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HARMONIZED BIOSAFETY POLICY FRAMEWORK FOR THE EAST AFRICAN COMMUNITY (EAC)

East African Community

One People, One Destiny

IN COLLABORATION WITH

AFRICAN UNION

Directorate of Human Resources, Science and Technology

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TABLE OF CONTENTS

LIST OF ACRONYMS

AIA – Advance Informed Agreement (or prior Informed Consent/ PIC)

AIDS – Acquired Immuno-Deficiency Syndrome

AU – African Union

AUC – African Union Commission

BCH – Biosafety Clearing House

CBD – Convention on Biological Diversity

CBO – Community Based organizations

CHM – Clearing House mechanism of the CBD

CNA – Competent National Authority

COMESA – Common Market for Eastern and Southern Africa

CPB – Cartagena Protocol on Biosafety

EAC – East African Community

EAC – East African Community

EAC-BCH –East African Community Biosafety Clearing House

GEF – Global Environmental Facility

GM – Genetically Modified/ Genetic Modification

GMO(s) – Genetically Modified Organism(s)

HIV- Human Immuno-deficiency Virus

LMO(s) – Living Modified Organism(s)

LMO-FFP – Living Modified Organisms destined for use as Food, Feed or Processing

MoU – Memorandum of Understanding

NBSAPs – National Biodiversity Strategies and Action Plans

NDPs – National Development Plans

NFP – National Focal Point

NFP-BCH – National Focal point for the Biosafety Clearing House

NGOs – Non- Governmental Organizations

RA – Risk Assessment

REC – Regional Economic Cooperation organisation

RM – Risk Management

SADC – Southern African Development Community

SCBD – Secretariat to the Convention on Biological Diversity

UN – United Nations

UNEP – United Nations Environment Programme

EXECUTIVE SUMMARY

The developments in modern biotechnology using recombinant DNA techniques, otherwise known as genetic engineering has been hailed by some as a major breakthrough that will unlock the potential in breeding, medicine, bio-remediation and industrial applications; while to some, it is regarded a risky misadventure that poses lots of risks to biodiversity, the environment and human health. Either side of the continuum has some merits that warrant some consideration.

However, there is general consensus, globally that the science of genetic engineering has a great potential for human development if developed and applied judiciously with the necessary safety measures and regulations to ensure its safe development, transfer and use, to ensure full benefit from the technologies and eliminating or at least minimizing any potential risks associated with these technologies. The term Biosafety is a collective term used to refer to the measures put in place and enforced to ensure the safe development, transfer and use of genetic engineering products / genetically modified organisms. The CPB is one of the international treaties is an international treaty under the auspices of the CBD, that strives to promote biosafety globally.

The African Union Commission put in place some regional measures in form of strategies, Issues papers and a model law to help its member states to put in place their national biosafety frameworks, laws and standards as well as helping its sub-regional components to do the same at sub-regional level. The East African Community having committed itself to promote harmonized Biosafety policies among its member states, requested the AU Commission for assistance in form of a study to produce a harmonized EAC Biosafety Policy guidelines to form a basis for this EAC harmonized policy framework on biosafety; a call this document addresses.

The document in its section one first gives a background to Biosafety, at the international regional and sub-regional scenes, before delving into the status of implementation of the requirements under the CPB to which all EAC partner states are parties in section 2, first summarising what obligations under the CPB require implementation by parties. Section three addresses the harmonized policy framework for EAC, using the obligations under the Protocol; identifying the key issues/ challenges and policies that would be put in place to address the key challenges.

Section four deals with the issue of Capacity building for Biosafety as well as proposes ways and means of raising the necessary resources for biosafety capacity building, while section five proposes an institutional mechanism for implementation of the harmonized policies.

1. BACKGROUND AND JUSTIFICATION

1.1. Background

Biotechnology has been defined as any technological application that makes use of biological systems, living organisms, or their derivatives to make or modify products or processes for a specific use (CBD, 1992). The use of biotechnology is very old spanning perhaps to when human beings started manipulating plants, animals and microorganisms for personal use in food, feed, farming, medicine among other things, through such processes as brewing, bread making, yoghurt and cheese making, making of vaccines, plant and animal breeding to mention but a few.

In the past several decades, however, biotechnology has been taken to a higher level through the use of recombinant DNA techniques otherwise known as genetic engineering (GE) or genetic modification, where scientists have been able to alter natural DNA by either adding foreign DNA or parts DNA, or removing parts of DNA to produce novel organisms with altered characteristics that can be inherited in a usual Mendelian fashion as the new DNA or segments of DNA are integrated in the recipient organism's genome. Organisms produced through genetic modification or genetic engineering are collectively referred to as Genetically Modified Organisms (GMOs) or Living Modified Organisms (LMOs). These new techniques have made it possible to transfer desired traits of interest across different organisms that are not closely related as was the case before using traditional breeding techniques where genes could only be transferred between species within the same taxonomic family.

Whereas these new techniques have been hailed by some as a major breakthrough that has made it possible to produce GMOs with enhanced traits such as disease/ pest resistance, higher productivity, drought tolerance as well as in other processes such as disease diagnostics, bio-remediation, environmental cleaning as well as a host of possible industrial applications; others are worried that though the technology is useful, it could also be used for non useful purposes such as making of biological weapons such, or other malicious purposes such as more virulent plant pathogens that can be created if ordinary pathogens can be engineered to become more pathogenic. There are also worries as to how the novel genes inserted in GMOs are likely to behave in the new organisms over time and how the novel organisms (GMOs) are likely to interact with other organisms in the receiving environment. There are possibilities of say organisms engineered to produce pesticides harming non-target organisms, or the transgenes being transferred to non-target organisms through cross-pollination, or plants modified to resists herbicides for example becoming "Super-weeds" that may require stronger chemicals to control thus negatively affecting the environment. There are equally worrying concerns that GMOs being made in a manner that enables genes

to cross natural barriers to produce organisms with novel traits could lead to production of organisms or traits that are harmful to human health, say through production of new or more dangerous human pathogens or production of foods that contain toxic or allergenic components arising from the inserted genes or reactions between the inserted genes and the recipient organism genes.

There is a general consensus worldwide therefore that modern biotechnology (genetic engineering) is a useful tool that has a lot of promise for humanity if applied judiciously with carefully chosen and implemented safety measures; while at the same time avoiding possible negative impacts that could arise from improper use of the same technology by unscrupulous persons or through the GMOs responding in unpredictable manners after being released into the environment or onto the market.

The need to ensure environmentally sound use of biotechnology was agreed upon as far back as 1992, during the Rio Earth summit, when world leaders through Agenda 21 (chapter 16), undertook to consider international cooperation to ensure safety in development, transfer and application of modern biotechnology. Following from Agenda 21, through the CBD, one of the treaties arising from the Rio Earth Summit of 1992 in its Article 8 (g), calls upon parties to put in place or maintain mechanisms to manage or control risks associated with the use and release of LMOs which are likely to have a negative impact on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Biosafety is the term used to collectively refer to all measures and means that are put in place and used to ensure the safe development, transfer and use of LMOs to prevent harm to the environment, biological diversity and human health.

Again pursuant to the CBD Article 19 (3), the international community negotiated and adopted the Cartagena Protocol on Biosafety (CPB), to regulate the transboundary movement, transit, handling and use of LMOs that may have a negative impact on the conservation and sustainable use of biological diversity, taking into account risks to human health. The CPB as part of its obligations requires its parties to put in place the necessary legal, policy and administrative measures to enable them fulfil their obligations under the Protocol.

The African Union Commission, during the course of the protracted negotiations that led to the adoption of the CPB drafted and its member states adopted the African Model law on safety in biotechnology, which was adopted by AU Council of ministers in 2001 and recommended to member countries to use the model law in drafting their own national laws to ensure safety in application of modern biotechnology but also ensure more or less harmonized standards of these safety measures. This was meant to fill the gap in

the absence of an international treaty on Biosafety as it took time between the Rio Earth Summit (1992) to the adoption of the CPB (2000) and its coming into force (2003). When the CPB finally came on board in 2003, there was need to revise the AU model law on safety in biotechnology to bring it in line with the CPB.

In furtherance of its lead role as regional body for Arica in the area of Biosafety the AU Commission drafted an AU Biosafety Strategy (adopted in 2007) with the following as its pillars:

a) Establishment and strengthening of Institutional frameworks

b) Awareness raising and Biosafety Information exchange

c) Capacity building & Preparedness for negotiations

d) Policy and Legal Frameworks

e) International cooperation

f) Sustainability mechanism

Each of the pillars had its clear strategic actions required to have it move from concept to reality.

The AU Biosafety strategy among other things aims at guiding modern biotechnology developments at national, sub-regional and regional (Africa-wide) levels, as well as providing guidance on how Africa deals with the rest of the world, say during international negotiations forums of relevance to biosafety. The strategy targets the national and sub-regional levels for strategic interventions to be undertaken by the AU and its member states to ensure harmony in modern biotechnology and biosafety; focusing actions at the sub-regional levels and where strategically feasible focusing on the existing and active RECs such as the EAC. The drafting of this document therefore is one of the areas aimed at furthering the implementation of the AU Biosafety strategy at the REC level in EAC sub-region.

The East African Community (EAC) is a Regional Economic Community (REC) within Eastern Africa, comprising of five member states of Burundi, Kenya, Rwanda, Uganda and the United Republic of Tanzania. The community was first formed in 1967 mainly focusing on Economic cooperation between the three EAC countries then of Kenya, Uganda and Tanzania. The first EAC later broke down in 1977, mainly due to political differences at the time between the member states.

The EAC was revived in 1999 by the original three member states, but was later expanded following the application by the two states of Rwanda and Burundi to join the

community. The revived EAC community expanded its original mandate to bring on board more areas that the partner states felt required a regional approach including Environment and Natural resources. In the revised EAC Treaty in its objective 1 Article 5, member states committed themselves to "develop policies and programmes aimed at widening and deepening cooperate among partner states in political, economic, social and cultural fields, research and technology, defence, security and legal and judicial affairs for their mutual benefit.

The East African Community (EAC) REC has Environmental and Natural Resources Management as one of the areas of cooperation provided for under Chapter 19 of the EAC Treaty, leading to negotiations and adoption of the EAC Protocol on Environment and Natural Resources Management in 2005.

1.2. Justification /Why harmonized Biosafety Policy Framework

The EAC Protocol on Environment and Natural Resources Management, Article 27 (Biosafety and Biotechnology), section 1, member states undertook to "***develop and adopt common policies, laws and take measures to ensure that the development, handling, transport, use, transfer and release of any Living modified organisms are undertaken in a manner that reduces the risks to the environment, natural resources and human health****"*. This provision is also implied in the Cartagena Protocol on Biosafety, a treaty that all EAC member countries are parties to.

In section 2, Article 27 of the EAC Protocol Environment and Natural Resources Management, the partner states undertook to cooperate in:

a) Building research capacity in Biosafety and Biotechnology

b) Identifying LMOs or specific traits which may have adverse effects on the conservation and sustainable use of the environment, natural resources and risks to human health and take measures to treat such LMOs or specific traits.

