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Review

Biosafety systems in Eastern and Central Africa

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This review examines the biosafety systems of selected countries in the Eastern and Central Africa. The biosafety systems are meant to safeguard human health, animal health and the environment against any possible risks posed by development and application of modern biotechnology. Though the focus is in the Eastern and Central African region, the study gives an overview of worldwide biosafety frameworks as guided by the Cartagena protocol on biosafety. The Eastern and Central African countries covered in this study are Tanzania, Kenya, Uganda, Rwanda, Burundi, Ethiopia and the Democratic Republic of Congo (DRC). An attempt is made to assess the current status on the countries' compliance to biosafety international conventions, institutional arrangements and regulatory regimes. A critical look is given to the existing biosafety frameworks, pinpointing their weaknesses and giving suggestions on what could be done to address the shortfalls. The study shows that Kenya is leading the group by having all the requirements in place, followed by Uganda. Tanzania has cleared the legal frameworks hurdles, but it is rather slow in processing applications of genetically modified organisms (GMOs) for containment and confined trials. Ethiopia, Rwanda, Burundi and DRC are still in the process of formulating their biosafety laws. The challenges facing the operationalization of the biosafety systems are financial constraints, insufficient trained human resources, poor facilities, low awareness and insufficient political will by some governments. It is argued that while biosafety frameworks stand to safeguard safe application of modern biotechnology, they should not have too stringent regulations, lest they impede the development of modern biotechnology in the Eastern and Central African region.

Key words: Biosafety, Cartagena Protocol, genetically modified organisms, regulatory regimes, institutional framework, liability and redress.

INTRODUCTION

Biosafety is widely understood as risk assessment, management, regulation, communication and mitigation in regard to safe development and application of modern biotechnology. In broader terms, biosafety is the prevention of large-scale loss of biological integrity, focusing both on ecology and human health. It is related to several fields: In ecology, it refers to imported life forms from beyond eco-region borders; in agriculture it is concerned with reducing the risk of alien or transgenic genes, and reducing the risk of food bacterial contamination. In medicine, it refers to organs or tissues from biological origin or genetic therapy products; in chemistry it may refer to chemical pollutants in water such as polychlorobiphenlyls (PCBs) levels affecting fertility and related hazards. The international biosafety protocol deals primarily with the agricultural definition, but many advocacy groups seek to expand it to include post-genetic threats such as new molecules and artificial life forms that may compete directly in the natural food chain (http://en.wikipedia.org/wiki/Biosafety). This review looks at not only agricultural aspects, but also biosafety aspects related to health and the environmental biotechnology in general.

Concerns on modern biotechnology

Concerns about modern biotechnology have mainly been directed to the living modified organisms (LMOs) or genetically modified organisms (GMOs) and their products. The main concerns lie on human health, animal health and abiotic environment. Under human health, there are concerns that genetically modified (GM) foods may contain novel protein toxins arising from introduction of foreign genes; they may also contain some proteins that may cause harmful immunological responses such

as allergic hypersensitivity. Also, it is feared that antibiotic resistance genes used as markers in genetic engineering may induce large-scale evolution of drug resistant bacteria (Hosea, 2004).

Under animal health, concerns are raised when GMOs and their products are used as feeds for poultry, pigs and ruminants. There are also concerns on chemical compositions, nutritional parameters and digestibility of GM feeds. Quality of milk from cattle subjected to GM feed, risks on animals fed on herbicide-tolerant or insect-protected crop silage are also considered. Concerns on the effect of GM feed on the bacteria present in the chicken gut can not be overruled.

Concerns for the abiotic environment dwell mainly on possible negative ecological impacts that may be caused by GMOs. Loss of biodiversity due to the dominance of GM strains; emergence of 'super weeds', gene escape and trans-genes effect are among them. On the other hand, direct and indirect side effects of GMOs on life support systems such as air, water and soil necessitate a thorough scrutiny before they can be used. Currently, other socio-economic controversies surrounding GMOs include products labeling to facilitate consumer choice, intellectual property rights related to ownership of the technology and ethical and cultural considerations in terms of community engagement and morality of modifying natural organisms (Hosea, 2004).

International convention on biological diversity

The brainchild behind biosafety systems is the International Convention on Biological diversity (CBD) which came into force in 1992. It recognizes the benefits of biotechnology and calls for safe management of biotechnology to ensure its safety to human health and the environment in general. Article 19.3 of CBD raises concerns on potential impact of biotechnology application and demands the precautions in safe handling of biotechnology products (http://www.cbd.int/). The CBD article has been the basis for the international biosafety regulatory systems, supplemented by the Cartagena protocol on biosafety (CPB).

Cartagena protocol on biosafety

The CPB is an international agreement which was adopted on 29th January 2000 and entered into force on 11th September 2003. It is an international mechanism to regulate trans-boundary movement of LMOs. It also regulates trade and use of GM crops and derived foods. The main objective of CPB is "to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account also of risks to human health and especial focusing on trans-boundary trade" (http://bch.cbd.int/protocol). The main feature of CPB is the use of the 'Precautionary Principle' as a policy tool of regulation of LMOs especially in risk management. The Principle states that "*If an action or policy has a suspected risk of causing harm to the public or environment, in the absence of scientific consensus that harm would not arise, the burden of proof falls on those who would advocate taking the action".* In general terms, it requires products to be proven safe before release to the market or into the environment (Bail et al., 2002; Cullet, 2006; Kinderlerer, 2008; www.ielcr.org). The protocol, however, excludes products of medical biotechnology application. The biosafety clearing house (BCH) is a mechanism set up by CPB to facilitate the exchange of information on LMOs and assist the parties to better comply with their obligations under the Protocol (http://bch.biodiv.org).

Other biosafety-related international treaties and agreements

The Agenda number 21 of the United Nations Conference on Environment and Development (UNCED; http://www.eoearth.org), also known as the Earth Summit, that took place in Rio de Janeiro, Brazil, in June 2nd to 14th 1992, raised the issue of safe application of biotechnology and safeguarding the environment from impact of modern biotechnology. It resulted to formation of specific institutions or organs to deal with global environmental issues under the United Nations Environment Program (UNEP) (http://www.unep.ch/biosafety). It also spearheaded the development of active environmental policies and regulations in over 100 developing countries including building capacity in developing biosafety policies and regulatory systems. Apart from CBD and CPB, there are a number of other international treaties related to biosafety:

1) International Plant Protection Convention (IPPC; https://www.ippc.int) was formed in 1997. It is an international agreement on plant health with 177 current signatories. It aims to protect cultivated and wild plants by preventing the introduction and spread of pests. It also emphasizes on the need of protecting and conserving genetic resources associated with food and plant crops.

