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The status of Regulations for Genetically modified crops in countries of Sub-Saharan Africa

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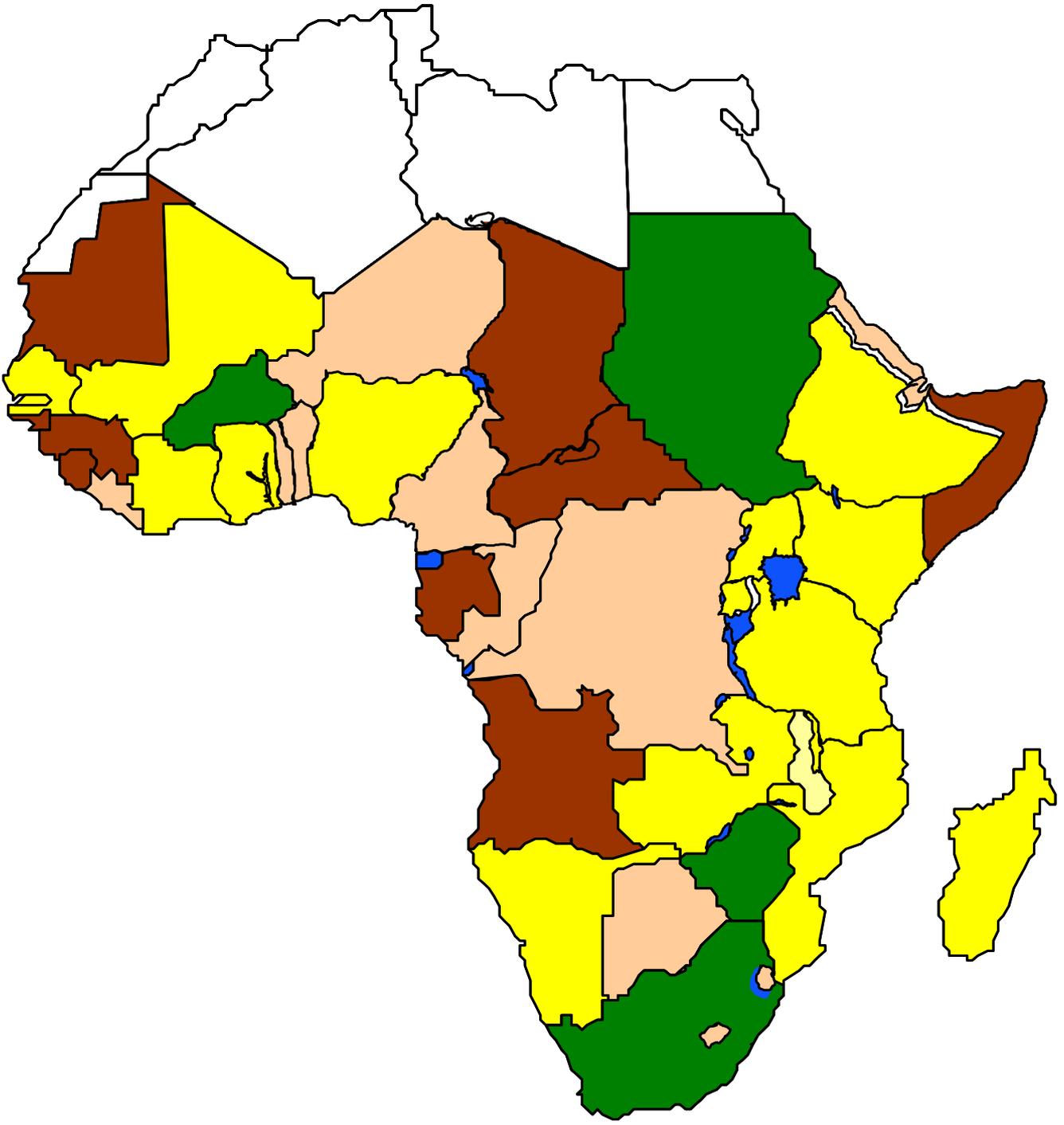


Table of Contents

Summary.....	3
Introduction.....	4
Methodology.....	5
The Convention On Biological Diversity And Regulation Of Gm Crops	6
TABLE 1: COUNTRIES THAT HAVE SIGNED AND RATIFIED THE CONVENTION ON BIOLOGICAL DIVERSITY IN SUB-SAHARAN AFRICAN ¹	6
TABLE 2: COUNTRIES THAT ARE CONTRACTING PARTIES TO CARTAGENA PROTOCOL ON BIOSAFETY IN SUB-SAHARAN AFRICA.....	7
COUNTRIES WITH FULLY-FUNCTIONAL NBFS	8
COUNTRIES WITH INTERIM NBFS.....	9
COUNTRIES CURRENTLY DEVELOPING NBFS.....	15
COUNTRIES WITHOUT NBFS.....	19
Conclusions.....	19
Acknowledgements.....	ERROR! BOOKMARK NOT DEFINED.
References	21