Section 3 of the same Article goes further to state that "*Partner states shall apply such safeguards, restrictions, prohibitions and other measures on trade to control and regulate entry and use of LMOs in the community"*.

Section 4 of the Article goes further to add that "*The partner states shall adopt common policies, laws and procedures relating to Liability and Redress for damage resulting from development, handling, transport, use, transfer and release, including trans-boundary movements of any LMOs"*.

Having committed themselves to cooperate in so many areas related to trade, agriculture, environment and natural resources as well as biotechnology and Biosafety,

it is imperative that the EAC member countries set similar standards relating to development and use of GMOs to ensure that what is approved in one member country would be of the same standard as would be accepted in other member states.

Against the above background, the EAC requested for support from the African Union in form of a consultancy to further enhance it endeavours to develop a harmonized Biosafety policy framework. The EAC request is specifically related to the *review and harmonization of its Biosafety policy frameworks which are crucial in the safe use of GMOs in the EAC region*. Some of the EAC Partner States are already conducting experimental trials on several GM crops and regional cooperation in Biosafety is fundamental to ensure that the goals of regional integration, especially trade related-provisions are not undermined by transboundary movements of GMOs.

This report therefore focuses on the development of a harmonized regional biotechnology and biosafety policy framework for the EAC.

In an attempt to start work on the harmonization of its Biosafety policy frameworks, the EAC has established an Ad Hoc working Group of EAC Partner States Experts on Biosafety, which has held several consultative meetings and the outcomes of these consultative meetings are expected to inform and guide this consultancy.

The AU on its part and in response to the EAC request has commissioned this consultancy with the following objectives:

i) Develop a harmonized regional biosafety policy to guide centralized risk assessment and management, decision-making on research, environmental release and trans-boundary movement of GMOs for trade or emergency food aid purposes.

ii) Develop guidelines and procedures to guide the operationalization of a regional biosafety framework. The guidelines and procedures should reflect the minimum requirements of the Cartagena Protocol on Biosafety

iii) Propose innovative mechanisms for resource mobilization and capacity building in biosafety.

iv) Identify and provide guidance on mechanisms for enhancing regional information sharing and networking in biotechnology and biosafety

2.0. STATUS OF IMPLEMENTATION OF BIOSAFETY IN THE EAC (BASED ON THE MINIMUM REQUIREMENTS UNDER THE CPB)

2.1 Introduction

All the EAC member countries have ratified the Cartagena Protocol on Biosafety (CPB), but the processes of establishing national policy, legal and institutional frameworks on biosafety is at varied stages. By ratifying the Cartagena Protocol on Biosafety, the EAC member countries individually committed themselves to "take the necessary and appropriate legal, administrative and other measures to implement their obligations to the Protocol" in accordance with Article 2 of the Cartagena Protocol on Biosafety; having at the same time recognized that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health (as recognized in the Biosafety Protocol).

With all EAC member states being parties to the Cartagena Protocol on Biosafety (CPB) and therefore having similar obligations the following sections in this chapter first reflect the minimum requirements under CPB as extracted from the Protocol text (paraphrased), while the country situations / status of implementation are derived from the country third national reports submitted to the SCBD as part of their reporting obligations under the Protocol. The reports were submitted around October 2015, which gives the latest state of affairs in each country and the accuracy of the information is as high as it can be, since the national reports represent the official government version provided by the responsible reporting authorities in the country charged with the responsibility of implementation and reporting to the Protocol Secretariat.

The Policy guidelines/ statements proposed under section 3 likewise take into account the obligations spelt out under the CPB, what is required under the EAC Protocol on Environment and natural resources, what the countries have reported as having done and what is reasonable feasible within the current policy, and economic environment, taking also into consideration what has been decided or is prevailing within the COMESA and SADC sub-regions to which EAC partner states have some commitments.

With most of the EAC member states still in the process of drafting and discussing their national biosafety legislations, it is rather difficult to predict which of the proposed policy guidelines would meet unanimous approval from all partner states and which may prove controversial. However, since all of them have a common denominator of being parties to the same Protocol (CPB) as well as the EAC Protocol on Environment and natural resources, there should be no justification for major divergence in policy as long as they all take into consideration the minimum requirements under the CPB while drafting their

national laws on biosafety. The Kenya national law on biosafety which is publicly available on the national biosafety website looks sufficiently drafted to take into account all requirements under the CPB and the Kenya law could serve as a reference material for those parties that are still drafting theirs.

Bearing in mind some peculiarities that may be country specific, however, one cannot rule out some minor areas of divergence between partner states, but these should be easily resolved through negotiation in the relevant forums and committees under the EAC.

2.2 Legal, Administrative and other measures

The CPB all parties to take the necessary and appropriate legal, administrative and other measures to implement their obligations under the Protocol. It further obliges all parties to ensure that the development, handling, transport, use, transfer and release of any LMO are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

The EAC countries have all tried to put in place the necessary legal, administrative and other measures but the processes are at different levels. Where the process of legislation is still incomplete, the frameworks are either being used as they are, pending the completion of the legislation process at national level or their application is on hold pending completion, depending on the level of completion of the legislation process, the availability of alternative laws related to Biosafety and the need for application of Biosafety frameworks in decision making regarding LMOs.

In Burundi, only a draft framework exists and is being subjected to the national legislative process; while in Kenya on the other hand, a domestic regulatory framework is in place and functional, with a National Biosafety law, regulations already in place and some Guidelines having been completed while a few others are in their final stages of completion. The NBF in Kenya has been operational since 2009. In Rwanda, their national Biosafety law and regulations are still in draft form (since 2014), undergoing the due process of law making, with Uganda more or less at the same stage as Rwanda, though the draft law has been under scrutiny since around 2008. However, a National Biotechnology and Biosafety Policy has been in place since 2008; and LMOs for Confined Field Trials have been assessed and approved using an Administrative arrangement deriving from a related law, the Uganda National for Science and Technology Act.

In the United Republic of Tanzania, a domestic regulatory framework is fully in place; operational since 2006; comprising of One or more national Biosafety regulations; One

or more sets of Biosafety guidelines and Other laws, regulations or guidelines that indirectly apply to Biosafety.

All the five member countries to the community have dedicated some human and financial resources albeit at different levels to handle Biosafety issues at national level. The level of financial and human resources commitment appears to vary depending on the level of development of the National Biosafety frameworks; ranging from Kenya which has a fully fledged National Biosafety Authority and relatively more financial and human resources commitment, followed by Tanzania which has functional Biosafety Regulations; with the other countries that are still drafting their national laws having just skeleton staff and limited financial resources commitments. However, this is expected to improve as they each complete their legislative processes, as each new law comes with its own implementation mechanism, in form of Institutional, human resource and financial arrangements.

Furthermore the Cartagena Protocol creates other obligations and standards, which by virtue of ratification of the Protocol, the EAC member states committed themselves to implement. There are issues covered by the Cartagena Protocol on Biosafety which the EAC member states, being parties to the Protocol need to address, both as part of their obligations under the protocol but also as individual countries to address some of their national needs, opportunities and challenges that may arise relating to LMOs. Having committed themselves to regional cooperation in different aspects of Biosafety, there is an imperative that they develop their policies, laws and administrative processes in close collaboration with each other to ensure harmony in trade, health, agriculture, environment and natural resources.

2.3. Pharmaceuticals for humans that are LMOs or derived from LMOs

The CPB recognizes the right of parties to subject all LMOs falling within the scope of the Protocol to Risk Assessment, though it exempts pharmaceutical LMOs that are covered by other relevant international agreements or organizations. At the time of drafting the CPB, no such international treaty or organization dealing with LMO-pharmaceuticals for humans was known to exist; and hence it was presumed that all LMO human pharmaceuticals that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. However, due to ambiguity in the relevant article of the CPB, it is necessary for individual countries that wish to subject LMO-pharmaceuticals for human use to Risk Assessment should put it in their national legislation to avoid the ambiguity in the CPB.

All the five member countries are either regulating LMOs that are Pharmaceuticals for human use or the regulation is planned in their draft legislation. Some are regulating

LMO Pharmaceuticals for human use using Biosafety laws and frameworks while others are regulating them using other existing laws relating to Pharmaceuticals.

The partner states of EAC will have to put in place harmonized standards for dealing with / using Pharmaceuticals that are LMOs for use within or transiting through the sub-region.

2.4 Transit and Contained use of LMOs

The CPB leaves the decision on whether to subject LMOs in transit and LMOs destined for contained use to individual parties subject to their national laws. Once put in the national laws then such provisions would be shared with other countries through the BCH and such provisions would be internationally respected. Bearing in mind that even goods in transit can be subjected to accidents leading to accidental releases into the environment and into the food chains of the transit country, it becomes prudent that countries should subject both LMOs in transit and those destined for contained use to regulation. Whereas LMOs in transit may not necessarily have to undergo a full AIA and Risk Assessment, it would be prudent to subject them to national laws regarding notification and labelling so that in case of an accident, the country of transit may handle them appropriately. For those destined for contained use, it would be prudent to subject them to a full Risk Assessment as some of them may have not been approved for release anywhere including their countries of origin, being still subjects of research under containment.

Despite differences in the level of regulation of Transit and Contained use of LMOs in the EAC partner states deriving from the levels of development of national Biosafety legislation there is a general feeling that LMOs in Transit and LMOs destined for Contained use should be regulated. Those that do not currently regulate Transit are those that are lacking a law to use in doing so. Indeed there is need for regulation of Transit of LMOs in that much as the LMOs may be destined for use in another country, accidents may happen while in transit leading to unintentional releases into the environment, when the first persons(s) of contact with them may have no idea regarding what they are and how they may be handled safely and what they may or may not be used for. With regard to LMOs destined for contained use, it is even more compelling to regulate them as most of them are still subjects of research and investigations and may have never been subjected to a fully fledged Risk Assessment or been approved for release anywhere.

2.5 Procedures and standards for dealing with LMOs destined for deliberate introduction into the Environment (The AIA and Notification Procedures)

Parties to the CPB are obliged to establish legal requirements for exporters under their jurisdiction to notify in writing the Competent National Authority of the Party of import prior to the intentional transboundary movement of an LMO that falls within the scope of the AIA procedure, that is to say, LMOs destined for deliberate introduction into the Environment. The parties are also required to ensure that there is a legal requirement upon the notifier that such information which is required for informed decision –making is accurate /correct. This entails operation of the Advance Informed Agreement (AIA) procedure of the Protocol (and associated processes) or a domestic regulatory framework consistent with the Protocol regarding the transboundary movement of LMOs for intentional introduction into the environment.

In the EAC member states the requirement for notification and decision making under the AIA procedure is almost fully complied with, whether they have received applications for deliberate releases of LMOs into the environment or not, except in Burundi where the putting in place of the necessary procedures and processes relating to the AIA procedure is awaiting the passing of the national Biosafety law. Other EAC member states that have no biosafety laws but have handled requests for releases of LMOs are using administrative procedures to handle such requests. Burundi has not received any such requests so far, perhaps that is why they are not yet applying the AIA procedure.