2) Office International des Epizooties (OIE; http://www.oie.int) was established in 1924. Currently it has 172 member states and is led by an international Committee from member states with a Central Bureau elected by that Committee, which deals with the day-to-day running of the organization. Its mandate includes setting of sanitary standards for the international movement of animals or animal products.

3) International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA; http://www.planttreaty.org) was established in 2001. It enhances policies on conservation and sustainable use of plant genetic resources for food and agriculture, and ensures fair and equitable sharing of benefits derived from their use in food crops. It is also involved in the use of "Material Transfer Agreements" (MTAs) which is an aspect related to intellectual property (IP) issues related to CBD.
4) Codex Alimentarius Commission (CAC; http://www.codexalimentarius.net) was created in 1963 by Food and Agricultural Organization (FAO; www.fao.org) and World Health Organization (WHO; www.who.int) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The main purposes of this Program are to protect health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards. It also sets standards, guidelines and procedures for risk analysis and assessment of safety of food, including foods derived or produced from transgenic food crops and microorganisms.
5) Organization for Economic Cooperation and Development (OECD; http://www.oecd.org) was founded in 1961 to stimulate economic progress and world trade. It is a forum of countries committed to democracy and market economy, providing a platform to compare policy experiences, seeking answers to common problems, identifying good practices, and coordinating domestic and international policies of its members.
6) International Centre for Genetic Engineering and Biotechnology (ICGEB; http://www.icgeb.org) was formed in 1983. The Centre is dedicated to advanced research and training in molecular biology, biotechnology and biosafety, and holds out the prospect of advancing knowledge and applying the latest techniques in the fields of biomedicine, crop improvement, environmental protection/remediation, biopharmaceuticals and biopesticide production.

The World Trade Organization (WTO; http://www.wto.org) Agreements dealing with biosafety and biotechnology issues are:

1) The General agreement on Tariffs and Trade (GATT; http://www.gatt.org). It was signed in 1947 and lasted until 1993, when it was incorporated into the WTO 1995. The original GATT text (GATT, 1947) is still in effect under the WTO framework, subject to the modifications of GATT 1994. It advocates that GMOs and other products derived from them should be treated like conventional counterparts as long as they are safe.
2) The Agreement on the Application of Sanitary and Phytosanitary Measures - also known as the SPS (http://www.wto.org/english/tratop_e/sps_e/sps). It was negotiated during the Uruguay Round of the GATT, and entered into force with the establishment of the WTO. Under the SPS agreement, the WTO sets constraints on member-states' policies related to food safety (bacterial contaminants, pesticides, inspection and labeling).
3) The Agreement on Technical Barriers to Trade (TBT; http://www.wto.org/english/tratop_e/tbt_e/tbtagr_e.htm) is concerned with animal and plant health and safety, and with product standards in general. It tries to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles, while also providing members with the right to implement measures to achieve legitimate policy objectives, such as protection of human health and safety, or the environment; and
4) Trade-related Aspects of Intellectual Property Rights (TRIPS;http://www.wto.org/english/tratop_e/trips_e/trips_e.htm) which is an international agreement that sets down minimum standards for many forms of intellectual property (IP) regulation as applied to nationals of other WTO members. It was negotiated at the end of the Uruguay Round of the GATT in 1994. The TRIPS agreement introduced Intellectual Property Law into the international trading system for the first time and remains the most comprehensive international agreement that deals with IP issues.

WORLDWIDE BIOSAFETY FRAMEWORKS

Worldwide, by 2008 a total of 143 countries signed and became parties to the Cartagena protocol on biosafety (CPB) in the following distribution: Africa (40), Asia Pacific (37), Central and Eastern Europe (20), Latin America and Caribbean (25), Western Europe and other groups (21). However, it is noteworthy that some mega GMO-producing countries such as USA, Argentina, Canada, Uruguay and Australia who had already commercialised GMO crops, are yet to be members of CPB. Although it is encouraging to note that more than 75% of the members of the CBD are now members of the CPB (http://www.cbd.int/biosafety/signinglist.shtml; Kinderlerer, 2008), in the world stage there are still fierce debates on the types of regulatory mechanisms, especially on the issue of liability and redress.

The UNEP, through the Global Environmental Facility (GEF; www.thegef.org), established worldwide projects on "development of national bioafety frameworks (NBF)" in July 2001. It supported developing countries that were already members of the CBD and CPB to set up their NBFs for the management of LMOs. Whilst allowing for countries specific situations, needs` and priorities, UNEP-GEF Projects insisted on the inclusion of the following elements in their NBFs: Biosafety policies; regulatory regimes; systems to handle requests (administrative, risk assessment and management, decision making processes); follow-up actions (monitoring, inspections

and enforcement); and public awareness and participation (UNEP-GEF, 2001; www.unep.org/biosafety/Documents/DevtInfoPaper).

BIOSAFETY IN AFRICA

The African countries that are members to CPB are Algeria, Benin, Botswana, Burkina Faso, Cameroon, Cape Verde, Chad, Congo, DRC, Djibouti, Egypt, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Kenya, Lesotho, Liberia, Libya, Madagascar, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Seychelles, South Africa, Sudan, Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia and Zimbabwe (Kinderlerer, 2008). However, biosafety regulations and legislations are in place only in few African countries, and such limitation constitutes a serious constraint that impairs the use, evaluation and release of genetically modified organisms (Brink et al., 1998). South Africa, Egypt and Zimbabwe are the leading countries in developing functional GMO legislations, while other countries such as Ghana, Nigeria, Cameroon, Malawi, Cote d'Ivoire, Mauritius, Namibia and Zambia follow suit. The UNEP-GEF Project on Development of National Biosafety Frameworks supported at least 43 African countries (Morris and Koch, 2002).

BIOSAFETY SYSTEMS IN EASTERN AND CENTRAL AFRICA

The major objectives of biosafety systems in Eastern and Central Africa are: To establish a science-based, holistic and integrated, efficient, transparent participatory administrative and decision making system so that member countries can benefit from modern biotechnology while avoiding or minimizing the possible environmental, health, and socio-economic risks; and ensure that research, development, handling, trans-boundary movement, transit, use, release and management of GMOs and products are undertaken in a manner that prevents or reduces risks to human and animal health, biological diversity and the environment in general (Jaffe, 2006; Sengooba, 2008). The Eastern African Regional Program and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN; http://www.bio-earn.org) benefited Ethiopia, Kenya, Tanzania and Uganda.

