



## **Part I: Project Information**

### **GEF ID**

10584

### **Project Type**

FSP

### **Type of Trust Fund**

GET

### **CBIT/NGI**

**CBIT No**

**NGI No**

### **Project Title**

Strengthening the Implementation of National Biosafety Frameworks in Southern Africa (SINBF)

### **Countries**

Regional, Congo DR, Madagascar, Namibia

### **Agency(ies)**

UNEP

### **Other Executing Partner(s)**

Regional Agricultural and Environmental Innovations Africa (RAEIN-Africa), Ministry of Environment and Sustainable Development (CONGO DR); Ministry of Environment and Sustainable Development (MADAGASCAR); and the Biosafety Council of the National Commission on Research, Science and Technology of Namibia (NCRST), NAMIBIA)

### **Executing Partner Type**

Government

### **GEF Focal Area**

Biodiversity

### **Sector**

**Taxonomy**

Influencing models, Strengthen institutional capacity and decision-making, Transform policy and regulatory environments, Demonstrate innovative approaches, Stakeholders, Local Communities, Indigenous Peoples, Private Sector, Civil Society, Academia, Non-Governmental Organization, Trade Unions and Workers Unions, Community Based Organization, Beneficiaries

**Rio Markers****Climate Change Mitigation**

No Contribution 0

**Climate Change Adaptation**

No Contribution 0

**Biodiversity**

Principal Objective 2

**Land Degradation**

No Contribution 0

**Submission Date**

3/23/2020

**Expected Implementation Start**

11/1/2022

**Expected Completion Date**

10/31/2026

**Duration**

48in Months

**Agency Fee(\$)**

271,547.00

**A. FOCAL/NON-FOCAL AREA ELEMENTS**

<b>Objectives/Programs</b>	<b>Focal Area Outcomes</b>	<b>Trust Fund</b>	<b>GEF Amount(\$)</b>	<b>Co-Fin Amount(\$)</b>
BD-3-8	National implementation of the Cartagena Protocol on Biosafety and the Nagoya?Kuala Lumpur Supplementary Protocol on Liability and Redress is enhanced	GET	2,858,390.00	9,000,000.00
<b>Total Project Cost(\$)</b>			<b>2,858,390.00</b>	<b>9,000,000.00</b>

## B. Project description summary

### Project Objective

The project seeks to strengthen institutional, infrastructural, human & regulatory biosafety capacities of the Governments of Democratic Republic of Congo (DRC), Madagascar and Namibia in the implementation of NBFs in support of the CPB and (its) Nagoya-Kuala Lumpur Supplementary Protocol on Liability & Redress. The project will achieve this by (i) building on existing national biosafety baselines to strengthen regulatory, institutional, infrastructural and human capacities of the participating countries in the implementation of National Biosafety Frameworks (NBFs); (ii) Promoting cooperative measures in the implementation of NBFs across the three countries (iii) Stimulating regional dialogues on biosafety and effective cooperation on technical tools and relevant support for the safe use and transboundary movement of Living Modified Organisms (LMOs).

<b>Project Component</b>	<b>Financing Type</b>	<b>Expected Outcomes</b>	<b>Expected Outputs</b>	<b>Trust Fund</b>	<b>GEF Project Financing(\$ )</b>	<b>Confirmed Co-Financing(\$ )</b>
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Project Component	Financing Type	Expected Outcomes	Expected Outputs	Trust Fund	GEF Project Financing(\$)	Confirmed Co-Financing(\$)
I. Biosafety Policy and Regulatory Regime	Technical Assistance	1) National biosafety policies and regulatory regimes in DRC, Madagascar and Namibia consistent with the CPB and Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress strengthened and mainstreamed into national plans, national systems to permit effective evaluation, management and monitoring of LMO(s).	<p>i) Cooperation achieved to create capacity for review, update and alignment of biosafety laws and policies, guided by local context and in compliance with the CPB</p> <p>ii) Biosafety Governance regimes are put in place/ improved and aligned with the CPB and Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, legally mandated</p> <p>iii) Biosafety mainstreamed into relevant national sustainable development policies and strategies, including National Biodiversity Strategies and Action Plans (NBSAPs) and the Post 2020 GBF)</p>	GET	500,427.00	2,799,622.00

Project Component	Financing Type	Expected Outcomes	Expected Outputs	Trust Fund	GEF Project Financing(\$)	Confirmed Co-Financing(\$)
II. Strengthening Biosafety Institutional Systems	Technical Assistance	1) Biosafety institutional systems enhanced and strengthened for decision making	<p>i) Capacity of selected national experts, on implementation of biosafety institutional and thematic areas cooperatively enhanced</p> <p>ii) National biosafety administrative systems strengthened</p> <p>iii) Biosafety risk assessment and risk management systems strengthened</p> <p>iv) Capacity for biosafety socioeconomic considerations developed and/or strengthened</p> <p>v) Monitoring and enforcement systems for follow-up activities strengthened</p> <p>vi) Guidelines and technical tools on biosafety cooperatively developed, adapted and shared</p> <p>vii) Systems of public information, public awareness and public participation</p>	GET	1,619,556.00	3,000,000.00

Project Component	Financing Type	Expected Outcomes	Expected Outputs	Trust Fund	GEF Project Financing(\$)	Confirmed Co-Financing(\$)
III. Project Monitoring and Evaluation	Technical Assistance	Effective project monitoring, tracking and evaluation to meet agreed measurable outputs and indicators	<p>i) M&amp;E framework institutionalized and operationalized and Lessons learnt shared to influence biosafety at regional levels for impact continuity beyond the Project.</p> <p>ii) Mid Term and Terminal Evaluation Reports</p>	GET	595,485.00	2,750,378.00
<b>Sub Total (\$)</b>					<b>2,715,468.00</b>	<b>8,550,000.00</b>
<b>Project Management Cost (PMC)</b>						
			GET	142,922.00	450,000.00	
			<b>Sub Total(\$)</b>	<b>142,922.00</b>	<b>450,000.00</b>	
			<b>Total Project Cost(\$)</b>	<b>2,858,390.00</b>	<b>9,000,000.00</b>	

**Please provide justification**

Global concerns about the risks of LMOs led to adoption in 2000 of the Cartagena Protocol on Biosafety, which came into force in 2003. Since the adoptions of the Protocol, there have been many interventions particularly from the GEF to assist Parties develop and implement their National Biosafety Frameworks to enable Parties meet their obligations to the Protocol. The overall goal of this project is to assist the Democratic Republic of the Congo (DRC), Madagascar and Namibia to enhance and/or strengthen national capacities through cooperative facilitative mechanisms for the implementation of the Cartagena Protocol on Biosafety and have a workable and transparent national biosafety framework by 2026. In the project preparatory phase, the project reviewed the biosafety related policies and legislation in each of the participating countries and analyzing each

country's strategic focus on biosafety. The highlighted the strategic importance that biosafety issues are assuming in each country's National Biodiversity Strategy and Action Plan (NBSAP), other strategic policies and development plans have served as inputs into the design of the project. The project is therefore designed to help the participating countries to overall: a) Integrate biosafety into the national biotechnology strategies; b) Put in place a fully operational and responsive regulatory regime in line with their existing national laws and other international obligations; c) Establish an efficient national system for handling requests and decision-making; d) Put in place an effective national system for follow-up activities, namely monitoring, inspections and enforcement; and e) Establish an active national system for public awareness and participation. The project consists of three components. The first two, A and B are technical components whilst the third Component C is for project administration. The three components are as follows: Component A - Biosafety Regulatory Regimes and Policy; Component B - Biosafety institutional systems and Component C - Project Management, Monitoring and Evaluation. The envisaged results of the project in the three participating countries are enhanced, strengthened and operational National Biosafety Frameworks.



**C. Sources of Co-financing for the Project by name and by type**

<b>Sources of Co-financing</b>	<b>Name of Co-financier</b>	<b>Type of Co-financing</b>	<b>Investment Mobilized</b>	<b>Amount(\$)</b>
Recipient Country Government	National Commission on Research, Science and Technology, Namibia	Grant	Investment mobilized	1,000,000.00
Recipient Country Government	National Commission on Research, Science and Technology, Namibia	In-kind	Recurrent expenditures	2,000,000.00
Recipient Country Government	Ministry of Environment and Sustainable Development, Democratic Republic of Congo	In-kind	Recurrent expenditures	2,500,000.00
Recipient Country Government	Ministry of Environment and Sustainable Development, Madagascar	Grant	Investment mobilized	300,000.00
Recipient Country Government	Ministry of Environment and Sustainable Development, Madagascar	In-kind	Recurrent expenditures	2,200,000.00
Other	RAEIN-Africa	Grant	Investment mobilized	300,000.00
Other	RAEIN-Africa	In-kind	Recurrent expenditures	500,000.00
GEF Agency	UNEP	Grant	Investment mobilized	200,000.00
<b>Total Co-Financing(\$)</b>				<b>9,000,000.00</b>

**Describe how any "Investment Mobilized" was identified**

Project co-finance will be contributed by all project partners in the form of Grant and In-kind. The co-finance Grant are the contributions made by partners in the project when they pay actual cost related to the project, maintain the laboratory equipment, provide technical advice and support operational costs of laboratory and national biosafety administrative systems in the day to day operations of the project execution. In-kind contributions will support partners services and products to the project in order to facilitate the smooth implementation of the project, such as laboratory space, office space, project support staff costs. In-kind cost and the Grant for the project are summarized above.

**D. Trust Fund Resources Requested by Agency(ies), Country(ies), Focal Area and the Programming of Funds**

<b>Agency</b>	<b>Trust Fund</b>	<b>Country</b>	<b>Focal Area</b>	<b>Programming of Funds</b>	<b>Amount(\$)</b>	<b>Fee(\$)</b>	<b>Total(\$)</b>
UNEP	GET	Namibia	Biodiversity	BD STAR Allocation	1,100,000	104,500	1,204,500.00
UNEP	GET	Madagascar	Biodiversity	BD STAR Allocation	798,390	75,847	874,237.00
UNEP	GET	Congo DR	Biodiversity	BD STAR Allocation	960,000	91,200	1,051,200.00
<b>Total Grant Resources(\$)</b>					<b>2,858,390.00</b>	<b>271,547.00</b>	<b>3,129,937.00</b>

**E. Non Grant Instrument**

NON-GRANT INSTRUMENT at CEO Endorsement

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Includes Non grant instruments? **No**

Includes reflow to GEF? **No**

**F. Project Preparation Grant (PPG)**

PPG Required **true**

**PPG Amount (\$)**

93,490

**PPG Agency Fee (\$)**

8,882

<b>Agency</b>	<b>Trust Fund</b>	<b>Country</b>	<b>Focal Area</b>	<b>Programming of Funds</b>	<b>Amount(\$)</b>	<b>Fee(\$)</b>	<b>Total(\$)</b>
UNEP	GET	Namibia	Biodiversity	BD STAR Allocation	30,000	2,850	<b>32,850.00</b>
UNEP	GET	Madagascar	Biodiversity	BD STAR Allocation	23,490	2,232	<b>25,722.00</b>
UNEP	GET	Congo DR	Biodiversity	BD STAR Allocation	40,000	3,800	<b>43,800.00</b>
<b>Total Project Costs(\$)</b>					<b>93,490.00</b>	<b>8,882.00</b>	<b>102,372.00</b>

## Core Indicators

### Indicator 11 People benefiting from GEF-financed investments

	Number (Expected at PIF)	Number (Expected at CEO Endorsement)	Number (Achieved at MTR)	Number (Achieved at TE)
<b>Female</b>	1,000			
<b>Male</b>	2,000			
<b>Total</b>	3000	0	0	0

Provide additional explanation on targets, other methodologies used, and other focal area specifics (i.e., Aichi targets in BD) including justification where core indicator targets are not provided

The SINBF project belongs to the Biodiversity Focal Area Strategic Objective 3 Program 8 ? Further development of biodiversity policy and institutional frameworks through the implementation of the Cartagena Protocol on Biosafety is consistent with GEF?s strategy for financing Biosafety. The proposed project fits into the GEF 7 Biodiversity Focal Area as defined in the Biodiversity Strategy. The results and deliverables shall contribute to the new Post 2020 Global Biodiversity Framework especially Target 17 on Biosafety through safeguarding biodiversity, managing genetic resources and related benefits through sound science risk assessment, pre- and post- approval monitoring measures and engagement with the end users of genetic resources. It will also contribute to Targets 20 ? 21 by ensuring informed and prior consent or Advanced Inform Agreements in the handling of biological introductions, inclusion and transparency in decision making with clearly defined roles for indigenous and local communities. In addition, the Cartagena Protocol on Biosafety is an environmental safeguards framework instrument which ensures that Parties put in place interventions with scientifically sound risk analysis and detection processes that restore and safeguard ecosystem services The three participating countries, Democratic Republic of the Congo (DRC), Madagascar and Namibia, are rich in different ecosystems, species and varieties. The project, through its components, contributes directly to the implementation of the capacity building interventions outlined in the ?Framework and Action Plan for Capacity Building for Effective Implementation of the Cartagena Protocol on Biosafety (2011 - 2020)? and also fits into the post-2020 global biodiversity framework currently being finalised. The post 2020 global biodiversity framework builds on the Strategic Plan for Biodiversity 2011-2020 and sets out an ambitious plan to implement broad-based action to bring about a transformation in society?s relationship with biodiversity, ensuring that by 2050 the shared vision of ?living in harmony with nature? is fulfilled. The project is in line with Goals A and B of the Global Post 2020 Biodiversity Framework. The framework?s theory of change

assumes that transformative actions are taken to deploy solutions to reduce threats to biodiversity. Actions should ensure that biodiversity is used sustainably to meet people's needs. The Framework is complementary to and supportive of the 2030 Agenda for Sustainable Development. The SINBF objective will be synergistically contributing to the post 2020 global biodiversity framework's theory of change. The project is designed to build and complement the outcomes from other national, previous and/or existing or ongoing GEF supported interventions on implementation of NBFs in the southern Africa region. Furthermore, the SINBF will also contribute to ongoing work on the COMESA biotechnology/biosafety regional policy and the draft SADC Policy on transboundary movements for Living Modified Organisms. The project will create a platform for assessment and functioning of the intercountry approach to updating, reviewing and preparation of countries to implementation of the National biosafety frameworks. Lessons learnt from the project would be useful in both the development and implementation, of the COMESA and SADC biotechnology/biosafety policy in the region. The proposed project will assist the participating countries to implement the provisions of the Cartagena Protocol on Biosafety, including capacity-building related to risk assessment and risk management and pre- and post-approval monitoring and enforcement measures on the safe transfer, handling and use of living modified organisms. In line with the GEF 7 strategy on Biosafety, the project will have both a thematic and a coordinated approach to build on a common set of targets and opportunities for implementation of the national biosafety frameworks.

## **Part II. Project Justification**

### **1a. Project Description**

1a. Project Description. Elaborate on: 1) the global environmental and/or adaptation problems, root causes and barriers that need to be addressed (systems description); 2) the baseline scenario and any associated baseline projects; 3) the proposed alternative scenario with a brief description of expected outcomes and components of the project; 4) alignment with GEF focal area and/or Impact Program strategies; 5) incremental/additional cost reasoning and expected contributions from the baseline, the GEFTF, LDCF, SCCF, and co-financing; 6) global environmental benefits (GEFTF) and/or adaptation benefits (LDCF/SCCF); and 7) innovativeness, sustainability and potential for scaling up. ?

Advances in science and technology offer new products and new solutions which can, among others, come with new concern and new issues. The latter issues can however be addressed by regulations providing protection from potential harm while allowing the marketplace to optimize use of potential benefits by society. For example, the products of modern biotechnology, in particular genetically modified organisms (GMOs), have been subjected to close regulatory scrutiny. However, many countries are still in the early stages of developing or implementing regulatory systems for GMOs. Most of the countries are low-income ones, which are further constrained by limited resources and expertise.

The Southern African region has one of the highest levels of biodiversity in the world. Southern Africa has eight centres of plant diversity (hotspots; UNEP, 2008). This high level of diversity is because of the broad range of climates, geological, soil and landscape forms found in the region. However, many species and ecosystems have been found to be under threat of extinction. Products of modern biotechnology including Living Modified Organisms (LMOs) are considered an attractive source of effective innovations to contribute to food security, among others. In 2019, the 24th year of commercialization of biotech crops, over 190.4 million hectares across 29 countries, was under GM crops. By 2011, in the Southern African region, South Africa grows three Genetically modified commercial crops (maize, cotton and soya). There is intercountry movement of agricultural products in the region both through formal and informal trade. In addition to trade, frequent food relief and donations move grain and other living products from international and regional sources. About 70% of Southern Africa's population survives on agriculture for food, income and employment. Equally important for the livelihoods in Southern Africa is conservation and safe use of biological diversity.

The proposed project is focused on ensuring that biological diversity in Madagascar, Namibia and DRC is adequately protected from possible adverse effects of living modified organisms. Potential modern biotechnology threats are centered on national priorities and compounded by regional, political and economic agenda. The transboundary nature of ecosystems in the region, as well as transboundary trade in seed and agricultural commodities, both formal and informal, exacerbate the management of potential threats. The high fragility of biodiversity in the region's ecosystems is already under threat from intensification of production systems including commercial agricultural practices, increased

climatic variability, frequent encroachment into forest and other natural ecosystem areas, and increasing population densities.

The three participating countries, Democratic Republic of the Congo (DRC), Madagascar and Namibia, are rich in different ecosystems, species and varieties. For example, DRC is endowed with a variety of ecosystems and natural habitats with exceptional biological diversity that makes it one of the 17 mega-biodiverse countries in the world. With a forest cover of over 155 million hectares, the DRC represents about 10% of the world's and more than 47% of Africa's forests. DRC holds one of the main reserves of wildlife biodiversity in the world, consisting of more than 352 species of reptiles, 216 species of amphibians, 1,086 species of birds, 421 species of mammals, 5,220 species of butterflies, 1,596 species of aquatic invertebrates, of which 1,423 are freshwater and 183 marines, and 544 species of terrestrial invertebrates.

DRC's ichthyological (fish) fauna has about forty families representing more than 1,000 species, of which about 80% live in the river system and the rest in the lakes of the East. The country is also home to more genera of primates than any country in the world. Out of more than 50,000 plant species known in Africa, the DRC occupies the first place in local plant species. The national flora, of a remarkable originality, counts approximately 10,531 species, all the large groups combined including the algae: 249 species, the fungi (basidiomycetes): 582 species, the bryophytes: 154 species, the pteridophytes: 383 species, the spermatophytes: 9,142 species with 275 exotics. The DRC has five natural sites recognized as World Heritage, more than all the other African countries combined. The preservation of biodiversity in the DRC is above all ensured by the system of protected areas. It is therefore important to manage them in a sustainable manner so that they continue to play their role of preserving ecosystems and biodiversity. The Government's objective is to reach at least 15% of the territory covered by protected areas, compared to the current 13.5%.

Madagascar, being an island state, is well-known for its high concentration of endemic species (Myers et al., 2000; Goodman & Benstead, 2005). The recent discovery of many new taxa has renewed the focus on environmental conservation in Madagascar (Lourenço & Goodman, 2000). This endemism is not restricted to the specific level but includes genera, subfamilies and families for both fauna (Wilson & Reeder, 2005; Raherilalao & Goodman, 2011) and flora (Schatz, 2002; Callmander et al., 2011). Furthermore, Madagascar is one of the few countries with a high level of natural resource wealth. It is therefore essential for the country to consider its natural capital and to manage biodiversity rationally. Madagascar's ecosystems include many types of forests, savannah, steppes, rivers, lakes, wetlands, mangroves, drylands and reefs. Currently, these unique ecosystems are home to approximately 12,000 species of vascular plants (96% endemic), 700 species of ferns (47% endemic), 202 species of palms (96% endemic), 1,000 species of orchids (86% endemic), 398 species of reptiles (90% endemic), 284 species of amphibians (100% endemic), 282 species of birds (37% endemic), 159 species of fish (66% endemic), 112 species and subspecies of lemurs (100% endemic), 60 species of non-flying small mammals (92% endemic), 43 species of bats (73% endemic) and 13 species of carnivores (80% endemic)

Namibia, though mainly arid and semi-arid, has its unique biodiversity. Biodiversity in Namibia is shaped by a diverse range of factors including climate, topography, geology and human influence. As the most arid country south of the Sahara, limited rainfall and a high level of variability are perhaps the



key drivers of the unique biodiversity. Namibia is characterized by a steep south-west to north-east rainfall gradient. Despite its arid climate, Namibia holds a remarkable variety of habitats and ecosystems ranging from deserts (with less than 10 mm of rainfall per year) to subtropical wetlands, savannah and woodlands (with over 600 mm of rainfall per year) (Mendelsohn et al 2003). Namibia has one of the lowest population densities in the world; with a population of 2,540,905 inhabitants and a density of 3.0 people per square kilometre. The low population density therefore has low human impact on the environment (Namibia Statistics Agency, 2020). About 4 500 taxa within 195 families have been recorded inside Namibia's borders (Klaassen & Kwembeya, 2013), of which some 605 are endemic. Two of the global biodiversity hotspots are found in Namibia; the succulent Karoo ecosystem that constitutes a refuge for an exceptional level of succulent plant diversity, shaped by the winter rainfall and fog of the southern Namib Desert of which the large portion of its plants is endemic, and the rugged Namib Escarpment.

### **Threats, root causes and barriers**

The project preparatory phase highlighted the limited development, establishment and implementation of the of national biosafety frameworks that respond to the obligation of the CPB. Furthermore, biosafety activities are limited in the three participating countries. The study identified limited: institutional and human capacity, awareness of the importance of biosafety for sustainable development in general and lack of prioritization of biosafety as general barriers hindering the development and/or full implementation of national biosafety frameworks.

Further analysis identified root causes for the lack of functional national biosafety systems in the three countries as: (i) Lack of clear strategic focus and prioritization of biosafety issues by legislature; (ii) Inadequate biosafety legal regimes to support establishment of the national biosafety frameworks; (iii) Inadequate administrative and institutional frameworks supported by law; (iv) Inadequate human and institutional capacities and resources of national systems to assist in the development and/or implementation of the biosafety regulatory regimes; (v) Limited guidance on possible strategic, legal and technical issues required to refine and operationalize national biosafety systems; (vi) Limited awareness across the relevant biosafety chain actors and other stakeholders; and (vii) Limited engagement and cooperation within the region on transboundary movement of LMOs.

The proposed project interventions are guided by the above root causes. The national stocktaking exercises further clearly identified the following barriers as those limiting the implementation of the CPB:

### **Low prioritization of biosafety issues among policy makers and legislators, mainly due to lack of awareness on the importance of biosafety and its implications on sustainable development**

There is limited awareness among senior government officials, and policy and lawmakers on the importance of biotechnology and biosafety in national plans on sustainable development. This is the situation in most developing countries and is mainly because biosafety is relatively new area. Although earlier investments by UNEP-GEF, other bilateral development partners and the national governments

created some level of awareness for these decision makers, the frequent government changes and movement of legislators and policy makers necessitates continued efforts for awareness and lobbying among this vital group of biosafety chain actors. The lack of biosafety awareness makes the high-level government officials accord very low priority to biosafety, making biosafety draft laws take long to be included in parliamentary agenda.