2.6 Decision-making mechanisms for LMOs destined for deliberate introduction into the Environment

The protocol sets the stage of decision making regarding LMOs destined for deliberate release of LMOs into the environment. This follows notification and granting of the AIA, which can only be granted on the grounds that Risk Assessment has been conducted and proved that the movement/ introduction poses no harm and if any harm is envisaged then necessary sufficient Risk Management measures have been put in place. The decision-making procedure thus refers to the process of making decisions by the party of import after being notified of an impending transboundary movement of an LMO into its territory, the allowed timelines involved in making a decision to allow or refuse the import to take place (with or without conditions) or to request for more information. This particularly applies to the first transboundary movement of an LMO destined for deliberate release into the environment.

Releases of LMOs into the environment are supposed to be after consent in writing has been given by the Competent National Authority of the importing country, having carried out or reviewed a Risk Assessment (carried out by say the exporter) and got satisfied that the transboundary movement shall not cause any harm to the Biodiversity, environment or human health and if any Risks are foreseen, such Risks are

manageable and having put in place the necessary Risk Management procedures/ measures to contain any foreseen Risks.

The mechanism established at national level can be in form of a law or regulation; but it can also be in form of a Statutory Instrument or some other administrative procedure taken by a country to be used pending the completion of the legislative process.

All EAC member countries except Burundi have established such mechanisms (legal or administrative). In Burundi it is expected to be spelt out in their national law which is not yet completed. In Uganda and Rwanda, administrative measures have been instituted pending the completion of their legislation process, whereas in Kenya and Tanzania it is part of their national Biosafety legislation.

2.7 Procedures for decision-making regarding LMOs destined for direct use as Food, Feed or Processing (LMOs-FFP)

The Cartagena Protocol on Biosafety sets minimum standards to be followed regarding LMOs destined for direct use as Food, Feed or for Processing (LMOs-FFP). The Protocol requires that a Party which makes a final decision regarding domestic use, including placing on the market of a LMO-FFP that may be subject to transboundary movements informs other parties of its decision within fifteen days of making such a decision through the BCH. The protocol also allows parties to make decisions on import of LMOs-FFP in accordance with their domestic legislation consistent with the objective of the Protocol, but such domestic laws/regulatory frameworks should also be availed to other parties through the BCH.

The procedures are premised on the assumption that such LMOs are not going to be released into the environment and hence are expected to be subjected to a less stringent process than the AIA procedures (for LMOs destined for environmental release), except where a developing country party decides that within its national jurisdiction to subject all LMOs including LMOs –FFP for their first import, to Risk Assessment. In reality, however, some of these LMOs-FFP especially where they are in form of viable seed, may end up being released into the environment through planting, especially in Africa and Eastern Africa in particular where sale and supply of seed is to a great extent carried out through the informal sector, and where there is no strict packaging and labelling to differentiate between “seed” meant for planting only and “seed” for cooking that may end up being planted.

It may therefore be necessary for the member countries to consider a two tier process, where LMOs-FFP that are in form of viable seed are subjected to Risk Assessment while LMO-FFP that are either milled or processed in any other way that may impair their capacity to grow or breed are subjected to a different procedure mainly

emphasising testing for toxicity and allergenicity as opposed to effects on biodiversity and environment.

In the EAC member states, only Kenya and Tanzania which have completed their National Biosafety legislation have provisions for LMOs-FFP, while the rest of the countries, the provisions are still pending the completion of the national legislation.

2.8 Review of decisions taken regarding LMOs

This is a provision in the Protocol that is meant to cater for circumstances that may arise where a party needs to review a decision either in light of new information or change in circumstances. Situations may arise where a consent had been granted based on available information at the time of application, and there arises new information in future that warrants a change in the earlier decision that may lead say to a cancellation of any permission that may have been granted for release of an LMO; or where an application had been rejected based on lack of sufficient information which later becomes available, leading to the party re-considering its earlier stand. Alternatively, the review could entail imposition of extra conditions in addition to what may have earlier been imposed at the time of issuance of the approval, or relaxation of earlier terms and conditions resulting from new information becoming available or due to a change in circumstances.

All the EAC member states have no experience of reviewing of decisions, mainly due to absence of decisions to warrant the review since none of the partner states have released LMOs on a commercial scale either into the environment or onto the market. However the mechanism for review of decisions is provided for in the laws of those states that have them as well as in the draft laws for those countries that have not yet completed their Biosafety laws. They will therefore need to adopt similar standards for review of decisions to ensure harmonious trade and exchange of LMO commodities and LMOs for environmental releases when they start commercial releases of LMOs within the EAC.

However, the Kenya Biosafety Act has provisions for review of decisions; clearly spelling out different circumstances that may lead to review of decisions, the time frame in which the review of decision and substitution of the old decision with the new decision will occur. Though they have no experience with review of decisions, they have foreseen the need and made provisions for it in advance in line with the requirements under the CPB.

2.9 Application of a Simplified Procedure

The Cartagena Protocol makes provisions allowing parties that may wish to apply a simplified procedure in decision making regarding releases of LMOs into the

environment or on the market. This is envisaged to apply for cases of subsequent movements of an LMO previously approved by a party, to the same Party and the party feels it has sufficient trust and confidence with the applicant and hence there is no need to subject subsequent transboundary movements to the lengthy process of AIA and Risk assessments when the same LMO had been subjected to the same.

Currently, however, none of the EAC member states has provisions for application of a simplified procedure, perhaps because experience with LMOs is still in its infancy and the level of confidence with different LMOs and different notifiers is still low, all LMOs have to be subjected to Risk Assessment. There has been therefore no necessity to apply simplified procedures since there are no commercial releases of LMOs in the EAC region, which makes experience with LMOs very limited, making application of simplified procedures irrelevant at the moment.

In future, perhaps after a number of commercial releases and monitoring them over sufficient lengths of time, time will come where transboundary movements of certain LMOs may be subjected to simplified procedures. However, when time comes to consider application of such procedures, all member states will have to agree over it so that they apply these procedures similarly and to the same LMOs to avoid a scenario where actions of one member state may undermine the interests/ concerns of other partner states.

2.10 Entry into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms into the EAC

The CPB recognizes that parties may enter into bilateral, regional and multilateral agreements or arrangements regarding intentional transboundary movement of LMOs provided such agreements / arrangements are consistent with the objective of the protocol and provided such agreements and arrangements do not result into lower levels of protection than those stipulated under the protocol. Parties are supposed to inform each other of any such agreements/ arrangements through the BCH. This process can be either the EAC partner states entering into agreements with each other or one or more or all the EAC partner states entering into bilateral agreements with other states or other entities outside the EAC.

Currently there are no functional bilateral, regional or multilateral agreements for intentional transboundary movements of LMOs in EAC or any of its partner states. However, discussions are underway within the EAC partner states to harmonize their Biosafety laws and policies for the sake of combining their efforts in ensuring safety, more pragmatic use of the limited capacity and resources as well as to facilitate cross-border trade in LMO commodities within the community. Some discussions have also

taken place within the Common Market for Eastern and Southern Africa (COMESA) as well as within the Sothern African Development Community (SADC), to which some or all EAC partner states are also members regarding the need for regional harmonization of certain principles of Biosafety as well as harmonization of certain procedures such as Risk Assessment techniques, though the general view is that decision making would remain a prerogative of individual member states.

Due to the enormous nature of trade between the EAC, COMESA and SADC member countries, which is envisaged to increase even further in the future, it becomes imperative indeed that the member countries agree on certain principles and standards regarding specific aspects of LMOs that would be allowed within their national jurisdictions so that trade and regional cooperation is not constrained by application of different standards by individual member countries.

Currently all but one of the EAC partner states are members of COMESA while one partner state is a member of the SADC block. This implies that whatever LMO event / transformation event that happens or is introduced within one of the member countries of either EAC or COMESA or SADC member countries would later in one way or another affect the other EAC countries.

The COMESA regional block on its part has already gone ahead in this endeavour and produced Draft Policy guidelines for:

1. Commercial Planting of GMOs;

2. Trade in GMOs; and

3. Emergency Food Aid with GMO Content.

The policy guidelines on Commercial Planting of GMOs have the following objectives:

a. To provide COMESA Member States with a mechanism for centralized regional assessment of GMOs destined for commercial planting.

b. To provide an approach for conducting sustainable science-based risk assessments of international quality, on GMOs intended for commercial planting.

c. To promote harmonized risk assessment requirements according to internationally developed guidelines for GMOs.

d. To build the capacity of COMESA member states to conduct science-based risk assessment and management

e. To establish a regional information sharing mechanism on biotechnology and biosafety issues in the COMESA region.

The COMESA Policy guidelines on Trade in GMOs the following objectives were stated:

a. To provide centralized guidance on COMESA trade in GMOs ;

b. To provide a harmonized mechanism for decision-making on trade in GMOs among COMESA member countries;

c. To provide guidance on handling of GMOs on transit for sale within the COMESA region.

The COMESA Policy guidelines on Emergency Food Aid with GMO Content, the objectives are:

a. To provide for harmonised handling procedures of food aid with GM content in the COMESA region.

b. To expedite delivery of food aid with GM content to the needy during emergencies.

2.11 Risk Assessment (RA) and Risk Management (RM) -standards and Procedures within the EAC;

The CPB requires its parties to conduct Risk Assessments prior to decision making for LMOs destined for deliberate release into the environment; following notification about intentional introduction into the environment of the receiving country. In addition, the protocol requires parties to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified during RA provisions associated with the use, handling, and transboundary movement of LMOs. Measures based on Risk assessments are supposed to be taken to the extent necessary to prevent adverse effects of LMOs on biodiversity and human health within the territory of the party of import and each party is also required to take appropriate measures to prevent unintentional transboundary movements of LMOs including measures as requiring a RA to be carried out prior to the first release of an LMO into the environment.

Risk Assessment and Risk management are very important aspects of Biosafety that any country should consider carrying out and establishing the capacity and mechanisms for prior to making any decision on working on LMOs be they for contained use, transit, release into the environment (including for Confined Field Trials) as well as releasing them on the market (including LMOs-FFP). Risk Assessment and Risk management and the capacity thereof are therefore a critical “must have” before any country makes a decision regarding dealing with LMOs.

In response to the above, all EAC member states except Burundi, have established a mechanism at national level for carrying out Risk Assessment and for Risk management as well as LMO monitoring, in addition to training some national experts in RA and RM

though at different levels of proficiency. However, even those countries that have developed some capacity for RA and RM still admit that they still do not have sufficient personnel in these fields. Even where capacity has been developed, the partner states will have to take deliberate steps to maintain such capacity as such highly specialized experts are often lost due to brain drain as they get more lucrative employments in developed countries and international organizations, leave alone capacity losses due to natural processes like retirement and death.

The reported lack of capacity or national mechanisms for RA and RM in one of the partner states is probably because they have not yet received any applications for release or research in LMOs, hence they may not have seen the urgency, though this is a requirement under the Cartagena Protocol on Biosafety and will be a necessity as the rest of the EAC partner countries start commercializing LMOs. However, it is reportedly one of the provisions in their draft Biosafety law and in the absence of the biosafety law, the country relies on the COMESA guidelines to which it is party.

