With the training provided, Ghana became the first country in the sub region to make decisions on moving straight to multi-location field trials of Bt cotton after reviewing the data available on CFTs from Burkina Faso that has similar agroecological conditions. ABNE is currently in the process of assisting Ghana with establishing its National Biosafety Authority as the government of Ghana moves forwards making its regulatory system fully functional. Furthermore, as in the case of Burkina Faso, ABNE is working with University of Ghana to offer biosafety courses for regulators and decision makers. Two faculty members from the University of Ghana were a part of ABNE's ToT network to help institutionalize biosafety educational programs at local universities in Africa.

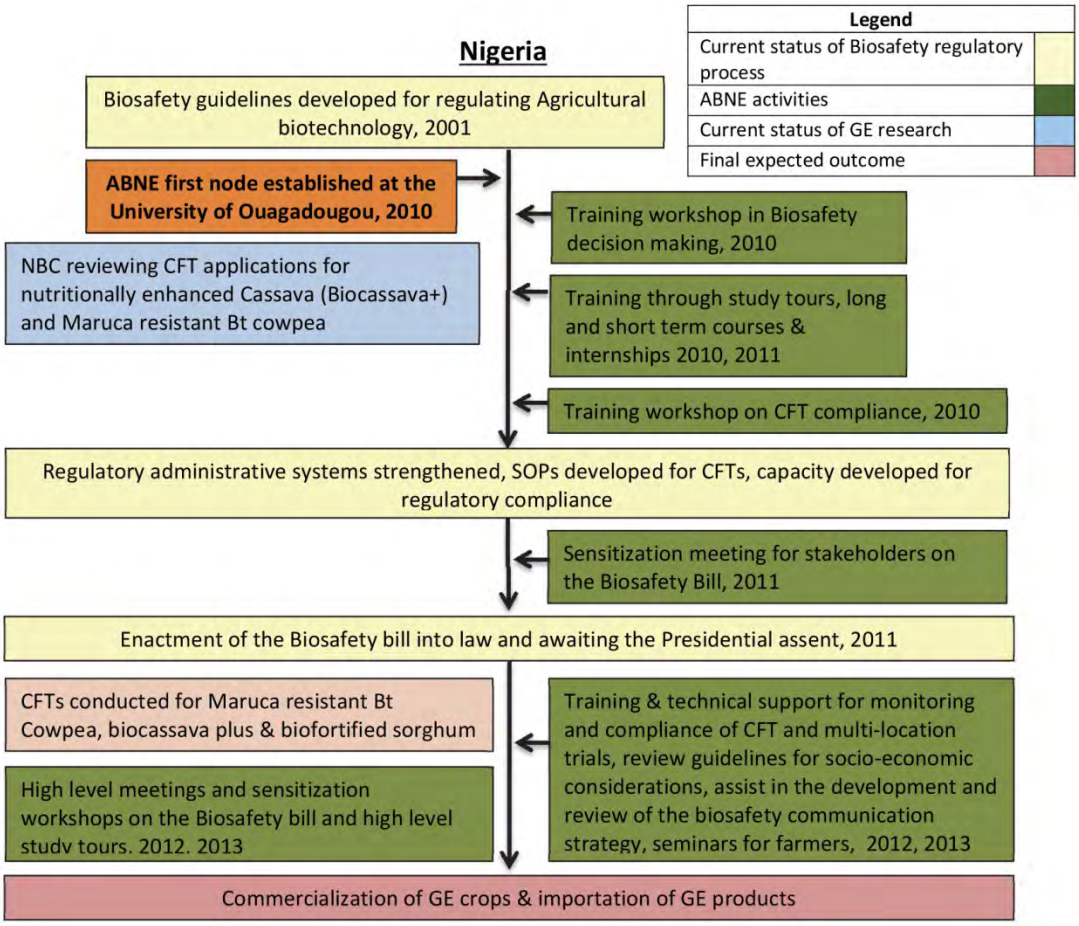
Figure 4. ABNE's interventions in Ghana



Nigeria

Nigeria developed biosafety guidelines as early as 2001 and the Senate passed the Biosafety Bill into a law in June 2011 but was not assented to by the Presidency for some technical reasons. The Bill is back in the National Assembly and it is hoped that it will be passed and assented to before the end of 2014. There are three CFTs currently being conducted in Nigeria including nutritionally enhanced cassava (biocassava+), *Maruca*-resistant cowpea, and biofortified sorghum, with plans to scale up and conduct multi-location trials in the near future. Nigerian regulators have requested ABNE's support for strengthening its regulatory administrative systems through providing assistance in sensitizing legislators, access to up-to-date information for decision-making, training in risk assessment and management as well as in the development of SOPs and guidelines for conducting CFTs. For the past four years, ABNE has been assisting with strengthening capacity of Nigerian regulators. More than 550 regulators, policy makers and other relevant stakeholders in Nigeria have benefitted from ABNE services. Future efforts of ABNE in Nigeria will focus on building a fully functional regulatory system. This will include providing support for creating an enabling policy environment for regulatory decision making, building a critical mass of trained regulators, and assist regulators in developing a biosafety communication strategy for enhanced cooperation among stakeholders. ABNE's interventions in Nigeria are highlighted in Figure 5.

Figure 5: ABNE's interventions in Nigeria



CONCLUSION

African governments are recognizing the enormous potential of biotechnology in terms of enhancing agriculture productivity and food security. During the past five years, there have been many positive developments on the biotechnology front in several African countries. More than 15 countries have now enacted biosafety laws and/or developed national biosafety frameworks that are in line with international best practices. Several countries have recently reviewed and revised their Biosafety policies and acts to meet the international guidelines and best practices. Countries including Ghana, Malawi, Cameroon, Burkina Faso, Nigeria Uganda and Kenya are moving forward with CFTs and considering multi-location trials and general release of GE crops.

The NEPAD Agency ABNE has established itself as a credible source of biosafety information and up-to-date training. NEPAD Agency and Michigan State University have developed an effective partnership for empowering African regulators and are partnering with other service providers to expand the ABNE service network. ABNE is emerging as a unique and new model of providing biosafety services to African regulators and policy makers.

With many positive developments on biotechnology in Africa, the need and demand for biosafety services is growing. Along with ABNE, a number of service providers are playing a key role in building regulatory capacity in Africa. There needs to be better coordination and communication among the various service

providers to avoid duplication and make efficient use of limited resources. Just as the need and demand for biosafety services are growing, it is important to strengthen African universities to offer biosafety and biotechnology education to regulators and other non-academic stakeholders. As the development of biotech crops move forward, more investments are needed in building capacity and infrastructure that would support risk assessment activities (food safety labs etc.). Stakeholders are demanding tools and resources for risk assessment, risk management and risk communication. This would require continued sharing of information and networking among regulators of different countries to exchange biosafety resources and experiences. African representation and input at international meetings related to biotechnology and biosafety is critical and needs to be further enhanced.

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Chapter 18. Capacity building in biosafety: African Union biosafety programme

BATHER KONE

INTRODUCTION

The implementation of the OAU/AU-GTZ/GiZ Biosafety Initiative, according to the agreement "Support to the AU in the Matters of Biosafety," was initiated by the Organization of the African Unity (later the African Union) as a regional approach to support its Member States in implementing Biosafety.

The birth of the initiative occurred during the last sessions of negotiation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and its early entry into force (between 1999 and 2003). It was implemented from January 2006 to February 2011.

BACKGROUND

The African Union is an Intergovernmental Organisation representing 54 Member States with the recent membership of South Sudan that occurred in 2011. The African Union Commission Headquarters is located in Addis Ababa, Ethiopia. The vision of the Commission is "to create an integrated, prosperous and peaceful Africa, driven by its own citizens and representing a dynamic force in the global arena". The mission of the Commission is to be "an efficient and value-added institution driving the African integration and development process in close collaboration with Member States, the Regional Economic Communities and African Citizens." The objectives stated in Article 3 of the Constitutive Act include:

- To achieve greater unity and solidarity,
- Accelerate political and socio-economic integration,
- Promote and defend African common positions,
- Encourage international cooperation,
- Establish the enabling conditions for Africa to play a meaningful role in the global economy and in international negotiations,
- Advancing the development of the continent by promoting research in all fields in particular in science and technology, and
- Promote sustainable development and the integration of African economies.

The mandate of the portfolio of the Department of Human Resources Science & Technology (HRST) within the AU Commission is the promotion and coordination of human resources development and science and technology policies, for the social and economic development of Africa. The policies are to enhance the integration process through programmes and activities that are perceived by Member States as reflective of their priority development objectives and political stability. The overall objective of the HRST is to establish priority and specific programmes that can be implemented in an effective manner in order to achieve regional integration and economic development.

African negotiators were very active during the development of the Cartagena Protocol on Biosafety which started in July 1996 in Aarhus, Denmark and finally concluded in January 2000 in Montreal, Canada. In February 1999, when the negotiations of the Cartagena Protocol on Biosafety were stalled, the African Group in the Convention for Biological Diversity and the Organization for African Unity (OAU) as it was called then started to develop the African Model Law on Safety in Biotechnology. Its primary purpose was to provide for a harmonized approach towards biosafety in Africa serving as a model legal instrument for developing national biosafety legislations in case the international negotiations would fail. The first draft was developed by an OAU workshop of experts from Africa and other developing countries in Addis Ababa in

June 1999. This draft was based on the proposal of the African Group for a biosafety protocol, which it submitted to the CBD Secretariat during the 3rd Conference of the Parties in Buenos Aires in 1996 and which was introduced at the second meeting of the working group to negotiate the Biosafety Protocol in 1997. In May 2001, this draft was finalized by an OAU working group in Addis Ababa, with 50 participants from representing 28 African governments, 34 representatives of NGOs, scientific institutions, and the biotechnology industry as well as 5 representatives of the OAU and UNEP.

The period 1999 – 2001 was marked by the lack of knowledge on the status of GEO introductions in Africa, the lack regulation at national and regional as well as continental levels and the concern of Africans to let the continent open to illegal introduction of GEOs. It was felt that the Cartagena Protocol on Biosafety, as an internationally negotiated legally binding agreement, sets only minimum standards "*to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from the modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specially focusing on transboundary movements.*" Furthermore, the Cartagena Protocol on Biosafety did not address key issues important for Africa like the domestic GEOs, the contained use, the deliberate releases into the environment and labeling of food consisting of or derived from GEOs.

It is in this context that the OAU, based on its awareness on various challenges faced by Member States including weaknesses of regulations and lack of capacity, developed the first version of the African Model Law entitled "*African Model Law on Safety in Biotechnology*" in July 2001 and later on the "*Decision on the Report of the Interim Chairperson the Africa-wide Capacity Building in Biosafety, DOC.EX/CL/Dec.26 (III)*, in Maputo in July 2003. The implementation of that decision led to the AU-GTZ/GiZ agreement on the Project "Support to the African Union in Matters of Biosafety" in August 2004.