Founded in 1998, its aim, among others, was to promote collaboration in biotechnology and biosafety for member states (Mugoya and Bananuka, 2004). Kenya is regarded as East Africa's most advanced country in terms of combining biotechnology research capacity with the necessary policy frameworks and biosafety regulatory systems (Sithole-Niang et al., 2004). Burundi and Rwanda joined the East African Community (EAC) in July 2007. Alongside with the Democratic Republic of Congo (DRC), a Central African vast country which is also lined up to join the EAC block, they are beneficiaries of the UNEP-GEF biosafety development project that helped them develop their national biosafety systems.

Features of biosafety frameworks for Eastern and Central African countries

The national biosafety frameworks (NBFs) in the Eastern and Central African countries covered in this study were drafted between 2001 and 2007. The NBFs for Tanzania, Kenya, Uganda, Ethiopia, Rwanda, Burundi and DRC have the following main features:

1) Conceptual framework - the background and context of NBFs are given including the objectives, justification, scope and key elements;
2) Review of national (sectoral and institutional) policies related to biosafety. These include, self assessments on agricultural, health, industrial, trade and environmental policies;
3) Development of national biosafety policies and guidelines;
4) Development of biosafety administrative systems – these include institutional arrangements, decision making mechanisms, risk assessment and management;
5) Legal frameworks and regulatory regimes – they take on board existing biosafety-related legislations and their mechanisms; draft biosafety bills and biosafety laws;
6) Monitoring, inspections and enforcement mechanisms;
7) Institutional arrangements – these include administrative structures and decision making mechanisms as regards safe introduction and application of modern biotechnology; focal points, competent authorities, governmental and private institutional organs and all constituted committees;
8) Public awareness, education and participation strategies; and
9) Socio-economic and ethical considerations.

NATIONAL BIOSAFETY FRAMEWORK FOR TANZANIA

Following Tanzania's ratification of the CBD on 8th March 1996, the government created an enabling environment for establishment of mechanisms for safe application of modern biotechnological research and development. The National Biosafety Framework (NBF; www.unep.org/biosafety/files/TZNBF, URT, 2005a) for Tanzania (TZ) was drafted by a multidisciplinary steering committee, coordinated by the Vice President's Office in October 2004 under the auspices of UNEP-GEF. It is a combination of policy, administrative, legal, and technical instruments that were developed to address safety issues

with respect to human and animal's health, environmental conservation, as well as socio-economic and ethical concerns in the context of safe development and application of modern biotechnology in accordance to national needs and international legislation (URT, 2009).

The main underlying principles of the TZ-NBF are strict liability, prior informed consent and precautionary approach. It aims at:

1) Establishing science based, holistic and integrated, transparent and participatory administrative and decision making system so that Tanzania can benefit from modern biotechnology, while avoiding or minimizing the environmental, health and socio-economic risk; and
2) Ensure that the research, development, handling, trans-boundary movement, transport, use, transfer, release and management of GMOs are controlled in a manner that does not cause any harm.

The key elements of TZ-NBF are: Regulatory systems and means of implementing them, means of validating the presence of GMOs, means of enforcing the compliance and information communication systems (URT, 2009).

Tanzania biosafety regulations

The Tanzania biosafety guidelines (2009) are based on the National Environmental Management Act (United Republic of Tanzania, 2004; CAP 191 (URT, 2004); government Notice No. 265 of 24th July 2009). They apply to the movement, use and commercial application of GMOs and their products. The TZ regulations cover the following areas: It gives preliminary provisions, general principles, administration and institutional arrangements, decision making procedures and approval mechanisms, risk assessment and management, GMO transportation, liability and redress, offenses and penalties, and general provisions (URT, 2005b).

The main principles that are involved in the Tanzania biosafety regulation are the precautionary principle *(*approval or refusal should depend on clear scientific knowledge and lack of such knowledge shall not be used as a basis for not taking preventive measures); prevention principle (risk assessment and environmental impact assessment to be carried out so that informed decisions may be made); and the principle of strict liability (any party, individual or corporate that deals with the introduction of a GMO or its products shall be liable for any harm, injury or loss caused directly or indirectly by those GMOs and their products or any activity related). It further states that: "In case of harm to the environment or to biological diversity, redress shall include the costs of clean up and rehabilitation whether incurred or to be incurred and costs of any preventive measures to follow, to the satisfaction of the national biosafety focal point". It is the right of individual and legal persons to seek redress in respect of breach or threatened breach of the (biosafety) regulations. Such persons shall *not* be expected to pay costs if their action failed, if it was out of reasonable concern. The stated penalties of offenders are monetary fines and prison terms. Most of the provisions given in the TZ biosafety regulations are a reflection of the CPB provisions (URT, 2005b).

Tanzania NBF institutional arrangement

The national biosafety focal point (NBFP) is the vice president's office (VPO; http://www.vpo.go.tz), division of environment. Its role and responsibilities include to: Review and approve biosafety applications for research, confined release, pre-commercial release; oversee the implementation of biosafety issues including collection and distribution of biosafety information to the public; establish contact and linkages with national, regional and international agencies or institutions; establish database for the purpose of facilitating collection, storage, retrieval and distribution of information relevant to biosafety; and establish and update a register of experts in biotechnology and biosafety (URT, 2005c). So far, the NBFP has issued a permit to only one research-based GMO application on virus resistant cassava while 3 others (GM cotton, GM potato and GM maize) are being processed.

The national biosafety committee (NBC) coordinated by the NBFP, is a multidisciplinary team of 15 members drawn from government, non-governmental organizations and private sector, including the academia. It consists of experts from the ministries of agriculture and food security, livestock development and fisheries, health and social welfare, industries trade, and also some members are drawn from the commission of science and technology (COSTECH; http://www.costech.or.tz), University of Dar es Salaam (UDSM; http://www.udsm.ac.tz), Muhimbili University of Health and Allied Sciences (MUHAS, http://www.muhas.ac.tz); Sokoine University of Agriculture (SUA; http://www.suanet.ac.tz) and other related research and development (R and D) institutions. Its functions include to review relevant applications from NBFP; advice on biosafety policy, legislation and other instruments; ensure that adequate testing of GMOs developed elsewhere has been performed in the country of origin and propose mitigation measure to be undertaken in case of any accidental release; and review biosafety regulation guidelines from time to time as necessary. The TZ-NBC may perform any other assignment as directed by the NBFP.