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Summary

The advent of modern biotechnology, especially genetic modification (GM) technology, was associated with the potential for resolving several agricultural constraints ranging from inherently low crop yields to stress-related issues arising from pests, diseases and drought to mention a few. This partly explains the ever rising adoption of transgenic crops worldwide during the past 10 years; initially from 1.7 million hectares in 1996 to 102 million hectares in 2006. Although the application of GM technology is hailed as a major success in some quarters, there are persistent concerns about the safety, ethical and trade-related aspects of genetically modified organisms to consumers and the environment necessitating the need for regulation of GM products. In a bid to exploit the potential benefits of modern biotechnology while safeguarding against potential risks, most African countries have signed and ratified the Convention on Biological Diversity as well as the Cartagena Protocol on Biosafety. It is obligatory for such countries to take appropriate legal, administrative and other measures to ensure that development, handling and utilization of living modified organisms (LMOs) is undertaken in a manner that reduces the risks to biological diversity and human health through the oversight of functional national biosafety frameworks (NBFs). This paper provides an in-depth account of progress so far made regarding developing NBFs and the status of regulations for GM crops in African countries as at December 2006. Four categories of countries are described herein based on the existing operative NBF ranging from *Fully-functional biosafety frameworks*, *Interim biosafety frameworks*, NBFs that are *'work-in-progress'* to a category of countries without NBFs.

Introduction

The seriousness of extreme poverty and hunger in the world attained global dimensions at the turn of the 21st century with the recognition that this challenge be made the foremost Millennium Development Goal (United Nations, 2006). This challenge is especially critical in low-income, food-deficient countries of Sub-Saharan Africa where an estimated 70% of the population comprises of small scale farmers living on small family gardens where soils have over the years become impoverished, in environments that are prone to drought, soil erosion, famine and epidemics of pests and diseases. It is against this background that the advent of modern biotechnology, especially genetic modification (GM) technology, was associated with the promise and potential for resolving some of the major agricultural constraints ranging from low crop yields to stress-related issues arising from pests, diseases and drought to mention a few. To date, advances in GM technology are being exploited into a multi-million dollar industry in the field of agriculture and pharmaceuticals (Paul and Lova, 2005). For example, since the initial

commercialization of transgenic crops in 1996, the global area planted with GM crops has soared by more than sixty-fold to stand at 102 million hectares in 2006 up from a bare 1.7 million in 1996 (James, 2006). It has been estimated that a total of 10.3 million farmers planted GM crops in 2006, all valued at \$6.15 billion (James, 2006). Despite this impressive account regarding the potential of GM technology, there are persistent concerns about the safety, ethical and trade-related aspects of genetically modified organisms to consumers and the environment necessitating the need for regulation of GM products.

The significance of regulating modern biotechnology can be traced back to the text of the Convention on Biological Diversity (CBD) which expressly recognizes the potential of modern biotechnology in promotion of human well being, particularly in helping meet critical needs for food, agriculture and health care (SCBD, 1992). In the same vein, the CBD also emphasizes the need to ensure development of appropriate procedures to enhance the safety of biotechnology by minimizing potential threats to biological diversity taking also into account risks to human health. Indeed, Articles 8(g) and 19(3) of the Convention (SCBD, 1992) obligate contracting parties to develop national biosafety systems as well as set out *“appropriate procedures in the field of safe transfer, handling and use of living modified organisms resulting from biotechnology that may have adverse effect on conservation and sustainable use of biological diversity”*.

To exploit the potential benefits arising from modern biotechnology applications while safeguarding against potential risks, most African countries have signed and ratified the CBD as well the Cartagena Protocol on Biosafety. Thus, such countries agreed on taking necessary and appropriate legal, administrative and other measures to implement certain obligations to ensure that the development, handling, transport, use, transfer and release of living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health by developing functional National Biosafety Frameworks (NBFs) to oversee the development and utilization of GM products. Although components of NBFs vary from country to country, they typically comprise existence of: (1) a policy on biotechnology, (2) laws and regulations on biosafety constituting a regulatory regime for biotechnology, (3) an administrative system for handling applications and issuance of permits and (4) a mechanism for public participation in biosafety decision-making process (SCBD, 2000). This paper gives an account of the status of regulatory frameworks for GM crops in African countries based on the four elemental components that constitute functional NBFs as at December 2006 with a view to determine the level of preparedness in handling GM crops and associated products on the continent.

Methodology

Information collected during this study was obtained via internet searches in Biosafety Clearing-House (BCH) of respective African countries as at December 2006. The BCH is an information exchange mechanism established under the aegis of

Cartagena Protocol on Biosafety to assist Contracting Parties implement provisions of the Protocol and to facilitate sharing of information on, and experience with LMOs. Thus, BCH serves as a "one-stop shop" where users can readily access or contribute relevant biosafety-related information. However, information in the BCH is owned and updated by the users themselves and its accuracy is therefore dependent on the timeliness with which it is updated. In addition to BCH information, various documents on biosafety relating to GM crops in Africa were consulted.

The convention on biological diversity and regulation of GM crops

The recognition of the Convention on Biological Diversity as an international commitment to conserve biological diversity, to use biological resources sustainably and to share equitably the benefits arising from the use of genetic resources, was shared by all nations of the world including those from Africa (IUCN, 1994). This is explained by the rapidity with which the Convention received signatures and instruments of ratification by Contracting Parties enabling it to come into force on 29 December 1993, barely eighteen months after it was opened for signature in Rio de Janeiro in June 1992. To date, all countries in Sub-Saharan African except Somalia are Parties to the CBD (Table 1). The CBD clearly recognizes some two critical aspects of modern biotechnology. On the one hand, the Convention provides for access to, and transfer of, technologies including modern biotechnology that are relevant to conservation and sustainable use of biological diversity thereby promoting human well being as well. On the other hand, the CBD is also explicit regarding the need to put in place appropriate procedures to enhance the safety of biotechnology in the context of the Convention's overall goal of reducing potential threats to biological diversity and human health. Article 8(g) of the CBD spells out such measures to be taken by Contracting Parties at national level while Article 19, paragraph 3, sets the stage for the development of an international legally binding instrument to address the issue of biosafety. It is from this latter provision that emerged negotiations which culminated in the adoption of Cartagena Protocol on Biosafety to the Convention on Biological Diversity in January 2000 (SCBD, 2000).