2.12 Monitoring of LMOs within member states of the EAC;

The CPB requires each party to endeavour to subject each LMO, whether locally made or imported is subject to an appropriate period of observation, commensurate with its life cycle or generation time before it is put to its intended use. Monitoring of LMOs s necessary as the experience with them is still limited. Even those few that are getting familiar to some people in some countries, experience with them is still limited in the EAC region. Moreover all LMOs are produced with novel traits and their effects (especially long term effects) are hardly known as the period over which they are observed during Confined Field Trials are often insufficient. Each LMO is supposed to be monitored for a sufficient length of time commensurate with their life cycle/ generation time, both pre and post release as mutations often occur and different LMOs react differently to different elements in the environment.

All EAC countries that have had some applications/ experiments with LMOs have some national mechanisms to ensure some level of monitoring of the behaviour of LMOs that are released / that may be released into the environment, with Burundi as the only exception due to lack of any experience with LMOs at present. At the EAC level there is need to strengthen but also harmonise the requirements for monitoring of LMOs to ensure that the same standards are applied throughout the region which would lead to harmonized safety standards and measures.

2.13 Unintentional Transboundary Movements of LMOs and Emergency Measures

The CPB requires its parties to take appropriate measures to notify affected or potentially affected states, the BCH and, where appropriate, relevant international organizations when any of them knows of an occurrence under its jurisdiction resulting into a release that leads to or may lead to an unintentional transboundary movement of an LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The protocol also spells out the minimum content of the notification regarding unintentional transboundary movement. Furthermore, each party is also required to designate a National Focal Point for emergency measures (contact person to be informed on behalf of the country in case of emergency/ emergencies relating to LMOs) and inform the BCH of the Protocol.

This provision is intended to protect biological diversity and human health from any potential and real adverse effects that may result from unintentional release of LMOs into the environment. This could be as a result of an accident (like if a truck carrying GM seed for experimental work somewhere overturns and spills its content into the environment); or worse still as a result of lawlessness, such as in case of the truck accident above, people come and help themselves to the contents of the vehicle and either eat them or plant them without knowing that they were not meant for eating or planting. Unintentional releases of LMOs into the environment could also result from carelessness by users or developers of LMOs at experimental/ trial level, not disposing of them in the appropriate way.

To minimise the potential risk to biodiversity and human health resulting from unintentional releases of LMOs into the environment, parties to the Protocol are required to cooperate by putting in place emergency measures aimed at informing the relevant authorities and affected and potentially affected persons and countries of any unintentional releases of LMOs into the environment. They are also supposed to put in place emergency measures in form of mechanisms that can quickly swing into action upon notification of an unintentional release of LMOs so that the LMOs can be removed and controlled from spreading beyond the point of release, hence control of their possible adverse effects.

At the EAC level, all partner states except Burundi have put in place some measures for emergency measures/ emergency response in case of unintentional release of LMOs into the environment. However, even the countries that have put in place some mechanisms for addressing emergencies in case of unintentional releases of LMOs into the environment still need to enhance the capacities further to ensure and enhance their effectiveness.

2.14 Handling, Transport and Packaging of LMOs destined for use in or Transit through the EAC

According to the provisions of the Cartagena Protocol and its decisions of the Conference of Parties, LMOs are supposed to be handled, transported and packaged in a way that minimises their risks to biodiversity, the environment and human health. This entails different measures including the packaging methods, labelling and transportation methods; with different measures being prescribed depending on the final use of the LMO: whether for contained use, transit, use as Food, Feed or Processing or for deliberate release into the environment. It is a requirement to also provide a contact person for further information, should it be necessary.

Identification and labelling of LMOs is critical in dealing with LMOs in that it does not only link with the need for traceability which is vital in monitoring, but also linked with emergency measures, Liability and redress (the need to link any harm to biodiversity and / or human health to the cause and hence claim redress/ compensation from the right entity); but also labelling and identification links to consumers'/ users' rights to know what they are being offered either to plant, eat or use in any other way so that they can make informed decisions. This is very important in trade in LMO commodities and associated products.

Different EAC partner states are at different levels of implementing this requirement, with Kenya being the most advanced, drafting Regulations to the Biosafety Act to deal with Handling, Transport and Packaging of LMOs, while those partner states still that are still drafting their national legislation on Biosafety have their provisions still in draft form awaiting discussion of and possible passing of the laws. Partner states without complete legislation but which have been carrying out experiments or trials with LMOs have put in place interim measures to handle the requirements for transport, handling and packaging of LMOs pending completion of their legislative processes.

Whatever direction these discussions take these are very important provisions that can make or break regional trade and hence they will need to expedite and harmonize their standards so that whatever commodity in trade is allowed in one of partner states can also be accepted in other partner states in order not to constrain trade within the region.

Establishment and operationalization of the capacity for detection and therefore monitoring of LMOs in form of laboratories (and associated reagents) and the training of the required personnel and putting is at different levels within the EAC partner states but still requires further development and improvement. This may be one of the areas which need a concerted effort at regional level as establishment and maintenance of the required capacity at national level could be out of reach or at best too expensive for individual countries on their own.

2.15 Administrative procedures for LMOs in the community (CNAs and NFPs)

All parties to the Cartagena Protocol on Biosafety are required to designate one National Focal Point (NFP) to coordinate communication with the Secretariat to the Protocol and other stakeholders and a Competent National Authority/ Competent National Authorities (CNA) to carry out the administrative requirements under the Protocol (including but not limited to decision making regarding on behalf of the party concerned). This is necessitated by the need for harmony and certainty and streamlining decision making and communication within and between parties.

All the partner states have designated their National Focal Points and Competent National Points, but the processes of empowering them with the necessary personnel and other resources is at different levels of development. The putting in place of the necessary infrastructure to enable such officials and institutions perform their duties effectively is also still under development and at different levels of facilitation and efficiency.

2.16 Information sharing and the Biosafety Clearing House - BCH

The BCH is established under the Cartagena Protocol on Biosafety (CPB) to serve as a mechanism for exchange of authenticated information between parties, countries and other organizations regarding but not limited to:

a) National Contacts (responsible for the implementation of Biosafety-related activities (such as the National Focal Point and Competent National Authority, National Contact person for emergency measures and their coordinates);

b) Existing national legislation, regulations and guidelines for implementing the Protocol (as well as the contents/ standards set by such laws so that anyone interested in dealing with the country know in advance what is required of them under the national laws;

c) Information required by Parties for the advance informed agreement procedure (regarding LMOs for intentional release into the Environment);

d) National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing;

e) Any existing bilateral, multilateral and regional agreements and arrangements regarding Biosafety that a party may have entered either with a another party or non-party states;

f) Decisions made by the party on transboundary movements / releases of LMOs for Direct Introduction into the Environment, on LMOs-FFP, Transit of LMOs, or LMOs prohibited from entry into the country;

g) Any Unintentional releases of or illegal releases of LMOs that may have occurred into the country;

h) Any LMOs released within the country that may be a subject of transboundary movements in future;

i) LMOs that may be allowed in the country without prior notification or those that may be allowed entry into the country by applying a simplified procedure;

j) LMOs that are regarded as pausing no risks to the biodiversity, environment and human health (if any) in the country;

k) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof.

Under the Biosafety Protocol at international level, the BCH is a mechanism for exchange of information but also for authentication of such information as only nationally authorized persons (National Focal Points/ NFPs – BCH of each country) are allowed to publish or alter or edit information regarding their country and information submitted by any other person is first sent to the NFP for authentication before it is published on the BCH.

Currently all the EAC states have submitted some information to the BCH, though some of it is not yet complete or is not yet available. A number of EAC partner states reported some information being available nationally but not yet on the BCH. At the same time, all the partner states reported to have used the BCH, some reporting to have experienced difficulties in accessing the information or uploading national information onto the BCH. Though the failure to upload all the available and eligible information onto the BCH by EAC partner states can partly be attributed to limited capacity on the use of the BCH and limited and unreliable access to internet facilities the other major challenge is the capacity of lack of coordination between the national BCH Focal Point, National BCH Focal Point and the Competent National Authority to get the required information uploaded onto the BCH. This is exacerbated by absence of Biosafety national laws in most of the EAC partner states where the relationship and responsibilities of each of these offices (NFP, NFP-BCH and CNA) would be spelt out and streamlined.

A similar arrangement of an EAC-BCH would be required under the EAC arrangement where the partner states would publish all relevant Biosafety information, standards and

say thresholds allowed/ agreed upon within the EAC countries. LMOs that are prohibited from entering the sub-region would also be published on the same website. It would be essential that the standards set for different types of transboundary movements are harmonized to avoid trade distortions and potential conflicts. The partner states would also have to agree on the maximum thresholds allowed for say adventitious mingling of GM into non GM grain or seed for it to be allowed in the sub-region, as setting different standards/ thresholds for different individual states would be a recipe for disaster and conflict between partner states.

2.17 Procedures for dealing with Confidential Information relating to LMOs

There is a provision under the CPB where a party is required to allow a notifier to identify categories of information submitted to the party that the notifier requires the party receiving it to treat it as confidential and protect it from improper use by other persons, subject to agreement by the recipient party that such information indeed merits confidentiality. The party of import is further required to consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to the disclosure.

This provision is meant to protect Confidential Business Information (CBI) from unauthorised use or misuse by say the business competitors of the notifier to the latter's detriment. The protocol however stipulates that the following information shall not be treated as confidential:

a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response

Some of the EAC partner states have provisions for protection of Confidential information while others do not have, mainly because they lack the necessary national Biosafety legal framework to operationalize this provision of the Biosafety Protocol or because they have not yet received and processed any application for LMO releases, neither for research under contained or confined use nor for commercial release. Those that are still in the process of drafting and debating their national laws have to ensure that the provision is catered for since it is an obligation under the Biosafety Protocol, but also to make sure that the standards set for handling confidential business information

on Biosafety are the same across the entire EAC partner states so as not to constrain trade and other relations across the partner states.

2.18 Capacity Building/ Capacity Development and enhancement

The CPB requires all parties to cooperate in the development and / or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that is required for biosafety for purposes of the effective implementation of the protocol in developing country parties, in particular the least developed and Small island developing states; and in parties with economies under transition, including through existing global, regional and sub-regional and national institutions and organizations and, as appropriate, through facilitating private sector involvement. In addition, it is there stated that the needs of developing countries for financial resources and access to and transfer of technology and know-how shall be taken into consideration in accordance with the relevant provisions of the CBD.

The science of LMOs and Biosafety is still relatively new especially in the developing countries and as such there is still limited capacity among a few specialized persons in a limited number of institutions. The levels of training in national institutions within the EAC are also still limited and the levels of commitment of financial resources by the EAC partner states are also still limited, mainly because of lack of an enabling law to provide for funding of Biosafety activities, but even where national Biosafety laws have been enacted still funding for biosafety capacity building are still constrained by budgetary shortfalls and limited awareness among policy makers who are responsible for resource allocation and prioritization of funding areas.