Unfortunately, the African Model Law, instead of encouraging open dialogue between stakeholders on the real opportunities and risks associated with the use of the modern biotechnology in Africa, partitioned the continent into two camps, strict opponents and strict proponents to biosafety/biotechnology/GEOs with very little dialogue between the two groups.

At the same time other activities were initiated such as:

- The African Position on Genetically Modified Organisms under the Department of Rural Economy and Agriculture (DREA),
- The African Biosafety Network of Expertise under the New Partnerships for Africa's Development Planning and Coordinating Agency (NEPAD/NPCA), and
- Programmes related to biotechnology/biosafety under the various Regional Economic Communities (Southern African Development Community, Common Market for Eastern and Southern Africa, Economic Community of West African States, West African Economic and Monetary Union).

Objective

The objective of the project was "to support the African States to ensure safety in use, handling, and transfer as well as research and development of genetically modified organisms and products thereof. This support is given by the African Union which is going to incorporate the topic biosafety into its political and institutional frameworks and into its services for the Member States." In other words, to provide the AU necessary capacity and efficient instruments to assist its' Member States in the implementation of the Cartagena Protocol on Biosafety and the African Model Law on Biosafety, with an ultimate aim that the AU integrate biosafety issues in its regular policies and programmes.

African Union Biosafety Project: "Support to the AU in Matters of Biosafety"

Decision EX/CL/Dec.26 (III), the EXECUTIVE COUNCIL Third Ordinary Session, 4 -8 July 2003, Maputo Mozambique

DECISION ON THE REPORT OF THE INTERIM CHAIRPERSON ON THE AFRICA-WlDE CAPACITY BUILDING IN BIOSAFETY DOC. EX/CL/31(III)

The Executive Council:

1. TAKES NOTE of the Report;
2. STRESSES the need for Member States to equip themselves with the necessary human and institution al capacities to deal with Biosafety issues within the framework of the implementation of the Cartagena Protocol on Biosafety;
3. ENDORSES the steps so far attended at national, regional and continental levels aimed at putting in place an Africa-wide Biosafety System as weIl as an Africa-wide Capacity Building Programme in Biosafety in order to strengthen the abilities of Member States to deal with Biosafety issues;
4. URGES Member States, in abiding by the provisions of the Cartagena Protocol, to use the African Model Law in Biosafety prepared by the AU Commission as a basis for drafting their national legal instruments in Biosafety, taking into account their national peculiarities, in order to create an harmonized Africa-wide space and system in Biosafety for the regulation of Genetically Modified Organisms movement, transportation and importation in Africa;
5. APPEALS to the developed countries, particularly Africa's development partners willing to assist Africa in this endeavour, to grant the necessary resources as weIl as financial and technical support towards the implementation of this programme;
6. REQUESTS the Chairperson of the Commission to convene a meeting of Experts and Civil Society Organizations to give further consideration to this issue and come out with proposals for an African Common Position for adoption by the policy organs of the African Union;
7- ALSO REQUESTS the Chairperson of the Commission to ensure sustainability of the programme on Capacity Building in Biosafety in Member States and ensure that Council is regularly informed on annual basis.

Implementation Strategy

The AUC-HRST Biosafety Project was based in the Department of Human Resources Science & Technology, which brought the project under the umbrella of the African Ministerial Council for Science and Technology (AMCOST), while the Cartagena Protocol on Biosafety is, in the majority of cases, under the Ministries of Environment in Member States. The African Ministerial Conference on the Environment (AMCEN) is linked to the Department of Rural Economy and Agriculture (DREA) and in the negotiations of the Protocol the environmentalists and the scientists (supporting the technology) were not necessarily on the same side.

As soon as the Biosafety Unit was established, part of the project implementation strategy was to create a Technical Advisory Committee with membership from different institutions and perceptions to provide guidance to the project activities and the interdepartmental cooperation. The project has been engaged in the development of African Strategy on Biosafety and the review of the original "African Model Law on Safety in Biotechnology." Due to the limited time and funding of the project, the aim was first to provide Member States with overall technical documentation to implement the Cartagena Protocol on Biosafety; and second, since the original version of the Model Law was perceived very negatively by some stakeholders, even though there is nothing in it contrary to the Cartagena Protocol, it was felt necessary to revise it in order to make it more acceptable, taking into account the entry into force of the Cartagena Protocol, the new developments in Member States, the Regional Economic Communities (RECs) as pillars of the African Union and at the international level.

The followings key developments commended the revision of the Model Law:

- The Cairo Declaration of the Extraordinary Conference of the African Ministerial Council on Science and Technology (AMCOST) which re-affirms that science and technology are key to socio-economic development,
- The AU decision EX. CL/Dec. 26 (III) calling for an African common position on biosafety and resolving to have common approach to address issues pertaining to modern biotechnology and biosafety,
- The progress made by the UNEP-GEF project on building national biosafety frameworks with emerging draft national biosafety regulations developed in Member States,
- The countries dealing with food aid and trade issues related to GEOs,
- The will of African countries to invest in biotechnology as spelt out in some sub-regional initiatives and at the AU level,
- Some RECs have taken on biotechnology and biosafety in their mandates engaging in its development and common approach, and
- Some Member States were in position to commercialize GEOs or research projects on them.

Within such an environment there was no other alternative for the Project but to involve as many stakeholders as possible in the implementation activities. This includes the RECs, the Civil Society Organizations, and stakeholders with different responsibilities and backgrounds from Member States.

Pillars of Activity

The Biosafety Unit developed activities based on the following six key Pillars identified in the African Strategy on Biosafety:

- Capacity Building and Preparedness for Negotiations,
- Awareness Raising and Biosafety Information Exchange,
- Establishment and Strengthening of Institutional Frameworks,
- Policy and Legal Frameworks,
- International Cooperation, and
- Sustainability Mechanism.

From 2006 to 2011, the activities undertaken under the six pillars included the following:

- Development of African Strategy on Biosafety which clearly outlines the major domains and the roles and responsibilities of the various actors to implement biosafety in Africa namely, the AUC, RECs, MS and international partners;
- Establishment of a Technical Advisory Committee on Biosafety to provide guidance to the project;
- Revision of the African Model Law on biosafety through an Africa wide participatory process;
- African preparatory meetings before international negotiation sessions in collaboration with the CBD Secretariat;
- Regional Training Courses on risk assessment and risks management of genetically modified organisms organized in collaboration with the RECs (SADC, ECOWAS-WAEMU) and Civil Society Organizations (RAEIN Africa, COPAGEN);
- Issue Papers on Biosafety thematic areas produced to support Member States' National Focal Points in implementation of Biosafety: Seven thematic areas: "A Guide to Genetic Engineering," "Biosafety Risk Assessment," "Identification and Labelling in Biosafety," "Compliance and Dispute Settlement Mechanisms for Biosafety," "Precautionary Principle," "Public Participation in African Biosafety Regulation and Policies" and " Liability and Redress for damage resulting from living Modified Organisms;"
- Regional Meetings organized with the RECs (CEN-SAD, ECOWAS-WAEMU, SADC, EAC) to present the Revised Model Law and discuss Harmonization/Coordination of Biosafety Issues in Africa;

- Interdepartmental collaboration with the Department of Rural Economy and Agriculture-Multilateral Environment Agreements' Project (DREA-MEAs): support to develop national and additional policy on biosafety;
- Collaboration with the GiZ Access and Benefit Sharing (ABS) Capacity Development Initiative for Africa to develop guidelines on ABS that will serve as modification of the OAU Model Law on ABS;
- Ongoing partnerships with the EU Joint Research Centre on the issue of Harmonization of GEO Detection and Analysis for African Countries;
- Presentation of the project progress to AU Organs: AMCOST, AMCEN.

Achievements/Results

The Project did become involved in the activities of key institutions having biosafety and biotechnology issues in their portfolio, including the Regional Economic Communities and Civil Society Organizations in organizing key activities as well as contributing to the production and dissemination of relevant documents. Among the organisations worked with were the following:

- Community of Sahel-Saharan States (CEN-SAD);
- Economy of West African States (ECOWAS);
- West African Economic and Monetary Union (WAEMU);
- Southern African Development Community (SADC);
- East African Community (EAC);
- Regional Agricultural and Environment Initiatives Network-Africa (RAEIN-Africa);
- Coalition pour la Protection du Patrimoine Génétique (COPAGEN);
- Réseau Interdisciplinaire de Biosécurité (RIBios);
- African Centre for Biosafety (ACB);
- NEPAD Agency African Biosafety Network of Expertise.

The project identified the following achievements that have been made since 2006:

- Strong African common positions were achieved and supported to reflect in international negotiations on Supplementary Protocol;
- More than 90 African experts benefited from exchange of experiences and development of capacities in the application of biosafety risk assessment and management techniques;
- The training courses on risk assessment and risk management of GEOs benefited more than 95 participants from 31 African countries;
- The issue papers used as technical tools in published materials, electronic copies accessible through the website for the use at national level;
- Agreement was reached that RECs should mainstream biosafety in their priority actions and coordination on biosafety issues to be established and led by the AUC;
- Continental Coordination meetings for biotechnology/biosafety, including Phytosanitary Measures and Food Safety and Animal Health;
- The African Strategy on Biosafety and the Model Law provide roles and responsibilities on biosafety for the RECs with key areas of activities;
- Many African countries have borrowed provisions from the African Model Law in the development of their national laws on biosafety;
- The discussion on the revision of the Model Law presented an opportunity where Member States also considered the need to amend national laws based on developments at the international level;
- Transboundary control of GEOs is to be annexed to the Revised African Biosafety Model Law for Member States to apply as current guidelines in implementing biosafety domestically;
- Increasing international visibility of the AU's mandate and leadership roles, to coordinate biodiversity, biosafety and related issues in the continent;

- Recommendations from AMCOST and AMCEN, and relevant Executive Council Decisions based on the project activities;
- Sustainable cooperation established with the Secretariat of the Convention on Biodiversity in preparing Africans Delegates for its sessions;
- Partnership underway with EU-JRC on Harmonization of GEO Detection and Analysis (capacity building and regional/continental networking);
- Standard Partnership with the Secretariat of the Convention on Biological Diversity to support Member States in international negotiations; and
- Finally a P2 Permanent Position on Biosafety has been adopted in the AU Commission Structure.