Table 1: *Countries that have signed and ratified the Convention on Biological Diversity in Sub-Saharan African*¹

Angola	Ethiopia	Namibia
Benin	Gabon	Niger
Botswana	Gambia	Nigeria
Burkina Faso	Ghana	Rwanda
Burundi	Guinea	Sao Tome and Principe
Cameroon	Guinea-Bissau	Senegal
Cape Verde	Kenya	Seychelles
Central African Republic	Lesotho	South Africa

Chad	Liberia	Sudan
Comoros	Madagascar	Swaziland
Congo	Malawi	Togo
Côte d'Ivoire	Mali	Uganda
Democratic Republic of the Congo	Mauritania	Tanzania
Djibouti	Mauritius	Zambia
	Mozambique	Zimbabwe

¹Equatorial Guinea, Eritrea and Sierra Leone are parties to the CBD by accession

The conclusion of the Biosafety Protocol was hailed as a significant step forward since it provided an international regulatory framework that reconciles the respective needs of trade and environmental protection with respect to trans-boundary movement of LMOs. Several African countries (36 as at December 2006) (CBD, 2006; <http://bch.biodiv.org/about/parties.shtml>) had so far signed and ratified the Protocol (Table 2) implying that by so doing, the said countries accepted to be bound by the provisions in the Protocol notably the need to establish: (1) a policy on biotechnology, (2) a regulatory regime for biosafety, (3) a system for handling applications and issuance of permits and (4) a mechanism for public participation in biosafety decision-making process. Addressing the four elements cited above is a time-consuming exercise whose accomplishment does not necessarily commence and end with the signing and ratification of the Biosafety Protocol.

Regarding implementation of the Protocol therefore, the results from this investigation shows that countries in Sub-Saharan Africa typically fall into four categories namely (1) countries with fully-functional NBFs, (2) countries with interim NBFs, (3) countries whose NBF is 'work-in-progress', and (4) countries without NBFs.

Table 2: Countries that are Contracting Parties to Cartagena Protocol on Biosafety in Sub-Saharan Africa

Benin	Gambia	Nigeria
Botswana	Ghana*	Rwanda
Burkina Faso	Kenya	Senegal
Cameroon	Lesotho*	Seychelles
Cape Verde*	Liberia*	South Africa*
Chad	Madagascar	Sudan - accession
Congo	Mali	Swaziland*
Democratic Republic of Congo*	Mauritania*	Togo
Djibouti*	Mauritius*	Uganda
Eritrea*	Mozambique	Tanzania*
Ethiopia	Namibia	Zambia*
Gabon*	Niger	Zimbabwe

*Contracting Parties to Cartagena Protocol on Biosafety by accession

Countries with fully-functional NBFS

A total of five countries (Burkina Faso, Mauritius, South Africa, Sudan and Zimbabwe) in Sub-Saharan Africa appear to have so far met the basic obligations of the Cartagena Protocol on Biosafety. These countries have taken the necessary and appropriate legal, administrative and other measures to ensure that the development, handling, transport, use, transfer and release of living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health by developing functional NBFs.

South Africa

Leading the pack in this category is the Republic of South Africa. This country has a framework for GMO regulation including a specific GMO Act that governs activities relating to research and commercialization of GMOs. So far, it is the only African country that has permitted commercial planting of transgenic plants. As such, South Africa has a number of public and private laboratories adequately equipped to carry out GM research and development work. There are over 160 plant biotechnology projects and by 2003, about 172 GM crop field trials including: glyphosate tolerance in eucalyptus, genetically inserted bromoxynil, and *Bt* cotton development, among others had been sanctioned. South Africa is the only African country to date where GM crops are commercially planted including GM maize, soybean and cotton (Evenson *et al.*, 2002).

Burkina Faso

The other four countries have similarly taken appropriate steps to implement the obligations of the Protocol but none of these have been able to commercialize planting of GM crops in their territories. For instance, Burkina Faso has had a policy on biotechnology and biosafety that enabled development of regulations and guidelines which were adopted by government decree in June 2004. This has now been strengthened with recent passage of Biosafety Law in 2006. Field trials in *Bt* cotton varieties were initiated in 2003 at the Institut National de l'Environnement et de Recherches Agronomique (INERA) in Faracoba near Bobo Dioulasso and Kouré. In July 2003, Burkina Faso Fibre and Textile Company (SOFITEX) rolled out plans to embark on the production of GM cotton. However, there are no known commercial releases of GMOs to date.

