PROJECT DOCUMENT

1. SECTION 1: PROJECT IDENTIFICATION

1.1 Project title: Multi Country Project to Strengthen Institutional Capacities on LMO Testing in Support of National Decision Making

1.2 Project number: GFL/5283
PMS: Addis No. 936

1.3 Project type: FSP

1.4 Trust Fund: GEF

1.5 Strategic objectives:

GEF strategic long-term objective: BD3

Strategic programme for GEF V: Biosafety

1.6 UNEP priority: Ecosystem Governance

1.7 Geographical scope: Regional (Angola, Congo DR, Lesotho, Madagascar, Malawi, Mozambique)

1.8 Mode of execution: External

1.9 Project executing organization: Regional Agricultural and Environmental Innovations Network-Africa (RAEIN-Africa)

1.10 Duration of project: 48 months
Commencing: October 2016
Technical completion: September 2020

Validity of legal instrument: 54 months

1.11 Cost of project	**US$**	**%**
Cost to the GEF Trust Fund	**3,860,000**	**37%**
Co-financing		
Cash		
Sub-total	**3,860,000**	
In-kind		
Countries	**6,075,252**	
RAEIN-Africa	**306,500**	
Free State University	**165,000**	
Sub-total	**6,546,752**	**63%**
Total	**10,406,752**	**100%**

1.12 Project summary

The guiding objectives on the conservation, sustainable use of Biodiversity and equitable sharing of benefits thereof, are commitments that signatories to the Convention on Biological Diversity (CBD) agreed to adhere to. It is recognized that modern biotechnology holds great potential if developed and used with adequate protection for safety to the environment and to human health. The Cartagena Protocol on Biosafety (CPB) was put in place to guide safe use, handling and transboundary movement of any living modified organisms (LMOs), arising from modern biotechnologies, that may have adverse effects on biodiversity and human health. SADC countries are party to the CPB and are to domesticate and implement its provisions.

Identified national barriers to implementing the CPB include; lack of national biosafety legislations and regulations, inadequate capacity and resources to enable countries to carry out LMO Detection for informed decision making, limited awareness and limited stakeholder participation in decision making. Lack of human and institutional capacity in LMO detection is a major impediment to effective implementation of biosafety regulatory systems. Science-based tools are required to inform decision-making on LMOs handling, use and transboundary movements.

It is therefore, imperative that countries are equipped with capacities and relevant knowledge to carry out LMO detection ensuring traceability and segregation of LMOs; in compliance with national regulations in terms of LMO labelling, and international regulations for trade and the safe handling, transport, packaging and identification of LMOs and, carryout informed monitoring and surveillance of LMOs. As part of the project preparation phase and the stocktaking process, the proponents recommended harmonised approaches be used due to costs involved in CPB implementation to leverage supportive technical assistance as a shared regional or multi country service

This project aims at assisting six countries in the region: Angola, Democratic Republic of Congo, Lesotho, Madagascar, Malawi and Mozambique; on pre- and post-approval monitoring of LMO, in general surveillance, and in monitoring transboundary movements of LMOs as part of the risk management processes under Articles 16 and 17 of the CBP. The project will also provide tools to assist the designated Competent National Authorities in decision making.

Laboratory infrastructure required for LMO detection, technical backstopping to the designated laboratories, training of scientific and regulatory staff, development and adoption of harmonized quality management systems, assistance with international accreditation, technical advice including experience-sharing and scientific collaboration are activities that the proposed project will coordinate through a central hub. Sharing resources and expertise through a network will be cost-effective compared to fragmented and standalone efforts by national institutions. The project takes a harmonised approach in sharing expertise and resources in building capacity through a thematic intervention in support of implementation of the Cartagena Protocol on Biosafety. Capacity building takes up the bulk of the proposed activities.

The expected outcomes are: i) Designated LMO laboratories fully capacitated and achieving a minimum level of functionality on LMO detection; ii) Minimum level of competence achieved in the designated LMO testing laboratories; iii) Sustainable Opportunities for sharing expertise, experiences and resources on LMO detection created; and iv) Sustainable Opportunities for sharing expertise, experiences and resources on LMO detection.

The project intends to; (i) increase the capacities of relevant officers and technicians at national level in LMO related issues, (ii) expand laboratories' capability to perform testing, measurement and/or calibration activities, (iii) enhance their management systems, and (iv) build a resource pool to back the handling and monitoring of LMOs in support of the implementation of the Cartagena Protocol on Biosafety.

The project design was guided by an on the ground assessment during the project preparation phase on the status of the physical structures, the equipment, the quality management systems (QMS), the human capacity and the laboratory capabilities

The project falls under the UNEP Medium-term Strategy's sub programme on Environmental Governance, whose objective is to ensure that environmental governance at country, regional and global levels is strengthened to address agreed priorities to support implementation of MEAs.

To implement the provisions of the CPB efficiently and abide by its general provision as provided for in Article 2 of the CPB, the project focuses on development of tools and methodologies to support safe handling, transport, and use of LMOs in the area of identification and surveillance.

The project is anchored on interventions to support the participating countries to have the basic infrastructure and technical capacity, including equipment, tools and practical know-how to identify and quantify LMOs to support decision making on movements on Living Modified Organisms.

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ACRONYMS AND ABBREVIATIONS

ABNE	African Biosafety Network of Expertise
AU	African Union
BCH	Biosafety Clearing House
CARI	Chitedze Agricultural Research Institute
CBD	Convention on Biological Diversity
CBP	Cartagena Protocol on Biosafety
CB-UEM	Biotechnology Centre of Eduardo Mondlane University
CLA	Central Laboratory of Angola - Agostinho Neto University
CGEA/ CREN-K	General Atomic Energy Commission / Regional Centre for Nuclear Studies-Kinshasa
Can	Competent National Authority
COP/ MOP	Conference of the Parties/ Meeting of Parties (to the Convention on Biological Diversity)
DRC	Democratic Republic of Congo
FAO	Food and Agriculture Organization
ELISA	Enzyme-Linked Immunosorbent Assay
EO	Evaluation Office
GEF	Global Environment Facility
GM	Genetic Modification
GMOs	Genetically Modified Organisms
LEA	Lead Executing Agency
IIAM	Agriculture Research Institute of Mozambique
LMOs	Living Modified Organisms
MBL-UA	Molecular Biology Laboratory - University of Antananarivo
M&E	Monitoring and Evaluation
MEAs	Multilateral Environmental Agreements
MRBLI	Mozambique Research Institute Biotechnology Laboratory
NBFs	National Biosafety Frameworks
NBSAPs	National Biodiversity Strategies and Action Plans
NFPs	National Focal Points
NTF	National Task Force
NUL	National University of Lesotho
PCR	Polymerase Chain Reaction
PIR	Project Implementation Review
PMU	Project Management Unit
PPG	Project Preparation Grant
QMS	Quality Management Systems
RA	Risk Assessment
RAEIN-Africa	Regional Agricultural and Environmental Innovations Network-Africa
RM	Risk Management
RSC	Regional Steering Committee
SANBio	Southern Africa Network for Biosciences
SADC	Southern African Development Community
SANGL	Southern African Network for GM Detection Laboratories
SCBD	Secretariat of the Convention on Biological Diversity
SOPs	Standard Operating Procedures
TBM	Transboundary Movement
UNDAF	United Nations Development Assistance Framework
UNEP	United Nations Environment Programme
USAID-PBS	United States Agency for International Development - Program on Biosafety Systems
VLK	Veterinary Laboratory of Kinshasa

WEMA	Water Efficient Maize for Africa

Section 2: Background and Context

2.1. Background and Context

1. Biological diversity (the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part) plays a central role in sustaining humanity and other life forms. However, this biological diversity is being lost at an unprecedented scale as a result of natural and anthropogenic factors. Globally it has been acknowledged that the rate of biodiversity losses, if unchecked, will threaten the livelihoods of current and future generations. As a result, in 1992 the world met in Rio de Janeiro and agreed on a common framework for managing biological diversity - the Convention of Biological Diversity (CBD). The objectives of the Convention are i) the conservation of biological diversity, ii) the sustainable use of its components, and iii) the fair and equitable sharing of benefits arising from the utilization of genetic resources. The applications of modern biotechnology and the release of its products into the environment were identified as some of the potential threats to biological diversity. Article 19.3 of the CBD states that "*the Parties to the Convention shall consider the need for and modalities of a protocol setting out appropriate procedures in the field of safe transfer, handling and use of Living Modified Organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity*". In the year 2000, the Cartagena Protocol on Biosafety (CPB) was concluded and opened for signature, providing a comprehensive international framework for the safe transfer, handling and use of LMOs.

2. Southern Africa, like the rest of the continent, faces a high demand for food and other biodiversity dependent services to sustain growing populations. Southern African countries are predominantly agriculture based economies. Most communities, especially in the arid parts of the region, depend on species and varieties that can tolerate several biotic and abiotic stresses while producing reasonable yields. Local genetic resources, including wild relatives of crop species, are a rich source of the biodiversity needed to introduce resilience into cropping systems. Thus risk assessment and risk management to prevent contamination of the biodiversity contained in these local genetic resources are imperative for sustainable co-existence of LMOs and non-Genetically Modified (GM) crops.

3. All the countries in the Southern Africa Development Community (SADC) are Parties to both the CBD and the CPB. Consequently, they have undertaken a number of initiatives to ensure the effective implementation of both the CBD and the CPB. These include among other things: development of National Biosafety Frameworks (NBFs), and building of capacity for their implementation through raising awareness, training, networking and information sharing.

4. The Regional Agricultural and Environmental Innovations Network - Africa (RAEIN-Africa) was instrumental in assisting countries in the SADC region to develop capacity for implementing NBFs. RAEIN-Africa promotes participatory development of appropriate science and technology innovations for sustainable management of the environment and agricultural activities. RAEIN-Africa has built and coordinated partnerships to facilitate sharing of experiences and capacities at national and regional levels. RAEIN-Africa promotes conservation efforts and the sustainable use of biodiversity by responding to needs and gaps identified by partners at local, national and regional levels. Using a range of activities that support the use of science, technology, innovation and indigenous knowledge to overcome challenges, RAEIN-Africa has played a pivotal role in building capacity in Africa, especially in the SADC region, in sustainable biodiversity management and biosafety.

5. RAEIN-Africa and its partners identified among other things, the need to build human and institutional capacity in LMO detection in the SADC region. LMO detection plays an important role in ensuring; i) LMO traceability and segregation; ii) compliance with national regulations in terms of LMO labelling; iii) compliance with international regulations for trade; and iv) monitoring and surveillance to ensure compliance with regulations at all levels.

6. Major identified constraints to LMO detection in the region included inadequate levels of both human and infrastructural capacities, absence of a platform for sharing information and experiences in key areas required for effective regulation of the technology, and lack of harmonized standards for LMO detection and quantification. RAEIN-Africa established the Southern Africa Network for GM Detection Laboratories (SANGL), a forum for joint learning and technical support for laboratories designated by National Biosafety Authorities (NBA) to support the implementation of National Biosafety Frameworks (NBFs). Membership to SANGL was based on two criteria: i) membership to the SADC and ii) being Party to the CPB. The network's main objective was to establish a regional collaboration for LMO detection laboratories in the SADC to support the implementation of National Biosafety Frameworks in compliance with the Cartagena Protocol on Biosafety. In a bid to address some of the identified needs and gaps, RAEIN-Africa allocated resources to implement the SANGL project. The SANGL project was implemented under the broad objectives of the network.

7. The specific objectives of SANGL are:
   - To build and strengthen human and infrastructural capacities for LMO detection in Southern Africa
   - To establish guidelines and harmonized methods for sampling and LMO detection in Southern Africa, based on internationally accepted approaches
   - To achieve international recognition (accreditation) in LMO detection in all member laboratories
   - To establish linkages and partnerships with other international LMO detection laboratories and networks as well as other institutions and
   - To establish an collaborative communication platform for LMO detection laboratories

8. Whilst the Cartagena Protocol on Biosafety is implemented at national level, commodity trade in the region is undergoing liberalization. Currently, trade within the SADC is unevenly distributed among member states, with South Africa accounting for about 50% of intra-regional exports and a somewhat balanced import level across member states. There is therefore a high level of transboundary movement (TBM) of commodities and goods in the region that justifies harmonization[1] or development of common standards across the regional market players. Harmonization of toolkits, guidelines, protocols and standard operating procedures (SOPs) would help in validation of test results and will ensure confidence in the safe transfer, handling and use of LMOs, as well as in exchange of information. Harmonization would also indirectly contribute to ease of movement of goods and thus ease of trade.

9. This project therefore seeks to build on the RAEIN-Africa SANGL Project by strengthening the institutional capacity for LMO detection in support of national decision making process in biosafety regulatory systems in the selected Southern African

[1] Harmonization is a process of creating consistency of laws, regulations, standards and practices, so that the same rules will apply to businesses that operate in more than one member State, and so that the businesses of one State do not obtain an economic advantage over those in another as a result of different rules. It also leads to reduced compliance and regulatory burdens for businesses operating nationally or trans-nationally.

countries. Six countries in the region will participate, thus forming a multi-country project whose main objective will be to strengthen institutional capacities on LMO Testing in support of national decision making. Participating countries are: Angola, Congo Democratic Republic, Lesotho, Malawi, Madagascar and Mozambique.

10. The proposed project aims to strengthen biosafety decision making capacities through enhancement of national LMO detection capacities. Thus, the project's baseline is built on an in-depth study of the status of existing regulatory, human and infrastructural capacities and gaps thereof, for LMO detection. The needs finding exercise, facilitated through the UNEP-GEF Project Preparatory Grant and carried out in the six participating countries, established the baseline status for this project. The needs finding phase assessed the policy environment around biotechnology, biosafety and biodiversity conservation, and furthermore established the capacity status of at least two selected referral laboratories in each of the participating countries. An exception was Lesotho, where the status of only one laboratory was assessed. The project is designed to maximize the potential for safe transfer, handling and use of LMOs through strengthening the institutional capacities of participating laboratories and of national decision making systems by responding to the identified gaps and needs. The project will assist parties in the region on pre- and post-approval monitoring of LMOs, general surveillance and also in monitoring TBMs as part of the risk management processes under the NBFs and as required under Article 17 of the CPB. Collaborative regional initiatives will harmonize regional biosafety instruments, unify scientific practice and standards for detection of LMOs, and promote decision making based on awareness and understanding of the guiding principles. A network model, consisting of a Central Coordination Hub and the designated national laboratories as proposed, will ensure a more cost effective approach for sharing resources and expertise in the provision of technical support services to the national regulatory systems within the Southern African Region compared to stand-alone national systems for identification and handling of LMOs as required under paras 2 a - c of Article 18 of the CPB and is a direct response to the GEF Strategy on Biosafety in coordination and sharing of resources to support capacity building on thematic interventions in the implementation of the Cartagena Protocol on Biosafety. The network will also help in building partnerships and mentoring of scientists and regulators amongst the countries as there are varying capacities within the region.

2.2. Global significance

11. The earth's biological resources are vital for maintaining and sustaining the provision of food, income and employment to those relying on it for survival. Many people in Africa rely on agricultural activities and the exploitation of natural resources to eke out a living (African Economic Outlook 2013). Thus, safe and sustainable use and management of biodiversity is vital. It is with this understanding that an international treaty, the Convention on Biological Diversity (CBD) was endorsed by 196 countries of the world. The recognition of the importance of biological diversity as a global asset of tremendous importance for the present and the future is increasing. However, threats to species and ecosystems, mainly due to human activities, remain an issue of concern. Balancing technological development while ensuring biodiversity conservation is a global challenge, and yet increased food insecurity in the face of growing population, climate change and socio-economic shocks and stresses makes LMOs an attractive source of effective innovations. The potential of LMOs to contribute to increased food productivity through the introduction of innovative resilience mechanisms in germplasm and farming methods makes it one of the most adopted technologies worldwide. Over 180 million hectares of global crop land was under GM crops in 2014, accounting for ~12% of total arable land (Baulcombe et al., 2014; James 2014). GM

crops are under production in over 30 countries scattered over the whole world. Southern Africa is the first region in Africa to have one of its member states, introduce LMOs for food security and livelihoods enhancement.

12. Concerns regarding the possible adverse effects of the LMOs on the conservation and sustainable use of biological diversity are globally recognised and governed by the Cartagena Protocol on Biosafety. At its fifth meeting, in decision BS-V/9 the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) mandated a number of activities for laboratories involved in the detection and identification of living modified organisms (LMOs). Specifically, the COP-MOP requested the establishment, through the Biosafety Clearing-House (BCH), of an electronic network of laboratories involved in the detection and identification of LMOs and the organization of workshops for heads of detection laboratories.

13. In decision BS-V/16 the COP-MOP adopted the Strategic Plan for implementation of the Protocol for the period 2011-2020. Among the outcomes set out by the Strategic Plan, the following are relevant to LMO detection and identification:

- Easy to use and reliable technical tools for the detection of unauthorized LMOs are developed and made available,
- Guidance developed to assist Parties to detect and take measures to respond to unintentional releases of living modified organisms; and
- Personnel are trained and equipped for sampling, detection and identification of LMOs

14. At its sixth meeting, in decision BS-VI/3 Capacity-Building, the COP-MOP adopted a framework and action plan aimed at advancing the implementation of the capacity-building components of the Strategic Plan. The indicators, results and activities linked to outcome (iii) above as adopted in the capacity-building action plan are available in the annex to the decision.

15. Detection is a vital element of a broad system aiming at taking informed decisions on the handling, transport and use of LMOs. It is therefore internationally recognised that for effective implementation of the CPB, countries will need capacities to test, detect and quantify LMOs in commodities and the local environments. Such capacities will contribute to safe transboundary movement, handling and use of LMOs as well as safeguard biodiversity from possible contamination arising from intentionally and unintentionally released LMOs. Assessing the environmental impacts of LMOs as a result of transboundary movements or the introduction of new species is a major challenge in addressing the food security requirements whilst ensuring no adverse effects on the conservation and sustainable use of biodiversity. The environmental review of LMOs will take place when measures on risk assessment (RA) and risk management (RM) are implemented in accordance with the policies, laws and regulations duly established and formally adopted by the corresponding authorities. Results of monitoring and surveillance, supported by testing facilities, will provide valuable information, allow for validation of illegal and unintentional movements, as well as provide knowledge on the adequacy of RA and RM arrangements. Such knowledge will in turn strengthen the "environmental reviews" in handling of LMO requests. It will also allow, in some cases, for reviewers to verify and cross check data provided in applications for introductions on a case by case basis to guide decisions on environmental releases. Safe handling, transfer and use of LMOs will contribute to the conservation and protection of genetic resources and biodiversity; thereby maintaining and sustaining the provision of food, income and employment to those relying on it for survival. In addition to the above, the project intends to develop SOPs and protocols for LMO detection laboratories in the region, in support of national biosafety systems. By

establishing these standards, national decision making, including monitoring measures, will be supported and harmonised.

