

## **PART 4**

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# **CAPACITY BUILDING IN BIOSAFETY IN AFRICA**

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

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## **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
<b>Commercially approved</b>										
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									
<b>Greenhouse trials (GHT), Confined Field Trials (X) that are conducted (C), approved (A) or Pending approval (P)</b>										
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](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.

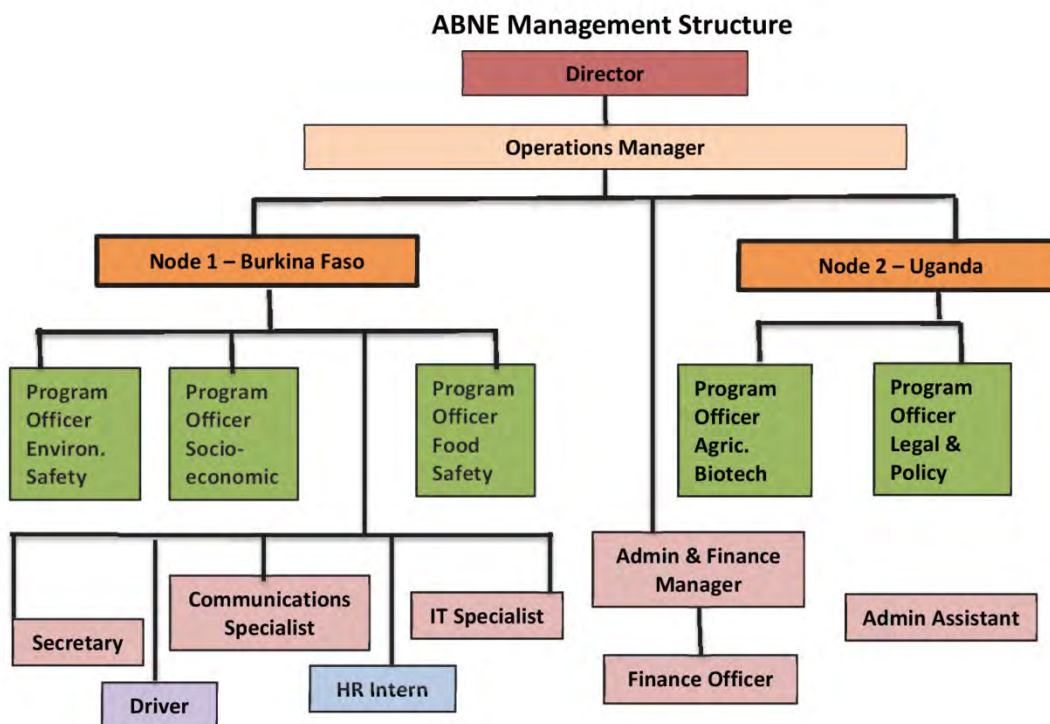
Based on the biosafety needs identified through the consultative process, a five-year implementation plan was developed by the NEPAD-MSU Partnership and submitted to the BMGF. This plan was approved and a five-year grant was awarded in July 2009 for the implementation of ABNE service network.

#### ***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 (IBC), 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](http://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**