Mauritius

Mauritius is a signatory to the CBD and ratified the Cartagena Protocol on Biosafety in April 2002, five months before the protocol came into force on September 11, 2003. Much earlier in 1999, the country had prepared "National Guidelines for the Safe development and Introduction of Genetically Modified Organisms" to provide guidelines for the administrative and institutional procedures necessary to implement and enforce the guidelines. Legislation to regulate GMOs, the Genetically Modified Organisms Bill, was passed into law in March 2004 (<http://bch.biodiv.org/default.aspx>). So far, the law has the most stringent precautionary regulations on the African continent since it does go beyond the

minimum requirements of the Cartagena Protocol on Biosafety. There also exists a National Biosafety Committee responsible for risk assessment and thus is the de facto decision-making authority on matters pertaining to GMOs (<http://bch.biodiv.org/default.aspx>). Under this framework, Mauritius Sugar Industry Research Institute (MSIRI) has developed two transgenic sugar cane varieties, one resistant to Basta® herbicide and the other to Roundup Ready® herbicide that have undergone confined field trial experimentation but no commercial releases of GM crops have been approved in Mauritius to date.

Sudan

Sudan finalized the development of its NBF that was published in November 2005. In the framework the then Biological Safety Bill of 2005 was passed by the National Assembly into law (<http://bch.biodiv.org/default.aspx>). The Act is meant “to ensure adequate level of protection in the field of safe transfer, handling and use of GMOs resulting from modern biotechnology” with emphasis on the conservation and sustainable use of biological diversity and human health. However, there is no known research, field trials or commercial release of GMOs to date. Earlier on, Sudan had banned the import of GM food in 2003 but issued a series of temporary waivers enabling food aid shipments into the country to continue while alternatives were sort.

Zimbabwe

Finally, Zimbabwe has a legally binding biosafety system with regulations and guidelines and some capacity for monitoring and detection of the presence of GM elements in food products (<http://bch.biodiv.org/default.aspx>). In April 2006, the Biotechnology Authority Bill was passed into law by the Zimbabwean parliament paving way for the setting up of a body responsible for managing the import, research, development and production of biotechnology products. The law explicitly supports advancement of all aspects of modern biotechnology in Zimbabwe. Under this legal framework, field trials of *Bt* cotton and *Bt* maize were approved in 2001. There are, however, no commercial releases of GMOs to date. Even in cases of emergency, the government of Zimbabwe can only accept GM food aid provided the grain is milled prior to distribution (Omamo and Grebmer, 2005).

Countries with interim NBFS

Twelve countries (Ethiopia, Ghana, Kenya, Madagascar, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Uganda, Tanzania and Zambia) fall into this category. Typically, these are countries that have partially met the provisions of the Cartagena Protocol on Biosafety to the extent that allows them to commission research and development (R&D) activities involving GM crops in containment and confinement but NOT to commercially release GM crops. Most of these countries have moved on to develop policies and legislation on GM crops but this process is yet to receive full parliamentary and/or cabinet endorsement in the respective countries.

Ethiopia

Ethiopia is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. The country started the process of developing a Biosafety framework in 1999 by designating the Federal Environmental Protection Authority (EPA) as a National Executing Agency (NEA) mandated for all types of authorization of genetically modified organisms. The EPA has so far established a Biosafety Secretariat Office which assumed the task of developing the National Biosafety Framework (NBF) in 1999 based on the provisions of the Cartagena Protocol on Biosafety and the African Model Law. There is National Biotechnology Steering Committee (NBSC) and Sectoral Biotechnology Committees (SBC) in place. Guidelines for regulating GM crops are non-existent and no field trials or commercial release of GMOs have been approved by Ethiopia.

Ghana

Ghana has finalised the drafting of a comprehensive National Biosafety Framework that was submitted to cabinet for consideration for endorsement and approval in 2006. The framework covers a proposed Biosafety Bill to govern the introduction of GMOs, biosafety guidelines, a mechanism to handle applications for permits, procedures for enforcement regulations and monitoring of trials and a mechanism for public awareness, education and participation, and risk assessment and management. Other areas addressed are the establishment of a National Biosafety Authority, provisions for application of contained use of GMOs, introduction into the environment, importation or placing on the market, exportation, GMOs in transit and guidelines for risk assessment and risk management. To date, a National Biodiversity Committee comprising of representatives from local universities, research institutes and other agencies has been set up to advise the Ministry of Education Science and Technology. However, operationalization of this framework is yet to be sanctioned. Meanwhile, the National Biodiversity Committee is mandated to receive and review applications for confined field trials for GM crops based on the existing Plant Quarantine legislation.

Kenya

In Kenya, there exists an explicit policy on modern biotechnology that was recently published by Ministry of Science and Technology. Regulations and Guidelines for safety in Biotechnology were published in 1998 by the National Council for Science and Technology (NCST), the government agency currently responsible for overseeing the implementation of the Biosafety regulatory system (Traynor and Macharia, 2003). These regulations were issued under the Science and Technology Act of 1980, a piece of legislation without *locus standi* on regulatory agencies and no means to enforce compliance with the regulations. The NCST established the National Biosafety Committee (NBC) to review GMO applications and approve or decline issuance of permits. In July 2002, the country began working on a number of legal documents to turn its interim biosafety regulatory system into a comprehensive system by developing revised regulations, a Biosafety Bill, and a national Biotechnology and Biosafety Policy. Although the process of developing these documents has progressed in the last few years, none (except the Biotechnology

Policy) has been finalized (Gregory Jaffe, 2006). Nevertheless, the interim regulatory system has allowed for confined trials on several crops including sweet potato, Bt Maize, Bt cotton and transgenic cassava in Kenya (Traynor and Macharia, 2003).