It is also important to note that various declarations/decisions have been adopted by various bodies of the AU since 2006, including the following:

- AMCOST-Cairo Declaration of November 2006, commitments included " to develop and harmonize national and regional regulations that promote the application and safe use of modern biotechnology;"
- AMCOST Ministerial Decision of November 2007 and the Executive Council Decision , requested "the AUC to present the revised African Model Law on Biosafety to all relevant Ministries for their comments, calling upon the AUC to provide leadership on biosafety issues and institutionalize a Biosafety Unit within the Commission;"
- The Executive Council Decision of January 2008 , allocated budget line on the " Integration of the Biosafety Unit within the HRST;"
- The 12th Session of the AMCEN in June 2008, requested "the AUC to take a leadership role in spearheading the development and implementation of biosafety strategies and policies and institutionalizing biosafety in its programs".

CHALLENGES TO SUSTAIN EFFICIENT BIOSAFETY SYSTEMS IN AFRICA

The major challenges to sustain efficient biosafety systems in Africa are mainly funding issues and the commitment to establish an efficient and functional coordination mechanism.

The support from the GiZ was provided to let the African Union start the implementation of biosafety policies and program, it was expected to be a long term support. This support came to an end officially in February 2011. Thereafter, the Unit got a one-year support from the EU and biosafety activities came to an end. The only way to sustain biosafety issues in the Commission and to guarantee biosafety without conflict of interest is that Member States themselves provide the necessary funding to implement its biosafety activities with the possibilities of establishing a continental coordination with the RECs.

After that there is a need for a full commitment of Member States to agree on minimum requirement for an effective regional approach to biosafety/biotechnology issues, at least the obligation to share information and the right to information for all countries and citizens.

International partners' funding can be complementary to the efforts of Member States, but such funds should be unconditional to avoid any conflict of interest. If not, it will be 'like asking a mosquito to develop mosquito repellent.'

CONCLUSION

It is evident that Africa needs food security, but it should be through minimum risks and safe application of the technology. The other important issue is capacity building on biosafety and biotechnology experts on technology development adoption and risk analysis.

The African continent needs on biotech/biosafety are many, including Risk Assessment and Risk Management, Public Awareness and Participation, the Socio-economic Considerations, GEO Detection and Analysis, among others. Unfortunately, the biosafety initiatives rely mainly on donor support which cannot cover all the needs.

It is encouraging and positive to see that the dialogue on biosafety and biotechnology issues in Africa is moving from stalemate to a more open dialogue between the opposing groups. This is the only way to achieve positive results on the continent. Africa needs biotechnology but along with it also is the appropriate biosafety measures - this should be the core of dialogue and initiative.

In Africa, at present we have a number of countries with commercial releases, countries conducting confined field trials and countries in the process of adopting the gene technology. Knowing that the countries have interlinked economies, and the status of borders and neighbourhood between countries sharing the same ethnic groups and farming systems across these borders, may render biosafety systems inefficient if there is no regional and continental approaches. Such an approach will maximize the use of the scare capacity, resources and funding that is available. Of course, it needs the time and commitment of all the stakeholders, starting with the biosafety initiatives of the African Union and the NEPAD Planning and Coordination Agency's project "African Biosafety Network of Expertise," initiated in 2008 and endorsed by the AMCOST.

It is in this context that the Biosafety Unit, within its new broadened mandate of Life and Earth Sciences Unit, will continue the following activities, which have already been started, if funding is secured:

- Interdepartmental collaboration for additional policy documents on biosafety issues and the establishment and functioning of a Continental Coordination Committee on biotechnology/biosafety, Phytosanitary Measures, Food Safety and Animal Health;
- Follow up the process of the revised Model Law within the AU (process for new adoption), including submission to other organs;
- International Cooperation with the SCBD and the EU-JRC on support to Member States in the process of the Convention on Biological Diversity and GEOs Detection and Analysis;
- Facilitate organization of training courses in thematic areas of biosafety and biotechnology.

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Chapter 19. Capacity building in biosafety: Ensuring the sustainability of GE technologies in Africa – a systems approach based on South African experiences

JAN-HENDRIK GROENEWALD AND BEN DURHAM

INTRODUCTION

Modern biotechnology and specifically the genetic modification of crops, micro-organisms and animals hold great potential benefits, but the lessons from Africa, where the commercial release of genetically engineered (GE) crops is still very limited nearly 20 years after they have been introduced, clearly illustrate that mere benefits are not enough to ensure their acceptance. This chapter argues that for sustainable introduction of genetically engineered organisms (GEOs) in Africa, there is a need for a systems-thinking approach, an approach which recognises the enormous complexity and interconnectedness of actors and stakeholders, institutions, practices and cultures within the receiving environment and market forces, trade issues and environmental concerns, in order to strategically position this introduction.

The South African experience, where GE crops were first commercialised in 1997, offers some critical lessons which should guide further developments nationally and may prove instructive to other countries on the continent.

SCIENCE TRADITION IN SOUTH AFRICA

South Africa has a long history of science development. In the mid 1940's, the Council for Scientific and Industrial Research (CSIR) was created with a mandate to develop science for South Africa. The agency function for supporting academic research was subsequently outsourced to the Foundation for Research Development (FRD, now the National Research Foundation, NRF), as a means of 'professionalising' support to academics. More recently the Technology Innovation Agency (TIA) was created as an agency to stimulate and support the commercialisation of science-based innovation.

In a significant break with the past, the White Paper on Science & Technology (1996) refocused the South African scientific effort towards the broader national objectives and socially relevant research. The resulting Research & Development Strategy of 2002 identified the need for a national system of innovation approach. The National Biotechnology Strategy (2001) specifically focussed attention on the commercialisation of biotechnology, and resulted in the establishment of four biotechnology regional innovation centres (BRICs), which were the principle agents of the strategy. In addition, the Department of Science & Technology (DST) created the Public Understanding of Biotechnology (PUB) programme, with the objective of raising the public's awareness of biotechnology and to stimulate engagement around several of the technologies. While the BRICs were mandated to promote the responsible utilisation of biotechnology, the PUB programme was specifically limited to promote evidence-based perspectives, favourable or not, on biotechnology. More than a billion Rand has been invested in the National Biotechnology Strategy since 2003 and DST funding is currently continuing in excess of 270 million Rand per year.

Legislation relevant to GEOs

The GMO Act, 1997 (Act No. 15 of 1997) came into effect in 1999 and provides the biosafety framework for the introduction and responsible use of GEOs in South Africa. It is complemented by a variety of other legislation that has specific implications for GEO risk assessment, introduction and management. For

example, the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004), which regulates aspects of environmental biosafety and environmental risk assessments; the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) relating to food safety; and the Consumer Protection Act, 2008 (Act No. 68 of 2008), relating to the labelling of goods containing GEOs.

Despite this broad and strategic national approach, South Africa has had numerous system and technical failures. To date only three crops, maize, soybean and cotton, with various combinations of only two GE traits (insect resistance and herbicide tolerance) - all the products of multinational companies - have received general release status in South Africa. GE maize, soybean and cotton are grown on 2.364 (86.6% of total), 0.478 (~92% of total) and 0.008 (100% of total) million hectares respectively (James, 2013). Despite the apparent successful deployment of these GE crops, few new GE traits and crops are in the pipeline and technology developers, particularly in the public and academic sectors, seem to be fairly pessimistic about their potential to develop new GE crops.

System flaws

Failures of the South African system relate to the interpretation and application of GE related policies and legislation rather than the structure or intent thereof. Although the focus of the GMO Act is, for example, on the "responsible utilisation" of GE technology, the regulatory framework has seemingly adopted a more precautionary approach and currently focuses more on risk assessment than having a balanced risk-benefit assessment. This is especially evident in the varying approaches of the individual government departments involved in the regulatory framework, based on their divergent views regarding national imperatives and related policies, which results in discordant visions for the regulatory framework. In addition, the isolated but vocal criticism of anti-technology groups against GE technology and related industrial developments has increasingly placed pressure on political decision makers, further eroding the scientific-basis of the risk analysis process (Aerni, 2005).

As a result, the original science-based biosafety assessment of GE products has evolved into a highly detailed and often convoluted process which impacts directly on the timeframes, costs and complexity of the GE innovation system. The disproportionate large focus on socio-economic and socio-political issues has also greatly expanded the influence of regulations, that initially only focused on safety issues. Where local GE technology developers initially focused almost exclusively on the technical barriers of GEO development, they are now starting to realise that the complex, costly and often unpredictable regulatory process for GE products could be an even more daunting challenge to commercialisation. One of the potentially most valuable advantages of GE technology is that it could place an unlimited number of genetic traits into organisms relevant to a wide variety of specific requirements, but this potential is seriously constrained by the complexity and costs associated with the current regulatory environment.

WHY A SYSTEMS APPROACH?

Systems-thinking, the recognition of the complex dynamics and interrelationships between components of a system and the various influencing factors is becoming increasingly necessary in the 21st century global environment. The growing linkages and relationships between industry, government regulators and academic actors (the triple helix, for example) have dramatically increased the complexity of any given sector and globalisation has increased the competition within and between markets. While simplistic 'market failure' solutions can successfully address a challenge in a functioning system, or in a single value-chain process, the complexity of many systems suggests that simplistic interventions may not have the desired effect, or may result in unintended consequences.

The offering of GEO crops as the solution to Africa's food security dilemmas is one such example of a linear approach, which has had the unintended consequence of provoking a storm of anti-GE sentiment (Scoones,

2008), raised perceptions of multinational exploitation, and provoked African governments to adopt an extreme precautionary approach, effectively stifling any opportunity for GEO's to be gainfully adopted.

While particular countries will vary on their attitude to GE crops, the sustainable development of GE crops for Africa will require a holistic systems approach which includes at least the following interrelated elements:

- Government ownership of and participation in, agricultural solutions.
- Market analysis and local industry participation.
- Local research participation in GE crop developments.
- Local biosafety research capacity development.
- Science communication.

In other words, it needs a systems approach which requires an interactive, non-linear process in which actors, (*e.g.* entrepreneurs & companies), interact with a variety of other organisations (*e.g.* research institutes, customers, regulating authorities, financial organisations) in multiple cultural and/or practical settings (*e.g.* intellectual property rights, regulations, culture and scientific literacy). This complex process, characterised by reciprocity and feedback mechanisms, determines the success of innovation (Woolthuis *et al*, 2005).

CONSIDERATIONS FOR REGULATORY DECISION MAKING

Regulation of the introduction of GE crops is then a complex matter fraught with all sorts of danger. To illustrate the interconnectedness of these issues from a regulatory perspective, three main components to the decision-making process can be identified.