### **Lack of/ or inadequate biosafety laws to support institutional and administrative frameworks**

Regulatory regimes form the legal basis to administer and safely manage LMOs. The absence of regulatory regimes, or lack of full alignment of regulatory regimes with CPB and its Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety is a barrier to the establishment and full implementation of institutional and administrative frameworks for NBFs. Madagascar and Namibia benefited from earlier GEF supported project that facilitated development of their draft legal frameworks as early as 2003 and 2004 respectively and later received support for implementation. Whilst Namibia approved a biosafety Law in 2006, Madagascar like many other Developing countries experienced multiple changes in Government administrative systems requiring awareness creation and mobilization for promotion of parliamentary debates and approval of their legislation. Despite these setbacks, Madagascar, has a draft framework which needs to be approved, according to Madagascar's prevailing legislation framework and needs to be supported by a law, implementing regulations and technical guidelines. A preliminary draft law on the biosafety regime (2004), based on the African Union Model Law, has long been under development, remaining at the conceptual level within the Ministry of Environment and Sustainable Development (MEDD). The main impediment is the absence of a legal instrument with clarity on institutional roles in implementation of the NBF, as well as on the financial aspects that would allow the biosafety bodies to be operational. Of the three participating countries, the Democratic Republic of the Congo did not have the opportunity to implement the national biosafety framework project supported by UNEP-GEF but took part in only the development and BCH projects. The draft biosafety bill has not been prioritized by the legislators for debate and enactment. The draft biosafety laws of DRC and Madagascar need to be finalized and translated into functional biosafety laws. The laws also require further regulations to operationalize handling of applications for field trials and commercialization. Operationalization, mentoring and sharing of experiences will create good entry points for cooperation and development of national regulations and facilitating technical tools which can be replicated and taken on board as cases of interest by Regional Economic Communities, including COMESA (DRC and Madagascar are member States) and SADC (Namibia, DRC and Madagascar are member States). Namibia has a Biosafety Act (2006), which lacks provisions on Liability and Redress, in line with the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress, full alignment with the CPB and the new trends in biotechnology and biosafety. Thus, the Namibian law needs to be reviewed and updated. The Act also needs implementing regulations and technical guidelines to allow for review and decision making on multi-event/trait applications, field trials and potential releases into the environment. All three countries do not have implementing regulations on Liability and Redress. The regulatory instruments developed will support pre- and post-approval measures to support biosafety decision making on field trials and deliberate release in the environment and onto the markets.

Whilst the review and update of the biosafety legal frameworks and policy across the three countries requires an informed participation by the legislators and policy makers, awareness at this level of decision makers is limited. Sensitization of members of the relevant legislature, including Parliamentary Committees, in DRC and Madagascar is crucial. The legislators and policy makers' awareness on national and international obligations of their countries arising from the CPB, and the implications of having functional and effective NBFs, including role of biosafety in sustainable development plans (plans for sustainable use and conservation of biodiversity, free trade, in which seeds and agricultural commodities move more or less freely across borders) will influence their prioritisation of biosafety issues. Furthermore, creating awareness at the highest levels will raise the profile of biosafety in these countries and motivate their national parliaments to debate, improve and enact the draft bills by parliament, to ensure their countries have functional biosafety laws and the other benefits that come with the passing and operationalization of national laws (personnel, budget and equipment to implement provisions of the law).

#### **Lack of fully functional technical, administrative and institutional frameworks supported by law**

A functional biosafety system relies on an institutional and administrative framework that can receive, review and process applications. Institutional and administrative frameworks are set up by a regulatory regime, which forms the legal basis for regulating LMOs. The administrative structure needs to have an established framework for scientifically assessing potential risks and recommending risk management practices, with clearly defined permit conditions. The permit conditions need to allow for pre- and post-approval monitoring, for compliance and enforcement in the decision-making processes and are supported by a clearly defined regulatory framework.

Whilst, from earlier UNEP-GEF supported projects, the participating countries developed some capacity to build the required institutions, these have either not been established due to lack of supporting laws which would otherwise define the institutional arrangements and their coordination mechanisms (DRC and Madagascar) or were established but lack continued human capacity development and experience in the implementation of biosafety (Namibia). DRC and Madagascar only have 'interim' measures but no functional laws to back decision making. All three countries are yet to undertake confined field trials, which would give hands-on experience in managing limited releases into the environment, thereby testing the tools developed. Namibia has however handled applications for food, feed and processing and will act as a good mentor and would bring in experience in the thematic cooperative processes. Namibia envisages potential applications for confined field trials and will need to update its capacity. In addition, the absence of coordinating mechanisms that allow relevant stakeholder inputs tend to limit the 'buy in' and urgency with which decisions are accepted by end users and integrated into national plans and priorities, including local mobilization financial resources.

#### **Inadequate human resource, institutional and technological capacities in biosafety**

Inadequate relevant human resource across the three countries is a barrier to supporting the development and implementation of NBFs. The required human resource capacities are varied, as biosafety is a multi-disciplinary, multi-institutional discipline. The participating countries indicated relative head count of human resources in relevant disciplines. However, most of available national

human resource requires technical support and hands-on experience in the technical and administrative skills relevant for building a cohesive pool and enabling participation in administrative and in biosafety decision-making structures. Addressing the human resource barrier, working with a diverse range of developmental, socio-technical and technological conditions, will enrich the learning process. Biosafety knowledge mapping will enable tailored solutions adapted to country-specific social, political, environmental and developmental situations. Hence, considering that Namibia is a transit country, DRC a landlocked country and Madagascar an island state, addressing human resource barriers in an intercountry project will develop and/or translate the varied NBFs into practical, workable and sustainable systems from which countries with similar contexts can learn. The intercountry approach to capacity development will serve to augment the knowledge base for processes of implementing multilateral environmental agreements.

### **Limited technical tools and guidance for the implementation of biosafety regulatory framework and information on best practices**

For most countries, the establishment and implementation of biosafety frameworks would benefit from guidance and tools (model regulations, procedures, guidelines, Standard Operating Procedures (SOPs) and toolkits) provided by regional and international experts. Regional efforts such as the African Union (AU) Biosafety Policy, Biosafety Strategy and the Biosafety Model Law provide useful guidance for countries that wish to adopt them, either in full or in part. However, these are not legally binding instruments/ treaties. Furthermore, guidance documents and tool kits for biosafety (risk assessment, standards for shipment of LMOs, liability and redress), developed at international level, are useful starting points for countries that are yet to implement NBFs. The absence of adapted guidance documents at sub regional levels that would have taken into account sub regional contexts, presents challenges for countries with limited capacity to adapt the tools in response to national social, political, environmental and developmental contexts. The barrier is compounded by the limited efforts at sub regional levels (Regional Economic Communities (RECs) level e.g., SADC) to develop, adapt, and/or harmonize tools and guidance documents. The absence of model regulations, procedures, guidelines, Standard Operating Procedures (SOPs) and toolkits has impacted negatively on the quest of Parties to develop, coordinate and implement the transboundary measures to support biosafety regulatory process. In addition, the absence of monitoring and compliance tools or the required skills to guide decision making, impacts negatively at the borders where transboundary movement of LMOs are likely to occur.

### **Limited sharing of information and participation across the relevant biosafety chain actors and other stakeholders in biosafety activities.**

Even though the CPB is a transboundary instrument, interventions are mainly Party-based because decision making is at the national level. This has led to very little awareness and limited inter Party cooperation among Parties within regions or regional economic blocks. Although the BCH serves as a platform for Parties to cooperate, to share experiences and best practices to support decision makers or to give regulatory guidance to end users of the technology, there is limited awareness of, and use of the platform. Despite the investments by UNEP-GEF and other actors across all three countries on the use of BCH, there is limited participation on the platform. Lack of awareness on biosafety and sources of information on biosafety, is a barrier to information sharing, informed decision making and

engagement throughout the implementation of the CPB by Parties. The lack of awareness on biosafety and related information platforms, has also led to limited dialogue at the regional level for cooperation and/or guidance on technical tools and guidelines for the implementation of the CPB. This limited inertia has led to trade and unscientific barriers on LMOs, mainly due to lack of knowledge through limited technical and scientific cooperation among countries. The lack of awareness also partly contributes to the slow establishment and implementation of the national biosafety systems and limited national activities on biosafety, as relevant stakeholders, who could have catalyzed the processes, do not participate in biosafety dialogues and are not fully aware of the importance of biosafety in sustainable development.

### **Limited engagement across countries in the region to share information on biosafety to facilitate transboundary movement of LMOs**

The SADC region has had limited discussions on biosafety, as evidenced by the development of a SADC harmonised seed regulation system which is silent on biosafety. Countries within the region formally and informally share seeds and other agricultural commodities as there are common trade areas across countries, shared cultures and intermarriages across the borders, and cross border migration. There are currently limited sub regional efforts to create a common understanding on movements of LMOs across the region. In addition, there is a limited sub-regional platform for information and experience sharing on biosafety which limits the efficiency of management of transboundary of LMOs. Given that Namibia is a transit country, DRC is almost landlocked (with a small strip of coastal land) and Madagascar is an island, an intercountry project will create learning experiences for the SADC region as well as for many developing countries.

### **Institutional, sectoral and policy context**

The objective of this project is to enhance and strengthen national capacities of the three countries through cooperative facilitative mechanisms for the implementation of the Cartagena Protocol on Biosafety. All the participating countries are Parties to the Cartagena Protocol on Biosafety (CPB) are therefore obliged to implement its provisions through national law.

The preparatory phase of the project reviewed the biosafety related policies and legislation in each of the participating countries and analyzing each country's strategic focus on biosafety. An assessment of the positioning of biosafety and biodiversity conservation goals, priorities and targets in national sustainable development goals and plans was also carried out. The assessment sought to highlight the strategic importance that biosafety issues are assuming in each country's National Biodiversity Strategy and Action Plan (NBSAP), other strategic policies and development plans. The review confirmed that of the participating countries, only Namibia currently has an NBF, which however has not been fully operationalized. There are, interim measures available in each country, which provide the basis for some decision making to be undertaken. DRC and Madagascar have some elements in their draft National Biosafety Framework.

The political and legal will to ensure conservation and sustainable use of Biodiversity is entrenched in the Constitution and the Environment Protection Law (No. 009/2011) and the draft Biosafety Bill in the Democratic Republic of Congo. Whilst the law does not deal directly with biosafety, chapter 6 gives

some basic legal guidance for the management of Genetically Modified Organisms in the Democratic Republic of Congo, until the draft Biosafety Bill developed by the Government is passed by Parliament as a Biosafety Act and promulgated by the President of the Republic. 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. NBSAP of the Democratic Republic of the Congo includes: - a specific objective on Biosafety, which aimed at having a fully operational NBF by 2018. Through UNEP-GEF Project on the "Development of National Biosafety Framework", 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 food, animal feed or processed product or whether a product is derived from genetically modified organisms. The draft bill also provides for the institutional arrangements of the National Biosafety Framework. Other relevant legislation including Law No. 73-009 of 5 January 1973: which 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. 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

Biosafety National Policy and Structure in Madagascar's (2004) objective 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. The country is yet to develop implementing regulations and technical guidelines to support decision making. Public awareness has been initiated but further work to engage relevant stakeholders including parliamentarian committees and other decision makers to influence the enactment process of the draft bill, women, youth is needed to assist in operationalizing the Malagasy framework including Decree no. 2018-397. Madagascar's draft bill provides from the draft rules and procedures of use, and safe handling of Living Modified Organisms, and for Risk Assessment methods and Risk Management for LMOs, institutional arrangements for their management as well as the procedures for the import, export, transit and marketing of LMOs. The bill, if passed into law will regulate 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 (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. Objective 4 focuses on risk reduction (biotechnology development and biosafety) with emphasis on- reduction to the risks to agrobiodiversity identifies the following relevant actions to be achieved in the short-medium term: the development of a national biotechnology policy, minimization of the risks arising from the use of biotechnology and enhancing knowledge on GMOs.

Namibia has a biotechnology policy which has specific provisions and actions to support the implementation of the Cartagena Protocol on Biosafety. Namibia through both national, bilateral and GEF support enacted a Biosafety Act in 2006. There is the need for additional implementing regulations including Liability and Redress clauses, operating guidelines and toolkits to make the framework fully functional.

All the participating 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. Namibia has a National Biosafety Council under the National Commission on Research, Science and Technology with a supportive Biosafety Act 2006 law. Whilst the structures of the NBF are in place, they are not fully operationalized. Madagascar and Democratic Republic of Congo have interim measures under the umbrella national laws on Environment Management and temporary national biosafety committees without the institutional framework to be fully operational. All countries are yet to have the critical mass of fully trained experts and designated Biosafety regulatory officials to support national Biosafety decision makers especially on risk assessment/risk management, monitoring, inspection and enforcement at the Borders, the marketplace, and deliberate releases to the environment.

The three countries do not have liability and redress provisions or specific biosafety measures to support transit, border and port handling of shipments or consignments containing Living Modified Organisms. This is a key area where the countries can share expertise and experience in institutional capacity building. The GEF support can be harnessed in the delivery of these interventions ensuring that each introduction of an LMO have regulatory, technical and cooperative measures that inform biosafety decision making.

Cooperative measures in the development and implementation of NBFs is increasingly becoming a strategic priority. It allows for countries to go beyond their national boundaries in their implementation of NBFs and is in line with the GEF 7 Focal Area strategy on Implementation of the Cartagena Protocol on Biosafety. The proposed project also intends to contribute to ongoing work on the COMESA biotechnology/ biosafety regional policy and the Draft SADC Policy on transboundary movements for living modified organisms. It intends to create a platform for assessment and testing of

the process and lessons learnt in both the development and implementation to date of the COMESA and SADC biotechnology/Biosafety policy.

The project will address the capacity building needs of the three countries to catalyze the enactment of biosafety laws in Madagascar and DRC and implementation of NBFs in all the three countries. Specifically, the project will develop capacities in a cooperative manner to drive national processes to evaluate and strengthen the legal and regulatory frameworks, prioritize biosafety and facilitate the inclusion of biosafety in national sustainable development plans, to carry out risk assessments with appropriate scientific and technical skills; to implement necessary activities for risk management; to setup mechanisms for monitoring and enforcement for implementation and follow-ups and develop infrastructure for information exchange and data management, as well as achieve broad participation of actors in biosafety matters. The development of national capacities in a cooperative manner in these areas will help consolidate the sharing of experiences, strengthening of each other's NBFs and setting practical experiences and cases for the region at large. The project is expected to snowball into other regional dialogues and prioritization of cooperative approach to implementation of the CPB, with impact on the vision of SADC countries to safely handle and use utilize biotechnology for sustainable development and economic growth.

The three participating countries have different implementation levels of their NBFs, mainly developed through support from UNEP-GEF and national governments. Namibia has an NBF in place, which includes the biosafety policy, a regulatory regime, systems for handling applications, inspection and monitoring, and public participation and awareness. However, the Namibian NBF is not fully operational, and requires reviewing and updating. Madagascar has a national policy on biosafety, some legislative and regulatory texts on the establishment of various biosafety bodies, LMO testing facilities and other fundamental components of its NBF. Madagascar requires support to review, update, fully establish and implement its NBF. Furthest in the establishment of an NBF is DRC, which has a draft bill and LMO testing facilities among other fundamental components of its NBF. Therefore, DRC needs support to have their draft biosafety bill revised, updated, and passed into law, and in the development of other NBF components. In all the three countries, biosafety regulatory regimes (laws or draft bills) are not fully aligned with the CPB and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress and are not integrated into national development plans and priorities for sustainable development. Hence, laws or draft bills in all the three countries require review and updating. Through participation in UNEP-GEF funded projects, the three countries have accrued varied experiences in the development and implementation of the various NBF components. Thus, targeted cooperative activities in the proposed project will support equitable and sustainable development of their various NBFs.

The three countries do not have provisions /specific biosafety measures to support transit, border and port handling of shipments/ consignments containing LMOs. All three countries have biosafety provisions in their NBSAPs at varied levels. These need to be strengthened. Furthermore, the fragmented pieces of legislation, environmental policies and plans have to be integrated into biodiversity conservation. There is limited link of biosafety to national resources for sustainable implementation of NBFs. The project countries are at varied levels of development and implementation of institutional structures and thus can share expertise and experiences on institutional capacity



building. In the three countries, personnel experienced and skilled in specific biosafety issues are few. Thus, through an intercountry approach, human resources can be shared, resulting in efficient resource management.

There have been several interventions by both the UN and other development agencies and Governments to support biosafety capacity building at national levels. The proposed project will add value to ongoing and/or just concluded UNEP/GEF projects on implementation of NBFs in the southern Africa region. Associated baseline projects include: (i) The UNEP-GEF Global Umbrella Project on "Development of National Biosafety Frameworks" ? Madagascar and the Democratic Republic of Congo developed their Draft National Biosafety Frameworks in 2003 and 2007 respectively; (ii) Implementation of National Biosafety Framework for Madagascar, 2011 - 2017. Further efforts are needed on supplementary regulatory instruments and institutional capacity on thematic issues, including Risk Assessment, Monitoring and Enforcement, Border Controls and Transit Measures; (iii) Implementation of Biosafety Act 2006 - 2017 (Namibia). The National Biosafety Council in Namibia, through its program of work, is attempting to develop additional regulatory and technical instruments to support decision making at limited pace as a national intervention. Further interventions are needed to review and update the policy and regulatory framework with supplementary regulations and to issue specific interventions for field trials and environmental release, including Risk Assessment, Monitoring and Enforcement; (iv) The UNEP-GEF Biosafety Clearing House Phase III Project - Democratic Republic of Congo and Namibia - the Project is ongoing; (v) The Multi Country Project to Strengthen Institutional Capacities on LMO Testing in support of national decision making (MCP-ICLT) in which two of the participating countries are (DRC, Madagascar) are beneficiaries. The Regional Agricultural and Environmental Innovations Network-Africa (RAEIN-Africa) has been instrumental in assisting countries in the SADC region to develop capacity for implementing NBFs. RAEIN-Africa is the Lead Executing Agency (LEA) of the MCP-ICLT. The MCP-ICLT focuses on building capacity on LMO testing to strengthen science-based decision-making systems. Due to the overlap between the MCP-ICLT and SINBF projects, the later project does not allocate resources to laboratory infrastructure capacity building in the MCP-ICLT countries (Madagascar and DRC). The SINBF will add value to benefits accrued from earlier UNEP-GEF investments. Apart from harmonization of LMO testing protocols across the three participating countries, additional LMO testing capacity building activities in the proposed project will be allocated to Namibia. Furthermore, the SINBF will also contribute to ongoing work on the COMESA biotechnology/ biosafety regional policy and the Draft SADC Policy on transboundary movements for Living Modified Organisms. The project will create a platform for assessment and testing of the intercountry approach to updating, reviewing and preparation of countries to implementation of the National biosafety frameworks. Lessons learnt from the project would be useful in both the development and implementation, of the COMESA and SADC biotechnology/Biosafety policy in the region. The need to develop and implement a long-term strategic framework for capacity building beyond 2020 was decided on at the COP14/MOP9 meeting in Egypt. Cooperative measures in the development and implementation of NBFs are increasingly becoming a strategic priority. It allows for countries to go beyond their national boundaries in their implementation of NBFs and is in line with the GEF 7 Focal Area strategy on Implementation of the Cartagena Protocol on Biosafety.

#### **Incremental/additional cost reasoning and expected contributions from the baseline**

The three participating countries have not fully met Parties' obligations under the CPB, although progress towards biosafety implementation has been achieved through several funding cycles from UNEP-GEF. DRC's draft bill on biosafety (2008) is still pending in parliament. Thus, the NBF was never completed and is not ready for implementation. The Madagascar draft bill was reviewed and is awaiting enactment. Other components of the Madagascar NBF; regulations, guidelines, supporting documents, are not fully in place. In addition, the biosafety implementation institutions require clarification of roles through legal mandates. Unlike the other two countries, Namibia has biosafety a Biosafety Act (2006), regulations, guidelines and administrative structures, including the biosafety council committees in place. However, these have not been fully operationalized. Therefore, common to all the three Parties is the inability to implement NBFs due to lack of comprehensive regulatory frameworks, limited human resources and capacity for biosafety implementation, limited biotechnology expertise and activities at the local level, lack of technical tools and guideline documents, and absence of/ inadequate support mechanisms (infrastructure, funding, political support and awareness on the need for biosafety).

Without GEF Support, the project countries will have limited access to technical support and the necessary resources to build effective institutional and regulatory capacities for handling and use of LMOs. The three participating countries will not be able to manage and scientifically assess potential risks and socio-economic impacts of LMOs or the movements of LMOs across the region.

With GEF support, through the SINBF project, incremental financial resources will enable translation of draft biosafety laws and associated implementation frameworks, including clearly defined roles and responsibilities. The GEF support will allow for review and update of NBFs, including bills and other legislations, to facilitate functional and operational biosafety frameworks with clearly defined entry points for applications, risk assessment and risk management, public engagement, informed decision making and the follow-up measures for approved permits. The project will provide the technical and additional financial resources for institutional and human capacity building for the relevant biosafety chain actors. The project will also empower frontline staff in handling transboundary movements of LMOs. The SINBF project will harness the results of the ongoing 'Multi country LMO Testing project' to enhance capacities on Monitoring and Enforcement to support pre- and post-approval follow-up measures and compliance. The SINBF project's communication strategies will facilitate harnessing of relevant expertise in engaging the diverse stakeholders on the benefits and potential risks of LMOs through clearly defined communication platforms that utilize both modern and traditional channels of communication.

The initial stocktaking assessment, undertaken during the PPG, identified coordination of biosafety frameworks, interchange of regional expertise, and capacity building on priority thematic areas in the implementation of NBFs, as common intervention needs. At the SADC regional level there has been limited cooperative work on biosafety issues. The CPB Article 14, Paragraph 1, states that 'Parties may enter into bilateral, regional and multilateral agreements regarding intentional transboundary movements of LMOs, consistent with the objectives of the Protocol and provided that such agreements and arrangements do not result in lower level of protection than provided for by the Protocol'. Considering the number of years from ratification to date, the implementation of the CPB has been slow across the region. Some countries raise unscientific reasons as barriers to making decisions on

transboundary movement of LMOs. Efforts such as the COMESA policies on movement of goods and services have not been directly used in decisions on transboundary movement of LMOs. The SINBF project will facilitate cooperation among partner countries on sharing of resources and technical support for further development of NBFs and on effective biosafety implementation. Intercountry cooperation will include a platform for experience sharing and peer-to-peer learning and collaboration on common needs and capacity building activities and technical backstopping on relevant thematic biosafety issues, targeted at national core teams that will be selected to lead in establishment and/ or in supporting the biosafety institutional systems. All three countries will be supported with the relevant knowledge, skills, guidelines, and tools, based on national baseline contexts, while learning from experiences of others and supported by a cooperatively established technical advisory committee.

The SINBF project will contribute to development of core national teams of experts and establishment of relevant national infrastructure and institutional capacities through sharing of resources and experiences. The development of validated criteria, tools, methods, learning experiences and relevant local information on biosafety will be documented as lessons and disseminated for reference on the various regional trade settings, port handling and transit, landlocked, island state

**The proposed alternative scenario with a brief description of expected outcomes and components of the project**

The envisaged project interventions will contribute to the conservation and sustainable use of Biological Diversity from any adverse effects of living modified organisms. The project will strengthen institutional, infrastructural, human and regulatory biosafety capacities of the participating countries in the implementation of National Biosafety Frameworks (NBFs) in alignment with the Cartagena Protocol on Biosafety and (its) Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress. The aim is to provide a more coherent, coordinated and effective delivery of biosafety capacity building and technical support at all levels, in response to identified country gaps/priorities and needs. The project will also develop coherent partnerships across the three participating countries for continued and sustainable sharing of biosafety resources, expertise, information and experiences aimed at strengthening implementation of the CPB. The project countries are at varied levels of the development and implementation of the five pillars of NBFs. Thus, cross-country lessons will contribute to partners strengthening each other on relevant NBF pillars. In addition, the project will form a nucleus for catalysing a regional approach to biosafety, as project experiences and outcomes will be shared with other SADC countries and the relevant regional structures. Involvement of the SADC in the intercountry project interventions will be aimed at triggering action towards future effective cooperation, especially on technical tools across the region. The project will focus on gaps and needs identified by the project preparatory phase, across the following five pillars of the NBFs:

- a) Biosafety policy,
- b) Regulatory regime (national laws, regulations and guidelines),

- c) Institutional setups (administrative systems for handling notifications or requests for authorization for imports, exports, transit, transport, handling, contained use, release into the environment, and/or placing on the market, and risk assessment and risk management setups),
- d) Mechanism for enforcement and monitoring (for effects on the environment or on human and animal health), and
- e) Mechanisms for promoting and facilitating public participation, education and awareness.