Madagascar

Madagascar is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. The country operates interim system whereby a Decree on Environmental Impacts is used to regulate biosafety. In October 2004, Madagascar started developing its draft National Biosafety Framework that includes drafting biosafety policy. The NBF was created with Association National pour la Gestion des Aires Protégées (ANGAP) as the National Executing Agency and the National Office for Environment as the Competent Authority. The biosafety framework being developed explicitly covers all aspects Biosafety pursuant to the Cartagena Protocol on Biosafety such as risk assessment and management, mechanisms of decision-making, public participation, and legal regulations. There are research projects on agricultural biotechnology going on in Madagascar at the Centre National de la Recherche Appliquée au Développement Rural (FOFIFA) and the Centre de Développement Rural et de Recherche Appliquée in the Faculty of Agriculture at the University of Antananarivo. However, there have been no field trials or commercial release of GMOs in Madagascar to date.

Mali

Mali is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. Currently biosafety is regulated by provisional laws such as the Environment and Sanitation Laws and Forestry Laws which do not have explicit provisions for regulating modern biotechnology. However, Mali has formulated National Biosafety Framework with the National Competent Authority being the Ministry of Environment. The draft NBF spells out protocols on notification, decision-making, public participation, risk assessment and management, release of GMos into the environment, identification and labelling, export and socio-economic consideration. There are research and development activities on cotton involving IER and the University of Mali. In 2004, the IER embarked on a five year project with USA's USAID, the U.K based Monsanto, the Swiss Syngenta and Dow Agrosiences of USA, to develop and commercialize transgenic cotton (*Bt* cotton) but this effort has not yet advanced to field testing level.

Malawi

Malawi is party to the Convention on Biological Diversity but is yet to ratify the Cartagena Protocol on Biosafety. The country has legislation on biosafety, with a National Biosafety Committee. The 2002 Biosafety Act regulates matters pertaining to modern biotechnology. However, Malawi is yet to develop a critical mass essential for risk assessment relating to GMOs. In March 2006, the government met to review a draft biotechnology policy which is currently under development. There are research projects on agricultural biotechnology in the department of Agricultural Research and Technical Services; the Forestry Research Institute of Malawi (FRIM);

the University of Malawi; and the Bunda College of Agriculture. GM research on cassava improvement and confined Bt cotton trials have been carried out but there is no known commercial release of GMOs.

Namibia

Namibia is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. In 1999, the country passed a National Biosafety Policy prepared by the Namibian Biotechnology Alliance (NABA). The policy document “identified possible interim and permanent mechanisms to address safety of GMOs”. There is a National Biosafety Committee and a draft legislation for governing activities relating to modern biotechnology being developed with support from UNEP-GEF. UNEP-GEF also supported in September 2004 the establishment of a GMO testing, training and research lab at the University of Namibia. The Department of Research and Training has a project addressing resistance to downy mildew in pearl millet through GM approaches. There are no known field trials or commercial release of GMOs to date. The government rejected GM maize in 2002, and instead received wheat for food aid on the recommendation of National Biosafety committee.

Nigeria

Nigeria is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. It has also finalized the process of developing a National Biosafety Framework that has seen the development of a Policy on Modern Biotechnology and draft Biosafety Bill that is still pending ratification by Federal Executive Council and onward submission to the National Assembly. The overall objective of the policy on modern biotechnology is to provide a regulatory regime and guidance for the sustainable development of the science of modern biotechnology, its application and safe use of its products without prejudice and risk to public health, environmental health, national sovereignty, human dignity and fundamental human rights. In this regard, the country also has comprehensive National Biosafety Guidelines and a National Biosafety Committee created in 2001. The guidelines seek to facilitate the establishment and development of national capacities to assess and manage potential risks associated with biotechnology, and are implemented under the Environmental Impact Assessment Decree (1992). The Government set up National Biotechnology Development Agency (NABDA) to harness the full potential of biotechnology for Nigeria’s economic development. In 2003, the Nigeria-based IITA embarked on research for second-generation genetically engineered crops (maize, cassava, and sweet potato) project. GM research has also been conducted on virus resistant cassava and insect resistance in cowpeas, and on transformation and regeneration of cowpeas, yam, cassava, and banana. However, there are no known field trials or commercial release of GMOs in Nigeria to date.

Rwanda

The National Environmental Bill and the Ministry of Agriculture decrees are used as interim processes for regulating GMO activities in Rwanda. In January 2003, Rwanda formed the National Executing Agency with a National Coordinating Committee under the Ministry of Lands, Human Settlement and Environment Protection to develop the NBF. The committee came up with a draft NBF which designated the Rwanda Environment Management Authority (REMA) as the National Competent Authority, for handling all GMO applications. The draft National Biosafety Framework consists of three parts: the national biosafety policy; the national biosafety regulatory regime i.e. Biosafety Bill and Guidelines; and an institutional framework to operationalise the policy and regulatory instruments including handling of notifications and authorisations; risk assessment and management; enforcement and monitoring; information management; public awareness, education and participation. A National Biosafety Committee and Institutional Biosafety Committee are in place. Rwanda is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety.