All EAC countries admit they do not have adequate capacity for Biosafety and still have numerous areas where they need capacity building to be carried out. In addition, the field of modern biotechnology and biosafety are fast growing, with new techniques and technologies being churned out necessitating regular training and re-training of regulators to cope with the constantly changing circumstances.

Capacity building is another area where EAC partner states will need a concerted effort, not only considering the economic costs involved and the need for combining resources to maximise benefits, but also to harmonise training materials to ensure the quality and uniformity of the training offered by EAC institutions and trainees within the sub-region. EAC countries in the quest for capacity building in biosafety may need to earn from the proposed mechanism under the AU Biosafety Strategy (2007).

To be effective and focussed, the EAC countries will need to carry out a capacity needs assessment, as well as areas where different countries have a comparative advantage over others so that those who are better off in expertise can assist others in improving

where they are deficient. To make the training relevant to the region, it would be beneficial to use sub-regional (EAC-based) expertise to ensure that the knowledge shared is more focused to the sub-regional needs and conditions. The SCBD roster of experts in Biosafety and the UNEP/GEF Regional Advisors on Biosafety / Biosafety Clearing House could be a learning experience. In both case, experts in different aspects of Biosafety would provide their CVs which would be published on the organizations' websites. Countries eligible for and needing technical assistance would look at the experts' profiles and select the expert they felt suited their needs and understood their socio-economic and environmental set best and request the responsible body (SCBD or UNEP/ GEF) to pay the selected expert and facilitate him/her to come to the country and give the required advice or training as appropriate and as agreed between the responsible body and the requesting country.

In cases where there are no expertise in the sub-region and there is need to outsource the expertise, care should be taken to identify the relevant courses with the required training, identify resourceful persons from the sub-region who can be sent for training so that they would later come back and train the other professional within the sub-region to minimise costs of training abroad and to make the courses and content more tailor-made for the needs and conditions within the EAC.

2.19 Public Awareness and Participation with regard to LMOs

Parties to the Biosafety Protocol are required to promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health, in collaboration with other states and relevant organizations. Parties are also supposed to consult the public in decision making processes regarding LMOs and t make any such decisions made regarding LMOs available to the public.

The EAC countries have all tried to address this requirement, albeit to different levels, with mainly those that have national Biosafety legislation having gone a step further than those without, perhaps because it is a requirement within their national Biosafety laws. Those without national Biosafety laws but a functional National Biosafety Framework have also to some extent tried to implement the provision. There is need to harmonize and standardize the awareness programs and awareness materials used so that the quality of information used across the sub-region is comparable. EAC partner states need to harmonize the modalities and mechanisms for public participation in decision-making and modalities for sharing the decisions so reached with members of the public for purposes of socio-economic harmony and quality assurance regarding the information/ education materials used.

2.20 Transboundary Movements of LMOs from non –Parties to the Protocol into the EAC member states or export of LMOs from EAC to non-parties to the Protocol

The CPB stipulates that transboundary movement of LMOs between parties and non-Parties to the Protocol shall be consistent with the objective of the Protocol. The parties may enter into bilateral agreements and arrangements with non-parties regarding such transboundary movements and such Parties shall encourage non-parties they are dealing with to adhere to the provisions of the Protocol and to contribute relevant information to the BCH, with regard to LMOs released or moved into or out of their national jurisdiction.

This provision in the Biosafety Protocol regarding transboundary movement of LMOs between parties and non-Parties to the Protocol is meant to enable parties that may need to access particular LMOs from non-parties or export LMOs to non-parties to do so within the precincts of the Protocol.

Ordinarily, one would expect parties to exchange LMOs with other parties to the Protocol since they would all be bound by the same terms and conditions spelt out in the Protocol that they both are bound by. However, in the event that there is need to exchange LMOs with non-Parties, parties can do so by entering into bilateral agreements with the non-parties as long as such bilateral agreements do not impose less stringent measures than are stipulated in the Protocol to the non-party if the party to the protocol is to remain compliant to the Protocol. The imposition and insistence on the minimum standards set by the Protocol would in this case have to be insisted on by the party to the Protocol since the non-party has nothing to lose, but probably everything to gain by not meeting the standards set by the Protocol.

The EAC member states that have been doing some Confined Field Trials on LMOs admit having imported some LMOs from non-Party states to the Protocol, but with the import being done in accordance with the objectives and provisions of the Biosafety Protocol. The EAC partner states that have not yet carried out any trials of LMOs have not yet had any dealings with non-Parties to the Biosafety Protocol.

However, since some non-parties are among the countries that have carried out most extensive research and releases of LMOs, it is a matter of time for these remaining EAC countries to have something to do with non-parties. What is important though is to ensure that such dealing with non-parties will not go below the standards set under the Biosafety Protocol and the EAC partner states set similar and harmonized standards for dealing with non-parties to the Biosafety Protocol lest one partner state sets lower standards and serve as an entry point into the community for LMOs that do not meet the minimum standards set under the Biosafety Protocol or under the EAC.

2.21 Illegal Transboundary Movements (into or out of EAC member states)

The CPB requires its parties to adopt appropriate measures aimed at preventing and if appropriate penalizing transboundary movements carried out in contravention of its domestic measures to implement the Protocol. Such movements carried out in contravention of domestic measures are regarded as illegal transboundary movements. The proposed penalties may entail the affected party requesting the Party of origin to dispose of the LMO in question at its (country of origin) own expense, by repatriation or destruction as appropriate.

This provision in the Protocol is aimed at preventing or penalizing transboundary movement of LMOs from one country to another in contravention of the domestic measures (be they legal or policy or administrative arrangements) of the receiving country.

Three out of five EAC partner states currently have put in place measures to prevent or penalize illegal transboundary movements of LMOs into their territory, these mainly being the countries where there is a national law on Biosafety is in place or where another law related to Biosafety is being applied as an interim measure awaiting the passing of the national Biosafety laws. The remaining two countries' provisions for prevention of or penalization of illegal transboundary movement are awaiting the passing of their national Biosafety laws.

When the national Biosafety laws of all the partner states are finally completed, they will not only have to ensure inclusion of provisions for preventing and penalizing illegal transboundary movements of LMOs into their territories, but also ensure that they set similar standards and measures to avoid some countries that may have "weaker" provisions in their national Biosafety laws creating loopholes for illegal entry of LMOs into the community (EAC), as such LMOs would thereafter freely circulate within the sub-region.

2.22 Socio-Economic Considerations

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

Whereas the provision in the Biosafety Protocol is not strong and mandatory upon parties due to failure to reach consensus on this issue during negotiations of the Protocol, this may be one of the most important issues to consider especially for developing countries. Due to the diversity of small scale farming systems and the very high proportions of the populations in developing countries involved in small-scale farming in developing countries, introduction of an LMO that is going to substitute say a local crop variety that is depended upon by a majority of their population of a country for their socio-economic wellbeing should be of critical interest for the potentially affected country. However the measures to be taken have to be considered carefully so that they are not misinterpreted as “non-tariff barriers to trade” and any measures taken should be consistent with other existing obligations for the country under international law.

Currently in the EAC, three out of five countries that have so far taken decisions regarding LMOs take into account Socio-economic considerations during decision – making processes. However experience within the region and globally on the subject is still limited and more capacity development is required.

At the global level, under the auspices of the Cartagena Protocol on Biosafety, consultations are on-going regarding the application of socio-economic considerations in decision-making and hopefully when the process is complete, parties in the EAC and other parties will get further guidance on the modalities of application of socio-economic considerations in decision-making regarding releases of LMOs. Kenya already has provisions in their national Biosafety Act requiring mandatory consideration of Socio-economic consideration in decision-making for LMOs destined for release into the environment and this is probably the best way to go, for the rest of the partner countries, given the importance of the issue. In drafting their biosafety laws the rest of the EAC partner states will have to include this important subject and ensure that they set similar standards to ensure harmony in trade and exchange of LMO seeds, goods and commodities.

2.23 Liability and Redress regarding harm to Biodiversity or human health resulting from LMOs;

Liability and Redress under the CPB was left as un-finished business that was to be handled by a mechanism that would be put in place by the Conference of Parties serving as the Meeting of the Parties to the Protocol; that was requested to adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of Liability and Redress for damage resulting from transboundary movement of LMOs. The mechanism was as such put in place and after protracted negotiations led to the drafting and adoption of Nagoya-Kuala-Lumpur Supplementary Protocol (to the CPB) on Liability and Redress. Liability and Redress is therefore at international level

addressed in the Nagoya-Kuala-Lumpur supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety. The supplementary Protocol may be seen as a means to preventing damage as well as a means of confidence building in the development and application of modern biotechnology as users would be assured of redress in case something goes wrong in the course of development and application of LMOs. The Nagoya-Kuala-Lumpur Supplementary Protocol is still lacking a six more ratifications / accessions (as of June 2016) before it can enter into force.

Issues relating to Liability and Redress are meant to address any damage or harm that may occur to Biological diversity, or human health resulting from transboundary movement, transfer and use of LMOs. The supplementary protocol being an international treaty, applies to damage resulting from LMOs that find their origin in transboundary movement. (This means that countries, in their national legislation would also make provisions for Liability and Redress for damage resulting from home-made LMOs as the likely consequences would be similar). The scope of the supplementary Protocol covers LMOs intended for direct use as Food, Feed or for Processing (LMOs-FFP); LMOs destined for contained use; as well those intended for intentional introduction into the environment. It also applies to damage resulting from Unintentional transboundary movement of LMOs.

The supplementary Protocol however, puts substantial responsibility to the national law on biosafety which should prescribe the modalities of application of Liability and redress as well as applying the set rules and requirements to LMOs originating from both parties and non-parties to the supplementary Protocol, as well as exemptions (if any) that may be made to the requirements for Liability and Redress.

The Supplementary Protocol also requires that “A causal link be established between the damage and the LMO in question in accordance with domestic law”.

The above requirement dictates that Liability and redress be catered for in national Biosafety law, but also the provisions in the national Biosafety law be sufficient enough to address all concerns and possible concerns that may arise in future. Furthermore the requirement to link the damage to the cause implies that we need strong provisions on Identification and Labelling of LMOs throughout the entire value chain to ensure Traceability, otherwise it would be practically impossible to prove this link between damage and the LMO responsible for the damage. Establishment of a causal link would also require a robust monitoring system in countries of all LMOs that may be released in their jurisdictions, be they intentional or unintentional releases.

Within the EAC countries, only one country has so far ratified/ acceded to the supplementary Protocol, though all the remaining partner states are at different stages

of ratification/ accession/ acceptance in accordance with their national requirements. Furthermore most countries are reported to have administrative or legal instrument that provide for response measures for damage to biodiversity resulting from living modified organisms, derived from other existing laws and administrative arrangements, which implies that they already know the need for such response measures.

The EAC countries that have finalized their national Biosafety legislation, when they ratify the supplementary Protocol will therefore have to amend their laws accordingly to include sufficient provisions on Liability and Redress while those that are still drafting their laws have their opportunities to include provisions on Liability and Redress before completing their laws and including sufficient provisions to ensure sufficient protection of their biological diversity and human health.