### **Project Objectives**

The SINBF **project goal** is to contribute to adequate protection of biological diversity in the participating countries from any adverse effects of living modified organisms (LMOs). The **intended impact** of the project is the global environmental benefit to which it contributes through enhanced conservation and sustainable use of biological diversity. The **project purpose** is to strengthen National Biosafety Frameworks (NBFs) in DRC, Madagascar and Namibia in support of the Cartagena Protocol on Biosafety and (its) Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.

### **Project Objectives:**

The project seeks to strengthen institutional, infrastructural, human & regulatory biosafety capacities of the Governments of Democratic Republic of Congo (DRC), Madagascar and Namibia in the implementation of NBFs in support of the CPB and (its) Nagoya-Kuala Lumpur Supplementary Protocol on Liability & Redress.

The project will achieve this by (i) building on existing national biosafety **baselines to** strengthen regulatory, institutional, infrastructural and human capacities of the participating countries in the implementation of National Biosafety Frameworks (NBFs); (ii) Promoting cooperative measures in the implementation of NBFs across the three countries (iii) Stimulating regional dialogues on biosafety and effective cooperation on technical tools and

The project interventions will focus on reviewing and/or updating national regulatory frameworks and policies, scientific risk assessment reviews, risk management practices; socio-economic considerations; public education, public awareness and participation; and monitoring and enforcement. An advisory panel will be promoted and established through dialogue with the participating countries.

The compilation of the proposal is guided by common (intercountry) and country-specific national needs for supporting the establishment and/or operationalization of all the five components of NBF, in

alignment with the CPB. There are some common limitations in the implementation of the CPB to all the three project countries, namely, inadequate regulatory regimes, limited technical guidance and tools, lack of capacity for managing transboundary movement of LMOs, limited capacity for informed decision making, limited biosafety activities in-country, and limited awareness and/or prioritisation of biosafety. Madagascar and Namibia must deal with transit-related issues in handling of LMOs at the ports, and DRC, although landlocked, is central to trade issues in the region. Thus, a thematic and joint-country project to promote cooperative implementation of NBFs, shared expertise and resources in the transboundary management of LMOs is justified. Furthermore, an inter-country project would avoid duplication of efforts, build synergies, and enhance efficiency and cost effectiveness through shared expertise and resources while providing lessons and best practices for potential uptake by other countries in the region, and the Regional Economic Communities. This cooperative approach could serve as a catalyst for other countries that are yet to finalize the development and implementation of their NBFs. To cater for the different national needs, the partner countries will retain national specific responsibilities while collaborating with the other countries through a cooperation agreement and generating tools for uptake by the Regional Economic Communities as pilots for upscaling.

The project will be implemented using an 'incremental approach', through which achievements accrued from earlier projects, as highlighted by the stocktaking exercise, will constitute the baseline for the SINBF activities. For example, DRC and Madagascar who benefited from the MCP-ICLT project, have established GMO testing facilities and Namibia has a GM testing facility from earlier investments. Thus, the project will only support strengthening activities related to these GM testing facilities. In addition, the project will address common needs using the central inter-country strategy, and replicate at national level e.g., for capacity building where a multiplier effect will be achieved through using the Training of Trainers (ToT) approach, with technical backstopping from relevant experts. The joint-country components will have the responsibility to: establish and manage SINBF technical advisory team of experts, provide platforms for information and experience sharing on biosafety; train selected national experts on thematic biosafety issues, and facilitate adaptation and/or development technical guidelines and tools. In addition, **the intercountry activities** will be instrumental in dialogues and development of wider partnerships with other countries in the region, the SADC and ensuring global project visibility. Soft skills required for effective project delivery and efficient functioning of NBF institutions, including provision of platforms for information and experience sharing on biosafety. will be facilitated by at the intercountry level.

The project will endeavor to balance gender, vulnerable groups including indigenous people representation and participation across all levels of project implementation. Throughout the implementation of the project, gender disintegrated data will be compiled on the project personnel and on project participants/ beneficiaries. Gender access, participation, and benefits among women and men will be monitored and remedial action incorporated to redress any gender inequalities in project implementation. Regularly report on how gender is mainstreamed and ensure that mid-term review, assessments, audits, etc. include gender as a specific criterion/component.

The envisaged results of the project in the three participating countries are established and implementable national biosafety laws that are aligned with the CPB and its supplementary protocol. The NBF institutional, infrastructural, human and regulatory capacities will be strengthened. An

offshoot of the project will be increased participation by SADC in dialogue on effective cooperation on biosafety technical tools in the region. A pool of experts in biosafety will be built and will foster intercountry collaborations on risk assessment and risk management, and in monitoring and enforcement of the use, handling and transboundary movement of LMOs. Full implementation of NBFs in the three countries will contribute to sustainable use and conservation of biological diversity.

The project is conceptualized as per the Theory of Change elaborated in Annex 1. The project consists of three project components. The first two, Components I, II, each has Immediate Outcomes (IO) at inter-country and national levels. The three components are as follows:

Component I - Biosafety Regulatory Regimes and Policy

Component II - Biosafety Institutional Systems

Component III ? Project Management, Monitoring and Evaluation

The following outcomes and outputs will lead to the accomplishment of the project objective.

### **Project Component I- Biosafety Regulatory Regimes and Policy**

Component I focuses on enhancing the biosafety regulatory regimes and policy across the three countries. The biosafety policy framework establishes and informs regulatory decision making, legal requirements, administrative procedures for handling applications, storing information related to applications, gives procedures for evaluation of applications, establishes communication and consultation with stakeholders and citizens throughout the decision making process, gives processes that ensures informed decisions are made, elaborates on procedures to monitor for compliance with conditions of authorization, ensures capacity for compliance and investigation of possible bridges of approval conditions, and ensures capacity to check and review processes is in place.

The identified gaps across all the three countries are lack of clear strategic focus outlining the intentions and values of the government as it relates to biotechnology and biosafety, lack of clarity on the scope and functions of the regulatory authority, and the role of stakeholders, including other government departments and agencies. DRC and Madagascar lack legal frameworks, regulatory authorities and operational policies that assist government implement their international obligations under the CPB. Namibia and DRC have non-alignment of the established laws and draft biosafety bills respectively with the provisions of the Cartagena Protocol on Biosafety and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress across all the three countries.

The expected outcome is Governments of DRC, Madagascar and Namibia adopt a revised legal framework on biosafety aligned to the CPB and Nagoya-Kuala Lumpur Supplementary Protocol and have taken measures to accelerate effective management and monitoring of LMOs.

The project will result in establishment and/ or strengthening of biosafety policy frameworks and operational regulatory systems that establish and inform regulatory decision-making, legal requirements, administrative procedures for receiving, processing and storing of information related to applications, evaluation of applications, communication and consultation processes with various stakeholders throughout the decision-making process, processes leading to informed decision making, including conditions placed on authorizations, procedures to monitor for compliance.

The **expected outputs** are:

1.1 Set of National Core teams? multidisciplinary teams of experts from each project country supported with training and backstopping to cooperate in the review of national biosafety laws, policies and plans, and prepare national decisions to meet the CPB and Nagoya-Kuala Lumpur Supplementary Protocol requirements

1.2 Decision makers in project countries supported with information, training and technical assistance to influence prioritization and promotion of policies and legal instruments to meet obligations to the CPB and the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress

1.3 Biosafety mainstreamed into relevant national sustainable development policies and strategies, including National Biodiversity Strategies and Action Plans (NBSAPs) and the Post 2020 GBF)

## **Project Component II - Biosafety Institutional Systems**

Component II is mainly the capacity building component across the administrative, institutional and thematic biosafety issues. This project component will build on earlier gains accrued from UNEP-GEF and other bilateral interventions on biosafety capacity development. These include projects on development of NBFs, the Biosafety Clearing House and thematic projects on specific capacities.

Capacity building will take into consideration national laws and regulations and other country-specific social, economic, political and developmental contexts. The project will endeavor to balance gender representation and participation across all levels of project implementation. Similarly, these considerations will apply as the project reviews and adopts existing manuals and guidelines for local regional needs. For some specific technical tools that are internationally developed (by UNEP or SBCD, etc.), Countries will aim to cooperatively develop draft guidelines at intercountry level. Countries will retain the responsibility of implementation of activities that address country-specific

challenges. The national activities will lead to enhanced national institutional setups, enforcement and monitoring and public participation capacities or biosafety implementation.

To achieve a multiplier effect on capacity development, the project will cooperatively train National Core Teams (NCTs) at intercountry level, using the Training of Trainers (ToT) approach. The national activities will be led by the trained National Core Teams of experts. The NCTs will set up national level forums based on thematic areas and expertise of the trainers. Thus, at national level, a number of NCTs specialized on specific thematic and technical issues will be established and nurtured. National project coordinators will manage the work of the NCTs at national level and quality of work will be guided and monitored by the Technical Advisory Committee (TAC). The TAC will provide mentorship and technical support to ensure quality and standardized outputs such as technical support on adaptation and utilization of biosafety guidelines and technical tools. The intercountry training will guide on specific technical issues that countries should consider in adapting or using tools and guidelines at national level.

The **expected outcome** of component II is enhanced and strengthened Biosafety institutional systems for decision making.

*2. National mandated institutions and stakeholders take measures to strengthen implementation compliance and enforcement of updated **National Biosafety** frameworks.*

The **expected outputs** are:

- 2.1 Multidisciplinary teams of national experts from project countries capacitated and backstopped to train government officials and their stakeholders in the implementation of biosafety and thematic areas
- 2.2 National biosafety administrative systems strengthened *with training and technical assistance to review, update processes and systems for implementation of **national biosafety** considerations.*
- 2.3 Biosafety risk assessment and risk management systems strengthened with technical support to provide data for informed decision making.
- 2.4 National Biosafety systems supported with capacity to develop and strengthen national guidelines on ~~capacity~~ for biosafety socioeconomic considerations
- 2.5 National Biosafety systems provided with technical support to develop and/or strengthen monitoring and enforcement systems for follow-up
- 2.6 Tools and guidelines on **RA&RM**; handling and review of applications; socio economic considerations, public participation cooperatively developed for adaptation to the national context, disseminated to decision makers from legally mandated institutions and key stakeholders from Academia and civil society in the project countries



2.7 Capacities and systems on biosafety communication for public information, public awareness and public participation -strengthened through provision of *communication products and services* and support mobilised through participation in key forums to influence sound management of LMOs in SADC and COMESA

### **Component III ? Project Monitoring and Evaluation**

Component III will ensure that the project is well administered managed and meets deliverables,

The Component will result in:

3. Effective project monitoring, tracking and evaluation to meet agreed measurable outputs and indicators

Expected Outputs

3.1 M&E framework institutionalized and operationalized and lessons learnt shared to influence biosafety at regional levels for impact continuity beyond the Project.

3.2 Mid Term and Terminal Evaluation Reports

### **Project Management**

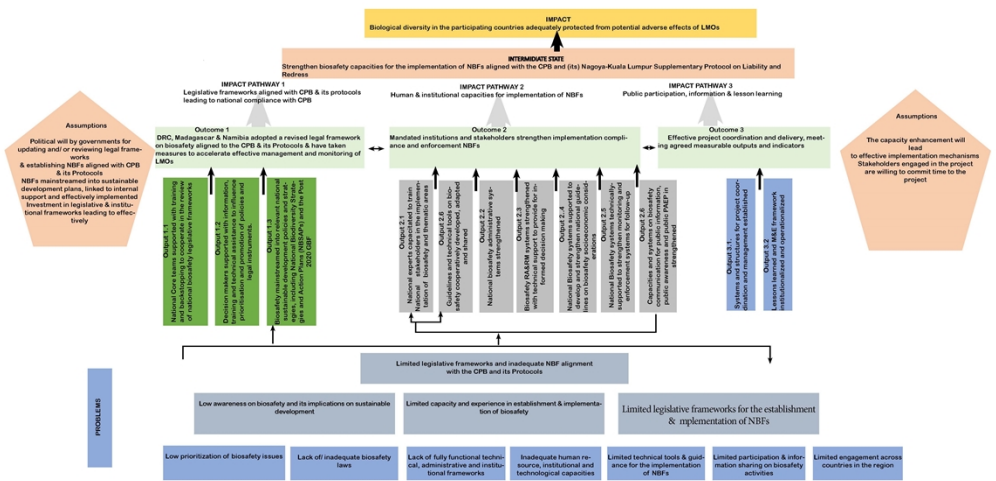
The project management cost will be utilised to establish effective project coordination and management systems for efficient delivery

Expected Outputs

4.1 Systems and structures for project coordination and management established

The proposed project is conceptualised as depicted in Figure 1

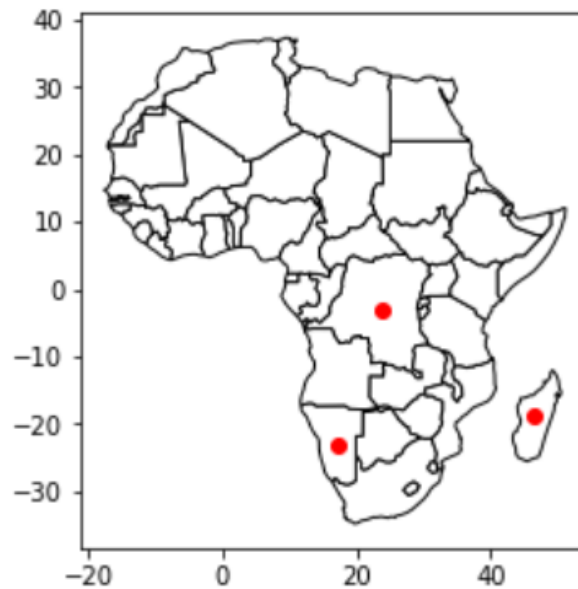
### **Figure 1 - Theory of Change**



## 1b. Project Map and Coordinates

Please provide geo-referenced information and map where the project interventions will take place.

	Country	Longitude	Latitude	geometry
0	Democratic Republic of the Congo	23.822264	-2.981434	POINT (23.82226 -2.98143)
1	Namibia	17.323111	-23.233550	POINT (17.32311 -23.23355)
2	Madagascar	46.441642	-18.924960	POINT (46.44164 -18.92496)



## 1c. Child Project?

If this is a child project under a program, describe how the components contribute to the overall program impact.

### 2. Stakeholders

Select the stakeholders that have participated in consultations during the project identification phase:

Civil Society Organizations Yes

Indigenous Peoples and Local Communities Yes

Private Sector Entities Yes

**If none of the above, please explain why:**

**Please provide the Stakeholder Engagement Plan or equivalent assessment.**

The multilevel, multi-institutional and multi-actor nature of biosafety entails targeting a broad range of actors for any intervention. The project is designed to be all inclusive, participatory in its implementation and to accrue global biodiversity benefits as well as benefits to those whose livelihoods depend on the productive and sustainable interaction between technologies and the environment. The project is guided by the CPB article 23 which makes public participation, education and consultation in decision making in biosafety is obligatory

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

- i. Activities would be needs based and incremental in nature, thus strengthening implementation of biosafety through enhancement of identified gaps in the participating countries, inform the missing link in regulatory frameworks, biosafety administrative and 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,
- ii. 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,
- iii. 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 Institutional and national levels.

Specific national level key stakeholders involved in the biosafety regulatory chain at national levels, as identified by the PPG are presented in Table 1 Categorized by the stakeholder group they represent. Further analysis of these stakeholders will be done during the project execution phase. **The stakeholder roles will be reviewed, new roles will be assigned and potential partnerships will be agreed on to support the process at the inception phase and in course of project execution.**

Mapping the stakeholders by their roles in the project, the following groups were identified:

- i. **Decision makers?/policy makers.** These stakeholders will be key in influencing high-level decisions on prioritisation of project activities, regulatory frameworks updating and/or reviewing and participation in decision making. The stakeholders will be involved in the consultations and meetings on key issues at national, sub-regional and inter-country level. In addition, decision makers, policy makers are members of the decision-making structures especially the national biosafety steering committees. This group of stakeholders is highly influential, are highly interested in the project and have high interest in its implementation. They will be the champions of the project and will be actively involved throughout the project. The project will manage their participation in the project closely.
- ii. **Scientists, technical experts, researchers and technicians from public and private sectors** including academic institutions. These are mainly participants who once empowered became resource persons in programmes on awareness raising and the technical aspects. They are beneficiaries of the Train the trainers? approach through consultations and workshops for training of trainers and awareness. They are also involved in developing training modules, reviewing training curriculums to

incorporating biosafety, issue in national research programmes and working knowledge documents. This group of stakeholders is also involved in developing outreach materials for different target groups. They are also involved in the Technical Advisory Panels. Less powerful yet highly influential as both beneficiaries of the project and providers of technical information for informed decision making. They will be consulted, involved and engaged where necessary.

iii. Legal experts and economists Consultations on documents related to socio-economic assessment and legal issues such as enforcement, revision of existing laws and updating and completion of drafting of the draft laws, interaction between biosafety laws and other related laws and enforcement institutions in the participating countries.

iv. Regulatory Agency officials including Customs, Plant Quarantine, Environment Inspectors, Animal and Food Safety Experts Participate in training workshops for post-release monitoring and enforcement at border controls, finding information for enforcement purposes from different sources including the BCH. Carry out monitoring and enforcement duties. Highly interested in the project, they will be the beneficiaries of capacity building initiatives and lead implementers of the project.

v. Interest groups (women & youth), teachers, students, mass media and extension workers, NGOs, Farmers' Associations, Consumer groupings. This stakeholder group participate in awareness raising meetings, trainings and create awareness amongst their group members. They advocate for public participation and their inputs can influence decisions on the implementation of biosafety. This group has less power; however, they are highly interested in the project. They will be kept involved and informed through the project.

vi. Public Institutions mandated to implement biosafety: Coordinate the project activities driving them towards achieving the set outcomes, participate in capacity building, education and awareness, participate, review and develop and disseminate outreach materials designed for the different target groups.

The objective of stakeholder engagement in the SINBF is twofold: to help the participating organizations to proactively consider the needs and desires of anyone who has a stake in the project. Engagement will foster connections, trust, confidence, and buy-in for the initiative on strengthening and implementation of the biosafety regulatory framework. Stakeholder engagement will also mitigate potential risks and conflicts with stakeholder groups, including uncertainty, dissatisfaction, misalignment, disengagement, and resistance to the implementation of the Biosafety frameworks. Secondly stakeholder engagement will be aimed at ensuring participation in biosafety decision making. Inputs from the various stakeholders will shape the decisions to be made by the participating countries on management, handling and use of modern biotechnology products. Thus, Stakeholder engagement in the project is an intrinsic part of the project

Consultation with key stakeholders will be continuous and will start as early as project inception. It will continue through all stages of the strengthening of project implementation and the regulatory cycle. This will help to identify and understand potential problems and to define options, and quantify the associated regulatory costs, thereby improving the quality of the biosafety systems to be put in place.

Broad-based consultation will also help to identify the risks of regulatory capture, which occurs if the regulator ends up acting in ways that benefit the industry that it is supposed to be regulating, rather than the environment and the public. Activities for engaging with the various stakeholders are budgeted for under Component A, Output 1.2; Component B, Outcomes, 2.1, 2.7, and Component C, Outcome 3.2

The Stakeholder Engagement plan is attached as an Annex to the CEO Endorsement Template.

In addition, provide a summary on how stakeholders will be consulted in project execution, the means and timing of engagement, how information will be disseminated, and an explanation of any resource requirements throughout the project/program cycle to ensure proper and meaningful stakeholder engagement

Table 1 SINBF Mapping the stakeholders by their roles in the project

Stakeholder category	Representation	Roles in SINBF
Government/Public Institutions including ministries, departments and agencies (Legislature, judiciary, opinion leaders and high-level policy makers)	Ministries/departments and public Institutions responsible for environment and sustainable development, science, technology and innovation, Agriculture, forestry, Livestock and Fisheries, Public Health - Industry, Commerce and industry, Higher Education and Scientific Research Ministry of Economy and Finance Ministry of Communication and Culture Population, Social Protection and Ministry of Justice National Codex Alimentarius Committee, Standards offices, National Parks Nutrition promotion of women; transport, tourism and meteorology ministry of national defense.	The public institutions mandated to implement biosafety will be the lead coordinating and implementing agency of the SINBF at national level of the project including the review, update of the regulatory regime, implementation of biosafety administration, coordination of the decision-making process.

<p>Research Institutions working in the field of biotechnology and environment</p>	<p>University Faculties of Science - Economics, Management sciences, Sociology, law and <b>Biotechnology Research</b> Institutions</p>	<p>Participate in technical committees that inform Decision making processes, contribute to risk assessment including environmental aspects and Risk Management processes, carry out environmental risk and biotechnology research. Carry out <b>GMO detection and Provide scientific evidence to support r informed decision making.</b></p> <p><b>Participate in decision making processes through Technical Advisory Committees.</b></p> <p>Control and apply biosafety rules for research, carry out biotechnology research, are directly or indirectly involved in biosafety. Educate and share knowledge on biotechnology and biosafety.</p>
<p>Civil society, NGOs, Community-based organizations and Media</p>	<p>Those involved in biodiversity Conservation (Animal and Plant Resources), on follow-up of environmental infractions Follow-up of illicit exploitation of natural resources Manage the Protected Areas under delegation of management.</p>	<p>Educate the public, create awareness on biosafety, facilitates information sharing and participate in monitoring of imported products advocating for enforcement, advocate for public participation in decision making.</p>

Private Sector including seed companies, seed traders and distributors, product importers and exporters	Private companies that import/export Commercial companies working in agriculture, breeding and phytochemicals seeds, agricultural inputs, animal feed, phytosanitary and veterinary products  Importer and distributors of livestock and agricultural inputs agricultural producers.	Applicants for non-GMO certification, share Information Contribute to the import database, participate in decision making (give feedback on the efficiency of the biosafety system). Private sector roles will continue to be updated.
General public including traditional and cultural institutions	General public including Consumers, church community, traditional and cultural institutions.	Participate in Decision making, giving feedback on the NBF gaps and efficiency.

Mapping the stakeholders by their roles in the project, the following groups were identified:

i. Decision makers?/policy makers. These stakeholders will be key in influencing high-level decisions on prioritisation of project activities, regulatory frameworks updating and/or reviewing and participation in decision making. The stakeholders will be involved in the consultations and meetings on key issues at national, sub-regional and inter-country level. In addition, decision makers, policy makers are members of the decision-making structures especially the national biosafety steering committees. This group of stakeholders is highly influential, are highly interested in the project and have high interest in its implementation. They will be the champions of the project and will be actively involved throughout the project. The project will manage their participation in the project closely.

ii. Scientists, technical experts, researchers and technicians from public and private sectors including academic institutions. These are mainly participants who once empowered became resource persons in programmes on awareness raising and the technical aspects. They are beneficiaries of the Train the trainers? approach through consultations and workshops for training of trainers and awareness. They are also involved in developing training modules, reviewing training curriculums to incorporating biosafety, issue in national research programmes and working knowledge documents. This group of stakeholders is also involved in developing outreach materials for different target groups. They are also involved in the Technical Advisory Panels. Less powerful yet highly influential as both beneficiaries of the project and providers of technical information for informed decision making. They will be consulted, involved and engaged were necessary.

iii. Legal experts and economists Consultations on documents related to socio-economic assessment and legal issues such as enforcement, revision of existing laws and updating and completion of drafting of the draft laws, interaction between biosafety laws and other related laws and enforcement institutions in the participating countries.

iv. Regulatory Agency officials including Customs, Plant Quarantine, Environment Inspectors, Animal and Food Safety Experts Participate in training workshops for post-release monitoring and enforcement at border controls, finding information for enforcement purposes from different sources including the BCH. Carry out monitoring and enforcement duties. Highly interested in the project, they will be the beneficiaries of capacity building initiatives and lead implementers of the project.

v. Interest groups (women & youth), teachers, students, mass media and extension workers, NGOs, Farmers? Associations, Consumer groupings. This stakeholder group participate in awareness raising meetings, trainings and create awareness amongst their group members. They advocate for public participation and their inputs can influence decisions on the implementation of biosafety. This



group has less power; however, they are highly interested in the project. They will be kept involved and informed through the project.

vi. Public Institutions mandated to implement biosafety: Coordinate the project activities driving them towards achieving the set outcomes, participate in capacity building, education and awareness, participate, review and develop and disseminate outreach materials designed for the different target groups.