Senegal

The country is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. Senegal has finalised preparing its National Biosafety Framework comprising of a draft Biosafety Bill, biosafety regulations and biotechnology policy in 2005. A draft GMO-specific Bill on biosecurity was recently presented to the National Assembly for examination and adoption. There are research projects on agricultural biotechnology at the Institut Sénégalais de Recherches Agricoles (ISRA); thé Institut de Technologie Alimentaire (ENSA) ; Université Cheick Anta Diop ; Faculté des Sciences Economiques et Gestion – Centre de Recherches Economiques Appliquées ; thé Centre d’Etude Régional pour l’Amélioration de l’Adaptation and la Sécheresse (CERAAS) ; and thé Université Gaston Berger de Saint Louis (UGB).

Uganda

Uganda is party to the Convention on Biological Diversity and ratified the Cartagena Protocol on Biosafety way back in 2001. The interim Biosafety regulatory system existent in Uganda is coordinated by the Uganda National Council for Science and Technology (UNCST). That office established in 1995 the National Biotechnology Committee (NBC) made of representatives from other government agencies and civil society. The NBC is the national administrative arm on matters concerning Biosafety. The main function of the NBC is to offer technical advice on Biosafety issues, including the assessment of individual applications for activities with genetically engineered (GE) organisms. The NBC has been responsible for writing the draft National Biotechnology and Biosafety Policy, draft National Biosafety regulations, Guidelines on Biosafety in Biotechnology for Uganda, and a number of draft manuals addressing specific issues surrounding biosafety regulation, such as confidential business information. Those documents set forth the current and

proposed biosafety regulatory framework for Uganda. Under the biosafety system identified in those documents, the UNCST will be the competent authority to carry out Biosafety regulation. It will be advised on policy matters by the National Biotechnology Advisory Committee (NBAC), which is an inter-ministerial committee and the NBC. (Gregory Jaffe, 2006). Biosafety in Uganda is regulated by the National Environment Statute (1995) which does not contain specific provisions expressly regulating modern biotechnology. There is however a new draft GMO-specific Bill.

Uganda embarked on a national biotechnology programme focusing on several transformative biotechnology innovations, and genetic engineering linked to Uganda's policy to eradicate poverty by 2015. Uganda's Poverty Eradication Action Plan (PEAP) has an action Plan for Agricultural Modernisation (PAM) which promotes genetic engineering. The UNCST developed a National Policy on Biotechnology (PBB) in 2003 to enable the country to safely utilize biotechnology, including genetic engineering, within the framework provided by PEAP.

The National Agricultural Research Organization has been involved in biotechnology research and built state of the art laboratory for biotechnology research, the Kawanda Agricultural Research Institute (KARI) for research on banana. There have been reports on field trials involving GM crops. In August 2004, field trials on disease resistant bananas and on *Bt* cotton were put aside pending enactment of biosafety laws.

Tanzania

Tanzania started developing the framework in 2002. The structure of Tanzania's Biosafety regulatory system is described in its National Biosafety Framework (NBF) issued in March 2005. In the system, the National Biosafety Focal Point (NBFP), which is responsible for review and approving applications and overseeing the implementation of Biosafety issues, is the Ministry responsible for environment. The NBFP gets advice on technical and policy issues from the National Biosafety Advisory Committee, comprising of government and non-governmental organisations, as well as the competent authorities, which are other agencies with areas of relevant expertise within the government. The NBF also discusses Institutional Biosafety Committee, which performs biosafety functions within any institution conducting genetic engineering.

The regulations that will establish Tanzania's Biosafety system will be promulgated under authority recently established in the Tanzanian Environmental Management Act of 2004 (EMA). The law provides the legal authority for the Ministry of Environment to regulate GE organisms. The NBFP is working on the regulations to implement the Biosafety provisions of the Act and to establish the procedures identified in the NBF.

Tanzania also has established a specific interim Biosafety regulatory process for permitting small-scale confined field trials of plant and plant products. That

document puts in place a review and approval process for all small-scale confined field trials involving GE plants. (Gregory Jaffe March 2006).

The National Biosafety Guidelines (2004) were set down to 'facilitate the importation and use of GMOs and their products in Tanzania'. There is Ministerial Biosafety Advisory Committee and a phytosanitary unit to conduct biosafety inspection. Tanzania is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. There is limited research on GM virus resistance in bananas at Maruku, HORTI-Tengeru, and Sokoine University of Agriculture. The programme puts more emphasis on disease and pest control, breeding and soil fertility activities. There have been trials on Bt tobacco.

Zambia

Zambia is party to the CBD and has ratified the Cartagena Protocol on Biosafety. The country has so far established a National Biosafety Committee, has a Biotechnology and Biosafety Policy that received cabinet approval in 2003 and a draft legislation on Biosafety (that is yet to become law). Meanwhile the Environment Protection Act (1995) has mandate for regulating environmental safety although its current state does not contain specific provisions for regulating modern biotechnology. However, the interim system in place in Zambia has permitted research on GM cassava to be carried out, and also confined trials of Bt cotton were carried out in 1999/2000.

With sustained support for developing functional biosafety systems especially through support from UNEP-GEF and USAID supported Program on Biosafety Systems (PBS) (Alhassan, 2003), it is anticipated that in due course, some countries in this category may eventually progress to the first category.