16. Effective RA & RM of LMOs contribute to safeguarding of the natural ecosystems and indigenous genetic resources, an issue which remains a vital responsibility for all communities. It is for this reason that the Cartagena Protocol on Biosafety, a supplementary agreement to the CBD, deals with the protection of biological diversity from the potential risks of LMOs. This project will thus build capacity to ensure regulatory compliance and provide support for pre and post approval monitoring, safeguarding unregulated transboundary movements and minimizing risks to biodiversity as per the obligations of parties to the CPB, to ensure conservation and sustainable use of biodiversity of global significance in the region. The environment will be protected and ultimately people will continue to sustainably derive the various environmental goods and services. The Global Environmental Benefits under the Cartagena Protocol on Biosafety derived from this project will become measurable and tangible with the implementation of all main provisions of the CPB.

17. Countries in the Southern African Region depend a lot on technology for improvement of existing crop species to enhance their performance and tolerance to both abiotic and biotic stresses. The need for food and germplasm for planting leads to transboundary movement of genetic materials, which in normal agricultural practices and trade require the development of procedures to ensure safe transfer, handling and use of the new germplasm. To facilitate harmony in the management and trade of planting materials in Southern African, the region developed and implemented the 'SADC Harmonized Seed Regulatory System'. The SADC harmonized seed system is silent on transboundary movement of LMOs. The ability to detect, trace and monitor the use of GMO technologies is vital for regulatory and surveillance purposes in both the environment and the markets. National regulatory systems should take into account the cross cutting nature of modern biotechnology, navigating the complex and interconnected issues of scientific, economic, social and environmental significance. Thus, regulatory and scientific institutions need adequate capacitation with human and infrastructural resources that are relevant to making informed decisions on pertinent biotechnological and biosafety issues. Parties to the protocol must strive to ensure the safe use, handling and transportation of LMOs, to contribute to sustainable use of biodiversity and protection of the integrity of genetic resources.

18. The policy instruments of the countries in the region are guided by their obligations to the Cartagena Protocol on Biosafety, which emphasizes safe handling, transfer, and use of LMOs and the importance of science-based tools in decision making. The establishment of centers of biodiversity arose from the need to promote informed engagement with policies and decision making; and advocacy and information sharing, using scientific evidence to administer judicial and procedural fairness with regard to rulings on agro-ecological activities involving LMOs. There is need therefore to facilitate informed biosafety decision making for safe and sustainable use and management of LMOs to arrest potential impact on the environment and food security. The key problem faced is the inadequate capacity and resources of national systems to assist in developing tools to help in the safe handling, transport and use of LMOs.

19. Through the planned project interventions, parties in the region will have additional supportive measures in the implementation of their international obligations as per Articles 16 (Risk Management), 17 (Unintentional transboundary movements and emergency measures) and 18 (Handling, Transport, Packaging and Identification) of the

protocol, ensuring that each can be detected and managed within the region in line with the Decisions BS V/9, BS V/16 and BS V1/3 http://bch.cbd.int/onlineconferences/portal_detection/lab_network.shtml). It will also build confidence in parties in the region in terms of potential releases and capacities to manage accidental or unapproved releases.

20. Capacity to carry out LMO detection will therefore play an important role in: i) ensuring traceability and segregation; ii) compliance with National Regulations in terms of LMO labelling as highlighted in Table 3; iii) compliance with International Regulations for Trade; iv) compliance with legislation on the handling, transport, packaging and identification of LMOs; v) compliance with International Agreements including the CPB; and vi) monitoring.

21. Capacity building takes up the largest proportion of this intended project. Therefore in the training of regulators and technical staff in LMO related issues, the project will mainstream gender by ensuring balanced gender representation within each training workshops and in other project activities.

2.3. Threats, Root Causes and Barrier Analysis

22. Threats, root causes and barriers to the implementation of the countries' international obligations have been analyzed through broad-based consultations with stakeholders, and meetings with participating countries' line agencies, national custodians of the biosafety laws (the national biosafety authorities and councils), and scientific institutions that are supposed to be informing decision making systems. The findings of these consultations were further validated through a regional workshop with representatives from the biosafety focal points, the participating laboratories (from Angola, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, and Mozambique) and the Technical Experts of the Southern Africa Network of LMO Detection Laboratories (SANGL), who later were part of the team that developed the full project proposal.

23. To provide a suitable framework for the implementation of the biosafety measures, Article 16 of the CPB stipulates that parties must establish appropriate domestic mechanisms to regulate, manage and control risks associated with LMOs. Thus the status of NBFs, biosafety related policies and interim arrangements for managing safe transfer, handling and use of LMOs were assessed during the project preparatory phase. Furthermore, the project evaluated existing LMO identification capacities in the participating laboratories.

24. The threats, barriers and root causes to effective implementation of the CPB in participating countries include;

- policy impediments - the absence of/or the inadequacy of legal and policy frameworks,
- limited institutional capacity and poor coordination including; inadequate technical support services for science-based regulations, limited capacities for LMO detection leading to inadequate support for decision makers, lack of certification and harmonized detection thresholds, and limited communication among the various stakeholders in-country and at regional level, who are mandated with the implementation of the CPB.
- Knowledge gaps - scarcity of relevant information relevant information on LMOs in the region. Available information may be scattered across various agencies and institutions and not readily accessible to decision makers, researchers and planners, thus impeding the full assessment of impact on the conservation of biodiversity and the quantification of threats to ecosystem functionality. The absence of comprehensive monitoring and surveillance

systems places serious limits to the effective implementation of safe transfer, handling, packaging and transboundary movement of LMOs as provided for under the CPB.

- Lack of awareness - there is limited knowledge on the importance of efficiently implementing the CPB at national level among the general public, planners, and policy makers and in some cases even those that are directly responsible for sustainable use and conservation of biological diversity. Policy makers are unaware of how safe handling and transboundary movement of LMOs can contribute to local economic development and help alleviate poverty in rural areas.
- Difficulty in mainstreaming biosafety into sectoral policies and plans - although most countries have mainstreamed biosafety into NBSAPs and other related national and provisional policies and plans, this seems not be fully disseminated into line agencies and other stakeholders.
- Financial barriers – historically, governments seem have preferred to invest into basic infrastructures, education and health. Funding for environment and other related activities appear to be weak. Thus many governments have relied on donor funding for biodiversity conservation programmes. Many have prioritized sustainable land management and other biodiversity conservation interventions over biosafety and related biological safeguards requirements.

25. Even with the above barriers and causes, identified as a key problem faced is the inadequate capacity and resources of national systems to enable countries to carry out LMO Detection for informed decision making, create awareness, prioritize biosafety, and develop and implement systems and tools for safe handling, transporting, packaging and identification of Living Modified Organisms (LMOs). This gap is confirmed by findings of the Food and Agriculture Organization (FAO). FAO, in its own consultation highlighted the need for supportive technical services to facilitate the implementation of the CPB. FAO further recommended that, due to costs involved in CPB implementation, supportive technical assistance be better handled as a shared regional or multi country service (see http://www.fao.org/food/food-safety-quality/a-z-index/biotechnology/LLP/en/).

26. There is need therefore, to establish a multi-country mechanism for sharing experiences, expertise and know-how, and to develop a platform for information sharing and networking amongst technical staff in LMOs detection laboratories. Such an intervention will create a platform for backstopping technical services support among the countries. In addition, capacitated individuals who are conversant with biotechnological and biosafety issues are needed to interface between scientific expertise and legislation for coherent implementation of biosafety frameworks. Many developing countries lack the resources and expertise to build their own competences in LMO detection. Consequently, pooling resources as a multi-country effort will help in brain sharing, economies of scale and learning from those ahead. The project intends to; (i) increase the capacities of relevant officers and technicians at national level in LMO related issues, (ii) expand laboratories' capability to perform testing, measurement and/or calibration activities, (iii) enhance their management systems, and (iv) build a resource pool to back the handling and monitoring of LMOs in support of the implementation of the Cartagena Protocol on Biosafety.

2.4. Institutional, sectoral and policy context

27. All the participating countries are contracting parties to the Cartagena Protocol on Biosafety (CPB); hence, they are obliged to implement its provisions through national law. All six countries have designated National Focal Points (NFPs) and at least one Competent National Authority (CNA), in line with the requirements of the CPB. A

summary of the status of their NBFs is further presented under the section on baseline and gaps (see Table 3 - Section 2.6).

28. The results of the project preparatory phase and review of the biosafety related policies and legislation in each of the participating countries provided an analysis of each participating country's national development goals, positioning of biodiversity and biodiversity conservation goals, priorities and targets. The assessment sought to highlight the strategic importance that biosafety issues are assuming in each country's National Biodiversity Strategy and Action Plan (NBSAP) and other development plans. As earlier indicated, the review confirmed that none of the participating countries except Malawi currently have a fully functional NBF. There are however, interim measures available in each country, which provide the basis for some decision making to be undertaken. All the six countries have biosafety elements in their NBSAPs. For a detailed analysis of the instruments used in the interim in countries see Table 1.

Table 1 National Biosafety Frameworks and interim arrangements for the implementation of the CPB in the six participating countries

Country	National Biodiversity Strategy and Action Plans (NBSAPs) – versions 1 and 2	Biosafety Environmental Framework and other legal basis for environmental protection
Angola	Angola's NBSAP – -Notes some gaps in the country's environmental regulatory framework - Raises the need to amend outdated laws and fill gaps in a range of areas including biodiversity and biosafety among others. -Identifies Research and information dissemination as one of its strategic objectives -Identifies lacuk of legislation on biosafety and Genetically Modified Organisms (GMOs) as one of the main challenges with respect to sustainable use of biological diversity in the country[2].	The legal basis for environmental protection in Angola is provided by the Republic's Constitution. **Article 12 of the Constitution** states that all the country's natural resources are owned by the state and that the State shall promote the protection, conservation and exploitation of natural resources for the benefit of all the citizens. **Article 24** states that all citizens have a right to a healthy environment and places onus on the State to take requisite measures to protect the environment and the country's fauna and flora and generally maintain an ecological balance, further stipulates that acts that damage the environment are punishable by law. **The Environmental Framework Law No. 5/98 (EFL):** The EFL[3] lays down the principles for the protection, preservation and conservation of the environment, promotion of quality of life and the rational use of natural resources in line with the provisions of the Constitution. Specific Articles that may have a bearing on LMOs include: **Article 8** (Participation of Citizens), **Article 14** (Prohibits all activities that harm biodiversity), **Article 24** (provides for citizens' rights to appeal if their rights to an ecologically balanced environment have been compromised), **Article 27** (Environmental Impact Assessment legislation protection by liability insurance); **Article 28** (obliges repair damage and /or indemnify the State regardless of fault where damage to the environment has occurred). **Presidential Decree Nº. 194/11, of 7 July 2011 (Environmental Damage Regulations)[4]:** establishes the "polluter pays" principle as the cornerstone for managing damage to the environment. Provides for application of strict liability for environmental damage, is applicable with a very wide scope including provision of financial guarantees for remediation/compensation of environmental damage.

[2] Ministry of Urban Affairs and Environment (2006). National Biodiversity Strategy and Action Plan: 2007-2012. NBSAP. Project 00011125. Luanda, Angola.
[3] **The Environmental Framework Law No. 5/98. Downloaded from http://www.arc-angola.com/downloads/General%20Environmental%20law%20(GEL).pdf**
[4] http://faolex.fao.org/cgi-

	- The proposed project is aligned with **Action 2 of this strategic objective (Identify processes and activities that can have impact on biodiversity in Angola through research programmes and other environment management instruments).**	**Law of Aquatic Biological Resources (New Fisheries Law) – Law No. 6A/04[5]:** lays down the principles and objectives for the exploitation and conservation of aquatic biological resources and aquatic ecosystems. **Article 75** of this Law prohibits the introduction into the environment of Genetically Modified Organisms and exotic species into the aquatic environment without the authorization of the Minister. **Presidential Decree Nº 120/10:** prohibits importation into Angola of genetically modified or transgenic grain and seed of any variety except where it is destined for Food Aid, in which case it can only be imported under the authorization of the Minister of Agriculture and Rural Development. Other important pieces of legislation are: **Regulation on Soil, Flora and Fauna Protection [Decree no 40.040, Series 1 of 9 January 1955**]: **Decree no 92/04 of 14 December, 2004** which regulates the importation of transgenic/ genetically modified seeds or grain into Angola. **Dispatch no. 12/97 of 2 April** which establishes the fundamental conditions for obtaining licenses for the importation of seed. **Baseline Law on Agricultural Development (Law no. 15/05 of 7 December, 2005)** In the interim, Angola has opted to restrict movement of LMOs into the country whilst she attempts to put in place a regulatory framework.

[5] http://faolex.fao.org/cgi-bin/faolex.exe?rec_id=041362&database

DRC	NBSAP of the Democratic Republic of the Congo includes: - a specific objective on Biosafety, which states; "By 2018, the National Biosafety Framework is fully operational". - **The proposed project would thus contribute towards achievement of this objective by enhancing capacities and establishing an institutional framework for LMO testing to support all aspects of decision-making in the area of biosafety.**	The legal basis for environmental protection in DRC is provided by the Republic's Constitution **promulgated February 18, 2006 - Article 53 (**citizens' right to an environment that is healthy and conducive to full development). It places an onus on the State to defend it. **Paragraph 36m of Article 202 gives the central government the exclusive competence in the development of legislation concerning among others, artificial fertilization in humans, manipulation of genetic information, and transplant organs and human tissues.** The constitution thus provides the basis for legislation on the use of modern biotechnology. **Law No. 11/009 of 09 July 2011 (Basic Principles on the Environmental Protection)** provides for regulation of LMOs in **Section 5 of Chapter 6. Section 63 of the Act** stipulates that a specific Act must be taken to regulate the methods of assessment and management of biotechnology and the process of decision making on transboundary movements of GMOs. **Law No. 011-2002 of 29 August 2002 (the Forest Code)** has specific provisions relating to the protection of biodiversity and the natural habitat, forestry, forest research, processing and trade in forest products, safeguarding of protected forest species and conditions for introduction in the national territory of forest plant material, etc. **Article 34 of the Code for forestry research** includes in particular the management, inventory, conservation, exploitation, processing of forest genetics, forestry, wood technology and marketing of forest products. **Law No. 14/003 of 11 February 2014 on the Conservation of Nature** also contains provisions that may be capitalized as part of biosafety. These include provisions for environmental and social impact assessment. Through UNEP-GEF UNEP/GEF Project on the "Development of National Biosafety Framework"[6], **DRC drafted a Bill on Biosafety** which was submitted to parliament in 2007. The scope of the Bill covers all types of use of LMOs and products thereof, including production, dissemination, circulation, import, handling, storage, transportation and disposal. In particular, this legislation applies to the import, export, transit, contained use, dissemination or marketing of any genetically modified organism that is intended to be released into the environment or for use as a,

[6] Ministry of Environment, Nature Conservation, Waters & Forests (2007). National Biosafety Framework in the Democratic Republic of the Congo. Downloaded from http://www.unep.org/biosafety/files/CDNBFrepEN.pdf

		food, animal feed or processed product or whether a product is derived from genetically modified organisms. The Bill also provides for the institutional arrangements of the National Biosafety Framework **Other relevant legislation include:** **Law No. 73-009 of 5 January 1973:** sets specific rules on trade. **Article 13** of this law gives the right to the Minister of foreign trade in its attributions to limit or ban the export of a product when the supply needs of the country require. Likewise, the Minister is empowered to take restrictive measures, to prohibit the import, introduction and circulation in the DRC of products considered hazardous to health or affecting morality. In addition to the aforementioned 1973 law, trade import and export is governed especially by: • **The Inter-ministerial Order No. 016 / CAB / FIN / MENIPME / 96 of 20 June 1996** which lays down detailed rules for the import of wheat and wheat flour (and provides for these products compulsory subscription of a license to import); • **The Ministerial Decree No. 14 / CAB / MIN / Fin & Bud / 2000 of 25 October 2000** on import and export licenses and the license for import and export regulation.

Lesotho	Lesotho's first NBSAP - Plans for management of Biotechnology and its risks and identifies the following sub-actions - **Establishment and Strengthening of Biotechnology Management Institutions (**strengthening national capacity to reduce the risks associated with biotechnology, expansion of international information exchange and networks on LMOs and their products and setting up of a national tracking system for movement of LMOs). - **Strengthening the Management of Living**	The legal basis for environmental protection is derived from **Section 36 of the Constitution of Lesotho,** which states that "Lesotho shall adopt policies designed to protect and enhance the natural and cultural environment of Lesotho for the benefit of both present and future generations and shall endeavour to assure to all its citizens a sound and safe environment adequate for their health and well-being" [7][8] **Lesotho's National Vision 2020** whose mission statement clearly states among other issues [9] "*By 2020, Lesotho shall …… Its economy will be strong, its environment well managed and its* ***technology well-established.****"* **Draft Biotechnology Policy**'s main objective is to **guide the judicious use of LMOs** in Lesotho for sustainable development, in ways which do not in any way jeopardize human and environmental health including Lesotho's biodiversity and genetic resources, Other objectives include: effective control of trans-boundary movements of GMOs, development of human resource and institutional development for informed decision on applications, guiding in the establishment of administrative structures, creation of public awareness of biotechnology and biosafety, research and development, scientific risk assessment and precaution. **The Environment Act (2008):** The Environment Act provides for the protection and management of the environment as well as the sustainable use of Lesotho's natural resources and matters incidental thereto.10 Whilst it does not directly address modern biotechnology, it does address issues of conservation and sustainable use of biological diversity.

[7] Government of the Kingdom of Lesotho (1993). *The Constitution of Lesotho.* Government Printer, Maseru, Lesotho

[8] Southern African Institute for Environmental Impact Assessment (2012). Chapter 6: Lesotho. Downloaded from http://www.saiea.com/dbsa_handbook_update09/pdf/6Lesotho09.pdf

[9] Government of the Kingdom of Lesotho (2001). *Report of the First National Dialogue for the Development of a National Vision for Lesotho (Vision 2020).* Government Printer, Maseru, Lesotho.

[10] Government of Lesotho. The Environment Act 2008. Government Printers, Maseru.