TZ-NBFP designates national competent authorities (NCAs), which are advisory sub-committees comprising of multidisciplinary team of expert in the field of biotechnology and biosafety, to review relevant GMOs

applications or proposals for development, introduction, import, export, transit, contained use, release or placing on the market. In Tanzania, the agricultural biotechnology scientific advisory committee (ABSAC) is an example of a competent authority in agricultural biotechnology. Moreover, NBFP has established a network biosafety centre of excellence (CE) to oversee biosafety issues pertaining to training, GMOs detection, regulation and research in general. The CE is constituted by all biosafety-related institutions including Mikocheni Agricultural Research Institute, (MARI; www.mari.or.tz), National Medical Research Institute (NIMRI; http://nimr.or.tz), the Department of Molecular Biology and Biotechnology (DMBB; http://mbb.udsm.ac.tz) at UDSM, SUA, MUHAS, Ifakara Health Institute (IHI; http://www.ihi.org), Tanzania Food and Drug Authority (TFDA; http://www.tfda.or.tz), Tanzania Bureau of Standards (TBS; www.tbstz.or), Tanzania Pesticide Research Institute (TPRI; http://tpri.or.tz), Animal Diseases Research Institute (ADRI; www.mifugo.go.tz), Kizimbani Research Station, Zanzibar, and Tanzania Government Chemist Laboratories Agency (TGCLA; http://gcla.go.tz).

Institutions in Tanzania that are involved in importing, exporting, handling, contained use, release or placing GMOs or GM products on the market are obliged to establish institutional biosafety committees (IBCs) to institute and control safety mechanisms and approval procedures at the institution level. Roles and responsibilities of TZ-IBCs are: To review the containment and confinement level required by guidelines for the proposed research; to make decision on the comparative ecological, economical, and social impacts or alternative approach to attain the objectives of the proposed GMOs; and to report to the relevant ministries and appropriate office in the concerned organization any significant GMOs activities, problems with or violation of regulation in any significant research related accidents or illness (URT, 2005c). In Tanzania, some of the functional IBCs are at MARI, NIMRI and DMBB-UDSM.

Tanzania biosafety guidelines

The Tanzania biosafety guidelines were developed alongside the NBF in 2005 (URT, 2005c). They apply to research, development, handling, transit, contained use, trans-boundary movement, release or placing of GMOs or their product on the market whether for release in the environment, for use as food, feed or processing. They are prepared with the view of ensuring their complimentarity and mutual supportiveness with the national policies and legislations. Tanzania biosafety guidelines spell out procedures on decisions making and decisions review, importation and exportation of GMOs, GMOs on transit, application procedures, GMO handling, transport, packaging and identification.

Under risk assessment (RA), the guidelines emphasize on technical and non-technical procedures of gathering diverse data to identify possible risk in research and development involving GMOs, their processes or products. Its main objective is to identify and evaluate the potential adverse effects of GMOs, taking into account the potential risks on human and animal health, and to the environment. The underlying principles of RA are: Scientifically sound and transparent manner of execution; lack of scientific knowledge or consensus should not necessarily be interpreted as indicating a particular level of risk, or an absence of risk, or an acceptable risk; and that RA should be carried out on a case-by-case basis.

Risk management (RM) is aimed at establishing and maintaining appropriate mechanisms, measures and strategies to regulate, manage and control risk identified in the risk assessment regarding the use, handling, introduction and field release of GMOs (Traynor, 1999; URT, 2005c). Risk management is conducted in contained and confined procedures. Whereas containment refers to safe methods of managing infectious agents or hazardous compounds in the laboratory environment, growth room or greenhouse where they are being handled or maintained in order to prevent escape outside the prescribed spaces in order to reduce exposure of potential hazardous agents, confinement, on other hand, is the use of controlled areas such as isolated and fenced, limited access fields to prevent GMO spread. The procedures and levels of physical, chemical and biological containment/confinement are stated in the TZ biosafety guidelines. Biosafety laboratory (preferably level 2) for basic research, confined field trials and pre-commercial testing are the chronological procedures that need to be followed. In Tanzania, biosafety level 2 containment facilities are at MARI, NIMRI and DMBB, while a confined GM maize trial site is set at Makutopora, Dodoma.

In biosafety monitoring and enforcement processes, TZ guidelines define monitoring as a process of keeping track of activities so as to determine whether they meet the objectives with a purpose of gathering data on GMOs in order to assess its impact on biotic and abiotic environment. Both case-specific (short term, related to individual GMOs) and general (long-term observation) monitoring processes are adopted. It is carried out before, during and after introduction of GMOs. Monitoring, inspection, enforcement and supervision are performed by the competent authorities under the TZ-NBFP.

Under socio-economic, cultural and ethical considerations, the Tanzania biosafety guidelines cover a wide range of safety and non-safety issues which are relevant for general release of GMOs and their products. Issues related to intellectual property rights (IPR) such as patenting biotechnology innovations, protection of indigenous varieties and undisclosed traditional knowledge and biodiversity; implications of crossing with

local varieties (GMOs contaminations), customer choices and contradictions to religious beliefs are highlighted.

Biosafety communication and public participation are key to any successful safe development and application of biotechnology. Its objective is to educate the public about biosafety processes, inform the public about the specific risks associated with the GMOs and actions taken to alleviate them; improve communicators' understanding of public values and concerns; develop mutual trust between the developers, regulators and the public; reduce conflicts or controversies; promote transparency in the regulatory process and collect stakeholders' views. The types of biosafety risk communication strategies outlined in the Tanzania biosafety guidelines include public notices in-print and electronic media; scientific publications from expert groups and decision documents. As a rule, all GMO products should be labeled (URT, 2005a, b, c).

It is noteworthy that although Tanzania is leading in having biosafety regulatory framework in place, it is lagging behind among other two East African Community (EAC) member states (Kenya and Uganda) in processing permits for GMOs research, import and applications. There seems to be poor political will and skepticism on the part of the decision makers. Equally, the public and private media are not educated enough on matters related to modern biotechnology, resulting to under-reporting and sometimes distorted reporting about the technology. On the other hand, strict liability clause in the Tanzania biosafety regulations is scaring away not only local researchers, but also prospective foreign investors of GMO technology in the country.

NATIONAL BIOSAFETY FRAMEWORK FOR KENYA

Kenya developed regulations and guidelines for biosafety in biotechnology since 1998 (RoK, 1998) and ratified the CPB in January 2002. The national biosafety framework for Kenya (KE-NBF; www.biosafetykenya.co.ke) was developed by the national council for science and technology (NCST; www.ncst.go.ke) in September 2002 through funding and technical assistance from the UNEP-GEF (RoK, 2003).