Countries currently developing NBFS

Countries in this category comprise Benin, Eritrea, Botswana, Cameroon, Congo, Democratic Republic of Congo, Djibouti, Gambia, Lesotho, Liberia, Niger, Seychelles, Swaziland and Togo. Like countries with interim NBFs, in this category are to be found nations that have lately been receiving support for developing functional biosafety systems through support from UNEP-GEF and PBS. However, since the process of developing NBFs takes a long time to complete, regulatory frameworks for countries in this category can be best described as 'work-in-progress' since only drafts of bills, draft biosafety regulations and guidelines have so far been achieved. As result, none of these countries has any work going on GM crops, and wherever that exists this tends to be limited to contained laboratory investigations.

Benin

Benin is party to the Convention on Biological Diversity (CBD) and has ratified the Cartagena Protocol on Biosafety (CPB), and is therefore currently drafting a National Biosafety Framework to align itself with provision of the CPB. The country is yet to formulate a biotechnology/biosafety policy. It however has draft Biosafety Guidelines or regulations. Since 2002, import of GMOs and products into Benin was

banned and a moratorium declared on GM crops for five years. The moratorium prevents the importation of GM food until such a time there is national legislation in place (<http://bch.biodiv.org/default.aspx>). There are no known trials or commercial release of GMOs to date.

Eritrea

The country is a contracting Party to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. The country embarked on the formulating the NBF in July 2004 and a process that was expected to finish by January 2006 under the leadership of the Department of Environment, Ministry of Land, Water and Environment as the National Executing Agency. However, there is no official status report to date.

Botswana

Botswana, a contracting party to the CBD and Cartagena Protocol on Biosafety is in the final stage of drafting a policy and a regulatory framework that will regulate modern biotechnology. The draft biosafety framework was initiated by UNEP-GEF in 2002. However, it is not clear whether Botswana is ready to engage in biotechnology even though the governing framework and guidelines are being developed owing to longstanding trade in agricultural products with the European Union (Mmegi, 2006). There is therefore, no known research trials involving GMOs in Botswana currently.

Cameroon

Cameroon is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. It has enacted a Biosafety Law and a Biosafety Policy. The law is an enabling or framework law that governs biosafety in modern biotechnology and stipulates the safe development, use including contained use, manipulation and cross border movement of GMO that may negatively affect human and animal health, biodiversity and the environment in line with the Cartagena Protocol on Biosafety. However, there are no Biosafety guidelines and no established mechanism for receiving and reviewing applications for R&D activities on GMOs. Thus, no known field trials, or commercial release of GM crops have been made in Cameroon.

Congo

Congo party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. It published its final draft National Biosafety Framework in July 2004 that is yet to be implemented. There is no record of research, trials or commercial release of GMOs.

Cote d'Ivoire

The country is a contracting party to the Convention on Biological Diversity but it is not contracting party to the Cartagena Protocol on Biosafety. Nevertheless, Cote d'Ivoire has been drafting its National Biosafety Framework that was just finalised in 2006 under the UNEP-GEF support. The framework addresses a policy on biosafety, legal and regulatory regime, decision-making procedures, risk assessment and management system, and public awareness, education and participation. There are National Guidelines on modern biotechnology and the Commission Nationale de Développement Durable has been designated as the Competent National Authority. In the meantime, food safety is regulated by Law No 63-301 (1963) while plant safety is regulated by Decree No. 63-647 both of which do not contain provisions for regulating GMOs. There is no known research, trials or commercial release of GMOs. There is no known research, trials or commercial release of GMOs to date.

Democratic Republic of Congo

The Democratic Republic of Congo (DRC) is party to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. DRC started developing national biosafety framework in December 2004 with the Ministry of Agriculture as the Competent Authority but it is yet to finalise the drafting of the process. The country has draft legislation on biosafety and a biosafety inspectorate (Ministerial Biosafety Advisory Committee) is under creation which if completed will serve as an interim framework to regulate biosafety. There is no reported research, trials or commercial release of GMOs to date.

Djibouti

Djibouti is party to the Convention on Biological Diversity, and has acceded to the Cartagena Protocol on Biosafety. The country is currently developing its NBF. There are no regulations for biosafety or policy on biotechnology and no known research, trials or commercial release of GMOs to date.

Gambia

It is party to the Convention on Biological Diversity and is a party to the Cartagena Protocol on Biosafety by accession. The country has a number of legislations that touch on governance of safety in Biotechnology. For instance, the Environment Management Act (1994) makes reference to Biosafety. Similarly, the food safety issues are regulated by the Public Health Act (1989) which can also be invoked to regulate on GM foods. The need for stricter regulations for GMOs and LMOs was identified and the process of developing an NBF that is currently underway will primarily address this. Gambia's biosafety policy is described in the draft NBF published in February 2005 but is yet to develop a policy on agricultural biotechnology.

Lesotho

Lesotho, a party to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety published its draft National Biosafety Framework in a bid to making it legally binding. Its main objective is safe application of biotechnology. The contents of the framework include the national biosafety policy; national biosafety law; risk assessment and management; and monitoring and inspection etc. However, the country is yet to adequately build monitoring capacity as it is even suspected that food products regularly imported into the country from South Africa may contain GM food products. It has permitted the distribution of non-milled GM food aid but warned the public to consume the grain but not to use it for cultivation. There is no known research, trials or commercial release of GMOs to date in Lesotho.