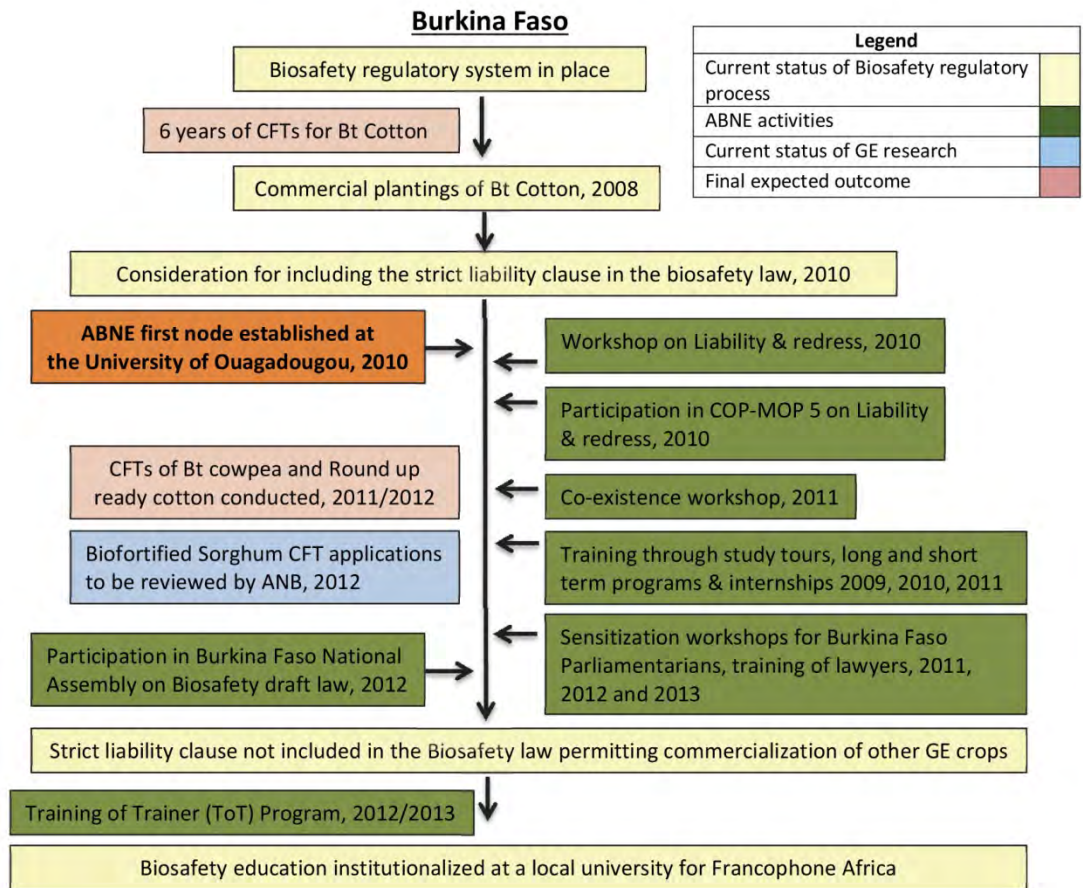
Burkina Faso is one of four countries in Africa that has approved commercial planting of GE crops. Farmers in Burkina Faso have been growing Bt cotton since 2008. The Biosafety Agency (Agency National Biosecurite or ANB) houses the NBC in Burkina Faso. In addition to Bt cotton, confined field trials 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