Evaluation of the science-based risk assessment

Providing the information in the application is appropriate and contains the necessary detail, this is the relatively straight forward component within the decision-making process. In South Africa this is supported by a "Scientific Advisory Committee" (SAC), which comprises independent scientists with relevant expertise, who have been trained in biosafety, and which makes recommendations to the Executive Council (EC), the decision-making body. All GEO introduction applications are sent to a subcommittee of the SAC, the members of which are unaware of fellow members and hence unable to discuss the application between themselves (as a further means of addressing independence of thought). The members forward their individual evaluations and recommendations (or questions to the applicant) to the chairman of the subcommittee, who will review the comments and compile a final recommendation (which nevertheless includes each reviewer's comments) to the EC.

Evaluation of the application for alignment with policy

This component is done by each of the national government departments represented on the EC (Agriculture, Forestry & Fisheries; Health; Environmental Affairs; Science & Technology; Trade & Industry; and Labour), and each will independently submit their recommendation to the Registrar of the GMO Act in advance of, or at an EC meeting. This component also deals with the consideration of the likely socio-economic impacts of the introduction of the GEO in question. Such socio-economic considerations incorporate reflections on alignment with national strategies, policies and legal frameworks. Also included in this section are stakeholder perspectives; consideration of job creation/loss implications, possible industry/trade impacts and risk management requirements. Although a department's decisions are brought to the meeting of the EC, the meeting affords discussion on the application and there remains the scope for any department's decision to be affected by the discussion.

The above two components introduce relatively minor uncertainties into the decision-making process. It is suggested, however, that the third component has significant, if unquantifiable impact, particularly across Africa.

Social conscience issues

This includes a wide spectrum of psycho-social issues that are usually not overtly addressed. They originate from the widely diverging opinions available in the broader social context and include religious, ethical and societal perspectives on genetic engineering. As part of the range of cultures and social institutions that make up the agricultural system, such perspectives can have a significant impact.

The uncertainties and ambiguities in a psycho-social component of biosafety is given credence - with the best intentions - in the adoption of the precautionary principle of the Rio Declaration on Environment and Development (June 1992), which states in Principle 15:

> *In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation*.

Rather than determining whether the threats are indeed serious, this principle can be used by regulators to block GEO introductions.

Although literacy in South Africa has increased significantly to a total of nearly 89% of adults in 2007 (UNESCO), with expenditure on education amounting to 19.2% of total government expenditure, the majority (80%) of South Africans do not understand the term biotechnology or genetic modification (Public Understanding of Biotechnology survey, 2004) and have a poor scientific literacy. This then, is a rich feeding ground for polarising viewpoints on genetic modification, particularly as the media (including the internet), after universities and before the government, was perceived by the public as providing trust-worthy information. The African Centre for Biosafety, for example, is a South African based NGO that "campaigns against the genetic engineering, privatisation, industrialisation and corporate control of Africa's food systems and commodification of nature and knowledge," which has publications and information on its website (such as "*Hazardous Harvest: Genetically Modified Crops in South Africa: 2008-2012;" "The dirty politics of the global grain trade - GM maize farmers face ruin in SA*") that provide an alarmist perspective on genetic engineering (www.acbio.org.za).
AfricaBio, a pro-biotechnology stakeholder grouping, in contrast promotes the "safe, responsible and ethical use of biotechnology" and concludes that responsible biotechnology is beneficial in publications such as "GM crops: Addressing your concerns in SADC" and "How Genetic Modification Impacts On Sustainable Agriculture" (www.africabio.com). The polarising controversies undoubtedly provoke confusion and uncertainty in the social conscience, particularly when there are, as in South Africa, a wide range of distinct language and cultural groupings in society.

As uncertainties can have a significant impact on decision-making, the lack of biosafety education and skills, as is widespread in Africa, could have a dramatic effect on the introduction of GEOs to the continent (Bontempi et al, 2010; Black et al, 2011). Recognising certain of these problems, some multinational companies have offered conditional royalty-free licences for their patented traits to certain African countries (Eicher et al. 2006), presumably as a means of demonstrating goodwill and assisting the development of local capacity. The uptake, however, has been limited and slow, most probably due to the systemic failures associated with the introduction of GEOs as discussed above.

A SYSTEMS APPROACH TO ENSURE THE SUSTAINABLE UTILISATION OF GE TECHNOLOGY

A systems approach needs to take account of all possible differences and peculiarities in a particular country, but should include approaches to address at least the following.

Political buy-in and policy alignment

Government-wide support is a critical element in the commercialisation of GE crops. Most importantly it includes overt political leadership, with clear accountability at very senior levels to engender the public's trust, but it also relates to a wide range of issues, such as policy alignment, IP protection, trade considerations, regulatory competence, etc. While biosafety capacity in Africa is limited (Black et al. 2011), there is significant international support and goodwill to assist Africa and it should not be an insurmountable constraint.

A key approach to developing such leadership is through senior level coordination, such as the EC of the South African GMO Act, where the various government ministries have the opportunity to discuss and resolve a uniform approach to the wide range of issues raised through any particular GEO application.

A market focus

The biosafety of any GE crop, defined in terms of its food/feed and environmental safety, is an indispensable element of its sustainability and is a focus in all regulatory frameworks. In principle these two aspects of biosafety are interpreted and regulated similarly in most territories. However, to be sustainable in the true sense of the word, a GE product should also be acceptable to all its intended consumers and be of some value to them to ensure its long-term utilisation. Such value could be direct or indirect economic benefits or a wide range of possible social benefits related to agricultural practices and/or food-security. In contrast to the biosafety aspects, possible socio-economic impacts and interrelationships could vary dramatically between different consumers and/or products. As a consequence, the way in which these issues are incorporated, considered and weighed in different regulatory frameworks vary greatly. Technology developers, especially those in the public and academic sector, should therefore consider all these issues proactively, not only to help ensure regulatory compliance but also the durability of the GE product. Insufficient funding and the lack of technical skills (i.e. technology 'push' aspects) are often indicated as some of the reasons for this lack of biotechnology innovation, but the absence of well defined, lucrative markets and the associated support of a well-established local industry (i.e. product "pull" aspects) have probably contributed more to the current low success rate.

GE products should, in the first place, be relevant. GE technology in itself is only a means to an end, and to be relevant a particular GE product should impart clear benefits to the target market/ community under their particular circumstances. Moreover, the identified benefits should be a priority for the targeted community, i.e. there should be a real, quantifiable demand for the product. Other factors that could impact on the relevance of GE technologies under specific conditions include other technologies which could deliver the same benefit and the general acceptability of GE technology within its primary and secondary target markets. The highly variable and localised nature of small-scale producers' needs and fragmented markets in the African context further complicate the matter as it could result in relative small markets, which are rendered non-viable for GE products within the current regulatory environment. The best way in which to ensure relevance is to develop products locally, based on local knowledge, priorities, capacities and constraints.

Secondly, the GE product must be accessible. Many technical and practical aspects surrounding the deployment of a GEO can impact on its accessibility within a particular market. The potential costs and/or legal obligations associated with intellectual property rights could for example place GE products out of

reach of poor markets or exclude it from territories without the necessary legislative frameworks. Also, technology deployment should never be at the expense of freedom to choose. Similarly, sophisticated management practices associated with particular GE traits could make them non-viable on a small scale or in an informal environment. Seed saving and the associated genetic introgression could, for example, result in the dilution and eventual loss a GE trait or render it obsolete in cases where segregation or low-dosage could impact negatively on the longevity of the trait. Ingrained cultural practices and preferences could also impact on the acceptability of a GE product. Examples of this include an undesirable, indirect or non-related phenotypic characteristic associated with the GE trait, e.g. a colour or texture change, and the use of an unacceptable base-variety.

Finally, integrating GE technology effectively and seamlessly into current, local agricultural systems is crucial for the sustainable use of the technology. If the deployment of a GE technology stays dependent on sophisticated distribution, implementation and/or management programs the distribution of its benefits will be severely limited in the developing world. Role players along the entire GE technology innovation pipeline should therefore interact and collaborate extensively to ensure a shared understanding of the innovation process, from discovery to the market. This is especially crucial for the highly fragmented public innovation systems in developing countries where capacity and institutional development have to go hand in hand with technology development.

A balanced approach is required; care should be taken that the choice of factors which are considered and the extent to which they should be assessed and addressed do not pose an even greater challenge to the implementation of the technology (Falck-Zepeda, 2009). Moreover, the resources necessary to conduct these assessments and the current lack of relevant data could in the short term further hinder access to the potential benefits offered by GE crops.

Local GM technology R&D capacity

All the GE crops commercialised in South Africa at this stage are derived from multinational companies. While local GE developments are under way, the lag behind the multinationals in developing GE crops could also be seen as a mixed blessing. Undoubtedly local entrepreneurs have avoided the uncertainties, goal shifts and confusions that inevitably arise in the first several years of regulatory implementation, but there is also a down side. The cost implications for biosafety compliance are significant and the details of requirements have been developed without a clear consideration of a cost-benefit ratio, a perspective that would have been provided had the applicants been local. The stringency of the biosafety hurdles is likely to remain a significant challenge for local developers in the foreseeable future.

A combination of technical difficulties, fund constraints and market issues, e.g. acceptance of GE products and competition, has constrained the commercial development and deployment of local GE crops. More recent collaborations between various national industries and multinational companies have resulted in a new surge in development, which will most probably result in the release of new commercial GE crops within the next five years. Many of these collaborations are evidently aimed at combining the knowledge and market access of the local industries with the technical and regulatory know-how of the multinational companies. Although various GE developments have been aimed at improving the output traits of the crops, using them as bioreactors to produce alternative products, or improving whole crops for bio-fuel production, the majority of the current, advanced GE trials are aimed at more ‘traditional’ GE traits to improve the agronomic efficiency/productivity of the crop.

A systems approach to biosafety implementation, therefore, should ensure consideration given to the requirements of locally developed GE crops and not only imported products.

Local and regional biosafety and sustainability research and regulatory capacity

The establishment of broad policy and more specific regulatory frameworks for GEOs has long been the focus of many African countries as this is the minimum requirement for the effective management of the possible introduction, cross-border movement, development and utilisation of GE technology. Many countries have already succeeded in this goal and quickly realised that the effective implementation and management of these frameworks require significant and continued investment and capacity development. In fact, capacity development is the single most important need, continuously highlighted by all biosafety stakeholders in Africa. Access to competent and independent technical and research capacity is an essential part of a government's biosafety assessment and should be ensured through government financing of research capacity development.

Regulators are not only in need of training on the principles of GEO risk analysis but also require technical assistance and input such as locally generated biosafety baseline data, where appropriate. The availability of local expertise, data and eventually experience do not only ensure effective and accurate decision making and risk management, but also install external trust and internal self-confidence in a system, which currently predominantly manages what is often considered as being alien products.