	Modified Organisms and their Products (control of trans-boundary movement of LMOs, improvement of national capacity to monitor the effects of LMOs and, prevention of the illegal trafficking of LMOs by setting up information and alert system as well as monitoring and assessing the illegal movement of LMOs at the national level)	To ensure that the above Policy is turned into law, Lesotho is currently (2011-2015) participating in the UNEP/GEF project entitled 'support the Implementation of the Nation Biosafety Framework (NBF) Project of Lesotho'. The main purpose of this project is to help Lesotho to strengthen the existing institutional and technical infrastructure needed to meet the obligations of the Protocol and have in place a national biosafety system to guide decision making on biosafety issues. As a result, Lesotho managed to develop a Biosafety Bill 2014 which is in very advanced stages and maybe enacted by the Parliament very soon. The Bill provides for the institutional arrangements of the National Biosafety Framework including designation of National Focal Point (NFP), Competent National Authority (CNA) and National Biosafety Council (NBC). The NBC consists of 7 members nominated by the Minister responsible for Environment based on the expertise required; 2 members from the civil society organisations, and 5 ex-officio members, coming from 5 key Ministries which are: Ministry responsible for Environment, Ministry responsible for Agriculture and Food Security, Ministry responsible for Health, Ministry responsible for Trade and Industry and, Ministry responsible for Science and Technology
Madagascar	Madagascar's first NBSAP - -Objective 4 focuses on Risk Reduction (Biotechnology Development and Biosafety) with emphasis on- reduction to the risks to agro-biodiversity -identifies the following relevant actions to be achieved in the short-	**Biosafety National Policy and Structure in Madagascar [2004].** The Objective of the National Policy[11] is to address the issue of LMO in a rational, objective and secure way on the basis of well controlled information, a legal tool, and appropriate technical and scientific capacities, and according to a process of decision-making based on public participation. It lays down the Principles for Biosafety in Madagascar as: Precautionary Principle, Polluter Pays Principle, Participation Principle, Preventive and corrective action principle, and Intergenerational equity principle **Madagascar's Biosafety Act** aims to implement the rules and procedures of use, and safe handling of Genetically Modified Organisms. It provides for Risk Assessment methods and Risk

[11] Republic of Madagascar (2004). **Biosafety National Policy and Structure in Madagascar**

	medium term - the development of a National Biotechnology Policy, - minimization of the risks arising from the use of biotechnology and - enhancing knowledge on GMOs	Management for GMOs, institutional arrangements for their management as well as the procedures for the import, export, transit and marketing of GMOs. The Act regulates[12] the transboundary movement, transit, marketing, handling and use of any GMO and products that may have adverse effects on human health, animal and plant, biodiversity and the environment. **Decree No. 167 of 2004** on the Environmental Compliance of Investments (MECEI) establishes the rules and procedures for implementation of investments compatible with the environment and clarifies the responsibilities in this regard. **Article 3** requires all projects, whether private or public, that are likely to harm the environment, to be subjected to an Impact Assessment (IA) in the form of either full scale Environmental Impact Assessment (EIA) or Environmental Commitment Program (EERP) as outlined in Articles 5 and 6. Introduction of LMOs into the country, together with introduction of new species, is included in the schedule of activities for which EIA is required. **LOI n°2011-002 portant Code de la Santé[13]** (The Health Code) replaced its 1962 predecessor. Of particular importance with regards to LMOs, **Article 48** of the Code declares food products of plant origin derived from LMOs as dangerous for human consumption and thus prohibits sale of such food commodities throughout Madagascar territory. Violation of this provision is a criminal offence. **Decree No. 2012-833 on the powers of the organs of biosafety** in Madagascar sets out the institutional framework for management of biosafety in Madagascar.
Malawi	Malawi's first NBSAP devotes a whole theme to biotechnology. - Recognizes the potential	Malawi's **National Biotechnology and Biosafety Policy 2008** provides an enabling framework to promote and regulate the development, acquisition, and dissemination of relevant biotechnology to fulfil the needs of Malawi and provides a springboard for development in the agricultural, nutrition, health, environment, industry and trade sectors. It also provides a **biosafety regulatory**

[12] http://bch.cbd.int/database/record.shtml?documentid=30877

[13] Repoblikan'I Madagascar (). **LOI n°2011-002 portant Code de la Santé**

	of biotechnology in its broadest sense - The scope for the biotechnology theme centres on developing enabling mechanisms to enhance wise use of technologies whilst managing the potential adverse impacts[14]. The desired outcomes by 2020 under this theme include: • A definitive biotechnology policy governing the development and handling of biotechnology in Malawi is developed and implemented. • The Cartagena Protocol on Biosafety and the Biosafety Act of 2002 are	**framework** to ensure that new biotechnology products or services do not threaten the environment and human health or undermine ethics, human rights and international trade. **The Biosafety Act [Act No. 13 of 2002]** provides for the safe management of biotechnological activities and all matters connected with such activities. The Biosafety Act applies to: the genetic modification of organisms; importation, development, production, testing, release, use and application of genetically modified organisms; and, ease of gene therapy in animals, including human beings. The Biosafety Act also establishes the Biosafety Fund, prohibits carrying out of any of the activities within its cope without a GMO License, allows the Minister to issue a Permit for purposes of research as well as emergency supply of food, prohibits trade, supply and transboundary movement of LMOs and/or their products without a Product License, establishes mandatory labelling of LMOs and/or products thereof and provides for inspection to monitor compliance with its provisions. The **Biosafety (Management of Genetically Modified Organisms) Regulations 2007** provide for the implementation of the Biosafety Act.

[14] Ministry of Energy, Mines, and Natural Resources (2006). National Biodiversity Strategy and Action Plan. Government of Malawi, Lilongwe.

	enforced fully for the creation of an enabling environment for the environmentally sound application of biotechnology. • Guidelines are available to guide public awareness programmes on biotechnology and its products and biosafety issues surrounding the technology. • Human and infrastructure capacity is developed in the field of biotechnology.	

Mozambique	**Mozambique's NBSAP in objective 2.8** focuses on mechanisms to regulate the handling, safe use and transfer of GMOs. It also emphasises on institutional capacity building including development of a laboratory to support handling, identification and risk assessment of GMOs.[15] Specific priorities on policy, regulatory and institutional capacity building are captured and prioritised in the NBSAP	**Mozambique's Constitution** makes provision for issues of environmental protection through a number of clauses. **Article 81** provides the citizens with rights to prevent, cessation or prosecute for offenses against public health, consumer rights, the preserving the environment and the cultural heritage. **Article 90 entitles** citizens to a balanced environment and a duty to defend it. **Article 117** places an obligation on the State to promote conservation and preservation of the environment[16]. Mozambique - considers development and access to adequate novel technology for food and agricultural production of crucial importance. **The Environment Law (Lei do Ambiente), No. 20/97 of 1 October 1997,** is the basis for Mozambique's legal framework for the preservation of the environment[17]. The Environment Law seeks to define the legal basis for judicious utilisation and management of the environment and its components, with a view to achieving sustainable development in the country. **Article 12** of the Environmental Law[18] provides for protection of biological diversity. **Clause 1 of this Article** prohibits all activities that threaten conservation, reproduction, quality and quantity of biological resources. The Law also provides for a range of citizens' rights including the right to information, the right to education and the right of access to justice. **The Draft NBF was published in 2005** and further refined through a public consultation process leading to the development of a consolidated document which was the basis of **Decree no. 6/2007 being the Biosafety Regulations.** The Decree aims at establishing regulation of LMOs activities in Mozambique with intention to contribute to adequate protection of the environment, biological diversity, and human health, thus

[15] See NBSAP for Mozambique (https://www.cbd.int/doc/world/mz/mz-nbsap-v2-en.pdf). The NBSAP has been revised and is in final stages covering the period 2015 – 2035 and has focused actions on management of GMOs

[16] Republic of Mozambique, 2000. Programa do Governo para 2000–2004. Government Bulletin No. 12. Maputo:

Government of Mozambique.

[17] SADC **Environmental Legislation** Handbook 2012. Chapter 10: Mozambique. Available on

[18] Republic of Mozambique (1997). Environment Law: **LAW Nº / 97 of July 30.**

		setting the framework for an enabling environment for safe and responsible application of LMOs in Mozambique[19]. Under current arrangements, imports of GM crops intended for use as Food, Feed and for Processing (FFPs) are allowed under authorization of the National Biosafety Authority, dependent on a risk assessment and risk management plan for human health and the environment. GM food aid consignments are also allowed where no alternative solutions can be sought, but there is a requirement that these are processed prior to distribution. Mozambique's CAN, the Ministry of Science & Technology, is in the process of revising the Regulations to take into account the needs of the country; among them to review the liability and redress clauses.

[19] Esterhuizen D. & Zacarias A. (2013). Agricultural Biotechnology in Mozambique. USDA Foreign Agricultural Service. Global Agricultural Information Network Report.

2.5 Stakeholder mapping and analysis

29. The multilevel and multi-actor nature of biosafety entails targeting a broad range of actors for any intervention. Building on the experiences from the SANGL, RAEIN-Africa's activities are designed to accrue benefits to the marginalized communities whose livelihoods depend on the productive and sustainable interaction between technologies and the environment. Considering that African women play a major role in the conservation and use of biodiversity in national activities, the project will ensure that where stakeholders are involved, gender representation will be taken into consideration. Where possible on resource use and capacity development, gender-segregated data will be collected. In the identification of training participants, efforts will be made to ensure balanced representation of women and men.

30. The direct beneficiaries of this project are the biosafety decision makers, implementers of the biosafety systems and, the selected referral laboratories in the participating countries. These stakeholders' mandates are relevant to LMO detection and decision making. Implementation of the programme will also benefit decision makers in national, regional and international bodies working on biosafety and allied issues. In addition to strengthening and consolidating capacities in the implementation of the CPB, this project will also increase the visibility and prioritization of enacting and implementing NBFs at various decision-making platforms and, enable safe transboundary movement of LMOs.

31. The proposed project will be stakeholder-centered and shall be guided by the following principles:

- Activities to be needs based and incremental in nature, thus strengthening LMO detection through enhancement of identified gaps in the participating laboratories, inform the missing link in biosafety decision making systems at national, regional and international levels and have an incremental value on the current situation on biodiversity conservation and use at all levels,
- Implementation of the project activities to be multi-stakeholder in nature, involving the relevant stakeholder representation in both the prioritization and implementation of the interventions and,
- Project planning and implementation to be transparent, participatory, innovative, and strive to establish sustainability measures in the continued relevant use of the developed capacity both at laboratory level and national decision making levels.

32. Specific National level key stakeholders involved in the biosafety regulatory chain at national levels, as identified by the PPG, are presented in section on stakeholder participation as Tables 7 & 8. Further analysis of these stakeholders will be done during the project execution phase, the stakeholder roles will be reviewed, new roles will assigned and potential partnerships will be agreed to support the process

2.6 Baseline analysis and gaps

33. Assessing the environmental impacts of Living Modified Organisms as a result of transboundary movements and the introduction of new species is a major challenge in addressing the needs of growing population whilst ensuring no adverse effects on the conservation and sustainable use of biodiversity. Different countries have different policy instruments whose objectives are guided by their obligations to the Cartagena Protocol on Biosafety, national priorities and resources for implementation of the policy. The CPB focuses on the safe transfer, handling and use of LMOs and the importance of science based tools in decision making. For its implementation therefore, there are prerequisite legal, human and infrastructural capacities required. The national priorities also influence the

focus of the national frameworks. Some countries' policies take advantage of the potential benefits thus encouraging the development of new species including LMOs. On the other hand, other countries focus on developing precautionary mechanisms based on perception of potential risks to the environment.

34. It is vital that the proposed project responds to needs and increases chances of informing decision making processes. Furthermore, establishing the role that LMO detection capacities will impact on the development of science based regulations to meet the CPB, contribute to the environmental review of LMOs and empower countries to continue to actively participate in global and regional systems of trade, ensuring that their own needs are met, requires an understanding of the current baseline of the detection capacities and their impacts thus far.

35. The project preparatory phase was aimed at providing a deeper understanding of the root causes of the inefficient implementation of CPB, including assessment of available capacities for supporting the development and implementation of science based regulations to meet the CPB obligations. The stocktaking and needs assessment was carried out using a double pronged approach. This included i) a status assessment, which was done using a survey complemented by on-site physical assessment of the current functionality and capacity needs of the designated LMO detection referral laboratories and, ii) review of the biosafety regulatory environment in the six countries that are participating was based on relevant literature and other sources of information and validation through a national consultative process and a regional workshop carried out by the RAEIN-Africa in all the six participating countries.

2.6.1 Review of the regulatory environment for the implementation of the CPB

36. Based on Second National Reports submitted to the Secretariat of the Convention on Biological Diversity (SCBD)[20] in 2011 and as validated by the project preparatory phase, the status of development of National Biosafety Frameworks in the participating countries are as illustrated in Table 2 below. Only Madagascar and Malawi have received applications and/or notifications regarding intentional Transboundary Movement (TBM) of LMOs for intentional introduction into the environment. These two countries also report that they have made a decision on the application /notification. Malawi has approved confined trials of GM Cotton and is preparing to go into multi-location trials. She has also recently received an application for confined trials of insect tolerant cowpea. Mozambique is currently participating in the Water Efficient Maize for Africa (WEMA[21]) Project and is carrying out mock-trials. As shown under subsequent sections of the participating countries, only Lesotho has established mechanisms for monitoring potential effects of LMOs that are released into the environment.

Table 2: Status of development of National Biosafety Frameworks in the six participating countries

Status of Biosafety	Countries
Only interim measures in place	Angola
Domestic regulatory framework partially in place	DRC, Lesotho Madagascar and Mozambique

[20] http://bch.cbd.int/database/reports/

[21] Esterhuizen D. & Zacarias A. (2013). Agricultural Biotechnology in Mozambique. GAIN Report. USDA, Pretoria.

Domestic regulatory framework fully in place	Malawi

In addition to review of the regulatory environment for the management of LMOs, the country situation in relation to identification of LMOs was assessed to ascertain the existing legal provisions on labelling. The current scenario is captured as Table 3 below

Table 3: Countries Provision for Labelling of LMOs/Products

COUNTRY	STATEMENT	SOURCE
LABELLING		
Angola	Decree No. 92/04 of December 2014, limits the use of biotechnology products to food aid usage, and restricts any production of genetically engineered (GE) products in Angola. This Decree, serving as a provisional measure until the establishment of a comprehensive National Biosafety System, does not stipulate compulsory labelling requirements.	http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Pretoria_Angola_7-22-2015.pdf
Democratic [22]Republic of Congo	Article 7 of the Ordinance number 41-361 of October 27, 1953 governs products and substances intended as animal feed. Article 7 requires that any composite substance intended for the animal feed, offered on sale, held for sale, transported, sold or delivered have to be provided with a label mentioning: 1) the name or legal status of the manufacturer; 2) minimum guaranteed proportion, expressing the percentages of the essential nutritive elements (digestible rough albumin, grease, sugar, starch) contained in the mixture, with specification, with regard to the proteins, of the percentage in which the proteins of animal origin intervene; 3) maximum content of moisture, total mineral matters, crude fibre; 4) the date of manufacturing; 5) the destination (use) of food; 6) possibly: the presence of smut; 7) The nature and the content of the products sodium chloride, carbonate calcium, phosphate, charcoal, sulfur, when the content exceeds 2% for one of these products. However, the content for the whole of these products cannot exceed 6%;	National Biosafety Framework in Democratic Republic of Congo - Final draft. See http://www.unep.org/biosafety/files/CDNBFrepEN.pdf

[22] The DRC has a draft national legislation for fulfilling the whole of the implementation requirements of the Cartagena Protocol with regard especially to:
• advance informed agreement procedure;
• transboundary movements of GMOs/LMOs (import, export and transit);
• handling, transfer, packing and identification (labelling) of GMOs/LMOs in accordance with the requirements of the Protocol;
• documentation accompanying GMOs/LMOs fulfilling the requirements of the Protocol;
• risk assessment and management procedures related to the use of GMOs/LMOs)

	8) the nature and content of other trace elements not mentioned above	
Lesotho	Adequate policy framework should at least have elements specified below. • Objectives: encompassing national needs and priorities, customs and aspirations, ethics, capacity, economic needs, international obligations, transboundary movements, liability and redress, public involvement • Scope: describing the activities and organisms covered • Responsible Ministry or Ministries for implementation and a specified government department or agency • Advisory Bodies to advise on technical aspect of technical decisions • General prohibition on activities involving LMOs unless authorization/license or other approval has been obtained • System of permits or authorizations for activities involving LMOs • Exemptions or simplified procedure for fast tracking processes for low-risk LMOs • Public information and consultation system on permit applications and policy issues • Protection of confidential commercial information • Risk assessment procedure and risk assessment criteria • Risk management conditions (e.g. labelling and markir requirements) • Monitoring and inspection • Liability for damage	Draft National Biosafety Framework for Lesotho. See http://www.unep.org/biosafety/files/LSNBFrep.pdf
Madagascar	To ensure a free choice of the consumer and to contribute to facilitate the expression of the public concerning the GMO products, marketing, labelling must be systematic. The labels will relate to the presence of GMO or not, the GMO percentage in the considered product if necessary, and the co-ordinates of the structures to be contacted in case additional information are necessary. **Article 16:** Any GMO and/or derivatives intended for marketing must be identified by affixing the label of the producer and/or shipper and with the mention "GMO Products", and the identification must specifically mention its particular features and characteristics with sufficient details to ensure its traceability, and in order to indicate if it can possibly involve risks or reactions of the allergic types. In addition, this labelling must comply with the standards defined by the NCA with the collaboration of the other administrations concerned.	Republic of Madagascar (2004). National Policy And Framework on Biosafety in Madagascar. See **http://www.unep.org/biosafety/files/MGNBFrep.pdf**

Malawi	Section 41 (1) No person shall, in the course of a business carried on by him, sell or supply or have in his possession for the purpose of selling or supplying GMOs or products thereof in a container or package which is not labelled in accordance with regulations made under section 41. (2) Without prejudice to subsection (1), no person shall, in the course of a business carried on by him, sell or supply, genetically modified organisms or products thereof of any description in a container or package which is labelled or marked in such a way that the container or package- (a) falsely describes the genetically modified organisms or product; or (b) is likely to be misleading as to the nature, efficacy or quality of genetically modified organism or product or as to the uses or effects of genetically modified organisms or product of that description. (3) Any person who contravenes this section shall be guilty of an offence.	http://bch.cbd.int/database/attachment/?id=13824
Mozambique	**Article 15** (Labelling) 1. All the packages and/or containers containing GMOs and their products shall have a label or an informative booklet in accordance with the valid national or international rules regarding labelling, and in clear visible letters stating **"CONTAINS GENETICALLY MODIFIED ORGANISMS."** 2. With the exception of GMOs and their products in transit through the national territory destined to countries in the Region, all other items destined for food, feed, processing, research, deliberate release to environment must present the information contained in the labels written in the Portuguese language and easily legible.	Grupo Inter-Institucional Sobre Bio-Segurança (GIIBS), 2005. Draft National Biosafety Framework of Mozambique. Ministry Of Republic of Mozambique. See www.unep.org/**biosafety**/files/MZNBFrep.pdf

2.6.2. Assessment of the Current Functionality and Capacity Needs of the LMO Detection Laboratories in the Six Participating Countries

37. The human, institutional and infrastructural capacity gaps/ needs, for GMO detection laboratories in the six participating countries (Angola, Democratic Republic of Congo, Lesotho, Madagascar, Malawi and Mozambique), were assessed. A detailed assessment report is attached as Appendix 19. The regional review provided the strategic context for the proposed project and highlighted the achievements of RAEIN-Africa through the Southern Africa Network of GMO Detection Laboratories (SANGL). The significant progress in building institutional capacities and regulatory frameworks in some Southern African countries, through SANGL was recognised. However, it is accepted that in general, laboratories in the region are still at different levels in terms of capability, infrastructure and expertise on LMO detection. Against this background, RAEIN-Africa

and its partners took stock of the functionality of designated LMO detection laboratories in order to identify evident capacity building requirements. The assessment established the current functional status of laboratories; conducted a human, institutional and infrastructural audit and identified gaps; provided feedback to stakeholders on the results of the capacity assessment, and developed a plan that consolidates and creates synergies between the national laboratories in each participating country to maximise on resource use efficiency.