To become effective, the provisions on Liability and Redress will have to be taken into account and included as a precondition or understanding at the decision making / approval process as it would be extremely difficult to invoke such provisions if no mention was made at the time of approval of the responsible LMO.

3. HARMONIZED REGIONAL BIOSAFETY POLICY GUIDELINES FOR EAC COUNTRIES

3.1. Legal, Administrative and other measures on Biosafety to ensure that the development, handling, transport, use, transfer and release of any Living modified organisms are undertaken in a manner that reduces the risks to the environment, natural resources and human health

3.1.1 Issues and challenges

Much as all EAC partner states have ratified the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, both of which treaties require parties to put in place national legal, policy and administrative frameworks on biosafety, all the partner states have tried to implement the requirement but are at very different stages despite the time that has passed since they ratified these treaties. This means that they are currently applying different standards and in some cases no standards at all in cases where neither law nor administrative measures have been put in place. In addition, different countries have been working on their national legislations and policies, which could lead to setting of different standards though all are aimed at reaching adequate levels of safety in application of modern biotechnology, yet they have committed themselves to cooperate in trade and ease border controls to expedite trade within the sub-region.

3.1.2 Objective

The overall objective is to harmonize their biosafety policies, laws and administrative measures to ensure that whatever LMO is accepted in one of the partner states would be acceptable in all the other partner states as it would eventually end up being introduced into the other partner states either through trade or informal cross border exchange of seeds and commodities.

3.1.3 Policy statements

The EAC will:

a) Develop a regional policy to harmonize the individual national policies and guide national law development, setting minimum standards that are supposed to be adhered to by individual partner states;

b) Develop regional guidelines to guide the legal frameworks formulation in the sub-region;

c) Set up a regional framework for cooperative or where feasible joint implementation of national biosafety laws to ensure harmony in enforcement of safety measures and facilitation of trade within the sub-regional;

d) Establish harmonized penalties for those convicted of violating national laws regarding releases of LMOs into the environment, to avoid situations where some countries with less stringent laws serving as entry points for LMOs that would otherwise have not been approved for entry into the sub-region;

e) Promote regular exchange of information and regular meetings between Biosafety regulatory institutions in the sub-regions to exchange experiences and find solutions to challenges they may be facing.

3.2 Pharmaceuticals for humans that are LMOs or derived from LMOs

3.2.1 Issues and challenges

Currently the EAC countries are regulating LMO pharmaceuticals using the provisions in other biosafety-related laws or are planning to include regulation of LMO pharmaceuticals in their draft biosafety national laws. There have been reported trials of some LMO pharmaceuticals for treatment of some of the health challenges such as HIV/AIDS in some of the member states without the necessary regulatory approval in some cases.

3.2.2 Policy statements

The EAC will:

a) Support development of joint research and trials of LMO pharmaceuticals whether generated within EAC or generated from outside EAC with foreign partners and sharing of research and trial results;

b) Support the development of alternative treatment methods for different diseases challenging people in the sub-region and allow trials and use of LMO pharmaceuticals as a last resort;

c) Support joint and exhaustive Risk assessment of LMO pharmaceuticals before they are approved for use in East Africa to ensure they will not cause any problems for human health;

d) Support joint monitoring of any LMO pharmaceutical introduced in the sub-region and the patients / subjects used for the trials for appropriate periods depending on the nature of LMO in question and their life cycles / generation periods;

e) Support sharing of information resulting from research and trials of LMO pharmaceuticals to ensure that any LMO pharmaceuticals tried in one EAC state are not tried in another EAC state without consideration of the trial results from trials in the other EAC member state;

f) Support the development of research capacity within the sub-region to generate "home-made" LMO pharmaceutical technologies to address any health challenges that may be facing the sub-region.

3.3 Transit of LMOs through the EAC;

3.3.1 Issues and challenges

Currently there are different levels of regulation of transit of LMOs through the East African Community states, depending on whether there is a functional biosafety law or not, with countries with functional biosafety laws reporting to be regulating Transit of LMOs through their territories. Two of the EAC partner states have busy coastlines with active seaports that serve as main entry points for imports into the EAC and as points of exit for exports from the EAC. These seaports do not only serve the EAC partner states but also South Sudan and Eastern Democratic Republic of Congo, both of which countries are more than 1000km from the East African coast. These neighbouring countries may at some time wish to import or even export LMOs through EAC partner states, which may lead to inadvertent release of LMOs during transit, due to accidents or thefts.

3.3.2 Policy statements

The EAC will:

a) Harmonize policies, laws and administrative arrangements for transit of LMOs within all its partner states and to govern transit of LMOs through the community to neighbouring countries to protect the biodiversity and human health in the partner states against harm that could result from unauthorised release of LMOs during transit;

b) Train and sensitize all relevant officials at border entry points for all partner states including plant and animal health officers and customs officers to handle all LMOs in transit in accordance with the laws and policies;

c) Prescribe the necessary information to accompany LMOs in transit to facilitate safe handling by the people who may have to handle them during transit or in case of accidents during transit;

d) Establish harmonized packaging and labelling of LMOs in transit through the sub-region, taking into account the minimum standards set by the CPB and its processes, to reduce chances of them being planted or being put to any other use without approval in case of an accident or other occurrence that leads to their release while in transit;

e) Establish harmonized guidelines for incorporation of measures for Liability and Redress regarding harm to Biodiversity or human health resulting from LMOs in transit through the sub-region;

f) Cooperate with neighbouring countries whose goods transit through EAC countries to comply with the requirements and standards set by the EAC to avoid delays in handling the consignments of LMOs/ LMO containing consignments destined for neighbouring countries;

g) Encourage exchange of information between EAC partner states on LMOs that may be transiting / likely to transit through the partner states as any breach of the set standards in EAC may end up affecting other partner states.

3.4 Contained use of LMOs in the EAC

3.4.1 Issues and challenges

Currently different partner states are applying different rules in regulating LMOs destined for contained use (mainly those that are already carrying out some trials of LMOs), while others are awaiting for the adoption of their national biosafety laws that are still undergoing the due processes for enactment of laws.

Use of LMOs in containment is necessary in that most of LMO development has to go through rigorous research and testing before they can be recommended for use/ release into the environment or market. However, some of these LMOs still under research are poorly known and could pose potential challenges since they are not yet well known in terms of impacts and the necessary mechanisms for safe handling and use. Some have not yet even undergone comprehensive Risk Assessment and Risk Management, yet we cannot ban their import into the EAC since we need to generate information needed for their use (if proved useful) or their prohibition (if not useful).

3.4.2 Policy statements

The EAC will:

a) Put in place laws, policies and administrative arrangements to ensure safe generation, development, transfer and use of LMOs destined for contained use within the EAC;

b) Put in place adequate policies and regulations to ensure safe disposal of LMOs for contained use (after use) within the partner states;

c) Encourage cooperation and exchange of information on best practices for laboratories and other research facilities dealing with LMOs under contained use amongst partner states and relevant institutions within the sub-region;

d) Encourage cooperation between partner states in setting standards for containment facilities for LMOs within the sub-region;

e) Establish harmonized packaging and labelling of LMOs destined for contained use in the sub-region, taking into account the minimum standards set by the CPB and its processes, to reduce chances of them being planted or being put to any other use without approval.

3.5 Procedures and standards for dealing with LMOs destined for deliberate introduction into the Environment

3.5.1 Issues and challenges

The Advance Informed Agreement procedures are necessary before LMOs can be approved for release into the Environment. Currently all but one have established mechanisms to regulate the LMOs for deliberate release into the environment, either through their national biosafety laws or administrative arrangements established under other laws related to biosafety, pending the enactment of national biosafety laws.

However, with each country working alone to draft and approve its national law, though they all have to meet the minimum standards set in the Cartagena Protocol on Biosafety, there is a possibility and worry that different partner states can set different standards for AIA and notification procedures which could impact negatively on the conservation and sustainable use of biological diversity and human health in the sub-region.

Any laxity in one partner state could in the long run affect all other partner states due to the relatively free trade between them or through informal exchanges across borders as well as the many shared cross-border natural ecosystems where what escapes into the wild in one country can easily find its way into the natural ecosystems of another neighbouring state.

3.5.2 Policy statements

The EAC will:

a) Harmonize procedures and standards for notifications, handling applications and decision making for deliberate releases of LMOs into the environment;

b) Encourage exchange of information between partner states about any LMOs that may have been denied approval in one of the partner states to avoid the same LMO being introduced to another partner state;

c) Establish harmonized packaging and labelling of destined for intentional release into the environment, taking into account the minimum standards set by the CPB and its processes, to inform the relevant administrative and monitoring authorities in the receiving environment;

d) Establish harmonized guidelines on the consideration of Socio-economic considerations in the decision-making process for LMOs destined for deliberate release into the environment;

e) Establish harmonized guidelines for incorporation of measures for Liability and Redress regarding harm to Biodiversity or human health resulting from LMOs destined for deliberate release into the environment during decision-making;

f) Encourage sharing of information about LMOs that have been approved in one partner state and summary of the basis for the decision;

g) Establish harmonize procedures for dealing with illegal transboundary movements of LMOs into the environments of EAC partner states and procedures for prosecution of offenders that violate the national laws , policies and administrative arrangements for release of LMOs into the environment;

h) Establish testing facilities at key ports of entry into the sub-region to ensure that any suspicious consignments can be tested prior to being allowed entry into the sub-region;

i) Encourage sharing of information among partner states on entities that may be proven to have violated national laws regarding releases of LMOs into the environment;

j) Establish harmonized guidelines for review of decisions taken regarding LMOs destined for deliberate release into the environment, should it become necessary in light of new information or change of circumstances;

k) Establish harmonized guidelines for application of a Simplified Procedure should it become necessary (eg. cases of subsequent movements of an LMO for deliberate release into the environment previously approved by a party, to the same Party);

l) Encourage the establishment of an EAC representative and balanced panel of experts, that can be called upon or consulted by partner states during the process of decision making regarding LMOs destined for deliberate release into the environment.

3.6 Procedures for decision-making regarding LMOs destined for direct use as Food, Feed or Processing (LMOs-FFP) within the EAC;

3.6.1 Issues and challenges

Currently LMOs-FFP are not yet officially in commercial trade in the EAC sub-region. A couple of the partner states have provisions in their national laws while the rest are awaiting the completion of their national biosafety laws. The only recorded experience is with occasional supplies of GM food aid for refugees and other people in emergency situations.

Measures currently taken to reduce chances of such GM commodities being planted is to impose a condition for them to be milled before being transported into the different EAC countries. However, this measure is only feasible for those foods that are usually consumed in their ground form such as maize; while those that are usually consumed as whole seeds such as most legumes are let in as such as milling them would undermine their acceptability and usability. This poses a risk as some of these GM seeds can end up being planted, yet they were not approved for planting in the affected countries.