**Select what role civil society will play in the project:**

**Consulted only;**

**Member of Advisory Body; Contractor;**

**Co-financier;**

**Member of project steering committee or equivalent decision-making body; Yes**

**Executor or co-executor;**

**Other (Please explain)**

### **3. Gender Equality and Women's Empowerment**

**Provide the gender analysis or equivalent socio-economic assesment.**

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. The project will purposefully ensure participation and involvement of gender and vulnerable groups including indigenous groups, women and youth, in planning any project activity under the SINBF, the project. The project will take into consideration time constraints, knowledge, and socio-cultural impediments to the full participation by women. This approach will guide the selection and representation during the finalization of the draft Biosafety laws to ensure women, youth, civil society and private sector are represented on envisaged statutory bodies as per the law through affirmative action. The proposed project recognizes the importance of involving women in setting up and implementing the National Biosafety Framework processes because women play a critical role in assessing genetic resources both at the farm level, the marketplace and trade across borders with neighbouring countries. Women in the case of the Democratic Republic of Congo, Madagascar and Namibia depend heavily on the use of natural resources therefore ensuring gender equity will benefit all including women and men in the balanced allocation of resources, involvement and decision-making will result in greater incomes and overall well-being for all persons including

women, men, youth and local communities. These groups support efforts on conservation and sustainable use of biological resources.

Achieving gender equity requires an integrated approach geared towards behavioural and procedural changes at several levels in the biosafety regulatory process namely at the regulatory, administrative, technical and the outreach levels. In response to this, the project will incorporate the following elements:

Analysis of livelihoods, gender and vulnerable groups will continue to inform the project design and implementation, through assessments of women engagements in handling biotechnology related activities, needs and aspirations, collection of gender specific data and ensuring participation in project activities by the relevant stakeholders by gender. Because gender relations, aspirations, and opportunities can vary greatly, the analysis will begin with a closer look at the social set up that define the roles, burdens, access to and control of resources for men, women, youth and local communities. This will ensure gender sensitivity throughout the project design and implementation process that considers the needs and priorities of both women and men. The analysis itself will be organized in a way that allows varying approaches and availability to meet the needs and participation of women and men.

Gender-balance will guide the setting up, selection and participation in meetings and training workshops and may lead to organizing separate sector/thematic based meetings for different end users to ensure that that women, youth and local communities are fully informed of the activities to date, to obtain their input, and to collaboratively work together to develop a strategy for their long-term inclusion and participation of the biosafety regulatory processes in all the participating countries.

- i. Gender-balanced management: Behaviour change and gender-balanced management within various implementing entities and beneficiaries is key to opening spaces that empower women. In the case of regulatory officials and end users of technology, women and men will be trained and tools provided on the national biosafety systems guided by needs captured during the gender analysis.
- ii. Women will be adequately represented in regulatory mandates as per the law and the guidelines developed not only at the policy level but also at the technical and training levels. Trainers will be taught how to be aware of, responsive to and advocate for gender issues in their training context and community and equipped to counter negative behaviour.
- iii. Technical and financial capacity building: Targeted, gender-balanced capacity building, budgeting and technical assistance packages will be refined based on the results of the stocktaking analysis. The timing and structure of workshops will take care not to overburden participants, particularly women, who tend to shoulder more of the household and caregiving responsibilities. In addition to the core training activities, specialized technical assistance may be provided in support of handling of modern biotechnology products and the required obligation of biosafety measures in the country especially where in relation to in country use, transit and transboundary movement of LMOs and its impact on biodiversity as the safe use of genetic material is of supreme value to the livelihoods of women and their families. This can include direct support to women's organizations. Women have

shown significant interest in tools that help build consumer confidence and acceptability of their products.

iv. Gender-balance will guide the setting up, selection and participation in meetings and training workshops and may lead to organizing separate sector/thematic based meetings for different end users to ensure that that women, youth and local communities are fully informed of the activities to date, to obtain their input, and to collaboratively work together to develop a strategy for their long-term inclusion and participation of the biosafety regulatory processes in all the participating countries.

Gender-disaggregated performance indicators will be assessed. Monitoring and evaluation will include gender specific indicators in management/regulatory agency positions and of the presumed result of greater gender equity including the impact of biosafety at household community and household levels (increased family income, improved household wellbeing, more efficient businesses, and improved Biosafety measures). Results will be disaggregated to demonstrate distribution of results across the different genders, biosafety expertise, opportunities in decision making (through the Technical Committees/Advisory Panels and the Expert Technical Groups), socio-economic and local communities. A gender plan of action has been developed and is attached to the UNEP Prodoc as Appendix 17. This will be further refined during the first three months of implementation after inception and stock taking.

**Does the project expect to include any gender-responsive measures to address gender gaps or promote gender equality and women empowerment?**

Yes

**Closing gender gaps in access to and control over natural resources; No**

**Improving women's participation and decision making Yes**

**Generating socio-economic benefits or services or women**

**Does the project's results framework or logical framework include gender-sensitive indicators?**

Yes

**4. Private sector engagement**

**Elaborate on the private sector's engagement in the project, if any.**

Private Sector including seed companies, seed traders and distributors, product importers and exporters	Private companies that import/export seeds, agricultural inputs and products. Commercial company working in agriculture and breeding Commercial company working in agriculture, breeding and phytochemicals Seeds, agricultural inputs, animal feed, phytosanitary and veterinary products Importer and distributors of livestock and agricultural inputs agricultural producers.	Applicants for non-GMO certification, share Information  Contribute to the import database, participate in decision making (give feedback on the efficiency of the biosafety system). Private sector roles will continue to be updated.
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**5. Risks to Achieving Project Objectives**

**Elaborate on indicated risks, including climate change, potential social and environmental risks that might prevent the project objectives from being achieved, and, if possible, the proposed measures that address these risks at the time of project implementation.(table format acceptable):**

Risk analysis and risk management measures

Issue	Rating	Identified Risk	Mitigation measure
COMMUNICATION	Medium	Language barrier - 2 different national language groupings within participating countries; Several main languages within each participating country. This will require translation of especially awareness materials into key languages spoken in each of the participating countries	Budget and allocate enough resources for translation of documents and facilitation of meetings
		Inadequate collaboration and engagement between the labs in participating countries; and between Labs and decision makers/ CNAs and NFPs	RAEIN-Africa to support (through the Project), networking initiatives and create ongoing dialogue between the participating labs; and between Labs and CNAs and NFPs of participating countries
		Absence of formal coordination mechanism at national levels	Ensure the review and updating of national biosafety laws clearly spells out the Institutional frameworks for implementation of the biosafety laws and the coordination and chain of command between the different participating national / sub-national institutions; Establish an electronic platform for information sharing

		Insufficient moderation of platforms/project forums	The Official Communication and Information exchange forums to be established under this project, to have a Moderation mechanism to streamline content and ensure authenticity of information/ materials posted on the forums
STAKEHOLDER RELATIONS	Medium	Government approval/endorsement for participation in the project	Engage political principals on the project for approval
		Limited participation by a Regional entity that can facilitate and enforce governments/regional cooperation for the implementation of the biosafety regulatory regimes	Engage the SADC to take on board implementation of biosafety regulatory regimes, develop and implement a regionally acceptable agenda for its member countries
		Limited participation by regulators in the regional project?s capacity development initiatives	Sensitization of regulatory decision makers at national and regional levels on the importance / benefits of participating on the project
		Long national process to put in place regulatory frameworks and/or adopt revised/reviewed Frameworks	Project partner to sensitize and lobby key stakeholder ministries (ministry of science and technology, agriculture, environment or health); and legislative bodies/ Parliaments in case of laws
		Political instability/will	Ongoing lobby and sensitization actions
		Standards are coordinated by different ministry	Carefully identify key/ relevant stakeholders and encourage them to regularly interface/ involve them in the Inter-institutional Biosafety Technical committees, to exchange ideas on issues of national importance, especially the cross-sectoral issues like Biosafety
HUMAN RESOURCES	Medium	Inadequate skills for implementation of the biosafety frameworks, and where available skills developed/ transferred not adequately used	Need driven capacity and skills developed, attached to existing biosafety activities across all relevant sectors. Resource sharing platform updated and Skills sharing facilitated across the Project countries.

		<p>High staff turnover including constant changing of staff participating in the project and Project based staff not permanently employed</p>	<p>Engage governments to absorb trained personnel into permanent positions; where possible, assign Project work to already serving officers in permanent positions to ensure retention of the enhanced knowledge/capacity from the Project;</p> <p>Incentivize participation in the project through the mentorship programme as the trained National Core Teams remain a local resource; resources for further training of other officers in biosafety (multiplier effect in capacity building).</p> <p>Promote continuous on job learning for biosafety personnel including immigration or boarder officials.</p> <p>Incorporate Biosafety in relevant Courses and curricula of tertiary institutions, to ensure local pool graduates knowledgeable in biosafety.</p> <p>Promote the development of a biosafety programme at tertiary level for scientists and legal personnel to ensure human capital development in the area of biosafety. ;</p> <p>Lobby government to raise the profile of Biosafety positions in the Public Service hierarchy, to provide incentives for trained staff to stay as they foresee opportunities for professional growth and advancement</p> <p>Inform top management about the importance of committing constant staff to the project; this could change if the laws are passed increasing the levels of staffing for Biosafety work.</p>
		<p>Number of qualified personnel including men and women to participate in the project</p>	<p>Recruit more personnel with the requisite skills for further development with a target to achieving gender equity;</p> <p>Lobby for completion and updating of the National Biosafety laws, to create more opportunities to fill vacant positions that will be created by the new/revised laws</p>
SYSTEMS	Medium	<p>Absence of national biosafety frameworks</p>	<p>Use the regional project to catalyze action at national levels, including sharing of best practices;</p> <p>Sensitize and lobby Law-makers and high level government Officials on the importance of having functional NBFs and the obligations to the countries as Parties to the CPB</p>
		<p>Lack of harmony at national and regional level for the safe use, handling and transboundary movement of LMOs</p>	<p>Regional cooperation and harmonization of systems for risk assessment, risk management, LMO testing, information, experience and expertise sharing, lesson learning and continuous engagement through relevant regional instruments to be developed and practiced through this Project</p>

	Poor Governance systems	Biosafety regulatory regimes (with functional laws) will designate the Competent Authorities. The updated and legally supported regulatory Framework will identify the relevant ministries that work with the Authority in the implementation of the NBF; defining their roles, responsibilities and their coordination mechanisms; Component I will result in biosafety mainstreaming (into NBSAPs, Policies and plans) thus, diversify and enhance resources for implementation of biosafety.
	Non-uptake of training content	Diversify capacity building methods and include practical, experience sharing through exchange visits etc; Clarify the importance of the training for National development and the importance of having functional NBFs at country level, to enhance interest of the trainees in the training
	Poor recording of biosafety information and data in the BCH, leading to low compliance by countries	Assign and train staff to ensure information and data is collected and timely posted on BCH, Raise awareness on the importance of timely and accurate information in the BCH for use in decision-making and enforcement and monitoring at national level (if you like using information posted by others to the BCH, then you should also post yours for others to use)
	Technology shortcomings e.g. data transfer	Include project equipment such as laptops and computers
	No national standards on technical issues	Lobby for setting of guideline Standards at inter-country level and for national ?buy in?/ adaptation where national standards are lacking
	Inadequate/ unclear institutional arrangements	Decide on appropriate national coordination mechanisms in a participatory manner; Incorporate the Institutional arrangements in national Biosafety laws and draw clear Terms of Reference for their coordination and chain of command

## 6. Institutional Arrangement and Coordination

**Describe the institutional arrangement for project implementation. Elaborate on the planned coordination with other relevant GEF-financed projects and other initiatives.**

*Coordination.* Outline the institutional structure of the project including monitoring and evaluation coordination at the project level. Describe possible coordination with other relevant GEF-financed projects and other initiatives.

The cooperation of Parties for the execution of the project; Strengthening the Implementation of National Biosafety Frameworks in Southern Africa (SINBF) (Fig. 2) involves an agreement between the

UN Environment Programme (UNEP) as the Implementing Agency for the Global Environment Facility (GEF) and the Regional Agricultural and Environmental Innovations Network-Africa (RAEIN-Africa) as the Lead Executing Agency (LEA). UNEP, represented by its Director, Ecosystems Division, will provide supervisory and technical advisory oversight for the project. The LEA, RAEIN-Africa, will co-execute the project with the participating countries. RAEIN-Africa is the legal entity that will engage directly with the UNEP-GEF in the execution of the project on behalf of the three partner countries, the Democratic Republic of the Congo (DRC), Madagascar and Namibia. The partner countries are represented by National Executing Agencies (NEAs), through the respective National Biosafety Authorities.

The LEA will sign Memoranda of Agreement (MoA) with each of the three participating countries. The SINBF project consists of a mix of intercountry and national activities. Through the intercountry activities, a cooperative approach in addressing common needs and gaps will be adopted. The participating countries will implement national activities, through their respective NEAs, taking into consideration the varied baseline status and national contexts.

## **Figure 2: Institutional arrangements for project implementation**

RAEIN-Africa will coordinate project execution, ensuring that; (i) The project effectively and efficiently meets set objectives; (ii) The project results framework is continuously monitored, reviewed and updated; (iii) Technical guidance is provided as required, and (iv) Project accountability and timely reporting to UNEP-GEF and all partners is assured.

The day-to-day intercountry management and coordination of project will be facilitated by the Project Management Unit (PMU), hosted by the LEA. At national level, management and coordination of activities will be coordinated by the NEA. In collaboration with the UNEP Task Manager, the LEA will ensure that the project meets the UNEP-GEF policies and procedures and facilitates the establishment of an effective network of stakeholders in the implementation of national biosafety frameworks in the three participating countries, and with other relevant stakeholders in the SADC region.

The Intercountry Project Steering Committee (IPSC), made up of the National Biosafety Authorities of the participating countries, a representative from UNEP (the UNEP Biosafety Task Manager) and the Lead Executing Agency, will oversee the implementation of the project and guide the project's technical performance and progress, receive periodic reports on progress, review project execution and progress, approve revised work plans and make recommendations concerning any revisions of the results framework and the monitoring and evaluation (M&E) plan, ensuring that strategic decisions are made with due consideration of the planned activities and objectives. In addition, the IPSC will provide strategic and policy guidance, and exchange experiences and best practices in the region's approach to biosafety management. Thus, the IPSC will advise the LEA on regional and international biosafety issues, including those pertaining to the Cartagena Protocol. The RSC will also provide frequent input and support to the project and ensure participation and ownership by all project partners through the delivery of project outputs. The IPSC will meet bi-annually to review work plans, budgets and progress reports.

The National Executing Agencies (NEAs) from each of the participating countries will designate the National Project Coordinators (NPCs) from their respective national biosafety authorities. The NPCs are seconded from the NEAs employees and will oversee the overall national project implementation and stakeholder involvement. The NPCs will liaise directly with the PMU, and will prepare technical and financial reports, including work plans and budgets, ensuring adequate articulation of national activities and priorities, ensuring compliance of project implementation with the UNEP-GEF procedures. The NPCs will also coordinate and update the project's national M&E framework, support the LEA and UNEP field missions, coordinate and support regional technical experts that may be assigned to the project's national capacity building activities, and ensure adequate inter-institutional coordination and stakeholder participation in support of project implementation. The national activities, through the NEAs and the National Project Coordinators, will be guided by National Taskforces (National Project Steering Committees).

National Project Taskforces (National Steering Committees) will be constituted in each of the participating countries. The national Task Forces (NTFs), will preferably be constructed from key institutions that participated in previous UNEP-GEF projects on development of National Biosafety Frameworks (NBFs), are involved with on-going implementation of NBFs and/ or are institutions



mandated with some role in biosafety implementation. These should be representatives from all relevant Ministries including agriculture, trade, environment, health and science and technology. The NPCs nominated representatives from the LMO detection facilities and technical experts (from academia and research institutions) will also sit on the National Taskforce. Experts from various institutions may assist the NTFs on fixed term or ad hoc basis depending on the scientific expertise or advisory roles required and as per national arrangements. The NTFs are expected to meet every 3-6 months (two to four times a year) to review project progress and provide the necessary administrative, technical and financial support to the NEAs and the NPCs. The NTFs must also meet before the intercountry review and planning meeting, to review project progress and work plans for the national project components. The NTFs will also assist in facilitating cooperation amongst the relevant government agencies and with NGOs, private sector, and other stakeholders. In addition, the NTFs will; (i) Ensure that project reports, financial accounts and other requests are prepared and submitted within the set deadlines; (ii) Approve the detailed work plans and budgets produced by the NPC; (iii) Review and advise on the main project outputs, ensuring that all documentation from the national project activities are consistent with national policies, programs and legislation; (iv) Mobilise national expertise, as needed, for the implementation of the project; (v) To maximise on resources, and enable cooperative, focused and sustainable implementation of synchronised intercountry activities, a technical advisory committee be promoted and established through consultation with the participating countries.

The SINBF Technical Advisory Committee (SINBF-TAC) will provide technical backstopping, and will constitute relevant experts, to be identified from the region. The TAC will design technical content, deliver on specific capacity building activities, and provide on-going technical backstopping on relevant biosafety thematic issues as may become necessary. The TAC members will include the following technical expert areas: knowledge and experience in; implementation of the CPB, drafting of legal documents such as biosafety laws, biosafety risk assessment and risk management, monitoring and enforcement systems, LMO detection and identification, establishment of administrative and institutional set-ups for biosafety implementation, incorporation of issues of liability and redress and biosafety socio-economic considerations. The TAC will provide technical backstopping to partner countries as they review, update and align their national laws and finalise bills on biosafety with the CPB, the Nagoya-Kuala Lumpur Supplementary Protocol to the CPB, and the Post 2020 Global Biodiversity Framework.

The TAC will support biosafety capacity building within the participating countries, through their NEAs, ultimately to operationalisation of national biosafety frameworks. The TAC will undertake a capacity assessment, to assess the level of infrastructural, human, institutional and financial resources required to establish biosafety implementation. In addition, the TAC will provide advisory, training and technical backstopping for human and institutional capacities to the all the relevant aspects of the NBF. Where specific technical support cannot be identified within the region, the expertise will be outsourced from international consultants. Consultants will develop training materials to suit the context and needs of the respective participating countries.

The project will complement and build on earlier UNEP-GEF Global Project on the "Development of National Biosafety Frameworks" The NBF for Namibia was developed through the UNEP GEF Biosafety Demonstration Project. Most of draft National Biosafety Frameworks (NBFs) had clear plans of action on implementation of the National Biosafety Frameworks. The project will also provide the required data, participating countries' perspectives and contributions to the earlier USAID-funded COMESA Biotechnology and Biosafety Project, which focused on a harmonized sub-regional biosafety regulatory framework based on the existing National Biosafety Frameworks. Two (DRC and Madagascar) of the three participating countries on this project are members of COMESA. In addition, the project coordinates with the ongoing UNEP-GEF Multi Country Project to Strengthen Institutional Capacities on LMO Testing in Support of National Decision Making (MCP-ICLT). The MCP-ICLT is assisting Angola, Democratic Republic of Congo, Lesotho, Madagascar, Malawi and Mozambique through its three key components to build capacity on LMO Testing to support the implementation of the National Biosafety Frameworks. The proposed project will support Namibia in LMO Testing and related measures and support harmonization of LMO testing systems. This is done to avoid 'double dipping' and duplication. The MCP-ICLT envisages an electronic platform which will be used to share best practices on standard operating procedures, experiences and protocols on LMO testing onto which the other countries could join. These best practices and tools will assist countries in the implementation of NBFs as a resource used in monitoring of LMOs in

contained use, transit and transboundary movements. The following countries: Namibia and, DRC are participating in the ongoing ?UNEP-GEF Project for Sustainable Capacity Building for Effective Participation in the BCH (BCH III)?. The proposed project will be implemented in synergy and will benefit from subregional training on the BCH. The project will enhance the countries? capacity to compile and post the required information on BCH, through the establishment and implementation of a repository of biosafety information which is considered as a catalyst to generating and updating information on the national and global BCH, as well how to retrieve information from the global BCH for decision-making at national level for monitoring and enforcement activities such as by officials at ports of entry. Project components on Global and sub-regional networking on information sharing for effective management of the BCH and the BCH educational packages are of direct relevance and will support the implementation of public awareness, education and public participation in the SINBF project.

The proposed SINBF project will share and coordinate its experience in the elaboration of legislative, technical and administrative frameworks through new integrated Clearing House Mechanism portal under the CBD.

### **7. Consistency with National Priorities**

Describe the consistency of the project with national strategies and plans or reports and assessments under relevant conventions from below:

NAPAs, NAPs, ASGM NAPs, MIAs, NBSAPs, NCs, TNAs, NCSAs, NIPs, PRSPs, NPFE, BURs, INDCs, etc.

- National Biodiversity Strategies and Action Plan (NBSAP) under UNCBD

- National Biosafety Frameworks under the Cartagena Protocol on Biosafety

- Others

#### **National Biodiversity Strategy and Action Plans (NBSAPs)**

National biosafety frameworks constitute of a biotechnology/ biosafety policy, and legal, administrative and technical instruments developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The implementation of the National Biosafety Frameworks is in line with the National Biodiversity Strategy and Action plans (NBSAPs) of all three SINBF partner countries. Madagascar and Namibia have had opportunity to establish some regulatory and operational components of their NBFs and are more focused on specific interventions that will enable full implementation. Thus, the proposed implementation project focuses on capacity building to operationalize and implement the NBFs and address common and country-specific priorities and gaps. The SINBF project will support urgent national needs, foster regional collaboration in managing transboundary issues related to LMOs and bolster national strategies to alleviate poverty in an environmentally sustainable manner.

**Democratic Republic of the Congo** - The project is consistent and falls within the priorities set in the National Biodiversity Strategy and Action Plan (NBSAP 2016-2020). The project directly addresses Strategic Priorities 8 on Biosafety and 9 on Promotion on Scientific Research and acquisition of knowledge. The aim is to set up an operational and implementable biosafety Framework supported by a Biosafety Act. Strategic Priorities 8 and 9 identify specific actions required to drive the establishment of an operational biosafety framework. These include (i) Adoption of the Biosafety Bill to provide the required legal support for the implementation of the NBF; (ii) Updating the national biosafety framework; (iii) Strengthening all the structures provided for by the NBF, including capacity building to support

implementation of the administrative and technical frameworks to support decision making on safe use of modern biotechnology; and (iv) promotion of research in the uptake and safe use of modern technologies including modern biotechnology. The NBSAP (2016-2020) is currently under review, providing an opportunity for the SINBF project activities to support the national objective on operationalizing the NBF and contribute to the plans of action on biosafety implementation and mainstreaming.

The implementation of the NBF in DRC aligns with the targeted sustainable development and poverty reduction objectives of the Congolese Poverty Reduction Strategy (CPRS). The Ministry of Environment and Sustainable Development has been tasked to promote the development and deployment of Science and Technology at all levels to increase industrial production, employment and natural resource utilisation, enhance food security, sustainability, self-sufficiency and environmental health. Appropriate and new innovative technologies, including modern biotechnology, have been targeted as potential tools to support agriculture, health and enterprise development in the NBSAP under Strategic Priority Area 8. The SINBF project is focused on capacity building to operationalise and implement the draft NBF and support priorities that support sustainable use of biodiversity and sound environmental management.

The DRC Third National Report on the implementation of the CPB highlights the need for updating the NBF, with a strong emphasis on institutional capacity building on handling of LMOs, risk assessment to support decision making and the setting up of a biosafety law to guide biosafety practices in the DRC.