To unlock the true potential of GE technology it should be made more accessible through the development of a multitude of locally relevant products. Many African institutions involved in GE technology development have thus far only focused on early stage research and developmental work. They may lack the knowledge, skills and capacity to facilitate biosafety assessments and the advancement of their own biotech products from the laboratory to the market. This chasm between early stage research and the development of a marketable product could be bridged through partnerships with any of the non-profit biotechnology support service organisations active in Africa. These organisations could potentially support African agricultural innovation by fulfilling an advisory, supportive and/or funding role in partnership with industry stakeholders, including national regulators, technology developers and/or sustainability/biosafety researchers.

Science and technology communication

While the farmer and his/her needs may be seen as the key market for GE crops, insufficient attention is usually paid to the consumer, the ultimate market for GE foods. Despite this, it needs to be better realised that consumer acceptance of GE foods cannot be based on a deficit model, where mere education and information will be sufficient to transform perceptions. The consumer should be divided into a series of 'publics', each of which have different backgrounds, beliefs, cultures and worldviews. Engagement on GEOs needs to be sensitive to each of the publics' interests and must adapt to these interests. Regular surveys should be undertaken to understand, not merely the public's perceptions of biotechnology, but also the context for their perceptions.

It further needs to be recognised that opposing viewpoints to GE technologies are unlikely to disappear. There will always be vocal critics, just as there will be vocal promoters of GE technologies. The strategic approach, sensitive to the varied publics, should be to permit and promote choice by each community. This implies the labelling of GE goods. Arguably, as food security and price are key determinants of much consumer activity in Africa, and as the regulatory process should ensure the safety of the GE products, the price premium for labelling should be borne by the non-GE products earmarked for niche markets. Ultimately labelling will cease to be viewed as a negative discriminant, particularly when GE products come to dominate the market.

Current GE crops do not present any obvious, direct benefits to end consumers (recognising, however, that small-scale and subsistence farmers are a significant component of consumers in Africa), and this has contributed to the scepticism as to why GE foods should be accepted. The development of GE biofortified

staple crops, which aim to reduce micronutrient deficiencies in the general population, will provide direct health and economic benefits to the end consumer and could mark a watershed in terms of consumer acceptance of GE technology (Bouis, 2007).

CONCLUSION

Consistent political will, support and accountability is vital to ensure the timely and sustained development and implementation of a national GE technology strategy, including appropriate and aligned regulatory and policy frameworks. Political decision makers and the citizenry should, therefore, be actively engaged on all issues related to the technology to establish a shared framework for the evaluation of cost-benefit ratios. Where necessary, governments should be urged and supported to establish effective, fit-for-purpose biosafety regulatory frameworks and adapt them as the sector matures to allow the effective and efficient development, utilisation and/or management of the GE technology. Harmonisation between regional biosafety frameworks will make the technology more accessible, save resources and ensure more efficient risk management systems.

Sustainability assessments, based on systems-thinking, could play a critical role in the successful commercialisation of GE crops and should be considered as an integral part of any GE research and development program to help ensure the safety, relevance and accessibility of the technology. More emphasis should be placed on the local development of locally relevant GE products as identified by local stakeholders and where appropriate, the expertise of international biotechnology and biosafety support service organisation should be utilised to help ensure efficiency and relevance. The availability of local biosafety and sustainability expertise, infrastructure and baseline data is crucial for the safe and effective utilisation of GE technologies and should therefore be supported as a strategic imperative.

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PART 5

BIOSAFETY TOOLKITS

Chapter 21. Guidelines on the role and functions of a Biosafety Committee (NBC) within a regulatory system – a case study from South Africa

JULIAN JAFTHA

INTRODUCTION

A competent and practical biosafety framework is essential to facilitate the effective regulation of genetically engineered organisms (GEOs) in any country. In South Africa (SA), GEOs have been allowed since 1992; and the activities were conducted using permits issued under an amendment of the Agricultural Pests Act, 1983 (Act No. 36 of 1983). Knowledge and expertise acquired through this trial period led to the development and implementation of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997). South Africa is one of the few countries that have commercialized GE crops, and to date only genetically engineered cotton, maize and soya bean have been granted approval for commercial planting. In this chapter the South African biosafety regulatory system in dealing with agricultural biotechnology is discussed.

BACKGROUND OF BIOSAFETY IN THE COUNTRY

In 1979 the South African Committee on Genetic Experimentation (SAGENE) was established, as the initial South African regulatory body relevant to genetically engineered organisms. The regulatory body was responsible for evaluating the health and environmental impact assessments of all applications requesting authorization to conduct activities with GEOs. SAGENE continued to act as the regulators until the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) came into effect on December 1999. The main objectives of the Genetically Modified Organisms Act are to:

- Provide measures to promote responsible development, production, use, application, import and export of GMOs;
- Ensure that all activities involving GMOs are conducted in such a manner as to limit possible harmful consequences to the environment, human and animal health;
- Ensure effective waste management
- Stipulate requirements and criteria for risk assessment
- Ensure that GMOs are appropriate and do not present a hazard to the environment
- Establish appropriate procedures for the notification of specific activities involving GMOs

INTERNATIONAL OBLIGATIONS

South Africa (SA) is a Contracting Party to the Convention on Biological Diversity (CDB). In 1994 the meeting of Parties to the CBD recognized the need to develop a protocol for the safe transfer, handling and use of genetically modified organisms. As a result, the Cartagena Protocol on Biosafety (CPB) was adopted by Parties to the Convention. South Africa acceded to the Protocol in 2003 and as a Contracting Party, has to provide appropriate legal, administrative and other measures to implement the provisions of the Protocol.

To ensure alignment of the Act with provisions of the Protocol, amendments to the Act were undertaken resulting in the GMO Amendment Act, 2006 (Act No.23 of 2006). In addition to the provisions required in terms of the Protocol, other legislations that may impact on the regulation of GEOs in South Africa were considered and these included the National Environmental Management Act, 1998 (Act No. 107 of 1998) and the National Environment Management Biodiversity Act, 2004 (Act No. 10 of 2004), administered by the Department of Environmental Affairs, and the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) administered by the Department of Health. The GMO Act complies with all of the provisions in the above-mentioned legislation with regard to risk assessment.

The protocol specifies requirements on identification by setting out the type of information that must be provided in documentation that accompany transboundary shipments of GEOs. This specifically applies to imports and exports of GEOs. Transboundary movement of GEOs can be categorized either as GE seed for intentional introduction into the environment (planting) or as a commodity for direct use as food, feed or processing (not for planting). Import and export procedures required for both of these categories of GEOs strictly comply with provisions as prescribed by articles 7, 8, 11 and 18 of the Protocol.

This means that before an import takes place, South Africa has the right to firstly be notified of the GE events contained in the consignment, request all the relevant risk assessment information to assess the safety of these specific GE events and thereafter make a decision on whether to import based on the outcome of the safety assessment. The decision to authorize importation may be subject to specific conditions to ensure safety and manage potential risks as it relates to the human and animal health and the environment.

A similar process is followed for the export of GE consignments from South Africa where measures are taken to ensure that the GEOs involved in an intentional transboundary movement are accompanied by documentation that identifies the GEOs and provides contact details of persons responsible for such movement. However, the details of the requirements may vary depending on the intended use of the GEOs but require that the following basic requirements be fulfilled:

- A letter indicating the intent of the potential importer/exporter
- Completed application forms
- Payment of appropriate fees in terms of the GMO Act
- Notification of the country of import into whose environment the GEOs will be introduced intentionally
- Affidavit from the applicant
- Acknowledgement and confirmation by the Party of Import of the intended introduction of the GEOs into its environment; (failure by the Party of Import to acknowledge receipt a notification shall not imply its consent to the proposed import)

REGULATORY SYSTEM IN THE COUNTRY - THE BIOSAFETY ADMINISTRATIVE SYSTEM

Biosafety regulatory systems intend to provide a balance between promoting learning and innovation in biotechnology, while considering public interests. South Africa has a National Biotechnology Strategy (NBS), which was approved by Cabinet in 2001 in order to fully exploit the benefits associated with biotechnology. The NBS is a policy framework, which is aimed at creating successful establishment of a biotechnology sector, by recommending specific interventions in terms of institutional arrangements, human resource considerations, funding for biotechnology research and development, commercialization of biotechnology, policy and legal instruments, as well as ethics and public understanding of biotechnology.

South Africa also has a Biosafety policy, which aims to provide mechanisms to ensure the safe use of biotechnology, and in particular, activities with GEOs, to strengthen the economy and enhance livelihoods without prejudice to public health or the environment. The objectives of this policy include:

- The establishment of mutual measures, requirements and criteria for risk assessments, environmental impact assessments and assessment of the socio-economic impact of GEOs,
- Promoting and facilitating access to information not classified as confidential in terms of Chapter 4 of Promotion of Access to Information Act 2 of 2000,
- Creating public awareness, education and participation in the biosafety regulatory framework,
- Supporting and facilitating capacity building, and

- Aiming to cooperate with other developing countries, especially countries in the region with overlapping borders such as the Southern African Customs Union (SACU) and the Southern African Development Community (SADC), in harmonizing regulatory oversight in biosafety

The Act makes provision for the establishment of a Registrar, two regulatory bodies constituting of an advisory committee (AC), and the Executive Council (EC), the decision-making body (the EC). The two bodies provide guidance and decisions respectively, relating to all activities of GEOs in South Africa.

The existence and application of the GMO Act in South Africa provides the country with a decision making tool that enables authorities in South Africa to conduct a scientifically based, case by case assessment of the potential risks that may arise from the development of a particular genetically engineered organism. The Biosafety regulatory framework thus provides an enabling policy environment that facilitates the availability and adoption of genetic engineering technology in SA by ensuring the safety thereof.

CROPS COMMERCIALIZED OR IN THE PIPELINE

South Africa has a functional regulatory law, policy framework and infrastructure that have facilitated the commercial release of numerous traits in maize, cotton and soybean. The commercialized GEO events in SA can be imported, exported, commercially planted, and also be used as food and/or feed. South Africa's first genetically engineered crop was commercialized in 1997 and currently all GE crops in South Africa have been engineered to be either insect resistant or herbicide tolerant or to contain both of these traits and this is depicted in Table 8.1. In terms of the regulatory process, the GE events that are currently available on the South African market have been assessed in accordance with internationally prescribed food safety standards (CODEX) and are considered as safe as conventionally produced ones. Although commercial clearance have been granted for maize, cotton and soybean, additional experimentation, that is contained use, field/clinical trials as depicted in Table 8.2, are undertaken to improve on the initial GE events through the combination of different traits or manipulating the control and expression of the different genes.