3.6.2 Policy statements

The EAC will:

a) Harmonize rules and procedures releases of LMOs-FFP within the EAC and for importation of LMOs-FFP into the sub-region;

b) Encourage the milling of LMOs-FFP where feasible before they are released into the sub-region for whatever use;

c) Establish harmonised minimum allowable thresholds for adventitious presence of LMOs-FFP into non-GM commodities that may be allowed in the sub-region;

d) Establish harmonized guidelines on the consideration of Socio-economic considerations in the decision-making process for LMOs-FFP destined for use in the sub-region;

e) Establish harmonize procedures for dealing with illegal transboundary movements of LMOs-FFP into the EAC territories and procedures for prosecution of offenders that violate the national laws , policies and administrative arrangements for release and / or use of LMOs-FFP in the sub-region;

f) Establish harmonized guidelines for incorporation of measures for Liability and Redress regarding harm to Biodiversity or human health resulting from LMOs during decision-making regarding LMOs-FFP;

g) Train responsible officials in the trade and food processing value chains to ensure sampling and testing can be carried out at any time in the value chain to ensure compliance with national laws of the EAC partner states;

h) Establish sampling facilities at key ports of entry into the sub-region to ensure sampling of any suspicious consignments prior to their entry into the sub-region;

i) Establish harmonized packaging and labelling of LMOs-FFP, taking into account the minimum standards set by the CPB and its processes, to reduce chances of them being planted or being put to any other use without approval;

j) Establish harmonized guidelines for review of decisions taken regarding LMOs-FFP should it become necessary in light of new information or change of circumstances;

k) Establish harmonized guidelines for application of a Simplified Procedure should it become necessary (eg. cases of subsequent movements of an LMO-FFP previously approved by a party, to the same Party);

l) Encourage exchange of information on any LMOs-FFP that may have been approved or that may have otherwise found their way onto the markets within the sub-region;

m) Encourage sufficient monitoring any LMOs-FFP that may have been approved for use as food, feed or processing within any of the member states to ensure they are not diverted for other uses other than what they have been approved for.

3.7 Entry into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms into the EAC

3.7.1 Issues and challenges

Currently, the EAC states have no operational bilateral, regional or multilateral arrangements regarding the intentional release of LMOs. However, given the trend of customs union and trade liberalization, any such arrangements in future entered into by one of the partner states would inevitably affect the other partner states. However, a partner state may wish to enter into bilateral, regional or other form of agreements or arrangement to access a given LMO for a given purpose. It would therefore be necessary that any such agreements or arrangements are entered into with due consideration of likely impacts not only on the state that enters into such agreements or arrangements but also possible impacts on other partner states.

3.7.2 Policy statements

The EAC will:

a) Establish standards for any partner state(s) that may wish to enter into bilateral, regional or multilateral agreements or arrangements with regard to deliberate transboundary movement of LMOs into any of the partner states;

b) Encourage partner states to take into consideration minimum standards set by the EAC, COMESA, SADC and the CPB and its processes while entering into any such agreements or arrangements;

c) Encourage partner states to share information resulting from the implementation of such agreements or arrangements with other partner states;

d) Encourage the partner states to involve other partner states in the negotiations (at least as observers) since they are interested / potentially affected parties to the consequences that may arise out of any such agreements or arrangements.

3.8 Transboundary Movements of LMOs from non –Parties to the CPB into the EAC member states or export of LMOs from EAC to non-parties to the Protocol;

3.8.1 Issues and challenges

The CPB, which all the EAC countries are party to, prescribes the mechanisms and processes to govern transboundary movements of LMOs between parties to the Protocol. However, some of the advanced countries in the science of modern biotechnology and generation of LMOs for different functions are yet to ratify the same Protocol. It may be necessary therefore for the EAC partner states to access LMOs

from some non-parties to the Protocol, as is already happening within some of the EAC partner states.

Such transboundary movement between parties and non-parties to the Protocol are premised on bilateral agreements between the two entities (a party and a non-party to the Protocol). For the party to the Protocol to enter into such bilateral agreement(s) with a non-party but remain compliant with the provisions of the Protocol, such bilateral agreements should be consistent with the objective of the CPB and should not go below the standards set under the protocol (CPB).

3.8.2 Policy statements

The EAC will:

a) Establish harmonized guidelines for its partner states to follow in entering into bilateral agreements with non-parties to the CPB with respect to transboundary movements of LMOs from a non-party to the EAC;

b) Encourage partner states to involve sister partner states during negotiations (at least as observers) to ensure whatever is agreed is within the interests and agreed standards within the EAC;

c) Encourage sharing of information between partner states regarding the execution of the bilateral agreements between EAC partner states and non-parties to the CPB;

d) Encourage partner states to always bear in mind the minimum standards for transboundary movements of LMOs set by the EAC and its other trading blocs such as COMESA, SADC and the CPB so as not to disrupt free flow of commodities within the EAC and its neighbouring regions, as well as remain compliant with the provisions of the CPB when entering into such dealings with non-parties.

3.9 Risk Assessment (RA) and Risk Management (RM) within the EAC;

3.9.1 Issues and challenges

RA is a critical requirement for informed decision making prior to allowing/ approving transboundary movements of LMOs into any country; while RM another critical issue to consider if any Risks (both currently known and unforeseen) are to be managed to minimize the risks to biological diversity and human health.

Currently some limited capacity for RA and RM exists in most of the EAC partner states each partner state being at a different level of proficiency. However, this existing still needs to be further improved and constantly updated to keep it relevant to new developments. Each country for those that have made decisions regarding LMOs does

its RA and RM as it deems best fit without necessarily looking at standards set/ followed by other partner states.

3.9.2 Policy statements

The EAC will:

a) Establish harmonized standards and procedures for Risk Assessment to be followed by all the partner states prior to making decisions regarding transboundary movements of LMOs into the sub-region;

b) Encourage and provide joint training and refresher courses for experts within the sub-region on RA and RM to bring them to the same level of knowledge so that a decision made on a given LMO in one partner state is based on the same criteria as would have been used in another partner state;

c) Establish a sub-regional panel of Technical experts on RA and RM that can be called upon and engaged by any of the Partner state that may be constrained in the area of RA and RM in order to make informed decisions;

d) Establish sub-regional centre(s) of excellence in RA and RM that can be relied upon by the sub-region in case of any challenge regarding any LMO and possible risks and their management;

e) Encourage sub-regional cooperation in monitoring of any LMOs that may have been released in any of the partner states for a period commensurate with the life cycle/ generation time of the LMO to further minimise the risks and detect any risks early enough to ease their control;

f) Encourage information exchange between the partner states on all matters of relevance to RA and RM within the sub-region, including but limited to summaries of RAs carried out in each partner state prior to making decisions regarding transboundary movements of LMOs into the sub-region.

3.10 Unintentional Transboundary Movements of LMOs and Emergency Measures;

3.10.1 Issues and challenges

These measures are required in case something unusual such as an accident involving LMOs in which there is an accidental or malicious release of LMOs in the environment or the market without approval. Parties to the CPB are required to put in place measures and personnel to respond to such emergencies and inform all potentially affected countries. Given the nature of trade and social interaction / integration within the EAC partner states, any emergency regarding LMOs could easily affect all partner states.

Currently almost all the EAC partner states have instituted some measures to respond to emergencies as individual countries. Given the nature of emergencies and the costs

and resources needed to address them urgently and the level of harm that can occur if the response is nut urgent enough, it is necessary that the EAC partner states would need to respond as a group to reduce on the costs, but also to reduce the possible risks to manageable levels.

3.10.2 Policy statements

The EAC will:

a) Establish a sub-regional emergency measures/ response multi-disciplinary task force to be called upon on short notice in case of unintentional transboundary movements of LMOs within the sub-region;

b) Put in place an emergency response trust fund to facilitate such emergency response should it be required to avoid emergency responses being bogged down by lack of financial resources;

c) Train the members of this emergency measures task force to ensure they have the necessary skills required for emergency response;

d) Encourage sub-regional cooperation and cooperation with other neighbouring countries/ sub-regional blocs in cases of emergencies involving unintentional releases of LMOs.

3.11 Administrative procedures for LMOs in the community (CNAs and NFPs);

3.11.1 Issues and challenges

All partner states in the EAC have instituted some administrative procedures for LMOs by designating Competent National Authorities and National Focal Points for Biosafety. However, their empowerment and facilitation is at different levels, depending on whether the country has a functional national law on biosafety and a functional biosafety framework.

There is need to put in place the necessary institutional framework to facilitate them perform their duties effectively as well as encourage cooperation and coordination at sub-regional levels to enhance harmonization of actions and sharing of experiences and expertise.

3.11.2 Policy statements

The EAC will:

a) Encourage partner states to put in place the necessary institutional frameworks to ensure effective coordination between CNA s and NFPs for improved efficiency;

b) Encourage partner states to avail adequate financial and human resources to their CNA and NFS to increase their efficiency;

c) Establish a sub-regional forum (could transact most of its work on-line to reduce on coasts) for CNAs and NFPs to regularly share experiences and challenges they face and how they are being handled in different partner states.

3.*12 Information sharing and the Biosafety Clearing House* (BCH*)*

3.12.1 Issues and challenges

As already outlined in section 3 above, the BCH under the CPB was established as a mechanism to exchange information of relevance to LMOs in the different countries globally. The categories of information that are required under the Biosafety Protocol are also outlined in section 2.16 of this document.

The EAC partner states have submitted some of the required information while some other information is still pending either because it is not yet available; while in some cases, information is available but not yet uploaded onto the BCH.

Some of the information of relevance for Biosafety in the EAC may not be of relevance at the international level, while yet other categories of information will be unique to EAC countries such as standards and thresholds that are set by the EAC sub-region and will therefore not be available on the BCH of the CPB.

3.12.2 Policy statements

The EAC will:

a) Establish a BCH for serving the sub-region's needs of Biosafety information (EAC-BCH) where partner states will submit their relevant authentic information, to serve the information need of the sub-region and its partners;

b) Establish a mechanism for authenticating such information before it is published on the EAC-BCH, such as requiring each partner state to designate a National Focal Point –BCH to upload and certify national information before it is published;

c) Establish a well maintained webpage on the EAC website for purposes of housing and servicing the EAC-BCH;

d) Develop standard formats for partner states' submission of information to the EAC-BCH to make easily searchable, comparable and user-friendly;

e) Encourage partner states to keep submitting and updating all their national information of relevance to the EAC-BCH.

3.13 Procedures for dealing with Confidential (Business) Information relating to LMOs

3.13.1 Issues and challenges

This is meant to protect proprietary/ business information that a notifier may identify as confidential and request for confidentiality of such information to be granted and respected in the EAC partner states. The CPB already set standards regarding categories of information that cannot be regarded as confidential as outlined under section 2 above. Some of the partner states of the EAC already have provisions for protection of confidential information while others do not have, owing to the incomplete national biosafety legislation processes.

In order to promote harmony in trade and other processes that may have to deploy LMOs, there is need for the sub-region to harmonize criteria for recognition of confidential business-related information and even the methods of protecting such information and to what extent the protection will apply.

3.13.2 Policy statements

The EAC will:

a) Establish harmonized criteria for receiving, using and protecting confidential business information in the EAC and its partner states;

b) Establish harmonized prescriptions on what categories of information may or may not be recognized as confidential in the EAC;

c) Prescribe what categories of individuals will have the privilege of accessing and using Confidential Business Information (CBI);

d) Prescribe how such individuals privileged to access and use CBI shall protect the interests of the information owner by not sharing it with unauthorized persons or putting it to unauthorized use.