Liberia

Liberia is signatory to the Convention on Biological Diversity and also accession to the Cartagena Protocol on Biosafety. Currently the country does not have explicit policy on biosafety or biotechnology but has however finalised the draft legislation that will regulate all activities concerning modern biotechnology, which include contained use, environmental releases, placing on the market, transit, import, and export of GMOs-except those GMOs for human use which are regulated by other international agreements. The Liberia Biosafety Act is a component of the NBF whose provisions include procedures for release into the environment, transit and contained use, releases for experimental purposes as well as notification procedures, risk assessment and management, decision-making procedures as well as institutional arrangement for implementation of Biosafety regulations. Although the NBF looks practically finished, there is no known research and development, field trials or commercial release of GMOs in Liberia.

Niger

Niger published its National Biosafety Framework in January 2005. Environmental safety is regulated by Law 98-07 of April 1998 and its decree. There is no known research, trials or commercial release of GMOs to date.

Seychelles

Seychelles is party to the Convention Biological Diversity and has ratified the Cartagena Protocol on Biosafety and is currently implementing a UNEP-GEF project on development of the national biosafety framework. This process entails developing a biosafety policy and framework. There is no known research, trials or commercial release to date.

Swaziland

Swaziland is party to the CBD and has ratified the Cartagena Protocol on Biosafety. The country has a biosafety framework that is at advanced stage of development.

There is a draft National Biosafety Policy and a National Biosafety Bill, 2005 which was created by a Biosafety Committee set up in 2001. The draft policy seeks to provide a supportive and enabling environment for the introduction of GMOs in Swaziland. The core regulatory provisions have been crafted requiring that risk assessments, and decision-making on GMOs be based on the precautionary principle but these only apply to domestic commercial sales and plantings of GMOs. The country however, pays little regard to GM food aid and public participation in decision-making process. Swaziland has permitted the distribution of non-milled GM food aid, but however warned the public to consume the grain and not use it for cultivation. There is no known research and development, field trials or commercial release of GMOs to date.

Togo

Togo published its final draft National Biosafety Framework (NBF) in December 2004 paving the way for the establishment of legal and institutional frameworks. The objective of the document is to define orientation for a national policy; a legal system; an administrative system; a risk assessment and information sharing. It is party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety. There is no known research and development, field trials or commercial release of GMOs to date.

Countries without NBFS

Eleven countries in Sub-Saharan Africa (Angola, Burundi, Chad, Comoros, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mauritania, Sierra Leone and Somalia) have not made significant efforts towards developing frameworks for regulating GMOs. For instance as at December 2006 there was no available information on Angola as regards the National Biosafety Framework except previously in 2004, that country had introduced a ban on imports of non-milled GM food aid (<http://bch.biodiv.org/default.aspx>). Elsewhere, Chad and Mauritania are yet to develop biosafety regulations/guidelines and a policy on biotechnology. In both countries issues of food safety are regulated by a number of decrees that do not contain provisions for GMOs (<http://bch.biodiv.org/default.aspx>). In Somalia, the unending civil strife since 1991 and the absence of formal government has inhibited any efforts at developing binding legislation.

There was hardly any information posted on the BCH for Cape Verde, Central Africa Republic, and Sao Tome and Principe. This made hard for us to ascertain the status of Biosafety frameworks in these countries, a matter that merits further research in the coming years.

Conclusions

In 1992, countries of the world adopted the Convention on Biological Diversity in effect reaching a landmark agreement that both biological diversity and biological

resources should be conserved for reasons of ethics, economic benefit and indeed human survival (IUCN, 1994). However, the CBD goes somewhat beyond the conservation of biodiversity *per se*, to encompass other attendant issues such as access to genetic resources, sharing of benefits accruing from the use of genetic material and access to technology especially modern biotechnology (IUCN, 1994). This is important for Africa and indeed the developing world considering the fact that globally, biological diversity is unevenly distributed in favour of the South where bountiful biological resources exist in sharp contrast to the biologically poorer North. The South therefore, is a more significant stakeholder compared with the North regarding conservation of biodiversity. Thus, when developing countries were signing the CBD, their greatest motivation was conservation of biodiversity. To date, all countries in Sub-Saharan Africa except Somalia are Parties to the CBD.

However, the Convention also provides for access to, and transfer of, technologies including modern biotechnology and especially the use of such technologies in the promotion of human well-being, provided, this is accomplished in a manner that minimizes threats to biological diversity and human health. That is why the CBD also put into account *provisos* for an international framework in the field of safe transfer, handling and use living modified organisms resulting from biotechnology that may have adverse effect on conservation and sustainable use of biological diversity also referred to as the Cartagena Protocol on Biosafety (CBD, 2000). To date many African countries have signed and ratified the Protocol but implementation of the requirements of the Protocol remains a daunting challenge to many. Only five countries (Burkina Faso, Mauritius, South Africa, Sudan and Zimbabwe) in Sub-Saharan Africa appear to have so far met the basic obligations of the Cartagena Protocol on Biosafety. To many other countries, putting into place legal and administrative procedures and structures for full implementation of the Protocol remains largely 'work-in-progress' that will require concerted investment in capacity building to bring Africa to the threshold where it can exploit the benefits accruing from modern biotechnology in safe and environmentally responsible manner. However, it is worth mentioning that the situation remains relatively fluid, and with several countries operating interim NBFs, the number of countries with functional Biosafety frameworks is poised in due course.

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