38. The assessment of the laboratories in the six countries started with a functionality and Capacity Needs Assessment Questionnaire which was developed and used across all laboratories visited, addressing the following; laboratory facilities, laboratory organisation and management, equipment, personnel, reagents and consumables, laboratory quality control and management (SOPs, Quality manuals, validated methods), capacity challenges/ gaps and capacity needs and priorities (human, equipment, infrastructure). Physical inspection of facilities complimented by interviews of key informants was carried out to establish the status quo and the GMO testing operational challenges.

39. Analysis of the data collected was done using the earlier developed SANGL Key on rating the GM Detection Capacity of the various laboratories (see key to Table 3). The assessment is based on the status of the physical structures, the equipment, the quality management systems (QMS), the human capacity and the laboratory capabilities at the time of assessment. Table 4 below shows the results of the status of laboratories' capacity in LMO Detection.

Table 4 [23]: Status of Designated Laboratories Participating In the Multi-Country LMO Detection Project

Angola, *Central Laboratory of Angola*					
Lab Facilities	**Personnel**	**Reagents**	**QMS**	**Gaps/Challenges**	**Recommendations**
A new building with a PCR room available. However, building does not appear to be purpose built and lacks uni-directional flow of work design.	2 MSc. Personnel did not have GMO specific testing qualifications. No organizational structure or organogram posted	No GMO related reagents and consumables observed.	QMS system for food testing methods being set up but no system for GMO specific methods.	The laboratory model does not fulfil PCR accommodation requirements despite having a PCR anteroom. The staff available lack GMO testing training. The equipment available is not adequate to enable PCR level GMO testing to begin. No accredited metrologist to calibrate equipment.	• Available personnel require GMO competency training. An additional science college graduate may be recruited. • Space adjustment changes are required to accommodate areas as specified in Annex 2. The available space will work best if laminar flows are incorporated in the PCR room to isolate pre and post PCR events as well as creation of extra space for a unidirectional flow of work. Infrastructure and equipment to augment existing: • Two conventional PCR thermal cyclers, • One Fluorimeter/Nanodrop/Biodrop/Spectrophotometer, • One microwave, • One water bath, • One micro centrifuge, • One vortex mixer and • Micropipettes Other areas to address at lab and national level include: • Establishing a reliable reagent supply chain with accelerated clearing at ports of entry • Establishing an accredited metrology service for reliable equipment maintenance and calibration • Validation of GMO detection methods • Constant reliable source of reference material • Implementation of QMS requirements
Democratic Republic of Congo, *General Atomic Energy Commission / Regional Centre for Nuclear Studies Kinshasa (CGEA / CREN-K.); Biotechnology & Molecular Genetics Department*					
Lab	**Personnel**	**Reagents**	**QMS**	**Gaps/Challenges**	**Recommendations**

[23] A review of these recommendations from the gaps analysis was done by the stakeholders at the validation workshop and with justification , some laboratories planned on practically possible solutions to identified gaps including identification of space for repartitioning into a n acceptable laboratory standard,

Facilities					
Facilities are well-demarcated into the PCR recommended areas as in Annex 2 and possibly require minor upgrade to be fully compliant.	2 x PhD 3 x MSc but all require training in GMO aspects and methodologies. Organizational structure and organogram could not be verified.	The laboratory currently not involved in GMO detection and, therefore, no reagents and consumables were available.	No system in place.	Equipment inadequate. Personnel have a GMO testing methods skills and knowledge gap. Equipment maintenance service and calibration system is not available. QMS required documentation is not available.	Available personnel require GMO competency skills upgrade and certification. This can be done at a GMO competent facility. **Equipment and infrastructure:** Basic equipment to commence GMO testing currently available, with minimum reinforcement required. However aligning the available resources with outline in Annexe 2 is necessary. The following items standout as required , • Two conventional thermal cyclers • Flourimeter/Nanodrop/ Biodrop/spectrophotometer • Two pH meters **Institutional/Funding/Other:** • Establishment of a reliable equipment maintenance, servicing and calibration system • Support in developing and implementing laboratory a QMS as prerequisites for accreditation. • Participation in proficiency schemes • Availability of reference materials
Lesotho National University: Molecular Biology Laboratory					
Lab Facilities	**Personnel**	**Reagents**	**QMS**	**Gaps/Challenges**	**Recommendations**
Extensive upgrade of facility is required to accommodate GMO PCR level testing area and isolation as specified in Annex 2.	3 x PhD (molecular biology, microbiology, genetics), 2 x laboratory technicians but no GM specific training. One of the PhD holders has worked extensively	GMO specific reagents and consumables were not in place.	No system in place.	Lesotho laboratory requires extensive support from infrastructure, equipment installation and human resource training.	The rest of the personnel require competency training in GMO testing methodologies. **Infrastructure and equipment**: • A physical structure is required. Only two thermal cyclers and a gel electrophoresis system were seen. The rest of equipment as indicated under Annex 2 was still being purchased. • Equipment maintenance and service system would need to be established.

	with SANGL and therefore deemed competent in GM detection methodologies. No organizational structure or organogram posted				
Madagascar, *Molecular Biology Laboratory, Department of Plant Biology and Ecology, Faculty of Science, University of Antananarivo*					
Lab Facilities	**Personnel**	**Reagents**	**QMS**	**Gaps/Challenges**	**Recommendations**
At time of assessment, laboratory was undergoing major renovations	4 x PhD graduates (1 geneticist, 1 plant breeder, 1 biologist and 1 ecologist). 2 x laboratory technicians with undergraduate degrees in microbiology and molecular biology One with GMO specific training received at EU-JRC lab, Italy. No organizational structure or organogram	No GM reagents and consumables	No system in place	Due to ongoing renovations, these could not be established.	Available personnel require GMO competency training. The EU-JRC trained member could coordinate in-house training once facility is well established with required equipment. **Infrastructure and equipment:** As space becomes available on completion of renovations, a clear demarcation of the molecular biology areas is required as specified in Annex 2. The donated equipment may have outlived its lifespan and can serve as backup equipment while the following require purchasing, • One Freezer (-20^{o}C & -80^{0}C), • Two pH meters, • One refrigerator , • One digital scale from 0,1 g to 2000 g; • One analytical digital scale to 5 decimals, max, 60 g, d=0,1 mg; • Deionized water supply • Fluorimeter/Nanodrop/Biodrop/Spectrophotometer • A single gel documentation system • Two additional gel tanks • At national and lab levels the following:

	posted				• An accredited metrology service for reliable equipment maintenance and calibration • Validation of GMO detection methods • Constant reliable source of reference material • Implementation of QMS requirements
Madagascar, Environmental Laboratory of Microbiology					
Lab Facilities	**Personnel**	**Reagents**	**QMS**	**Gaps/Challenges**	**Recommendations**
Adequate space is available and only minimal adjustments will be required.	1 x PhD (molecular biology), 1 x MSc 3 x laboratory technicians with undergraduate degrees But no GM specific training. No organizational structure or organogram posted	GMO specific reagents and consumables were not in place.	No system in place yet. However, laboratory participated in the SANGL proficiency testing in 2012. Currently participating in SADCMET proficiency testing in microbiology.	Accommodation requirements setup was not clear due to renovations taking place. Centrifuge was out of order. Equipment challenges, a skills gap and QMS void exists.	Despite having requisite academic qualifications the available personnel will require GMO specific methodologies training at a GMO competent facility. **Infrastructure and equipment:** Basic molecular work equipment is available but requires reinforcing with the following: • One Flourimeter/Nanodrop/Spectrophotometer/Bio drop • One Freezer (-20^{0}C/80^{0}C) • One centrifuge, 15000-rpm capacity • Two Gel electrophoresis tanks and a power pack • **Institutional /Funding/Other:** • Additional funding will be required to cover the following activities; • QMS cost and implementation • Establishing equipment maintenance and service system
Malawi, *Chitedze Agricultural Research Institute*					
Lab Facilities	**Personnel**	**Reagents**	**QMS**	**Gaps/Challenges**	**Recommendations**

Standard laboratory building in place. Laboratory space is deficient with available space already crowded. PCR specific isolation of activities not possible	1 PhD, 1 MSc, 2 BSc and a certified technician. Only one person with GMO testing specific training. No organizational structure or organogram posted	Indication of primers being available but not verified. No GMO related reagents and consumables observed.	No system in place, only adopted methods from journals for cassava viral diagnosis.	Laboratory space is deficient. Staffing is inadequate. Competency in GMO detection methodologies lacking. Available equipment for basic PCR is operating at almost maximum capacity for cassava viral diagnosis. Water supply into the lab has no pressure. No guaranteed uninterrupted power supply. No accredited metrologist to calibrate equipment.	Recruitment and training of at least one key person dedicated to GMO testing alone key. • Creation of space to accommodate separation of areas into distinct spaces as outlined in Annex 2. • One additional conventional PCR thermal cycler, • One reagent and sample storage cabinet/space, • Complete set of consumables , • One freezer (-20/-80), • One grinder, • One micro centrifuge, • One complete set gel tanks • One four point power pack • One Fluorimeter/ Nanodrop/ spectrophotometer/ biodrop. • Increased water pressure. • Training for ABI step one real-time.
Malawi, *Bunda (Lilongwe University of Agriculture and Natural Resources)*					
Three laboratory structures; tissue culture, plant pathology and plant biology laboratories. Facilities totally inadequate.	1 BSc in Microbiology but no GMO specific training. No organizational structure or organogram posted	No GM or molecular reagents except for tissue culture work.	No system in place	Laboratory completely lacks the minimum requirements for GMO testing.	Capacitation of this laboratory to any level of testing would need the minimum requirements. These include: • erection of a new lab altogether as upgrade of existing facility is not practical[24] • equipment acquisition, • reagents and consumables acquisition system, • QMS implementation • GMO specific methodologies training of personnel. At a minimum the laboratory can be capacitated for strip/ELISA based GMO testing
Mozambique, *Molecular Toxicology and Environment Biotechnology Centre-Eduardo Mondlane University (EMU)*					
Lab Facilities	**Personnel**	**Reagents**	**QMS**	**Gaps/Challenges**	**Recommendations**
A new	1 x MSc with	GMO testing	No system	No major challenges	The rest of the staff will require training and certification in

[24] Malawian team proposed partitioning of an existing laboratory space and establishment of a workflow that meets the minimum requirements

laboratory was under construction and was claimed to be tailor-made for regulatory, commercial and research GMO work	GM training done at the JRC in Italy and through SANGL. 1 x PhD, 2 x MSc with no GM training No organizational structure or organogram posted	is already being carried out. However, because the laboratory was moving premises, it was not possible to verify the actual reagents and consumables on hand.	in place yet. However, laboratory participated in the SANGL proficiency testing in 2012 QMS documents were being drafted with accreditation being the main aim.	cited except lack of a reliable equipment backup system in case of breakdowns.	GMO testing at a competent facility. **Infrastructure and equipment:** Renovations were in progress and therefore layout could not be clearly established. However, Annex 2 layout is recommended. Basic equipment is available and required are, • One thermo block/incubator shaker • One Grinder • Two pH meters • Flourimeter/Nanodrop/Biodrop/Spectrophotometer • An additional complete gel electrophoresis system Also of importance are the following activities; • QMS implementation and scaling up to an international accreditation system • Establishing equipment maintenance and service system
Mozambique Research Institute Biotechnology Laboratory (MRIBL)					
Available space not clearly demarcated; however, existing space could be partitioned to requirements of PCR level GMO testing (Annex 2). No suitable storage facilities identified.	1 x MSc 1 x BSc 1 x laboratory technical training. However, none of the staff had training specifically on GMO testing.	No GMO testing taking place, therefore no reagents and consumables.	No system in place	The laboratory would require upgrading to PCR level for GMO testing (Annex 2). GMO testing specific equipment also required.	Capacitation of this laboratory to any level of testing would need the minimum requirements as listed in Annexes 2 and 3. These include: • Portioning of existing facility • Equipment acquisition, • Reagents and consumables acquisition system, • QMS implementation • GMO specific methodologies training of personnel. At a minimum the laboratory can be capacitated for strip/ELISA. The lab would require training/ mentoring by accredited laboratories in • SOP writing and documentation , • method validation, • QMS implementation & accreditation requirements setup.

40. Based on the assessments, the laboratories were rated on status of infrastructure guided by an assessment key on LMO Detection laboratories and the results summarized as Table 5 below

Table 5: The ratings of GM detection capacities of the project participating laboratories[25].

Country /Laboratory	**Rating**					
Angola, Central laboratory of Angola (CLA)	L4	F2	E1	Q4	P4	C1-C2
Democratic Republic Congo General Atomic Energy Commission / Regional Centre for Nuclear Studies Kinshasa (CGEA / CREN-K)	L2	F1	E2	Q4	P4	C2
DRC Veterinary Laboratory of Kinshasa (VLK)	L1	F1	E1	Q4	P4	C1-C2
Malawi Chitedze Agricultural Research Institute (CARI)	L4	F2	E1	Q4	P3	C1-C2
Malawi Lilongwe University of Agriculture and Natural Resources (Bunda)	L4	F4	E4	Q4	P4	C4
Madagascar Molecular Biology Laboratory- University of Antananarivo (MBL)	L4	F2	E2	Q4	P1	C2
Madagascar Environmental Laboratory of Microbiology (ELM)	L4	F1	E2	Q4	P4	C2
Mozambique Biotechnology Centre of Eduardo Mondlane University (CB-UEM)	L2	F2	E1	Q4	P1	C1-C2
Mozambique, Biotechnology Laboratory of the Institute of Agricultural Research (MRBLI)	L4	F2	E2	Q4	P4	C4
Lesotho National University of Lesotho (NUL).	L4	F2	E2	Q4	P1	C2
Lesotho - Seed Testing Laboratory[26], Ministry of Agriculture and Food Security, Department of Agricultural Research,	*L4*	*F2*	*E4*	*Q4*	*P2*	*C0*

[25] Use the Key in below

[26] The Lesotho seed testing laboratory was assessed based on submitted reports to the Ministry of Environment in Lesotho.

Key for GM Detection Capacity in Assessed Laboratories

	Level (L)	Functional Physical Structure (F)	Equipment (E)	QMS (Q)	Personnel (P)	Current Capability (C)
1	GMO Conventional PCR and Real-Time PCR testing	Available	PCR and Real-Time system	Quality manual, Safety manual, SOPs	Trained in GMO screening and quantitation	Real-time PCR
2	GMO Conventional PCR testing	Under construction	PCR system only	GMO with validated methods	Trained in qualitative PCR GMO	PCR
3	Strip/ELISA GMO testing	Requires remodelling (division/ laminar airflow)	Strip/ELISA	Methods not validated	Trained in strip/ELISA	ELISA
4	Unable to carry out GMO testing	Space /structure unavailable	No specialised equipment	No methods available	No training received	Strip

41. Whilst 3 of the 11 assessed laboratories have some capacity to carry out GMO; testing i.e. can perform PCR based LMO screening, none of the laboratories examined meets the highest acceptable standards of Level 1; i.e. able to perform Polymerase Chain Reaction (PCR) based LMO screening and Real-Time PCR LMO quantification, have quality management documents (SOPs, safety manuals, quality manuals) and have adequate levels of trained personnel. In all the laboratories, there was no quality management system (QMS) in place. All the laboratories visited were staffed with relevant academically qualified personnel. However, the laboratory staff, in the main, lacked competency in GMO detection, LMO laboratory management and will require training in modern GMO detection methodologies at a competent GMO testing facility.

42. Both the regional review of the biosafety regulatory environment and the stocktaking and needs assessment in the six countries confirmed inadequate human and infrastructural capacities for LMO detection as one of the key constraints to development of science based regulations and effective implementation of the CPB in the region. This was underscored by the importance of LMO detection in supporting international trade, monitoring and surveillance as well as compliance with national requirements. It was however noted that there were a number of limitations in the effective implementation of certain provisions in the Cartagena Protocol on Biosafety in the region that include; lack of harmonisation and standardisation of methods used in LMO testing laboratories as well as low capacity in LMO detection among designated staff. This status quo justifies the establishment of an intervention with the broad objective of building and strengthening institutional capacities for LMO detection in support of national decision making processes in biosafety regulatory systems in the participating countries.
43. Following the context setting/ background and guided by the results of the scoping exercise, the participating countries' unique national gaps and cross country national gaps were identified. The gaps identified were captured and summarised as Table 6 to guide the

design of country specific and cross cutting or potential regional activities in the intervention logic line with the project objective.

Table 6: Cross cutting and unique national gaps and needs in LMO Detection as validated by the stakeholders in the participating countries

Country	Human Capital gaps	Infrastructure and equipment	Other issues requiring attention
Angola	Capacity building of locals in LMO Detection, Quality management systems and, on mobilization of support for the regulatory system	- Laboratory is fairly equipped but requires supplementary equipment as guided by the assessment - Required technical advice on laboratory spatial orientation	- Need regulatory support for LMO Decision making, implementation arrangement and guidelines (NBF) - One laboratory identified for participation in project - Lack of communication channels between biosafety stakeholders
DRC	Insufficient managers trained on the detection of GMOs and laboratory management	- Need for equipment for sampling and PCR, - Need for nanodrop, centrifuges, Real-time PCR machine, Hotte PCR, - Need for reference materials, standards, and reagents, - Need for maintenance and calibration of equipment	- The absence of the regulatory framework on biotechnology and biosafety in the DRC - Lack of guidelines on quality management systems for LMO detection
Lesotho	Laboratory Personnel lack GM detection capacity Limited capacity laboratory Quality management systems Poor communication among biosafety regulatory chain stakeholders Insufficient capacity on sampling, packaging and documentation of products	- Laboratory not structurally appropriate, - Laboratory will receive some equipment from the UNEP-Biosafety project but still requires supplementary equipment from this intervention - Need for laboratory space and spatial orientation to improve work flow,	- Mandate for LMO Detection laboratory not yet in place - Absence of NBF - Lesotho highly depends on seeds and planting material from South Africa, a country were LMOs are commercialised and yet there is a lack of skills for an effective, informed Monitoring decision making process.
Madagascar	Insufficient capacity for LMO detection and laboratory management for both labs Insufficient capacity on sampling, packaging and documentation of products	- Elisa plate reader - Real time PCR - Ultra-freezer	- Two laboratories to be upgraded - No Biosafety regulations
Malawi	Insufficient capacity to	- Real time PCR	- Second laboratory to be

	undertake the LMO detection and laboratory management Insufficient capacity on sampling, packaging and documentation of products	- Elisa plate reader - Ultra-freezers	used for capacity building
Mozambique	- Limited training of personnel in: LMO detection, especially on real time PCR for laboratory personnel. - Needs for training on procedures for handling and disposal of laboratory wastes/ residues - Limited training on Laboratory management and Monitoring and Evaluation for Project manager.	- At IIAM there is a lack of separation of activities in the laboratory. - Laboratory currently used only for virus detection - Need for accreditation of the laboratory	- Limited communication between the National Authority and the Biosafety group (GIIBS), probably due to changes of the ministers - Limited communication between focal point and the laboratories - Need for established thresholds on LMO detection. - The Biosafety regulation is revised and approved. However, there is need for public awareness of the decree

44. The common regional gaps and needs as verified by the project preparatory phase were further summarised as presented below:

i. Lack of efficient implementation of National Biosafety Frameworks and interim measures in the participating countries

As stated in Article 16 of the CPB, all parties to the protocol are obliged to domesticate the CPB through a national framework that enables countries to regulate, manage and control potential risks associated with LMOs. Whilst only Malawi has a fully established regulatory framework consisting of a policy, a law and regulations, all six countries have legal instruments to use as interim measures in the absence of standalone biosafety laws. Implementation of these instruments is however lacking efficacy. Only Madagascar and Malawi have received and made decisions on applications or notifications regarding intentional Transboundary Movement (TBM) of LMOs for intentional introduction into the environment. These two countries also report that they do not have established mechanisms for monitoring potential effects of LMOs that are released into the environment. As interim arrangements exist in all the participating countries, through the NBSAPs and other related national laws, assessments of such applications would be more efficient with the existence of technical capacities to identify the LMOs thus supporting the development and implementation of science based regulations.