Table 8.1 GMO events approved for conditional commercial release under the GMO Act, 1997

Event	Crop	Trait	Company	Year approved
BT11xGA21	Maize	Insect resistance Herbicide tolerant	Syngenta	2010
GA21	Maize	Herbicide tolerant	Syngenta	2010
MON89034xNK603	Maize	Insect resistance Herbicide tolerant	Monsanto	2010
MON89034	Maize	Insect resistance	Monsanto	2010
Bollgard IIxRR flex (MON15985x MON88913)	Cotton	Insect resistant Herbicide tolerant	Monsanto	2007
MON88913 (RR flex)	Cotton	Herbicide tolerant	Monsanto	2007
MON810xNK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2007
Bolgard RR	Cotton	Insect resistant Herbicide tolerant	Monsanto	2005
Bollgard II, line 15985	Cotton	Insect resistant	Monsanto	2003
Bt11	Maize	Insect resistant	Syngenta	2003
NK603	Maize	Herbicide tolerant	Monsanto	2002
GTS40-3-2	Soybean	Herbicide tolerant	Monsanto	2001
RR lines 1445 & 1698	Cotton	Herbicide tolerant	Monsanto	2000
Line 531 / Bollgard	Cotton	Insect resistant	Monsanto	1997
MON810 / Yieldgard	Maize	Insect resistant	Monsanto	1997

Table 8.2 Current contained use, field and clinical trials release activities approved under the GMO Act, 1997.

Event	Crop/Vaccine	Trait	Company	Purpose
SAAVI MVA-C TBC-M456	HIV Vaccine	-	Wits	Trial release
HIV vaccine Ad26.ENVA.01 & Ad35-ENV		-	Triclinium	Trial release
pihUMPS	Sugarcane	Increased yield & sucrose content	SASRI	Trial release
pCel	Sugarcane	Increased cellulose content	SASRI	Trial release
piHADK	Sugarcane	Increased yield & starch content	SASRI	Trial release
piAGPase	Sugarcane	Decreased starch content	SASRI	Trial release
Rolou A2:1 & A2:4	Ornithogalum x thyrsoides	-	ARC-VOPI	Contained use
PHP37050	Maize	Insect resistant Herbicide tolerant	Pioneer	Trial release
59122	Maize	Insect resistant	Pioneer	Trial release
VPM 1002	TB Vaccine	-	Triclinium	Trial release
TC1507	Maize	Insect resistant	Pioneer	Trial release
TC1507 x MON810	Maize	Insect resistant Herbicide tolerant	Pioneer	Trial release
TC1507 x MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Pioneer	Trial release
PHP36826	Maize	Insect resistant	Pioneer	Trial release
PHP36827	Maize	Insect resistant	Pioneer	Trial release
PHP37046	Maize	Insect resistant	Pioneer	Trial release
PHP37047	Maize	Insect resistant	Pioneer	Trial release
Bollgard II x LLCotton25	Cotton	Insect resistant Herbicide tolerant	Bayer	Trial release
Twinlink x GlyTol	Cotton	Insect resistant Herbicide tolerant	Bayer	Trial release
Bollgard II x LLCotton25	Cotton	Insect resistant Herbicide tolerant	Bayer	Trial release
Bollgard II x GlyTol x LLCotton25	Cotton	Insect resistant Herbicide tolerant	Bayer	Trial release
ZM70774	Maize	Insect resistant	Monsanto	Contained use
LAJ136	Maize	Insect resistant	Monsanto	Contained use

Event	Crop/Vaccine	Trait	Company	Purpose
TC1507 x NK603	Maize	Insect resistant Herbicide tolerant	Pioneer	Trial release
TC1507 x 59122 x MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Pioneer	Trial release
TC1507 x 59122 x NK603	Maize	Insect resistant Herbicide tolerant	Pioneer	Trial release
TC1507 x 59122	Maize	Insect resistant	Pioneer	Trial release
AERAS-422	TB Vaccine	-	Triclinium	Trial release
MON87460	Maize	Drought Tolerance	Monsanto	Trial release
	OncoVEX	-	Triclinium	Trial release
MON87460	Maize	Drought Tolerance	Monsanto	Trial release
MON87460	Maize	Drought Tolerance	Monsanto	Trial release
356043 x 40-3-2	Soybean	Herbicide tolerant	Pioneer	Trial release
AERAS 402	TB vaccine	-	Triclinium	Trial release
PHP37048	Maize	Insect resistant Herbicide tolerant	Pioneer	Trial release
PHP36676	Maize	Insect resistant Herbicide tolerant	Pioneer	Trial release
PHP36676	Maize	Insect resistant Herbicide tolerant	Pioneer	Contained use
PHP36682	Maize	Insect resistant Herbicide tolerant	Pioneer	Trial release
PHP36682	Maize	Insect resistant Herbicide tolerant	Pioneer	Contained use
MVA85A	TB vaccine		Triclinium	Trial release

The approval of GEOs is a step-wise process and may require approvals firstly for contained laboratory activities, followed by proof of concept field trials (contained) to generate local data and then only application for commercial release. The process for commercial release of GEOs in South Africa may take in excess of five or more years dependent on the extent of data required for submission.

APPLICATION REVIEW PROCESS-ADMINISTRATIVE HANDLING OF APPLICATIONS, CONSIDERATIONS IN THE RISK ASSESSMENT AND DECISION-MAKING PROCESS AND PROSPECTIVE APPLICATIONS

The Registrar is responsible for the administration of all activities in terms of the GMO Act. The following activities: are facilitated by the Office of the Registrar:

- Importation or exportation of GMOs
- Contained use of GMOs (i.e. greenhouse trials)
- Trial release of GMOs (i.e. limited environmental release)
- Conditional general release of GMOs (i.e. unlimited environmental release)

- Time extension permits for approved GMO activities
- Registration of facilities where GMO activities are undertaken
- Commodity clearance and use of GMOs for food, feed and processing
- GMO status certificates for exports.

During the regulatory process the Registrar receives all applications for activities with GEOs and applications that comply with GMO Act are forwarded to the AC. Application dossiers for GEOs are submitted containing safety assessment data relating to environmental impacts and food and feed. To ensure that GEOs are safe for human, animal consumption and the environment, the Advisory Committee conducts the food safety assessment in accordance with international food safety guidelines and principles developed by Codex Alimentarius (Codex), an international body involved in food safety, together with the World Health Organisation (WHO) and Food and Agriculture Organisation (FAO). The Codex principles that are strictly applied by the scientific Advisory Committee follows a case-by-case assessment, the use of science based risk assessment methods, consideration of newly introduced genetic material and new proteins, characteristics of the GE food, consideration of intended and unintended effects of genetic modification and a comparison with conventionally produced foods. If the scientific Advisory Committee determines that the GEO poses no additional safety concerns it will make a recommendation to the GMO Executive Council based on its evaluation of the scientific evidence provided.

The general public is also informed and consulted on intended activities relating to GEOs through notification in major and local newspapers. Comments from the public are therefore considered in the process of evaluating any relevant application. If the EC is satisfied that a certain activity with a GEO may be conducted, the Registrar is authorized by the EC to issue the necessary permit.

Decisions made through the GMO Act allow for approval, amendment, conditional approval and rejection of the applications. An appeal process along with reviews of decisions is accommodated in the Act. Any person who feels aggrieved by any action or decision taken by the EC, the registrar or an inspector in terms of the Act can appeal to such a decision or action to the Department of Agriculture, Forestry and Fisheries (DAFF) Minister. The existence and application of the GMO Act in South Africa provides the country with a decision making tool. This functional tool enables authorities in South Africa to conduct scientifically based case by case assessment of the potential risks that may arise from the creation of a particular genetically modified organism. In addition, this enables the country to collect information on the impact and implications of deliberate release of a particular genetically modified organism.

LESSONS LEARNED, OPPORTUNITIES AND CHALLENGES

Socio-economic factors such as the impact of commodity imports on the production of a crop in South Africa and potential price distortions are considered by the Executive Council when taking a decision on any proposed GEO activity. In 2005, the Executive Council decided to suspend all existing and new applications requesting commodity clearance approval. This decision was based on concerns regarding developments in the trade of agricultural commodities and the extent to which these approvals may disadvantage local producers. To facilitate informed decision-making by the Executive Council, a study was commissioned on the potential impact of GE grain imports on the South African trade. Nonetheless, all commodity applications submitted to the office of the Registrar since the 2005 moratorium continued to be subjected to the required regulatory review process whilst consultations with several stakeholders and impact studies continued.

The outcome of the study broadly confirmed the benefits to the country if domestic production of approved GE events were allowed and that policy decisions to restrict access to new GE events will gradually disadvantage both domestic producers and consumers of maize. Their specific recommendation regarding

commodity imports follows that such imports should be the exception rather than the rule during times of severe domestic shortages. An SABS standard was also developed in collaboration with key industry role players. The standard specifies requirements for receiving; handling, transportation and storage of GEOs not approved for general release. One should be mindful that the standard is not legally binding and therefore the exact terms of the standard has been captured in the respective commodity permits issued under the GMO Act.

All outstanding commodity applications, which were compliant to the Act were issued in 2011. This process ultimately led to the review and amendment of permit conditions for commodity permit holders, commodity importers and buyers. Through this process, the appropriate responsibilities were assigned to the various stakeholders in the commodity chain and the potential risks posed by the unintentional release of the consignment into the immediate environment sufficiently addressed.

Labelling of GE foods, feeds and other consumer products has been a point of contention. The Regulations relating to the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification were made in terms of the Foodstuffs, Cosmetics, and Disinfectants Act, 1972 (Act 54 of 1972) which is administered by the Department of Health. These Regulations were published after an extensive consultative process and were approached from a health perspective (safety and nutrition), while taking into account the ability of the relevant authorities to enforce them. The Regulations basically require the following:

- A genetically modified food must be labelled as such if it differs significantly in composition, nutritional value, or in mode of storage, preparation or cooking from that of the corresponding existing foodstuff
- The label of a genetically modified food must indicate the presence of an allergen from crustaceans, egg, fish, groundnuts, milk, molluscs, soybeans, tree nuts and *Triticum* species
- The food must be labelled as such if a plant-derived food contains genetic material derived from a human or from an animal, or if an animal-derived food contains genetic material derived from a human or from a different taxonomic animal family
- A claim relating to improved or enhanced characteristics of a genetically modified food must be validated and certified by a competent body which is accredited to the South African National Accreditation Services, and the name of the certifying body must appear on the label in close proximity to the claim.