The Fifth National Biodiversity Report highlights sustainable use of biotechnology to support national development efforts and places a call for expedited action on enhanced national capacity on implementation of a science-based NBF, supported by a biosafety act. The report also emphasizes the NBF should be effectively implemented.

The SINBF project activities are in line with the new constitution adopted in 2006, which clearly introduces environmental rights and obligations (Articles 48 and 53 to 55) and provides for the creation of other domestic laws concerning, inter alia, the protection of the environment and tourism (Article 123).

**Namibia** - Namibia implemented its first National Biodiversity Strategy and Action Plan from 2001 to 2010 with a vision for Namibia's biodiversity to be healthy and resilient to threats, and for conservation and sustainable use of biodiversity to be key drivers of poverty alleviation and equitable economic growth, particularly in rural areas. The second NBSAP (2013-2022) highlights that biosafety is critical to the conservation and sustainable utilization of biodiversity, in line with Aichi Target 12 as follows - *Namibia has developed a legislative framework to promote the safe use of biotechnology and the management of living modified organisms through the Biosafety Act passed in 2006*. The legal and administrative basis to implement the Biosafety Act has been identified as a challenge. Infrastructural and human resource capacities, and insufficient awareness on biosafety contribute to limited progress in the implementation of the NBF. These challenges will be targeted directly through NBSAP 2. The SINBF project will give opportunity for institutional capacity building, and revision of legal, technical and institutional frameworks to equip Namibia for handling confined field trials, potential environmental releases and handling of Living Modified Organisms for Food, Feed and for Processing (LMOs-FFP). The envisaged deliverables are hinged on the Key Development Indicator - *Operational Institutional Framework in place to implement and enforce the Biosafety Act of 2006*. The Strategic Initiative is to *strengthen capacity and institutional frameworks to implement and enforce the (Biosafety) Act of 2006*. The need for strong institutional capacity on monitoring and enforcement is also highlighted in the National Biosafety Report as a capacity gap. Support for the proposed GEF 7 project is highlighted in the National Biosafety Report as an area to support capacity building under Articles 14 and 22. The areas for capacity building are highlighted in the report and mirror the intervention areas proposed by the SINBF project

**Madagascar** - National Biodiversity Strategy and Action Plan 2020-2025 has 5 global objectives; (i) To improve awareness about the value of biodiversity, the causes of biodiversity loss and the ecological, economic and cultural consequences of its destruction; (ii) To minimize direct pressures on biodiversity by addressing the main causes and the development of various strategies; (iii) To enhance biodiversity status by safeguarding ecosystems, species and genetic diversity like the creation and management of terrestrial protected areas by at least 10% of the area of its ecosystems and 70% of coastal and marine areas; (iv) To strengthen the benefits of biodiversity for all and the services provided by ecosystems through sustainable management of biodiversity; (v) To strengthen the implementation of an effective NBSAP using the

participatory planning of knowledge management and capacity building through setting up a system to protect traditional practices and knowledge of local communities.

Effective implementation of the NBSAP hinges on strategies for communication and education of policy makers and planners of the national economy, youth and the public and sharing knowledge and basic science on biodiversity to inform decision making and to stimulate investment in biodiversity conservation. Sustainable use of biodiversity is safeguarded through good governance, rational management and reduction in the loss or degradation of habitats and ecosystems. Thus, Madagascar places considerations for biosafety within the objective on sustainable management biodiversity. This includes protection of genetic resources from potential threats resulting from handling LMOs.

Biosafety issues are captured under Strategic Objective 12 on management and conservation of threatened species, and it specifically relates to Guidelines 12:2 - "Develop and implement management practices on new biological introductions with emphasis on monitoring, enforcement and compliance". The proposed project will assist Madagascar to finalize its Biosafety Bill and develop operational, technical and regulatory guidelines to make the national biosafety framework operational. The project will also create a platform to strengthen a team core of national experts who will be capacitated to provide expert advice and guidance to decision makers on handling of LMOs and the related pre- and post- approval biosafety measures. Madagascar's Third National Report on the implementation of the CPB, under Article 22 identifies institutional and human capacity building, monitoring and enforcement, Liability and Redress, Risk Assessment and Risk Management, Socio-economic considerations, Public Awareness, Participation and Education in Biosafety, etc., as areas where further capacity building is required.

#### **Regional Biotechnology and Biosafety Activities**

At the regional level, the project is in line with the Common Market for Eastern and Southern Africa (COMESA, DRC and Madagascar are member states) Biotechnology and Biosafety Policy Implementation Plan (COMBIP 2015) which aims to assist member states in building institutions and regulatory frameworks that will guide the use of biotechnology in agriculture. The COMBIP is designed to translate the COMESA Policy on Biotechnology and Biosafety into an effective, region-wide implementation program. The plan will enable the member states to realize their aspirations of becoming active participants in the global biotechnology enterprise through commercial planting of GM crops, trade in products of GM technology and handling of emergency food aid containing GMOs. The plan includes enhancing awareness and outreach activities on an on-going basis. A regional biosafety risk assessment mechanism is also envisaged in the plan. This will rely on the establishment and efficient functioning of a COMESA Biotechnology and Biosafety Panel of Experts and a COMESA Biosafety Risk Assessment and Management Desk. The plan will also support capacity building for biosafety regulation, biotechnology research at the local level. All three countries are members of the SADC which also has initiated activities on harmonization of National Biosafety Frameworks particularly as it relates to transboundary movement and handling of LMOs.

The project is consistent with National Strategies and Plans, or reports and assessments under relevant conventions Table 2 below shows

*If the project consistent with the National strategies and plans or reports and assessments under relevant conventions? (Key - yes 1 /no 0).*

<b>country</b>	<b>DRC</b>	<b>Madagascar</b>	<b>Namibia</b>
National Biodiversity Strategy and Action Plan (NBSAP)	1	1	1
CBD National Report	1	1	1
Cartagena Protocol National Report	1	1	1
Nagoya Protocol National Report	1	1	1

UNFCCC National Communications (NC)	0	0	0
UNFCCC Biennial Update Report (BUR)	0	0	0
UNFCCC National Determined Contribution	0	0	0
UNFCCC Technology Needs Assessment	0	0	0
UNCCD Reporting	0	0	0
ASGM National Action Plan (ASGM NAP)	0	0	0
Minamata Initial Assessment (MIA)	0	0	0
Stockholm National Implementation Plan (NIP)	0	0	0
Stockholm National Implementation Plan Update	0	0	0
National Adaptation Programme of Action Update	0	0	0
Others			
Poverty Reduction Strategy (CPRS). Biotechnology	1	-	-
Biosafety Policy Implementation Plan (COMBIP)	1	1	-

## 8. Knowledge Management

**Elaborate the "Knowledge Management Approach" for the project, including a budget, key deliverables and a timeline, and explain how it will contribute to the project's overall impact.**

**Learning and Knowledge Management:** The project will identify, analyse, document, and share biosafety information and lessons learnt, and disseminate results from the project beyond the project intervention zone through several existing information sharing networks, including online based forums, newsletters, national and a regional BCH, learn and share forums and SADC platforms. The project will establish a knowledge management hub and work on its sustainability beyond the project lifespan. Identification and analysing lessons learnt will be an ongoing process. Deliverables will be shared quarterly as applicable or at least twice a year. Publications and thematic reports will be developed and disseminated in the participating countries and at regional level. The project shall use the UNEP reporting format for categorizing, documenting and sharing of lessons learnt. In every annual review and planning meeting, information sharing will be promoted. To enable effective management of information, an Information Hub will be established during the project implementation period. The project will lobby for building of information management tasks into existing regional institutions/ structures e.g., the SADC or any other such institution. This will promote continuity beyond the project lifespan. In addition, relevant information will be posted on all BCH portals at national and regional levels, and the CBD BCH portal. UNEP has an existing platform through the library of its project management database ANUBIS (A New UNEP Biosafety Information System) for Biodiversity and Land Degradation projects and related initiatives to learn from each other, share experiences and expertise, and tools and methodologies to support biosafety decision making. ANUBIS also allows the projects to assess project outputs and reports in a user-friendly form. In addition, UNEP has created an annual forum, funded by the Biosafety Technical Fund, for the projects to physically meet at regional/sub regional levels to learn and share experiences on project management, including best practices and challenges, in addition to training on emerging issues in biosafety. The project will also have access to both the SCBD and UNEP Biosafety's YouTube channels to access media files and share materials for the benefit of the projects in the Biosafety Portfolio. Existing mechanisms and training will be offered for the project to assess and share information on the Biosafety Clearing House in line with obligations of Article 20 of the Cartagena Protocol on Biosafety and the ongoing BCH III Project.

The project will have access and contribute stories and news to the UNEP Biosafety website <https://www.unenvironment.org/explore-topics/biosafety> which is a forum set up to enable projects access information, publication, events and knowledge materials on Biosafety among the project partners.

At the national level, the knowledge management will help to build and maintain supportive and useful knowledge, attitudes, skills and practices via a number of workshops and trainings with participation of various stakeholders, including governmental sector, media, parliament, researchers, academia, farmers, women, the youth and local and Indigenous Communities. Manuals and guidelines will be developed and published and made available for all the relevant stakeholders. The national BCH websites will be updated periodically with new /relevant information and made accessible via the internet, mobile telephony, social media - Facebook, Twitter and YouTube. Communication sites will be used to disseminate information. Special publications, brochures, leaflets, posters, calendars on best practices on biosafety, etc. will be provided and disseminated through the relevant actors and stakeholders. On-line fora and webinars to discuss and share information will be used to facilitate inter-country and sub-regional communication and networking.

Furthermore, outreach materials used by the participating countries will be shared and or developed, targeted at different stakeholders, including Extension workers, Parliamentarians, Media, Women, Youth and Local communities, among others, as will be identified in the stocktaking process under Component Substantial time and efforts will be devoted to ensuring involvement of the public in meeting the national obligations on Biosafety. The National Biosafety Frameworks will be extensively reviewed, and key entry points identified and used for training on public participation in the decision-making processes. Procedural manuals and tools including gender considerations will be translated into easy and user-friendly modules to assist the public on biosafety measures. The national BCH will be updated, and a website created to serve as both an information repository and platform for the public to follow and input into the national decision-making processes on biosafety. In addition, experiences in the mainstreaming of biosafety into educational curricula at various levels will be shared, lesson learnt will be incorporated by those countries that are yet to mainstream biosafety into national development processes.

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 in relevant and appropriate, scientific, policy-based and/or any other networks, which may be of benefit to project implementation through lessons learned.

## **9. Monitoring and Evaluation**

### **Describe the budgeted M and E plan**

?In line with the GEF Evaluation requirements and UNEP's Evaluation Policy, GEF Full-Sized Projects and any project with a duration of 4 years or more will be subject to an independent Mid-Term Evaluation or management-led Mid-Term Review at mid-point. All GEF funded projects are subject to a performance assessment when they reach operational completion. This performance assessment will be either an independent Terminal Evaluation or a management-led Terminal Review.

In case a Review is required, the UNEP Evaluation Office will provide tools, templates, and guidelines to support the Review consultant. For all Terminal Reviews, the UNEP Evaluation Office will perform a quality assessment of the Terminal Review report and validate the Review's performance ratings. This quality assessment will be attached as an Annex to the Terminal Review report, validated performance ratings will be captured in the main report.

However, if an independent Terminal Evaluation (TE) of the project is required, the Evaluation Office will be responsible for the entire evaluation process and will liaise with the Task Manager and the project implementing partners at key points during the evaluation. 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 staff and implementing partners. The direct costs of the evaluation (or the management-led review) will be charged against the project evaluation budget. The TE will typically be initiated after the project's operational completion. If a follow-on phase of the project is envisaged, the timing of the evaluation will be discussed with the Evaluation Office in relation to the submission of the follow-on proposal.

The draft TE report will be sent by the Evaluation Office to project stakeholders for comment. 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 finalized. The evaluation report will be publicly disclosed and will be followed by a recommendation compliance process. The evaluation recommendations will be entered into a Recommendations Implementation Plan template by the Evaluation Office. Formal submission of the completed Recommendations Implementation Plan by the Project Manager is required within one month of its delivery to the project team. The Evaluation Office will monitor compliance with this plan every six months for a total period of 12 months from the finalisation of the Recommendations Implementation Plan. The compliance performance against the recommendations is then reported to senior management on a six-monthly basis and to member States in the Biennial Evaluation Synthesis Report

The monitoring and evaluation plan is costed as presented in the table below

#### SINBF Monitoring and Evaluation costed plan

Type of M&E activity	Responsible Parties	Budget from GEF	Budget co-finance	Time Frame
Inception Meeting	Lead Executing Agency (RAEIN-Africa), and National Executing Agencies (NEA)? DRC, Madagascar and Namibia	63,628	267,797	Within 2 months of project start-up
Measurement of project progress and performance indicators (Project Implementation Review) and reporting	(LEA), and National Executing Agencies (NEA)? DRC, Madagascar and Namibia.	130,246	548,177	Annually
Baseline measurement of project outcome indicators, GEF Core indicators (Tracking tools?)	UNEP and RAEIN-Africa	181,166	762,489	Project inception
Mid-point measurement of project outcome indicators, GEF Core indicators (Tracking tools?)	RAEIN-Africa and NEAs			Mid-Point
End-point measurement of project outcome indicators, GEF Core indicators (Tracking tools?)	UNEP, RAEIN-Africa and NEAs			End Point

Monitoring visits to field sites	RAEIN-Africa,			As appropriate
Semi-annual Progress/ Operational Reports to UNEP	RAEIN-Africa and NEAs			Within 1 month of the end of reporting period i.e. on or before 31 January and 31 July
Project Steering Committee (PSC) meetings and National Steering Committee meetings	RAEIN-Africa, UNEP and NEAs			Once a year minimum
Reports of PSC meetings	RAEIN-Africa	94,917.00	399,485	Annually, part of reporting routine
Project Operational Completion Report	RAEIN-Africa			Within 2 months of the project completion date
Co-financing reporting (including supporting evidence for in-kind co-finance)	NEAs and RAEIN-Africa	24,676.	103,856	Within 1 month of the PIR reporting period, i.e. on or before 31 July
Publication of Lessons Learnt and other project documents	RAEIN-Africa and NEA			Annually, part of Semi-annual reports & Project Final Report
Mid Term Review/Evaluation	UNEP and RAEIN-Africa	49,224	207,1734	At mid-point of project implementation
Terminal Review/Evaluation ( <i>whether a project requires a management-led review or an independent evaluation is determined annually by UNEP's Evaluation Office</i> )	UNEP	51,628	217,291	Typically initiated after the project's operational completion
<b>Totals</b>		<b>595,485</b>	<b>2,506,268</b>	

## 10. Benefits

**Describe the socioeconomic benefits to be delivered by the project at the national and local levels, as appropriate. How do these benefits translate in supporting the achievement of global environment benefits (GEF Trust Fund) or adaptation benefits (LDCE/SCCF)?**

The project activities in all the three participating countries will take into account socio-economic impact on all sectors of society, including both men and women, while preparing regulations, guidelines and outreach material. The project will also contribute to promoting good governance through the participation of all stakeholders in decision-making on LMOs. Project staff recruitment, project activities, workshops and training activities will not discriminate against any group or gender. Target groups like farmers, local communities, the general public, youth, particularly students and women will be involved in development



of awareness raising materials and help enhance social sustainability. Translation of outreach material in local languages will further promote effective participation by all stakeholders.

The use of LMOs would have great impact on the livelihood of local groups/population, country wide awareness workshops/campaigns would be organised for concerned stakeholders including representatives from NGOs, community-based organizations, mass media, students, farmers etc. Mechanisms for wider dissemination of outreach material through various extension networks will be developed. Efforts to reach out to all social segments would be made by translating outreach material in local languages. The national Biosafety Clearing House (nBCH) will be established and updated regularly for use by the stakeholders in all three participation countries. All project information will be disseminated through the nBCH. The progress of project will be shared through extensive circulation of monthly newsletters.

### 11. Environmental and Social Safeguard (ESS) Risks

Provide information on the identified environmental and social risks and potential impacts associated with the project/program based on your organization's ESS systems and procedures

#### Overall Project/Program Risk Classification \*

<b>PIF</b>	<b>CEO Endorsement/Approval</b>	<b>MTR</b>	<b>TE</b>
<b>Low</b>	<b>Low</b>		

#### Measures to address identified risks and impacts

Elaborate on the types and risk classifications/ratings of any identified environmental and social risks and impacts (considering the GEF ESS Minimum Standards) and any measures undertaken as well as planned management measures to address these risks during implementation.

Risk	Rating	Mitigation measure
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<p>a) Slow administrative and political response to biosafety issues</p>	<p>High</p>	<p>Cooperation between government structures, institutions and special awareness and lobbying programs for targeted and relevant authorities (including Parliamentarians and policy makers) will be organized at the inception of the project, with follow ups to strengthen the political support for the NBF implementation process;</p> <p>Efforts will be made to ensure biosafety is placed on a higher level in the agenda of governments and national assemblies;</p> <p>Designated Stakeholder institutions will be strengthened to do continuous outreach, lobby and network as a means of getting political leverage.</p>
<p>b) Inadequate mechanisms for institutional coordination in the management of biosafety</p>	<p>Medium</p>	<p>Regular coordination meetings for relevant ministries and agencies will be held, defining clear procedures, roles and responsibilities for all the key stakeholders identified and incorporated in the relevant policies and laws;</p> <p>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 inter-country 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, consumers, and women groups to be represented in the steering committees as part of the coordination mechanism</p>
<p>c) Low institutional capacity to manage handling of LMOs in sub-region</p>	<p>Medium</p>	<p>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 Training 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 inter-country level, efforts will also be made to get 'buy-in' by the SADC secretariat through coordination of similar interventions, lobbying and periodic briefs.</p>

<p>d) Due to climate change impacts, public perception towards LMOs change, especially if LMOs perform better under climate change conditions</p>	<p>Low</p>	<p>Potential use and import of LMOs may increase under increased temperature and other climate change related results due to tolerance to abiotic stresses.</p> <p>For DRC, the main projections under climate change suggest that seasons of heat, drought and rainfall will become more intense. These changes are likely to result in an increased frequency of extreme events, primarily floods (resulting in erosion, landslides, and crop failure) but in some cases also droughts. Food security will be affected by land and infrastructure degradation due to erosion/landslides, an increase in livestock and crop diseases due to temperature increase, direct crop failure due to floods and heavy rains. Water availability will be affected by possible periods of drought[1]<sup>1</sup>.</p> <p>Climate projections (for year 2100) for Madagascar include projected increase in temperature of 2.5°C -3°C, increased unpredictability of seasonal rains, and increased incidence or intensity of extreme weather events including droughts, cyclones and floods. Key climate impacts are crop loss/failure, loss of pasture lands and water resources for livestock, loss of marine habitat, increased ranges of vector-borne diseases and increased risk from waterborne diseases and degradation of water quality and reduced access to water supplies[2]<sup>2</sup>.</p> <p>Climate change projections for Namibia for period 2045 ? 2065 suggest: (i) minimum expected temperature increase of 1-2 °C and a maximum of 2-3.5°C in the summer, and 2.5 - 4°C in winter; and (ii) rainfall projections are uncertain with differences among regions. Implications are: (i) projected temperature rises could result in evaporation and evapotranspiration increases from 5-15%; (ii) hotter days, in tandem with shorter growing seasons, would make it harder even for resilient crops; (iii) Productivity among crops could drop by 20 ? 50%; (iv) increased difficulty in the provision of sufficient grazing for livestock; (v) heat stress on livestock which can affect feeding and reproduction[3]<sup>3</sup>. Due to the effects on food security and food production in the countries, potential use and import of LMOs that are better adapted (or perceived to be) or tolerant may increase. During PPG, the potential of climate change scenarios on the countries? response will be integrated into capacity building interventions and into the design of the ten-year strategic plans and policies to ensure that such changes to public attitude to LMOs are anticipated and proactively managed. Furthermore, the project. purpose is to strengthen [participating countries?] capacity to effectively manage safe handling and use of LMOs in such cases.</p>
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<p>e) An outbreak of diseases (Covid-19)</p>	<p>Low/Medium</p>	<p>Namibia has had as of 22<sup>nd</sup> August 2021, 124,032 total cases of COVID-19 since the start of the epidemic; 3,346 COVID-19 related deaths occurred and there was a total of 2,391 active cases. Madagascar (as of April 28<sup>th</sup>, 2021, had had a total of 36,696 cases, (the deaths and active cases were not available). DRC (as of September 8<sup>th</sup>, 2021) had 55,877 recorded total cases, 1,061 deaths<sup>[4]</sup>. Although the three countries seemingly escaped the full impact of the pandemic as compared to total and active cases of other countries, the global economic slowdown will have an economic impact on the three countries. For example, tourism is a major contributor (14.5%) to Namibia's GDP, and created 18.2% of all employment pre-COVID. This will have a major impact on the economy of the country. Under such conditions, governments are expected to focus public resources on rebuilding the economies of countries. This might affect the co-financing of the project and the ability of the project to deliver on the GEBs. However, biosafety and the set-up of stringent biosecurity conditions will also be priorities post-COVID to mitigate the recurrence of such pandemic and diseases. During PPG and project implementation the importance of having a strong biosafety regime will be communicated as part of the green recovery programme of country and building back better. Potential impacts on the commitment of co-financiers and partners will be assessed in detail during the PPG phase to develop adequate risk mitigation actions. The outbreak of Covid-19 has already affected work nationally and regionally. Travel restrictions have been in place. Should the situation continue, or should similar situations take place, the risk will be mitigated by trying to carry out relevant activities via alternative working methods (e.g., videoconferences, telecommuting, recourse to national human resources in the countries, etc.). Any mitigation measure will have to be discussed between the implementing and the executing partners/agencies. Whatever mitigation measures are tried, there will inevitably be a negative impact on the Project's capacity building activities due to restrictions on travel and assembling of many people in one place. Much as this can partially be mitigated through teleconferencing and other virtual methods of training, some stakeholders who are not computer literate or those without the requisite appliances and those in areas with poor or no internet connectivity will lose out.</p> <p>The risk is only partly under project control. Nationally and regionally, the recent outbreak of Covid-19 is already affecting work and the way people implement projects. Travel restrictions have been in place. Biosecurity considerations which is at the core of Biosafety capacity building and implementation will be fully triggered in a phased approach both to ensure human and environmental safety to project implementation measures and execution of activities guided by the technical principles of ensuring genetic and material confinement and management measures in project delivery. Standard Project Operational Procedures will be developed and followed as applicable</p>
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[1] <https://reliefweb.int/sites/reliefweb.int/files/resources/DRC%2B%28east%29.pdf>

[2]

[https://www.climatelinks.org/sites/default/files/asset/document/2016%20CRM%20Factsheet%20Madagascar\\_use%20this.pdf](https://www.climatelinks.org/sites/default/files/asset/document/2016%20CRM%20Factsheet%20Madagascar_use%20this.pdf)

[3] [https://www.geog.ox.ac.uk/events/seminars/ht09\\_water-climate-newsham.pdf](https://www.geog.ox.ac.uk/events/seminars/ht09_water-climate-newsham.pdf)

[4] <https://www.worldometers.info/coronavirus/>

#### **Supporting Documents**

Upload available ESS supporting documents.

<b>Title</b>	<b>Module</b>	<b>Submitted</b>
<b>Annex O_Safeguard Risk Identification Form_Southern Africa-Biosafety</b>	<b>CEO Endorsement ESS</b>	
<b>10584_SRIF SAfrica-Biosafety</b>	<b>Project PIF ESS</b>	
<b>Multi country Biosafety Project_ESERN</b>	<b>Project PIF ESS</b>	

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**ANNEX A: PROJECT RESULTS FRAMEWORK** (either copy and paste here the framework from the Agency document, or provide reference to the page in the project document where the framework could be found).