It is therefore noted that whilst the existence on NBFs would have allowed for the intervention to serve existing policy, legal, regulatory and administrative frameworks, developing the LMO information will enable the countries in the meantime, to implement their international obligations through interim arrangements whilst at the same time supporting the development of science based regulations to meet

the CPB obligations.

ii. Low capacity in LMO Detection among designated laboratories

All the participating countries have nominated laboratories to participate in this project and are working towards officially mandating them as referral laboratories for implementation of their national laws. The following nominated referral laboratories were assessed: in Angola - the Central laboratory of Angola (CLA); in DRC - General Atomic Energy Commission / Regional Centre for Nuclear Studies Kinshasa (CGEA / CREN-K) and the Veterinary Laboratory of Kinshasa (VLK); Lesotho - National University of Lesotho (NUL), Seed Testing Laboratory[27], Ministry of Agriculture and Food Security, Department of Agricultural Research, Lesotho; Madagascar - Molecular Biology Laboratory- University of Antananarivo (MBL) and the Environmental Laboratory of Microbiology (ELM); in Malawi - Chitedze Agricultural Research Institute and Lilongwe University of Agriculture and Natural Resources (Bunda); in Mozambique - Biotechnology Laboratory of the Institute of Agricultural Research in Mozambique and the Biotechnology Centre of Eduardo Mondlane University (CB-UEM); and in As established by the status assessment, none of the nominated laboratories is fully capacitated to carry out LMO detection and quantification.

The following capacity needs are common to all participating countries: limited trained personnel and supportive infrastructure for LMO detection, lack of guidelines for LMO quality management and, limited capacity for LMO detection laboratory management and for monitoring on handling, packaging and transportation of LMOs.

iii. Inadequate support for decision making

Across the participating countries, inadequate support for decision makers was recognized as a major cause for inefficient implementation of national obligations to the CPB. Other problems stemming from this are: limited communication between the various stakeholders participating in the implementation of the CPB and related national policies, lack of public awareness on the national laws and international obligations under the CPB, and limited public understanding of the CPB and the role played by LMO detection on monitoring and evaluation of the safe transfer, handling and use of LMOs in the environment.

iv. Lack of certification and harmonized detection thresholds

The lack of communication between and among implementers of the CPB was identified to be both at national and regional levels. This has led to limited efforts for harmonized standards in LMO detection and the absence of coordinated detection thresholds across countries in the region. Detection thresholds are guided by the laboratory protocols and equipment available. A harmonized approach in sampling, with agreed thresholds, means that regulators have the same parameters to help in the identification and detection of LMOs. It also means movements can be expedited and where there are doubts on data from the region, analyses could be repeated. Proficiency testing can also increase confidence in data across nations. Having baseline data on capacities helps to design training activities at the regional level and tailor make specific activities at national levels. Making such data available on the E-network or creating a platform for sharing will help mentor "low capacity institutions" through knowledge sharing and material support.

[27] The Lesotho seed testing laboratory was assessed based on submitted reports to the Ministry of Environment in Lesotho.

v. Inadequate mechanisms for monitoring and surveillance

With the exception of Lesotho, five of the countries reported that they have not established mechanisms for monitoring potential effects of LMOs that are released into the environment. Thus participating countries have inadequate mechanisms for monitoring and surveillance. Even in the absence of NBFs, there are fears about unintentional and intentional illegal movements of LMOs across countries in the region. Even in the presence of promulgated laws and decrees or interim arrangements which allow for case by case review of applications, the lack of LMO detection capacity makes it impossible to implement effective monitoring and surveillance mechanisms. LMO detection capacity will enable implement of measures developed to serve Risk Assessment and Risk Management of transport and use of LMOs, thereby safeguarding unregulated trans-boundary movements of LMOs in the region. Such mechanisms will assist in the implementation of: Article 17 - *unintentional transboundary movements and emergency measures and Article 18 - Handling, Transport, Packaging and Identification (especially identification measures).* Improved mechanisms will contribute to ongoing global discussions on the two articles and provide replicable tools to be used by other parties.

vi. Limited partnerships and networks for biosafety regulatory decision making systems at national levels and in the region

Lack of awareness within the biosafety regulatory authorities, poor coordination between the agencies and limited human resource and infrastructural development results in wasted time and resources at all levels. Whilst the level of coordination, capacity and experience differs from one country to another, there are limited resources to enable sharing of existing capacity, lessons learnt and experiences across the region.

The recommendations, identified gaps and identified areas of intervention in Tables 4 – 6 will be used to design country specific and regional or common capacity building interventions to support institutional, material and human resource development in the testing facilities in line with the stratified approaches to the planned project as par the guidance provided by STAP. This was reviewed and validated during the project preparation stage. The identified areas of support within the project objective will be reviewed annually at the country and regional level to ensure needs are captured and addressed.

2.7. Linkages with other GEF and non-GEF interventions

45. The proposed project intervention is related to ongoing UNEP GEF projects on Implementation of National Biosafety Frameworks and the Biosafety Clearing House. DRC, Lesotho, Madagascar, Malawi and Mozambique have all participated or are participating in UNEP-GEF supported interventions supporting implementation of National Biosafety systems. This proposed project aims to develop supportive measures to facilitate decision making for the implementation of National Biosafety Frameworks or interim measures intended to ensure countries meet their international obligations under the CPB.
46. Furthermore, this project falls under the UNEP Medium-term Strategy of the sub programme on Environmental Governance, whose objective is to ensure that environmental governance at country, regional and global levels is strengthened to address agreed priorities. Specific UNEP expected accomplishments for this sub programme that are relevant to this project are: (a) That the United Nations system demonstrates increasing coherence in international decision-making processes related to the environment, including those under multilateral environmental agreements (MEA); implementing this and other MEA defined projects will help UNEP accomplish this vision; (b) That States increasingly implement their environmental obligations and achieve their environmental priority goals, targets and objectives through strengthened laws and institutions. The biosafety projects already

implemented or ongoing direct a lot of assistance towards states in fulfilling their obligations to the CPB. In addition, UNEP through its Regional sub programme coordinator on Environmental Governance and staff members involved in UNEP's Programme of work on Enforcement and Compliance have been providing continuous support to the implementation of MEAs, especially in the area of liaison assistance to the wider UNEP and its partners. This will be further boosted through direct call up assistance on Biosafety Protocol related issues. This support will be in addition to in-house expertise on the Biosafety Protocol to be provided by the designated UNEP Task Managers, the Regional Office for Africa and the regional support officers (South Africa, Malawi and Mozambique) in the sub region.

47. Synergies will be developed with other projects to ensure sharing of lessons and cooperative measures are put in place. For example with the Caribbean regional biosafety project, under which a regional lab-detection network has been created, a strategy will be developed to ensure cooperative measures, sharing of best practices with other labs around the world.

48. The project directly supports on-going partnership between RAEIN-Africa and SANBio on the development of interventions to support the use and development of scienctific tools to support the development and utilization of LMOs in a sustainable manner as referenced in the support letter attached to the project document as Appendix 20. This will enhance ongoing efforts of SANBio in supporting science and technology innovation system in harnessing bioresources for the well being and development of economics in SADC.

3. Intervention Strategy (ALTERNATIVE)

3.1 Project Rationale, Policy Conformity and Expected Global Environmental Benefits

49. Entry into Force of the Protocol on the 11th of September 2003 meant that it is legally binding internationally and in the legal systems of all Parties to the Protocol. Parties are therefore obliged to comply with, and implement, all provisions of the Protocol.
50. To implement the provisions of the CPB efficiently and abide by its general provision as provided for in Article 2 of the CPB, and the protocol objective thus; ensure safe handling, transport, and use of LMOs, countries need to have capacity for LMO detection. It is imperative, therefore, that all countries have the basic infrastructure and technical capacity, including equipment, tools and practical know-how to identify and quantify LMOs to fulfill their obligations.

51. The proposed project is related to ongoing UNEP GEF projects on Implementation of National Biosafety Frameworks and/or the Biosafety Clearing House in DRC, Madagascar, Malawi, Mozambique and Lesotho. Enhancing LMO Detection capacity will strengthen decision making processes; generate information on LMOs that can be reposted on the BCH and will contribute to awareness creation on the importance and urgency for legal instruments and regulations for management of safe handling, transfer and use of LMOs. The biosafety projects already implemented or ongoing, direct a lot of assistance towards states in fulfilling their obligations to the Cartagena Protocol on Biosafety.

52. Information on LMOs and Biosafety assists decision makers in countries around the world, as well as civil society and the biotechnology industry in decision making, risk assessment and risk management, monitoring and surveillance. Enhanced capacity for LMO detection laboratories will therefore, provide tools and play an important role in ensuring traceability and segregation; compliance with National regulations in terms of labelling; compliance

with international regulations for trade; monitoring and surveillance, and management of illegal transboundary movements to ensure compliance with regulations at all levels to support decision making. Furthermore, the implementation of the project will contribute to the CBD Strategic plan for biodiversity 2011-2020, specifically to the Aichi Target 13, as effective implementation of the CPB will address the safeguarding of ecosystems and genetic diversity, and promote sustainable use.

3.2 Project goal and objective

53. The **project purpose** is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling, transport and use of LMOs resulting from LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health, and specifically focusing on transboundary movements.

54. The **project objective** is to build and strengthen institutional and human capacities for LMO detection in support of national biosafety decision making processes in selected Southern African countries.

- The project will enhance LMO detection capacities in each of the participating countries to a standard that is accepted and recognized regionally and internationally.
- LMO detection information generated will inform and strengthen decision making systems.
- Laboratories will participate periodically in relevant proficiency testing programs to monitor their compliance with the set standards. This will ensure confidence across the laboratory network participants and in the national decision making systems.
- Standard LMO detection methods used and results obtained will build confidence on levels of proficiency among participating laboratories. The project will also standardize the reporting of results. These comparable and validated methods, through proficiency testing, quality of analytical data and methodologies used in LMO detection across various laboratories will form the regional agreed on standards.
- Setting harmonized detection thresholds might be a long term investment, as most participating countries do not have legal instruments for guiding setting up and implementation of thresholds. Setting up of thresholds would help in the management of non-adventitious presence and Low Level Presence, which when there are no thresholds, leads to undue delays of shipments, repetitive tests and increases the cost of shipments and delivery.
- The developed standards will provide support to the development and implementation of regional guidelines on transport, handling, packaging and identification of LMOs across the region.
- All the generated project outputs will be translated into English, French and Portuguese to ensure that all the partners have access to the same materials. In addition, for the training activities provisions will be made for translation and interpretation of proceedings.

3.3 Project components and expected results

55. The project consists of six Project components as follows:

3.3.1. Project Component A: Strengthening infrastructure for LMO detection

Result 1: Designated LMO testing laboratories designed, equipped and able to carry out LMO detection.

This project component aims to improve laboratory infrastructure required for qualitative and quantitative testing of LMOs. According to the stocktaking survey of LMO testing laboratories in the target countries carried out during the project preparation grant, none of the laboratories have adequate infrastructure for carrying out LMO detection. Hence countries lack support for national

biosafety decision making, monitoring and enforcement. This consequently militates against the effective implementation of NBFs and biodiversity conservation. Two outputs will be produced under this result: A guidance document for minimal laboratory infrastructure, and procurement of equipment and supplies, refurbishment and improvement of laboratory layouts and workflow of laboratory facilities, for LMO detection and analysis. The capacities of the participating laboratories will be upgraded to various levels as determined by the need assessments. The project seeks to have at least one of the two participating laboratories in each the countries to capable of qualitatively detecting levels of LMOs.

The following project activities are planned at the regional and national levels:

i. A 3 day regional review and adaptation workshop for minimal infrastructure for LMO Detection laboratories.
ii. Development of technical guidance documents on setting up laboratories
iii. Technical backstopping and assistance to laboratories at the national level on infrastructure and spatial orientation of laboratories. The technical advisory support will include training on equipment use, maintenance and standardization. The laboratory assessment support will lead to re organization of existing laboratory set up and advice on equipment to be used.
iv. Development and implementation of a procurement strategy at the regional level, this will include selection of vendors guided by the national procurement plans for laboratory equipment and reagents. Service and maintenance contracts, group warranties will be included in the strategy in addition to on-site training of technicians during installation. MoUs will be signed between the laboratories and the Biosafety Competent Authority outlining roles and functions and also a mechanism to ensure continued supply of samples including referrals by the National Biosafety system to ensure sustainability of the laboratories.
v. The Participating Laboratories are already established with basic analytical tools which will be upgraded and designated as Testing Facilities. The choice of laboratories was guided by the established mandate and already existing institutional budgetary support to cover analytical services. The designated laboratories were carefully chosen such that with the planned upgrades and institutional capacity building, the testing services will be sustainable in the long run. To achieve this, the project proposes signing of MoUs between the upgraded laboratories and the governments (refer to sub paragraph iv above). MoUs with governments are necessary for assurance of long term sustainable relationships beyond government dynamics over time. This is extremely important as the laboratories based on national resources in a developing country context are either a shared resource between ministries or a third party institution to the National Biosafety Focal Point institution. The MoUs will be in the form of endorsements and partnerships where the governments give assurance that the equipped LMO testing laboratories will be the referral laboratory for all Government related testing to support monitoring, risk management practices and decision making in relation to the both for implementation of the national biosafety systems or interim measures thereof and for applicants that will be required to label or declare the GMO status of their products. Such an agreement will assure testing at a cost to be incurred by the owner of the sample(s) to be tested. The laboratories will then run as sustainable businesses, supported by the flow of samples stemming from the regulatory testing requirements for transboundary movement of living organisms and policy direction on testing services to support handling and identification of Living Modified Organisms. Such agreements are standard practices to support cross sectoral and inter institutional partnerships. This is extremely important in the case of the participating countries which do not have private sector testing facilities and also will

serve as an "institutional agreement" in the context of the countries where ministries, departments and agencies may change periodically.

vi. Recurring costs associated with the running costs of the upgraded laboratories will be covered by the Laboratories and recovered through the testing services and institutional budgetary allocation on analytical services. In addition, the focal institution on biosafety will provide annual additional support through its budgetary allocations to support the laboratories with an agreed allocation to be specified in the MoU to be reviewed periodically.

vii.

viii. Consultative process will be developed through the regional meetings for a harmonized and acceptable standard for LMO Detection. Standard Operating Procedures will be developed on sampling, analysis and documentation.

3.3.2. Project Component B: Strengthening Institutional and Human Capacities for LMO Detection

Result 2: Minimum level of competence achieved in the designated LMO testing laboratories

This component seeks to build a critical mass of laboratory staff with the requisite knowledge and skills for LMO detection and analysis. All participating countries have limitations when it comes to staff knowledge and skills in LMO detection and analysis. Although most of the laboratories had personnel trained in basic laboratory skills, they lacked proficiencies in LMO detection. However, the knowledge and skills are a prerequisite if the laboratories are to provide support to Competent National Authorities (CNAs) in ensuring the safe transfer, handling and use of LMOs.

Under this result, three outputs will be produced, namely: Laboratory personnel will be equipped with skills in Quality Management in line with the following ISO standards - 17025, 9000; Adequate technical backstopping in support of implementation provided; Guidance documentation on best practices in LMO detection produced and shared.

The following project activities are planned at the regional and national levels:

I. 3 day Regional workshop to review and define competence levels for LMO Detection for all the participating countries. The workshop will be held back to back with a regional workshop on defining infrastructural requirements. Provision will also be made for non-participating countries to take part in the planned regional workshop at their own cost.

II. 3 day Regional Trainer of Trainer workshop on quality management systems. Specific national spatial differences will be assessed prior to the regional training. Guidance will be provided in the training to assist the national project activities. National training workshops will be held on quality management systems as a follow up to the regional workshop.

III. Six national workshops shall be conducted on LMO Sampling and Detection (3 days each for 12 participants per country)

IV. A review and guidance will be developed or adapted on best practices in sampling and LMO detection. This will be developed at the regional level and shared with the participating laboratories

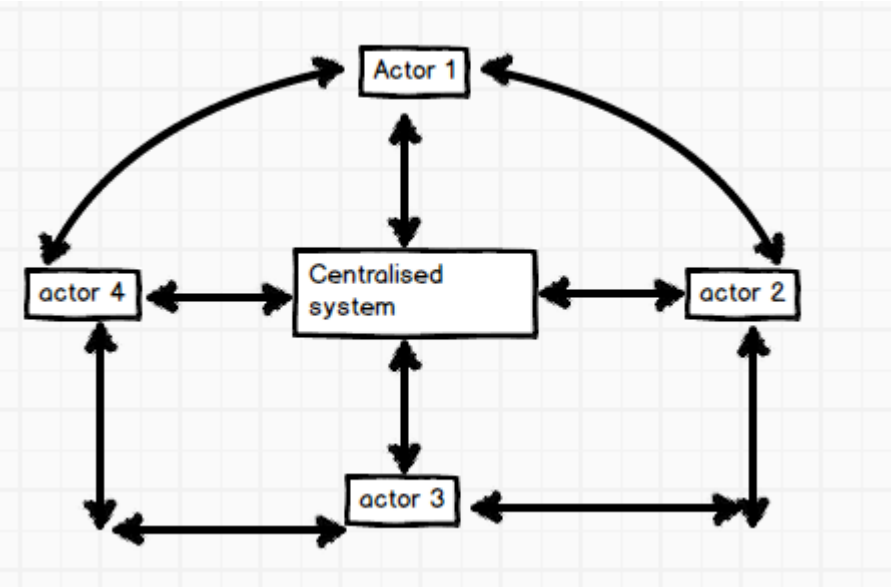
V. Project participants will be trained on "soft skills" for effective delivery of the project (training will include project planning and self-monitoring, narrative and financial reporting, communication skills, leadership skills, team building, conflict resolution and interpreting findings for policy decision makers). Training will be done both at the regional and national levels. Gender analysis will be done to guide selection of participants to ensure inclusion both at the regional and national level of women, men and key end users on handling and packaging of information.