Biosafety regulation in Kenya

Kenya has developed a number of policy and legal documents to operationalize its regulatory system. They include the National Biotechnology And Biosafety Policy (2007) and Biosafety Law (2009). The Kenya Biosafety Act (2009) created the National Biosafety Authority, which was operationalized in 2009/2010 financial year (Macharia, 2005; RoK, 2009; Kingiri and Ayele, 2009). There has been a comparatively good political will in Kenya and the biosafety regulations have already been gazetted. It is noteworthy that in the liability and redress clauses, the Kenyan biosafety regulations opt for 'fault-based' rather than 'strict' regimes. Applications to import or release GMOs are submitted to IBC where they are reviewed and assessed for compliance with the guidelines before they are submitted to NBC and finally to NCST (now those powers have been handled over to the newly formed national biosafety authority) for approval. Over ten applications have been processed so far (Traynor and Macharia, 2003; Macharia, 2005, 2010). The GMO applications/projects that have already been approved in Kenya include improved sorghum protein quality, cowpea protected from pod borer, cassava containing pro-vitamin A, water efficient maize, cassava resistant to mosaic virus, weevil resistant sweet potato, and insect resistant Bt cotton. The limitations in processing GMOs–related applications in Kenya include inadequate qualified potential applicants, insufficient competence on the part of experts who evaluate applications and public awareness is rather slow due to financial constrains (Harsh, 2005; Macharia, 2010).

KE-NBF institutional arrangement

The National Biosafety Authority (NBA; www.biosafetykenya.co.ke) is the national focal point on GMOs regulation in Kenya. Its main task is to acknowledge receipt and screen applications. The competent authorities are charged to do risk assessment. The 16-member Kenya National Biosafety Committee (NBC) (constituted in 1998) consists of experts drawn from the national council for science and technology (NCST; www.ncst.go.ke), National Environmental Management Authority (NEMA; www.nema.go.ke), Kenya Bureau of Standards (KEBS; www.kebs.org); together with ministerial agencies responsible for biotechnology and biosafety. Nominees from producers and consumers are also members of NBC. The Institutional Biosafety Committees (IBCs) are also formed out of institutions' multidisciplinary teams (RoK, 1998, 2009).

The Kenya's biosafety systems have been considered to be rather weak (Kingiri and Ayele, 2009). They could be improved further if the following are considered: Intensification of public awareness and participation, harmonization and consensus building among biotechnology and biosafety institutions and capacity building especially for regulators and other decision makers.

NATIONAL BIOSAFETY FRAMEWORK FOR UGANDA

During 1998 to 1999, the Uganda Council for Science and Technology (UCST; www.uncst.go.ug) undertook a country study with support from UNEP-GEF to develop the National Biosafety Framework for Uganda (UG-NBF;

www.unep.org/biosafety/Documents/NBFs) which was adopted by the Ministry of Environment in March 2001 (UCST, 2000). The project also resulted to formulation of the Uganda National Biotechnology and Biosafety (BAB) Policy in 2008 (www.absfafrica.org) consistent with the national environmental Act (1995) and the CPB (2000). The objective of the BAB Policy is to provide regulatory and institutional framework for sustainable and safe application of biotechnology for national development (www.uncst.go.ug).

Biosafety regulation in Uganda

In Uganda, It is noteworthy that there is no biotechnology and biosafety law in place yet, but a Biosafety Bill is being drafted (www.uncst.go.ug, cited August, 2011). Meanwhile, there are some biosafety regulatory interim arrangements under provisions of the BAB Policy and the National S and T Act (Cap 209). The interim biosafety regulatory system is coordinated by Uganda National Council for Science and Technology (UNCST). The NBC is the national administrative body on matters related to biosafety (RoU, 2004a; Nampala et al., 2005; Wafula and Clark, 2005). Several guiding documents such the standard operating procedures (SOPs) for contained and confined experiments are also available. The Biosafety Bill will provide a more unified approach to biosafety in biotechnology research. The national guidelines related to biosafety include the national guidelines for containment; for regulation of research with genetically modified organisms and microbes (2007); for confined field trials; for field experiments with genetically engineered plants (2006); procedures and forms for field experiments with genetically engineered crops (2006); biosafety inspection Manual for field experiments involving genetically engineered crops (2007); and crop specific compliance handbooks on bananas, cotton, maize (www.uncst.go.ug).

Institutional arrangement

The biotechnology and biosafety national competent authority in Uganda is the UNCST. It is responsible for issuing permits for applications on GMOs and is advised by the national biotechnology advisory committee (NBAC; (www.absfafrica.org) on biotechnology and biosafety policy matters (RoU, 2002). The national biosafety committee (NBC) has 15 members derived from different relevant disciplines. Established in 1996, NBC derives itslegal status from the UNCST statute of 1990. It provides technical advice on biosafety issues to the government and maintains links with biotechnology research centers (RoU, 2002, 2004a, b). The formation of Institutional Biosafety Committees (IBCs) is guided by the BAB Policy. Its members are drawn from a heterogeneous pool of experts from relevant ministries, including the end-users of GMO technology. It reviews Biotechnology research proposals and applications for contained and confined trials, and prescribes appropriate containment/confinement requirements, and spells out conditions for approval. So far, NBC has approved 5 confined field trials (CFTs) and 5 applications are under review. The approved GMO projects are: Black Sigatoka disease resistance in East African Highland Bananas (EAHBs); herbicide tolerant cotton - RR Flex™; Bt Cotton - Bollgard™; bio-fortified EAHBs (Iron, Pro-Vit A, Vit E); and virus resistant cassava (CMD). The applications under review are: BXW resistant banana, drought tolerant maize, virus resistant cassava (CBSV) and virus resistant sweet potato (www.uncst.go.ug; RoU, 2002, 2004a, b).

Uganda needs to speed up the process of having the Biosafety Bill passed. It also needs to strengthen its national capacity for biosafety monitoring and enforcement, and develop appropriate training programs related to biosafety for its regulators in order to contribute technical expertise in a sustainable manner. Furthermore, there is a need to bring about a broader perspective of biosafety, which balances benefits against risks (Sengooba et al., 2005; www.bio-earn.org).

NATIONAL BIOSAFETY FRAMEWORK FOR ETHIOPIA

Ethiopia ratified and became a member of the Convention on Biological Diversity (CBD) in 1994 and the Cartagena Protocol on Biosafety in 2004. It also joined the World Intellectual Property Organization (WIPO) in 1998. The Ethiopia's NBF is a combination of government sectoral and cross-sectoral environmental and biotechnology policy provisions. It is also in line with the Ethiopian constitution. It was drafted by the environmental protection authority of Ethiopia in 2007 (EPA, 2007; http://www.unep.org/biosafety) under the UNEP-GEF financial grant, and was recently endorsed by the Ethiopian parliament, with the objective of regulating the possible adverse impacts of genetically modified organisms (GMOs) on biological diversity, human health and the environment (www.et.undp.org).