# **ANNEX A: LOGICAL FRAMEWORK FOR THE UNEP-GEF SINBF PROJECT**

<b>Project Objective</b>	<b>Objective level Indicators</b>	<b>Baseline</b>	<b>Targets and Monitoring Milestones</b>	<b>Means of Verification</b>	<b>Assumptions &amp; Risks</b>	<b>UNEP MTS reference*</b>
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<p>Institutional , Infrastructural, human &amp; regulatory biosafety capacities of the participating countries in the implementation of NBFs in support of the CPB and (its) Nagoya-Kuala Lumpur Supplementary Protocol on Liability &amp; Redress</p>	<p>Number of successful simulations on biosafety decisions carried out by the end of the project</p> <p>Number of decisions made by the participating countries</p> <p>Quality of biosafety information posted on the BCH by the participating countries</p>	<ul style="list-style-type: none"> <li>- Namibia has a law in place but not yet fully functional and has inadequate capacity for biosafety implementation</li> <li>- Madagascar has a bill and draft biosafety systems</li> <li>- DRC has a bill</li> </ul>	<p><i>Strengthened national institutional, infrastructural, human &amp; regulatory biosafety capacities for implementation of NBFs</i></p>	<ul style="list-style-type: none"> <li>- Review of systems and structures for biosafety implementation adapted and used by participating countries</li> <li>- and biosafety decision making systems as regulated by the national law.</li> <li>- Sources of information include National reports,</li> <li>- Project Midterm and terminal review reports,</li> <li>- BCH</li> </ul>	<p>The national actors in each of the participating countries will promote and act in the strengthening and operationalisation of national biosafety frameworks</p>	<p><b>Foundation Programme - Environmental Governance</b></p> <p><i>Nature Action Programme</i></p> <p><b>(Governance, Institutional Capacity and Accountability for Nature - policy coherence, decision-making, metrics)</b></p>
<p><b>Project Outcome 1.0</b></p>	<p><b>Outcome Indicators</b></p>	<p><b>Baseline</b></p>	<p><b>Targets and Monitoring Milestones</b></p>	<p><b>Means of Verification</b></p>	<p><b>Assumptions &amp; Risks</b></p>	<p><b>MTS Expected Accomplishment</b></p>

<p>Government of DRC, Madagascar and Namibia adopted a revised legal framework on biosafety aligned to the CPB and Nagoya-Kuala Lumpur Supplementary Protocol and have taken measures to accelerate effective management and monitoring of LMOs.</p>	<p>Number of countries that have a legal framework on biosafety consistent with the CPB and Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress</p> <p>-</p> <p>Number of countries with NBSAPs and Post 2020 GBF Plans that include biosafety consideration</p> <p>-</p>	<p>- 0</p> <p>(Namibian Biosafety Act (2006) in place, but requires review and update of the law to be aligned with CPB Madagascar's draft bill requires submission to parliament for approval.</p> <p>DRC draft bill requires updating &amp; submission for parliament)</p>	<p>- 3</p> <p>(DRC and Madagascar Biosafety Bills for updated (aligned with Post 2020 GBF Plan)</p> <p>Namibia biosafety implementing regulations reviewed (aligned with Post 2020 GBF Plan)</p>	<p>- Namibia Government Gazette; DRC Official Gazette; Madagascar official decree</p> <p>- Country Reports to CPB; NBSAP published in government sites</p>	<p>- An enabling environment created by national actors for reviewing and updating of the laws/ bills</p> <p>- Broad participation by relevant stakeholders</p> <p><b>Risks</b></p> <p>- Lengthy legislative processes at national assembly in passing of the bills into law and/ or adoption of reviewed laws</p> <p>- Lack of internal support and champions within governments</p>	<p><i>Institutional capacity enhanced and accountability frameworks strengthened to adopt and act on national and international commitments.</i></p> <p><i>(Outcome 2B)</i></p>
<p><b>Project Outputs 1.1</b></p>	<p><b>Output Indicators</b></p>	<p><b>Baseline</b></p>	<p><b>Targets and Monitoring Milestones</b></p>	<p><b>Means of Verification</b></p>	<p><b>Assumptions &amp; Risks</b></p>	<p><b>PoW Output Reference Number</b></p>



<p>A set of National Core teams? (a set of selected multidisciplinary teams of experts from each project country) supported with training and backstopping to cooperate in the review of national biosafety laws, policies and plans, and prepare national decisions to meet the CPB and Nagoya-Kuala Lumpur Supplementary Protocol requirements</p>	<ul style="list-style-type: none"> <li>- Number of national core teams on policy &amp; regulatory regimes (established and operational)</li> <li>) Number of peer-to-peer mentoring, advisory services and training on biosafety to share knowledge and lessons among NTC members and between countries</li> <li>-</li> </ul>	<ul style="list-style-type: none"> <li>- Limited national capacity on biosafety policy &amp; regulatory regimes</li> <li>- Limited intercountry sharing of experiences on biosafety implementation</li> </ul>	<p>Updated and reviewed national laws and bills</p> <p>Available adapted guidance on review &amp; update of biosafety laws among participating countries.</p>	<ul style="list-style-type: none"> <li>- Committees established for review of laws and policies by end of Year 1</li> <li>- Available support systems for the committees to review by Year 1</li> </ul>	<p><b>Risks</b></p> <ul style="list-style-type: none"> <li>- Limited leadership, mechanism and technical support for review at national level</li> </ul>	<p>2.9, 2.11</p>
Project Outputs 1.2	Output Indicators	Baseline	Targets and Monitoring Milestones	Means of Verification	Assumptions & Risks	PoW Output Reference Number

<p>Decision makers in project countries supported with information, training and technical assistance to influence prioritisation and promotion of policies and legal instruments to meet obligations to the CPB and the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress</p>	<p>Number of government officials, judges and magistrates, and national experts who have gained new knowledge on biosafety legislation and enforcement reporting attitudes in support to biosafety enforcement and the skills to do so.</p> <p>Number of decision makers from biosafety mandated (related?) institutions and parliament who acknowledge being influenced by communication products and services</p>	<p>0 Core Teams capacitated and Promoting prioritisation of policies and legal instruments to meet obligations to the CPB.</p> <p>Existing Biosafety Act (Namibia) and draft biosafety bill (DRC) not fully aligned with CPB and NKLSF. Madagascar bill updated but not yet enacted</p> <p>All regulatory regimes require alignment with the Post 2020 GBF</p>	<p>3 National Core Teams (1 each in DRC, Madagascar and Namibia)</p> <p>Namibia updated law and its implementing legislation improved and aligned with CPB and its protocols,</p> <p>Madagascar &amp; DRC updated bills being considered for enactment</p> <p>Updated laws and bills validated by relevant <i>stakeholders</i></p>	<ul style="list-style-type: none"> <li>- Government Reports, Gazette, decrees</li> <li>- Reviewed laws and bills drafted by end of project</li> <li>- Document of analysis for alignment with CPB, NKLSF &amp; Post 2020 GBF by Year 3</li> </ul>	<ul style="list-style-type: none"> <li>- Financial support available for functions of governance regimes</li> </ul>	<p>2.9, 2.11</p>
<p><b>Project Outputs 1.3</b></p>	<p><b>Output Indicators</b></p>	<p><b>Baseline</b></p>	<p><b>Targets and Monitoring Milestones</b></p>	<p><b>Means of Verification</b></p>	<p><b>Assumptions &amp; Risks</b></p>	<p><b>PoW Output Reference Number</b></p>

<p>Biosafety mainstreamed into relevant national sustainable development policies and strategies, including NBSAPs and the Post 2020 GBF</p>	<ul style="list-style-type: none"> <li>- Number of sectors identifying opportunities for mainstreaming biosafety in each of the 3 countries</li> <li>- Number &amp; diversity of national policies &amp; plans in which biosafety has been mainstreamed</li> </ul>	<ul style="list-style-type: none"> <li>- 0 mainstreaming of biosafety to date achieved in all the 3 countries.</li> <li>- Madagascar has highlighted opportunities for mainstreaming biosafety into national plans &amp; policies</li> <li>- DRC's NBSAP has opportunities for mainstreaming biosafety</li> </ul>	<ul style="list-style-type: none"> <li>- All 3 countries mainstreaming biosafety into the main national sustainable development policies</li> </ul>	<ul style="list-style-type: none"> <li>- Reports identifying opportunities for mainstreaming biosafety into national policies &amp; plans in Year 1 by SINBF TAC responsible</li> <li>- National policies &amp; plans in which biosafety has been mainstreamed by end of Project</li> </ul>	<ul style="list-style-type: none"> <li>- Available Government support for the process</li> </ul> <p><b>Risks</b></p> <ul style="list-style-type: none"> <li>- Internal national challenges due to lack of clearly defined roles and responsibilities</li> </ul>	<p>2.9, 2.11</p>
<p><b>Project Outcome 2.0</b></p>	<p><b>Outcome Indicators</b></p>	<p><b>Baseline</b></p>	<p><b>Targets and Monitoring Milestones</b></p>	<p><b>Means of Verification</b></p>	<p><b>Assumptions &amp; Risks</b></p>	<p><b>MTS Expected Accomplishment</b></p>

<p><i>National mandated institutions and stakeholder s take measures to strengthen implementation compliance and enforcement of updated National Biosafety Frameworks.</i></p>	<ul style="list-style-type: none"> <li>- Number of institutions per project country with mandates on biosafety implementation that have adopted administrative procedures to institutionalized biosafety in thematic areas</li> <li>- Number of inter institutional committees on biosafety as per CPB requirements functional in project countries</li> </ul>	<p>Namibia has some institutional systems established, whilst Madagascar and DRC are yet to establish systems</p>	<p>Biosafety institutional systems established and strengthened</p>	<ul style="list-style-type: none"> <li>- SOPs;</li> <li>- Memos from Head of Institution,</li> <li>- Organisation al Manuals</li> <li>- Presence of institutions with clear mandates accompanied by pre-requisite capacities for biosafety implementation</li> </ul>	<ul style="list-style-type: none"> <li>- National Governmen ts grant mandates to the relevant</li> <li>- National government s allocate adequate resources and support for establishment and/ or functioning of the relevant biosafety institutions</li> </ul>	<p><i>Institutional capacity enhanced and accountability frameworks strengthened to adopt and act on national and international commitments .</i></p> <p><i>(Outcome 2B)</i></p>
<p><b>Project Outputs 2.1</b></p>	<p><b>Output Indicators</b></p>	<p><b>Baseline</b></p>	<p><b>Targets and Monitoring Milestones</b></p>	<p><b>Means of Verification</b></p>	<p><b>Assumptions &amp; Risks</b></p>	<p><b>PoW Output Reference Number</b></p>

<p>Multidisciplinary teams of national experts from project countries trained and backstopped to train government officials and their stakeholders in the implementation of biosafety and thematic areas</p>	<ul style="list-style-type: none"> <li>- Number of trained trainers on biosafety institutional and thematic areas</li> <li>- Number of national core teams actively involved in capacity building on biosafety institutional and thematic issues</li> <li>Number of countries that have conducted TOT</li> </ul>	<ul style="list-style-type: none"> <li>- <i>Limited number of national experts training on biosafety institutional and thematic issues</i></li> </ul>	<p>At least 1 trainer per thematic area per country</p> <p>National core teams actively undertaking capacity building activities with other national stakeholders on biosafety institutional and thematic issues</p>	<ul style="list-style-type: none"> <li>- Published proceedings of training workshops</li> <li>- National reports on project</li> </ul>	<ul style="list-style-type: none"> <li>- Trained trainers can train country teams on acquired skill sets on biosafety</li> </ul> <p><b>Risk</b></p> <ul style="list-style-type: none"> <li>- Trained trainers fail to effectively train at national level</li> </ul>	<p>2.9, 2.11</p>
<p><b>Project Outputs 2.2</b></p>	<p><b>Output Indicators</b></p>	<p><b>Baseline</b></p>	<p><b>Targets and Monitoring Milestones</b></p>	<p><b>Means of Verification</b></p>	<p><b>Assumptions &amp; Risks</b></p>	<p><b>PoW Output Reference Number</b></p>

<p>National biosafety administrative systems strengthened <i>with training and technical assistance to review and update processes and systems to implementation of national biosafety considerations</i></p>	<ul style="list-style-type: none"> <li>- Number of institutions with mandates on biosafety implementation</li> <li>- Number of functional inter institutional committees on biosafety constituted</li> <li>- Number of administrative procedures documented and published</li> <li>- Number of simulations undertaken</li> <li>- Number of decisions made on applications</li> </ul>	<ul style="list-style-type: none"> <li>- Namibia has mandated institutions that are not fully implementing the NBF</li> <li>- Madagascar biosafety institutions have no legal mandates</li> <li>- DRC has no institutional framework for biosafety</li> </ul>	<p>All countries have fully functional NBFs in place</p> <p>All participating countries have administrative structures in place</p>	<ul style="list-style-type: none"> <li>- Simulation of the whole biosafety 5 component process by Year 4</li> <li>- National biosafety country reports</li> <li>- Number of applications received and reviewed by end of project</li> </ul>	<p><b>Risks</b></p> <ul style="list-style-type: none"> <li>- Willingness by national governments to establish support systems for biosafety administration (infrastructural support, relevant personnel and adequate financial support)</li> </ul>	<p>2.9, 2.11</p>
<p><b>Project Outputs 2.3</b></p>	<p><b>Output Indicators</b></p>	<p><b>Baseline</b></p>	<p><b>Targets and Monitoring Milestones</b></p>	<p><b>Means of Verification</b></p>	<p><b>Assumptions &amp; Risks</b></p>	<p><b>PoW Output Reference Number</b></p>

<p>Biosafety risk assessment and risk management systems strengthened with technical support to provide data for informed decision making.</p>	<ul style="list-style-type: none"> <li>- Number of technical tools and resources on RA &amp; RM produced</li> <li>- Number of workshops on RA &amp; RM</li> <li>- Number of simulations on ?real case? studies</li> </ul>	<ul style="list-style-type: none"> <li>- Madagascar and Namibia have procedures for RA &amp; RM</li> <li>- Madagascar's documents require approval &amp; Namibia procedures require updating. In addition, <i>COMESA has published Guidelines on Free Movement of People and Goods. DRC &amp; Madagascar are members to COMESA</i></li> </ul>	<p>Namibia RA &amp; RM procedures updated and functional</p> <ul style="list-style-type: none"> <li>- Madagascar RA &amp; RM documents finalised and adopted</li> <li>- DRC RA &amp; RM procedures put in place</li> </ul>	<ul style="list-style-type: none"> <li>- RA &amp; RM documents for each partner country adopted and in use</li> <li>- Simulation reports with stakeholder comments published</li> </ul>	<ul style="list-style-type: none"> <li>- The RA &amp; RM tools are completed and validated within the project lifespan</li> </ul> <p style="text-align: center;"><b>Risks</b></p> <ul style="list-style-type: none"> <li>- General lack of interest in Biosafety</li> </ul>	<p style="text-align: center;">2.9, 2.11</p>
<p style="text-align: center;"><b>Project Outputs 2.4</b></p>	<p style="text-align: center;"><b>Output Indicators</b></p>	<p style="text-align: center;"><b>Baseline</b></p>	<p style="text-align: center;"><b>Targets and Monitoring Milestones</b></p>	<p style="text-align: center;"><b>Means of Verification</b></p>	<p style="text-align: center;"><b>Assumptions &amp; Risks</b></p>	<p style="text-align: center;"><b>PoW Output Reference Number</b></p>
<p>National Biosafety systems supported with capacity to develop and strengthen national guidelines on biosafety socio-economic considerations</p>	<p>National guidance documents on socio-economic considerations</p>	<p>Zero National guidance documents existing.</p>	<ul style="list-style-type: none"> <li>- a minimum of three national Socio-economic guidelines adapted to national contexts</li> </ul>	<ul style="list-style-type: none"> <li>- National Reports</li> <li>- The guidelines documents on socio-economic considerations (One intercountry and three national)</li> <li>-</li> </ul>	<p>Countries willing to adapt the developed socio-economic guidelines to local context.</p> <p style="text-align: center;"><b>Risks</b></p> <p>General national lack of interest</p>	<p style="text-align: center;">2.9, 2.11</p>

<b>Project Outputs 2.5</b>	<b>Output Indicators</b>	<b>Baseline</b>	<b>Targets and Monitoring Milestones</b>	<b>Means of Verification</b>	<b>Assumptions &amp; Risks</b>	<b>PoW Output Reference Number</b>
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<p>National Biosafety systems provided with technical support to develop and/or strengthen monitoring and enforcement systems for follow-up</p>	<ul style="list-style-type: none"> <li>- Number of biosafety inspectors trained &amp; certified</li> <li>- Number of frontline personnel trained on use of BCH for finding information to support decision making</li> <li>- Number of LMO testing facilities functional and meeting agreed on standards</li> <li>- Results from proficiency testing and lab audits</li> <li>- Results from simulation of monitoring and enforcement systems</li> </ul>	<ul style="list-style-type: none"> <li>- Inspectors not certified for biosafety Monitoring and enforcement,</li> <li>- 4 functional laboratories (2 in Madagascar &amp; 2 in DRC) from MCP-ICLT project and 1 in Namibia lab partially functional</li> </ul>	<ul style="list-style-type: none"> <li>- A minimum of six Certified inspectors per country</li> <li>- At least one Lab per country meets acceptable standards</li> <li>- Each country to have a functional monitoring and inspection system.</li> </ul>	<ul style="list-style-type: none"> <li>- Proceedings of the training workshops</li> <li>- Certified officers available for monitoring &amp; enforcement</li> <li>- Proficiency test results</li> <li>- Lab audit reports on quality management systems</li> <li>- Reports from simulation exercises</li> <li>- Number of functional LMO detection networks</li> </ul> <p>50% of the above implemented by mid-term</p>	<p>Government support for implementation of the monitoring and enforcement guidelines</p>	<p>2.9, 2.11</p>
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<b>Project Outputs 2.6</b>	<b>Output Indicators</b>	<b>Baseline</b>	<b>Targets and Monitoring Milestones</b>	<b>Means of Verification</b>	<b>Assumptions &amp; Risks</b>	<b>PoW Output Reference Number</b>
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<p>Guidelines and technical tools on biosafety, and shared</p> <p>Tools and guidelines on RA+RM; handling and review of applications ; socio economic considerations and public participation cooperatively developed for adaptation to the national context for disseminated to decision makers from legally mandated institutions and key stakeholders from Academia and civil society in the project countries</p>	<ul style="list-style-type: none"> <li>- Number of Guidance documents and technical tools cooperatively developed</li> <li>- Number of adapted guidelines &amp; tools adopted for use at country level</li> <li>- Number of reports on experience sharing activities</li> <li>- Number technical backstopping activities to countries</li> </ul>	<p>Technical tools and guidelines that can inform the intercountry process are available as follows:</p> <ul style="list-style-type: none"> <li>- <i>CBD guidelines on risk assessment and risk management</i></li> <li>- Namibia &amp; Madagascar have RA &amp;RM baseline documents that require alignment with CBP, on stacked/ multiple events.</li> <li>- Namibia and Madagascar have several documents developed by earlier projects that form a baseline.</li> <li>- Guideline document on spatial arrangements for LMO testing labs developed by the MCP-ICLT project.</li> <li>- Zero dedicated law(s) on liability and redress.</li> <li>- Voluntary guidance document on SE considerations available</li> </ul>	<p>Guidelines and technical documents adapted to national contexts</p> <p>Trained National Core Team to lead the national adaptation processes</p>	<ul style="list-style-type: none"> <li>- National Reports</li> <li>- An Inter-country manual on ?Procedures for handling and review of applications, decision-making and issuance of permits?</li> <li>- A training module on ?Practical risk assessment with real case studies? adapted and used</li> <li>- A model guideline on socio-economic considerations (including checklists),</li> <li>- A guideline document on Monitoring and Enforcement (on inspection, transit measures, packaging, identification &amp; labelling, and port handling systems) developed,</li> <li>- A guideline on communication strategy, public awareness, education and public participation (PAEP) (including awareness creation and participation strategies) developed for adaptation by countries</li> <li>- Technical backstopping</li> </ul>	<p>Partner countries are willing to adapt the cooperatively developed guideline documents</p> <p><b>Risk</b></p> <p>Slow adaptation of Guidelines at the national level</p>	<p>2.9, 2.11</p> <p><i>National experts trained on biosafety data management and sharing,</i></p>
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<b>Project Outputs 2.7</b>	<b>Output Indicators</b>	<b>Baseline</b>	<b>Targets and Monitoring Milestones</b>	<b>Means of Verification</b>	<b>Assumptions &amp; Risks</b>	<b>PoW Output Reference Number</b>
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<p>.Capacities and systems on biosafety communication systems for public information, public awareness and public participation in biosafety strengthened through provision of communication products and services and support mobilised through participation in key forums to influence sound management of LMOs in SADC and COMESA</p>	<ul style="list-style-type: none"> <li>- Level of awareness on biosafety by stakeholders</li> <li>- Level of stakeholder participation in Biosafety decision making</li> <li>- Number of awareness creation materials produced</li> <li>- - Number of Public awareness creation activities carried out at national level</li> <li>- Number of communication strategies adapted at national level</li> <li>- Number of knowledge management products developed</li> </ul>	<ul style="list-style-type: none"> <li>- Zero documentation and analysis of Public participation in biosafety decision making processes by the countries available,</li> <li>- Madagascar and Namibia have some materials on PAEP including survey reports on knowledge levels &amp; have implemented some public awareness creation activities</li> <li>- DRC engaged with the public in the development of the bill</li> </ul>	<ul style="list-style-type: none"> <li>- At least 4 peer reviewed publications on implementation of biosafety and PAEP</li> <li>- All three national Systems? public education, awareness, participation and access to biosafety information reviewed and updated</li> </ul>	<ul style="list-style-type: none"> <li>-</li> <li>-</li> <li>- National Reports, Midterm project review,</li> <li>- Terminal project review.</li> <li>- Media articles.</li> <li>- Survey results at start of project, at midterm and at end of project</li> <li>- Number of Knowledge management products developed</li> </ul>	<ul style="list-style-type: none"> <li>- Countries will adapt and mainstream public awareness creation activities into national activities and events</li> <li>- Informed public to participate in decision making</li> </ul>	<p>2.9, 2.11</p>
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Systems and structures for project coordination and management established	- Systems and structures for project coordination and management in place and functional	No systems developed yet	<i>National systems for project implementation functional and strengthened</i>  <i>National systems for implementation of project in place and functional</i>	- Existence of functional national biosafety coordinating institutions  - Structures for project coordination and management in place by Year 1	<i>Supporting personnel and funds provided by governments</i>	2.9, 2.11
<b>Project Outputs 3.2</b>	<b>Output Indicators</b>	<b>Baseline</b>	<b>Targets and Monitoring Milestones</b>	<b>Means of Verification</b>	<b>Assumptions &amp; Risks</b>	<b>PoW Output Reference Number</b>
M &E framework institutionalized and operationalized and Lessons learnt shared to influence biosafety at regional levels for impact beyond the Project.	- M&E framework developed ( <i>achieved, see Annex J and Appendix 8 Reporting Requirements</i> )  - Lessons learnt documented  - Lessons learnt institutionalised	- No M&E framework developed yet	<i>M&amp;E framework utilized for monitoring project outputs and for reporting</i>  M&E framework in place	- M&E framework document developed and circulated to partners by mid-term  - M&E reports reflecting outputs being monitored - ongoing  - Documented lessons learnt  - Assessment of national biosafety systems to verify incorporation of lessons learnt by end of project	Countries will adapt and use the M&E framework	2.9, 2.11

**ANNEX B: RESPONSES TO PROJECT REVIEWS (from GEF Secretariat and GEF Agencies, and Responses to Comments from Council at work program inclusion and the Convention Secretariat and STAP at PIF).**

**Responses to STAP and Council comments**

<b>Part I: Project Information</b>	<b>Response</b>		<b>Review Response</b>
<b>GEF ID</b>	10584		
<b>Project Title</b>	Strengthening the Implementation of National Biosafety Frameworks in Southern Africa (SINBF)		
<b>Date of Screening</b>	November 13 2020		
<b>STAP member screener</b>	Rosie Cooney		
<b>STAP secretariat screener</b>	Virginia Gorsevski		



**STAP Overall  
Assessment and Rating**

**Minor**

STAP welcomes this proposal from three southern African countries to establish robust National Biosafety Frameworks, to respond to the prospect of increased trade in Living Modified Organisms (LMOs) in the region.