3.14 Capacity Building/ Capacity Development and enhancement

3.14.1 Issues and challenges

The field of modern biotechnology and biosafety are still relatively new in the EAC sub-region and the expertise is still limited and mainly restricted in a few research institutions and tertiary education institutions. The training received is also sourced from diverse resource persons and institutions mainly determined by availability of financial support (usually external in nature) and hence the EAC and its partner states rarely have a key role in influencing the course content. In addition each partner state sources

its own training from whichever available sources, hence different partner states are at varying levels of training and awareness in biosafety.

3.14.2 Policy statements

The EAC will:

a) Carry out a biosafety capacity needs assessment in all its partner states to determine the nature of capacity that needs to be carried out;

b) Endeavour to harmonize training in biosafety for regulators within the sub-region to improve on relevance of the training materials to the needs and situations in the sub-region;

c) Encourage the use of EAC based experts preferably national of the EAC states where available to ensure relevance of the training materials/ course content to the needs and circumstances in the EAC;

d) Encourage joint fund-raising for the sub-region's capacity needs / training projects, to ensure all partner states benefit from such training;

e) Encourage joint development of course content for training of experts for short courses where the training is to be nationally based;

f) Encourage joint curricula development for Universities in the sub-region offering biosafety-related courses / long term training leading to awards of higher qualifications;

g) Encourage inter-EAC cooperation where Countries with higher capacity/ expertise in Biosafety offering assistance to those with less expertise in the spirit of EAC cooperation either free of charge or at subsidized rates;

h) Establish a Biosafety capacity building fund to which EAC partner states would contribute and donor countries/ agencies as well biotechnology companies would be encouraged to contribute to; to support regular capacity development in Biosafety in the EAC.

3.15 Public Awareness and Participation with regard to LMOs;

3.15.1 Issues and challenges

Parties to the CPB are required to encourage and support public participation, education and awareness regarding the safe development, transfer, and use of LMOs that may have adverse effects on biodiversity as well as human health.

Currently all EAC countries have endeavoured to implement this requirement but to different levels. There are also numerous sources of information on LMOs (from diverse with diverse intentions) within the EAC countries. Some of this is false, contradictory

and inconsistent, while others are somewhat exaggerated or not giving the whole truth. The citizens are left sometimes confused as to which one to believe and not to believe.

The information available among the population is both inadequate, sometimes incorrect leaving the population unsure what technology is useful or not, and which one has been or has not been approved by the appropriate authorities.

3.15.2 Policy statements

The EAC will:

a) Develop standard, correct and harmonized information for use in the different partner states for public information, education and awareness on LMOs to ensure what is disseminated in one state regarding a given LMO is similar to what is used in other partner states;

b) Endeavour to translate the information materials in languages that are understood by the citizens of the sub-region so that the content can be appreciated across the education divide;

c) Encourage and support incorporation of Biosafety training in the relevant curricula of higher institutions of learning within the sub-region, to produce a well informed future work-force in the sub-region;

d) Encourage official communication channels for each country to enable the consumers (the citizens) access authentic information regarding LMOs;

e) Encourage public participation, education, and awareness on all matters relating to LMOs, starting from decision-making on which LMOs are released and why/ what problem they are helping to solve, transportation and transit of LMOs, released on the market to create trust and harmony in the field of safe development, transfer and use of LMOs in the EAC.

4. CAPACITY BUILDING FOR BIOSAFETY IN THE EAC

4.1. General

Capacity-building is an area where EAC partner states will require a continuous and concerted effort if they are to positively exploit the benefits of modern biotechnology and avoid the risks associated with the same technologies. The levels of training in national institutions within the EAC are also still limited and the levels of commitment of financial resources by the EAC partner states are also still limited, mainly because of lack of an enabling law to provide for funding of Biosafety activities, but even where national Biosafety laws have been enacted still funding for biosafety capacity building are still constrained by budgetary shortfalls and limited awareness among policy makers who are responsible for resource allocation and prioritization of funding areas.

All EAC countries admit they do not have adequate capacity for Biosafety and still have numerous areas where they need capacity building to be carried out. In addition, the field of modern biotechnology and biosafety are fast growing, with new techniques and technologies being churned out necessitating regular training and re-training of regulators to cope with the constantly changing circumstances.

Capacity building is another area where EAC partner states will need a concerted effort, not only considering the economic costs involved and the need for combining resources to maximise benefits, but also to harmonise training materials to ensure the quality and uniformity of the training offered by EAC institutions and trainees within the sub-region.

4.2. Capacity needs assessment, strengths and weaknesses

Capacity-building cannot be effective if it does not make a study on what are the needs, what is available and what needs to be sourced for. The EAC countries will therefore have to first carry out a capacity needs assessment, as well as identify which countries have a comparative advantage over others and in what fields. The countries that are relatively better off in expertise can assist others in improving where they are deficient in the spirit of south-south cooperation as well as EAC cooperation.

To make the training relevant to the region, it would be beneficial to use sub-regional (EAC-based) expertise to ensure that the knowledge shared is more focused to the sub-regional needs and conditions. The SCBD roster of experts in Biosafety and the UNEP/GEF Regional Advisors on Biosafety / Biosafety Clearing House could be a learning experience. In both cases, experts in different aspects of Biosafety would provide their CVs which would be published on the organizations' websites. Countries eligible for and needing technical assistance would look at the experts' profiles and select the expert they felt suited their needs and understood their socio-economic and environmental set up best and request the responsible body (SCBD or UNEP/ GEF) to pay the selected expert and facilitate him/her to come to the country and give the required advice or training as appropriate and as agreed between the responsible body and the requesting country.

In cases where there are no expertise in the sub-region and there is need to outsource the expertise, care should be taken to identify the relevant courses with the required training, identify resourceful persons from the sub-region who can be sent for training so that they would later come back and train the other professional within the sub-region to minimise costs of training abroad and to make the courses and content more tailor-made for the needs and conditions within the EAC.

4.3. Resource mobilization for capacity building in Biosafety

In order to develop an effective mechanism for fund raising for biosafety capacity building, the EAC will have to devise innovative mechanisms for resource mobilization to achieve what the individual partner states have not been able to achieve.

a) Joint fund-raising (where advantageous) for the sub-region's capacity needs / training projects, to ensure all partner states benefit from such training;

b) The joint effort shall supplement but not replace individual effort by individual countries where they perceive an opportunity as individual countries which would contribute towards fund-raising for biosafety capacity building;

c) Establish a Biosafety capacity building fund to which EAC partner states would contribute and encourage donor countries/ agencies such as UNEP/ GEF as well to contribute towards capacity building efforts;

d) Establish a sub-regional fund for capacity-building and require biotechnology companies that would want to test or release their biotechnology products within the EAC or any of its member states to contribute; to ensure a sustainable source of funds to continuous training and sensitization to keep abreast with any new developments

e) Integration of Biosafety into National Biodiversity Strategies and Action Plans (NBSAPs) as well as national development plans (NDPs) in all the EAC partner states so that the profile of biosafety is raised and the biosafety agenda is seen as one of the national priorities that require both funding and enhanced personnel deployment.

5. INSTITUTIONAL ARRANGEMENTS

5.1 At the EAC level

In order to fully implement and operationalize the above policy recommendations, some institutional reforms may be necessary in the EAC, both at its secretariat and institutions in the partner states responsible for biosafety. However bearing in mind the financial implications involved, use shall be made of already existing institutions, with some modifications and improvements where necessary.

At the EAC secretariat, the EAC will strengthen its current Environment and natural Resources Unit to handle the expanded portfolio of coordinating the harmonization of biosafety policies and later coordination of the implementation phase of biosafety related activities resulting from the policy recommendations made in this report.

In addition an effort will be made at the EAC level to develop the capacity to coordinate the EAC-BCH functions envisaged under the recommendations made in this report. This can be done through retraining of the existing Information Communication

Technology (ICT) personnel where feasible or recruiting a specialized person to implement and oversee the EAC-BCH.

The web-page to be established should be inter-operable with the BCH of the CPB and other relevant web-sites to make it productive and effective as an information exchange and information management tool.

The LMO testing facilities recommended under section 3 would of essence have to be physical facilities and have to be located at already existing and functional ports of entry to EAC such as the port of Mombasa and dare s Salaam, which are major ports of entry into East Africa.

The EAC would discuss and agree whether they need more that these two facilities or not, bearing in mind convenience for trade and economic efficiency/ costs involved.

The EAC would either have to establish fully fledged testing facilities manned by full time employees of the EAC, or to reduce on costs, use could be made or modifications be carried out on already existing national facilities at these ports and the EAC would pay for the individual services rendered upon request and as need arises, which would be more cost-effective.

In order to use national facilities a Memorandum of Understanding (MoU) would have to be entered between the EAC Secretariat and the host country for the port in question, taking the necessary precautions to avoid challenges that could arise in case the host country of the port has interests in the commodities in question to avoid Conflicts of interests.

Regarding the regional Centre of Excellence on Risk Assessment recommended under section 3, again a new facility could be established fully under the EAC (funds permitting), or an existing facility / facilities within selected partner states would be facilitated and utilized, under a MoU as recommended above regarding the entry ports.

5.2 At national level in each EAC partner state

Personnel and institutions already charged with Biosafety work can be utilized, in accordance with their national laws and arrangements, perhaps with a bit of re-training to take advantage of the knowledge and experience in these persons and institutions.

Training curricula within existing institutions where available and feasible, should be reviewed to cater for biosafety training needs both for short, medium and long-term training. Outsourcing of specific experts to beef up those already existing in these institutions would be highly recommended, to make the courses richer and attractive to potential trainees.

The personnel in key Ministries, Departments and Organizations such as Parastatal bodies shall work with Local Government agencies and Extension personnel especially in awareness raising and education, but also in monitoring and other Risk Management activities as well Emergency measures /situations when need arises.

5.3 The role of Civil Society Organizations/ NGOs, Community Based Organizations (CBOs), Farmers' Organizations and Faith based Institutions

Governments should partner with relevant NGO, CBO and Farmers and Consumers' Organizations as these are vital in outreach activities especially as they are not only close to but also trusted by most of their stakeholders.

In countries where there are already existing national and sub-national farmers' Associations / Federations, these should be utilized not only in public education and general awareness about LMOs, but they can also be a very important means of communication by the Competent National Authorities or National Focal Points regarding which LMOs have been officially approved for use within their country and what attributes they bring on board, needs for their safe use and other relevant information.

Faith based organization always have a very strong following and where a technology has been proven useful or not useful, they can be instrumental in passing on the information to their followers.

The same can be done with relevant NGOs, and CBOs regarding not only sharing and dissemination of information, but also in translating some information materials where they have the requisite capacity.

Where governments partner with these different entities, care should be taken through regular follow up and interaction to ensure the information passed on is not distorted as some of the Biosafety related information tends to be highly technical and hence difficult to translate and communicate to lay people.

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