Biosafety regulatory framework in Ethiopia

In Ethiopia, the biosafety regulatory regime, which is based on the *Precautionary Principle*, is set to protect human and animal health, biological diversity and the environment at large against the adverse effects of GMO and products thereof. The draft Biosafety Regulations/Proclamation document is aimed at regulating all transactions related to GMOs including import, export, transit, confined and contained use, release, transport or placing on the market any GMO or its products whether intended for use in the environment

or for use as pharmaceutical, for food, feed or processing (EPA, 2007). Article 8 of the Biosafety Regulation/Proclamation states that the initial steps that should be taken in relation to any transaction of GMOs or products is to obtain an Advanced Informed Agreement (AIA) from the EPA. The regulations further set directives in management of GMOs. These directives are: the directive to determine the contents of an application or transactions involving GMOs or their products, the directive on risk assessment parameters of GMOs or their products, the directive on risk management schemes, the directive on the application for transport of GMOs or their products, the directive for the storage of GMOs or their products, and the directive for emergency measures for accidental release of GMOs or their products. As per the draft Biosafety Bill, all requests pertaining to transactions of GMOs should be made as a written application to EPA. The applicant is required to undertake risk assessment and submit a report and other necessary documents. EPA disseminates the report to experts as well as availing it to the general public to solicit comments before making final decision on whether to approve or reject the application.

Monitoring and enforcement of the regulations and directives are the responsibility of EPA, which appoints regulatory and enforcement experts. Article 29 of the Biosafety Regulations/Proclamation emphasizes on the CPB's *Strict Liability and Redress* clauses, stating that: "A person who is engaged in any transaction related to GMO or its products shall be *strictly* liable for any harm caused. Liability also extends to the provider, supplier or developer of the GMO or its products that has caused harm to human health, biodiversity or environment" (EPA, 2007).

Institutional arrangement

The competent authority responsible for administrative system pertaining to all matters related to GMOs including to handling notifications or requests for all research and development activities, import, export, transit, handling, release, contained use, transport and placing in the market are charged to the environmental protection authority (EPA). The same body is also responsible for setting up mechanisms of enforcement and monitoring of GMOs and public awareness and participation (EPA, 2007). Under EPA, the national coordinating committee (NCC) consisting of 33 members is constituted. It is drawn from diverse professions serving in federal and regional offices, Universities and research institutions. The establishment of the Ethiopian Intellectual Property Office in 2003 for implementation of intellectual property issues could also be considered as one step forward in biosafety initiatives (Kassa, 2011).

Currently, there is no stand-alone policy on biosafety in Ethiopia. However, there are other policies that address major issues related to biosafety. Such policies are the Constitution of Ethiopia, national environmental policy (1997; www.phe-ethiopia.org), national science and technology policy, national biodiversity conservations and research policy and agricultural research policy. All these policies are relevant when it comes to safe use of modern biotechnology including importation and exportation of biotechnological products and are implemented by relevant bodies within the responsible ministries.

In terms of regional cooperation and integration initiatives, Ethiopia has joined the world intellectual property organization (WIPO) in 1998 and the treaty establishing the common market for Eastern and Southern Africa (COMESA) in 1994. It is also a member of the partnership agreement between members of the African, Caribbean and Pacific (ACP) group of states and the European Union (EU), and has applied to become a member of WTO. However, the existing IPR legislations have to be in accordance to the agreement on trade related aspects of intellectual property rights (TRIPS). It is only after sorting out such discrepancies related to international treaties that the country can attract private companies involved in new technologies including biotechnology and biosafety research, development and trading (Kassa, 2011).

Public awareness and participation are facilitated by EPA to ensure that the public is made aware of any GMO transactions. Reasonable time is allowed for public interaction and inputs before any decision is made. The planned national biosafety clearing house (BCH) will serve as a public awareness instrument for all information regarding GMOs or products. More public education programs involving mass media and training on biosafety at tertiary level will also be created (EPA, 2007).

Overall, Ethiopia has moved in the right direction as far as setting up legal and institutional frameworks for biosafety is concerned. However, there is a feeling among local researchers as well as foreign would-be GMO investors that the draft biosafety bill is rather too restrictive, and would limit rather than advance modern biotechnology (Kassa, 2011). It remains to be seen how these regulations will impact on biotechnology research and development in Ethiopia.

NATIONAL BIOSAFETY FRAMEWORK FOR RWANDA

The national biosafety framework (NBF) for Rwanda was developed in 2005 by the national coordinating committee (NCC) under the Ministry of State in charge of lands and environment. financial and technical assistance to carry out the project was obtained from UNEP/GEF. The project was accomplished in August 2005. It has been developed not only to fulfil the requirements for CPB, but also to ensure that Rwanda intensifies safe application of modern biotechnology and derives optimum benefits from it (RoR, 2005; www.unep.org/biosafety/files/RWNBFrep; ETOA, 2008).

The NBF for Rwanda has 3 main components: The national biosafety policy, which highlights how biotechnology fits in the national development framework; the legal and administrative mechanisms for biotechnology and biosafety development in Rwanda, including the national biosafety bill and guidelines which operationalize the policy and provides regulatory regime for ensuring that biotechnology development in Rwanda is safe for human health, the environment and the economy; and the institutional framework spelling out responsibilities and mandates of stakeholder institutions. The main objectives of Rwanda's NBF are: To put in place appropriate policy, regulatory and institutional mechanisms to assist the country to optimise the potential benefits from modern biotechnology; and to ensure that biotechnology activities are undertaken in safe, participatory and transparent manner in order to prevent risks associated with modern biotechnology (RoR, 2005). The components on NBF include the national biotechnology and biosaftety policy and the national biosafety guidelines. These policies were developed in line with the country's Vision 2020, the national investment strategy and the poverty reduction strategy.

Legal framework

The biosafety bill has provisions for regulation of import, transit, contained and confined trials or placing GMOs on the market. It has three major elements: Institutional mechanisms for implementing the bill, risk assessment and management, and offences and penalties. Advanced informed agreement (AIA) is required for GMOs applications before entering the country. A permit system is issued by the Registrar of Rwanda Environmental Management Authority (REMA; www.rema.gov.rw) which avails to the BCH particulars of the GMOs that have been handled. Article 18 of the Bill mandates all foreign applicants to have local collaborating institutions including researchers and academicians (RoR, 2005).