The Regulations do not address the mandatory labelling of all foods produced by genetic engineering. The Department of Health is of the view that such a measure will have a significant economic effect that will impact directly on the price of food. Increase in food prices as a result of mandatory labelling is of particular concern to government taking into account the millions of South Africans living under poverty conditions.

In 2009 the Department of Trade and Industry also entered the GEO labelling spotlight with the inclusion of labelling provisions in the Consumer Protection Act, 2008 (Act 68 of 2008). The Consumer Protection Act provides for labelling of goods containing GE components or ingredients in the interest of consumers' rights to disclosure and information.

Industry together with SABS has developed standards for the implementation of an Identity Preservation System (IPS). When such an IPS is in place, segregation of GE and non-GE commodities would be possible and manufacturers will be able to account for the "identity" of all the ingredients along the full value chain of production.

In addition to the labelling debate a general comment often expressed by the anti-lobby groups is the lack of access to information. The GMO Act requires the applicant to make a public notification of his/her intention to introduce a GEO into the environment. Members of the general public can then access the non-

confidential information from the DAFF and provide comments on the application. The Executive Council also considers such comments prior taking a decision. South Africa is continuously striving to improve public access and participation. Information on permits issued, relevant information pertaining to EC decisions, guideline documents etc. are published on the departmental website. Apart from the DAFF website, stakeholders are able to access non confidential information relating to GEOs via administrative procedures provided for in terms of the Promotion of Access to Information Act (PAIA), 2000.

Once again, taking into the rigorous assessment of GM products, they are considered as safe as their conventional counterparts. To date no scientific evidence exist which supports the contrary.

WEB LINKS AND KEY PUBLICATIONS

Convention on Biological Diversity: http://biodiv.org
Public Understanding of Biotechnology (PUB): http://www.pub.ac.za
Biosafety Clearing House: http://www.bch.biodiv.org
Department of Health: http://www.doh.gov.za
Department of Environmental Affairs: http//www.environment.gov.za
Department of Science and Technology: http://www.dst.gov.za

REFERENCES

Genetically Modified Organisms Act, No. 15 of 1997
Regulations under the GMO Act, No. 15 of 1997, of 26 November 1999
Foodstuffs, Cosmetics and Disinfectants Act, No. 54 of 1972

Chapter 21. Guidelines on the role and functions of a plant quarantine office within a regulatory system – a case study from Ghana

RUTH WOODE AND HANNAH SERWAA NUAMAH

INTRODUCTION

The Plant Protection and Regulatory Services Directorate (PPRSD) is the National Institution with the mandate and capacity to organize, regulate, implement and coordinate the plant protection services required for sustainable growth and development of agriculture. The Directorate comprises of four divisions - Plant Quarantine Division, Crop Pest and Disease Management Division, Ghana Seed Inspection and Certification Division and the Pesticide and Fertilizer Regulatory Division. The functions of the Plant Protection and Regulatory Services Directorate are to:

- Issue phytosanitary import permits for plants, plant products and other related matters;
- Issue phytosanitary certificates for the export of consignment of plants, plant products and other related matters;
- Conduct surveillance of growing plants including areas under cultivation, fields, plantations, nurseries, gardens, green houses, laboratories, wild flora, plant and plant products in storage, transit, particularly to report the occurrence, outbreak and spread of pests and control of the pests;
- Inspect consignments of plants and plant products and where appropriate other regulated articles to prevent the introduction and spread of pests
- Carry out the disinfestation or disinfections of consignments of plant and plant products and other regulated articles moving in international traffic and ensure that they meet phytosanitary requirements;
- Protect endangered areas and designate, maintain and carry out surveillance of pest-free areas and areas of low pest prevalence;
- Conduct Pest Risk Analysis (PRA);
- Ensure that the phytosanitary security of consignments, after certification, as regards composition, substitution, and re-infestation of plants and plant products intended for exports are satisfactory;
- Train and develop staff;
- Disseminate information within the country about quarantine requirements and procedures to prevent and control plant pest; and
- Co-operate with member countries of the International Plant Protection Convention.

REGULATORY REGIME TO ADDRESS BIOSAFETY ISSUES IN GHANA

The regulatory safety of modern biotechnology is addressed through laws, guidelines and regulations to guide practices in modern biotechnology. The Ghana Biosafety Act 2011 (Act No. 831) provides an enabling environment for achieving an adequate level of protection in the safe transfer, handling and use of GEOs and also ensures a transparent reviewing process to enhance decision making. The Act is yet to establish a National Biosafety Authority (NBA) as the Competent Authority to manage the implementation of all issues related to Biosafety in Ghana. Presently, the National Biosafety Committee established in 2007 under the Legislative Instrument (L.I 1887) is providing administrative oversight on biosafety activities. The National Biosafety Committee is, therefore, in transition into the National Biosafety Authority. L.I 1887 is recognized by Act No. 831 (2011) and thus until new regulations are made to implement biosafety activities in Ghana, L.I 1887 will be enforced as if made under the Act.

The governing body of the proposed NBA is a Board and committees including a technical advisory committee comprising experts in the field of biosafety and socio-economics and regulatory agencies; the Customs Division of the Ghana Revenue Authority, Environmental Protection Agency, Food and Drugs Board, Veterinary Services Department, and the Plant Protection and Regulatory Service Directorate (PPRSD). There are also experts from various research institutions and academia collaborating to ensure the implementation of biosafety in Ghana.

The Plants and Fertilizer Act 2011(Act No. 803) provides guidelines for the importation of plants and plant products and regulated articles in accordance with international standards for phytosanitary measures (ISPMs) which are standards, guidelines and recommendations recognized by the World Trade Organization (WTO) under the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures and adopted by signatories to the WTO. A Phytosanitary risk that may be associated with GEOs falls within the scope of the International Plant Protection Convention (IPPC).

Draft Plant Protection Regulations have already undergone Parliamentary discussions and would be enacted as a legislative instrument for regulating all plants and plant products including GE crops/plants and living modified organisms under the Ghana's Biosafety Framework.

IMPORT REQUIREMENT

A special Import permit issued under the authority of the Plant Fertilizer Act 2011 (Act No. 803) and Regulations is required for the importation of GEOs for research purposes i.e. contained experiments and confined field trials. Persons intending to import agricultural GEO must apply for import permits in advance to the Director of PPRSD. An application for importation GEO inspection is also submitted to the National Biosafety Authority. Risk assessments are required to enable Board of the National Biosafety Authority and PPRSD to make informed decisions regarding the GEO.

An application for a special import permit should be made at least seven days prior to the importation of the consignment. Information required is in accordance with ISPM 11"Pest risk Analysis for Quarantine Pests including Analysis of Environmental Risks and Living Modified Organisms." It is also necessary to complete a pest risk analysis before issuance of the special import permit that should include the:

- Name, identity and taxonomic status of the LMO (including any relevant identifying codes) and the risk management measures applied to the LMO in the country of export;
- Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism;
- Description of the nucleic acid or the modification introduced (including genetic construct) and the resulting genotypic and phenotypic characteristics of the LMO;
- Details of the transformation process;
- Appropriate detection and identification methods and their specificity, sensitivity and reliability;
- Intended use including intended containment; and
- Quantity or volume of the LMO to be imported.

An import permit issued is valid for six months from the date of issue and for only one shipment of a consignment for an exporter, importer and country of origin. One copy of the import permit is forwarded to the export (by the importer) in advance to facilitate compliance with requirements prescribed in the import permit.

PEST RISK ANALYSIS

A pest risk analysis is required by PPRSD prior to the issuance of the special import permit since GEOs fall under the commodity class of regulated articles. Although the parent organism is normally not a plant pest,

the assessment determines if the genetic modification (i.e. gene, new gene sequence that regulates other genes, or gene product) has resulted in a new trait or characteristic that may pose a plant pest risk.

The procedures for evaluating the potential phytosanitary risks posed by genetically altered plants is based on guidance provided by International Standards for Phytosanitary Measures (ISPM No 11) and the provisions of the Ghana Biosafety Act (Act No. 831) which aims at identifying and evaluating the potential adverse effects of genetically modified organisms on the environment. The types of GEOs which would be assessed for phytosanitary risk include:

- Plants used as agricultural crops, for food and feed, ornamental plants or managed forests;
- Plants used in bioremediation (as an organism that cleans up contamination);
- Plants used for industrial purposes (e.g. Production of enzymes or bioplastics);
- Plants used as therapeutic agents (e.g. Pharmaceutical production);
- Biological control agents modified to improve their performance in that role; and
- Pests modified to alter their pathogenic characteristic and thereby make them useful for biological control.

IMPORT PROCEDURES

All consignments of plants, plant products and regulated articles imported into the country are inspected by designated officers of the PPRSD at the point of entry. Presently only materials intended for contained experiments and confined field trials are allowed to be imported into Ghana.

The inspection of consignments of plants, plant products and regulated articles moving in international traffic are carried out to prevent the introduction and/or spread of pests in accordance with the procedures of the IPPC.

Phytosanitary import inspections are carried out in accordance with the provisions of the Plants and Fertilizer Act 2011 (Act No. 803) and Plant Protection Regulations. A specific phytosanitary inspection of a GEO would include:

- Documentation checks;
- Verification of consignment integrity;
- Verification of treatment during shipment; and
- Visual inspection

The document check would include checking import permits, phytosanitary certificates, transit and pre-export inspection certificates. Phytosanitary inspections may be done at the point of entry or at an appropriate location.

EXPORT PROCEDURES

The designated inspectors of PPRSD are to ensure that persons intending to export a genetically engineered organism meet the requirements of the importing country to ensure the GEOs safe handling and transport. In this regard authority is required in the form of a written advance informed agreement from the competent authority of the importing country.

TRANSIT

The Ghana Biosafety Act 2011 (Act No. 831) requires that an applicant handling GEO products in transit informs the National Biosafety Authority prior to the transhipment across the territories of Ghana. The products are to be transported on terms and conditions specified by the Authority through a specific entry point manned by certified regulatory officers of PPRSD and the Customs Division of the Ghana Revenue

Authority. The GEO products shall be accompanied by the Customs Division of the Ghana Revenue Authority to ensure safe transport till it crosses the frontiers of Ghana.

FUNCTIONS OF PPRSD WITHIN GHANA'S BIOSAFETY REGULATORY SYSTEM

PPRSD responsibilities in the Biosafety Regulatory System include monitoring and enforcement of Plant Health related biosafety issues. The applicant's activities are monitored to ensure compliance with the requirements of Ghana Biosafety Act 2011 (Act No. 831) and the Plants and Fertilizer Act 2012, (Act No. 803) to safeguard plant health.