While this is an important priority with clear significance to biodiversity, the pathway through which this policy work will lead to eventual benefits for biodiversity conservation/sustainable use is not articulated.

STAP recognizes that it is challenging to give specific indicators for global environmental benefits (GEBs); however, the project should clarify how this work will (over longer timeframes) contribute to reducing threats to biodiversity. The problem statement is rather weak, providing no detail on the state of LMO trade/demand in these countries and no detail on the potential of LMO trade to either benefit or raise threats to biodiversity.

In general, the PIF leaves details on many aspects to the PPG stage. The Theory of Change is a good start but needs considerable development to go beyond being a logframe to being a useful and robust TOC. Such a TOC would enable the logical links among the project interventions, and between the interventions and achieving GEBs, to be clearly drawn, and assumptions more comprehensively identified.

Finally, climate change is likely to considerably alter the risks of LMOs in any particular context, raising the need for its explicit

The project overall objects have been clearly articulated to establish the pathways set for realizing the preparedness of the participating countries to minimize the threat to biodiversity. A robust Theory of Change has been developed which establishes the links among project interventions in contributing to global environmental benefits (GEBs). Southern African region being one of the hotspots of biodiversity in the world.

The guidance on potential risks on climate change is noted and will be considered in the development of risk assessment and risk management procedures

<b>Part I: Project Information</b>	<b>What STAP looks for</b>	<b>Response</b>	
<b>B. Indicative Project Description Summary</b>			

Project Objective	Is the objective clearly defined, and consistently related to the problem diagnosis?	<p>The project objective is "To strengthen institutional, human and regulatory capacities and promote cooperative measures in the implementation of National Biosafety Frameworks in the Participating Southern African countries." It responds to the emergent use of Living Modified Organisms in the region (in South Africa and Eswatini) in the absence of any multilateral agreement to regulate movement of these, and inadequate national frameworks in many countries, with obvious risks for biodiversity. However, the potential problems for biodiversity conservation/SU stemming from movement of LMOs is not spelt out in any detail, and not in any way specific to these countries or this region. It is also not clear that the project is specifically aimed at addressing biodiversity risks rather than e.g. facilitating movement and use of LMOs - in various places it reads rather as the latter. Further, the geographic scope of the project is odd or at least not explained, particularly as the transboundary nature of ecosystems is offered as a reason for the need for cooperation: Madagascar, Namibia and DRC - why these, and why not South Africa and Eswatini? Is there particular trade (current or envisaged) among these countries that</p>	<p>Even though the project is currently designed to address the following biosafety activities in the three participating countries, institutional and human capacity, awareness of the importance of biosafety for sustainable development in general and lack of prioritization of biosafety as general barriers hindering the development and/or full implementation of national biosafety frameworks; the outcomes of the project and lessons learned have been organized in the design to benefit the Southern African Development Community comprising 16 Member States in the region. Though all the countries in the region had expressed interest, the Parties due to limitations and demands on their STAR allocation, they could not join.</p> <p>The proposed project also intends to contribute to ongoing work on the COMESA biotechnology/ biosafety regional policy and the draft SADC Policy on transboundary movements for living modified organisms. It intends to create a platform for assessment and testing of the process and lessons learnt in both the development and implementation to date of the COMESA and SADC biotechnology/Biosafety policy.</p> <p>The project is expected to ?snowball? into other regional dialogues and prioritization of cooperative approach to implementation of the CPB, with impact on the vision of SADC countries to safely handle and utilize biotechnology for sustainable development and economic growth.</p>
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Project components	A brief description of the planned activities. Do these support the project's objectives?	Generally yes, but see weaknesses below under Theory of Change.	The Theory of Change (TOC) have been expanded and organized to reflect the planned activities and their linkages and paths to the overall goal. The proponents also extend appreciation for the guidance from the German Council Member
Outcomes	A description of the expected short-term and medium-term effects of an intervention.  Do the planned outcomes encompass important adaptation benefits?	Short term effects and medium-term effects are reasonably clear, but not how these link to long term biodiversity conservation.  This is very unclear, as GEBs are not articulated.	The project is designed to also contribute to Target 17 of the Post 2020 Global Biodiversity Framework through elaboration of biosafety measures that ensure the diversity of cultivated plants and domesticated animals and wild relatives/landraces, and the integrity of land races is maintained through management practices that contain and ensure material and genetic confinement. In addition, the Cartagena Protocol on Biosafety is an environmental safeguards framework instrument which ensures that Parties put in place interventions with scientifically sound risk analysis and detection processes that restore and safeguard ecosystem services.
	Are the global environmental benefits/adaptation benefits likely to be generated?	See above.	As above

Outputs	<p>A description of the products and services which are expected to result from the project.</p> <p>Is the sum of the outputs likely to contribute to the outcomes?</p>	<p>The outputs are not well specified at this point, though will be clarified in further planning. The range of potential activities/outputs which are included are generally appropriate for achieving the outcomes.</p>	<p>The outputs have been clearly specified in the project design and reflected in the Theory of Change</p>
<b>Part II: Project justification</b>	<p>A simple narrative explaining the project's logic, i.e. a theory of change.</p>		

<p><b>1. Project description.</b>  <b>Briefly describe:</b></p> <p>1) the global environmental and/or adaptation problems, root causes and barriers that need to be addressed (systems description)</p>	<p>Is the problem statement well-defined?</p>	<p>No, not really. While it is clear that there are inadequate mechanisms in place in these countries to regulate movement of LMOs, the biodiversity "problem" linked to this is not articulated with any specificity or detail, and it is therefore hard to assess whether the planned interventions will fully address it. Presumably for these countries there may be potential biodiversity benefits of (some forms of) biotechnology, but also specific dangers for biodiversity from its introduction and use. Text saying "This limited inertia has led to unscientific barriers to movements of LMOs" appears to assume barriers based on lack of knowledge are unscientific, rather than a perfectly rational response to highly uncertain risk (consistent with the precautionary principle embedded in the Biosafety Protocol). On p13/14 the description of the stages different countries are at is confusing only three of these countries are participants, it seems, so it is not clear why the rest are listed as participants here?</p>	<p>The project concept has been fully articulated with the problems stated and interventions identified clearly.</p>
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	<p>Are the barriers and threats well described, and substantiated by data and references?</p>	<p>The text conflates barriers and root causes, giving the same list for each. These are in any case really aspects of the problem, rather than being either root causes (deeper, more fundamental drivers leading to the proximate problem) or barriers (what stands in the way of change?)</p>	<p>The project has clearly identified root causes for the lack of functional national biosafety systems in the three countries as: (i) Lack of clear strategic focus and prioritization of biosafety issues by legislature; (ii) Inadequate biosafety legal regimes to support establishment of the national biosafety frameworks; (iii) Inadequate administrative and institutional frameworks supported by law; (iv) Inadequate human and institutional capacities and resources of national systems to assist in the development and/or implementation of the biosafety regulatory regimes; (v) Limited guidance on possible strategic, legal and technical issues required to refine and operationalize national biosafety systems; (vi) Limited awareness across the relevant biosafety chain actors and other stakeholders; and (vii) Limited engagement and cooperation within the region on transboundary movement of LMOs.</p> <p>(See section 2.3 of the UNEP Project Document)</p> <p>The proposed project interventions have been guided by the above root causes.</p>
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	For multiple focal area projects: does the problem statement and analysis identify the drivers of environmental degradation which need to be addressed through multiple focal areas; and is the objective well-defined, and can it only be supported by integrating two, or more focal areas objectives or programs?	N/A	
2) the baseline scenario or any associated baseline projects	Is the baseline identified clearly?	No, not really. The baseline scenario set out summarises the policy/institutional/capacity context of each country in relation to biosafety, albeit not entirely clearly, but does not set out a baseline in terms of relevant factors such as the level of interest in/use of LMOs, project increase intrade/use, potential biodiversity benefits of or risks posed by LMOs, etc.	After national consultations, baseline scenarios have been clearly identified with regards to potential biodiversity benefits of or risks posed by LMOs, etc. in the biodiversity rich region.
	Does it provide a feasible basis for quantifying the project's benefits?	No, see above.	Quantifiable project benefits have also been clearly identified.
	Is the baseline sufficiently robust to support the incremental (additional cost) reasoning for the project?	The incremental cost reasoning explains why this investment is necessary in order to improve the national biosafety frameworks of the countries, but not how this links to the project's biodiversity benefits.	The TOC has been designed and shows directly how project outcomes are linked to the project's biodiversity benefits.
	For multiple focal area projects:		
	are the multiple baseline analyses presented (supported by data and references), and the multiple benefits specified, including the proposed indicators;	N/A	



	<p>are the lessons learned from similar or related past GEF and non-GEF interventions described; and how did these lessons inform the design of this project?</p>	<p>No - a number of very closely related projects are listed, but no clear lessons drawn from these are articulated. Since it seems that a number of these aimed at achieving what this project is achieving (e.g. two prior projects aimed at establishing a biosafety framework for Madagascar), it seems vital to understand why this has not been adequately achieved to date. What were the problems and challenges, and how will this project overcome them?</p>	<p>The project is being executed using an incremental approach?. Achievements accrued from earlier projects, will constitute the baseline for the SINBF activities. For example, DRC and Madagascar who benefited from the MCP-ICLT project, have established GMO testing facilities and Namibia has a GM testing facility from earlier investments. Thus, the project will only support strengthening activities related to these GM testing facilities.</p>
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	how did these lessons inform the design of this project?	See above.	
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<p>3) the proposed alternatives scenario with a brief description of expected outcomes and components of the project</p>	<p>What is the theory of change?</p>	<p>A graphic TOC was provided in a separate document. However, it is really just a reorganised logframe. There are many cross-linkages and dependencies between the pathways that are not shown here. For example, the activities on common approaches to RA (pathway 3) will surely feed into the output of "tools etc on RA are strengthened" (pathway 1). And what about all the steps between policies/systems being developed and them actually having impact? For instance, for policies to have impact they need to be implemented consistently, which in turn requires understanding, political will, perhaps monitoring etc. A useful TOC will set out all the key steps towards actually having the real-world impact, allowing project planners to see critical assumptions at each step and monitor whether they are being fulfilled in practice. In the narrative description, there is a clear link between outputs and outcomes, but the relationship of the outcomes to the impact is not at all clear (going back to the unclear problem statement). How exactly do these outcomes promote the envisaged biodiversity benefits?</p> <p>Further, the outputs are quite general, and the descriptions of activities to achieve them are still quite amorphous. While they all appear generally appropriate for achieving the outputs/outcomes there is a great deal of specification required in the next stage of planning, and it is difficult to feel confident at this stage that the activities will be adequate to achieve outputs, and outputs adequate to achieve outcomes. There also seems a great deal of overlap between Outcome 1 and outcome 2b ? is the key difference that 2b involves those outputs/activities to be pursued cooperatively across countries? If so why is this element not grouped with Outcome 1? Clearer organisation/delineation of the</p>	<p>A TOC has been provided which sets out all the key steps towards achieving the overall goal of the project and the real-world impact.</p> <p>The TOC allows project planners to see critical assumptions at each step and monitor whether they are being fulfilled in practice.</p>
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	What is the sequence of events (required or expected) that will lead to the desired outcomes?	See above.	
	What is the set of linked activities, outputs, and outcomes to address the project's objectives?	See above.	
	Are the mechanisms of change plausible, and is there a well-informed identification of the underlying assumptions?	The mechanisms of change are unclear in terms of achieving the project impact (see above). The identification of assumptions (section 5) focuses very much on procedure i.e. that things planned will actually be done - rather than unpacking assumptions inherent in the logic of the project - a clear graphic TOC would assist in identifying these. For example, a key assumption might be that risk assessment procedures and capacity are adequate to identify highly uncertain potential biodiversity risks posed by novel LMOs. Or that the administrative structures and procedures established by the project persist after the end of the project.	A clear graphic TOC have been provided depicting the mechanisms of change, key assumptions and pathways.

	Is there a recognition of what adaptations may be required during project implementation to respond to changing conditions in pursuit of the targeted outcomes?	No, there does not appear to be any consideration of adaptations for changing circumstances.	The project design recognizes what adaptations may be required during project implementation to respond to changing conditions in pursuit of the targeted outcomes. This is further highlighted in the risk analysis section of the project document and the CEO Endorsement template
5) incremental/additional cost reasoning and expected contributions from the baseline, the GEF trust fund, LDCF, SCCF, and co-financing	GEF trust fund: will the proposed incremental activities lead to the delivery of global environmental benefits?	There do not appear to be any global environmental benefits articulated in this proposal.	<p>The project will result in global environmental benefits that include: conservation of globally significant biodiversity, sustainable use of biodiversity and fair and equitable sharing of the benefits arising from the utilization of genetic resources, including appropriate access to genetic resources. It will ensure that each decision made on an LMO is guided by a science-based risk analysis procedure that allows for monitoring and enforcement to ensure the benefits are accrued whilst potential negative impacts are minimised. The focus is strong environmental and social safeguards to maximise benefits of modern biotechnology.</p> <p>Progress vis-?-vis delivering the agreed project global environmental benefits will be assessed with the Steering Committee at agreed intervals.</p>

	<p>LDCF/SCCF: will the proposed incremental activities lead to adaptation which reduces vulnerability, builds adaptive capacity, and increases resilience to climate change?</p>	N/A	
<p>6) global environmental benefits (GEF trust fund) and/or adaptation benefits (LDCF/SCCF)</p>	<p>Are the benefits truly global environmental benefits/adaptation benefits, and are they measurable?</p>	See above.	<p>The global environmental benefits can be assessed in terms of level of preparedness of the participating countries to minimize the risk of living modified organisms in participating countries.</p>

	Is the scale of projected benefits both plausible and compelling in relation to the proposed investment?	See above ? none are identified.	
	Are the global environmental benefits/adaptation benefits explicitly defined?	No.	
	Are indicators, or methodologies, provided to demonstrate how the global environmental benefits/adaptation benefits will be measured and monitored during project implementation?	No.	
	What activities will be implemented to increase the project's resilience to climate change?	Climate change is identified within the risks (see below for more information)	
7) innovative, sustainability and potential for scaling-up	Is the project innovative, for example, in its design, method of financing, technology, business model, policy, monitoring and evaluation, or learning?	The project is not really particularly innovative (though still important) - it aims to establish a sound regulatory and administrative regime for biosafety and the underlying capacities for robust assessment, regulation and management.	
	Is there a clearly-articulated vision of how the innovation will be scaled-up, for example, over time, across geographies, among institutional actors?	There is a reasonably clear vision of how this will be scaled across the various institutional actors involved in effective biosafety regulation.	

	<p>Will incremental adaptation be required, or more fundamental transformational change to achieve long term sustainability?</p>	<p>Long term sustainability will require a major step change in the ability of these countries to effectively regulate and manage biosafety, whether that is considered adaptation or transformation.</p> <p>These countries have each already taken a number of steps toward that goal - this project aims to take them further.</p>	
<p><b>1b.</b> Project Map and Coordinates. Please provide geo-referenced information and map where the project interventions will take place.</p>		<p>Yes ? map of Africa with participating countries highlighted.</p>	



<p><b>2. Stakeholders.</b> Select the stakeholders that have participated in consultations during the project identification phase: Indigenous people and local communities; Civil society organizations; Private sector entities.</p>	<p>Have all the key relevant stakeholders been identified to cover the complexity of the problem, and project implementation barriers?</p>	<p>This is not clear. IPLCs have a lot at stake in relation to biosafety and a role for them in not identified here. More broadly, the precautionary risk assessment/management processes envisaged in the Protocol are not purely technical exercises - evaluating highly uncertain risks has a very strong values element (what does society value? what risks is it willing to take to these values, in situations where the level/type of risk is uncertain?). There therefore needs to be strong mechanisms for public/community consultation and input to ensure biodiversity values, and all the cultural/livelihood/social values linked to biodiversity, are fully captured in risk assessment/management. While no role for the private sector is foreseen, should they not be educated about biosafety regulatory procedures and requirements?</p>	<p>The project is designed to be all inclusive, participatory in its implementation and to accrue global biodiversity benefits as well as benefits to those whose livelihoods depend on the productive and sustainable interaction between technologies and the environment. The project is guided by the CPB article 23 which makes public participation, education and consultation in decision making in biosafety obligatory.</p> <p>The project has provided mapping of the stakeholders by their roles in the project and will ensure an inclusive approach for all including IPLCs and the public through the envisaged communication strategy and planned training activities.</p>
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<p>If none of the above, please explain why.</p> <p>In addition, provide indicative information on how stakeholders, including civil society and indigenous peoples, will be engaged in the project preparation, and their respective roles and means of engagement.</p>			
	<p>What are the stakeholders? roles, and how will their combined roles contribute to robust project design, to achieving global environmental outcomes, and to lessons learned and knowledge?</p>	<p>See above.</p>	

<p>3. Gender Equality and Women's Empowerment. Please briefly include below any gender dimensions relevant to the project, and any plans to address gender in project design (e.g. gender analysis). Does the project expect to include any gender-responsive measures to address gender gaps or promote gender equality and women empowerment? Yes/no/ tbd.</p> <p>If possible, indicate in which results area(s) the project is expected to contribute to gender equality: access to and control over resources; participation and decision-making; and/or economic benefits or services.</p> <p>Will the project's results framework or logical framework include gender-sensitive indicators? yes/no</p> <p>/tbd</p>	<p>Have gender differentiated risks and opportunities been identified, and were preliminary response measures described that would address these differences?</p>	<p>Generally this is adequate. Re i. here - it is not just gendered involvement in biotechnology activities, but gendered potential negative impacts of biotechnology (e.g. through impacts on agricultural biodiversity or socio-political organisation of agricultural activity).</p>	<p>The project has been designed to monitor gender access, participation, and benefits among women and men and remedial action incorporated to redress any gender inequalities in project implementation.</p> <p>Through the periodic reporting, there will be regular reports on how gender is mainstreamed and ensure that mid-term review, assessments, audits, etc. include gender as a specific criteria/component.</p>
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	Do gender considerations hinder full participation of an important stakeholder group (or groups)? If so, how will these obstacles be addressed?	Potentially. See above.	See above
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<p>5. Risks. Indicate risks, including climate change, potential social and environmental risks that might prevent the project objectives from being achieved, and, if possible, propose measures that address these risks to be further developed during the project design</p>	<p>Are the identified risks valid and comprehensive? Are the risks specifically for things outside the project's control?</p> <p>Are there social and environmental risks which could affect the project?</p> <p>For climate risk, and climate resilience measures:</p> <p>? How will the project's objectives or outputs be affected by climate risks over the period 2020 to 2050, and have the impact of these risks been addressed adequately?</p> <p>? Has the sensitivity to climate change, and its impacts, been assessed?</p> <p>? Have resilience practices and measures to address projected climate risks and impacts been considered? How will these be dealt with?</p> <p>? What technical and institutional capacity, and information, will be needed to address climate risks and resilience enhancement measures?</p>	<p>There are some weaknesses here. Under communication, the mitigation measure identified for "insufficient moderation" does not appear to respond to this risk. In stakeholder relations, lobbying actions are not adequate mitigation measures for political instability. In human resources, recruit more staff is not an adequate response to the potential lack of adequately qualified personnel to participate in the project (what if these don't exist?). The risks identified focus very much on project activities achieving the outcomes - but what about the risks of the outcomes achieving the project impact? What about risks of LMO trade taking place without adherence to official requirements and processes? Or about the procedures instituted failing to adequate guard against biodiversity risks? What about potential socio-economic impacts of LMO trade - could these be increased by an adequate environmental screening procedure boosting trade?</p> <p>Climate risk is addressed here. The project is aimed at reducing other environmental risks of LMO trade, but these need more explication (see above).</p> <p>This is considered under risk in terms of climate change influencing demand for LMOs. But there are other ways climate change could change risks. For instance, what if the risk posed by specific LMOs changes due to changing climatic conditions? It is well recognised that the risk posed by invasive plants, for example, will change under changing climate scenarios - is the same not true for LMOs? And how can the regulatory regime successfully take this into account?</p>	<p>Project risk analysis and risk management measures have been conducted in the project formulation.</p> <p>Project risk assessment and rating is an integral part of the Project Implementation Review (PIR). The quality of project monitoring and evaluation will also be reviewed and rated as part of the PIR.</p> <p>Project is designed to adopt adaptive management, mitigating risks and incorporating lessons learnt into the work programme,</p>
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		Climate resilience practices and measures are not explicitly considered, although successful implementation of the project would enable expanded use of appropriate LMOs that are well adapted to changed climatic scenarios.	
6. Coordination. Outline the coordination with other relevant GEF-financed and other related initiatives	Are the project proponents tapping into relevant knowledge and learning generated by other projects, including GEF projects?	There is little explicit learning of lessons from previous projects.	The project is designed to be executed using an ?incremental approach?. Achievements accrued from earlier projects, will constitute the baseline for the SINBF implementation and activities.
	Is there adequate recognition of previous projects and the learning derived from them?	Many previous projects are identified, but not the learning from them.	Lessons learned from previous GEF projects have been cited and are to be drawn into project execution.
	Have specific lessons learned from previous projects been cited?	No ? see above.	See above
	How have these lessons informed the project?s formulation?	See above.	Lessons from previous project have informed the project?s formulation
	Is there an adequate mechanism to feed the lessons learned from earlier projects into this project, and to share lessons learned from it into future projects?	While there is considerable focus on links with other ongoing projects, it is hard to see clear mechanisms for learning lessons from previous projects. While there are many mechanisms for information sharing, mechanisms to learn lessons from the experience in this project and to capture and share them with future projects are not obvious.	See above

<p><b>8. Knowledge management. Outline the ?Knowledge Management Approach? for the project, and how it will contribute to the project?s overall impact, including plans to learn from relevant projects, initiatives and evaluations.</b></p>	<p>What overall approach will be taken, and what knowledge management indicators and metrics will be used?</p>	<p>There is a lot of focus on knowledge sharing, but the mechanisms remain rather vague. For instance, it is staged that there will be a knowledge management hub and an information hub established, but the specific form and goals of these are very vague. Some specific dissemination channels are identified, which is useful (e.g. ANUBIS and the UNEP annual forum). There is a strong emphasis on utilising existing channels and platforms for information sharing, which is welcome.</p>	<p>The project is designed to identify, analyse, document, and share biosafety information and lessons learnt, and disseminate results from the project beyond the project intervention zone through a number of existing information sharing networks, including online based forums, newsletters, national and a regional Biosafety Clearing House (BCH), learn and share forums and SADC platforms.</p> <p>The project will establish a knowledge management hub and work on its sustainability beyond the project lifespan. Identification and analysing lessons learnt will be an ongoing process. Deliverables will be shared quarterly as applicable or at least twice a year. Publications and thematic reports will be developed and disseminated in the participating countries and at regional level.</p> <p>The project shall use the UNEP reporting format for categorizing, documenting and sharing of lessons learnt. In every annual review and planning meeting; information sharing will be promoted.</p>
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	What plans are proposed for sharing, disseminating and scaling-up results, lessons and experience?	See above.	The project is formulated to lobby for building of information management tasks into existing regional institutions/ structures e.g. the SADC or any other such institution. This will promote continuity beyond the project lifespan.
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Notes

STAP advisory response	Brief explanation of advisory response and action proposed
1. <b>Concur</b>	STAP acknowledges that on scientific or technical grounds the concept has merit. The proponent is invited to approach STAP for advice at any time during the development of the project brief prior to submission for CEO endorsement.
	* In cases where the STAP acknowledges the project has merit on scientific and technical grounds, the STAP will recognize this in the screen by stating that <i><b>?STAP is satisfied with the scientific and technical quality of the proposal and encourages the proponent to develop it with same rigor. At any time during the development of the project, the proponent is invited to approach STAP to consult on the design.?</b></i>
2. <b>Minor issues to be considered during project design</b>	STAP has identified specific scientific /technical suggestions or opportunities that should be discussed with the project proponent as early as possible during development of the project brief. The proponent may wish to:
	(i) Open a dialogue with STAP regarding the technical and/or scientific issues raised;
	(ii) Set a review point at an early stage during project development, and possibly agreeing to terms of reference for an independent expert to be appointed to conduct this review.
	The proponent should provide a report of the action agreed and taken, at the time of submission of the full project brief for CEO endorsement.
3. <b>Major issues to be considered during project design</b>	STAP proposes significant improvements or has concerns on the grounds of specified major scientific/technical methodological issues, barriers, or omissions in the project concept. If STAP provides this advisory response, a full explanation would also be provided. The proponent is strongly encouraged to:
	(i) Open a dialogue with STAP regarding the technical and/or scientific issues raised; (ii) Set a review point at an early stage during project development including an independent expert as required. The proponent should provide a report of the action agreed and taken, at the time of submission of the full project brief for CEO endorsement.