Institutional arrangement

The Rwanda's Environmental Management Authority (REMA) is the national competent authority (NCA) to whom all GMO related matters should be addressed, while the ministry responsible for environment is the national focal point (NFP) for CBD and CPB. It also houses the National biosafety committee (NBC), ad-hoc committees, and biosafety registrar. The REMA's function are: To receive, respond or communicate decisions made by the NBC of GMOs notifications and applications; to establish mechanisms for insuring the appropriate handling, dissemination and storage of documents and data; and to promote public awareness, education and involvement in the decision making process. The institutional biosafety committees (IBCs), biosafety officers and biosafety inspectors are part of the monitoring arrangements set in place (RoR, 2005).

The five-year (2006 to 2010) plan set for implementation of the NBF program components contains the following: Institutional set-up, institutional and human resources capacity building, monitoring and evaluation, and public education and awareness raising. Under public awareness and education, public participation in the decision making process and public access to information are emphasized (RoR, 2005).

Rwanda faces the challenge of effectively operationalizing the NBF's policy and legal provisions and realizes its objectives. Its five-year program that seeks to address the whole range of concerns related to developing scientific, technical and institutional capacities for the implementation of biosafety measures is proposed in the policy and legal framework.

Overall, the Rwanda's NBF is quite elaborate and comprehensive. Article 34 of the Biosafety Bill embraces the *strict* liability clauses of the CPB. As it has been the case for other countries covered in this study, it is argued that GMOs should not be looked at as "hazardous" materials, and therefore, for the sake of promoting modern biotechnology in the Sub-Saharan Africa in order to address the countries' development visions, 'fault-based', rather than 'strict' liability legislation should be considered.

NATIONAL BIOSAFETY FRAMEWORK FOR BURUNDI

The national biosafety framework for Burundi was prepared by the Ministry of Urban Planning, Tourism and Environment through the National Institute of Environment and Nature Conservation. Funded and supervised by UNEP-GEF Project, and accomplished in November 2006, it is a product of Government's political will to take advantage of the benefits that Burundi can draw from modern biotechnology while preserving the environment and the health of its population (RoB, 2006; www.unep.org/biosafety/files/BINBFrepEN). The biosafety policy, developed as part of the NBF, aims at protecting the population's health, safeguarding environment and biodiversity, and assurance of food security. Its broad objective conforms to the *Precautionary Principle* contained in the Rio Declaration: "To promote the development of modern biotechnology around a participatory biosafety system". Procedures for risk assessment and management; GMOs handling, transport, packaging and identification are part of the NBF. Regulation and enforcement mechanisms involve scientists, inspectors and the monitoring committees.

Legal and regulatory regime

Burundi do not have in place a specific legislation on biotechnology and biosafety, but even before it ratified the CPB, it had various laws related to movement of

biological materials. The Burundi's Draft Biosafety Bill (2006) with 13 chapters and 5 annexes sets the fundamental rules meant to guarantee safety of the population and the environment against the risks of GMOs and their derived products (RoB, 2006). It also incorporates the AIA procedure that guarantees the possibility of assessing potential adverse effects of GMOs before importation. Although the NBF mentions that in the Biosafety Bill there are liability provisions, it is not elaborated in the NBF text. Therefore, the type of liability and redress regime that will be embraced by the country is not clear.

Decision making mechanisms

The institutional structure of the NBF in Burundi consists of the competent national authority (CNA) in the Ministry of Urban Panning, Tourism and Environment. Its role is to oversee all functions related to biosafety in Burundi. The National Institute for Nature Conservation (NINC; www.nature-worldwide.info/burundi) plays a role of biosafety administration while the National Biosafety Consultative Committee (NBCC) assists the minister in charge of the Environment on matters related to biosafety. The National Biosafety Experts Committee (NBEC) is in charge of carrying out risk assessment and making recommendations, while the Public Biosafety Committee (PBC) is a non-governmental structure composed of members from civil society, and their main mission is to ensure protection of the environment. The National Correspondent of the Cartagena Protocol (NCCP), or the focal point, makes the connection between the country and Cartagena Protocol Secretariat, and achieves his/her mission with collaboration with the CNA. Finally, the national correspondent of the Biosafety clearing house (FP/BCH) establishes contacts with the BCH set up at the international level as per the CPB directives.

Under awareness creation mechanisms, education and public involvement in the decision making process, the Burundi's NBF is set to avail to the public GMO data, sensitise the public to be involved in biodiversity conservation and sustainable use of genetic resources, as well as engaging in public education and awareness on the GMO-related issues. In the implementation of its NBF, Burundi plans to embark on resource mobilization and capacity building drives in favour of development of biotechnology and Biosafety (RoB, 2006).

As Burundi moves towards having an operational biosafety framework with right policies and regulatory regimes in place, its organizational structure, though comprehensive, is rather cumbersome compared to other countries in the region. In case there is a chance of revising the NBF, it would be advisable to streamline its institutional structure in view of improving its management system and reduce a seemingly decision making bureaucracy.

NATIONAL BIOSAFETY FRAMEWORK FOR DEMOCRATIC REPUBLIC OF CONGO

The national biosafety framework for the Democratic Republic of Congo (DRC) was developed in December 2007 by the national coordinating committee (NCC) under the trusteeship of the Ministry of Environment, Nature Conservation, Water and Forests. Having joined the CPB in February 2005, DRC was ready to benefit from the UNEP-GEF funding on this activity, so as to create conducive regulatory conditions for application of modern biotechnology. There is no stand-alone Biosafety Policy for DRC, although there are some related policies such as the IPR and plant/animal protection policies. The NBF, therefore, incorporates the biosafety policy, based on the *Precautionary/Preventive* Principle (DRC, 2007). It also adopts the *Polluter Pays* Principle in its liability and redress regimes, aiming at charging the polluter the ecological, economic and social costs of pollution. Currently, there are no biosafety, legal or regulatory regimes in place for DRC. Therefore, the NBF document advises the government to draft a Biosafety Bill that would incorporate all the necessary ingredients pertaining to safe development and application of modern biotechnology (DRC, 2007).

Administrative structure and system of handling requests

The following biosafety institutional arrangement has been formulated: The national biosafety focal point is the in-charge person responsible for liaison with the CPB. The competent national authority (CNA) is responsible to make follow-ups and final decisions of any request related to GMOs. In DRC, the CNA is constituted by the ministries in charge of agriculture and environment. The CNA is assisted by the national biosafety consultative committee (NBCC), and the scientific and technical biosafety committee (STBC). The former leads a consultative mechanism to assist the CNA while the latter provides scientific and technical advice to facilitate final decision making process. The aforementioned-named authorities are also responsible for risk assessment and management issues. The biosafety clearing house (BCH) is in charge of collecting and exchanging scientific, technical, ecological and legal information on the trans-boundary movement of GMOs/LMOs (DRC, 2007).