The inspectorate functions of the National Biosafety Authority are handled by certified inspectors of the regulatory agencies. Designated officers of PPRSD would carry out routine surveillance of growing plants including areas under cultivation, fields, plantations, nurseries, gardens, green houses, laboratories, wild flora, plants and plant products in storage or in transit, particularly to report the occurrence, outbreaks and spread of pests and to facilitate the management and/or control of plant pests.

The mandate of PPRSD is extended to cater for monitoring of GEOs in transits and under confined field trials, contained use and commercial releases.

The regulatory agency is expected to review scientific information relating to approved activities of genetically engineered organisms which may have adversely affected the environment or pose potential risks not previously known. The NBA is informed on any new information and measures required to ensure the continued safe use of the genetically engineered organism.

DUTIES OF THE BIOSAFETY INSPECTORS

Designated officers of PPRSD will be trained and certified to implement regulatory activities related to biosafety plant health in addition to plant quarantine activities. The following functions of a biosafety inspector are prescribed under the Ghana Biosafety Act (Act No. 831):

- Enter any premises, vessel or property, which the inspector has reason to ascertain whether the requirements of the Act or Regulations approved under the Act are being complied with;
- Take possession of the equipment or material for the purpose for which the power to entry is being exercised;
- Carry out the tests and inspection and make the recordings that are necessary in the circumstances;
- Direct that a part of the premises, or anything in the premises, shall be left undisturbed for so long as it is reasonably necessary for the purposes of the test or inspection;
- Take appropriate samples of the organisms, articles or substances found in the premises for analysis or any other thing relevant to the provisions of Act;
- Cause the dismantling (not to damage or destroy it, unless it is necessary) or subjected to a process or test in the case of anything found in the premises appears to contain a genetically engineered organism which has adversely affected or is likely to adversely affect the environment, but not so as to damage or destroy it, unless it is necessary; and
- Inspect records required to be kept under the Act.

CONCLUSION

Ghana's strategies and measures required to control and regulate imports of GEOs are in line with implementation of the Cartagena Protocol. The Ghana Biosafety Act 2011, (Act No. 831) has been enacted recently and Legislative Instrument, L.I 1887 enacted in 2007 regulates confined field trials and contained use of GEOs.

There is now an urgent need to train designated officers of regulatory agencies to effectively conduct safety evaluation and related matters in biotechnology to improve their capacity to carry out their mandates.

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National Biosafety Framework for Ghana - Administrative Guidelines. ISBN: 9988-8275-3-9
Public Participation Guidelines. ISBN: 9988-8275-1-2
Biosafety (Management of Biotechnology) Regulations, 2007: Legislative Instrument 1887.
Biosafety Act, 2011 (Act No. 831 of 2011)

PART 6

THE WAY FORWARD

Chapter 22. The way forward: Transforming policy into action

AGGREY AMBALI

INTRODUCTION

Biotechnology is an important key to improving agricultural productivity and food production in Africa. According to the FAO there are more than 900 million undernourished people in the world with the numbers predicted to increase as food production is affected by population growth and climate change. Agriculture biotechnology holds the promise to mitigate some of Africa's chronic problems through the implementation of sustainable agriculture. Sustainable agriculture combines increased agricultural production and economic development while promoting environmental protection and more equitable sharing of social welfare benefits. A combination of the right investment in agricultural biotechnology and enabling policy is crucial to the implementation of technological innovations arising from bioeconomies. The need to feed a growing population on increasingly limited land will require new tools to accelerate the achievement of the goals.

The majority of governments in Africa have ratified the Cartagena Protocol on Biosafety that mandates them to set in place the necessary policy and regulation for biotechnology in their countries. National Biosafety Frameworks within different countries are at different stages of implementation with only Egypt, South Africa and Zimbabwe having both legislation and functional biosafety systems in place. However, it is notable that despite the anti GE lobby's efforts, most countries in Africa are enthusiastic to adopt modern biotechnologies especially where issues of food security, hunger and human health are concerned.

BEST PRACTICES AND LESSONS LEARNED

Transparency and dialogue

Apart from the NEPAD Agency African Biosafety Network of Expertise (ABNE), a lot of stakeholders have been brought to the table. These players include the Forum for Agricultural Research in Africa (FARA), the Sub-Regional Research Organisations such as CORAF/WECARD, Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA), and the Regional Economic Communities such as, COMESA and the Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa. These organisations are engaged in sharing of information and experiences. Most of these programs build on each other to allow for continuity. This also enables peer review of research progress to establish risks associated with biotechnology.

Most of the technologies being introduced to Africa have been developed using the best available and accessible science.

Documentation and access to resources

ABNE is leading in the dissemination of science-based information and making documents publicly available for both experts and the general public. Policy makers, regulators and the general public have access to all documents and standard operating procedures for all stages of biosafety framework. ABNE also works in synergy with other stakeholders in order to avoid duplication of efforts and create greater impacts. The ABNE website is designed to be a one stop shop for resources on biosafety systems in Africa. Experts have been trained to leverage knowledge for individual countries on functional biosafety systems.

Flexibility

The current biosafety framework has enabled countries with the capabilities to adopt GE technologies earlier by facilitating the enactment of biosafety regulations. The availability of information resources for making decisions on adoption of modern biotechnology is a supporting measure that has helped governments to adopt biosafety measures.

RECOMMENDATIONS

Capacity building

Translating policy into action will require a well-trained human resource base to be able to conduct the research and monitoring to make biosafety laws and biotechnology stewardship a success. This training should be aimed at all stakeholders in the field with special attention to technical experts in biotechnology, intellectual property rights, food and environmental safety and field trial monitoring. This also requires providing the necessary infrastructure to enable national scientists to develop and test new products that meet local consumer needs. Developing human capacity should be conducted through universities, national research centers and other technical support centers. All stakeholders including regulators, policy makers, scientists and extension agents need to be empowered with the right knowledge and skills to be able to take advantage of the opportunities offered by advances in agricultural biotechnology while ensuring environmental safety as well as human/animal health. While most governments have limited budgets for science and technology, building strong research partnerships will harness biotechnology for priority crops for Africa. This is particularly important as it ensures the advancement of indigenous scientists with interests in crops that are important to specific regions of Africa. ABNE will continue to build a body of skilled expertise to a critical mass that catalyzes a revolution in research in and adoption of biotechnology throughout many African countries.

The Universities in Africa are strategically placed to offer training in biotechnology and biosafety and other related issues as these are emerging sciences. Setting up curricula in biotechnology and related sciences is both a motivator to spur interest in the subject while, at the same time building the critical mass of expertise required. Development of joint research partnerships has potential to increase the infrastructure base for conducting world class research. Governments need to offer incentives to retain trained personnel to stem the high staff turnover rate in most institutions.

Communication and dissemination of science-based information

There is a need to build trust and understanding between consumers, farmers, scientists, policy makers and the private sector in the dialogue and conversation on biotechnology and biosafety. Developing communication tools that build bridges between technical experts and other stakeholders is a very important part of this component. Engaging consumers in the debate about GE products is more valuable than attempting to align their views with those of the experts.

Public involvement in promotion of biotechnology is an important avenue for building confidence. In societies where the public have trust in certain institutions it is necessary to leverage those for the communication of biotechnology and science in general. One major problem in science communication is that most vernacular languages are not as prolific in terms or definitions. This is particularly compounded when trying to communicate in such new fields as biotechnology. However most countries have one official language as the medium of communication and this can be exploited as the channel for accurate science based information.

There are increasing opportunities for widening public participation on the dialogue of agricultural biotechnology in Africa. This can be attributed to the advances made in the information technology sector.

While most basic technological infrastructure has lagged behind in many African countries, the adoption of modern communication platforms like mobile phones and internet has been unprecedented in most societies. The increasing presence of science and technology on all available media platforms to engage a media savvy society, while still promoting traditional communication tools like radio and television, is key to getting the message out and receiving feedback.

Strengthening existing regional networks

This is very crucial since the adoption of biotechnology and trade are closely tied in the development of every country. As many African countries plan for and experience economic growth there will be increasing investment in trade within regional blocks and foreign trade partners. Development partners and CGIAR centers also have a vital role to play in strengthening existing structures in science, technology and biosafety. Development partners have a unique role in that they can leverage both public and private funds for research and development.

Regional economic communities like SADC, COMESA and ECOWAS that are working towards easing trade between countries in Africa need to be strengthened with supporting infrastructure like transportation, energy and research facilities. This is particularly important because open borders do not necessarily mean that the citizens will take advantage of the opportunity unless there are deliberate efforts to promote cross border trade. Infrastructure development can also strengthen the adoption of technology especially in the information technology and communication sectors.

Engaging the Private Sector

Bringing the private sector to the table will open up the discussion on intellectual property rights, farmer's rights, and environmental stewardship. Allowing the private sector to participate in the dialogue will build trust among stakeholders. Partnerships need to be managed through existing regulations while the science in question is still subject to rigorous peer review. Resources from the private sector can be leveraged into infrastructure development, educational programs and community building.

Setting the platform to build bioeconomies for Africa

Africa has a lot of biodiversity which can be exploited to build economies of the future. With the advance in technology, there is a vast array of products that can be developed from living organisms which would benefit indigenous economies. This can only be achieved with a robust investment in technology and a working intellectual property rights regime. Universities and research centers need to be encouraged to be innovative as future economies will be knowledge and technology based. Innovation in biotechnology has a potential to be a major economic driver in Africa as has already been achieved by developed countries. While Africa is striving to achieve its green revolution, advances in genetic engineering, genome sequencing and high throughput genotyping can be leveraged to fast track innovations from the laboratory to the field and to market.

Making Policy Review routine

The periodic review of biosafety laws will be necessary to ensure that the laws remain relevant and enable deployment of technology without creating barriers to innovation or adoption of the new technology. Technology evolves very fast such that policy needs to be routinely reviewed to keep pace with the advancement of science especially since public opinion on the services and products plays an important role on marketing. Governments and their development partners need to set aside resources for regular review and alignment of policy with its science and technology action plan priorities. This will cut the bureaucratic

process and red tape in technology review and adoption, especially for technology that has already been adopted in other parts of the world.

Aligning Universities and Research Centers as Innovation Hubs

Most universities in Africa have specialized in imparting knowledge that does not meet the needs of the industries in the economic sectors of society. By reviewing curricula and emphasizing training, a new generation for future biotechnology innovation will translate biosafety policies into action. Universities and research centers need to be incentivized for translational research which can be applied into usable products. This calls for investment into multidisciplinary research and fostering partnerships to solve common problems. Instruction methods may also need to be overhauled as information becomes more abundant. This may mean that the focus should shift towards skills development and exploiting knowledge into scalable innovations that can be put to industrial use to solve chronic problems on the continent. This will require a functional and robust peer review process and also a willingness from investors to take some risk in venturing into new innovations.