3.3.3. Project Component C: Strengthening Information Sharing, Lesson Learning and Partnerships

Result 3: Sustainable opportunities for sharing expertise, lessons and resources on LMO detection created

This component is aimed at building a robust network of LMO detection laboratories in the region to facilitate sound biosafety decision making and environmental safety. It is building the work started by RAEIN-Africa under SANGL of facilitating the sharing of expertise, experiences and resources in LMO detection and analysis. Countries have different levels of exposure to LMOs, and are at different levels on development. Creating a platform for sharing experiences and resources will go a long way towards promoting regional harmonization and integration in line with the region's goals for economic integration. This result will be buttressed by the following outputs: Platforms for information sharing shall be established and made functional, Project materials and guidance manuals will be documented and published, linkages and partnerships with other regional and international LMO detection laboratories and networks shall be established.

The platform is as conceptualized as shown below.



Actors (designated laboratories and regional/national experts) shall interact via a centralised system, coordinated by RAEIN-Africa through the LMO Detection network of laboratories. Partners in country and across countries can also interact directly. The system will have both public sharing and privately shared forums. The public forums will be mainly for knowledge sharing, lessons learnt and best practices whilst the private forums, will be a hub for sharing protocols, guidelines, issue specific Standard Operating Procedures, cross laboratory referencing and validation of data and technical support to laboratories on testing issues.

The proposed platform will be a web based interactive platform allowing actors to make contributions towards discussions, questions or any specific issues about laboratory testing and associated biosafety regulatory issues arising thereof. User defined profiles and access credentials will be developed at different security, data sharing and management levels to facilitate information exchange on LMO Detection. The platform will be accessible via computers, mobile phones and other modern technology devices. The material can be shared as text, audio or video. The posts may comprise of relevant publications, lectures or be discussion fora where technical backstopping can be offered remotely, on a case by case basis. In addition, informal information such as testimonies, story-telling of practical day-to-day experiences, etc. will also be shared. Links will also be created to highlight

and share information through social media tools including Facebook, twitter, Instagram and YouTube among others.

Access will also be sought from the SCBD and other partners after all the relevant peer reviews and data testing, for the platform to be linked. In this vein, the platform will be linked to the online network of LMO Detection Laboratories as per the relevant COP/MOP decisions including BS V/9 and BS V/16 and BS VII/10 (http://bch.cbd.int/onlineconferences/portal_detection/lab_network.shtml)

Learning and Knowledge Management

The objective of the project component is to facilitate dissemination of results from the project will be within and beyond the project intervention zone through a number of existing information sharing networks including online based forums, newsletters, a network of LMO Detection laboratories and Learn and share forums. In addition:

- the project will participate, as relevant and appropriate, in UNEP/GEF sponsored networks, organized for Senior Personnel working on projects that share common characteristics; and
- the project will identify and participate, as relevant and appropriate, in scientific, policy-based and/or any other networks, which may be of benefit to project implementation though lessons learned.
- The network of laboratories will be linked to the LMO Detection Portal on the BCH (http://bch.cbd.int/onlineconferences/portal_detection/lab_network.shtml) to enable sharing and learning with similar networks or laboratories in other regions of the world

The project will identify, analyse, and share lessons learned that might be beneficial in the design and implementation of similar future projects. Identification and analysing lessons learned will be an ongoing process, and the need to communicate such lessons as one of the project's central contributions is a requirement to be delivered not less frequently than once every 12 months. This will be part of the knowledge management focus of the project. Publications and thematic reports will be developed and shared in the participating countries and beyond. The Project shall use the UNEP format for categorizing, documenting and reporting on lessons learned.

The following project activities are planned at the regional and national levels:

i. Annual knowledge sharing meetings will be held at the regional level back to back with the Annual Regional Steering Committee. This will be used to share progress on project execution both at the national and regional level. It will also give opportunity for new and emerging techniques and trends on detection and biosafety in general to be shared through the thematic reports developed
ii. Knowledge sharing and e-platform will be developed to allow for exchange of information and technical support in laboratory detection services through the project website at the Regional level with national nodes. Establish linkages with the LMO Detection Network Portal on the BCH. This will include laboratory twining Programmes beyond the project with other laboratories to allow for study visits, outreach materials shall also be developed including e-newsletters, brochures
iii. Linkages, partnerships with other international LMO detection laboratories and Networks as well as other relevant institutions will be established.

iv. Iv. Publications will be producted and packaged at the regional level for adaptation and translation at the national level on LMO detection, monitoring and sampling
v. In country workshops will be held to create communication channels and networks in LMO Detection and Monitoring

3.3.4. Project Component D: Strengthening Biosafety Decision Making

Result 4: Technical support to strengthen LMO detection and biosafety decision making processes in target countries provided

This component is aimed at ensuring a strong interface between LMO testing laboratories and biosafety decision making processes. The target is a national biosafety framework in which the results of LMO testing laboratories are used to inform policy and programmes. There is currently a very weak link between potential LMO testing laboratories and biosafety authorities. Although the biosafety authorities in target countries appreciate and are eager to work with LMO testing laboratories, there are no properly defined mandates and legally binding mechanisms.

The following outputs will contribute to the achievement of the above result: Policy makers are aware of the importance of LMO detection to biosafety decision making, and skills and techniques for sampling, handing and documentation of LMOs provided to regulatory chain actors.

The project will focus on activities that engages policy makers and stakeholders on integration of supportive detection mechanisms to facilitate national pre- and post-approval monitoring systems With scientific methodologies and hands on skills on sampling, detection and monitoring. The planned activities include the following

i. Regional and national inception workshop to enable engagement of policy makers and key stakeholders
ii. Signing of MoUs between laboratories and designated Government mandated competent authorities responsible for decision making
iii. In country training workshops for customs and related border control staff on quality management systems (sampling, handling and interpretation of documentation on
iv. LMO shipments

3.3.5. Project Component E: Monitoring and Evaluation

Result 5: A comprehensive project Monitoring and Evaluation (M&E) framework developed and used to monitor and evaluate performance against set targets.

This component is aimed at ensuring that the project is implemented in line with the intended objectives and outcomes, and that corrective action is taken in the event of variance against set targets. A Monitoring and Evaluation framework will be developed to be part of project documentation. Monitoring will be undertaken internally through review of annual work plans, budgets and progress reports by both national and regional project steering committees. Evaluation by outside consultants will be carried out twice, that is, a mid-term evaluation after two years and an end of project evaluation at the closure of the project.

Project activities will focus on the project's monitoring framework, proficiency testing of the laboratories and evaluation which will be handled by UNEP. A cost of monitoring and evaluation is captured both in the project budget and in Appendix 7 of the project document.

The planned project activities as summarised in Appendix 5 will be executed as a mix of national and regional activities. Issues which can be harmonised to achieve economies of scale will be done at the regional level whilst country specific issues and follow up activities will be executed at the national level. The training activities and related technical services will be supported by 2 Project Technical

advisors and consultants with expertise at the national level. All project technical outputs will be translated into English, French and Portuguese for uptake by the different project partners.

3.3.6. Project Component F: Project Coordination and Management

Result 6: Systems and structures for project coordination and management established

RAEIN-Africa will play the role of executing agency, and will therefore be responsible for liaising with UNEP during the lifespan of the project. It will also supervise the execution of both the regional component and support activities at national level. RAEIN-Africa will develop a comprehensive financial management system, and ensure that moneys used at both regional and national levels are accounted for. RAEIN-Africa will also provide technical backstopping to country activities through both the SANGL technical experts and RAEIN-Africa personnel. A regional project steering committee comprising of; a representative from each of the participating countries, RAEIN-Africa, the laboratory that will act as the center of excellence, and UNEP will be established. The regional project steering committee will meet annually to review work plans, budgets and progress reports and take corrective action where appropriate. At country level, a national project steering committee with a good key stakeholder representation will be established in each of the project countries. The national project steering committees will supervise project implementation at country level and ensure that the goals and outcomes of the project are achieved. The national project steering committee will be answerable to the regional project steering committee, and shall meet no less than twice annually.

3.4 Intervention logic and key assumptions

56. This multi country project provides an innovative approach to biosafety. It seeks to simultaneously address a number of challenges militating against the effectiveness of biosafety systems in the SADC and beyond. These challenges are at country and regional levels. At the country level, the national biosafety system is often fragmented, with key players in the biosafety system working in silos. This project seeks to bring together the key national players in biosafety such as policy makers, regulators, technology developers, laboratories and training institutions to a round table and talk to each other about their needs, priorities and find ways and means of working together. A National Biosafety Stakeholder's forum will be established to help keep the players together and complement each other's efforts.
57. The project will also ensure that national processes inform regional processes and are shaped by what is also taking place at regional level. At the regional level, an electronic platform for exchanging best practices, sharing information, expertise and resources will be established. This will help individual countries build and sustain competences in LMO detection and analysis.

3.5 Risk analysis and risk management measures

58. The potential risks to the implementation of the project were reviewed and captured at two levels direct in country risk plans and a consolidated approach across the project at national and regional levels. These are highlighted below with suggested mitigation measures.

Risk Mitigation Plans for in-country activities

Issue	Project Component	Identified Risk	Mitigation measure
COMMUNICATION	3	Language barrier – 3 different language groupings within participating countries	Budget and allocate sufficient resources for translation of documents and facilitation of meetings
	3	Inadequate collaboration and engagement between the labs in participating countries	RAEIN-Africa to support networking initiatives and create ongoing dialogue between the participating labs
	3	Absence of formal coordination mechanism for the labs	Establish an electronic platform for information sharing
	3	Insufficient moderation of platforms/project fora	Simplify workshop content
STAKEHOLDER RELATIONS	4	Government approval/endorsement for participation in the project	Engage political principles on the project for approval
	4	Labs do not have official government mandate for LMO detection	Engage government and political principles for mandate
	4	Limited participation by regulators in the project capacity development initiatives	Sensitization of regulatory decision makers at national and regional levels on the importance of participating in the project
	4	Long national process to obtain formal mandate for LMO testing	Project partner to lobby key stakeholder ministries (ministry of science and technology, agric, environment or health)
	1	Political instability/will	Ongoing lobby actions
	1	Standards are coordinated by different ministry	Carefully identify key/relevant stakeholders
HUMAN RESOURCES	2	Skills developed/transferred not adequately used	Ensure that sufficient samples are brought to the lab to keep the system working
	2	High staff turnover	Incentivize participation in the project through the

			mentoring programme
	2	Number of qualified personnel to participate in the project	Recruit more personnel with the requisite skills for further development
	2	Project based staff not permanently employed	Engage governments to absorb trained personnel into permanent positions
	2	Constant changing of staff participating in the project	Inform top management about the importance of committing constant staff to the project
PROCUREMENT	1	Long bureaucratic process that delays procurement of equipment and reagents	Project equipment should be centrally procured by the project
			Plan and initiate procurement process early in the project
		No national supplies of equipment and reagents	Coordinate at regional level as appropriate
SYSTEMS	4	Absence of national biosafety frameworks	Lobby for adopting of biosafety act
	2	Non-uptake of training content	Diversify capacity building methods eg – technology transfer
		Poor recording of data in the database	Assign staff to ensuring register is updated
	2	Technology shortcomings eg data transfer	Include project equipment such as lap tops and computers
	2	No national laboratory standards	
	3	Inefficiency of LMO detecting system	Ensure that LMO detection and monitoring is integrated into government plans and budgets
	4	Inadequate/unclear institutional arrangements	Decide on appropriate national coordination mechanism Clarify institutional arrangements

Consolidated cross cutting risk issues

Risk	Rating	Mitigation measure
a) Slow administrative and political response to biosafety issues	High	Cooperation between government structures, instituitions and special awareness programs for targeted and relevant authorities will be organized at the inception of the project, with follow ups to strengthen the political support for the NBF implementation process. Efforts will be made to ensure biosafety is placed on a higher level in the agenda of government and the national assembly. Project component 4 will be used to strengthen designated stakeholder institutions to do continuous outreach, lobby and network as a means of getting political leverage.
b) Inadequate mechanisms for institutional coordination in the management of biosafety	Medium	Regular coordination meetings for relevant ministries and agencies will be held, defining clear procedures and responsibilities for all the key stakeholders identified. Institutional capacity building will be placed on a high priority level throughout the planned project activities. The steering committees and the information sharing activities will be used to consciously support coordination and management of biosafety. Similar processes will also be initiated through the regional component of the project. Where feasible, concerted efforts will be put in place to develop guidance and easy to read materials to support the coordination mechanism. Entry points will also be created for key non-governmental stakeholders including private sector, NGOs, farmers and women groups to be represented in the steering committees as part of the coordination mechanism
c) Low institutional capacity to manage handling of LMOs in SADC	Medium	Capacity building activities coupled with strengthening of existing facilities will equip designated regulatory agencies to effectively execute their mandate. A high priority will be placed on building a critical mass of resource persons through the Trainer of Trainers approach, mentoring and training in "soft skills" as focal points who will contribute to the enhancement of public awareness through intensification of the contribution of national experts in this process. Through the planned initiatives at the regional level, efforts will also be made to get a full "buy in" by the SADC secretariat through coordination of similar interventions, lobbying and periodic briefs.
d) Climate change related risks	Low	Measures will be put in place to protect Laboratory equipment from potential damages that may be caused b flooding through the spatial design and set up laboratories. In addition to voltage regulators to absorb potential surges and outages that may arise especially due to cyclones. Standard Laboratory Operating and Emergency Management procedures will be put in place and staff

trained on emergency response measures including laboratory evacuation and also data management. Data generated will be stored in back up servers as part of the planned e-platforms.

3.6. Consistency with national priorities or plans

59. Parties in the region have prioritized the need to put up measures for the conservation and sustainable use of biological diversity in their National Biodiversity Strategy and Action Plans (NBSAPs). Management of Biotechnology and its risks is an important component of NBSAPs in most of the participating countries. Most of them are in the process of developing their second NBSAPs so here we draw from a few of the country's First NBSAPs. (For specific country plans under the NBSAPs, see Table 1).

60. Most NBSAPs highlights gaps in the country's environmental regulatory frameworks with some raising the need to amend outdated laws and fill gaps in a range of areas including biodiversity and biosafety among others (Angola and DRC). Other NBSAPs set specific targets for achieving the establishment full operation of National Biosafety Frameworks (Angola, Lesotho, Madagascar, Malawi, Mozambique and). A third action planned for in some of the NBSAPS is capacity building for effective implementation of the Biosafety systems put in place (Angola, DRC, Madagascar, Mozambique and Lesotho). Included also in some of the NBSAPS is a plan to develop guidelines for the creation of biosafety awareness for various stakeholders participating in decision making, and in handling, transporting and use of LMOs. The planned project is thus aligned to the NBSAPs of the participating countries.

61. A number of NBFs in the region (see Table 1) stipulate the need for labelling of LMOs/products destined for transit, use as Feed, Food and Processing, contained use and/or environmental release. The NBFs of all the targeted countries except Angola are published at http://www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx. Malawi took part in the pilot phase of UNEP GEF biosafety project and have since had support from several institutions including USAID-PBS (United States Agency for International Development – Programme on Biosafety Systems) and African Biosafety Network of Expertise (ABNE).

62. The project objective supports Malawi's UNDAF (2012 – 2016) on thematic issue 1 – Sustainable and Equitable Economic Growth and Food Security. Already Malawi is undertaking field trials of LMO Cotton. With the setting up of a testing facility, the country will be able to ensure where cotton seeds taken up by farmers are really LMO or hybrid seeds so as to set up proper risk and pest management practices. In addition, since access to approved germ plasm with appropriate safeguards in place will ensure sustainable use and impact positively in securing food for now and the future. In the case of the Democratic Republic of Congo's UNDAF (2013 -2017), the proposed project fits into the first axis or thematic intervention on strengthening institutional frameworks and reinforcing capacity to support sustainable development . The setting up of a harmonized LMO testing network will impact positively on the safe use and transboundary movement of planting materials and seeds. It will also foster cross sectoral collaboration between the key line institutions in agriculture and environment to work together to safeguard and ensure sustainable use of biodiversity.

63. In Mozambique, the agricultural sector represents the main source of livelihood for the populations that live in the rural areas of Mozambique (70%). It is estimated to sustain about 80% of the economically active population and 87% of the female labor force in the country, but only represents 29% of the GDP (IFAD 2010, INE 2006), as it remains largely based on subsistence agriculture with low yields and high post-harvest losses. The main challenges for sustainable employment creation both in rural and peri-urban areas, besides insufficient enabling policies and regulations, are high illiteracy levels, scarce vocational and technical training opportunities, limited access to micro-credits and other financial services for vulnerable groups, the insufficient availability of quality business information as well as weak management structures of many MSMEs. As women and youth often face the greatest challenges in accessing sustainable employment opportunities, specific considerations to women empowerment and youth development are vital for tangible poverty reduction. Furthermore, agricultural production is highly susceptible to the impacts of climate change and natural disasters. As repeated droughts, floods and tropical cyclones are further eroding already precarious livelihoods, food and nutrition insecurity are persistent.

64. Under outcome 1, the United Nations will support the Ministry of Agriculture, the Ministry of Fisheries and the Ministry of Industry and Trade to ensure that "Vulnerable groups (with a particular focus on women) demand and ensure production and productivity in the primary sector in order to increase their own food security". The project interventions will support the outcome by contributing to the creation of an institutional, policy and implementation framework that is conducive to the development of the agriculture and fishery sectors and support the transformation of subsistence agriculture into a competitive, sustainable and market-oriented venture through the testing facility to assist in decision making in the release of germ plasm to support the planned transformative agenda in Mozambique.

65. The project intervention contributes to Lesotho's United Nations Development Assistance Programme (UNDAP) clusters on environment, natural resources and Climate and Agriculture. As it plans to Lesotho adopts environmental management practices that promote a lowcarbon climate-resilient economy and society, sustainably manages natural resources and reduces vulnerability to disasters. In outcomes 2 and 6, National institutions (public and private) deliver quality services for increased agricultural growth and food security.

66. The project intervention will help to respond to risks threatening farming systems and help strengthen agricultural and environmental policies through the harmonized approach to testing and sharing of expertise within the region. Outcome 6 dopts environmental management practices that promote a low-carbon climate-resilient economy and society, sustainably manages natural resources and reduces vulnerability to disasters. The project is providing interventions to improve coordination and management and conservation of natural resource through education, capacity building and development of a supportive technical tool to support governance of LMOs in Lesotho and also among the six countries with a potential replication effect across the sub region

67. In the case of Angola, the proposed project interventions will contribute to Result 3.2 of the United Nations Partnership Framework (2015 – 2019) ***environmental stability is reinforced by an improvement in management of energy, natural resources, access to green technology, strategies for climate chance, conservation of biodiversity and plans and systems for risk and disaster reduction.*** The project will specifically support conservation of biodiversity and develop

tools to support risk management plans in the handling of LMOs through the testing facilty. It will also assist Angola to have a broader support base through the regional interventions to support management of its natural resources and set up measures to train its frontline border staff in the transboundary movement of LMOs.