The NBF has put in place all mechanisms necessary to carry out the follow-up actions, namely monitoring, inspection and enforcement under the management structure. Some initiatives involved include "bio-vigilance" and "safeguarding" mechanisms (DRC, 2007). Under public awareness, education and participation programs,

Table 1. Basic elements of the national biosafety systems in selected Eastern and Central African countries.

Country	Policy	Regulatory regime	Number of institutions involved
Burundi	Biosafety framework (November, 2006).	Biosafety bill (2006).	8
DRC	Biosafety framework (December, 2007).	Biosafety bill (2007).	6
Ethiopia	Biosafety framework (August, 2007).	Biosafety proclamation (August, 2007).	4
Kenya	Biosafety framework (September, 2002). Biosafety policy (2007).	Biosafety Act (February, 2009).	5
Rwanda	Biosafety framework (August , 2005).	Biosafety bill (2006).	5
Tanzania	Biosafety framework (2005).Biosafety guidelines (2005).	Environmental management Act CAP 191 (2004). Biosafety regulations (July, 2009).	5
Uganda	Biosafety framework (March 2001). Biotechnology and biosafety policy (2008).	Interim arrangements: National S and T Act CAP 209. (2002). Biosafety bill (2009).	4

the NBF provides for information dissemination methods, general and specialized training opportunities and sets different phases for communication, consultation, participation and partnership.

It is praiseworthy that the DRC biosafety framework is very elaborate and takes care of almost all the details suggested in the Cartagena protocol. However, by designating two separate ministries (one responsible for food/feed and another on environmental issues) to be the national competent authority on biosafety, it might reduce its efficiency due to unforeseen bureaucracy. In addition, much remains to be done, especially in the areas of public awareness and participation, as the public is not sufficiently informed on the issues related to biotechnology, and unfortunately, NGOs in the DRC are rather not interested in biosafety issues (ABSF-AFRICA; http://www.absfafrica.org).

The seven countries covered in this study demonstrate their commitment to adhering to the CPB by having in their NBFs all the key biosafety elements (Table 1). While Kenya and Tanzania are done with all the required legal and institutional arrangements, Uganda, Ethiopia, Rwanda, Burundi and DRC are still in the process of instituting their biosafety laws.

Challenges and way forward

The countries covered in this study are among the least developed in the world and therefore they are under-equipped in terms of technical capacity to conduct biotechnology and biosafety activities. Human and physical infrastructural resources are inadequate, forcing them to be dependant of external funding in order to carry out most of the biosafety activities. The general public awareness on matters pertaining to biosafety is rather low. To develop this awareness, there is a need to intensify development of human resource needs to extend beyond biosafety training in order to cover other related areas such as intellectual property rights, management and trade. Lack of, or insufficient political will is another hurdle. Some governments are undecided, and/or sometimes take too long to approve introduction of GMOs, even at the level of research, although biosafety frameworks are already in place. The 'strict liability and redress' clauses in the CPB, that have been adopted by most of the Eastern and Central African countries, have become a center of heated debates worldwide. While they are set to ensure maximum safety, they are, on the other hand, too stringent to the extent that they discourage not only foreign investors, but also local biotechnology researchers and developers (Cullet, 2006; www.ielcr.org). Furthermore, the biosafety laws and regulations in Eastern and Central African region are fragmented along country lines, each country having its own laws and regulations. This trend is contradicting the political climate in the region where governments are discussing political and economic integration policies (www.eac.int).

Funding of biosafety and biotechnology R and D activities in the region should be a top priority of governments by engaging in short, medium and long-term interventions. They should intensify public awareness and develop biosafety curricula in all levels of education, and also increase support in specialized training (Sengooba et al., 2009). The governments should further invest and support capacity building initiatives in all these areas of biosafety and biotechnology initiatives. Awareness campaigns on biotechnology and biosafety issues should be intensified

to cover a wide range of audiences including the decision makers, media and the general public. The 'strict liability and redress clauses in the CPB should be re-examined carefully, in view of avoiding hampering home-grown and/or imported biotechnologies that are good for the countries' food security, improved health and poverty alleviation in line with the Millennium Development Goals 2015 (http://www.un.org/millenniumgoals), while still giving safety a deserving priority.

The Nagoya–Kuala Lumpur Supplementary Protocol on liability and redress to the Cartagena Protocol on biosafety was adopted in Nagoya, Japan, on 16th October 2010; http://bch.cbd.int/protocol/supplementary). The new supplementary protocol provides revised international rules and procedures on liability and redress for damage to biodiversity resulting from living modified organisms (LMOs). The g in Uganda, overnments should ratify the revised protocol in order to allow them to review national laws to revoke, if possible, the 'strict' liability and opt for more user-friendly 'fault-based' liability clauses. There is a need to develop home-grown biotechnology and biosafety capacity in order to instill "ownership" of thinking into the minds of scientists and policy makers, thereby enhancing public trust (Kingiri and Ayele, 2009). Furthermore, there is a need to harmonize biosafety regulations in the Eastern and Central Africa bloc in line with the envisaged approval of political and economic integration policies that are currently being discussed.

CONCLUSION

This study attempted to review the worldwide biosafety systems with special attention to selected Eastern and Central African countries namely Tanzania, Kenya, Uganda, Ethiopia, Rwanda, Burundi and the Democratic Republic of Congo, with an in-depth look on Tanzania. All the countries studied are members to the CBD and CPB, and have National Biosafety Frameworks, thanks to the UNEP-GEF financial and technical support. The national frameworks incorporate all the basic elements namely biosafety policies, regulatory regimes, systems to handle requests (administrative, risk assessment and management, decision making); follow-up actions (monitoring, inspections and enforcement), and public awareness and participation. The study shows that Kenya is leading the group by having all the requirements in place, followed by Uganda. Tanzania has cleared the legal frameworks hurdles, but it is rather slow in processing applications of GMOs for containment and confined trials. Ethiopia, Rwanda, Burundi and DRC are still in a process of formulating their biosafety laws. The challenges facing the countries in the region are financial constraints, insufficient trained human resources, poor facilities, low awareness and insufficient political will by some governments. In order to timely realize the benefits of modern biotechnology, countries are advised to review the rather stringent regulatory laws to make them more 'friendly' to local and foreign researchers and investors, without jeopardizing safe application of GMOs and their products.

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