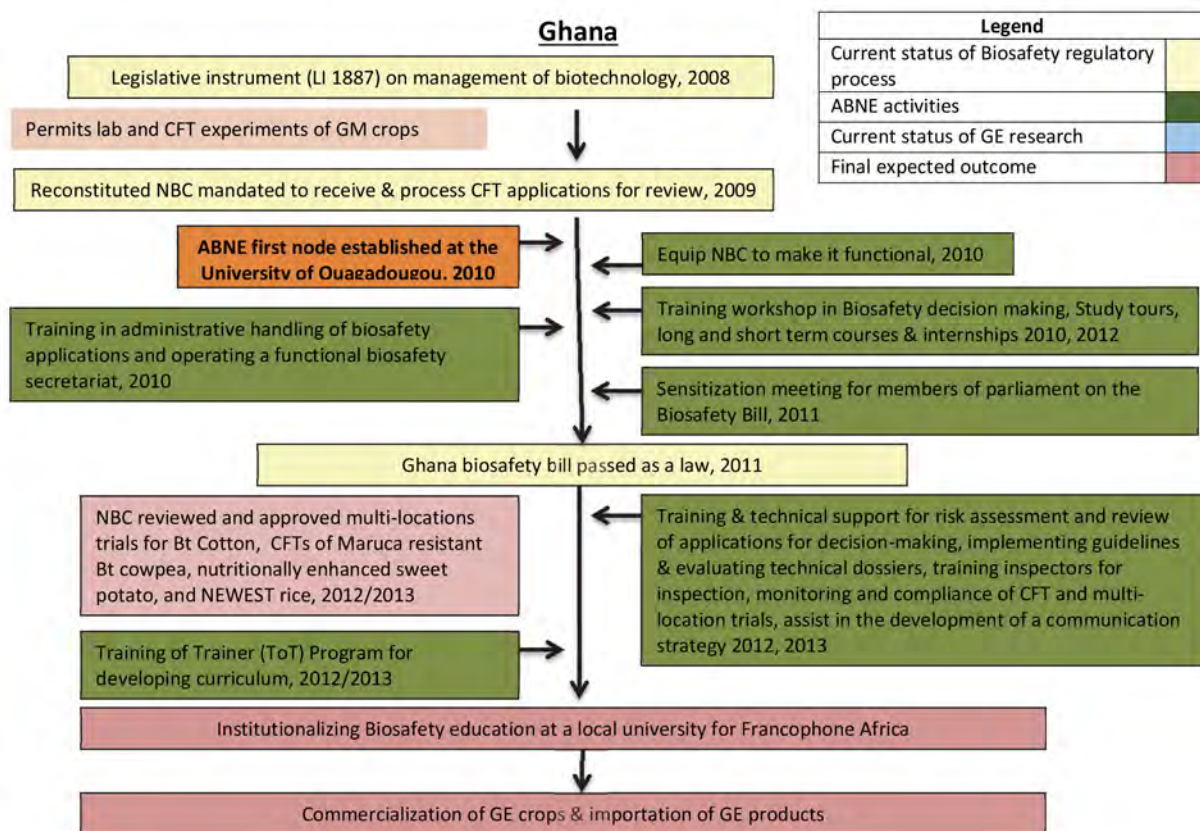


### Ghana

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.

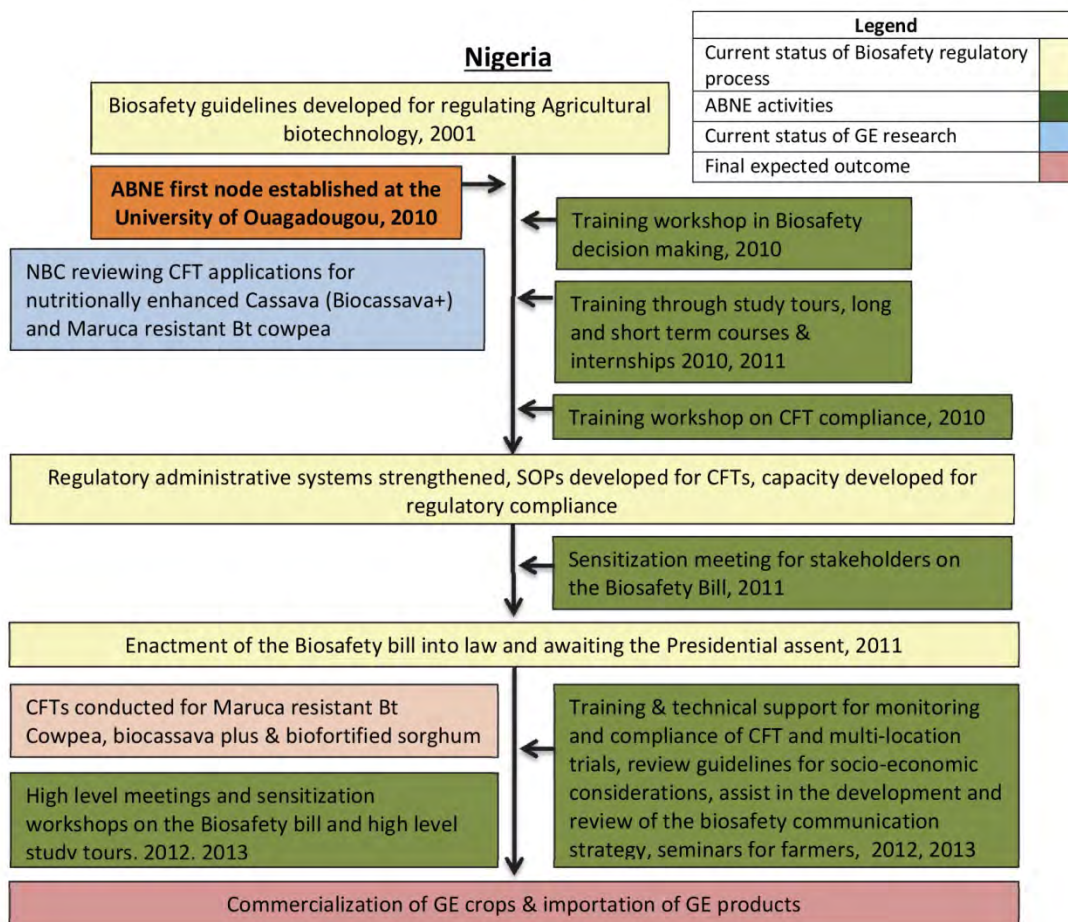
**Figure 4.** ABNE's interventions in Ghana



## 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-WIDE 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 institutional 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 well 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 well 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 following 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 scarce 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 21<sup>st</sup> 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](http://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](http://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**

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## **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

<b>Event</b>	<b>Crop</b>	<b>Trait</b>	<b>Company</b>	<b>Year approved</b>
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>

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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 disinfection or disinfestations 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 transshipment 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.

## **REFERENCES**

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## **PART 6**

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## **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.