68. In line with the project contribution to the United Nations mandate in the country, the project will contribute to the newly adopted UNDAF 2015 – 2019 of Madagascar specifically to outcome 1- The vulnerable population in intervention zones have access to revenues opportunities and employment and ameliorate their resilience and contribute to inclusive and equitable growth for a sustainable development. The project contribution to this outcome will be generated the strengthening of environmental governance and related management practices through institutional capacity building, outreach and awareness on the LMO testing facility to support national biosafety decision making.

69. Overall the scope of the UNDAFs for the six countries among this outcomes have expected outcomes to support strengthened environmental governance and management level within country and through interventions to strengthen transboundary management of natural resources. The envisaged interventions the proposed project will contribute and assist in Environmental sustainability in the utilisation of biodiversity.

70. On the regional level, the proposed project interventions will be an attempt to address the recommendations formulated by the SADC Advisory Committee on Biotechnology and Biosafety and were approved by the SADC in August 2003 as interim measures aimed at guiding the region on issues relating to biotechnology and biosafety. Parts of the recommendation that fits the project intervention are highlighted below

Handling of food aid

- The Southern African Development Community should develop and adopt a harmonized transit information and management system for GM food aid designed to facilitate transboundary movement in a safe and expeditious manner.
- The Southern African Development Community is encouraged to source food aid preferably from within the region, and advise all cooperating partners accordingly.
- Donors providing GM food aid should comply with the Prior Informed Consent principle and with the notification requirements in accordance with Article 11 of the Cartagena Protocol on Biosafety.
- Food aid in transit that may contain GMOs should be clearly identified and labelled in accordance with national legislation.

Policy and regulations

- Each member state should develop national biotechnology policies and strategies and expedite the process of establishing national biosafety regulatory systems.
- All member states should sign and ratify the Cartagena Protocol on Biosafety to the CBD.
- Member states without a regulatory framework for GM crops should use approved guidelines and should not import genetically modified grain for seed before approved guidelines are in place.

- Risk assessments should be done on a case-by-case basis and every genetic modification should be tested in the environment under which it will be released.

Capacity-building

- Member states should develop capacities at national and regional levels in order to develop and exploit the benefits of biotechnology.
- The Southern African Development Community should allocate resources for capacity-building in management of biotechnology and biosafety.
- The Southern African Development Community should encourage member states to commission studies on the implications of biotechnology and biosafety on agriculture, environment, health and socioeconomics as part of an integrated monitoring and evaluation system.

Public awareness and participation

- Member states should develop public awareness and participatory programmes on biotechnology and biosafety that involve all stakeholders.

3.7. Incremental cost reasoning

71. The six target countries have been involved in biosafety initiatives since the negotiations of the Cartagena Protocol on Biosafety. The countries have, in addition to using their own resources to develop and implement comprehensive biosafety frameworks, accessed capacity building resources under UNEP including that for the development of national biosafety frameworks and biosafety clearing house. They have also been involved in other biosafety initiatives championed by RAEIN-Africa, ABNE, Africa Bio, and Programme for Biosafety Systems, and the work at the continental level under the African Union (AU).

- The status assessment of the participating laboratories carried out by RAEIN-Africa revealed that the six countries have limited capacity to test and quantify the presence and levels of LMOs. This is so even though the target countries have prioritized biosafety as indicated in their NBSAPs. The experiences of the SANGL project will form a foundation upon which this project will be anchored and build from. The current status of the designated laboratories in the participating countries is shown in Table 3 of this project document. RAEIN-Africa and its SANGL technical partners, including the Testing Facility at the Free State University in South Africa, will provide a leading role in facilitating the capacity development in this project.
- The existing baseline conditions in each of the target countries will give an impetus for the planned activities. The existing NBFs and interim measures, in the case of those countries that do not have advanced NBFs, will provide the needed baseline infrastructure and capacity on which the GEF support can provide a catalytic role in terms of material and human resources to assist in addressing LMO identification and handling issues related to national decision making systems.
- What is vital to note is that all the six countries have indicated willingness, through their NBSAPs, to implement the CPB. Stakeholders also agreed during the PPG, that the outputs from this project will make a case for the NBFs and in so doing create a clearer mandate for the LMO detection activities. It was therefore concluded that there was scope for the proposed LMO detection capacity in the absence of biosafety regulatory frameworks in the partnering countries.

- The Project will build on the established baseline, which includes some level of commitment through some policy, law or an interim arrangement for decision making or commitment to the implementation of the CPB. The establishment of testing capabilities will therefore support the development of science based regulation to meet the CPB. The detection capabilities are meant to serve RA and RM of the transport and use of LMOs. The legal regulatory frameworks can be built progressively, parallel to the implementation of detection capacities. Incremental cost reasoning is further elaborated in Appendix 3 of the project document.

3.8 Sustainability

72. This project is one of the first attempts under the GEF Biosafety programme to develop a standardized and harmonized approach to addressing identification and detection of LMOs as a thematic intervention in support of national biosafety decision systems and in line with obligations under Articles 14, 16, 17 and 18 of the Cartagena Protocol on Biosafety and also the new Framework for Capacity Building http://bch.cbd.int/protocol/e-doc/?news=96593.

- The key innovation is to build a network model which would provide technical support and resources among the countries in the area of identification and detection of LMOs. It will also help the countries with less developed biosafety systems to have a ready resource within the region to assist in training and provision of technical support services. This thematic support means countries like Angola would have a ready resource to support its monitoring and enforcement obligations whilst it builds its national biosafety system. Countries are contributing laboratory space and retrofitting the laboratories through their national resources as co-finance support. The national biosafety authorities have shown interest to support LMO detection by designating laboratories to serve as referral laboratories.
- The designated laboratories will need to work out a system that will allow for a sustainable regulatory support service. On this issue, the system should officially designate the referral laboratories to ensure continued flow of specimens for analysis and to allow for laboratories to charge commercial testing and certification rates, thus building an element of laboratory sustainability beyond the project.
- On the issue of accreditation, it was concluded that the process is lengthy and expensive and sustainability will be of concern to the laboratories. The project will implement regional and national acceptable standards with guidance from national accreditation bodies that already in most cases have the mandate to assist national bodies to attain accreditation through internationally recognised institutions. It was agreed that given the complexity around the various global accreditations that exist, it would be better to focus on ensuring national approval of the participating laboratories.
- Countries agreed to enhance one or two laboratories each. However, the project will facilitate the upgrading of primary laboratories to the highest possible capacity on LMO Detection. The second laboratory will be upgraded for capacity building activities only. This would allow for continued availability of LMO detection capacity in either of the two institutions.
- Since the process is being established as part of the national biosafety system, the designated laboratories will in turn be expecting technical support in LMO detection in relation to approvals, general surveillance and monitoring mechanisms will be put in place for scale up in new and emerging areas of LMO detection. Secondly, the model developed can be used as a basis for an Africa region wide network of LMO Detection laboratories as envisaged by the African Union in its Africa wide Biosafety strategy on Centers of excellence in LMO Detection and Biosafety Training (http://www.africaunion.org/root/AU/AUC/Departments/HRST/biosafety/AU_Biosafety_1b.htm).

- The commitments to sustain the process are guided by national obligations as Parties to co-finance commitments and development activities. The beauty of this current approach is the assistance in harmonized approaches in terms of laboratory protocols, training materials and related resources. As per agreements between the countries and RAEIN-Africa, support is to be given only to countries whose laboratories are already designated by national governments with MoUs to support the national biosafety system. The GEF investment is therefore not a standalone intervention, but is assisting national efforts in building systems to support implementation of the Cartagena Protocol on Biosafety. In addition, the proposed intervention will support, as the first of its kind, a thematic intervention under the GEF Biosafety strategy for a designated network of LMO Detection Laboratories, under the CPB, as a multi country arrangement in line with Article 14 and is in line with COP/MOP decisions as captured. In course of the project efforts will be put in place for a harmonised testing fee system and continuous proficiency testing so that results can be replicated and accepted in the network and beyond.
- The network will be linked to LMO Detection network on the Biosafety Clearing House and also similar networks around the world to create a platform for sharing and also assessing best practices in sampling, threshold setting, documentation and trends in LMO Detection.
- Project guidelines, thematic reports and protocols will be prepared in the three languages English, French and Portuguese to ensure ease of use even beyond the project.
- Partners will be encouraged to motivate trained staff, offer periodic training opportunities and ensure the MoUs are functional beyond the project.

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3.9. Replication

73. This project builds on work done by RAEIN-Africa in the SADC region under the SANGL network. Other SADC countries have expressed an interest to be part of this intervention, and will join in when resources permit. In addition, this project is replicable in most countries in the African continent that have similar challenges to those experienced in the participating countries. The AU is looking forward to a continent-wide scaling up of RAEIN-Africa's biosafety capacity building work. This project will also forge some collaborative arrangement with the European Union's joint GMO detection laboratory and other planned networks in Asia and Latin America; and explore synergies and lessons for replication. The lessons learned will be shared with the Regional Biosafety Project for Caribbean which is planning a similar intervention for the ongoing project. The tools, methodologies and expertise developed from the project will be a ready resource for replication and support other parties in the region.

3.10. Public awareness, communications and mainstreaming strategy

74. This project will build on biosafety work being done in the target countries. The project inception and closure workshops will be held at both national and regional levels. The project activities and outcomes will be documented, properly packaged and shared. The project will also use the activities under component D (Strengthening Biosafety Decision Making) as a tool for public awareness, education, communication and knowledge sharing.

75. The e-platform for information sharing established, under project component C, will take on the role of mainstreaming the work of LMO detection and analysis into the public arena for public awareness and public participation in environmental matters. It will also serve as a resource for knowledge management among the participating countries and other countries in the region and beyond.

3.11. Environmental and social safeguards

76. No adverse environmental effects are anticipated to be generated by the execution of this project, save for those related to good laboratory practices where standard safe laboratory practices will be provided to the participating laboratories. No new land will be acquired for building laboratories and no social groups will be disadvantaged by this project. The project will ensure that males and females are equally represented in meetings and training workshops. A check list is attached as Appendix 16 on Environmental and Social Safeguards.

77. The project will also provide a useful tool which can support ongoing project interventions by UNEP and other organisations on monitoring and enforcement through the provision of testing services and DNA analysis in illegal natural resource trade and transboundary movements. It will support measures to safeguard the environment providing a science support basis to detect illegal or unapproved activities.

78. The project focuses on strengthening laboratory infrastructure and institutional support through planned capacity building intervention. The skill set required in LMO Detection is gender neutral and dependent on expertise in specialized areas. As part of project execution, a thorough gender analysis will be undertaken over the whole project delivery chain to identify entry points. This shall include training workshops, engagement of policy makers and outreach activities. Resources will be set aside as part of the training and outreach activities to capture gender disaggregated data. Training participation will be also be used as one area especially in the project component on Biosafety Decision making for balanced representation of men and women. Laboratory protocols and spatial designed with adequate containment measures to ensure or manage impact of reagents or samples that could impact on the health of scientists and technicians especially women as this will lead to loss of work time and delivery. In addition, laboratory design will be done to ensure that handicapped or physically challenged experts have easy and equal access to all the resources for sampling and testing. Outreach materials through the knowledge sharing component will highlight both the potential benefits and risks of LMOs and its impact among the several stakeholders including men, women, the youth and farming communities to ensure that impacts can be managed and the voices of end users especially small scale farmers most of whom are women are heard.

79. In addition, the information sharing and knowledge management platform and meetings will be used to create a forum for the participating countries to share experience and also give specific examples on how they are incorporating or mainstream gender dimensions into the project delivery including resource allocation. This will guide the regional steering committee on providing guidance on gender mainstreaming which is targeted to be highlighted especially in participation of women in the policy and decision making process

80. The project team will also be monitoring the ongoing discussions on socio economic considerations so as to capture issues and trends related to article 26 where parties are still engaged on conceptual clarity and mechanisms for implementation. The focus will guide the decision making processes and planned interventions on monitoring of LMOs (http://bch.cbd.int/onlineconferences/portal_art26/se_main.shtml) especially as it pertains to socio-economic considerations and the value of biological diversity to indigenous and local communities; environment-related aspects of socio-economic considerations, as well as the relationship, if any, with risk assessment and human health-related issues

Section 4: Institutional Framework and Implementation Arrangements

81. UNEP through its Division on Environmental Policy Implementation will be the GEF Implementing Agency responsible for the project. UNEP will provide supervisory and technical advisory oversight for the project.
82. RAEIN-Africa will be the Lead Executing Agency for this project and will co-execute with the participating countries. UNEP/GEF will sign a contract with RAEIN-Africa and Countries (Focal points) will sign MOUs with RAEIN-Africa. The Lead Executing Agency will be responsible for all project management, monitoring and evaluation, technical guidance and reporting. RAEIN-Africa's main role therefore, will be to coordinate the implementation of the project, overseeing that the projects timely meets the set objectives in a cost effective manner; ensure that the project results framework is continuously monitored and facilitate any revision that may be required, In collaboration with the UNEP Task Manager oversee that the project meets the UNEP-GEF policies and procedures, facilitate the establishment of an effective network of stakeholders in LMO Detection and Biosafety regulatory chain in the participating countries, and lead in the reporting and accounting of resources to UNEP-GEF.

83. In country Focal Points will sign MOUs with the participating laboratories the participating LMO Detection laboratories in collaboration with the Biosafety Focal Points will form a national project Task team.

84. A Regional Steering Committee (RSC), made up of the National Biosafety Authorities of the participating countries, the UNEP Task Manager and the Executing Lead Agency - RAEIN-Africa will oversee the implementation of the project, receive periodic reports on progress, review progress and make recommendation to UNEP concerning any needed revision of the result framework and the Monitoring and evaluation plan. The RSC will meet annually to review project work plans, budgets and progress reports. The work of the Regional Project Steering Committee will be supported by National Project Taskforces in each participating country (see appendix 10). The institutional and implementation arrangements was conceptualised as shown in Figure 1 below

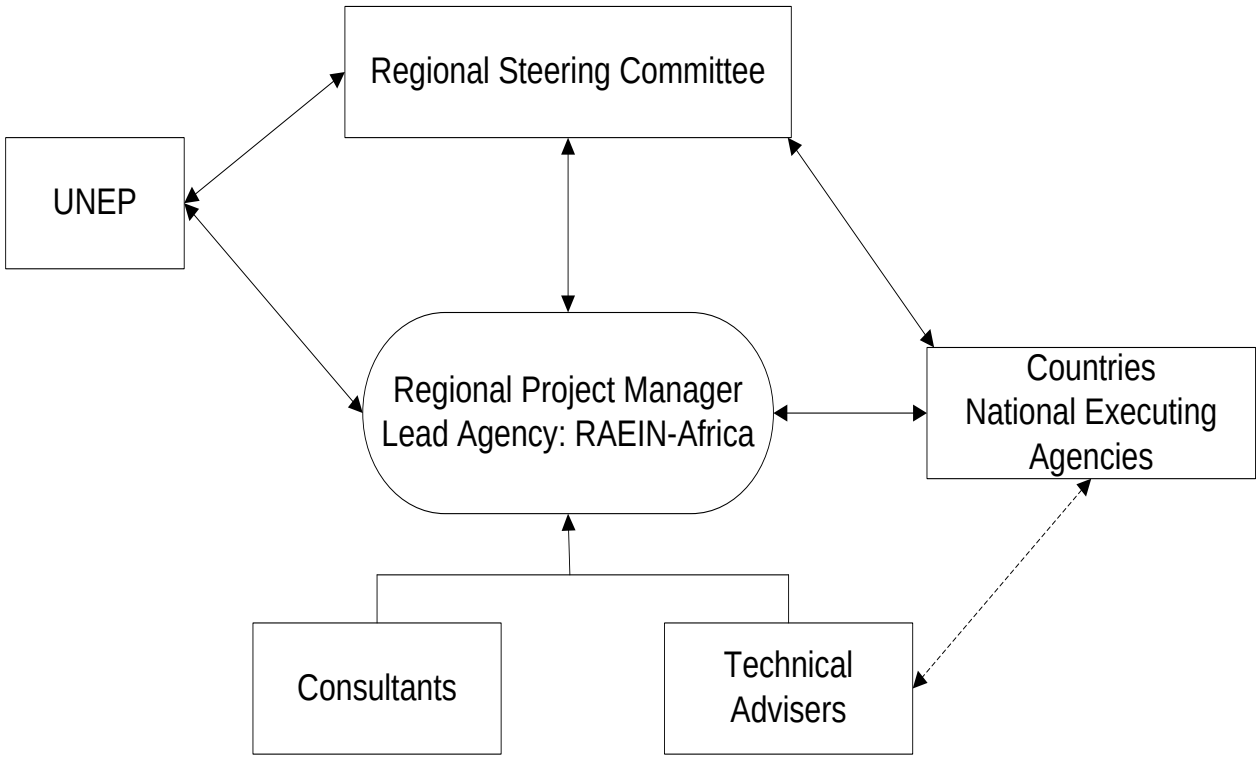

Figure 1: Institutional and Implementation Arrangements

The functions and responsibilities of the key project actors are outlined in the terms of reference and are captured as Appendix 11 of the project document.

Section 5: Stakeholder participation

85. Stakeholder engagements in this project will be guided by the need for successful fulfilment of the project goal; of ensuring effective implementation of the CPB thus, safe transfer, handling and use of LMOs. The project will promote effective participation of a broad range of stakeholders at national and regional levels in Biosafety regulatory chain including decision making. These include policy makers, regulatory agencies, testing laboratories, research and development organizations, training institutions, Boarder officials, civil society, the media and the consumers and producers at large. The needs assessment phase and stakeholder analysis done at the national level gave an indication of the various stakeholders that either participate in LMO detection and decision making or have a stake in the benefits and impacts of the project. Detailed national stakeholder mapping was planned for and was carried out with the participation of the broader representation at all levels. The analysis at the national level was used to identify potential stakeholders and is summarised as Table 7.