## Responses to Council Member Comments

Council Member	Comment	Response
UK	<p>The title is a bit unusual because the Congo is not exactly ?southern Africa? and Madagascar is usually referred to as the Indian Ocean. Does Namibia need this support?</p>	<p>"Congo Democratic Republic and Madagascar are part of the 14 Member SADC countries. Congo DR and Madagascar are among the unique African countries who are in more than one Regional Economic Community due to trade, political and cultural foot prints. Please find the link to SADC <a href="https://www.sadc.int/member-states">https://www.sadc.int/member-states</a>. Namibia requested prioritization for this project and the support the project will provide is in line with thematic or issue-based support as per the COP-MOP guidance (<a href="https://www.cbd.int/doc/decisions/cp-mop-09/cp-mop-09-dec-04-en.pdf">https://www.cbd.int/doc/decisions/cp-mop-09/cp-mop-09-dec-04-en.pdf</a> ) and the GEF 7 strategy on Biosafety. Namibia?s request was for support on thematic interventions to strengthen institutional capacity in methodologies and tools for their national biosafety system to handle commercial or deliberate releases to the environment.</p>

Germany

Germany approves the following PIF in the work program but asks that the following comments are taken into account:

Suggestions for improvements to be made during the drafting of the final project proposal:

-

- Under the identified risks for the category of Human Resources, the following risks seem to be identical: high staff turnover and constant changing of staff. It would be good to clarify the difference between those or otherwise combine them into one. In addition, the mitigation measures would have to be strengthened. These risks are listed as medium, however at NCRST for example, the staff turnover rate is a great concern and affects sustainability of capacity building measures. The area of intervention of this project is of a specialized technical nature and would require strong and convincing mitigation measures

- In terms of feasibility of the project, we would also like to suggest that all relevant ministries in the countries are involved. In case of Namibia, the NCRST and the Biosafety Council would have to work closely with the Ministry of Agriculture, Water and Land Reform (MAWLR), as well as this Ministry controls seed imports and is the focal point for phytosanitary issues.

- Another are that also might benefit from strengthening is capacity building at tertiary level, In addition to the current involvement (scientists, academia) through consultations, workshops, trainings, inclusion in technical advisory panels etc.), the development of a targeted biosafety academic programme to ensure continuation of the human capital development in the area could be beneficial, for example the introduction of a biosafety stream within the law faculty will ensure

The guidance provided is noted with thanks.

The issues raised were used to guide the development of the updated theory of change and project results framework.

The comments of Germany are noted with appreciation. The issues raised are addressed in the updated documents in the updated texts, the theory of change and project results framework and also noted as key issues to focus on during project inception and throughout the project execution phase with respect to Namibia specifically and is also noted as key operational support items that would facilitate the execution of the project at the national level (See section 5 - page 32, in the CEO endorsement template in the section on stakeholder participation and para 90 of the UNEP Prodoc). The comments have also been highlighted to the NCRST in relation to staff turnover and the Biosafety Council where the role of Biosafety Research as a decision support element has been highlighted and will be integrated through updated procedures in line with the mandate of the Biosafety Council.

Canada	- Modern Biotech was not specifically implicated by IPBES as a direct or indirect driver of biodiversity loss, but the biosafety angle (managing potential modern biotech threats to sustainable use and conservation) is complementary to CBD Work re. Art. 8(g) (if not Aichi as there is no biosafety target). Canada supports the Secretariat's recommendation.	The proposal with the new developments has highlighted the potential linkages to be made when Target 17 of the Post 2020 Global Biodiversity Framework is approved at the next COP15/COP-MOP 10
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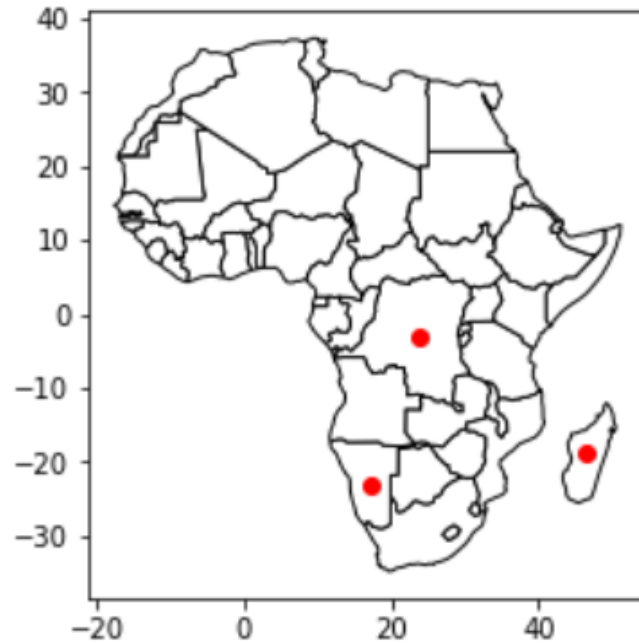
**ANNEX C: Status of Utilization of Project Preparation Grant (PPG).  
(Provide detailed funding amount of the PPG activities financing status  
in the table below:**

PPG Grant Approved at PIF: <b>Strengthening the Implementation of National Biosafety Frameworks in Southern Africa - SINBF</b>			
<i>Project Preparation Activities Implemented</i>	<i>GEF/LDCF/SCCF/NPIF Amount (\$)</i>		
	<i>Budgeted Amount</i>	<i>Amount Spent To date</i>	<i>Amount Committed</i>
1201-National Consultancy	12,600	12,600	
1202-International Consultancy	10,500	10,500	
3301-Meetings	45,313	45,313	
5301-Sundry Operational Costs	25,077	25,077	
<b>Total</b>	<b>93,490</b>	<b>93,490</b>	

**ANNEX D: Project Map(s) and Coordinates**

**Please attach the geographical location of the project area, if possible.**

	Country	Longitude	Latitude	geometry
0	Democratic Republic of the Congo	23.822264	-2.981434	POINT (23.82226 -2.98143)
1	Namibia	17.323111	-23.233550	POINT (17.32311 -23.23355)
2	Madagascar	46.441642	-18.924960	POINT (46.44164 -18.92496)



## ANNEX E: Project Budget Table

Please attach a project budget table.

UNEP Budget Summary

**ANNEX I-1 - RECONCILIATION BETWEEN GEF ACTIVITY BASED BUDGET AND UNEP BUDGET LINE (GEF FUNDS ONLY US\$)**

Project title:		Strengthening the Implementation of National Biosafety Frameworks in Southern Africa (SINBF)								
Project number:		10584								
Project executing partner:		RAEIN-Africa, Congo DR, Madagascar, Namibia								
Project implementation period:		Expenditure by project component/activity (provide description)						*Insert actual year		
From:	2022	Add additional components/activities as required						Add additional years as required		
To:	2026							Expenditure by calendar year		
<b>UNEP Budget Line</b>		<b>I</b>	<b>II</b>	<b>III</b>	<b>PMC</b>	<b>Total</b>	<b>Year 1*</b>	<b>Year 2*</b>	<b>Year 3*</b>	<b>Year</b>
<b>PERSONNEL COMPONENT</b>										
1100	Project personnel									
1101	Project Coordination				84,922	84,922	21,230.50	21,230.50	21,230.50	21.2
1102						-				
1103						-				
<b>1199</b>	<b>Sub-total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>84,922</b>	<b>84,922</b>	<b>21,231</b>	<b>21,231</b>	<b>21,231</b>	<b>2</b>
1200	Consultants									
1201						-				
1202						-				
1203						-				
<b>1299</b>	<b>Sub-total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	
1300	Administrative Support									
1301						-				
1302						-				
1303						-				
<b>1399</b>	<b>Sub-total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	
1600	Travel on official business									
1601						-				
1602						-				
1603						-				
<b>1699</b>	<b>Sub-total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	
<b>1999</b>	<b>Component total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>84,922</b>	<b>84,922</b>	<b>21,231</b>	<b>21,231</b>	<b>21,231</b>	<b>2</b>
<b>SUB-CONTRACT COMPONENT</b>										
2100	Sub-contracts (MOUs/LOAs for cooperating agencies)									
2101						-				
2102						-				
2103						-				
<b>2199</b>	<b>Sub-total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	
2200	Sub-contracts (MOUs/LOAs for supporting organizations)									
2201						-				
2202						-				
2203						-				
<b>2299</b>	<b>Sub-total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	
2300	Sub-contracts (for commercial purposes)									
2301						-				
2302						-				
2303						-				
<b>2399</b>	<b>Sub-total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	
<b>2999</b>	<b>Component total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	
<b>TRAINING COMPONENT</b>										
3200	Group training									
3201	Training Costs	105,379	739,893	-		845,272	251,654	361,467.33	153,785.33	78.3
3202						-				
3203						-				
<b>3299</b>	<b>Sub-total</b>	<b>105,379</b>	<b>739,893</b>	<b>-</b>	<b>-</b>	<b>845,272</b>	<b>251,654</b>	<b>361,467</b>	<b>153,785</b>	<b>7</b>
3300	Meetings/Conferences									
3301	Meeting Costs	223,928	337,155	269,441	-	830,524	287,480	197,260.62	181,975.62	163.8
3302						-				
3303						-				
<b>3399</b>	<b>Sub-total</b>	<b>223,928</b>	<b>337,155</b>	<b>269,441</b>	<b>-</b>	<b>830,524</b>	<b>287,480</b>	<b>197,261</b>	<b>181,976</b>	<b>16</b>
<b>3999</b>	<b>Component total</b>	<b>329,307</b>	<b>1,077,048</b>	<b>269,441</b>	<b>-</b>	<b>1,675,796</b>	<b>539,134</b>	<b>558,728</b>	<b>335,761</b>	<b>24</b>
<b>EQUIPMENT AND PREMISES COMPONENT</b>										
4100	Expendable equipment									
4101	Laboratory Supplies & Consumables		144,000			144,000	45,000	47,000.00	52,000.00	
4102						-				
4103						-				
<b>4199</b>	<b>Sub-total</b>	<b>-</b>	<b>144,000</b>	<b>-</b>	<b>-</b>	<b>144,000</b>	<b>45,000</b>	<b>47,000</b>	<b>52,000</b>	
4200	Non-expendable equipment									
4201	Laboratory Equipment		53,000			53,000	25,000	28,000.00	-	
4202						-				
4203						-				
<b>4299</b>	<b>Sub-total</b>	<b>-</b>	<b>53,000</b>	<b>-</b>	<b>-</b>	<b>53,000</b>	<b>25,000</b>	<b>28,000</b>	<b>-</b>	
<b>4999</b>	<b>Component total</b>	<b>-</b>	<b>197,000</b>	<b>-</b>	<b>-</b>	<b>197,000</b>	<b>70,000</b>	<b>75,000</b>	<b>52,000</b>	
<b>MISCELLANEOUS COMPONENT</b>										
5100	Operation and maintenance of equipment									
5101						-				
5102						-				
5103						-				
<b>5199</b>	<b>Sub-total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	
5200	Reporting costs									
5201	Publication, Translation & Reporting		141,200	205,842		347,042	98,416	96,392.50	67,717.00	84.5
5202	Audit Reports				58,000	58,000	14,500	14,500.00	14,500.00	14.5
5203						-				
<b>5299</b>	<b>Sub-total</b>	<b>-</b>	<b>141,200</b>	<b>205,842</b>	<b>58,000</b>	<b>405,042</b>	<b>112,916</b>	<b>110,893</b>	<b>82,217</b>	<b>9</b>
5300	Sundry									
5301						-				
5302						-				
5303	Technical Support	171,120	204,308	19,350		394,778	163,423	187,686	37,819	
<b>5399</b>	<b>Sub-total</b>	<b>171,120</b>	<b>204,308</b>	<b>19,350</b>	<b>-</b>	<b>394,778</b>	<b>163,423</b>	<b>187,686</b>	<b>37,819</b>	
5400	Hospitality and entertainment									
5401						-				
5402						-				
5403						-				

## **Budgeted Project Activities**

Outcomes	Project Outputs	Intercountry & Country Activities	Year 1	Year 2	Year 3	Year 4	Budget	Component	T
<b>COMPONENT I: BIOSAFETY POLICY &amp; REGULATORY REGIME</b>									
1 - Governments of DRC, Madagascar and Namibia adopted a revised legal framework on biosafety aligned to the CPB and Nagoya-Kuala Lumpur Supplementary Protocol and have taken measures to accelerate effective management and monitoring of LMOs	1.1 A set of National Core teams' (a set of selected multidisciplinary teams of experts from each project country) supported with training and backstopping to cooperate in the review of national biosafety laws, policies and plans, and prepare national decisions to meet the CPB and Nagoya-Kuala Lumpur Supplementary Protocol requirements	1.1.1 Implement an inter-country workshop for the national experts from legal community and selected scientists on drafting/ reviewing the laws, aligning with the provisions of Cartagena Protocol on Biosafety (CPB) and the Nagoya-Kuala Lumpur Supplementary Protocol (NKLSP) on Liability and Redress (L&R) to the CPB, the Post 2020 GBF/Implementation and Capacity Building Action Plans (2021 - 2030) and emerging technologies,	51,215				51,215	Biosafety Policy & Regulatory issues	
		1.1.2 Implement an intercountry workshop to share experiences on approaches for the integration of biosafety policies into national priorities, including how to mobilize resources (Virtual)	16,300				16,300		
		1.1.3 Establish SINBF Technical Advisory Committee (SINBF-TAC) to mentor and provide technical backstopping (Virtual)	3,200				3,200		
	1.2 Decision makers in project countries supported with information, training and technical assistance to influence prioritisation and promotion of policies and legal instruments to meet obligations to the CPB and the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress	1.2.1 National experts review, update, and align draft bills & laws with the CPB & the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (Formulate the legislative, regulatory and normative frameworks)	115,542	19,968	1,254		136,764		
		1.2.2 Carry out activities to create awareness, sensitize legislators on the legislative and regulatory framework, and countries' international obligations to the CPB and the Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress and lobby specific committees to influence prioritisation and promotion of the policies and legal instruments at relevant levels	60,644	5,076			65,720		
		1.2.3 Carry out consultation and validation workshops on the reviewed policy and legal instruments	46,680				46,680		
		1.2.4 Implement in-country training of law makers, including judges & magistrates, on how to deal with cases concerning violation of biosafety laws, regulations/ requirements		21,144	16,720		37,864		
	1.3 Biosafety mainstreamed into relevant national sustainable development policies and strategies, including NBSAPs and the Post 2020 GBF	1.3.1 Review and update and/or develop national biosafety-related policies and identify opportunities for mainstreaming biosafety into national policies, programs & strategies	13,080	21,276	14,500		48,856		
		1.3.2 Integrate National Biosafety Framework into NBSAPs, and related national policies and strategies and tap into the provisions of the Post 2020 GBF	14,780	27,176	8,916	2,000	52,872		
		1.3.3 Translate policies and strategies into coherent action plans			28,676	12,280	40,956		
<b>Component I Totals</b>			<b>321,441</b>	<b>94,640</b>	<b>70,066</b>	<b>14,280</b>	<b>500,427</b>		
<b>COMPONENT II: STRENGTHENING BIOSAFETY INSTITUTIONAL SYSTEMS</b>									
2 National mandated institutions and stakeholders take measures to strengthen implementation compliance and enforcement of updated national biosafety frameworks	2.1 Multidisciplinary teams of national experts from project countries trained and backstopped to train government officials and their stakeholders in the implementation of biosafety and thematic areas	2.1.1 Train national expert teams/ personnel on the establishment of administrative and institutional frameworks for implementation of NBFs	50,835				50,835	Biosafety Capacity Development	
		2.1.2 Training of Trainers (ToT) courses on LMO detection & quality management systems (Knowledge and hands on practice on GMO testing (learning from the MCP-ICLT experiences)		48,788			48,788		
		2.1.3 Training of Trainers (ToT) on biosafety Risk assessment and Risk management		60,470			60,470		
		2.1.4 Training of Trainers (ToT) on control mechanisms, including Biosafety inspections and monitoring and enforcement		10,800			10,800		
		2.1.5 Create an inter-country network (platform) for sharing biosafety technical resources & expertise	3,100	3,100	3,100	3,100	12,400		
		2.1.6 Provide technical backstopping in the establishment of administrative and institutional structures, and national capacity building activities on the above thematic areas	22,200	22,200	13,200	19,001	76,601		
		2.1.7 Training of Trainers (ToT) on communication for effective multi-institutional, multi-disciplinary implementation of NBFs / in-country collaboration between government and non-government agencies relevant to biosafety		14,100			14,100		
		2.1.8 Training of trainers (ToT) workshop for the biosafety actors on science communication for effective awareness creation and inter-institutional communications	10,800				10,800		
	2.2 National biosafety administrative systems strengthened with training and technical assistance to review and	2.2.1 Organise hands on training and increase capacity on administrative structures for handling of requests and decision making	102,682	85,102	67,383	35,975	291,142		
		2.2.2 Develop or strengthen administrative systems to handle notification /requests for permits		9,200	4,900	49,488	63,588		
	2.3 Biosafety risk assessment and risk management systems strengthened with technical support to provide data for informed decision making	2.3.1 Adapt technical tools and resources on Risk Assessment/Risk Management to national contexts and use		39,292			39,292		
		2.3.2 Provide national training workshop on biosafety risk assessment and risk management, including practical RA & RM real cases where available (simulation of NBFs using the enhanced tools)		17,936	17,520		35,456		
	2.4 National Biosafety systems supported with capacity to develop and strengthen national guidelines	2.4.1 Develop national guidelines on socio-economic considerations		6,000	9,396		15,396		
		2.4.2 Provide national training workshop on socioeconomic guidelines (Simulation - use practical cases)			31,680		31,680		
2.5 National biosafety systems provided with technical support to develop and/or strengthen	2.5.1 Capacitate mechanisms for enforcement and monitoring	5,600	85,720	18,600	900	110,820			
	2.5.2 Increase national human resources on monitoring and enforcement through training activities	90,620	90,060	50,200		230,880			
2.6 Tools and guidelines on RA&RM; handling and review of applications; socio economic considerations and	2.6.1 Capacitate national expert teams on developing and adapting guidelines and tools for strengthening Institutional frameworks for biosafety	11,800	67,001			78,801			
	2.6.2 Mentor countries on utilisation of guidelines and technical tools in biosafety	14,501	18,300		9,200	42,001			
2.7 Capacities and systems on biosafety communication for public information, public awareness and public participation strengthened	2.7.1 Review, update and implement systems for public education, awareness, participation and access to biosafety information	33,020	91,119	75,449	21,520	221,108			
	2.7.2 Regional support mechanism for the participating countries through SADC's scientific networks for sustainability established	52,250	40,783	40,783	40,783	174,599			
<b>Component II Totals</b>			<b>397,408</b>	<b>709,971</b>	<b>332,211</b>	<b>179,967</b>	<b>1,619,556</b>		
<b>COMPONENT III - PROJECT MONITORING AND EVALUATION</b>									
3 Effective project Monitoring and Evaluation to meet agreed project outputs and indicators.	3.1 M&E framework institutionalized and operationalized and Lessons learnt shared to influence biosafety at regional levels for impact continuity beyond the Project.	3.1.1 Develop & Implement a comprehensive project & Financial management & tracking system	16,880	8,330	5,630	5,630	36,470	M&E	
		3.1.2 Implement Intercountry & national Annual Review and Planning meetings	43,799	24,644	24,644	64,317	157,404		
		3.1.3 Intercountry Project Steering Committee & National Taskforce Meetings	23,729	23,729	23,729	23,729	94,916		
		3.2.1 Develop and Implement a comprehensive Project Monitoring and Evaluation (M&E) Framework, & track progress in achieving results at regular intervals (Including Stakeholder Inputs)	61,717	45,417	37,017	37,017	181,167		
	3.2 Mid Term and Terminal Evaluation Implemented	3.2.2 Adaptively manage the Project, mitigating Risks and incorporating lessons learnt into the work programme	6,000	11,076		7,600	24,676		
		3.2.3 Undertake mid-term Project evaluation and draw lessons to enhance project implementation		49,224			49,224		
		3.2.4 Carry out Terminal Evaluation and institutionalize the established systems for continuity beyond the Project				51,628	51,628		
<b>Component III Totals</b>			<b>152,125</b>	<b>162,420</b>	<b>91,020</b>	<b>189,921</b>	<b>595,485</b>		
<b>Project Management Cost (PMC)</b>									
4.0 Effective and efficient Project Coordination and management systems	4.1 Systems and structure for Project Management and Coordination (PMC) established	4.1.1 Establish and implement Project management structures and Reporting systems						PMC	
		4.1.2 -Auditing	14,500	14,500	14,500	14,500	58,000		
		4.1.3 - Project Staff costs, Management of technical Expert, Advisors, Consultations and Coordination, Accounting fee, bank Charges, Report & Records knowledge, Management	21,231	21,231	21,231	21,231	84,922		
	<b>Total PMC Costs</b>	<b>35,731</b>	<b>35,731</b>	<b>35,731</b>	<b>35,731</b>	<b>142,922</b>			
<b>Grant Project Totals</b>			<b>906,704</b>	<b>1,002,761</b>	<b>529,027</b>	<b>419,898</b>	<b>2,858,390</b>		



**A copy of the detailed Budget is attached as sheet 2 to Annex I-1 and labeled as "Budgeted Activities"**

**ANNEX F: (For NGI only) Termsheet**

Instructions. Please submit a finalized termsheet in this section. The NGI Program Call for Proposals provided a template in Annex A of the Call for Proposals that can be used by the Agency. Agencies can use their own termsheets but must add sections on Currency Risk, Co-financing Ratio and Financial Additionality as defined in the template provided in Annex A of the Call for proposals. Termsheets submitted at CEO endorsement stage should include final terms and conditions of the financing.

**ANNEX G: (For NGI only) Reflows**

Instructions. Please submit a reflows table as provided in Annex B of the NGI Program Call for Proposals and the Trustee excel sheet for reflows (as provided by the Secretariat or the Trustee) in the Document Section of the CEO endorsement. The Agency is required to quantify any expected financial return/gains/interests earned on non-grant instruments that will be transferred to the GEF Trust Fund as noted in the Guidelines on the Project and Program Cycle Policy. Partner Agencies will be required to comply with the reflows procedures established in their respective Financial Procedures Agreement with the GEF Trustee. Agencies are welcomed to provide assumptions that explain expected financial reflow schedules.

**ANNEX H: (For NGI only) Agency Capacity to generate reflows**

Instructions. The GEF Agency submitting the CEO endorsement request is required to respond to any questions raised as part of the PIF review process that required clarifications on the Agency Capacity to manage reflows. This Annex seeks to demonstrate Agencies' capacity and eligibility to administer NGI resources as established in the Guidelines on the Project and Program Cycle Policy, GEF/C.52/Inf.06/Rev.01, June 9, 2017 (Annex 5).