Table 7: Identified potential stakeholders in the participating countries of the LMO Detection for strengthening decision making project

Participating Country	**Sector**	**Specific stakeholder**
Angola	Government	Ministry of Agriculture and Rural Development, Ministry of

	Ministries	Environment , Ministry of Energy and Water Resources, Ministry of Fisheries, Ministry of Science and Technology, Ministry of External Relations Ministry of Health
	Academia & Research Institutes	Central Laboratory of Angola (CLA), Agostinho Neto University, Angolan Catholic University, National Institute for Fisheries Research, National Centre for Scientific Research, National Technological Centre Luanda Herbarium
	Regulatory agencies	National Institute for Nature Conservation, National Institute for Environmental Promotion, National Educational Development Institute, Directorate for Natural Resources, Directorate for the Environment Forest Development Institute, Environmental Protection Associations, National Centre for Phytogenetic Resources, National Museum for Natural History
DRC	Government Ministries	Ministry of Agriculture, Ministry of the Environment, Nature Conservation, Waters and Forests, Ministry of Scientific Research, Ministry of Rural Development Ministry of External Trade, Ministry of Industry and Small and Medium-Sized Enterprises
	Academia & Research Institutes	University of Kinshasa, University of Kasingani General Atomic Energy Commission / Regional Centre for Nuclear Studies Kinshasa (CGEA / CREN-K), Veterinary Laboratory of Kinshasa (VLK), National Natural Science Research Centre (CRSN-Lwiro), National Institute For Agronomic Study and Research (INERA), Agri-food Research Centre (CRAA) National Seed Service (SENASEM), Maize Research Centre (CRM), National Livestock Development Authority (ONDE), National Institute of Biomedical Research (INRB), Animal and Plant Quarantine Service
	Regulatory agencies	The Biosafety Focal Point, The National Biosafety Consultative Council, The National Competent Authority, The Technical and Scientific Committee The National Biosafety Clearing House
Lesotho	Government Ministries	Ministry of Tourism, Environment and Culture, Ministry of Agriculture and Food Security, Ministry of Health and Social Welfare, Ministry of Trade and Industry, Ministry of Communications Science and Technology, Ministry of Local Government and Chieftainship Affairs, Ministry of Education and Training, Ministry of Finance , Ministry of Development Planning
	Academia & Research Institutes	National University of Lesotho (NUL), Health Research and Laboratory Services, Agricultural Research
	Regulatory agencies	National Executive Agency - National Environment Secretariat, National Coordinating Authority (NCC) Focal Points, Competent Authorities, Scientific Advisory Committee, Socio-Economic Panel, Disaster Management Authority
Madagascar	Government Ministries	Ministry of Environment, Water, Forests and Tourism Ministry of Agriculture, Livestock and Fishing Ministry of Industrialization, Trade and Private Sector

		Development, Ministry of Health and Family Planning, Ministry of National Education and Scientific Research
	Academia & Research Institutes	Molecular Biology Laboratory - University of Antananarivo (MBL-UA), Environmental Laboratory of Microbiology (ELM), Environment National Research Center, Industrial and Technological National Research Center , Horticultural Technical Center of Antananarivo, Malagasy Institute of Applied Research Malagasy Institute of Veterinarian Vaccines Plant Protection Management Research Centers
	Regulatory agencies	National Office for Environment (CNA - Competent National Authority), The National Association for the Management of Protected Areas (ANGAP) (NEA), Biosafety National Committee, Scientific and Technical Committee, Official Service of Mixed Control, Standards Office of Madagascar, Office of Public Participation, Making Investments Compatible with the Environment, Control Unit of the Foodstuffs Quality
Malawi	Government Ministries	Ministry of Environmental Affairs, Ministry of Agriculture and Food Security, Ministry of Industry and Trade, Ministry of Health, Ministry of Local Government
	Academia & Research Institutes	Chitedze Agricultural Research Institute (CARI), Lilongwe University of Agriculture and Natural Resources (Bunda) Chancellor College, Central Veterinary Laboratories University of Malawi, University of Mzuzu, Natural Resources College, Forestry Research Institute of Malawi National Herbarium & Botanical Gardens, Mokoka Research Station, Bvumbwe Agricultural Research Station, Lunyangwa Agricultural Research Station
	Regulatory agencies	National Commission for Science and Technology (NCST), National Biotechnology Committee, Department of Environmental Affairs (EAD), National Biosafety Regulatory Committee (NBRC), Agricultural Biotechnology and Biosafety , Committee (ABBC), Biosafety Regulatory Authority of Malawi
Mozambique	Government Ministries	Ministry of Agriculture, Ministry of Health, Ministry of Coordination of Environment Affairs, Ministry of Industry and Trade, Ministry of Science and Technology, Ministry of Fisheries, Ministry of Finance/Customs
	Academia & Research Institutes	Biotechnology Centre of Eduardo Mondlane University (CB-UEM), Mozambique Research Institute Biotechnology Laboratory (MRIBL), Agriculture Research Institute of Mozambique (IIAM), National Institute for Disasters Management
	Regulatory agencies	National Biosafety Committee (NBC), National Biosafety Competent Authority (NBCA), National Biosafety Committee (NBC), Biosafety Technical Secretariat (BTS) National Biosafety Focal Point (NBFP), National Coordinating Committee, Biosafety Working Group, National Directorate of Agriculture, National Directorate for Livestock, National Directorate for Environment Impact Assessment, National Directorate for Environment , Management, National Directorate of Health, Department of Seeds

71. The findings of the in country stakeholder analysis was subjected to a regional validation review at a workshop. The stakeholder groups were further harmonised based on commonalities of function and envisaged potential roles both at the national and regional level and is captured as Table 8.

Table 8: Key Stakeholder groups and their envisaged role in the LMO testing for strengthening decision making in biosafety project

Stakeholder	Potential roles
Government Ministries (multi-sectoral) Ministries with the following portfolios participate in decision making: Environment; Agriculture and Food Security; Health; Trade and Industry and, Science and Technology	Involved in the Project Steering Committee, development of regulatory instruments and technical execution of project activities through designated agencies.
Academia (universities, Laboratories & research institutes)	Technical execution of the project, provide technical support in the development of operational manuals and delivery of training
Regulatory agencies	Development of monitoring and enforcement instruments and contribute capacity on regulatory oversight
Parastatals/NGOs	Supportive role to communities in terms of Public awareness creation, public education and advocacy on LMO detection, the usefulness of informed decision making processes and safe handling, transport and use of LMOs
Private sector and civil society	Involved in activities on public awareness and capacity building
Farmer Groups and Seed companies	Involved as end users of the technology and will be involved in knowledge sharing and distribution/handling of genetic material/seeds. In addition to be potential sources of information to the biosafety authorities on use of unauthorised germ plasm of seeds/on handling of genetic material/seeds, emergency or accidental releases or illegal transboundary movements
Regional Institutions (eg. SANbio)	Collaborative partnerships to link jointly review and add inputs to developed biotechnology and biosafety instruments to support policy direction. Support public awareness engagement on biotechnology innovation in a sound regulatory environment and uptake with outreach materials. Collaborate with RAEIIN-Africa to provide a platform to provide technical advice to SADC member states on Biotechnology and Biosafety.

72. The Key Stakeholders identified are the policy makers, regulatory agencies and the LMO testing laboratories. Farmers, civil society organizations, academia and the media will participate in project inception workshops at regional and country levels so they are aware of the project goals and, can input into decision making processes as provided for the CPB. These stakeholders can also participate in the review of progress and use the results of this project in their own programming.

Section 6: Monitoring and evaluation Plan

73. In-line with UNEP Evaluation Policy and the GEF's Monitoring and Evaluation Policy, the project will be subject to a Terminal Evaluation and, additionally, a Mid-Term Review will be commissioned and launched by the Task Manager before the project reaches its mid-point. If project is rated as being at risk, a Mid-Term Evaluation will be conducted by the Evaluation Office.

74. The Regional Steering Committee will participate in the MTR/MTE/TE and develop a management response to the evaluation recommendations along with an implementation plan. It is the responsibility of the UNEP Task Manager to monitor whether the agreed recommendations are being implemented.

75. The Evaluation Office will be responsible for the Terminal Evaluation (TE) and will liaise with the Task Manager and Executing Agency(ies) throughout the process. The TE will provide an independent assessment of project performance (in terms of relevance, effectiveness and efficiency), and determine the likelihood of impact and sustainability. It will have two primary purposes: (i) to provide evidence of results to meet accountability requirements, and (ii) to promote learning, feedback, and knowledge sharing through results and lessons learned among UNEP, the GEF, executing partners and other stakeholders. The direct costs of the evaluation will be charged against the project evaluation budget (see Appendix 7). The Terminal Evaluation will be initiated no earlier than six months prior to the operational completion of project activities and, if a follow-on phase of the project is envisaged, should be completed prior to completion of the project and the submission of the follow-on proposal. Terminal Evaluations must be initiated no later than six months after operational completion.

76. The draft TE report will be sent by the Evaluation Office to project stakeholders for comments. Formal comments on the report will be shared by the Evaluation Office in an open and transparent manner. The project performance will be assessed against standard evaluation criteria using a six point rating scheme. The final determination of project ratings will be made by the Evaluation Office when the report is finalised and further reviewed by the GEF Independent Evaluation Office upon submission. The evaluation report will be publically disclosed and may be followed by a recommendation compliance process.

77. The GEF tracking tools are attached as Appendix 15. These will be updated at mid-term and at the end of the project and will be made available to the GEF Secretariat along with the project PIR reports.

Monitoring Responsibilities and Events

78. At the first meeting of the Project Steering Committee (RSC), the Lead Agency shall present a full 48 month schedule including (i) tentative time frames for Steering Committee Meetings and meetings of the Project review and planning meetings and (ii) project related Monitoring and Evaluation activities.

Day to day monitoring of implementation progress will be the responsibility of the Lead Agency based on the Project's Annual Work Plan and its indicators. The Executing Lead Agency (ELA) will be the Project Coordinating Unit (PCU)[28]. Whilst the project will have a Project Manager, He/She will be contracted by the ELA hence, the ELA is responsible and accountable to UNEP-GEF and partner executing agencies. The Executing Lead Agency will inform UNEP and the partner executing agencies of any delays or difficulties faced during implementation so that the appropriate support or corrective measures can be adopted in a timely and remedial fashion. The PCU will fine-tune the progress and performance/impact indicators of the Project in consultation with the full Project team and with support from UNEP and the partner executing agencies. These indicators will be used to assess whether implementation is proceeding at the intended pace and in the right direction and will form part of the Annual Work Plan. Targets and indicators for the subsequent years will be defined as part of the internal evaluation and planning processes undertaken by the Project Team and will be approved by the Project Steering Committee.

Periodic monitoring of implementation progress will be undertaken by both UNEP and the partner executing agencies through the provision of half-yearly reports submitted by each. Furthermore, specific meetings can be scheduled between the Project Team, UNEP, the partner executing agencies and other pertinent stakeholders as deemed appropriate and relevant (e.g. Steering Committee members, Co-funding partners, etc). Such meetings will allow parties to troubleshoot any problems pertaining to the Project in a timely fashion and to ensure smooth implementation of project activities. A Report will be prepared by the Project Team in coordination with UNEP and the EAs, and circulated to the all RSC members, the EAs and Implementing partners and any accompanying stakeholders.

Project Monitoring Reporting

The Regional Project Manager in conjunction with the Project extended team (PMU staff, UNEP and the national task forces in partner executing agencies) will be responsible for the preparation and submission of the following reports that form part of the monitoring process. Items (a) through (e) are mandatory and strictly related to monitoring, while (f) through (g) have a broader function and the frequency and nature is project specific to be defined throughout implementation.

(a) Inception Report (IR)

A Project Inception Report will be prepared immediately following the first Regional Steering Committee meeting. It will include a detailed First Year Work Plan divided in quarterly time-frames detailing the activities and progress indicators that will guide implementation during the first year of the Project. This Work Plan will include the proposed dates for any visits and/or support missions from UNEP, ELA, Technical Advisers (TA), consultants, as well as time-frames for meetings of the RSC. The Report will also include the detailed project budget for the first full year of implementation, prepared on the basis of the Annual Work Plan, and including any monitoring and evaluation requirements to effectively measure project performance during the targeted 12 months' time-frame.

[28] In this project the ELA and PCU will be interchangeably used

The Inception Report will include a more detailed narrative on the institutional roles, responsibilities, coordinating actions and feedback mechanisms of project related partners. In addition, a section will be included on progress to date on project establishment and start-up activities and an update of any changed external conditions that may affect project implementation, including any unforeseen or newly arisen constraints.

When finalized, the report will be circulated to project counterparts who will be given a period of one calendar month in which to respond with comments or queries. Prior to this circulation of the IR, both UNEP and partner executing agencies will review the document.

(b) Half-yearly Progress Report, Annual Project Report and Project Implementation Review (PIR)

The Half-yearly Progress Report is a self-assessment report by project management to the UNEP Office and provides them with input to the reporting process as well as forming a key input to the Project Review undertaken by the Project Steering Committee.

The PIR is an annual monitoring process mandated by the GEF, to be conducted by the UNEP Project Manager in consultation with the partner executing agencies. It has become an essential monitoring tool for project managers and offers the main vehicle for extracting lessons from ongoing projects. In addition, UNEP Task Manager, based on the knowledge of the project progress, will submit to UNEP Evaluation Office an annual project report, which is a UNEP self-evaluation tool.

An Annual Project Report (APR) is prepared on an annual basis. The purpose of the Annual Project Report is to reflect progress achieved in meeting the project's Annual Work Plan and assess performance of the project in contributing to intended outcomes through outputs and partnership work. The Annual Project Report and Project Implementation Review (PIR) are discussed in the Project Steering Committee so that the resultant report represents a document that has been agreed upon by all of the primary stakeholders.

The items in the APR/PIR to be provided by to the UNEP GEF Task Manager include the following:

- An analysis of project performance over the reporting period, including outputs produced and, where possible, information on the status of the outcome;
- The constraints experienced in the progress towards results and the reasons for these;
- The three (at most) major constraints to achievement of results;
- Annual Work Plans and related expenditure reports;
- Lessons learned; and
- Clear recommendations for future orientation in addressing key problems in lack of progress.

UNEP analyses the Annual Project Report and Project Implementation Review for results and lessons. The Reports are also valuable for the Independent Evaluators who can utilize them to identify any changes in project structure, indicators, work plan, etc. and view a past history of delivery and assessment.

(c) Periodic Thematic Reports

As and when called for by UNEP or the EAs, the project team will prepare Specific Thematic Reports, focusing on specific issues or areas of activity. The request for Thematic Reports will be provided to the project team in written form by UNEP/NEAs and will clearly state the issue or activities that need to be reported on. These reports can be used as a form of lessons learnt exercise, specific oversight in key areas, or as troubleshooting exercises to evaluate and overcome obstacles

and difficulties encountered. UNEP and the LEA will endeavour to minimize their requests for Thematic Reports, and when such are necessary will allow reasonable timeframes for their preparation by the project team.

(d) Financial Monitoring

The LEA will monitor finacial cost effectiveness of the partner executing agencies and will will provide UNEP with quarterly financial reports as well as certified annual financial statements with an audit of the financial statements relating to the status of UNEP (including GEF) funds according to the established procedures to be set out in the project document. The Audit will be conducted by the legally recognized auditor, or by a commercial auditor.

(e) Project Terminal Report

During the last three months of the project the project team will prepare the Project Terminal Report. This comprehensive report will summarize all activities, achievements and outputs of the Project, lessons learnt, objectives met or not achieved structures and systems implemented, etc. and will be the definitive statement of the Project's activities during its lifetime. It will also lay out recommendations for any further steps that may need to be taken to ensure sustainability and replicability of the Project's activities.

(f) Technical Reports

Technical Reports are detailed documents covering specific areas of analysis or scientific specializations within the overall project. As part of the Inception Report, the project team will prepare a draft Reports List, detailing the technical reports that are expected to be prepared on key areas of activity during the course of the Project, and tentative due dates. Where necessary this Reports List will be revised and updated, and included in subsequent Annual Project Reports.

(g) Project Publications

Project Publications will form a key method of crystallizing and disseminating the results and achievements as part of the knowledge sharing strategy of the Project. These publications may be scientific or informational texts on the activities and achievements of the Project, in the form of journal articles, multimedia publications, etc. These publications can be based on Technical Reports, depending upon the relevance, scientific worth, etc. of these Reports, or may be summaries or compilations of a series of Technical Reports and other analyses. The project team will determine if any of the Technical Reports merit formal publication, and will also, in consultation with UNEP, the partner executing agencies and other relevant stakeholder groups, plan and produce these publications in a consistent and recognizable format. The publications will be cleared with UNEP and the partner executing agencies prior to publications. Project resources will allocated for these activities as appropriate and in a manner commensurate with the project's budget.

SECTION 7: PROJECT FINANCING AND BUDGET

7.1 Overall project budget

79. The Overall Project budget is divided into two main sections. The first appendix being the UNEP-GEF Funds, this comprises the Project budget to be funded by the UNEP-GEF. The second component of the budget is the Government and Partners Co-finance budget. A Total budget of US$3,860,000 is being requested from UNEP-GEF is shown below as Table 9.

Table 9: Summary of UNEP GEF Budget in US$ from year 1 to year 4

Narration	Year	Year	Year	Year	Total

	1	2	3	4	
10. Project Personnel Component	265,675.14	161,756.50	154,155.54	144,407.22	**725,994.40**
20. Sub-Contract component	1,563.28	1,563.28	1,563.28	1,563.28	**6253.12**
30. Training Component	605,973.84	249,668.84	255,726.34	213,856.34	**1,325,225.36**
40. Equipment and Premises	823,778	83,666	77,550	67,518	**1,052,512**
50. Miscellaneous Component	269,301.28	145,495.28	180,864.28	146,354.28	**750,015.12**
Total Costs	**1,966,291.54**	**642,149.90**	**677,859.44**	**573,699.12**	**3,860,000**

7.2. Project co-financing

80. The Government and Partners will contribute in kind co-finance to the Project a total amount of US$6,546,752 as per the Table 10 below.

Table 10 – Summary of the Co-finance budget.

2. Narration	Year 1	Year 2	Year 3	Year 4	Total
10. Project Personnel Component	519,463.28	519,463.28	519,463.28	519,463.28	**2,077,853.13**
20. Sub-Contract component	33,681.73	33,681.73	33,681.73	33,681.73	**134,726.91**
30. Training Component	294,246.50	294,246.50	294,246.50	294,246.50	**1,176,985.98**
40. Equipment and Premises	523,743.29	523,743.26	523,743.26	523,743.26	**2,094,973.07**
50. Miscellaneous Component	265,553.23	265,553.23	265,553.23	265,553.23	**1,062,212.91**
Total Costs	**1,636,688.02**	**1,636,687.99**	**1,636,687.99**	**1,636,687.99**	**6,546,752.00**

7.3. Project cost-effectiveness

81. The project is planned to ensure cost effectiveness. The project is systematically planned to ensure maximum return per dollar invested. Among the cost reduction actions will be:

1. A number of regional activities are planned back to back to reduce the costs
2. Planning and review meetings are to be held back to back with task force and regional project committee meetings.
3. Virtual meetings will be held where issues to be discussed can be handled instead of waiting for annual or bi annual planned meetings
4. In countries where other biosafety related projects are being implemented certain activities, e.g. awareness creation meetings will “piggy back” on the original plans of the other projects.
5. On human capacity building, training of trainers is implemented at regional level and the trained personnel will train others at national level
6. Non performing contracts and/or processes will be terminated.
7. Special service and maintenance contracts including installation training and periodic technical assessment of equipment will be developed and signed at the regional level as a joint activity to support the laboratories
8. Procurement of equipment and reagents will be done as a joint activity to maximize economies of scale and leveraging to support the national laboratories

APPENDICES